THE EFFECT OF ROBOTIC TECHNOLOGY ON PERIOPERATIVE OUTCOMES IN TOTAL KNEE ARTHROPLASTY

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A thesis submitted to University College London for the degree of Doctorate of Philosophy. I, Babar Kayani confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Dedication

To my parents Zafar and Zakria Iqbal, brother Muddasar, sister Sadia and wife Hina for instilling in me the value of education, providing me with moral and emotional support, and always encouraging me to follow my dreams.

To my daughter, Laila Naz Kayani, for your smiles, hugs, and kisses that have given me my greatest happiness, pleasures and joys in life.
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Dr Elliot Onochie and Dr Iakovos Amygdalos for sharing with me the greatest of friendships, enriching my life with their eternal optimism, and always believing in me.
Abstract

Introduction
Robotic technology has recently regained momentum in total knee arthroplasty (TKA) but the effects of this technology on accuracy of implant positioning, intraoperative soft tissue injury and postoperative functional rehabilitation remain unknown. The objectives of this research thesis were to compare a comprehensive range of radiological objectives and perioperative outcomes in conventional jig-based TKA versus robotic-arm assisted TKA, and use optical motion capture technology to quantify the effects of anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) resection on knee biomechanics.

Methods
A series of prospective cohort studies were undertaken in patients with established knee osteoarthritis undergoing primary conventional jig-based TKA versus robotic-arm assisted TKA. Predefined radiological and perioperative study outcomes were recorded by independent observers. Optical motion capture technology during robotic TKA was used to quantify the effects of ACL and PCL resection on knee biomechanics.

Results
Robotic-arm assisted TKA was associated with improved accuracy of implant positioning, reduced periarticular soft tissue injury, decreased bone trauma, improved postoperative functional rehabilitation, and reduced early systemic inflammatory response compared to conventional jig-based TKA. The Macroscopic Soft Tissue Injury (MASTI) classification system was developed and validated for grading intraoperative periarticular soft tissue injury and bone trauma during TKA. ACL resection created flexion-extension mismatch by increasing the extension gap more than the flexion gap, whilst PCL resection increased the flexion gap proportionally more than the extension gap and created mediolateral laxity in knee flexion but not in extension.

Conclusion
Robotic-arm assisted TKA was associated with increased accuracy of implant positioning, reduced iatrogenic soft tissue injury, and improved functional rehabilitation compared to conventional jig-based TKA. ACL and PCL resections created unique changes in knee biomechanics that affected flexion-extension gaps and mediolateral soft tissue tension during TKA. On the basis of this thesis, further clinical trials have been established to determine the long-term clinical significance of these findings.
Impact Statement

The findings of the various prospective cohort studies undertaken within this thesis fill important gaps in the existing medical literature comparing conventional jig-based TKA versus robotic-arm assisted TKA. The study outcomes were selected based on existing studies showing their clinical relevance to long-term functional outcomes and implant survivorship following TKA. Optical motion capture technology was validated as an investigative tool for assessing knee kinematics, and used to quantify the effects of anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) resection on knee biomechanics.

Robotic-arm assisted TKA did not have a learning curve effect for accuracy of implant positioning or limb alignment but there was a learning curve of seven cases for achieving operative times and surgical team comfort levels comparable to conventional jig-based TKA. These findings will facilitate safe implementation, theatre planning, and scheduling of operative cases during the learning phase of robotic-arm assisted TKA.

Robotic-arm assisted TKA was associated with improved accuracy of achieving the planned implant positioning, limb alignment, native joint line restoration, and posterior tibial slope compared to conventional jig-based TKA. These findings indicate that robotic TKA offers an avenue for reducing surgeon-controlled errors in component positioning, which may help to improve implant survivorship following TKA.

Robotic-arm assisted TKA was associated with reduced intraoperative periarticular soft tissue injury and decreased bone trauma compared to conventional jig-based TKA. The Macroscopic Soft Tissue Injury (MASTI) grading system was developed and validated as an assessment tool with high intraobserver and interobserver reliability for stratifying soft tissue injury and bone trauma during TKA. This classification system may be used a research tool in further studies grading periarticular soft tissue injury and bone trauma during TKA.

ACL resection created flexion-extension mismatch by increasing the extension gap more than the flexion gap. PCL resection increased the flexion gap proportionally more than the extension gap and also increased the lateral flexion gap more than the medial flexion gap, which created mediolateral ligamentous laxity in knee flexion but not in extension. These specific biomechanical changes following ligamentous resections should be appreciated during flexion-extension gap balancing and mediolateral soft tissue tensioning in TKA.

Robotic-arm assisted TKA was associated with decreased pain, reduced opiate analgesia consumption, reduced intraoperative blood loss, decreased inpatient physiotherapy, improved maximum knee flexion, and shorter time to hospital discharge compared to conventional jig-based TKA. These findings suggest that robotic technology may help to reduce postoperative pain, enhance rehabilitation and facilitate earlier hospital discharge following TKA.

Conventional jig-based TKA and robotic-arm assisted TKA had comparable immediate (<48 hours) and late (day 28) postoperative systemic inflammatory responses but robotic-arm assisted TKA was associated with reduced early (day 7) systemic inflammatory response compared to conventional jig-based TKA. These findings suggest robotic-arm assisted TKA helps to better limit the systemic surgical insult of surgery compared to conventional jig-based TKA.
The various studies undertaken within this research thesis have helped to establish a series of prospective randomised controlled trials to compare outcomes in conventional jig-based TKA versus robotic-arm assisted TKA and robotic mechanically aligned TKA versus robotic functionally aligned TKA. The findings of these studies will help to develop the optimal TKA procedure with higher levels of patient satisfaction, better functional outcomes, longer implant survivorship, improved cost-effectiveness, and reduced complications.
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<th>Description</th>
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<tbody>
<tr>
<td>2D</td>
<td>Two-Dimensional</td>
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<tr>
<td>3D</td>
<td>Three-Dimensional</td>
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<tr>
<td>ACL</td>
<td>Anterior Cruciate Ligament</td>
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<tr>
<td>A.A</td>
<td>Babar Kayani</td>
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<td>ASA</td>
<td>American Society of Anesthesiologists</td>
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<td>B.K</td>
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<td>BMI</td>
<td>Body Mass Index</td>
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<td>CAD</td>
<td>Computer-aided design</td>
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<td>CK</td>
<td>Creatine Kinase</td>
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<td>CR</td>
<td>Cruciate retaining</td>
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<td>CRP</td>
<td>C-Reactive Protein</td>
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<tr>
<td>CT</td>
<td>Computerised Tomography</td>
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<tr>
<td>CUSUM</td>
<td>Cumulative Summation</td>
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<tr>
<td>EQ-5D</td>
<td>European Quality of Life questionnaire with 5-dimensions for adults</td>
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<tr>
<td>ESR</td>
<td>Erythrocyte Sedimentation rate</td>
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<td>F.S.H</td>
<td>Fares Sami Haddad</td>
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<tr>
<td>FA</td>
<td>Functional Alignment</td>
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<tr>
<td>FFD</td>
<td>Fixed Flexion Deformity</td>
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<td>FJS</td>
<td>Forgotten Joint Score</td>
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<td>Hb</td>
<td>Haemoglobin</td>
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<td>ICC</td>
<td>Inter-/Intra-class Correlation Coefficient</td>
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<td>IL-1β</td>
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<td>IQR</td>
<td>Interquartile Range</td>
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<td>J.R.T.P</td>
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<tr>
<td>KOOS</td>
<td>Knee Injury and Osteoarthritis Outcome Score</td>
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<td>Lactate Dehydrogenase</td>
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<td>MASTI</td>
<td>Macroscopic Soft Tissue Injury</td>
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<tr>
<td>MCL</td>
<td>Medial Collateral Ligament</td>
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<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<tr>
<td>NRS</td>
<td>Numerical Rating Scale</td>
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<tr>
<td>ODP</td>
<td>Operating Department Practitioner</td>
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<tr>
<td>PCA</td>
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<td>PCOR</td>
<td>Posterior Condylar Offset Ratio</td>
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<td>POL</td>
<td>Posterior Oblique Ligament</td>
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<td>PS</td>
<td>Posterior-stabilised</td>
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<td>RMSE</td>
<td>Root Mean Square Error</td>
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<td>Radiostereometric Analysis</td>
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<td>Sujith Konan</td>
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<td>S.O</td>
<td>Sam Ouseddik</td>
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<tr>
<td>SAE</td>
<td>Serious Adverse Event</td>
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<td>SD</td>
<td>Standard Deviation</td>
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<td>Straight Leg Raise</td>
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<td>STAI</td>
<td>State-Trait Anxiety Inventory</td>
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<td>Tumour Necrosis Factor-α</td>
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<td>University College Hospital</td>
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<td>UCL</td>
<td>University College London</td>
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<td>University of California at Los Angeles</td>
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Chapter 1

Introduction
Abstract

Total knee arthroplasty (TKA) is performed in over 90,000 patients per year in the United Kingdom. However, patient satisfaction and functional outcomes remain inferior to total hip arthroplasty. Robotic technology has been used within several surgical specialities to improve surgical precision and reduce manual errors, and over the last decade this technology has regained momentum in TKA. This chapter discusses the limitations of conventional jig-based TKA, differences in computer navigated versus robotic TKA, variations in fully active versus semi-active robotic systems, and the operative stages of robotic TKA. The existing literature is reviewed to provide a comprehensive overview of existing studies comparing accuracy of implant positioning, limb alignment, iatrogenic soft tissue injury, postoperative rehabilitation, and functional outcomes in conventional jig-based TKA versus robotic-arm assisted TKA. The gaps identified within the existing medical literature comparing conventional jig-based TKA versus robotic-arm assisted TKA were used to form the foundations of the various prospective studies undertaken within this thesis.
Background

Total knee arthroplasty (TKA) is an established and highly-effective treatment for patients with symptomatic end-stage knee osteoarthritis.\textsuperscript{1,2} The procedure is performed in over 90,000 patients per year in the United Kingdom.\textsuperscript{3} Pooled registry data has shown that implant survivorship, assessed with revision as the primary endpoint, is approximately 82% at 25 years follow-up.\textsuperscript{4,5} However, patient satisfaction and functional outcomes remain inferior to total hip arthroplasty (THA).\textsuperscript{2,6} Despite advances in implant design, implant material, enhanced recovery programmes, thromboembolic prophylaxis, antibiotic prophylaxis, patient-specific implants, and computer navigation, recent studies have shown that up to 20% of patients remain dissatisfied following TKA\textsuperscript{2,7-12}. Accurate implant positioning, balanced flexion-extension gaps, proper ligament tensioning, and preservation of the periarticular soft tissue envelope are important surgeon-controlled variables that affect functional outcomes, implant stability, and long-term implant survivorship.\textsuperscript{6,13-18} Conceptually, technology that enables these technical objectives to be delivered with greater accuracy and reproducibility may help to further improve outcomes in TKA.

The term robot originates from the Czech word “Robota”, which means forced labour or activity. Karel Capek first used the term robot in his 1921 play “Rossum’s Universal Robots”, in which robots were a series of factory-manufactured artificial people made from synthetic material that undertook mundane tasks for their human masters.\textsuperscript{19} The robots eventually became frustrated with their roles and masterminded a robotic rebellion, leading to the extinction of the human race. Since then, the term “robotics” has evolved to describe an array of computer machines that perform pre-programmed, precise, and repetitive procedures. These computer machines have now become integrated into the routine workforce of several industries, including aviation, military, healthcare, finance, construction, and engineering.\textsuperscript{16,20} Robotic technology has helped each of these sectors to achieve and sustain levels of precision, productivity, and efficiency that were not possible with humans alone. Within each of these sectors that have integrated robotic technology into their workforce, the use of this technology has never diminished or exited from the industry.\textsuperscript{16}

The first robotic surgical procedure was performed by Kwoh et al in 1988 using the PUMA 560 robotic system (Westinghouse Electric, Pittsburgh, Pennsylvania, USA) to undertake neurosurgical biopsies with improved precision.\textsuperscript{21} The same robotic platform was used by Davies et al in 1991 to undertake transurethral resections of the prostate with greater accuracy and reduced iatrogenic soft tissue injury.\textsuperscript{22} Over the following two decades, several other surgical robotic devices were developed, including the Zeus (Computer Motion, Inc., Goleta, California, USA) and Da Vinci (Intuitive Surgical, Sunnyvale, California, USA) robotic platforms, which enabled a variety of surgical procedures to be performed remotely using robotically-controlled arms and a three-dimensional camera to improve the visual field.\textsuperscript{22-24} These robotic devices have been used to perform cholecystectomy, hysterectomy, lobectomy, mitral valve replacement, coronary artery bypass grafting, and prostatectomy. Compared to conventional open surgery or laparoscopic surgery, robotic surgery with these devices is associated with smaller skin incisions, improved precision of soft tissue dissection, better visualisation of the surgical field, and more comprehensive data capture for surgical training.\textsuperscript{23,24} Clinically, this has translated to robotic surgery enabling faster postoperative rehabilitation and decreased length of hospital stay compared to conventional open and laparoscopic surgery for these procedures.\textsuperscript{23-25}

Over the last decade, robotic TKA has regathered momentum as an avenue for improving the accuracy of implant positioning and reducing outliers in limb alignment compared to conventional jig-based TKA.\textsuperscript{26-32} However, many
clinicians remain sceptical about robotic TKA owing to the substantive installation costs and extensive industry-driven marketing drives promoting this technology, despite the limited evidence showing any clinical or functional benefit compared to conventional jig-based TKA. In this section, we will discuss the limitations of conventional jig-based TKA, differences in computer navigated versus robotic TKA, variations in fully active versus semi-active robotic systems, and the operative stages of robotic TKA. The existing literature is also reviewed to provide a comprehensive overview of existing studies comparing accuracy of implant positioning, limb alignment, iatrogenic soft tissue injury, postoperative rehabilitation, and functional outcomes in conventional jig-based TKA versus robotic TKA. The gaps identified within the existing medical literature comparing conventional jig-based TKA versus robotic TKA were used to form the foundations of the various prospective studies undertaken within this research thesis.

**Limitations of conventional jig-based TKA**

Conventional jig-based TKA uses preoperative radiographic films, intraoperative anatomical landmarks, and manually-positioned alignment jigs to guide bone resection and implant positioning. However, these techniques are poorly reproducible and accuracy of achieving the planned implant position is dependent on the skill and expertise of the operating surgeon. Achieving balanced flexion-extension gaps and proper mediolateral ligamentous tensioning is dependent on subjective intraoperative gap assessments with limited capacity for fine-tuning bone resections and implant positioning. Intraoperative tensioning devices may help to guide soft tissue releases but there these are associated with inter-surgeon variability in their anatomical positioning and heterogeneity in the distraction forces applied. Conventional jig-based TKA uses a manually-controlled sawblade to perform bone resections and handheld retractors to protect the periarticular soft tissue envelope. This manual technique for bone resection may lead to inadvertent periarticular soft-tissue injury, which is associated with poor functional outcomes, reduced stability, and decreased implant survivorship. Conventional jig-based TKA also provides limited real-time feedback on the thickness or orientation of the femoral and tibial bone resections undertaken. The use of intramedullary referencing guides for bone resection during conventional jig-based TKA may also increase the risk of thromboembolic events and cardiorespiratory complications.

**Rationale for robotic TKA:**

Robotic TKA offers an avenue for reducing subjective, surgeon-dependent errors in bone resection and implant positioning. This technology aims to limit human error that stems from misjudgements in preoperative two-dimensional (2D) templating, suboptimal identification of intraoperative anatomical landmarks and malpositioning of femoral and tibial alignment guides. In addition, robotic TKA uses haptic windows with stereotactic boundaries to reduce iatrogenic periarticular soft tissue injury compared to conventional jig-based TKA with a manually-controlled saw blade and handheld surgical instruments. Furthermore, robotic TKA aims to provide live, intraoperative data on knee biomechanics that the surgeon can use to fine-tune bone resections and implant positioning to achieve the desired bone coverage, limb alignment, flexion-extension gaps, and range of motion. This technology offers an avenue for the surgeon to deliver the patient-specific surgical plan as guided by the periarticular soft tissue envelope, whilst respecting the boundaries of safe component position and limb alignment with current implant designs.

**Functional alignment**
Total knee arthroplasty with mechanical alignment (MA TKA) aims to restore neutral alignment of the limb. This is achieved by placing implants perpendicular to the mechanical axis of the femur and tibia, and externally rotating the femoral component to obtain a rectangular, balanced flexion-extension gap, which also aids patella tracking.\textsuperscript{47} The principle of neutral mechanical alignment is to distribute load evenly across the implants, which provides a mechanical advantage in flexion and limits asymmetrical bearing surface wear.\textsuperscript{48} However, the native knee is known to possess an oblique joint line in the coronal plane in the bipedal stance. During walking or running, the centre of mass shifts laterally with the single leg stance, and the hip adducts, which causes the joint line to become more horizontal to the ground. Although there is significant intra- and inter-population variances, most patients have a slightly varus native limb alignment, which is achieved by a combination $0^\circ$ - $4^\circ$ valgus alignment of the distal femur and $1^\circ$ - $5^\circ$ varus alignment of the proximal tibia.\textsuperscript{49,50} Therefore, in the large majority of patients undergoing MA TKA, the knee is forced into an unnatural position with resultant changes in knee biomechanics that alter the native femoral flexion axis, ligament tension, quadriceps function, patella tracking and overall knee kinematics.\textsuperscript{49-52}

Total knee arthroplasty with functional alignment (FA TKA) aims to restore the native joint line height and obliquity, and achieve the planned knee biomechanics by manipulating implant positioning as guided by the soft tissue envelope. The goal is to place the components in the positions that least compromises the soft-tissue envelope by restoring the plane and obliquity of the joint line as dictated by the soft tissues. This is most commonly achieved using robotic technology, which uses optical motion capture tracking to provide objective intraoperative data on limb alignment, mediolateral soft tissue tension, flexion-extension gaps, and range of motion. The robotic arm with sawblade action confined to the stereotactic boundaries is used to intraoperatively modify bone resections in the coronal, sagittal, and axial plane to execute individualised patient-specific limb alignment and knee kinematics, whilst ensuring limb alignment is achieved within the predefined safe zones. Robotic TKA with functional alignment aims to reduce the need for controlled soft tissue releases to achieve the planned knee biomechanics compared to MA TKA. There is optimism that TKA with functional alignment will enable better restoration of patient-specific knee biomechanics and further improve patient satisfaction and functional outcomes in TKA.

**Computer navigated versus robotic TKA**

Computer navigated TKA involves the use of computer systems that provide live on-screen information on patient anatomy and knee kinematics during surgery. This osseous anatomical map of the patient’s knee joint may be obtained using preoperative computerised tomography (CT) scans (imaged-based navigation) or intraoperative mapping of bony anatomical landmarks on a generic model of the knee joint (non-image-based navigation). Computer navigation provides patient-specific anatomical data with recommendations for bone resection and optimal implant positioning, but the computer system does not actively control or restrain the motor function of the operating surgeon. Robotic TKA uses computer software to convert anatomical information into a virtual patient-specific three-dimensional (3D) reconstruction of the knee joint, which the operating surgeon uses to calculate optimal bone resection and implant positioning. An intraoperative robotic device helps to execute this preoperative patient-specific plan with a high level of accuracy.\textsuperscript{27,32,53}

Depending on the degree of control that the robotic device provides the operating surgeon, robotic assistants are classified as either fully active or semi-active systems.
**Fully active versus semi-active robotic TKA systems**

The first robotic TKA was performed in 1988 using the ACROBOT robotic system (Imperial College, London, UK) but there has been a resurgence in this procedure over the last decade.\(^{54}\) This has been attributed to recent developments in computer software and surgical engineering, and the ease with which modifications can be made to existing technology such as computer navigation.\(^{16,20}\) There are two broad categories of robotic TKA systems: fully active versus semi-active systems. Fully active robotic systems work autonomously to perform the planned femoral and tibial bone resections. The surgeon oversees the bone resection and may activate an emergency deactivation switch if required. ROBODOC (THINK Surgical Inc., Fremont, California, USA) is an example of a fully active robotic TKA application system.\(^{55}\) The surgeon performs the surgical approach, positions retractors to protect the periarticular soft tissues, and then secures the limb into a fixed device. The robotic device then independently executes the planned bone resections. There has been limited uptake of fully active robotic TKA systems owing to the substantial installation costs associated with these robotic devices and increased risk of complications during the learning phase of this procedure. Park et al reported that six of their initial 32 fully active robotic TKA procedures had short-term complications including superficial infection, patellar ligament rupture, patellar dislocation, supracondylar fracture, patellar fracture, and common peroneal nerve injury.\(^{53}\)

Semi-active robotic systems enable the surgeon to maintain overall control over bone resection and implant positioning but provide live intraoperative feedback to limit deviation from the preoperative surgical plan. The Robotic Arm Interactive Orthopaedic System (MAKO Surgical Corp, Kalamazoo, Michigan, USA) is an example of an image-guided semi-active robotic platform for TKA.\(^{56}\) The robotic arm has visual, tactile, and audio feedback that help the surgeon to control the force and direction of sawblade motion within the confines of the stereotactic femoral and tibial bone resection windows. The patient’s limb is secured within a mobile leg holder that can be manually adjusted during bone resection to improve visualisation of the operative field. Rapid or jerking movements will deactivate the robotic device to help limit iatrogenic bone and soft tissue injury. The Navio Surgical system (Smith & Nephew, Andover, Texas, USA) is an imageless semi-active robotic system that uses a handheld platform to intraoperatively map osseous anatomy and guide bone resection without stereotactic boundaries.\(^{57}\) More recently, the Rosa knee system (Zimmer-Biomet, Warsaw, Indiana, USA) has gained FDA approval.\(^{58}\) This robotic system offers a computer software programme to convert 2D knee radiographs into a 3D patient-specific bone model. Virtual plans for optimal bone resection and implant positioning are created and used to guide intraoperative placement of femoral and tibial cutting blocks.

**Equipment for robotic TKA**

The robotic device used in this thesis was the Robotic Arm Interactive Orthopaedic System (MAKO Surgical Corp, Kalamazoo, Michigan, USA). This robotic system consists of the following components (figures 1a-e):

- **The Mako System**
  - Robotic Arm
  - Camera Stand
  - Guidance Module
Mako (MAKOplasty) TKA Application software

Mako Knee Instrumentation
- Mako Knee Array/Balancing Kit
- Mako Power System and Attachment Kit (Cutting System)
- Leg Positioner Kit

Sterile Disposables
- Mako Drape Kit
- Leg Positioner Disposable Kit
- Silicone Retractor Cords
- Bovie tip
- VIZADISC Knee Procedure Tracking Kit
- Checkpoints
- Bone Pins
- MAKO Integrated Cutting System (MICS) consists of a MICS handpiece, right angle saw attachment, sagittal saw attachment, standard saw blade and narrow saw blade.
- MICS Saw Blades (Standard or Narrow)

Implant System Instrumentation
- Mako Triathlon Knee system

Figure 1a: Intraoperative photo of the bovie tip with VIZADISC infra-red arrays used for bone registration
Figure 1b: Intraoperative photo of the VIZADISC infra-red arrays attached to the Mako robotic device

Figure 1c: Intraoperative photo of the surgical tray with mobile leg holder prior to assembly
Figure 1d: Intraoperative photo of the Mako robotic cutting saw used for bone resection

Figure 1e: Intraoperative photograph showing the bone registration process with infra-red receivers on the camera stand and monitor displaying osseous registration points
Surgical technique for robotic TKA

In patients undergoing robotic-arm assisted TKA, computer software (Mako system software, Stryker Limited, Kalamazoo, MI) was used to convert the preoperative CT scan of the knee joint into a patient-specific, virtual 3D computer-aided design (CAD) model. The preoperative scan CT scan and CAD model were used to plan bone implant size, alignment and positioning to achieve the desired bone coverage, limb alignment and component positioning. Implant positions were planned to achieve neutral mechanical limb alignment, and then adjusted intraoperatively to restore the plane and obliquity of the joint as dictated by the soft tissues (figure 1f).

Figure 1f: Preoperative virtual CAD model used to plan optimal bone resection and implant positioning
The femoral component was initially planned perpendicular to the mechanical axis of the femur and parallel to the transepicondylar axis (TEA). Distal femur and posterior femur resection landmarks were determined by the most distal and posterior points on the medial and lateral condyles respectively. Bone resection depths of 8mm were planned to accommodate the femoral component which is 8mm thick distally and posteriorly. Resection depth of 8mm from the medial femoral condyle was used for varus knees, and a resection depth of 8mm from the lateral femoral condyle was used for valgus knees. Femoral component size and flexion were selected to achieve maximal bone coverage whilst preventing any overhang or notching. The tibial component was also initially planned perpendicular to the mechanical axis of the tibia with a neutral slope. The virtual proximal tibial resection landmarks were placed in the centre of the medial and lateral plateau in the coronal plane and posterior two-thirds of the anterior-posterior distance of the lateral plateau. A resection depth of 7mm from the lateral tibial plateau was used for varus knees and a resection depth of 5mm from the medial tibial plateau was used for valgus knees. Tibial implant size was planned to achieve maximum mediolateral coverage without any overhang.

The standard medial parapatellar approach was used in all study patients. A midline longitudinal incision was made over the knee joint with the knee in flexion. The initial incision extended proximally from the tibial tubercle for approximately 10-15cm and further proximal extension was undertaken to improve exposure and reduce skin stretching if required. Dissection was continued in the midline until the quadriceps tendon was identified. The medial parapatellar incision was extended through the medial parapatellar retinaculum and along the medial border of the patella tendon distally. A 3mm cuff of quadriceps tendon was left attached to vastus medialis and a cuff of medial retinaculum attached to the patella to aid surgical closure. The medial capsule was released subperiosteally off the proximal tibia to gain exposure to the medial compartment. In patients with a varus deformity, the dissection was extended to include the deep medial collateral ligament and posteromedial corner if required. In patients with a valgus knee, the medial release was minimised to the anteromedial corner. The knee was then extended, the patella everted, and retropatellar fat partially excised. The remnants of the menisci were excised, and the ACL and PCL resected. Osteophytes were resected at this stage. The synovial membrane at the anterior cortex of the distal femur was subperiosteally undermined in order to seat the anterior flange of the femoral component.

Two intra-incisional femoral registration pins and two extra-incisional tibial registration pins were inserted four finger breadths below the tibial tubercle. Fixed arrays were mounted onto these to enable optical motion capture tracking during surgery. Bone registration was performed by intraoperatively mapping radiological landmarks displayed on the computer screen to verify anatomy and establish bone geometry. Joint balancing captured femoral and tibial poses with corrective forces, assessed kinematics through the arc of motion, and enabled fine-tuning of implant positioning based on laxity of the soft tissue envelope. The Mako Robotic Arm Interactive Orthopaedic system (Stryker Ltd, Kalamazoo, MI, USA) with visual, tactile, and audio feedback was used to execute the planned femoral and tibial bone resections within the confines of the stereotactic boundaries. Tibial and femoral osteotomies in the coronal plane were performed perpendicular to the tibial and femoral mechanical axes respectively to achieve neutral overall alignment (figure 1g). In the sagittal plane, 0°–5° of femoral component flexion were used to optimise implant sizing whilst preventing notching. The tibial slope was initially set to zero degrees and then adjusted as required based on intraoperative assessment of the flexion gap and range of motion. A Mikhail retractor was used to protect the posterior structures, and blunt Hohmann retractors were used to protect the medial and lateral soft tissue structures during bone resection.
Functional alignment was performed in all robotic TKA cases with implant position manipulated in all three planes to restore the plane and obliquity of the joint as dictated by the periarticular soft tissues. Joint line obliquity was restored by applying valgus correction to the distal femoral resection and varus correction to the proximal tibial resection, and retaining overall limb alignment within the 0° to 3° safe zone of coronal alignment. Over-resection of the distal femur was avoided to maintain joint line height and minimise the risk of mid-flexion instability, whilst under-resection of the distal femur was avoided to minimise the use of thinner polyethylene inserts that may induce flexion instability. Tibial slope was revised based on intraoperative assessments to within 7° of combined femoral and tibial component flexion, as per implant recommendations. The revised bone resections were then executed, and the flexion-extension gaps, range of motion, and limb alignment reassessed using the aforementioned technique with corrective varus and valgus strains (figure 1h and 1i). Further periarticular soft tissue releases as described by Whiteside could be undertaken at this stage if required. The remaining femoral bone resections were performed using the robotic arm. The femoral box cut was performed with manual instrumentation, and the polyethylene insert selected after assessing flexion-extension gaps, mediolateral soft tissue tension, alignment and range of motion with trial femoral and tibial components in place.
Figure 1h: Intraoperative photograph showing the surgeon applying valgus force to assess medial soft tissue laxity in knee extension.

Figure 1i: Intraoperative photos showing virtual flexion-extension gaps used to fine-tune bone implant positioning.
All patients underwent patella resurfacing with asymmetrical components. The surgical site was washed and a layered closure of the medial retinaculum, quadriceps tendon, subcutaneous tissue, and skin performed with absorbable sutures. All patients received an intraarticular vacuum drain with a silicon tube extending from a 1cm incision over the anterolateral aspect of the knee joint. All patients received 40ml of 0.25% Marcaine into the joint capsule prior to wound closure. The cemented Stryker Triathlon (Stryker Navigation, Kalamazoo, Michigan), cruciate sacrificing knee system with patellar resurfacing was used in both groups.

**Accuracy of implant positioning**

Preliminary studies have shown that robotic TKA is associated with improved accuracy of achieving the planned implant positioning and limb alignment compared to conventional jig-based TKA. Sawblade action is limited to the confines of the planned haptic bone resections windows, which helps to execute the planned femoral and tibial bone resections with a high level of precision. Song et al conducted a prospective randomised study on 50 conventional jig-based TKAs versus 50 robotic TKAs, and found robotic TKA improved accuracy of achieving neutral mechanical alignment and reduced outliers of greater than 3° in limb alignment compared to conventional jig-based TKA. Bellemans et al reviewed outcomes in 25 patients undergoing robotic TKA and reported femoral and tibial implant positioning within 1° of the planned positions in all three planes. Hamp et al performed a cadaveric study on six specimens undergoing conventional jig-based TKA on one side and robotic TKA on the contralateral side. The authors found that robotic TKA was associated with improved accuracy of femoral and tibial implant positioning in the coronal, sagittal, and axial planes compared to conventional jig-based TKA. Moon et al also conducted a cadaveric study using CT scans to assess accuracy of implant positioning and limb alignment in 10 conventional jig-based TKAs versus 10 robotic TKAs. The authors found that robotic TKA was associated with high levels of precision in achieving the planned component positioning and...
Reduced outliers in limb alignment compared to conventional jig-based TKA. Robotic TKA has also been shown to more accurately restore the native joint line and Insall-Salvati ratio compared to conventional jig-based TKA. Improved accuracy in achieving these radiological outcomes has been previously correlated to increased patient satisfaction, greater implant stability, and improved kinematics through the arc of knee flexion following TKA. There remains a paucity of studies comparing accuracy of achieving the planned implant positions, posterior tibial slope, and posterior condylar offset ratio between the two treatment techniques. Previous studies have also used different implant designs in each treatment group, which may have led to observer bias. In this research thesis, we aim to use identical implant designs in both treatment groups, which offers an opportunity to blind observers calculating radiological outcomes and limit any potential observer or measurement bias.

**Learning curve of robotic TKA**

The learning curve of robotic TKA is important for understanding the impact of implementing this procedure on the surgical workflow, scheduling of operative cases and theatre lists, and establishing any additional risks or complications during the acquisition of surgical proficiency. Proponents of robotic TKA cite that this technology helps to produce a more streamlined procedure than conventional jig-based TKA by reducing the need for instrument trays, alignment guides and cutting blocks; enabling more rapid computer-guided bone resections; and reducing the need for implant trialling due to the high accuracy of preoperative surgical planning. Sodhi et al explored the learning curve of robotic TKA in two different surgeons, and found operative times were increased during the initial 20 robotic TKAs. Thereafter, operative times in robotic TKA were comparable to those of conventional jig-based TKA in both surgeons. However, this study reported on the learning curve of each surgeon using mean operative times in consecutive groups of patients undergoing robotic TKA. It is possible to improve on these existing studies by assessing a more comprehensive range of learning outcome measures including operative times of individual stages of the robotic procedure, surgical team comfort levels, accuracy of implant positioning, restoration of limb alignment, and postoperative complications. Cumulative summation (CUSUM) analyses may also provide more detailed information on incremental changes in study outcomes with consecutive cases until predefined levels of surgical competence are achieved. To our knowledge, there are no existing studies assessing the effect of the learning curve of robotic TKA on achieving the planned implant positioning, native joint line restoration, posterior condylar offset ratio, and posterior tibial slope.

**Periarticular soft tissue injury**

Appropriate flexion-extension gap balancing and mediolateral ligamentous tensioning during TKA are essential for optimising knee kinematics and long-term implant survivorship. In conventional jig-based TKA, controlled soft tissue releases to ensure proper mediolateral tension are undertaken in 50-76% of patients, with some authors advocating for controlled soft tissue releases to be undertaken in all non-navigated TKAs. Robotic TKA uses optical motion capture technology to quantify intraoperative limb alignment, flexion-extension gaps, mediolateral soft tissue tension, and range of motion. This real-time intraoperative data may be used to fine-tune bone resections and manipulate implant positioning to achieve the desired knee kinematics, which limits the need for any additional soft tissue releases. Robotic TKA also utilises stereotactic boundaries to limit sawblade motion to the confines of the planned femoral and tibial bone resection windows. This may help to limit inadvertent iatrogenic periarticular soft tissue injury compared with conventional jig-based TKA, which uses a handheld sawblade and manually-positioned instruments to protect the soft tissue envelope. Khlopas conducted a cadaveric study in which six blinded observers reported iatrogenic soft tissue trauma.
following bone resection with conventional jig-based TKA versus robotic TKA. The authors found that robotic TKA was associated with reduced PCL injury, decreased tibial subluxation, and reduced need for patella eversion compared with conventional jig-based TKA. To our knowledge, there are no existing studies comparing intraoperative periarticular soft tissue injury or bone trauma in conventional jig-based TKA versus robotic TKA, and no existing studies correlating these findings to the postoperative inflammatory response, inpatient rehabilitation, or early functional outcomes.

**Functional outcomes**

Due to the relative novelty of robotic TKA, there are limited studies reporting on long-term functional outcomes between conventional TKA and robotic TKA. Siebert et al conducted a retrospective study on 70 patients undergoing robotic TKAs versus a matched historical cohort of 50 patients receiving conventional jig-based TKAs, and observed reduced postoperative soft-tissue swelling in the robotic group. Marchand et al compared outcomes in 28 robotic TKAs matched with 20 conventional jig-based TKAs and showed that pain, patient satisfaction, and physical function scores as measured using Western Ontario and McMaster Universities Arthritis Index (WOMAC) were better in the robotic group compared with the conventional group at six months after surgery. Kholpas et al conducted a prospective non-randomised multicentre trial comparing 102 conventional jig-based TKAs versus 150 robotic TKAs, and found robotic TKA was associated with greater improvements in walking and standing at 4-6 weeks and three months after surgery compared to conventional jig-based TKA. Ren et al recently conducted a meta-analysis of five studies that included 323 robotic TKAs versus 251 conventional jig-based TKAs, and found improved Knee Society Score (KSS) functional scores and WOMAC scores in the robotic group at six months follow-up. To our knowledge, there are no existing comparing early postoperative pain, opiate analgesia consumption, inpatient physiotherapy utilisation, range of motion, and time to hospital discharge in conventional jig-based TKA versus robotic TKA.

Improved accuracy of implant positioning in robotic TKA has not translated to any differences in middle- to long-term functional outcomes compared to conventional jig-based TKA. Song et al reported no difference in Hospital for Special Surgery (HSS) or WOMAC scores between 50 conventional jig-based TKAs and 50 robotic TKAs at two-years follow-up. Liow et al conducted a prospective randomised trial in 29 conventional jig-based TKAs versus 31 robotic TKAs, and found there was no difference between the two treatment groups with respect to the Oxford Knee Score (OKS) and KSS at two years follow-up. Yang conducted a prospective cohort study on 71 robotic TKAs versus 42 conventional jig-based TKAs, and found no difference in HSS and WOMAC scores at minimum 10 years follow-up. Cho et al recently reported outcomes in 155 robotic TKAs versus 196 conventional jig-based TKAs, and also found no difference in WOMAC, OKS, KSS, and SF-12 scores at minimum 10 years follow-up. However, these studies have used different implant designs within each treatment group, patients have not been randomised to their respective treatments, and outcomes for both image-based and imageless and semi-automated and fully automated robotic devices grouped together.

**Limitations of robotic TKA**

Robotic technology is associated with substantial installation and maintenance costs for the robotic device. Further costs are incurred for additional preoperative imaging, increased operating times during the learning phase, training the surgical team, updating of computer software, renewing servicing contracts and consumables. Most robotic devices are also only compatible with a limited number of implant designs, and different application systems need to be purchased for THA, TKA, and unicompartmental knee arthroplasty (UKA). There remains a paucity of studies comparing cost-effectiveness
and resource use in conventional jig-based TKA versus robotic TKA. Robotic TKA requires additional incisions for the insertion of femoral and tibial registration pins to enable optical motion capture tracking, and image-guided robotic TKA increases radiation exposure to the patient. There are additional time delays for the remote planning team to template the optimal implant size and positioning on the patient-specific virtual model, which then requires further preoperative fine-tuning by the operating surgeon. Fully active robotic TKA systems have been reported to cause periarticular soft tissue injury and technical issues with the robotic device have required intraoperative conversion to conventional jig-based TKA.\textsuperscript{53} The robotic device, computer screens, and infrared sensors reduce the intraoperative working space, and additional instruments and surgical trays may cause instrument crowding.

**Assessment of knee biomechanics**

Existing studies exploring the effects of anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) resection on knee biomechanics have shown conflicting findings, with some trials showing only their resections leads to flexion-extension mismatch, whereas other studies have shown no impact of ACL or PCL resection on flexion-extension ratios or mediolateral soft tissue laxity.\textsuperscript{74-81} The main limitations of these existing studies are that they were performed on healthy cadaveric specimens with secondary knee stabilisers excised, varying degrees of soft tissue releases were undertaken prior to ACL or PCL resection, and joint gaps were assessed using manually-controlled tensioning devices with heterogeneity in the distraction forces applied.\textsuperscript{76-81} Gap values recorded within healthy cadaveric specimens may not accurately reflect measurements under physiological conditions in patients with advanced disease and soft tissue contractures undergoing TKA.\textsuperscript{76-81} Robotic TKA is performed using optical motion capture technology to assess intraoperative changes in flexion-extension gaps, mediolateral soft tissue tension, limb alignment, and range of motion. Optical motion capture technology during robotic TKA offers a unique avenue for assessing the effects of ACL and PCL resection on knee biomechanics under more physiological knee conditions. This technology has not been previously validated as an investigative tool for assessing the effects of controlled ligamentous releases on knee biomechanics.

**Conclusion**

Robotic TKA uses preoperative imaging or intraoperative bone mapping to create a patient-specific virtual reconstruction of the knee joint. The surgeon uses this model to plan optimal bone resections and implant positioning, and an intraoperative robotic device to execute this plan with a high level of accuracy. Optical motion capture technology enables intraoperative assessments of knee biomechanics, which enables the surgeon to manipulate bone resections and fine-tune implant positioning to achieve the desired kinematics through the arc of flexion. Robotic technology with stereotactic boundaries also limits sawblade motion to the confines of the preoperative surgical plan, which may help to better preserve the periarticular soft tissue envelope compared to a handheld manually-controlled sawblade. Within the existing medical literature, there remains a paucity of clinical studies comparing accuracy of implant positioning, periarticular soft tissue injury, postoperative functional rehabilitation, postoperative systemic inflammatory response, and early functional outcomes in conventional jig-based TKA versus robotic TKA. Furthermore, optical motion capture technology during robotic TKA may offer an accurate and reproducible method for assessing the effects of controlled ACL and PCL resections on knee biomechanics. However, this technology has not been validated or previously used to quantify the effects of ligamentous releases on knee biomechanics. An improved understanding of these study outcomes
will help to develop the optimal TKA procedure with high levels of patient satisfaction, improved functional outcomes, increased implant survivorship, and reduced long-term complications.

**Objectives of research thesis**

The overall objectives of this research thesis are to compare a comprehensive range of perioperative radiological and clinical outcomes in conventional jig-based TKA versus robotic-arm assisted TKA, and use optical motion capture technology to quantify the effects of ACL and PCL resections on knee biomechanics. This research thesis includes seven prospective studies with 440 patients to assess the following outcomes: learning curve of robotic TKA; accuracy of implant positioning; periarticular soft tissue injury, effects of ACL and PCL resection on knee biomechanics; early functional rehabilitation; and the systemic inflammatory response in conventional TKA versus robotic TKA. This thesis presents a novel classification system, the Macroscopic Soft Tissue Injury (MASTI) classification system for grading soft tissue injury and bone trauma during TKA, and describes the protocol for an ongoing study assessing robotic TKA with neutral mechanical alignment versus robotic TKA with functional alignment.

Each chapter is written as a separate study with its own objectives, hypotheses, methodology, results, discussion, limitations and role of the student. However, there is an overlap from patients recruited into the following studies: learning of robotic TKA and accuracy of implant positioning (chapter 2); macroscopic soft tissue injury and validation of a new classification system (chapter 3); the effect of ACL resection on knee biomechanics (chapter 4); and functional rehabilitation in conventional jig-based TKA versus robotic-arm assisted TKA (chapter 7). Separate patient groups were recruited into the following studies: the effect of posterior cruciate ligament resection on flexion-extension gaps, mediolateral ligament tension, and fixed flexion deformity (chapter 5); a prospective randomised controlled trial comparing the systemic inflammatory response in conventional jig-based total knee arthroplasty versus robotic-arm assisted total knee arthroplasty (chapter 6); and prospective double-blinded randomised controlled trial comparing robotic functionally aligned TKA versus robotic mechanically aligned TKA (Study Protocol) (chapter 8).

*Robotic technology in total knee arthroplasty: A systematic review.*

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Chapter 2

Learning curve of robotic-arm assisted total knee arthroplasty and accuracy of implant positioning
Abstract

The learning curve of robotic TKA is important for understanding the effect of implementing this procedure on the surgical workflow, scheduling of operative cases and theatre lists, and establishing any additional risks or complications during the acquisition of surgical proficiency. The study included 60 consecutive conventional jig-based TKAs followed by 60 consecutive robotic-arm assisted TKAs. Independent observers recorded surrogate markers of the learning curve including operative times, stress levels amongst the surgical team using the state-trait anxiety inventory (STAI) questionnaire, accuracy of implant positioning, limb alignment, and complications within 30 days of surgery. This study found that robotic-arm assisted TKA was associated with a learning curve of seven cases for operating times (p=0.01) and surgical team anxiety levels (p=0.02). Cumulative robotic experience did not affect accuracy of implant positioning (p=0.90), limb alignment (p=0.61), posterior condylar offset ratio (p=0.87), posterior tibial slope (p=0.79), and joint line restoration (p=0.76). Robotic-arm assisted TKA improved accuracy of implant positioning (p<0.001) and limb alignment (p<0.001) with no additional risk of postoperative complications compared to conventional jig-based TKA. The findings of this study are clinically relevant as they provide an improved understanding of the effects of implementing robotic-arm assisted TKA on the surgical workflow. Theatre planning and scheduling of operative cases should consider increased operating times and heightened levels of anxiety amongst the surgical team during this initial learning phase.
**Background**

In this chapter, we explore the surgical team’s learning curve with robotic-arm assisted TKA through assessments of operative times, surgical team comfort levels, accuracy of implant positioning, and complications. As the surgical team were transitioning from conventional jig-based TKA to robotic-arm assisted TKA, we were able to use baseline measurements for all study outcomes from the conventional TKA group. In this study, we also assessed the accuracy of achieving the planned implant positioning and limb alignment in conventional jig-based TKA versus robotic-arm assisted TKA.

Accurate implant positioning and limb alignment are important surgeon-controlled variables that affect patient satisfaction, functional outcomes, and long-term implant survivorship following TKA.\textsuperscript{14-16} Robotic-arm assisted TKA aims to reduce surgical errors by using preoperative CT scans and computer-aided design (CAD) models to plan optimal implant positioning, and an intraoperative robotic device to execute this plan with a high level of accuracy.\textsuperscript{28,62,72} Robotic-arm assisted TKA has several unique intraoperative steps for which the surgical team must attend cadaveric workshops and gain certificates of competence before undertaking the procedure in clinical practice. Although many centres are implementing robotic-arm assisted TKA into routine practice, the surgical team’s learning curve for integrating this procedure into the operative workflow remains unknown. Furthermore, to our knowledge, there are no existing studies comparing accuracy of achieving the planned limb alignment, posterior condylar offset ratio, posterior tibial slope, and joint line height restoration in conventional jig-based TKA versus robotic-arm assisted TKA. In this study, we decided to explore the surgical team’s learning curve with robotic-arm assisted TKA and assess how this procedure effects the accuracy of achieving the planned implant positioning compared to conventional jig-based TKA.

Initial studies reporting on the learning curve of robotic TKA have used operative times as exclusive markers of surgical competence, and found surgical proficiency may be achieved by high-volume arthroplasty surgeons within a few months.\textsuperscript{82,83} It is possible to improve on these existing studies by comparing a more comprehensive and robust range of learning outcome measures including operative times of individual stages of the robotic procedure, surgical team comfort levels, accuracy of component positioning, restoration of limb alignment, posterior condylar offset ratio, posterior tibial slope, joint line height restoration, and postoperative complications. These outcomes will provide a more detailed understanding of how implementing robotic-arm assisted TKA into routine practice effects the surgical workflow, and any additional risks or complications of the procedure until surgical proficiency is acquired. We will also use cumulative summation (CUSUM) analysis to assess incremental changes in study outcomes with consecutive robotic-arm assisted TKA procedures until predefined levels of surgical competence are achieved.\textsuperscript{84} All operative procedures will be undertaken by a single surgeon and baseline values for study outcomes will be recorded from the conventional jig-based TKA group.

The objective of this study was to determine the surgical team’s learning curve for robotic-arm assisted TKA through assessments of operating times, surgical team comfort levels, accuracy of implant positioning, limb alignment, and postoperative complications. The study hypothesis was that cumulative experience with robotic-arm assisted TKA would reduce operating times and improve surgical team confidence levels but there would be no learning curve for accuracy of implant positioning and postoperative limb alignment. The secondary objectives were to compare accuracy of implant positioning and limb alignment in patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA.
Methods

Patient selection:
This study included 120 patients with symptomatic knee osteoarthritis undergoing primary TKA, which included 60 consecutive conventional jig-based TKAs followed by 60 consecutive robotic-arm assisted TKAs. Patients were allocated to their treatment groups based on the date of their surgery relative to installation of the robotic device into the institution. Conventional jig-based TKA was performed prior to installation of the robotic device, and robotic-arm assisted TKA performed after its installation. Patients were not randomised but this enabled assessment of learning curves associated with complete transition from conventional jig-based TKA to robotic-arm assisted TKA. All operative procedures were performed by a single surgeon (F.S.H) with extensive experience in conventional jig-based TKA and previous cadaveric training in robotic-arm assisted TKA. The robotic group was the first cohort of patients undergoing robotic-arm assisted TKA under the operating surgeon. Inclusion criteria for this study included the following: patients with knee osteoarthritis undergoing primary TKA; patient between 18 and 80 years of age; surgery using the conventional jig-based or robotic-arm assisted technique; surgery performed by a single surgeon (F.S.H). Exclusion criteria included the following: conversion of UKA to TKA; prior infection of knee joint; arthroplasty for fracture or previous osteotomy; underlying neurological dysfunction compromising mobility; and/or the use of other surgical techniques such as computer navigation for TKA. There were no systemic differences in baseline characteristics or demographics in patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA (Table 2a). Two independent observers (J.R.T.P and B.K) that were blinded to each other’s recordings collected all study outcomes. Written informed consent was obtained from all patients. Hospital review board approval was acquired prior to commencement of the study.

Table 2a: Baseline characteristics and demographics in patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Conventional TKA (N=60)</th>
<th>Robotic TKA (N=60)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>68.7 ± 6.1</td>
<td>67.6 ± 7.6</td>
<td>0.38</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>26.1 ± 3.6</td>
<td>27.2 ± 3.6</td>
<td>0.10</td>
</tr>
<tr>
<td>Gender (female/male)</td>
<td>F 33 (55.0%)</td>
<td>F 32 (53.3%)</td>
<td>0.86</td>
</tr>
<tr>
<td></td>
<td>M 27 (45.0%)</td>
<td>M 28 (46.7%)</td>
<td></td>
</tr>
<tr>
<td>ASA grade</td>
<td>I - 24 (40.0%)</td>
<td>I - 21 (35.0%)</td>
<td>0.76</td>
</tr>
<tr>
<td></td>
<td>II - 32 (53.7%)</td>
<td>II - 34 (56.7%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>III - 4 (6.7%)</td>
<td>III - 5 (8.3%)</td>
<td></td>
</tr>
<tr>
<td>Side of intervention</td>
<td>R 29 (48.3%)</td>
<td>R 33 (55.0%)</td>
<td>0.47</td>
</tr>
<tr>
<td>(Right/Left)</td>
<td>L 31 (51.7%)</td>
<td>L 27 (45.0%)</td>
<td></td>
</tr>
</tbody>
</table>

Summary statistics are: N (percentage) or mean with standard deviation, BMI=Body Mass Index, ASA score = American Society of Anaesthesiologists score.
Preoperative imaging and templating:
All patients underwent routine preoperative anteroposterior weight-bearing knee radiographs, lateral knee radiographs, and full-length hip-to-ankle radiographs. In patients undergoing conventional jig-based TKA, the operating surgeon used Traumacad software (Traumacad, Petach-Tikva, Israel) with plain radiographs to preoperatively template optimal bone resection, implant sizes, and implant positioning. In patients undergoing robotic-arm assisted TKA, computer software (Mako system software, Stryker Limited, Kalamazoo, Michigan, USA) was used to translate the preoperative CT scan into a patient-specific virtual 3D CAD model of the knee joint. The operating surgeon used the preoperative CT scan and CAD model to template optimal bone resection, implant positioning and implant sizes. Preoperative imaging and templating in conventional jig-based TKA and robotic-arm assisted TKA are discussed in further detail in appendix section 10.1.

Surgical technique:
All operative procedures were performed under general anaesthesia. The surgical techniques for conventional jig-based TKA and robotic-arm assisted TKA are described in detail in appendix section 10.2. In both treatments groups, the standard medial parapatellar approach was used with implantation of the cemented Stryker Triathlon (Stryker Navigation, Kalamazoo, Michigan, USA) cruciate substituting knee system with patella resurfacing using asymmetrical components.

Outcome measures:
Operative time:
Operative time was defined as time from initial surgical incision to final wound closure. In robotic-arm assisted TKA, surgical times for the following parts of the procedure were recorded: surgical tray, robotic device, and instrument set-up; surgical approach and insertion of registration pins; bone registration; joint balancing; bone preparation; implant trialling; cement implantation of final prosthesis; and overall operating time.

Surgical team anxiety levels:
The Spielberger State-Trait Anxiety Inventory (STAI) questionnaire is a validated subjective assessment tool for quantifying an individual’s stress levels with individual traits arising from the clinical environment. The six-item questionnaire has a 4-point rating scale and total scores range from 6 to 24, with higher values indicating higher levels of stress. The STAI questionnaire was completed by each member of the surgical team prior to the surgical time-out in all study patients. The surgical team included the operating surgeon, two consultant anaesthetists, two senior scrub nurses, one operating department practitioner (ODP), and one circulating nurse.

Accuracy of implant positioning and limb alignment:
All patients underwent postoperative anteroposterior weight-bearing and lateral knee radiographs, and full-length hip-to-ankle weight-bearing radiographs. Accuracy of implant positioning and limb alignment were assessed by comparing the values achieved in the postoperative radiographs to the planned values in the corresponding preoperative radiographs. Femoral and tibial axes were used as reference markers as described by Bell et al. Accuracy of achieving the planned femoral and tibial implant positioning was assessed using the techniques described by Moon et al. The femoral coronal implant alignment was measured as the medial angle subtended by the femoral mechanical axis and the line connecting
the distal points of the medial and lateral condyles of the femoral component. The femoral sagittal implant alignment was calculated as the angle subtended between the perpendicular line running proximally from the distal femoral surface in contact with the femoral component and the femoral mechanical axis. The tibial coronal implant alignment was measured as the medial angle subtended by the tibial mechanical axis and the medial to lateral axis of the tibial implant. The tibial sagittal alignment was calculated as the angle between the tibial mechanical axis and anterior to posterior axis of the tibial implant. Anteroposterior plain knee radiographs were used to measure the joint line height by calculating the perpendicular distance from a line extending through the distal points of the femoral condyles and a parallel line extending to the fibular head. True lateral knee radiographs were used to calculate the posterior tibial slope and posterior condylar offset ratio using the methods described by Gaudiani et al and Johal et al respectively.\textsuperscript{87,88}

**Complications:**
All patients were reviewed in outpatient clinic at 30 days following surgery by the independent observers for clinical assessment and full weight-bearing radiographs performed. Any postoperative complications and their respective treatments during this follow-up period were recorded for analysis.

**Power calculation:**
Previous studies comparing operating times between conventional jig-based TKA and computer navigated TKA have shown that the mean difference in operating time is 5 minutes.\textsuperscript{89} The minimum clinically important difference in operating time in this study was set at 1 minute. Assuming similar differences in operating time between conventional jig-based and robotic-arm assisted TKA, using a two-tailed, two-sample $t$-test with power of 80\% with an alpha value of 0.05, this study needed 120 patients to detect a minimal difference of 1 minute between the two treatment groups. Due to the limited follow-up time, no further adjustments were made to the sample size calculation to account for sample size attrition during follow-up.

**Statistical analysis:**
The CUSUM sequential analysis tool was used to assess learning curves in robotic-arm assisted TKA for operating time and surgical team stress levels as assessed using the STAI questionnaire. Standardised target values for the CUSUM analyses were set using the mean values for these outcome measures from the conventional jig-based TKA group. CUSUM values represent a running total of the differences between the value of each data point and the standardised target values for each outcome. The results of the CUSUM analysis were presented on a chart with chronologically ordered case numbers on the x-axis and the corresponding CUSUM score on the y-axis. This enabled performance over consecutive procedures to be visualized and inflexion points showing transition points in the learning curve to be identified. Learning curves for accuracy of implant position and limb alignment in robotic-arm assisted TKA were assessed by calculating root mean square error (RMSE) values for radiological outcomes in consecutive groups of 10 patients based on chronology of surgery. Categorical data was compared using the Fisher exact test and the chi-square test. Normally distributed continuous variables were compared using independent $t$-tests for unpaired data sets, paired $t$-tests for related (paired) data sets, and one-way analysis of variance (ANOVA) for multiple data sets. The Mann-Whitney test was used for non-parametric data. Statistical significance was set at $p<0.05$ for all statistical tests. All statistical analyses were performed using SPSS software version 21 (SPSS Inc., Chicago, Illinois, USA).
Results

Interobserver and intraobserver correlation coefficients:
Interobserver correlation coefficient was 0.88 (95% CI: 0.84-0.92) and intraobserver correlation coefficient was 0.90 (95% CI: 0.87 - 0.94) for all study outcomes recorded, which indicated moderately strong agreement on all parameters assessed by the two independent observers.

Operating times:
In robotic-arm assisted TKAs, CUSUM analysis for operative times revealed a sharp inflexion point after the first seven cases, which helped to identify two distinct phases in the learning curve (Figure 2a-c). Phase 1 represents the initial learning phase and Phase 2 represents the proficiency phase in robotic-arm assisted TKA. Comparison of the two phases demonstrated phase 1 procedures to be significantly longer (p=0.01) with no differences in baseline characteristics compared to phase 2 (Tables 2b-d). Overall, robotic-arm assisted TKA was not associated with increased operating times compared to conventional jig-based TKA (p=0.46) (Table 2e).

Figure 2: Cumulative summation (CUSUM) analysis charts demonstrating the learning curve for operative times with robotic-arm assisted TKA

Figure 2a: CUSUM chart for operative times in consecutive robotic-arm assisted TKAs. The dashed vertical line represents the inflexion point at which the learning curve transitions from the learning phase (Phase 1) to the proficiency phase (Phase 2).
Figure 2b: CUSUM chart for operative times in Phase 1 of the learning curve for robotic-arm assisted TKA

![CUSUM chart for operative times in Phase 1](image)

Figure 2c: CUSUM chart for operative times in Phase 2 of the learning curve for robotic-arm assisted TKA

![CUSUM chart for operative times in Phase 2](image)
Table 2b: Operative times for individual stages of the procedure in patients undergoing robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Operative stage (mins)</th>
<th>Cases 1-10</th>
<th>Cases 11-20</th>
<th>Cases 21-30</th>
<th>Cases 31-40</th>
<th>Cases 41-50</th>
<th>Cases 51-60</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrument, robotic device, and surgical tray set-up</td>
<td>15.8 ± 2.2</td>
<td>6.8 ± 1.7</td>
<td>8.1 ± 2.1</td>
<td>7.4 ± 1.2</td>
<td>7.3 ± 1.8</td>
<td>7.8 ± 1.3</td>
<td>0.01*</td>
</tr>
<tr>
<td>Surgical approach</td>
<td>7.8 ± 1.5</td>
<td>7.9 ± 1.1</td>
<td>7.2 ± 1.6</td>
<td>7.0 ± 1.2</td>
<td>7.5 ± 1.1</td>
<td>7.2 ± 1.8</td>
<td>0.52</td>
</tr>
<tr>
<td>Bone registration</td>
<td>17.0 ± 6.0</td>
<td>11.1 ± 1.2</td>
<td>10.6 ± 1.8</td>
<td>10.9 ± 1.4</td>
<td>11.5 ± 1.8</td>
<td>11.1 ± 1.6</td>
<td>0.04*</td>
</tr>
<tr>
<td>Joint balancing</td>
<td>14.3 ± 4.2</td>
<td>8.9 ± 1.1</td>
<td>8.7 ± 0.9</td>
<td>8.8 ± 1.2</td>
<td>9.1 ± 1.5</td>
<td>9.0 ± 1.8</td>
<td>0.02*</td>
</tr>
<tr>
<td>Bone preparation</td>
<td>17.1 ± 4.2</td>
<td>11.9 ± 1.2</td>
<td>11.7 ± 1.6</td>
<td>11.9 ± 1.8</td>
<td>12.1 ± 1.2</td>
<td>11.8 ± 1.6</td>
<td>0.01*</td>
</tr>
<tr>
<td>Implant Trialling</td>
<td>7.8 ± 1.1</td>
<td>7.6 ± 1.9</td>
<td>7.7 ± 1.5</td>
<td>7.9 ± 1.2</td>
<td>8.1 ± 1.1</td>
<td>8.5 ± 1.5</td>
<td>0.68</td>
</tr>
<tr>
<td>Cement implantation</td>
<td>14.4 ± 1.1</td>
<td>14.2 ± 1.4</td>
<td>13.6 ± 1.9</td>
<td>14.1 ± 1.3</td>
<td>13.8 ± 1.4</td>
<td>13.7 ± 1.3</td>
<td>0.51</td>
</tr>
<tr>
<td>Closure</td>
<td>6.5 ± 1.5</td>
<td>5.8 ± 1.4</td>
<td>5.8 ± 1.7</td>
<td>5.9 ± 0.7</td>
<td>6.1 ± 1.8</td>
<td>5.6 ± 1.9</td>
<td>0.60</td>
</tr>
<tr>
<td>Overall operating time</td>
<td>84.9 ± 14.6</td>
<td>66.2 ± 3.5</td>
<td>65.3 ± 3.2</td>
<td>66.5 ± 4.5</td>
<td>68.2 ± 3.7</td>
<td>67.1 ± 4.3</td>
<td>0.01*</td>
</tr>
</tbody>
</table>

Summary statistics are: Mean value and standard deviation. P-value for trend. * denotes statistically significant fall in study outcome after cases 1-10.

Table 2c: Comparison of the learning curve phases in patients undergoing robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Phase 1 (n=7)</th>
<th>Phase 2 (n=53)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>66.9 ± 6.9</td>
<td>69.1 ± 7.6</td>
<td>0.69</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>25.3 ± 4.4</td>
<td>27.4 ± 3.4</td>
<td>0.13</td>
</tr>
<tr>
<td>ASA grade 3</td>
<td>1 (14.2%)</td>
<td>6 (11.3%)</td>
<td>0.56</td>
</tr>
<tr>
<td>Male gender</td>
<td>3 (42.9%)</td>
<td>25 (47.2%)</td>
<td>0.43</td>
</tr>
<tr>
<td>Preoperative Hb (g/L)</td>
<td>132.4 ± 5.8</td>
<td>133.6 ± 9.8</td>
<td>0.75</td>
</tr>
<tr>
<td>Postoperative Hb Change (g/L)</td>
<td>15.1 ± 7.6</td>
<td>15.7 ± 6.9</td>
<td>0.61</td>
</tr>
<tr>
<td>Operative Time (min)</td>
<td>92.1 ± 10.6</td>
<td>66.8 ± 3.3</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Summary statistics are: N (percentage) or mean value and standard deviation. BMI=Body Mass Index, ASA score = American Society of Anaesthesiologists score, HB - Haemoglobin
Table 2d: Accuracy of implant positioning and limb alignment in patients undergoing robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Radiological outcome</th>
<th>Cases 1-10</th>
<th>Cases 11-20</th>
<th>Cases 21-30</th>
<th>Cases 31-40</th>
<th>Cases 41-50</th>
<th>Cases 51-60</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical alignment RMSE (°)</td>
<td>1.58 ± 0.77</td>
<td>1.80 ± 1.02</td>
<td>1.66 ± 1.16</td>
<td>1.11 ± 0.61</td>
<td>1.56 ± 0.90</td>
<td>1.33 ± 0.99</td>
<td>0.61</td>
</tr>
<tr>
<td>PCOR RMSE</td>
<td>0.23 ± 0.07</td>
<td>0.20 ± 0.07</td>
<td>0.22 ± 0.09</td>
<td>0.20 ± 0.11</td>
<td>0.24 ± 0.08</td>
<td>0.21 ± 0.10</td>
<td>0.87</td>
</tr>
<tr>
<td>Posterior tibial slope RMSE (°)</td>
<td>1.38 ± 0.68</td>
<td>1.44 ± 0.88</td>
<td>1.28 ± 0.62</td>
<td>1.47 ± 0.70</td>
<td>1.31 ± 0.63</td>
<td>1.39 ± 0.74</td>
<td>0.79</td>
</tr>
<tr>
<td>Joint line RMSE (mm)</td>
<td>0.98 ± 0.36</td>
<td>1.04 ± 0.56</td>
<td>1.07 ± 0.56</td>
<td>0.88 ± 0.60</td>
<td>1.11 ± 0.69</td>
<td>1.01 ± 0.61</td>
<td>0.76</td>
</tr>
<tr>
<td>Femoral coronal RMSE (°)</td>
<td>1.04 ± 0.38</td>
<td>0.98 ± 0.32</td>
<td>0.91 ± 0.41</td>
<td>1.01 ± 0.38</td>
<td>0.87 ± 0.48</td>
<td>1.04 ± 0.41</td>
<td>0.90</td>
</tr>
<tr>
<td>Femoral sagittal RMSE (°)</td>
<td>2.06 ± 0.83</td>
<td>1.99 ± 0.74</td>
<td>2.11 ± 0.52</td>
<td>2.03 ± 0.52</td>
<td>2.01 ± 1.01</td>
<td>1.96 ± 0.53</td>
<td>0.79</td>
</tr>
<tr>
<td>Tibial coronal RMSE (°)</td>
<td>0.93 ± 0.36</td>
<td>0.99 ± 0.47</td>
<td>1.03 ± 0.69</td>
<td>0.92 ± 0.45</td>
<td>1.06 ± 0.41</td>
<td>0.97 ± 0.47</td>
<td>0.68</td>
</tr>
<tr>
<td>Tibial sagittal RMSE (°)</td>
<td>2.01 ± 0.46</td>
<td>2.11 ± 0.47</td>
<td>1.90 ± 0.70</td>
<td>2.08 ± 0.67</td>
<td>1.87 ± 0.79</td>
<td>2.19 ± 0.45</td>
<td>0.82</td>
</tr>
</tbody>
</table>

Summary statistics are: RMSE (root mean square error) with standard deviation, PCOR - Posterior condylar offset ratio,

Table 2e: Study outcomes in patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Conventional jig-based TKA (n=60)</th>
<th>Robotic-arm assisted TKA (n=60)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative time (mins)</td>
<td>66.0 ± 6.2</td>
<td>69.8 ± 9.3</td>
<td>0.46</td>
</tr>
<tr>
<td>Preoperative STAI score:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating surgeon</td>
<td>12.1 ± 3.4</td>
<td>13.0 ± 4.1</td>
<td>0.45</td>
</tr>
<tr>
<td>Anaesthetist</td>
<td>9.1 ± 2.5</td>
<td>9.7 ± 2.5</td>
<td>0.63</td>
</tr>
<tr>
<td>Scrub nurse</td>
<td>12.8 ± 3.1</td>
<td>13.3 ± 2.6</td>
<td>0.13</td>
</tr>
<tr>
<td>Circulating nurse</td>
<td>11.1 ± 2.1</td>
<td>10.2 ± 2.9</td>
<td>0.42</td>
</tr>
<tr>
<td>ODP</td>
<td>8.6 ± 3.1</td>
<td>7.6 ± 2.4</td>
<td>0.15</td>
</tr>
<tr>
<td>Postoperative radiological outcomes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical alignment RMSE (°)</td>
<td>3.2 ± 1.2</td>
<td>1.5 ± 0.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>PCOR RMSE</td>
<td>0.03 ± 0.01</td>
<td>0.02 ± 0.01</td>
<td>0.66</td>
</tr>
<tr>
<td>Posterior tibial slope RMSE (°)</td>
<td>3.4 ± 1.1</td>
<td>1.8 ± 0.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Joint line RMSE (°)</td>
<td>2.9 ± 1.4</td>
<td>1.1 ± 0.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Femoral coronal RMSE (°)</td>
<td>4.0 ± 1.1</td>
<td>1.8 ± 0.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Femoral sagittal RMSE (°)</td>
<td>4.2 ± 0.8</td>
<td>2.4 ± 0.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Tibial coronal RMSE (°)</td>
<td>3.6 ± 0.8</td>
<td>1.4 ± 0.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Tibial sagittal RMSE (°)</td>
<td>3.9 ± 1.0</td>
<td>2.0 ± 0.6</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Summary statistics are: RMSE (root mean square error) with standard deviation, PCOR - Posterior condylar offset ratio,
STAI – State-trait anxiety inventory questionnaire score, ODP – Operating department practitioner
Surgical team anxiety levels:
CUSUM analysis of preoperative stress levels as assessed using the STAI questionnaire revealed an inflexion point after seven cases ($p=0.02$) with a pattern similar to operative times in robotic-arm assisted TKA (Figure 2d). Further analysis revealed STAI scores to be significantly higher in phase 1 than in phase 2 for all members of the surgical team (Figure 2e). There was no difference in the overall STAI scores amongst team members between conventional jig-based TKA and robotic-arm assisted TKA (Table 2e).

*Figure 2d: Chart displaying CUSUM analysis for state-trait anxiety inventory (STAI) scores amongst all surgical team members with consecutive robotic-arm assisted TKAs*
Implant positioning and limb alignment:

There was no learning curve effect for robotic-arm assisted TKA on accuracy of achieving the planned femoral (p=0.90) and tibial (p=0.68) implant positioning, mechanical alignment (p=0.61), posterior condylar offset ratio (p=0.87), posterior tibial slope (p=0.79), and native joint line restoration (p=0.76) (Table 2d) (Figures 2f and 2g). Robotic-arm assisted TKA improved accuracy of achieving the planned mechanical alignment (p<0.001), femoral coronal (p<0.001) and sagittal (p<0.001) implant positioning, tibial coronal (p<0.001) and sagittal (p=0.96) implant positioning, posterior tibial slope (p<0.001), and joint line height restoration (p<0.001) compared to conventional jig-based TKA (Table 2e). There was no difference between the two treatment groups in achieving the planned posterior condylar offset ratio (p=0.66).
Figure 2f: Bar chart showing root mean square errors (RMSEs) in accuracy of femoral and tibial implant positioning (degrees) in consecutive patient groups undergoing robotic-arm assisted TKA.

Figure 2g: Bar chart showing root mean square errors (RMSEs) in accuracy of achieving the planned mechanical alignment (degrees), posterior condylar offset ratio (PCOR), posterior tibial slope (degrees), and joint line restoration (mm) in consecutive patient groups undergoing robotic-arm assisted TKA.
Complications:
There were two inpatient complications in this study, which included one patient from each treatment group. In conventional jig-based TKA, one patient had minor wound dehiscence from the distal part of the midline incision, which was treated with adhesive skin strips to approximate the wound edges and prophylactic oral antibiotics. In the robotic-arm assisted TKA group, one patient had minor wound dehiscence over the incision for the proximal tibial registration pins. This was treated with regular dressings and prophylactic oral antibiotics. Both patients made a satisfactory recovery with no further complications.

Discussion
This study found that robotic-arm assisted TKA was associated with a learning curve of seven cases for achieving operating times and surgical team comfort levels equivalent to those of conventional jig-based TKA. Robotic-arm assisted TKA did not have a learning curve for accuracy of implant positioning, limb alignment, posterior condylar offset ratio, posterior tibial slope, and native joint line preservation. Robotic-arm assisted was associated with improved accuracy of implant positioning and limb alignment with no additional risk of complications compared to conventional jig-based TKA.

This study found that operative time decreased rapidly over the initial seven cases of robotic-arm assisted TKA as the surgical team became increasingly familiar with the robotic technology and accustomed to the operative stages of the robotic procedure. The most marked time improvements occurred with bone registration, and operative times for this stage of the procedure decreased by over 50% during the initial learning phase. Intraoperative anatomical landmarks for bone registration were similar in all patients and therefore with increasing surgical experience, the surgeon was able to predict and pre-emptively place the bovie tip over the appropriate osseous landmark for registration. More moderate improvements were observed in time for bone resection as the surgeon became progressively more responsive to feedback from the sawblade. As the surgeon became more adept with fine movements of the robotic arm and more receptive to the audio, visual, and tactile feedback, he was able to better control the movements of the arm and preform bone cuts with greater efficiency. This study also found that the mean time for joint balancing during the proficiency stage was 8.9 minutes (range; 7-12 mins). During this stage, the surgeon assessed knee kinematics through the arc of motion, flexion-extension gaps, limb alignment and range of motion. Using this intraoperative data, the surgeon was able to fine-tune bone resections and implant positioning to balance flexion-extension gaps and mediolateral soft tissue tension without having to perform more extensive soft tissue releases as often required in conventional jig-based TKA.90,91 This may have helped to limit the overall operating time of the robotic procedure.

The findings of this study complement those of Sodhi et al that explored the learning curve of robotic TKA using operative time as an exclusive marker of surgical proficiency.62 The authors reviewed operative times in two different surgeons and found mean operative time over the first 20 robotic TKA cases was increased compared to each surgeon’s mean operative time for conventional jig-based TKA. In surgeon 1, operative time for the first 20 cases ranged from 71-104 minutes and for surgeon 2, operative time ranged from 74-142 minutes. The wide range in operative times over the first 20 cases suggest that the learning curve may have already been in effect and operating times equivalent to those of conventional TKA may have been observed much earlier than reported. The authors also reported that after the initial learning phase, operative times in the robotic-arm assisted TKA group were comparable to that of conventional jig-based TKA, which is
consistent with the current study findings. In theory, robotic-arm assisted surgery may help to produce a more streamlined surgical procedure by reducing the need for instrument trays, alignment guides, and cutting blocks, with more rapid computer-guided bone resections, and reduced need for implant trialling due to the high accuracy of the preoperative surgical plan.31,32,61 However, we found that overall operating times were comparable between the two treatment groups. CUSUM analysis showed that after the surgeon became “time even” to conventional jig-based TKA, additional robotic procedures did not help to reduce operative times any further.

Implementation of robotic-arm assisted TKA was associated with heightened levels of anxiety amongst the surgical team during the initial learning phase. This is important as higher levels of stress and mental strain are associated with diminished operative performance, poor decision making, and reduced technical skills.85 Implementation of a new surgical approach or operative technique stimulates greater sympathetic nervous function with increased subjective and objective markers of stress.85 In this study, improvements in the surgical team’s anxiety levels with robotic-arm assisted TKA followed in a trend similar to that of operative times with baseline STAI scores reached after seven cases. Progressive improvements in anxiety scores during this initial learning phase correlated with the surgical team becoming more proficient with setting up the new surgical trays and instruments, positioning the robotic machine in theatre, attaching the sawblade to the robotic arm, and proactively preparing the registration pins, check points, and arrays. As the team became more confident with these steps, subjective anxiety levels and operative times diminished. The highest anxiety levels were observed in the operating surgeon and scrub nurse during the initial learning phase, but this did not translate to any difference in accuracy of implant positioning or additional perioperative complications.

Previous studies have shown well-established learning curves for accuracy of implant positioning with the integration of minimally invasive surgery, new implant designs, and computer navigation for TKA.92-94 Furthermore, recent registry data on UKA has shown that surgeon-controlled technical errors in implant positioning are the most common reason for implant failure, and low surgical case-volume is an independent risk factor for implant failure and revision surgery.95 In this study, cumulative robotic experience did not impact the accuracy of achieving the planned implant positioning, limb alignment, posterior condylar offset ratio, posterior tibial slope, or native joint line restoration. Robotic-arm assisted TKA uses bone registration to confirm intraoperative spatial orientation of the limb and fixed infra-red arrays accurately track the femoral and tibial bone resection windows throughout the procedure. Stereotactic boundaries also confine bone resection to the limits of the stereotactic boundaries, which helps to minimise manual errors in bone resection and implant positioning during the initial learning phase.31,32,63 These findings should be interpreted with caution as the operating surgeon in this study is a high-volume arthroplasty surgeon with extensive experience in manual and navigated TKA, and so the learning curve from this study may not be directly transferrable to all other arthroplasty surgeons.

Robotic-arm assisted TKA was associated with improved accuracy of implant positioning and limb alignment compared to conventional jig-based TKA, which is important as these prognostic variables affect patient satisfaction, functional outcomes, and long-term implant survivorship.31,32,89,91,96 Our findings are consistent with Song et al that performed a prospective randomised study on 100 patients undergoing primary TKA and found robotic-arm assisted surgery improved accuracy of achieving neutral mechanical alignment and reduced outliers of greater than 3 degrees from the planned alignment (0% vs 24%, p<0.001) compared to conventional jig-based TKA.31 The authors also reported that robotic TKA enabled better preservation of the flexion gap to within 2 mm of the extension gap (6% vs 20%, p=0.037) compared to
conventional jig-based TKA. Bellemans et al reviewed outcomes in 25 patients undergoing robotic-arm assisted TKA and found femoral and tibial implant alignment within 1 degree of the planned position was achieved in all three planes. Improved accuracy of preserving the native posterior tibial slope and joint line within the robotic group in this study are also significant findings as previous studies have shown these radiological outcomes correlate with improved patient satisfaction, stability, and kinematics through the arc of motion following TKA. Although robotic-arm assisted TKA may help to improve the accuracy of implant positioning and limb alignment compared to conventional jig-based TKA, there remains a paucity of data on how these radiological outcomes correlate to long-term differences in clinical outcomes and implant survivorship between the two treatment groups.

The findings of this study will enable healthcare professionals to better understand the impact of implementing robotic-arm assisted TKA on the surgical workflow. Theatre planning and scheduling of operative cases should consider increased operative times and heightened levels of anxiety amongst the surgical team during this initial learning phase. As team members become more familiar and adept with robotic technology, comfort levels improve and theatre efficiency increases thereafter. There is no learning curve effect of robotic-arm assisted TKA on accuracy of implant positioning or limb alignment, which is important for the safe implementation of this procedure into routine surgical practice. Robotic-arm assisted TKA improves accuracy of implant positioning with no additional risk of postoperative complications at short-term follow-up compared to conventional jig-based TKA.

The strengths of this study are that it is a prospective single surgeon study assessing several surrogate markers of the surgical team’s learning curve with complete transition in surgical practice from conventional jig-based TKA to robotic-arm assisted TKA. CUSUM analysis enabled accurate assessment of inflexion points for operative times and surgical team anxiety levels during the progression of the learning curve for robotic-arm assisted TKA. The surgical approach was standardised, the same implant design was used in both groups, and radiological outcomes were recorded by blinded observers with high interobserver correlation coefficients for all recorded outcomes.

There are several limitations that must be appreciated when interpreting the findings of this study. Accuracy of implant positioning and limb alignment were measured using 2D imaging instead of 3D imaging, and accuracy of implant positioning in the axial plane was not assessed in this study. This was also a single-surgeon study in which the operating surgeon was a high-volume arthroplasty surgeon with extensive experience in conventional TKA and computer navigated TKA. Previous studies have shown that surgeons’ with more extensive experience in laparoscopy that are transitioning to robotic prostatectomy have shorter learning curves for operative times and satisfactory tumour resection margins compared to those with more limited laparoscopic experience. The surgical team in this study may also have gained further navigation or robotic experience with other surgeons during the study period. Therefore, the generalisability of these findings remains unknown, and caution should be exercised in directly transferring the learning curve with this surgical team to all other surgical teams and healthcare institutions. Furthermore, follow-up time was limited to 30 days after surgery and the impact of the learning curve on other operative cases or costs to the institution were not assessed in this study.

It is also important to note that the STAI questionnaire assessed the surgical team’s confidence with robotic-arm assisted TKA but it did not assess the level of competence with which the tasks were completed. The Dunning-Kruger effect
suggests that, across a wide range of tasks, individuals with poor performance overestimate their ability, whereas the top performers assess their ability more accurately.\textsuperscript{101,102} The basic premise of this theory is that metacognitive insight requires the same skills as task performance, and therefore individuals that perform poorly at their tasks also lack the insight for accurate self-assessment. In this study, operative times and accuracy of implant positioning were used as surrogate markers of the surgeon’s competence but additional measures of surgical competence such as soft tissue handling, manual dexterity, economy of movement and intraoperative decision-making were not assessed. Furthermore, CUSUM analyses showed the surgical team had a learning curve of seven robotic TKA cases for operative times and confidence levels but no measurements of performance or competence with each team member’s tasks were assessed during the learning phase. Further studies on the learning curve of robotic-arm assisted TKA should assess the relationship between metacognitive insight and task-specific performance during the progression of the learning curve.

**Conclusion**

Robotic-arm assisted TKA was associated with a learning curve of seven cases for achieving operating times and surgical team comfort levels comparable to those of conventional jig-based TKA. Cumulative robotic experience did not affect accuracy of implant positioning, limb alignment, posterior condylar offset ratio, posterior tibial slope, and joint line restoration. Overall, robotic-arm TKA improved accuracy of implant positioning and limb alignment with no additional risk of postoperative complications compared to conventional jig-based TKA. In the following chapter, we will assess how the improved surgical precision for bone resection with robotic technology translates to any differences in perioperative soft tissue injury compared to conventional jig-based surgery.

**My role in this study:**

- Identified gap in the scientific literature on the learning curve of robotic TKA
- Generated study hypothesis
- Identified study outcomes for assessment of learning curve
- Measured radiological outcomes
- Collated study outcomes and performed statistical analysis
- Wrote manuscript for publication

**Robotic-arm assisted total knee arthroplasty has a learning curve of seven cases for integration into the surgical workflow but no learning curve effect for accuracy of implant positioning.**

Kayani B, Konan S, Huq SS, Tahmassebi J, Haddad FS.

Chapter 3

Macroscopic soft tissue injury and validation of a new classification system for grading intraoperative soft tissue injury during total knee arthroplasty
Abstract

Injury to the periarticular soft tissue envelope during TKA may compromise postoperative functional recovery, decrease clinical outcomes, reduce stability, and decrease implant survivorship. The objective of this study was to compare iatrogenic periarticular soft tissue injury in conventional jig-based TKA versus robotic-arm assisted TKA, and develop a validated classification system for reporting periarticular soft tissue injury and bone trauma during TKA. This study included 30 consecutive conventional jig-based TKAs followed by 30 consecutive robotic-arm assisted TKAs performed by a single-surgeon. Intraoperative photographs of the femur, tibia, and periarticular soft tissues were taken prior to implantation of prostheses. Using these outcomes, the macroscopic soft tissue injury (MASTI) classification system was developed to grade iatrogenic soft tissue injuries during TKA. Interobserver and intraobserver validity of the proposed classification system was assessed. This study found that patients undergoing robotic-arm assisted TKA had reduced soft tissue injury in both passively correctible (p<0.001) and non-correctible varus deformities (p<0.001); more pristine femoral (p<0.001) and tibial (p<0.001) bone resection surfaces; and improved MASTI scores compared to conventional jig-based TKA (p<0.001). There was high interobserver (ICC=0.92 [95% CI:0.88-0.96]) and intraobserver agreement (ICC=0.94[95% CI 0.92 - 0.97]) of the proposed MASTI classification system. In conclusion, robotic-arm assisted TKA was associated with reduced periarticular soft tissue injury and decreased bone trauma compared to conventional jig-based TKA. The proposed MASTI classification may facilitate further research correlating macroscopic soft tissue injury or bone trauma during TKA to long-term clinical and functional outcomes.
Background

In the previous chapter, we found that robotic-arm assisted TKA did not have a learning curve for accuracy of implant positioning or limb alignment, and robotic technology enabled improved accuracy of implant positioning compared to conventional jig-based TKA. In this chapter, we take this one step further by assessing how robotic technology effects the integrity of the surrounding soft tissue envelope and residual bone surfaces during TKA. In order to compare soft tissue injury and bone trauma between the two treatment groups, we developed and validated a new classification system for grading iatrogenic periarticular soft tissue injury and bone trauma during TKA.

The technical objectives of TKA are to replace diseased bone with artificial implants, restore alignment, preserve the joint line, balance flexion-extension gaps, and maintain the normal Q angle for patella tracking. In order to achieve these objectives, preservation of the surrounding soft tissue envelope during TKA is essential. Inadvertent injury to the periarticular soft tissue structures such as the collateral ligaments, posterior cruciate ligament (PCL), or extensor mechanism, may compromise postoperative clinical and functional recovery, reduce stability, and decrease implant survivorship. In conventional jig-based TKA, planned limb alignment and proper mediolateral soft tissue tensioning may be achieved using measured resection or gap balancing techniques. Bone resection is undertaken using intramedullary or extramedullary referencing with manually-positioned alignment guides and a handheld oscillating sawblade. Surgical instruments are used to protect surrounding ligamentous and neurovascular structures. Controlled selective soft tissue releases may be undertaken to balance flexion/extensions gaps and optimise mediolateral soft tissue tension in knee flexion and extension. However, manual error associated with inadvertent soft tissue releases during preparation for implantation or tissue damage from the sawblade is an accepted risk of the procedure. In many cases, this subtle soft tissue injury is unnoticed or underreported and its long-term clinical and functional significance remains undetermined. In robotic-arm assisted TKA, bone resection is confined to the stereotactic boundaries of the predefined haptic bone windows, which conceptually helps to limit bone trauma and periarticular soft tissue injury. To our knowledge, there are no existing clinical studies comparing periarticular soft tissue injury and bone trauma in conventional jig-based TKA versus robotic-arm assisted TKA, and no existing classification systems for grading periarticular soft tissue injury during TKA. A validated grading system would help to standardise reporting of periarticular soft tissue injury during TKA, and facilitate future studies exploring the effects of soft tissue injury on long-term clinical outcomes and implant survivorship.

The primary objectives of this study were to compare intraoperative periarticular soft tissue injury and bone trauma in conventional jig-based TKA versus robotic-arm assisted TKA. The study hypothesis was that robotic-arm assisted TKA would lead to improved preservation of the periarticular soft tissue envelope compared to conventional jig-based TKA. The secondary objective was to develop a validated classification system for documenting and researching intraoperative soft tissue injury and bone trauma during TKA.

Methods

Patient selection:
This prospective cohort study included 60 patients with symptomatic knee osteoarthritis undergoing primary TKA, which included 30 consecutive conventional jig-based TKAs followed by 30 consecutive robotic-arm assisted TKAs. All operative procedures were performed by a single surgeon (F.S.H) with extensive experience in conventional jig-based
TKA and previous cadaveric training in robotic-arm assisted TKA. The robotic group was the first cohort of patients undergoing robotic-arm assisted TKA under the operating surgeon. Inclusion criteria for this study included the following: patients with knee osteoarthritis undergoing primary TKA; patient between 18 and 80 years of age; surgery using the conventional jig-based or robotic-arm assisted technique; surgery performed by a single surgeon (F.S.H). Exclusion criteria included the following: conversion of unicompartmental to TKA; prior infection of knee joint; arthroplasty for fracture or previous osteotomy; underlying neurological dysfunction compromising mobility; and/or the use of other surgical techniques such as computer navigation for TKA. Written informed consent was obtained from all study patients. Hospital review board approval was obtained prior to study commencement.

Preoperative clinical and radiological data:
Baseline characteristics relating to age, gender, body mass index, American Society of Anaesthetist (ASA) grade, laterality of surgery, preoperative range of movement, and varus or valgus alignment with degree of passive correction were prospectively recorded for each patient. Patients in both study groups had routine preoperative anteroposterior weight-bearing knee radiographs, lateral knee radiographs, and full-length hip-to-ankle radiographs. In all patients undergoing robotic-arm assisted TKA, an additional CT scan of the knee joint was performed. Preoperative templating in patients undergoing conventional jig-based and robotic-arm assisted TKA are discussed in more detail appendix section 10.1.

Surgical technique:
All operative procedures were performed under general anaesthesia. The surgical techniques for both conventional jig-based TKA and robotic-arm assisted TKA are described in detail in appendix section 10.2. In both treatments groups, the standard medial parapatellar approach was used with implantation of the cemented Stryker Triathlon (Stryker Navigation, Kalamazoo, Michigan, USA) cruciate substituting knee system with patella resurfacing using asymmetrical components.

Baseline characteristics:
There were no differences in baseline characteristics between the two treatment groups in relation to age, gender, body mass index, ASA score, laterality of surgery, and preoperative coronal or sagittal plane deformities (Table 3a). There was no statistical difference in correctability of coronal plane deformities between the two treatment groups.
Table 3a: Baseline characteristics for patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA

<table>
<thead>
<tr>
<th></th>
<th>Robotic-arm assisted TKA (n=30)</th>
<th>Conventional jig-based TKA (n=30)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>68.5 ± 5.8</td>
<td>69.9 ± 6.3</td>
<td>0.91</td>
</tr>
<tr>
<td>Gender (Female/Male)</td>
<td>F 16 (53.3%)</td>
<td>F 17 (56.7%)</td>
<td>0.92</td>
</tr>
<tr>
<td></td>
<td>M 14 (47.7%)</td>
<td>M 13 (43.3%)</td>
<td></td>
</tr>
<tr>
<td>Body mass index (Kg/m²)</td>
<td>29.1 ± 4.5</td>
<td>30.7 ± 4.7</td>
<td>1</td>
</tr>
<tr>
<td>Side of intervention (Right/Left)</td>
<td>R 18 (60%)</td>
<td>R 14 (47.7%)</td>
<td>0.27</td>
</tr>
<tr>
<td></td>
<td>L 12 (40%)</td>
<td>L 16 (53.3%)</td>
<td></td>
</tr>
<tr>
<td>Coronal plane deformity (° varus)</td>
<td>4.8 ± 5.7</td>
<td>3.0 ± 7.0</td>
<td>0.36</td>
</tr>
<tr>
<td>Correctible coronal plane deformity</td>
<td>15 (50%)</td>
<td>18 (60%)</td>
<td>0.77</td>
</tr>
<tr>
<td>Sagittal plane deformity (°)</td>
<td>5.8 ± 3.9</td>
<td>5.8 ± 4.3</td>
<td>0.96</td>
</tr>
<tr>
<td>ASA Grade (mode; range)</td>
<td>2 (1-3)</td>
<td>2 (1-3)</td>
<td>1</td>
</tr>
</tbody>
</table>

Summary statistics are: N (percentage) or mean with standard deviation, BMI=Body Mass Index, ASA score = American Society of Anaesthesiologists score.

Intraoperative clinical photographs:
Standardised intraoperative photographs with a 100 mm lens (EF 100mm f/2.8L Macro IS USM, Canon Inc., Ohtaku, Tokyo, Japan) were obtained following femoral and tibial bone preparation to assess iatrogenic bone trauma and periarticular soft tissue injury. Six photographs were taken in each patient to assess the soft tissue condition within the medial, lateral, anterior (extensor mechanism) and posterior compartments, and the residual femoral and tibial bone surfaces. All photographs were taken from one metre to enable accurate and clear visualisation of the bone surfaces and periarticular soft tissues whilst ensuring that the sterile surgical environment was not compromised. Six blinded fellowship-trained surgeons were given a tutorial on the proposed classification system. Each of the blinded observers individually reviewed the intraoperative photographs and allocated scores to the each of the four zones and an overall grade to each patient. Scores were compared between observers to assess interobserver reliability. Each of the six blinded observers were given the same clinical pictures after 28 days and asked to rescore bone trauma and soft tissue injury according to the proposed classification to determine intraobserver reliability. The use of photographs allowed documentation and prevented exposure of the open knee wound to multiple observers.

Classification system
The proposed classification is called the Macroscopic Soft Tissue Injury (MASTI) classification system. The MASTI
classification system is based on intraoperative assessment of the periarticular soft tissue envelope during TKA. The classification system divides the knee into the four following: medial tibial zone; lateral tibial zones; anterior zone (the patellar tendon, patella and quadriceps tendon); and posterior zone. The tibia is divided into medial and lateral zones by a horizontal line from the posterior cruciate ligament (PCL) towards the most prominent point of the tibial tubercle (Figure 3a). The posterior zone incudes the PCL and posterior capsule, which is most easily evaluated in deep knee flexion. The macroscopic appearances of the soft tissue injuries in each of the four zones are evaluated. There are six potential soft tissue appearances and the score designated to each zone reflects the most severe soft tissue injury within that zone. Different points values are assigned to the corresponding macroscopic soft issue appearance for each zone (figure 3b). This includes:

6. Uninvolved soft tissue (10 points)
5. Planned soft tissue release (8 points)
4. Soft tissue contusion (7 points)
3. Soft tissue fibrillation (macroscopic incomplete damage) (5 points)
2. Soft tissue cleavage (3 points)
1. Complete unintentional soft tissue detachment (superficial MCL tear, LCL tear, partial or full patella tendon tear) (0 points)

Using this classification system, a maximum of 40 points may be awarded if there is no evidence of iatrogenic soft tissue injury in any of the four zones. If there is complete unintentional soft tissue detachment in any of the four zones, then the patient scores 0 points for all four compartments. The minimum score is therefore zero points. The grading system for each zone has been weighted to enable the total score of all four zones to accurately reflect the severity of periarticular knee injury and enable stratification of this information into four distinct groups (A-D) (table 3b).
Figure 3b: Intraoperative photographs showing soft tissue injury (white arrows) for each grade of the Macroscopic Soft Tissue Injury (MASTI) classification system. No type 6 injuries were observed in this study.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1</td>
<td>Uninvolved soft tissues (10 points)</td>
<td>![Type 1 Image]</td>
</tr>
<tr>
<td>Type 2</td>
<td>Planned soft tissue release. Tissues beyond release uninjured (8 points)</td>
<td>![Type 2 Image]</td>
</tr>
<tr>
<td>Type 3</td>
<td>Soft tissue contusion. Superficial layer involvement only. No involvement of deeper layers. No fibrillation. (7 points)</td>
<td>![Type 3 Image]</td>
</tr>
</tbody>
</table>
Table 3b: Description of the Macroscopic Soft Tissue Injury (MASTI) classification system

<table>
<thead>
<tr>
<th>MASTI Classification</th>
<th>Description of soft tissue preservation</th>
<th>Points</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade A</td>
<td>Excellent</td>
<td>&gt; 34 points</td>
<td>Iatrogenic injury to only 1 zone with relative soft tissue preservation of the other zones</td>
</tr>
<tr>
<td>Grade B</td>
<td>Average</td>
<td>25 – 33 points</td>
<td>Minimal iatrogenic injury to ≥ 2 zones with relative soft tissue preservation of the other zones</td>
</tr>
<tr>
<td>Grade C</td>
<td>Poor</td>
<td>&lt; 24 points</td>
<td>Significant iatrogenic soft tissue injury to ≥ 3 zones</td>
</tr>
<tr>
<td>Grade D</td>
<td>Defunctioned Knee</td>
<td>0</td>
<td>Injury to superficial MCL ± LCL ± extensor mechanism defunctioning the knee</td>
</tr>
</tbody>
</table>

LCL - lateral collateral ligament; MCL - medial collateral ligament.
Group A (34-40 points) indicates that the periarticular soft tissue envelope is well preserved with mild to no iatrogenic soft tissue injury in all 4 zones. Group B (25-33 points) indicates that there is moderate iatrogenic periarticular soft tissue injury with clear soft tissue injury in at least two zones. Group C (24-1 points) indicates more severe soft tissue injury with iatrogenic soft tissue injury to at least three of the four zones. Group D (0 points) indicates surgical trauma or complete disruption that has resulted in defunctioning of the superficial medial collateral ligament (MCL), lateral collateral ligament (LCL) or the extensor mechanism (patella or quadriceps tendon) irrespective of the soft tissue appearance in any other corresponding compartment.

The quality of the residual femoral and tibial bone surfaces is also evaluated and used to stratify the soft tissue injury score further. There are three distinct grades for the macroscopic appearance of the femoral and tibial bone surfaces. Grades are assigned to the femur (“F”) and tibia (“T”) based on the most severely injured part of the resected bone surfaces. Grade A indicates that the residual bone surfaces are pristine and unblemished. Grade B indicates that the bony surfaces are uneven or were inadvertently injured or damaged when performing the bone resections. Grade C indicates that repeat bone resection may be necessary to improve the bony surface condition and that tibial and/or femoral wedges may be necessary to restore the joint line.

Statistical analysis
Statistical analysis for interobserver and intraobserver correlation coefficients (ICC) to assess absolute agreement for study outcomes was performed using the two-way random effects model. The unpaired t-test was used for continuous variables with normal distributions and the Mann–Whitney U test for continuous variables that were not normally distributed. Categorical data was compared using the Chi-square test with the Fisher's exact test used where expected cases were <5 in more than 20% of cells within a given contingency table. Statistical significance was set at a p-value < 0.05 for all analyses and all statistical analysis was performed using SPSS software version 21 (SPSS Inc., Chicago, IL).

Results
MASTI score:
Robotic-arm assisted TKA was associated with improved MASTI scores compared to conventional jig-based TKA (30.9 ± 3.1 vs 27.7 ± 3.9 respectively, p<0.001). Patients receiving robotic-arm assisted TKA had increased grade A scores (10/30 vs 2/30 respectively, p<0.001) and reduced grade C scores (0/30 vs 8/30 respectively, p<0.001) compared to conventional jig-based TKA. There was no difference between robotic-arm assisted TKA and conventional jig-based TKA in grade B scores (18/30 vs 20/30 respectively, p=0.21). No study patients in either group received grade D scores.

Interobserver and intraobserver correlation:
There was high interobserver (ICC=0.92 [95%CI: 0.88-0.96]) and intraobserver (ICC=0.94 [95%CI: 0.92- 0.97]) agreement between the six blinded observers for the MASTI classification system.

Bone injury score:
Intraoperative assessment of femoral and tibial bone resections followed a similar trend with reduced iatrogenic bone trauma scores in robotic-arm assisted TKA compared to conventional jig-based TKA. The use of robotic-arm assisted TKA was associated with more pristine type A femoral (30/30 vs 12/30 respectively, p<0.001) and tibia (26/30 vs 15/30
respectively, p<0.001) bone resection surfaces compared to conventional jig-based TKA. Type B bone resection surfaces were less common in robotic-arm assisted TKA for both femur (0/30 vs 18/30 respectively, p<0.05) and tibia (4/30 vs 15/30 respectively, p<0.001) compared to conventional jig-based TKA. No patients in either group had type C femoral or tibial bone resection surfaces.

**Soft tissue injury:**

For correctible and non-correctible coronal plane deformities, robotic-arm assisted TKA was associated with reduced medial soft tissue releases compared to conventional jig-based TKA (table 3c). Of note, none of the patients in the robotic-arm assisted TKA group required complete release of the posterior oblique ligament and/or posterior capsule compared to 10 patients in the conventional jig-based TKA group.

*Table 3c: Medial soft tissue releases in patients with correctable and non-correctable coronal plane deformities in patients undergoing robotic-arm assisted TKA versus conventional jig-based TKA*

<table>
<thead>
<tr>
<th></th>
<th>Robotic-arm assisted TKA</th>
<th>Conventional jig-based TKA</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-correctable coronal deformity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medial Zone Soft Tissue Release</td>
<td>15</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>8</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>&lt;50%</td>
<td>7</td>
<td>5</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Complete release of POL and posteromedial capsule</td>
<td>0</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><strong>Correctable coronal deformity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medial Zone Soft Tissue Release</td>
<td>15</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>&lt;50%</td>
<td>12</td>
<td>10</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Complete release of POL and posteromedial capsule</td>
<td>0</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

**Alignment and fixed flexion deformity:**

In the cohort of patients that underwent robotic-arm assisted TKA, there was no correlation between preoperative fixed flexion deformity (FFD) and the MASTI score (Pearson’s correlation coefficient= -0.29, p=0.22). The extent of preoperative malalignment did not correlate with the MASTI score (Pearson’s correlation coefficient = -0.21, p=0.36). The clinical correctability of preoperative malalignment did not affect the MASTI score (Pearson’s correlation coefficient = -0.17, p=0.41). In the group that underwent conventional jig-based TKA, the preoperative FFD showed a weak negative correlation to the MASTI score (Pearson’s correlation coefficient = -0.35, p=0.03). In this group, there was also a negative correlation between the extent of preoperative malalignment and the MASTI score (Pearson’s correlation coefficient = -0.73, p=0.02).

**Discussion**

This study found that robotic-arm assisted TKA was associated with reduced periarticular soft tissue injury and decreased bone trauma compared to conventional jig-based TKA. The MASTI classification system had high interobserver and
intraobserver agreement for stratifying iatrogenic soft tissue injury and grading bone trauma during TKA. The proposed classification system may help to standardise reporting of soft tissue injury and bone trauma during TKA and facilitate further research correlating these intraoperative findings to long-term clinical outcomes and implant survivorship.

Accurate bone resections, optimal implant positioning, balanced flexion-extension gaps and proper mediolateral ligamentous tensioning are the cornerstones of a successful TKA. Suboptimal execution of these technical objectives may lead to increased risk of implant wear, instability, aseptic loosening, and early revision surgery.\textsuperscript{104,122-127} The most commonly adopted soft tissue releases for flexion-extension gap balancing are those described by Whiteside.\textsuperscript{59,110} In varus deformities, the sequence of medial releases is as follows: osteophytes, deep medial collateral ligament, posteromedial corner (capsule and semimembranosus) and superficial medial collateral ligament (posterior oblique portion released for medial flexibility tightness and anterior oblique portion released for medial flexion tightness). In valgus deformities, the sequence of lateral releases is as follows: osteophytes, lateral capsule, iliobibial band (released for lateral extension tightness), popliteus (release for lateral flexion tightness) and the lateral collateral ligament. However, there is no uniform consensus on the extent to which these soft tissue releases should be performed, with some authors suggesting that all TKAs performed without navigation should undergo ligamentous releases, whereas others suggest that soft tissue balancing may only be appropriate in 50-76\% of cases.\textsuperscript{125-127} In this study, optical motion capture technology during robotic TKA enabled the surgeon to assess intraoperative limb alignment, flexion-extension gaps and mediolateral soft tissue tension. The surgeon was able to manipulate bone resections and fine-tune implant positioning to optimise these technical outcomes, without having to perform more extensive soft tissue releases. None of the patients undergoing robotic-arm assisted TKA required release of the POL or posteromedial capsule compared to ten patients in the conventional jig-based TKA group, despite no difference between the two groups relating to preoperative alignment or passive correctability.

Bone resection in robotic-arm assisted TKA was performed using an oscillating saw with visual, auditory, and tactile feedback. The sawblade in robotic-arm assisted TKA was only active within the confines of the stereotactic boundaries, which may have helped to better protect the periarticular soft tissue envelope compared to the manually-controlled sawblade in conventional jig-based TKA. Our findings are in keeping with a previous cadaveric study in which six blinded observers reported soft tissue trauma in cruciate-retaining TKAs, and found robotic-arm assisted TKA was associated with reduced PCL injury, decreased tibial subluxation, and reduced need for patella evasion compared to conventional jig-based TKA.\textsuperscript{61} In our study, there was no gross ligamentous disruption in either treatment group and the observed differences in soft tissue injury may be considered subtle subclinical findings. However, previous studies on knee arthroplasty have shown that even limited soft tissue releases may promote changes in local and systemic inflammatory responses, leading to increased pain and delayed postoperative rehabilitation.\textsuperscript{127-130} Siebert et al reviewed outcomes in 70 robotic-arm assisted TKAs versus 50 conventional jig-based TKAs, and found robotic TKA was associated with reduced postoperative swelling, though this difference was not quantified.\textsuperscript{71} The authors reported that sawblade action confined to the stereotactic boundaries in robotic TKA may have helped to reduce periarticular soft tissue injury compared to conventional jig-based TKA.

In this study, we found that the conceptual benefits of the stereotactic window in robotic-arm assisted TKA were transferrable to clinical practice with reduced soft tissue injury and bone trauma compared to conventional jig-based TKA.
However, these findings should be interpreted with caution as there is no existing evidence correlating these differences in intraoperative periarticular soft tissue injury or bone trauma to clinical results, functional outcomes, or long-term implant survivorship. Patients undergoing robotic-arm assisted TKA had improved MASTI scores compared to conventional jig-based TKA but the clinical significance of these findings remains unknown at this stage. Studies have reported improved accuracy of implant positioning and short-term functional outcomes in robotic-arm assisted TKA compared to conventional jig-based TKA but the results of further higher quality studies comparing clinical outcomes, patient-reported outcome measures, complications, cost-effectiveness, and implant survival between the two surgical techniques are still awaited.

Current robotic systems improve the accuracy of bone resections and help to limit sawblade action to the confines of the surgical plan. However, this technology still does not intraoperatively identify or detect soft tissue structures and the operating surgeon must remain vigilant for potential soft tissue injury during the robotic procedure. Park and Lee conducted a prospective randomised study comparing outcomes in 30 patients undergoing conventional manual TKA versus 32 patients receiving robotic-aided TKA. The study found that robotic-aided TKA improved accuracy of femoral and tibial implant positioning but increased the risk of complications compared to conventional manual surgery. The complications reported included superficial infection, patellar ligament rupture, patellar dislocation, supracondylar fracture, patellar fracture and common peroneal injury. The operating surgeon must still remain highly attentive to the periarticular soft tissue structures and use appropriate surgical instruments to protect the soft tissue envelope with current robotic devices for TKA.

The MASTI classification system provides a structured and systematic reporting scheme for stratifying periarticular soft tissue injury and bone trauma during TKA. To our knowledge, this is the only grading system for recording periarticular injury in TKA. Despite its shortcomings in these early stages, this classification system records a comprehensive range of outcomes from the soft tissue envelope and stratifies femoral and tibial bone injury. The high interobserver validity of the classification system will also aid the adoption and integration of this grading system into clinical practice. The MASTI classification system may be used as a guide to analyse and record periarticular injury during TKA in more detail; standardise data collection between treatment centres; correlate postoperative pain, rehabilitation, and inflammatory response to the extent of soft tissue releases; and facilitate further research comparing the invasiveness of different surgical approaches to long-term clinical outcomes and implant survivorship.

In addition to the above drawbacks, there are several other limitations to this study that need to be considered when interpreting the findings. Firstly, the MASTI score provides an overall score for periarticular soft tissue injury during TKA but reports very limited information on the state of individual compartments of the knee joint. Secondly, clinical photographs were used for assessing the grade of soft tissue injury and bone trauma as opposed to determining injury at the time of the surgical procedure. Thirdly, the impact of this periarticular injury on the systemic inflammatory response, which can affect postoperative pain and early functional recovery was not assessed in this study. The MASTI classification provides a useful research tool but will need to be modified and updated with further studies to provide more useful prognostic and clinically meaningful information.
Conclusion

Robotic-arm assisted TKA was associated with reduced periarticular soft tissue injury and decreased bone trauma compared to conventional jig-based TKA. The MASTI classification system had high interobserver and intraobserver reliability for assessing periarticular soft tissue injury and bone trauma during TKA. The proposed classification system may help to standardise reporting of soft tissue injury and bone trauma during TKA and facilitate further research correlating these intraoperative findings to long-term clinical outcomes and implant survivorship. In the following chapter, we will further use the optical motion capture technology in robotic TKA to assess the effect of ACL resection on knee biomechanics.

My role in this study:
- Identified gap in the scientific literature on studies comparing soft tissue injury in conventional TKA versus robotic TKA
- Generated study hypothesis
- Created MASTI classification system
- Obtained intraoperative images to enable blinded grading and validation of MASTI classification system
- Collated study outcomes
- Wrote manuscript for publication

Iatrogenic Bone and Soft Tissue Trauma in Robotic-Arm Assisted Total Knee Arthroplasty Compared with Conventional Jig-Based Total Knee Arthroplasty: A Prospective Cohort Study and Validation of a New Classification System.

Kayani B, Konan S, Pietrzak JRT, Haddad FS.

Chapter 4

The effect of anterior cruciate ligament resection on knee biomechanics
Abstract

The anterior cruciate ligament (ACL) is resected in both cruciate-retaining and posterior-stabilised TKA implant designs. However, the effects of ACL resection on knee biomechanics during TKA remain unknown. The objective of this study was to assess the effects of ACL resection on flexion-extension gaps, mediolateral soft tissue laxity, maximum knee extension, and limb alignment during primary TKA. This prospective study included 140 patients with symptomatic knee osteoarthritis undergoing primary robotic-arm assisted TKA. Optical motion capture technology with fixed femoral and tibial registration pins was used to assess study outcomes pre- and post-ACL resection with knee extension and 90 degrees knee flexion. This study found that ACL resection increased the mean extension gap significantly more than the flexion gap in the medial (p<0.001) and lateral (p<0.001) compartments. The mean gap differences following ACL resection did not create any significant mediolateral soft tissue laxity in knee extension (p=0.89) or knee flexion (p=0.40). ACL resection did not significantly affect maximum knee extension (p=0.23) or fixed flexion deformity (p=0.61). ACL resection did not significantly affect overall limb alignment (p=0.11). The findings of this study will facilitate flexion-extension gap balancing during TKA.
Background

The previous chapter reported on the use of optical motion capture technology during robotic-arm assisted TKA to assess periarticular soft tissue and fine-tune implant positioning to balance flexion-gaps and mediolateral soft tissue tension, which reduced the need for periarticular soft tissue releases compared to conventional jig-based TKA. In this chapter, we validate the use of optical motion capture technology as an investigative tool for assessing knee biomechanics, and use this technology to quantify the effects of ACL resection on flexion-extension gaps, mediolateral soft tissue tension, limb alignment, and knee extension. Intraoperative data was collected from study patients with symptomatic degenerative knee disease undergoing primary robotic-arm assisted TKA.

Achieving balanced, symmetrical flexion-extension gaps and optimal periarticular soft tissue tensioning in TKA are important surgeon-controlled technical objectives that affect postoperative recovery, functional outcomes, and implant survivorship.\textsuperscript{74,75,79,110,132-134} Overtightening of the soft tissue restraints may lead to pain, stiffness, and reduced range of motion, whilst overly-loosening the periarticular soft tissue envelope is associated with instability, accelerated polyethylene wear, and early implant failure.\textsuperscript{135-138} Instability secondary to suboptimal periarticular soft tissue tensioning in TKA accounts for 17-20% of all revision procedures.\textsuperscript{139} A comprehensive understanding of the effects of specific ligamentous releases on knee biomechanics is imperative for achieving the planned flexion-extension gaps and adequate mediolateral soft tissue tension during TKA. Existing studies have reported on the effects of controlled medial and lateral soft tissues releases, femoral and tibial bone resections, PCL excision, and patella subluxation/eversion on overall knee biomechanics during TKA.\textsuperscript{140-143} However, there are no existing clinical studies reporting on the effects of ACL resection during TKA on knee biomechanics.

The ACL is the primary restraint to anterior translation of the tibia and provides secondary restraint to tibial internal and external rotation relative to the femur.\textsuperscript{144,145} A previous cadaveric study has shown that ACL resection increases the extension gap proportionally more than the flexion gap during TKA.\textsuperscript{74} However, this study was conducted on ten healthy cadaveric knee specimens with manually-positioned tensioning devices and heterogeneity in the distraction forces applied. In the current study, we aim to create more physiological knee conditions by recording outcomes in patients with established degenerative disease undergoing TKA, preserving the periarticular soft tissue envelope and secondary stabilisers, and using intraoperative optical motion capture technology to assess a more comprehensive range of biomechanical outcomes pre- and post-ACL resection. The findings of this study will enable clinicians to better understand the effect of ACL resection on knee biomechanics, and facilitate intraoperative gap balancing and periarticular soft tissue tensioning during TKA.

The primary objective of this study was to assess the effect of ACL resection on flexion-extension gaps during primary TKA. The study hypothesis was that ACL resection would lead to a flexion-extension mismatch by increasing the extension gap proportionally more than the flexion gap. Secondary objectives were to assess the effects of ACL resection on mediolateral soft tissue laxity, maximum knee extension, and limb alignment. This study also helps to validate the use of optical motion capture technology as an investigative tool for assessing the effects of controlled ligamentous releases on knee biomechanics.
Methods

Patient selection:
This prospective single-surgeon study included 140 patients with symptomatic knee osteoarthritis undergoing primary robotic-arm assisted TKA. Inclusion criteria for this study included the following: Patients with knee osteoarthritis undergoing primary TKA; patients between 18-80 years of age; TKA undertaken using robotic-arm assisted technique; patients with an intact ACL confirmed on intraoperative examination and direct visualisation; surgery performed by the senior author. Exclusion criteria included the following: conversion of unicompartmental knee arthroplasty to TKA; partial/complete tear of ACL; arthroplasty for fracture or previous osteotomy; previous ligamentous operations on the knee joint. Baseline characteristics and demographics for all study patients are shown in table 4a. Informed consent was obtained from all study participants. Hospital review board approval was obtained prior to study commencement.

Table 4a: Demographics and baseline characteristics for study patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>64.1 ± 6.8</td>
</tr>
<tr>
<td>Gender (Male/Female)</td>
<td>M 76 (54.3%)</td>
</tr>
<tr>
<td></td>
<td>F 64 (45.7%)</td>
</tr>
<tr>
<td>ASA grade</td>
<td>I - 11 (7.8%)</td>
</tr>
<tr>
<td></td>
<td>II - 123 (87.9%)</td>
</tr>
<tr>
<td></td>
<td>III - 6 (4.3%)</td>
</tr>
<tr>
<td>Laterality of surgery</td>
<td>R 61 (43.6%)</td>
</tr>
<tr>
<td>(Right/Left)</td>
<td>L 79 (56.4%)</td>
</tr>
<tr>
<td>Preoperative hip-knee-ankle</td>
<td>6.1 ± 4.6</td>
</tr>
<tr>
<td>deformity (° varus)</td>
<td></td>
</tr>
</tbody>
</table>

Summary statistics are: N (percentage) or mean with standard deviation, ASA score = American Society of Anaesthesiologists score

Surgical technique:
All operative procedures were undertaken using the standard medial parapatellar approach. Femoral registration pins were inserted within the proximal portion of the incision and tibial registration pins placed four finger breadths below the tibial tubercle. Fixed arrays were mounted onto these to enable optical motion capture tracking during surgery. All study outcomes were recorded prior to bone resection to limit any inadvertent injury from the sawblade to the cruciate ligaments or periarticular soft tissue envelope.146 All gap values therefore represent virtual on-screen recordings of gap measurements prior to bone resection.

The limb was placed into extension and the patella inverted back into its anatomical position. Whilst supporting the weight of the leg with one hand, the surgeon applied valgus and varus strains to the knee joint to assess medial and lateral joint laxity respectively. The surgeon placed one hand under the patient’s heel and the other hand applied valgus or varus force at the level of the tibial tuberosity. Hip rotation was controlled by an assistant maintaining neutral alignment of the femur by supporting the femur at the level of the femoral registration pins. The valgus and varus forces were controlled by the surgeon to obtain maximum physiological tensioning through the medial and lateral compartments based on intraoperative
assessment of ligamentous tension and live onscreen changes in medial and lateral gaps. The use of this technique to accurately assess soft tissue joint laxity and restore native kinematics in robotic-arm assisted unicompartmental knee arthroplasty has been previously described.\textsuperscript{147} Medial and lateral extension gaps measurements were repeated three times and mean values recorded for each outcome measure. Maximum knee extension and overall limb alignment without the application of any corrective forces were recorded.

The knee was flexed to 90 degrees to assess the medial and lateral flexion gaps. During this manoeuvre, the surgeon supported the tibia in one hand but did not control the rotation of the limb, which enabled the tibia and femur to assume their natural alignments at 90 degrees flexion. The surgeon applied valgus and varus forces at the level of the tibial tuberosity with one hand while cupping the heel in the other hand. The assistant maintained neutral alignment of the femur by supporting the femur at the level of the femoral registration pins. Valgus and varus strains were applied to the knee joint in 90 degrees flexion to ensure maximum physiological ligamentous tension based on the surgeon’s intraoperative examination and live onscreen changes in medial and lateral gaps. Measurements of medial and lateral flexion gaps were repeated three times and mean values recorded.

The knee was then placed into 90 degrees of flexion and the patella subluxed laterally. The ACL was resected from its femoral origin under direct vision using electrocautery and its remnants from the femoral and tibial insertions dissected from their origins. Both the anteromedial and posterolateral bundles were excised. Care was taken to ensure that the PCL was not released or resected at this time. Completeness of ACL resection was confirmed using manual palpation and the anterior drawer test and Lachman test. Medial and lateral gaps in extension and 90 degrees flexion, maximum knee extension, and limb alignment were assessed using the same techniques prior to ACL resection described above. Following bone registration, assessment of knee kinematics, and virtual fine-tuning of implant positioning, an intraoperative robotic arm (Mako Robotic Arm Interactive Orthopaedic System, Stryker Ltd, Kalmazoo, Michigan, USA) was used to execute the planned femoral and tibial bone resections.

**Study outcomes:**

*Flexion-extension gaps:*

Absolute values for medial and lateral joint gaps in extension and 90 degrees knee flexion were obtained after ACL resection and compared to their corresponding values prior to ACL resection. This data was used to calculate changes in extension and flexion gaps for the medial and lateral compartments following ACL resection.

*Mediolateral laxity:*

Absolute values for medial and lateral joint gaps in extension and 90 degrees knee flexion were used to calculate differences in mediolateral joint gaps in extension and 90 degrees flexion respectively. Mediolateral gap differences in extension and flexion were calculated before and after ACL resection in all study patients.

*Maximum knee extension:*

Maximum knee extension immediately after ACL resection was recorded and compared to maximum knee extension immediately prior to ACL resection. This was recorded without the application of any corrective forces by the operating surgeon. The scout image (coronal view) of the preoperative planning CT scan was used to calculate the length of the
femur as the distance measured from the top of the femoral head to the most distal end of the medial femoral condyle of the operated limb. The femoral component size implanted was recorded.

**Limb alignment:**
Limb alignment in extension immediately after ACL resection was recorded and compared to limb alignment in extension immediately prior to ACL resection. In both extension and 90 degrees flexion, the operating surgeon supported the limb and allowed the tibia and femur to assume their natural alignments.

**Power calculation:**
Prior to commencement of the study, a sample size of 140 patients was selected to achieve a power of 95% (1–β) for assessing changes in medial and lateral gaps in extension and flexion using an effect size of 0.27 and alpha value of 0.05. All study outcomes were collected intraoperatively and therefore no further adjustments were performed to account for sample size attrition during follow-up.

**Statistical analysis:**
Normally distributed continuous variables were compared using paired sample t-tests for all grouped (paired) data sets and one-way ANOVA for multiple data sets. Intraobserver correlation coefficient values to measure the absolute level of agreement for all study outcomes recorded were assessed using the two-way random effects model. The Pearson’s correlation coefficient was used to assess the association between normally distributed continuous variables. Statistical significance was set at p<0.05 for all statistical tests. All statistical analyses were performed using SPSS software version 21 (SPSS Inc., Chicago, Illinois, USA).

**Results**

**Intraobserver correlation coefficient:**
Intraobserver correlation coefficient values were high for all study outcomes recorded (Table 4b).

Table 4b: Intraobserver correlation coefficient values for gap measurements pre- and post-anterior cruciate ligament (ACL) resection

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Pre-ACL resection</th>
<th>Post-ACL resection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medial extension gap (95% CI; p-value)</td>
<td>0.89 (0.86 to 0.92; &lt; 0.001)</td>
<td>0.84 (0.81 to 0.87; &lt; 0.001)</td>
</tr>
<tr>
<td>Lateral extension gap (95% CI; p-value)</td>
<td>0.86 (0.83 to 0.89; &lt; 0.001)</td>
<td>0.88 (0.85 to 0.91; &lt; 0.001)</td>
</tr>
<tr>
<td>Medial flexion† gap (95% CI; p-value)</td>
<td>0.86 (0.83 to 0.90; &lt; 0.001)</td>
<td>0.89 (0.86 to 0.92; &lt; 0.001)</td>
</tr>
<tr>
<td>Lateral flexion† gap (95% CI; p-value)</td>
<td>0.88 (0.85 to 0.92; &lt; 0.001)</td>
<td>0.91 (0.88 to 0.93; &lt; 0.001)</td>
</tr>
<tr>
<td>Maximum knee extension (95% CI; p-value)</td>
<td>0.90 (0.87 to 0.93; &lt; 0.001)</td>
<td>0.86 (0.83 to 0.90; &lt; 0.001)</td>
</tr>
<tr>
<td>Limb alignment (95% CI; p-value)</td>
<td>0.87 (0.84 to 0.90; &lt; 0.001)</td>
<td>0.86 (0.83 to 0.89; &lt; 0.001)</td>
</tr>
</tbody>
</table>

Summary statistics are: Mean intraobserver correlation coefficient with 95% confidence interval (CI), †Flexion = 90° knee flexion, ACL- anterior cruciate ligament
Flexion-extension gaps:
ACL resection significantly increased the mean extension gap more than the flexion gap in the medial (1.2 ± 1.0mm vs 0.2 ± 0.7mm respectively, p<0.001) and lateral (1.1 ± 0.9mm vs 0.2 ± 0.6mm respectively, p<0.001) compartments (Table 4c) (Figures 4a-d).

Table 4c: Study outcomes in patients pre- and post-anterior cruciate ligament (ACL) resection

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Pre-ACL resection</th>
<th>Post-ACL resection</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medial extension gap (mm)</td>
<td>17.9 ± 2.0</td>
<td>19.2 ± 1.8</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Lateral extension gap (mm)</td>
<td>18.1 ± 1.8</td>
<td>19.2 ± 1.7</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Medial flexion† gap (mm)</td>
<td>18.1 ± 2.1</td>
<td>18.4 ± 2.3</td>
<td>0.78</td>
</tr>
<tr>
<td>Lateral flexion† gap (mm)</td>
<td>17.9 ± 1.7</td>
<td>18.1 ± 1.8</td>
<td>0.62</td>
</tr>
<tr>
<td>Mediolateral extension gap difference§ (mm)</td>
<td>0.1 ± 2.7</td>
<td>0.1 ± 2.4</td>
<td>0.87</td>
</tr>
<tr>
<td>Mediolateral flexion† gap difference§ (mm)</td>
<td>0.2 ± 2.9</td>
<td>0.2 ± 3.1</td>
<td>0.54</td>
</tr>
<tr>
<td>Maximum knee extension (°)</td>
<td>4.6 ± 4.0</td>
<td>4.5 ± 3.9</td>
<td>0.23</td>
</tr>
<tr>
<td>Limb alignment (° varus)</td>
<td>2.3 ± 3.9</td>
<td>2.0 ± 3.6</td>
<td>0.11</td>
</tr>
</tbody>
</table>

Summary statistics are: mean with standard deviation; ACL – anterior cruciate ligament, flexion† = 90 degrees knee flexion, Mediolateral gap difference = difference in medial and lateral gap measurements.

Figure 4a: Boxplot showing the effect of anterior cruciate ligament (ACL) resection on the medial gap (mm) with knee extension.
Figure 4b: Boxplot showing the effect of anterior cruciate ligament (ACL) resection on the lateral gap (mm) with knee extension

Figure 4c: Boxplot showing the effect of anterior cruciate ligament (ACL) resection on the medial gap (mm) with knee flexion
Figure 4d: Boxplot showing the effect of anterior cruciate ligament (ACL) resection on the lateral gap (mm) with knee flexion

Mediolateral laxity:
Prior to ACL resection, there were no significant differences in mediolateral gaps in extension (medial gap $17.9 \pm 2.0$ mm vs lateral gap $18.1 \pm 1.8$ mm, $p=0.65$) or flexion (medial gap $18.1 \pm 2.1$ mm vs lateral gap $17.9 \pm 1.7$ mm, $p=0.41$) (Table 4c). ACL resection did not create any significant gap differences in extension (medial gap $19.2 \pm 1.8$ mm vs lateral gap $19.2 \pm 1.7$, $p=0.89$) or flexion (medial gap $18.4 \pm 2.3$ mm vs lateral gap $18.1 \pm 1.8$ mm, $p=0.40$).

Maximum knee extension:
ACL resection did not significantly affect maximum knee extension (change in maximum knee extension $= 0.2 \pm 0.7^\circ$, $p=0.23$) (Table 4c) (Figure 4e). In total, 102 patients (72.9%) had preoperative fixed flexion deformities (FFDs). In these patients, ACL resection did not significantly affect overall FFD ($4.2 \pm 3.2^\circ$ pre-ACL release vs $3.9 \pm 3.7^\circ$ post-ACL release, $p=0.61$). Length of femur (Pearson’s correlation coefficient $=0.12$, $p=0.46$) and femoral implant size (Pearson’s correlation coefficient $=0.09$, $p=0.38$) were not significantly associated with the change in FFD following ACL resection.
**Limb alignment:**

ACL resection did not significantly affect overall limb alignment (change in limb alignment $= 0.2 \pm 1.0^\circ$ valgus, $p=0.11$) (Table 4c). Subgroup analysis of the 19 patients with preoperative valgus deformity (mean limb alignment $= 3.6 \pm 2.8^\circ$ valgus) revealed ACL resection significantly increased the extension gap more than the flexion gap (Table 4d). In this cohort of patients, ACL resection did not significantly affect mediolateral soft tissue tension in extension or flexion, maximum knee extension, or overall limb alignment.

**Table 4d: Subgroup analysis of the changes in study outcomes in patients with valgus deformity (n = 19)**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Change following ACL resection</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medial extension gap (mm)</td>
<td>$1.1 \pm 0.9$</td>
<td>$&lt; 0.001$</td>
</tr>
<tr>
<td>Lateral extension gap (mm)</td>
<td>$1.3 \pm 0.7$</td>
<td>$&lt; 0.001$</td>
</tr>
<tr>
<td>Medial flexion† gap (mm)</td>
<td>$0.2 \pm 0.6$</td>
<td>0.56</td>
</tr>
<tr>
<td>Lateral flexion† gap (mm)</td>
<td>$0.3 \pm 0.7$</td>
<td>0.23</td>
</tr>
<tr>
<td>Mediolateral extension gap difference (mm)</td>
<td>$0.1 \pm 2.8$</td>
<td>0.74</td>
</tr>
<tr>
<td>Mediolateral flexion‡ gap difference (mm)</td>
<td>$0.2 \pm 2.3$</td>
<td>0.23</td>
</tr>
<tr>
<td>Maximum knee extension (°)</td>
<td>$0.2 \pm 0.8$</td>
<td>0.67</td>
</tr>
<tr>
<td>Limb alignment (° varus)</td>
<td>$0.2 \pm 0.9$</td>
<td>0.18</td>
</tr>
</tbody>
</table>

Summary statistics are: mean with standard deviation; ACL – anterior cruciate ligament, Mediolateral gap = Difference in medial and lateral gap measurements, flexion† = 90 degrees knee flexion.
Discussion

Symmetrical and balanced flexion-extension gaps with proper periarticular soft tissue tensioning are important surgical objectives during TKA for optimising functional outcomes and implant survivorship. The most pertinent finding from this study supports our hypothesis that ACL resection creates flexion-extension mismatch by increasing the extension gap more than the flexion gap. ACL resection produced comparable gap changes in the medial and lateral compartments that enabled mediolateral soft tissue balance to be retained in extension and flexion. ACL resection did not affect maximum knee extension or overall limb alignment.

The ACL arises from the posteromedial corner of the medial aspect of the lateral femoral condyle in the intercondylar notch and attaches anterior to the intercondylar eminence of the tibia. The two components of the ACL include the smaller anteromedial bundle that is more isometric and tightest in flexion, and the larger posterolateral bundle that experiences greater changes in length and is tightest in extension. In this study, ACL resection increased the extension gap more than the flexion gap, suggesting that the larger posterolateral bundle plays a more dominant role than the smaller anteromedial bundle in the stabilising function of the ACL. The more dominant role of the posterolateral bundle over the anteromedial bundle in the ACL is also supported by biomechanical studies on ACL reconstructions showing double-bundle reconstructions have higher mean graft forces with tibial rotation or anterior translation compared to single-bundle reconstructions, and higher rupture rates in the posterolateral bundle compared to the anteromedial bundle of double-bundle reconstructions.

This study showed comparable gap changes within the medial and lateral compartments, which helped to maintain mediolateral soft tissue balance in extension and flexion. The flexion-extension mismatch created by ACL resection in this study was markedly different to that reported with PCL resection in previous studies. Park et al reviewed outcomes in 30 patients with severe varus deformity (>15 degrees) or FFD (>20 degrees) and found PCL resection increased medial and lateral extension gaps by 1.2 mm and 0.3 mm respectively, and medial and lateral flexion gaps increased by 4.5 mm and 3.4 mm respectively. Chaiyakit et al reviewed mediolateral gaps in 16 patients undergoing computer-assisted TKA, and also found that PCL resection did not affect the extension gap but increased the mean medial flexion gap by 1.3 mm (p<0.05) and the mean lateral flexion gap by 2.1 mm (p<0.05). Comparing the current findings to these existing studies suggests that ACL resection leads to flexion-extension mismatch by increasing the extension gap more than the flexion gap, but comparable gap changes in the medial and lateral compartments help to retain mediolateral soft tissue balance in extension and flexion. However, PCL resection creates flexion-extension mismatch by increasing the flexion gap more than the extension gap, and varying gap changes between the medial and lateral compartments create mediolateral soft tissue imbalance in knee flexion but not in extension. The effect of PCL resection on these outcomes will be explored in more detail in the next chapter.

Balanced mediolateral soft tissue tension during TKA may help to facilitate knee flexion and improve survivorship with current implant designs, but this may not accurately reflect mediolateral soft tissue tension in the native knee joint. In the majority of patients, the native distal femoral valgus alignment and proximal tibial varus alignment combine to produce an overall mild varus limb alignment, which leads to more load transmitted though the medial compartment of the knee joint. In TKA with neutral alignment, the mechanical axis is positioned through the centre of the knee joint to help equalise load through the medial and lateral compartments. The focus is to achieve balanced flexion-extension gaps with
equal mediolateral soft tissue tension, which will conceptually help to produce more symmetrical component wear and reduce the risk of implant failure.\textsuperscript{15,152} However, this is not consistent with mediolateral soft tissue tension and knee biomechanics in native knee joints as shown in cadaveric and MRI studies.\textsuperscript{74,153} Freeman assessed mediolateral soft tissue tension in ten cadaveric specimens and found that the medial collateral ligament remained relatively tight in flexion, whereas the lateral collateral ligament had relatively greater laxity in flexion, which permitted knee rotation around an axis medial to the midline.\textsuperscript{153} More recently, studies with distraction forces applied to fixed healthy cadaveric knee specimens have also shown that the medial collateral ligament remains taught whilst the lateral collateral has more laxity in knee flexion.\textsuperscript{74,154} Implant designs such as the medial pivot, medial congruent and sagittal stable knee systems have been developed to more accurately recreate native knee kinematics by providing a more constrained medial compartment. The amount of laxity required within the lateral soft tissues has yet to be quantified and it remains unknown if this should be achieved through the design of the polyethylene insert, asymmetry of the femoral condyles using medially constrained knees, and/or by more extensive lateral soft tissue releases.

The traditional teaching for TKA with neutral mechanical alignment is to obtain equal-sized, rectangular flexion-extension gaps.\textsuperscript{155} This is most commonly achieved by performing bone resections perpendicular to the mechanical axes of the femur and tibia, and externally rotating the femoral component by 3° to compensate for the native anatomical tibial varus.\textsuperscript{155} Symmetrical rectangular flexion-extension gaps are important as the femoral implant had a uniform thickness in flexion and extension. However, increasing flexion in the native knee joint produces greater femoral roll back in the lateral femoral condyle compared to the medial femoral condyle, which leads to internal rotation of the tibia relative to the femur.\textsuperscript{74,153} The associated tightening of the medial soft tissue structures may reduce the medial compartment gap compared to the lateral compartment gap with progressive knee flexion. These findings suggest that the native knee joint may have trapezoid flexion-extension gaps, and the rectangular flexion-extension gaps advocated in traditional TKA may distort native periarticular soft tissue tension and knee biomechanics.\textsuperscript{74,153} The rotational forces within the knee joint may be influenced by the muscle action, foot position, and load applied. In the current study, the operating surgeon allowed for the patients’ legs to assume their own native alignment in flexion and extension. The position of the foot was not standardised, which may have affected the rotation of the limb and therefore the flexion-extension gaps recorded. Also, all measurements were recorded under general anaesthetic without the application of a compressive force in a load-bearing joint, and therefore it remains unknown how these outcomes translate into clinical practice when the patient is weight-bearing through the knee joint.

Recent cadaveric studies further support the concept of the native knee joint having trapezoid flexion-extension gaps. Nowakowski et al assessed flexion-extension gaps in ten healthy cadaveric knee specimens following the medial parapatellar approach and prior to bone resection.\textsuperscript{74} Gap measurements were performed in full extension and 90° knee flexion with 100 Newtons and 200 Newtons per compartment using a prototype force-determining ligament balancer. Prior to ACL, PCL and bone resections, applying 100 Newtons force per compartment, the extension gap was 5.7 ± 0.9 mm medially and 6.9 ± 1.2 mm laterally, and the flexion gap measured 6.8 ± 1.0 mm medially and 9.2 ± 1.1 mm laterally. With 200 Newtons force per compartment, the extension gap was 7.8 ± 1.3 mm medially and 9.5 ± 1.6 mm laterally, and the flexion gap measured 9.0 ± 1.3 mm medially and 11.8 ± 1.4 mm laterally. Similarly, Tanaka et al assessed medial and lateral joint gaps throughout the range of motion in ten ACL-resected cadaveric knee specimens with a tensioning device and consistent distraction force of 40 lb.\textsuperscript{154} All measurements were taken after ACL resection and the tensioning
device was positioned between the osteotomised tibia and intact articular surface of the femoral condyles. The medial and lateral joint gaps in extension were smaller than in flexion, and the lateral flexion gap increased more than the medial flexion gap at 60° to 120°. The study showed that the extension gap was 4.0 ± 1.5 mm medially and 2.8 ± 1.2 mm laterally, whereas the flexion gap measured 6.2 ± 2.0 mm medially and 11.8 ± 3.1 mm laterally. In combination, these studies suggest that the native flexion-extension gaps are trapezoid in shape and mediolateral soft tissue tension varies with knee flexion. An important limitation of our study is that gap measurements were only recorded in full extension and 90 degrees knee flexion. An improved understanding of the effects of ACL resection on knee biomechanics may be ascertained by assessing changes in flexion-extension gaps through smaller increments in the arc of knee flexion, and recording tibial translation and rotation relative to the femur.

This study found that ACL resection created consistent changes in flexion-extension gap measurements but the varus and valgus forces applied by the observer and the size of the ACL were not recorded in this study. Hooke’s law \( F = kx \) states that the force needed to compress or extend a spring by some distance \( x \) scales linearly with respect to that distance, which is affected by a structure-dependent constant factor \( k \). This constant factor is directly proportional to the cross-sectional area of a structure.\(^{156}\) According to this law, different forces are required to obtain similar tensions in an 8 mm-thick ACL compared to a 10mm-thick ACL. In the current study, these forces were not quantified or adjusted to the size of the ACL, which may have influenced the flexion-extension values recorded. Intraoperative load measurements during soft tissue tensioning with dynamometers or force sensors may have helped to produce more standardised and reproducible forces for assessing gap measurements and reducing measurement bias. More research is required using controlled valgus and varus forces to tension the soft tissue envelope and correlation of the ACL size to changes in flexion-extension gaps. This will enable more accurate, patient-specific quantification of gap changes pre- and post- ACL resection.

The findings of this study are clinically important as they provide surgeons with objective data on changes in flexion-extension gaps following ACL resection, which are directly relevant to cruciate-retaining and posterior-stabilised TKA implant designs. In bicruciate-retaining implant designs, preserving physiological tension through the native ACL may offer an opportunity to limit flexion-extension mismatch whilst retaining anterior stability. This may help to achieve more natural, patient-specific knee kinematics compared to cruciate-sacrificing implant designs. The current study also shows the potential effects of an ACL injury on knee biomechanics in patients with bicruciate-retaining TKAs. Our study showed that ACL resection increased the extension gap more than the flexion gap, which is likely to produce altered tibiofemoral contact points through the arc of knee flexion. These findings may help to explain the elevated cartilage strain and loss of articular cartilage associated with chronic ACL deficiencies.\(^{157-159}\) In this study, we strived to assess knee biomechanics under physiological knee conditions by using a standardised surgical approach, preserving the periarticular soft tissue envelope, recording gap measurements prior to bone resection, and restoring the patella back to its anatomical position during data collection. The use of optical motion capture technology eliminated the need for manually-positioned tensioning devices and spacer blocks, which are highly-user dependent and associated with poor reproducibility.\(^{74,76,140,142,159}\) This study also validated the use of optical motion capture technology as investigative tool for further trials assessing the effects of ligamentous releases on knee biomechanics.
Conclusion

ACL resection created flexion-extension mismatch by increasing the extension gap more than the flexion gap. Gap differences following ACL resection did not create any mediolateral soft tissue laxity in knee extension or flexion. ACL resection did not affect maximum knee extension or overall limb alignment. Bone resection, implant positioning, and periarticular soft tissue balancing should account for these biomechanical changes following ACL resection during TKA. In the following chapter, we will use the optical motion capture technology used in robotic TKA to assess how controlled resections of the PCL impact flexion-extension-gaps, mediolateral soft tissue tension, FFD and limb alignment.

My role in this study:
- Identified gap in the scientific literature on the impact of ACL resection on knee biomechanics during TKA
- Generated study hypothesis
- Identified study outcomes
- Recorded intraoperative data
- Collated study outcomes and performed statistical analysis
- Wrote manuscript for publication

The effect of anterior cruciate ligament resection on knee biomechanics.

Kayani B, Konan S, Ahmed SS, Chang JS, Ayuob A, Haddad FS.

Chapter 5

The effect of posterior cruciate ligament resection on flexion-extension gaps, mediolateral ligament tension, and fixed flexion deformity
Abstract

The use of optical motion capture technology during robotic-arm assisted TKA offers an avenue for assessing the effects of posterior cruciate ligament (PCL) release on knee biomechanics. The objective of this study was to assess the effect of PCL resection on flexion-extension gaps, mediolateral soft tissue tension, fixed flexion deformity (FFD), and limb alignment during posterior-stabilised TKA. This prospective study included 110 patients with symptomatic knee osteoarthritis undergoing primary robotic-arm assisted posterior-stabilised TKA. All operative procedures were performed by a single surgeon using a standard medial parapatellar approach. Optical motion capture technology with fixed femoral and tibial registration pins was used to assess joint gaps pre- and post-PCL resection in knee extension and 90 degrees knee flexion. This study found that PCL resection increased the flexion gap more than the extension gap in the medial (p<0.001) and lateral (p<0.001) compartments. The gap differences following PCL resection created mediolateral laxity in flexion (p<0.001) but not in extension (p=0.51). There was a strong positive correlation between preoperative FFD and change in FFD following PCL resection (Pearson’s correlation coefficient=0.81, p<0.001). PCL resection did not affect limb alignment (p=0.60). Bone resection, implant positioning, and periarticular soft-tissue balancing should account for these changes in flexion-extension gaps, mediolateral soft tissue tension, and FFD following PCL resection during posterior-stabilised TKA.
Background

In the previous chapter, we validated the use of optical motion capture technology as an investigative tool for assessing knee biomechanics and established that ACL resection created flexion-extension mismatch by increasing the extension gap proportionally than the flexion gap. In this chapter, we will use optical motion capture technology during robotic TKA to assess the effects of PCL resection on flexion-extension gaps, mediolateral soft tissue tension, limb alignment, and knee extension. The findings of this study will enable clinicians to better understand the effect of PCL resection on knee biomechanics, improve preoperative planning of bone resections and implant positioning, and facilitate intraoperative balancing of flexion-extension gaps, ligament tensioning, and correction of FFD during TKA.

Intraoperative flexion-extension mismatch or suboptimal ligament tensioning during TKA may lead to instability, implant loosening, and early revision surgery.\(^{79,134,160,161}\) Residual flexion contractures after TKA, which have a prevalence of 3.5% at minimum 3 years follow-up, may also adversely affect knee kinematics, spinal alignment, and functional outcomes.\(^{162}\) Conceptually, surgical techniques that improve intraoperative flexion-extension gap balancing, ligamentous tensioning, and fixed flexion deformity (FFD) may therefore help to improve long-term functional outcomes and implant survivorship following TKA. A comprehensive understanding of the biomechanical effect of specific ligamentous releases is imperative to achieving these technical objectives in both cruciate-retaining and posterior-stabilised implant designs. To our knowledge, optical motion capture technology during robotic TKA has not been previously used to quantify the effects of PCL resection on flexion-extension gaps, mediolateral soft tissue tension, FFD, and limb alignment.

The PCL is the largest and strongest intraarticular ligament of the knee joint, providing primary restraint to posterior tibial translation through flexion and internal rotation after 90 degrees flexion.\(^{163}\) Existing studies exploring the effect of PCL resection on knee biomechanics have shown conflicting findings, with some trials reporting gross flexion-extension mismatch after PCL resection,\(^{74-78}\) whilst other studies have shown no effect on flexion-extension ratios or mediolateral soft tissue laxity.\(^{79,80}\) The main limitations of these existing studies are that they were performed on healthy cadaveric specimens with secondary knee stabilisers excised,\(^{74,77}\) varying degrees of soft tissue releases prior to PCL resection,\(^{75,76}\) and joint gaps assessed using manually-controlled tensioning devices with heterogeneity in the distraction forces applied.\(^{74-78}\) In this study, we aim to create more physiological knee conditions by recording outcomes in patients with established degenerative disease undergoing posterior-stabilised TKA, preserving the periarticular soft tissue envelope and secondary stabilisers, and using fixed femoral and tibial registration pins with intraoperative optical motion capture technology to assess a more comprehensive range of biomechanical outcomes pre- and post-PCL resection.

The primary objective of this study was to quantify changes in flexion-extension gaps following PCL resection in patients undergoing primary posterior-stabilised TKA. The hypothesis was that PCL resection would lead to flexion-extension mismatch by increasing the flexion gap more than the extension gap. Secondary objectives were to assess the effect of PCL resection on the mediolateral soft tissue tension, FFD, and limb alignment.

Methods

Patient selection:

This prospective study included 110 patients with symptomatic knee osteoarthritis undergoing primary robotic-arm assisted TKA. All operative procedures were performed by a single surgeon (F.S.H). Inclusion criteria for this study
included the following: Patients with knee osteoarthritis undergoing posterior-stabilised TKA; patients between 18-80 years of age; TKA undertaken using robotic-arm assisted technique; surgery performed by the senior author. Exclusion criteria included the following: conversion of unicompartmental knee arthroplasty to TKA; arthroplasty for fracture or previous osteotomy; previous ligamentous operations on the knee joint; and preoperative or intraoperative finding of PCL deficiency. Baseline characteristics and demographics for all study patients are shown in Table 5a. Informed consent was obtained from all study participants. Institutional review board approval was obtained prior to study commencement.

Table 5a: Demographics and baseline characteristics for study patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>68 ± 6.2</td>
</tr>
<tr>
<td>Gender (Male/Female)</td>
<td>M 54 (49.1%)</td>
</tr>
<tr>
<td></td>
<td>F 56 (50.9%)</td>
</tr>
<tr>
<td>ASA grade</td>
<td>I - 26 (23.6%)</td>
</tr>
<tr>
<td></td>
<td>II - 82 (74.5%)</td>
</tr>
<tr>
<td></td>
<td>III - 2 (1.8%)</td>
</tr>
<tr>
<td>Laterality of surgery</td>
<td>R 60 (54.6%)</td>
</tr>
<tr>
<td>(Right/Left)</td>
<td>L 50 (45.4%)</td>
</tr>
<tr>
<td>Preoperative hip-knee-ankle deformity</td>
<td>4.1 ± 3.4</td>
</tr>
<tr>
<td>(° varus)</td>
<td></td>
</tr>
</tbody>
</table>

Summary statistics are: N (percentage) or mean with standard deviation, ASA score = American Society of Anaesthesiologists score

Surgical technique:

All operative procedures were undertaken using the standard medial parapatellar approach. Femoral registration pins were inserted within the proximal portion of the incision and tibial registration pins placed four finger breadths below the tibial tubercle. Fixed arrays were mounted onto these to enable optical motion capture tracking during surgery. The ACL was resected under direct vision using electrocautery. All study outcomes were recorded prior to bone resection to limit any inadvertent injury from the sawblade to the periarticular soft tissue envelope, which may affect knee biomechanics. All gap values therefore represent virtual on-screen recordings of gap measurements prior to bone resection.

The limb was placed into extension and the patella inverted back into its anatomical position. Whilst supporting the weight of the leg with one hand, the surgeon applied valgus and varus strains to the knee joint to assess medial and lateral joint laxity respectively. The surgeon placed one hand under the patient’s heel and the other hand applied valgus or varus force at the level of the tibial tuberosity. Hip rotation was controlled by an assistant maintaining neutral alignment of the femur by supporting the femur at the level of the femoral registration pins. The valgus and varus forces were controlled by the surgeon to obtain maximum physiological tensioning through the medial and lateral compartments based on intraoperative assessment of ligamentous tension and live onscreen changes in medial and lateral gaps. The use of this technique to accurately assess joint soft tissue laxity and restore native kinematics in robotic-arm assisted unicompartmental knee arthroplasty has been previously described. Medial and lateral extension gaps measurements were repeated three times.
and the average values recorded for each outcome measure. Maximum knee extension and overall limb alignment without the application of any corrective forces were recorded.

The knee was then flexed to 90 degrees to assess medial and lateral flexion gaps. During this manoeuvre, the surgeon supported the tibia in one hand but did not control the rotation of the limb, which enabled the tibia and femur to assume their natural alignment at 90 degrees knee flexion. The surgeon applied valgus and varus forces at the level of the tibial tuberosity with one hand while cupping the heel in the other hand. The assistant maintained neutral alignment of the femur by supporting the femur at the level of the femoral registration pins. Valgus and varus strains were applied to the knee joint in 90 degrees knee flexion to ensure maximum physiological ligamentous tension based on the surgeon’s intraoperative examination and live onscreen changes in medial and lateral gaps. Measurements of medial and lateral flexion gaps were repeated three times and the average value recorded. The PCL was resected from its femoral origin under direct vision using electrocautery and its remnants from the femoral and tibial insertions dissected from their origins. Both the anterolateral bundle and posteromedial bundle were excised. Completeness of PCL resection was confirmed using manual palpation. Medial and lateral gaps in extension and 90 degrees knee flexion, maximum knee extension, and limb alignment were assessed using the same techniques prior to PCL resection described above.

Bone registration was performed by intraoperatively mapping radiological landmarks displayed on the computer screen to verify anatomy and establish bone geometry. Intraoperative data on knee kinematics was used to further fine-tune bone resection and implant positioning using the robotic computer software. An intraoperative surgeon-controlled robotic arm (Mako Surgical, Kalamazoo, MI, USA) with visual, tactile, and audio feedback was then used to execute the planned femoral and tibial bone resections.

**Study outcomes:**

**Flexion-extension gaps:**
Absolute values for medial and lateral joint gaps in extension and 90 degrees knee flexion were obtained after PCL resection and compared to their corresponding values prior to PCL resection. This data was used to calculate changes in flexion and extension joint gaps for the medial and lateral compartments following PCL resection.

**Mediolateral laxity:**
Absolute values for medial and lateral joint gaps in extension and 90 degrees knee flexion were used to calculate differences in mediolateral joint gaps in extension and 90 degrees flexion respectively. Mediolateral gap differences in extension and flexion were calculated before and after PCL resection in all study patients.

**Fixed flexion deformity:**
Maximum knee extension immediately after PCL resection was recorded and compared to maximum knee extension immediately prior to PCL resection. This was recorded without the application of any corrective forces by the operating surgeon. The scout image (coronal view) of the preoperative planning CT scan was used to calculate the length of the femur as the distance measured from the top of the femoral head to the most distal end of the medial femoral condyle of the operated limb. The femoral component size implanted was recorded.
**Limb alignment:**
Limb alignment in extension immediately after PCL resection was recorded and compared to limb alignment in extension immediately prior to PCL resection. In both extension and 90 degrees flexion, the operating surgeon supported the limb and allowed the tibia and femur to assume their natural alignments.

**Power calculation:**
Prior to commencement of the study, a sample size of 110 patients was selected to achieve a power of 95% (1–β) for assessing changes in medial and lateral gaps in flexion and extension using an effect size of 0.30 and alpha value of 0.05. All study outcomes were collected intraoperatively and therefore no further adjustments were performed to account for sample size attrition during follow-up.

**Statistical analysis:**
Normally distributed continuous variables were compared using paired sample t-tests for all grouped (paired) data sets and one-way ANOVA for multiple data sets. The Pearson’s correlation coefficient was used to assess the association between normally distributed continuous variables. Statistical significance was set at p<0.05 for all statistical tests. All statistical analyses were performed using SPSS software version 21 (SPSS Inc., Chicago, IL).

**Results**

**Flexion-extension gaps:**
PCL resection produced greater increases in flexion gaps than extension gaps in the medial (2.4 ± 1.5mm vs 1.3 ± 1.0mm respectively, p<0.001) and lateral (3.3 ± 1.6mm vs 1.2 ± 0.9mm respectively, p<0.001) compartments (Table 5b) (Figure 5a-d). Following PCL resection, the increase in the lateral flexion gap was greater than the increase in the medial flexion gap (3.3 ± 1.6mm vs 2.4 ± 1.0mm respectively, p<0.001).

<table>
<thead>
<tr>
<th>Study outcome</th>
<th>Pre-PCL resection</th>
<th>Post-PCL resection</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medial extension gap (mm)</td>
<td>18.0 ± 1.9</td>
<td>19.5 ± 1.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lateral extension gap (mm)</td>
<td>18.2 ±1.8</td>
<td>19.4 ± 1.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Medial flexion† gap (mm)</td>
<td>17.9 ± 1.9</td>
<td>20.2 ± 1.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lateral flexion †gap (mm)</td>
<td>18.0 ± 1.7</td>
<td>21.3 ± 1.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mediolateral gap difference in extension (mm)</td>
<td>0.1 ± 2.5</td>
<td>0.1 ± 2.1</td>
<td>0.58</td>
</tr>
<tr>
<td>Mediolateral gap difference in flexion† (mm)</td>
<td>0.1 ± 2.5</td>
<td>1.1 ± 2.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Maximum knee extension (°)</td>
<td>4.8 ± 4.9</td>
<td>2.0 ± 3.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Limb alignment (° varus)</td>
<td>1.7 ± 2.8</td>
<td>1.5 ± 2.1</td>
<td>0.60</td>
</tr>
</tbody>
</table>

Summary statistics are: mean with standard deviation; PCL – Posterior cruciate ligament, flexion† = 90 degrees knee flexion, Mediolateral gap difference = difference in medial and lateral gap measurements.

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Figure 5a: Boxplot showing the effect of posterior cruciate ligament (PCL) resection on the medial joint gap (mm) with knee extension.

PCL – Posterior cruciate ligament

Figure 5b: Boxplot showing the effect of posterior cruciate ligament (PCL) resection on the lateral joint gap (mm) with knee extension.

PCL – Posterior cruciate ligament
Figure 5c: Boxplot showing the effect of posterior cruciate ligament resection (PCL) on the medial joint gap (mm) with knee flexion

Figure 5d: Boxplot showing the effect of posterior cruciate ligament resection on the lateral joint gap (mm) with knee flexion
Mediolateral laxity:
Prior to PCL resection, there were no differences in mediolateral gaps in extension (medial gap 18.0 ± 1.9 mm vs lateral gap 18.2 ± 1.8 mm, p=0.74) or flexion (medial gap 17.9 ± 1.9 mm vs lateral gap 18.0 ± 1.7 mm, p=0.57) (Table 5b). Following PCL resection, there was no difference in mediolateral gaps in extension (medial gap 19.5 ± 1.7 mm vs lateral gap 19.4 ± 1.7, p=0.51), but a difference in mediolateral gaps was present in flexion (medial gap 20.2 ± 1.8 mm vs lateral gap 21.3 ± 1.7 mm, p<0.001).

Fixed flexion deformity:
Following PCL resection, overall knee extension improved by 2.9 ± 1.6 degrees (p<0.001) (table 5c). In total, 89 patients (80.9%) had preoperative FFDs (figure 5e). In these patients, PCL resection reduced overall FFD (6.3 ± 4.4° pre-PCL resection vs 3.1 ± 1.5° post-PCL resection, p<0.001) (Figure 5f). There was a strong positive correlation between magnitude of the preoperative FFD and change in FFD following PCL resection (Pearson’s correlation coefficient=0.81, p<0.001) (Figure 5g). Length of femur (Pearson’s correlation coefficient=-0.02, p=0.87) and femoral implant size (Pearson’s correlation coefficient=0.04, p=0.73) were not significantly associated with the change in FFD following PCL release.

Figure 5e: Histogram showing the magnitude of the preoperative fixed flexion deformity in study patients
Figure 5f: Boxplot showing the effect of posterior cruciate ligament resection (PCL) on fixed flexion deformity (FFD)

Table 5c: Table showing the change in fixed flexion deformity (FFD) following posterior cruciate ligament (PCL) resection with increasing preoperative FFD in study patients

<table>
<thead>
<tr>
<th>Preoperative FFD</th>
<th>Number</th>
<th>Change in FFD following PCL release</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-5 degrees</td>
<td>42</td>
<td>2.1 ± 1.0</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>6-10 degrees</td>
<td>29</td>
<td>3.2 ± 0.8</td>
<td></td>
</tr>
<tr>
<td>11-15 degrees</td>
<td>18</td>
<td>5.3 ± 1.0</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>81</td>
<td>2.8 ± 1.6</td>
<td></td>
</tr>
</tbody>
</table>

Summary statistics are: mean with standard deviation; FFD – Fixed flexion deformity, PCL – Posterior cruciate ligament,

*P- value is <0.001 for trend in change in FFD following PCL release with increasing preoperative FFD using one-way analysis of variance (ANOVA) test
Limb alignment:

Following PCL resection, limb alignment changed by 0.2 ± 1.2 degrees valgus (p=0.60) (table 5b). Subgroup analysis of the 14 patients with preoperative valgus deformity revealed PCL resection increased the flexion gap more than the extension gap, increased mediolateral laxity in flexion, and improved knee extension (Table 5d).

Table 5d: Subgroup analysis of the changes in study outcomes in patients with valgus deformity (n=14)

<table>
<thead>
<tr>
<th>Study outcome</th>
<th>Change in study outcome following PCL resection</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medial extension gap (mm)</td>
<td>1.2 ± 1.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lateral extension gap (mm)</td>
<td>1.4 ± 0.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Medial flexion† gap (mm)</td>
<td>1.9 ±1.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lateral flexion† gap (mm)</td>
<td>3.1 ± 1.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mediolateral extension gap difference (mm)</td>
<td>0.2 ± 1.0</td>
<td>0.65</td>
</tr>
<tr>
<td>Mediolateral flexion† gap difference (mm)</td>
<td>1.1 ± 1.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Maximum knee extension (degrees)</td>
<td>2.4 ± 1.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Limb alignment (degrees varus)</td>
<td>0.3 ± 1.1</td>
<td>0.39</td>
</tr>
</tbody>
</table>

Summary statistics are: mean with standard deviation; PCL – Posterior cruciate ligament, Mediolateral gap = Difference in medial and lateral gap measurements, flexion† = 90 degrees knee flexion
Intraobserver correlation coefficients were high for all study outcomes recorded (Table 5e). All robotic-arm assisted TKA procedures were completed without any intraoperative complications.

**Table 5e: Intraclass correlation coefficient values for gap measurements pre- and post-PCL resection in the medial and lateral knee compartments.**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Pre-PCL resection</th>
<th>Post-PCL resection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medial extension gap</td>
<td>0.87 (95% CI: 0.83-0.91, p&lt;0.001)</td>
<td>0.84 (95% CI: 0.80-0.88, p&lt;0.001)</td>
</tr>
<tr>
<td>Lateral extension gap</td>
<td>0.82 (95% CI: 0.78-0.86, p&lt;0.001)</td>
<td>0.79 (95% CI: 0.76-0.82, p&lt;0.001)</td>
</tr>
<tr>
<td>Medial flexion† gap</td>
<td>0.84 (95% CI: 0.81-0.87, p&lt;0.001)</td>
<td>0.80 (95% CI: 0.77-0.83, p&lt;0.001)</td>
</tr>
<tr>
<td>Lateral flexion† gap</td>
<td>0.80 (95% CI: 0.76-0.84, p&lt;0.001)</td>
<td>0.77 (95% CI: 0.74-0.82, p&lt;0.001)</td>
</tr>
<tr>
<td>Maximum knee extension</td>
<td>0.89 (95% CI: 0.86-0.92, p&lt;0.001)</td>
<td>0.87 (95% CI: 0.84-0.91, p&lt;0.001)</td>
</tr>
<tr>
<td>Limb alignment</td>
<td>0.77 (95% CI: 0.73-0.81, p&lt;0.001)</td>
<td>0.80 (95% CI: 0.77-0.83, p&lt;0.001)</td>
</tr>
</tbody>
</table>

Summary statistics are: Mean intraobserver correlation coefficient with 95% confidence interval (CI), †Flexion = 90° knee flexion, PCL= posterior cruciate ligament

**Discussion**

The principle finding of this study supports our hypothesis that PCL resection creates flexion-extension mismatch by producing a greater increase in the flexion gap compared to the extension gap. PCL resection increased the lateral flexion gap more than the medial flexion gap, which created mediolateral gap differences in 90 degrees of knee flexion. Improvements in FFD following PCL resection were directly related to the degree of FFD prior to PCL resection. PCL resection did not affect overall limb alignment.

Accurate implant positioning, balanced flexion-extension gaps, and proper ligament tensioning remain the cornerstone of a successful TKA. Our study showed that PCL resection increased the flexion gap substantially more than the extension gap during TKA, which is of significance to both cruciate-retaining and posterior-stabilised TKA implant designs. In cruciate-retaining TKA, manual tibial bone resection is associated with inadvertent PCL injury in 45-69% of patients.81,164 This may lead to varying degrees of flexion-extension gap mismatch and flexion instability, which is a common reason for implant failure at short- to mid-term follow-up after TKA.165 In posterior-stabilised TKA, PCL resection may lead to an excessive flexion gap that exceeds the “jump distance” of the femoral cam on the tibial post, leading to posterior tibial dislocation in up to 0.5% of cases.79 Furthermore, if tibial implants are selected to fill the flexion gap, extension will be blocked unless additional femoral bone resection is performed.75 If tibial implants are selected to fill the extension gap, then a larger femoral implant or more posterior positioning of the femoral component may be required to obtain balanced flexion-extension gaps.75 Modifications to the distal femoral resection surface and/or implant positioning are essential for establishing balanced flexion-extension gaps following PCL resection in TKA.

The findings of our study showing PCL resection creates flexion-extension mismatch is consistent with those from several previous trials.74-78 Park et al reviewed outcomes in 30 patients with severe varus deformity (>15 degrees) or FFD (>20 degrees) and found PCL resection increased medial and lateral extension gaps by 1.2 mm and 0.3 mm respectively, and medial and lateral flexion gaps increased by 4.5 mm and 3.4 mm respectively.76 The authors performed extensive medial
soft tissue releases prior to PCL resection, which may have selectively increased the medial soft tissue laxity and increased the medial gap measurements compared to those observed in our study. Kadoya et al reviewed outcomes in 30 patients with varus knee osteoarthritis in which the medial soft tissue were released and bone resections undertaken without preserving the bone segment of the tibia to which the PCL was attached. Following resection, flexion gaps increased in the medial compartment by 4.8 ± 0.4 mm and lateral compartment by 4.5 ± 0.4 mm, compared to extension gaps that increased in the medial compartment by 0.9 ± 0.2 mm and lateral compartment by 0.8 ± 0.2 mm. The authors reported that the mean flexion gap was 2mm less than the extension gap pre-PCL resection but increased to 1.7mm more than the extension gap post-PCL resection. Mikhalo et al used a motion tracking device to assess outcomes in 12 cadaveric knee specimens, and found PCL resection created gross flexion-extension mismatch with increases in the flexion gap of 5.26 ± 1.9 mm at rest and 6.4 ± 2.5 mm under tension. The authors used healthy cadaveric knee specimens in which stabilisers of the joint such as the quadriceps muscles and hamstrings muscles were deficient, and applied greater distraction forces through the tensioning device than in the current study. These factors are likely to have created non-physiological knee conditions and created greater increases in the flexion gap compared to those observed in our study.

The PCL consists of two functional bundles: the larger anterolateral bundle and the smaller posteromedial bundle. Although the two bundles have a synergistic effect during knee flexion, the anterolateral bundle functions more dominantly in flexion and the posteromedial bundle more dominantly in extension. PCL resection therefore increased both flexion and extension gaps, though the greater effect was on flexion owing to the larger and more dominant anterolateral bundle. Resection of the PCL increased the lateral flexion gap more than the medial flexion gap, which may be attributable to the increased laxity of the lateral collateral ligament compared to medial collateral ligament in flexion. Furthermore, the PCL is functionally the primary restraint to posterior tibial translation at all flexion angles and provides the primary restraint for internal rotation after 90 degrees flexion. Excessive tibial rotation combined with increased laxity of the lateral collateral ligaments may have led to the increased lateral flexion gap compared to the medial flexion gap. Importantly, patients with osteoarthritic knees often have contracted and tightened periarticular soft tissues such as the collateral ligaments. Despite improvements in FFD following PCL resection, the contracted periarticular envelope may limit overall change in the extension gap.

In this study, ACL resection was undertaken prior to assessment of PCL kinematics. Although this is clinically relevant as most surgeons undertake ACL excision prior to PCL resection during posterior-stabilised TKA, these findings should be interpreted with caution. Previous studies have shown that ACL deficiency affects the relationship of the femur and tibia in the sagittal plane, and tibial translation or rotation relative to the femur were not assessed in this study. Heesterbeek et al used an intraoperative imageless navigation system to assess knee kinematics following ACL resection in 50 patients undergoing ligament-guided TKA. After tibial resection, the flexion gap was distracted with a double-spring tensor using a force of 200 N. For each 1 mm of increase in the flexion gap, the tibia translated anteriorly by 1.7 mm. Christen et al used a custom-made, flexible tensor-spacer device in 91 patients undergoing cruciate-retaining TKAs to assess the relationship between the size of the flexion gap and anterior translation of the tibia in flexion following ACL resection. The study found that each increase of 1 mm in the flexion gap in the tensed knee produced a mean anterior tibial translation of 1.25 mm at 100 N to 150 N of distraction force. Increasing the flexion gap using distraction forces tension leads to increased tension through the oblique position of the PCL, which runs from the inferoposterior tibia to
the superoanterior medial femoral condyle. This leads to pivoting of the tibia around the femoral insertion of the PCL and anterior translation of the tibia relative to the femur.

Fixed flexion deformities after TKA are associated with increased physical demands and energy expenditure through the quadriceps mechanism, which leads to increased muscle fatigue, reduced functional performance, and worse clinical outcomes.\cite{143,151,169} There may also be abnormal forces through the contralateral knee, reducing walking velocity, and altered spine kinematics depending on the degree of deformity.\cite{191,192} Preoperative FFD is often multifactorial with several contributory factors including bony impingement, capsular contraction, ligament contractures, and hamstring shortening.\cite{169} Our study showed that there was a strong positive correlation between the degree of preoperative FFD and change in FFD following PCL resection. This suggests that the contributory effect of the PCL to the fixed flexion contracture increases as the FFD increases. Our findings support previous research showing PCL contractures contribute to preoperative FFD and advocating for its release to improve knee flexion contractures during TKA.\cite{169,170} The findings of this study may guide clinicians correcting preoperative FFD during posterior-stabilised TKA as to the relative contributory effect of the PCL and facilitate planning of further intraoperative techniques to correct FFD, such as additional bone resection, removal of osteophytes, posterior capsular releases, and further ligament releases (e.g. collateral ligaments). Current robotic systems are unable to perform capsular releases or excise residual posterior osteophytes, which must still be performed manually by the operating surgeon.

In this study, flexion-extension gap measurements were recorded prior to correction of the pre-existing FFD. Further bone resections or soft tissue releases to correct the FFD may lead to additional changes in the study outcomes recorded. In FFD, the posterior capsule of the knee joint is often stretched by the posterior femoral condyles, which limits further knee extension. Release of this posterior capsule may lead to a greater increase in the extension gap compared to the flexion gap. In the aforementioned study by Tanaka et al, knee flexion from 0° to 10° increased the medial compartment gap from 4.0 ± 1.5 mm to 6.5 ± 1.1 mm respectively, and the lateral compartment gap from 2.8 ± 1.2 mm to 8.8 ± 1.7 mm respectively. Sugama et al reviewed changes in the extension gap caused by preparation of the flexion gap in 50 varus osteoarthritic knees undergoing TKA.\cite{171} The extension gap was first prepared and measured whilst applying a 40lb distraction force before and after resection of the posterior femoral condyles and removal of the osteophytes. The extension gap increased on the medial side from 19.3 ± 0.3 mm to 22.0 ± 0.3mm and lateral side from 21.9 ± 0.3 mm to 24.0 ± 0.3 mm. Okamoto et al reviewed flexion-extension gaps in 54 PS TKAs undergoing capsular release around the intercondylar notch for fixed flexion deformities of more than 5°.\cite{172} Using a femoral trial with a knee balancer and joint distraction force of 44Ib, the extension gap increased by 1.7 ± 0.2 mm in the medial compartment and 2.3 ± 0.2 mm in the lateral compartment. These findings suggest that additional procedures such as posterior condylar resection, excision of osteophytes and release of the posterior capsule to correct FFDs may produce further increases in the extension gap compared to flexion gap. Repeat assessments of flexion-extension gaps must be performed prior to definitive implantation of components.

Our findings are consistent with previous studies showing that PCL resection does not affect overall limb alignment.\cite{173,174} In the subgroup of patients with valgus deformity, PCL resection increased the flexion gap more than the extension gap, increased mediolateral laxity in flexion, and increased overall knee extension, but there was no change in overall limb alignment. Existing studies have shown that isolated PCL resection does not affect limb alignment, but when PCL
resection is combined with medial or lateral ligament releases, this creates valgus and varus shifts in alignment respectively.\textsuperscript{173,174} Furthermore, bone resection using manually controlled sawblades during conventional jig-based TKA may lead to iatrogenic periarticular soft tissue injury.\textsuperscript{63,146} Therefore, studies assessing the impact of PCL on knee biomechanics following distal femoral and proximal tibial bone resections with conventional manual sawblades may have introduced confounding variables from inadvertent soft tissue releases.\textsuperscript{74,75,77} In our study, outcomes were assessed prior to femoral and tibial bone resections to limit the confounding effect of inadvertent soft tissue releases on PCL biomechanics, and also to ascertain changes in study outcomes under more physiological conditions of the knee joint.

The findings of this study are clinically significant as they provide clinicians with objective data on changes in knee biomechanics following PCL resection. This will aid preoperative planning of bone resection and implant positioning, and facilitate intraoperative flexion-extension gap balancing and ligament tensioning during TKA. Furthermore, PCL resection offers a unique soft tissue release that increases the flexion gap more than the extension gap and increases the lateral flexion gap more than the medial flexion gap, which may be deployed to improve flexion-extension gap balancing and mediolateral ligament tensioning during TKA. The increase in the flexion gap following PCL release may also help to explain previous findings in which deep flexion is improved in posterior-stabilised TKA compared to cruciate-retaining TKA. The flexion-extension mismatch and mediolateral laxity following PCL resection may lead to increased anteroposterior and mediolateral tibiofemoral translation, and help to explain the increased risk of patellofemoral and medial compartment osteoarthritis in patients with isolated PCL injuries.\textsuperscript{163} This study also supports the previous study on the effect of ACL resection on knee biomechanics by showing that optical motion capture technology has high intraobserver validity as an investigative tool for assessing the effects of controlled ligamentous releases on knee kinematics.

In addition to the above drawbacks of this study, there are several other limitations of this study that need to be considered when interpreting the findings. PCL resection led to statistically significant differences in flexion-extension gaps, mediolateral soft tissue tension in flexion, and FFD but the clinical significance of these differences remains unknown. To our knowledge, there are no existing studies reporting on acceptable cut-off values for these outcomes during TKA. Furthermore, the forces of the valgus/varus strains were not standardised, which may have affected the medial and lateral gap measurements recorded. However, all assessments were undertaken by an experienced arthroplasty surgeon using a standardised protocol with intraoperative assessment of physiological knee tensioning and live on screen gap changes to assess medial and lateral laxity. Importantly, this study assessed the correlation of the femoral length and femoral component size to FFD but the tibial length or tibial component size were not recorded.

**Conclusion**

PCL resection creates flexion-extension mismatch by increasing the flexion gap more than the extension gap during posterior-stabilised TKA. Following PCL resection, the lateral flexion gap increases more than the medial flexion gap, which increases mediolateral laxity in knee flexion but not in extension. Improvements in FFD following PCL resection are dependent on the degree of deformity prior to PCL resection. Bone resection, implant positioning, and periarticular soft tissue balancing should account for these changes in flexion-extension gaps, mediolateral soft tissue laxity, and FFD following PCL resection during posterior-stabilised TKA. In the following chapter, we will assess how improved accuracy of bone resection, reduced periarticular soft tissue injury and live intraoperative data on knee biomechanics to manipulate
bone resections and implant positioning with robotic TKA translate to any differences in the postoperative systemic inflammatory response compared to conventional jig-based TKA.

**My role in this study:**
- Identified gap in the scientific literature on the impact of PCL resection on knee biomechanics during TKA
- Generated study hypothesis
- Identified study outcomes
- Recorded intraoperative data
- Collated study outcomes and performed statistical analysis
- Wrote manuscript for publication

*Posterior cruciate ligament resection in total knee arthroplasty: Effect on flexion-extension gaps, mediolateral laxity, and fixed flexion deformity.*

Kayani B, Konan S, Horriot S, Ibrahim MS, Haddad FS.

Chapter 6

A prospective randomised controlled trial comparing the systemic inflammatory response in conventional jig-based total knee arthroplasty versus robotic-arm assisted total knee arthroplasty
Abstract

Serum measurements of inflammation and muscle degradation offer an objective method for comparing the invasiveness of different surgical techniques. Robotic-arm assisted TKA reduces periarticular soft tissue injury but it remains unknown how this translates to any differences in the systemic inflammatory response compared to conventional jig-based TKA. The objectives of this study were to compare the postoperative systemic inflammatory response in conventional jig-based TKA versus robotic-arm assisted TKA. This prospective randomised controlled trial included 30 patients with symptomatic knee osteoarthritis undergoing conventional jig-based TKA versus robotic-arm assisted TKA. Predefined serum markers of inflammation and temperature over the operated knee joint were collected preoperatively and postoperatively at 6 hours, day 1, day 2, day 7, and day 28 following TKA. The Macroscopic Soft Tissue Injury (MASTI) classification was used to grade intraoperative periarticular soft tissue injury and bone trauma.

This study found comparable changes with both groups in the postoperative systemic inflammatory response and localised thermal response at 6 hours, day 1, day 2 and day 28 after surgery. Robotic-arm assisted TKA had reduced levels of interleukin-6 (p<0.001), tumour necrosis factor-α (p=0.021), erythrocyte sedimentation rate (p=0.001), C-reactive protein (p=0.004), lactate dehydrogenase (0.007) and creatine kinase (p=0.004) at day 7 after surgery compared to conventional jig-based TKA. Robotic-arm assisted TKA was associated with improved preservation of the periarticular soft tissue envelope (p<0.001), reduced femoral (p=0.01) and tibial (p=0.02) bone trauma, and improved accuracy of implant positioning (p<0.001) compared to conventional TKA.
Background

In the previous chapters, we found that robotic-arm assisted TKA was associated with improved accuracy of implant positioning and reduced periarticular soft tissue injury compared with conventional jig-based TKA. We also validated the MASTI classification system as a grading tool with high interobserver and intraobserver validity for assessing intraoperative periarticular soft tissue injury and bone trauma during TKA. In this chapter, we take this one step further by assessing how these local differences in soft tissue injury between robotic TKA and conventional TKA translate to any systemic differences in the inflammatory response between the two treatment groups.

Robotic-arm assisted TKA uses preoperative three-dimensional surgical planning and an intraoperative robotic arm to help execute the surgical plan for bone resection and implant positioning with greater accuracy and reproducibility than conventional jig-based TKA. The action of the sawblade is confined to the stereotactic boundaries of the surgical plan, which helps to reduce iatrogenic periarticular soft tissue injury compared to conventional TKA. Intraoperative assessments of flexion-extension gaps, mediolateral soft tissue tension, range of motion, and limb alignment are used to fine-tune bone resection and implant positioning, that further reduces the need for controlled soft tissue releases. However, it remains unknown how these local differences in soft tissue injury between conventional jig-based TKA and robotic-arm assisted TKA translate to any differences in the systemic inflammatory response between the two treatment groups.

There is no uniform consensus on the optimal technique for quantifying the invasiveness of a surgical procedure. Existing studies comparing the surgical insult of conventional TKA versus robotic TKA have included unblinded observers performing non-validated assessments of the soft tissue envelope, qualitative descriptions of the periarticular soft tissue injury and bone trauma in cadaveric specimens, or assessments of implant positioning and soft tissue injury with no correlation to the systemic inflammatory response. Serum markers of inflammation and muscle damage offer a more objective method for comparing the invasiveness of different surgical approaches. This method was used in the development of minimally-invasive cholecystectomy, herniorrhaphy, and hysterectomy, in which laparoscopic surgery reduced the postoperative systemic inflammatory response and facilitated faster postoperative rehabilitation compared with conventional open surgery. Within TKA, systemic inflammatory markers have been used to quantify the surgical insult of minimally-invasive surgery, synovectomy, and intraoperative tourniquet application. The postoperative systemic inflammatory response following TKA has been correlated to postoperative pain, knee swelling, and rehabilitation time. Serial measurements of these serum markers following TKA offer an objective method for assessing and quantifying the invasiveness of a surgical procedure, whilst minimising any patient or observer bias. To our knowledge, there are no existing studies comparing the surgical invasiveness of conventional TKA versus robotic TKA using postoperative serum markers of inflammation or muscle degradation.

The primary objective of this study was to compare the postoperative systemic inflammatory response in patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA. The study hypothesis was that decreased periarticular soft tissue and reduced bone trauma in robotic-arm assisted TKA would translate to a reduced immediate (<48 hours) postoperative inflammatory response compared to conventional jig-based TKA. Secondary objectives were to compare intraoperative macroscopic soft tissue injury, femoral and tibial bone trauma, postoperative localised thermal response and accuracy of implant positioning between the two treatment techniques.
Figure 6a: Flowchart showing the postoperative proinflammatory cascade

**Activation of proinflammatory cells**

- Dendritic cells
- Mast Cells
- Macrophage
- Fibroblasts
- Neutrophils, monocytes, lymphocytes (T-cells, B-cells, NK cells)

**Release of cytokines**

- ↑ Interleukin-1
- ↑ Interleukin-2
- ↑ Interleukin-6
- ↑ Interleukin-8
- ↑ Interleukin-10
- ↑ Interleukin-12
- ↑ Tumour Necrosis Factor-α
- ↑ Interferon
- ↑ Transforming Growth Factor

**Acute Phase Proteins:**
- CRP, α-1 antichymotrypsin, fibrinogen, haptoglobin, complement components, ceruloplasmin, serum amyloid A, mannose binding protein

**Neuroendocrine response**
- Corticotrophin-releasing hormone
- Adrenocorticotrophic hormone
- Cortisol

**Metabolic response**
- Muscle degradation (E.g.; Creatine phosphokinase)
- Osteoporosis

**Haematologic response**
- Thrombocytosis
- Leukocytosis
Methods

Patient selection:
This study included 30 patients with symptomatic knee osteoarthritis undergoing primary TKA by two operating surgeons (S.K and S.O). Inclusion criteria for this study were as follows: patient with knee osteoarthritis undergoing primary TKA; patient age between 18 and 80 years at time of surgery; patient able to tolerate general anaesthesia; and patient able to give informed consent for TKA and study participation. Exclusion criteria included the following: inflammatory arthropathy; unable to tolerate general anaesthesia; previous infection of knee joint; conversion of unicompartmental to TKA; arthroplasty for fracture or previous osteotomy; and/or underlying neurological dysfunction compromising mobility. Following informed consent, patients were allocated to their respective treatment groups using an online number generator (www.random.org) to randomly produce a number from 1-30. Patients allocated 1-15 inclusive underwent conventional-jig based TKA (control group) and 16-30 inclusive received robotic-arm assisted TKA (investigation group). There were no systemic differences in baseline demographics or preoperative radiographic deformity between the two treatment groups (Table 6a). Research Ethics Committee (Ref: 18/LO/0926) approval was obtained prior to study commencement. The study was registered with clinical.trial.gov (NCT04192006).

Table 6a: Demographic data and preoperative radiographic deformity in patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Category</th>
<th>Conventional TKA (n=15)</th>
<th>Robotic TKA (n=15)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>-</td>
<td>68.7 ± 9.6</td>
<td>67.9 ± 8.6</td>
<td>0.81</td>
</tr>
<tr>
<td>Gender</td>
<td>Female</td>
<td>8 (53%)</td>
<td>9 (60%)</td>
<td>0.71</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>7 (47%)</td>
<td>6 (40%)</td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>-</td>
<td>27.5 ± 3.7</td>
<td>27.0 ± 3.0</td>
<td>0.67</td>
</tr>
<tr>
<td>ASA score</td>
<td>I</td>
<td>1 (7%)</td>
<td>1 (7%)</td>
<td>0.91</td>
</tr>
<tr>
<td></td>
<td>II</td>
<td>10 (67%)</td>
<td>11 (73%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>III</td>
<td>4 (27%)</td>
<td>3 (20%)</td>
<td></td>
</tr>
<tr>
<td>Side of intervention</td>
<td>Left</td>
<td>8 (53%)</td>
<td>7 (47%)</td>
<td>0.72</td>
</tr>
<tr>
<td></td>
<td>Right</td>
<td>7 (47%)</td>
<td>8 (53%)</td>
<td></td>
</tr>
<tr>
<td>Preoperative limb alignment (° varus)</td>
<td></td>
<td>3.4 ± 0.9</td>
<td>3.1 ± 0.7</td>
<td>0.61</td>
</tr>
</tbody>
</table>

Summary statistics are: N (percentage) or mean with standard deviation, BMI=Body Mass Index, ASA score = American Society of Anaesthesiologists score
Surgical technique:
All study patients underwent preoperative anteroposterior weight-bearing knee radiographs, lateral knee radiographs, and full-length hip-to-ankle weight-bearing radiographs. In both treatment groups, the senior surgeon used Traumacad software (Traumacad, Petach-Tikva, Israel) with plain radiographs to preoperatively template implant sizes and positions. All study patients also underwent preoperative computerised tomography (CT) scans of the knee joint. In both treatment groups, computer software (Mako system software, Stryker Limited, Kalamazoo, MI) was used to create a patient-specific virtual three-dimensional (3D) computer-aided design model to plan optimal bone resection and guide implant positioning. Preoperative templating using plain radiographs and CT scans with patient-specific CAD models are discussed in further details in appendix section 1.1.

All operative procedures were performed under general anaesthesia. A tourniquet was applied but not inflated to limit any confounding effects of muscle ischaemia or reperfusion injury affecting postoperative cytokine levels.58,178 The surgical techniques for both conventional-jig based TKA and robotic-arm assisted TKA are described in detail in appendix section 10.2. A Mikhail retractor was used to protect the PCL and posterior capsule, and blunt Hohmann retractors were used to protect the medial and lateral soft tissue structures during bone resection in both treatment groups. All study patients received the Triathlon cruciate-substituting knee system (Stryker Limited, Kalamazoo, Michigan) with patellar resurfacing using asymmetrical components. Postoperative dressings were extended to the mid-tibia in all study patients, and a small window created in the dressings over the patella for the localised thermal response to be recorded.

Postoperative inpatient care:
All patients received postoperative patient-controlled analgesia (PCA) with the background intravenous morphine infusion rate set at 0.5 mg/hour, a bolus dose of 2mg and lockout period of ten minutes. If the patient required additional analgesia then the nursing staff administered oral paracetamol over this time. The PCA was stopped 24 hours postoperatively and converted to an oral regimen of regular paracetamol and dihydrocodeine, with oral morphine available for breakthrough pain. No study patients received postoperative non-steroidal anti-inflammatory medications. All patients underwent a standardised postoperative rehabilitation programme with full weight-bearing and active range of movement exercises commenced from day of surgery. Patients were discharged home after adequate pain control, knee flexion to a minimum of 90°, independent mobilization with the use of crutches and independent ascent and descent of stairs.

Study outcomes:
Serum Inflammatory response
Two blinded research fellows (B.K and A.A) collected peripheral venous samples in all study patients preoperatively and postoperatively at 6 hours, day 1, day 2, day 7, and day 28. All time intervals were referenced to the index time of surgery in each patient. Serum samples were analysed for the following markers: C-reactive protein (CRP); interleukin-1β; interleukin-6 (IL-6); tumour necrosis factor-α (TNF-α); creatine kinase (CK); white cell count; haemoglobin; platelets; erythrocyte sedimentation rate (ESR); lactate dehydrogenase (LDH); alkaline phosphatase (ALP); and cortisol.

Localised thermal response
At the same time intervals as the serum sample collections, the two blinded observers used a digital infrared thermometer to independently record the temperature at four different locations on the anterior aspect of the knee joint, including the
superomedial, superolateral, inferomedial, and inferolateral borders of the patella. These recordings were used to calculate the mean skin temperature over the operated knee joint. The use of this technique to measure the thermal response has been previously reported and correlated to the localised inflammatory response.67

**Macroscopic soft tissue injury and bone trauma**
Standardised intraoperative photographs of the medial, lateral, anterior (extensor), and posterior compartments, and residual femoral and tibial bone surfaces were obtained prior to component insertion. Both blinded observers individually reviewed the intraoperative photographs and used the MASTI classification system to grade periarticular soft tissue injury and bone trauma.146 The use of intraoperative photographs for grading iatrogenic soft tissue injury and bone trauma ensured both observers remained blinded to the treatment group, the MASTI classification system could be referenced during independent scoring of study outcomes, and sterility during surgery was not compromised. In chapter 3, the MASTI classification system was validated as a grading system with high interobserver and intraobserver reliability for assessing intraoperative soft tissue injury and bone trauma during TKA.

**Radiological outcomes:**
All patients underwent postoperative anteroposterior weight-bearing and lateral knee radiographs prior to discharge, and full-length hip-to-ankle weight-bearing radiographs at four weeks after surgery. Accuracy of achieving the planned limb alignment and implant positioning were assessed using root mean square error (RMSE) values for these outcomes by comparing values achieved in the postoperative long-leg and lateral knee radiographs to their respective planned values with each alignment technique. Femoral and tibial axes were used as reference markers as described by Bell et al.86 Accuracy of achieving the planned femoral and tibial implant positioning were assessed using the techniques described by Moon et al.29

**Power calculation:**
Prior to commencement of the study, a sample size calculation was performed using the CRP level at 24 hours after TKA as the primary outcome measure. As there were no existing studies comparing postoperative CRP levels in conventional TKA versus robotic TKA, the sample size calculation was performed using previous data from a study reporting on the inflammatory response in TKA performed with and without synovectomy.178 The mean CRP level in TKA without synovectomy was 91.0 mg/L with standard deviation of 24.1 mg/L and mean CRP level in TKA with synovectomy was 88.0 mg/L with standard deviation of 23.7 mg/L at 24 hours after TKA.178 Using a two-tailed, two-sample t-test, and assuming similar changes in the inflammatory response in the current study, this study required 30 patients (15 patients in each treatment arm) to detect a minimum clinically important difference of 25 mg/L in the CRP level at 24 hours between the two treatment groups with a power of 80% and significance level of 0.05. Due to the limited follow-up time, no further adjustments were made to account for sample size attrition during follow-up.

**Statistical analysis:**
Statistical analysis of the baseline demographics and study outcomes were performed using the unpaired t-test for continuous variables with normal distributions and the Mann–Whitney U test for continuous variables that were not normally distributed. Categorical data was compared using the Chi-square test with the Fisher's exact test used where expected cases were <5 in more than 20% of cells within a given contingency table. Statistical significance was set at a
p-value < 0.05 for all analyses and all statistical analysis was performed using SPSS software version 21 (SPSS Inc., Chicago, IL).

Results:

Interobserver correlation coefficient:

Interobserver correlation coefficient was 0.92 [95% CI: 0.88-0.96]) for all study outcomes recorded by the two independent observers.

Serum Inflammatory response

There were no significant differences in preoperative baseline serum markers of inflammation or muscle degradation between the treatment groups (table 6b). Postoperative CRP levels at 6 hours, day 1, and day 2 were comparable between the two treatment groups (table 6b). Robotic-arm assisted TKA was associated with statistically significant reduced levels of IL-6 and TNF-α postoperatively at 6 hours, day 1, and day 2 compared to conventional TKA. There were no statistical differences in any other inflammatory markers within the first 2 days after surgery. At day 7 after surgery, robotic-arm assisted TKA was associated with statistically significant reduced levels of IL-6, TNF-α, CRP, ESR, LDH, and CK compared to conventional TKA (table 6b, figures 6b - g).
<table>
<thead>
<tr>
<th></th>
<th>Preoperative</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 7</th>
<th>Day 28</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CO TKA</td>
<td>RO TKA</td>
<td>CO TKA</td>
<td>RO TKA</td>
<td>CO TKA</td>
</tr>
<tr>
<td><strong>Interleukin-1β</strong></td>
<td>3.9 ± 2.3</td>
<td>3.8 ± 1.3</td>
<td>3.3 ± 0.5</td>
<td>3.3 ± 1.2</td>
<td>8.0 ± 3.2</td>
</tr>
<tr>
<td><strong>Interleukin-6</strong></td>
<td>17.1 ± 34.6</td>
<td>15.3 ± 18.1</td>
<td>101.1 ± 86.0</td>
<td>36.2 ± 42.6</td>
<td>325.1 ± 144.0</td>
</tr>
<tr>
<td><strong>Tumour Necrosis Factor - α</strong></td>
<td>2.3 ± 1.9</td>
<td>3.0 ± 1.9</td>
<td>12.6 ± 9.0</td>
<td>3.0 ± 2.0</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Haemoglobin</strong></td>
<td>131.9 ± 8.8</td>
<td>132.3 ± 19.9</td>
<td>121.0 ± 13.1</td>
<td>121.1 ± 13.9</td>
<td>0.979</td>
</tr>
<tr>
<td><strong>White cell count</strong></td>
<td>6.3 ± 1.5</td>
<td>6.4 ± 1.4</td>
<td>9.9 ± 2.4</td>
<td>10.1 ± 3.1</td>
<td>0.829</td>
</tr>
<tr>
<td><strong>Neutrophils</strong></td>
<td>59.2 ± 11.5</td>
<td>53.2 ± 10.4</td>
<td>71.6 ± 9.3</td>
<td>77.4 ± 11.7</td>
<td>0.145</td>
</tr>
<tr>
<td><strong>Lymphocytes</strong></td>
<td>30.1 ± 10.3</td>
<td>35.6 ± 10.1</td>
<td>15.7 ± 7.9</td>
<td>16.9 ± 8.5</td>
<td>0.811</td>
</tr>
<tr>
<td><strong>Platelets</strong></td>
<td>256.5 ± 69.4</td>
<td>230.7 ± 65.4</td>
<td>220.1 ± 41.6</td>
<td>221.7 ± 69.3</td>
<td>0.937</td>
</tr>
<tr>
<td><strong>Erythrocyte sedimentation rate</strong></td>
<td>9.3 ± 6.8</td>
<td>11.6 ± 11.6</td>
<td>11.5 ± 8.4</td>
<td>12.3 ± 11.8</td>
<td>0.846</td>
</tr>
<tr>
<td><strong>Lactate dehydrogenase</strong></td>
<td>239.1 ± 32.1</td>
<td>216.5 ± 43.1</td>
<td>218.3 ± 57.1</td>
<td>227.1 ± 45.3</td>
<td>0.643</td>
</tr>
<tr>
<td><strong>C-Reactive Protein</strong></td>
<td>3.6 ± 2.5</td>
<td>5.7 ± 8.7</td>
<td>7.3 ± 7.3</td>
<td>8.6 ± 12.4</td>
<td>0.717</td>
</tr>
<tr>
<td><strong>Cortisol</strong></td>
<td>264.9 ± 83.7</td>
<td>278.3 ± 130.5</td>
<td>348.8 ± 230.7</td>
<td>369.9 ± 219.3</td>
<td>0.799</td>
</tr>
<tr>
<td><strong>Alkaline Phosphatase</strong></td>
<td>75.9 ± 10.5</td>
<td>71.9 ± 13.0</td>
<td>67.2 ± 24.9</td>
<td>71.0 ± 19.8</td>
<td>0.647</td>
</tr>
<tr>
<td><strong>Creatine Kinase</strong></td>
<td>138.4 ± 45.5</td>
<td>128.8 ± 64.3</td>
<td>173.6 ± 51.1</td>
<td>124.4 ± 57.4</td>
<td>0.019</td>
</tr>
</tbody>
</table>

**CO TKA** - Conventional jig-based total knee arthroplasty, **RO TKA** – Robotic-arm assisted total knee arthroplasty
Figure 6b: Graph showing changes in interleukin-1β levels at baseline (preoperative) and postoperative time intervals

Figure 6c: Graph showing changes in interleukin-6 levels at baseline (preoperative) and postoperative time intervals
Figure 6d: Graph showing changes in Tumour Necrosis Factor-α levels at baseline (preoperative) and postoperative time intervals

Figure 6e: Graph showing changes in C-Reactive Protein levels at baseline (preoperative) and postoperative time intervals
Figure 6f: Graph showing changes in Creatine Kinase at baseline (preoperative) and postoperative time intervals

Figure 6g: Graph showing changes in Erythrocyte Sedimentation Rate at baseline (preoperative) and postoperative time intervals
Localised thermal response
Skin temperature over the operated knee joint was comparable in conventional jig-based TKA and robotic-arm assisted TKA preoperatively and postoperatively at all follow-up time intervals (table 6c).

Table 6c: Operative outcomes and Macroscopic Soft Tissue Injury (MASTI) scores in conventional jig-based TKA versus robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Category</th>
<th>Conventional TKA (n=15)</th>
<th>Robotic TKA (n=15)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of incision (cm)</td>
<td></td>
<td>11.1 ± 2.3</td>
<td>12.1 ± 2.6</td>
<td>0.22</td>
</tr>
<tr>
<td>Operative time (mins)</td>
<td></td>
<td>61.4 ± 3.1</td>
<td>62.4 ± 3.4</td>
<td>0.62</td>
</tr>
<tr>
<td>Change in Hb (g/L)</td>
<td></td>
<td>15.2 ± 6.3</td>
<td>15.8 ± 5.2</td>
<td>0.58</td>
</tr>
<tr>
<td>Temperature of operated knee joint (° Celsius)</td>
<td></td>
<td>35.9 ± 0.5</td>
<td>36.1 ± 0.4</td>
<td>0.23</td>
</tr>
<tr>
<td></td>
<td>Preoperative</td>
<td>36.8 ± 0.6</td>
<td>36.9 ± 0.3</td>
<td>0.34</td>
</tr>
<tr>
<td></td>
<td>Postoperative</td>
<td>36.5 ± 0.6</td>
<td>36.8 ± 0.1</td>
<td>0.22</td>
</tr>
<tr>
<td></td>
<td>- 6 hours</td>
<td>36.1 ± 0.8</td>
<td>36.4 ± 0.5</td>
<td>0.78</td>
</tr>
<tr>
<td></td>
<td>- Day 1</td>
<td>36.8 ± 0.3</td>
<td>36.6 ± 0.2</td>
<td>0.83</td>
</tr>
<tr>
<td></td>
<td>- Day 7</td>
<td>36.0 ± 0.5</td>
<td>36.2 ± 0.6</td>
<td>0.57</td>
</tr>
<tr>
<td>MASTI soft tissue score</td>
<td>Medial</td>
<td>6.9 ± 1.2</td>
<td>8.0 ± 1.3</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>Lateral</td>
<td>6.7 ± 1.2</td>
<td>8.1 ± 1.3</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>Extensor</td>
<td>6.8 ± 1.3</td>
<td>8.3 ± 1.2</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>Posterior</td>
<td>6.7 ± 1.5</td>
<td>6.8 ± 1.2</td>
<td>0.78</td>
</tr>
<tr>
<td></td>
<td>Overall</td>
<td>24.5 ± 4.4</td>
<td>31.2 ± 2.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>MASTI Femoral Bone trauma</td>
<td>Grade A</td>
<td>8/15 (73%)</td>
<td>15/15 (100%)</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>Grade B</td>
<td>7/15 (27%)</td>
<td>0/15 (0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grade C</td>
<td>0/15 (0%)</td>
<td>0/15 (0%)</td>
<td></td>
</tr>
<tr>
<td>MASTI Tibial Bone trauma</td>
<td>Grade A</td>
<td>7/15 (60%)</td>
<td>13/15 (87%)</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>Grade B</td>
<td>8/15 (40%)</td>
<td>2/15 (13%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grade C</td>
<td>0/15 (0%)</td>
<td>0/15 (0%)</td>
<td></td>
</tr>
<tr>
<td>Radiological outcomes (RMSE in degrees)</td>
<td>Planned limb alignment</td>
<td>3.1 ± 1.3</td>
<td>1.2 ± 0.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Femoral coronal alignment</td>
<td>3.8 ± 1.1</td>
<td>1.1 ± 0.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Femoral sagittal alignment</td>
<td>3.2 ± 1.0</td>
<td>1.4 ± 1.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Tibial coronal alignment</td>
<td>3.9 ± 0.8</td>
<td>1.3 ± 0.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Tibial sagittal alignment</td>
<td>3.1 ± 1.1</td>
<td>1.0 ± 0.4</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

RMSE – Root mean square error

Macroscopic soft tissue injury and bone trauma
Both treatment groups were comparable with respect to length of the surgical incision, operative time, and change in haemoglobin concentration (table 7c). Robotic-arm assisted TKA was associated with statistically significant improved
MASTI scores compared to conventional jig-based TKA (table 6c). Robotic-arm assisted TKA had improved preservation of the periarticular soft tissue envelope in all compartments except the posterior compartment, in which soft tissue injury was comparable between the two treatment groups. Robotic-arm assisted TKA was also associated with statistically significant reduced femoral and tibial bone trauma compared to conventional jig-based TKA (table 6c).

**Radiological outcomes:**
Robotic-arm assisted TKA was associated with statistically significant improvements in accuracy of achieving the planned limb alignment and implant positioning (table 6c) compared to conventional jig-based TKA.

There were no postoperative complications within either treatment group at 28 days follow-up.

**Discussion:**
The most pertinent findings from this study help to reject the study hypothesis as there was no difference in the immediate (<48 hours) postoperative systemic inflammatory response between conventional jig-based TKA and robotic-arm assisted TKA. Thereafter, robotic TKA was associated with a reduced early (day 7) postoperative inflammatory response compared to conventional TKA. There was no difference in the late (day 28) postoperative inflammatory response or localised thermal response at any time interval between the treatment groups. Robotic TKA was associated with reduced bone trauma, better preservation of the periarticular soft tissue envelope and improved accuracy of implant positioning compared to conventional TKA.

Measurements of serum markers of inflammation and muscle degradation offer an objective method for assessing the relative invasiveness of a surgical procedure. Variations in surgical approaches for THA may lead to five-fold differences in the levels of postoperative inflammatory cytokines. This method was also used to demonstrate that TKA is a significantly more invasive surgical procedure and produces a greater systemic insult than THA. In our study, there was no difference in the overall immediate postoperative inflammatory response in conventional versus robotic TKA, with time trends and CRP levels in both groups comparable to existing studies using the medial parapatellar approach for TKA. Honsawek conducted a prospective study on 49 patients undergoing primary TKA and reported CRP levels were 85.0 ± 21.7 mg/L at 24 hours after surgery. Tanavalee et al conducted a prospective randomised trial on 67 patients comparing the inflammatory response in conventional TKA performed with and without synovectomy, and found CRP levels were 91 ± 24.1 mg/L (SD 24.1) and 88 ± 23.4 mg/L, respectively at 24 hours after surgery. In combination with our findings, these results suggest that TKA performed using the standard medial approach produces relatively consistent increases in postoperative CRP levels. The dominant, overriding effect of the surgical approach, femoral and tibial bone resections, and component implantation may have masked any subtle changes in CRP levels due to intricate differences in periarticular soft tissue injury or bone trauma between the treatment groups. Furthermore, macrophages within the bone and bone marrow are important for the development of the acute phase response and directly affect serum CRP levels. The insertion of femoral and tibial registration pins within the robotic group may have activated these macrophages and increased CRP production, concealing any minor differences in CRP levels between the groups due to variations in periarticular soft tissue injury. No differences were observed in the localised thermal response between the two treatment groups, and findings were comparable to existing data on the temperature of the operated knee joint following TKA.
IL-6 is a major mediator of the acute phase response that is produced by macrophages, monocytes, T lymphocytes, endothelial cells, and fibroblasts following antigen activation, surgical stress, or major trauma. Cytokines such as IL-1β and TNF-α are responsible for the non-hepatic manifestations of the acute phase response and help to regulate IL-6 production from fibroblasts. Elevated levels of IL-6 and TNF-α are associated with increased risk of multiple organ failure, acute respiratory distress syndrome, sepsis, and mortality in trauma and general surgery. In this study, IL-6 levels within the first two days of surgery were almost half with robotic-arm assisted TKA compared to conventional jig-based TKA. Robotic TKA was also associated with reduced postoperative levels of TNF-α, though the difference between the two groups was less marked than IL-6. This may reflect the inherent difficulty in assessing serum TNF-α levels due to its very short half-life and endogenous counter-regulatory mechanism that upregulates TNF-α receptor affinity to excessive TNF-α activity. Confounding variables affecting the postoperative levels of these cytokines including length of incision, operative time, blood loss, tourniquet use, surgical approach, and BMI were comparable between the treatment groups. Increased levels of IL-6 and TNF-α in the early postoperative period with conventional jig-based TKA may be due to the greater overall systemic insult of this procedure compared to robotic-arm assisted TKA. This may attributable to reduced soft tissue injury and bone trauma in the robotic TKA group compared to the conventional TKA group. Another plausible explanation is the use of intramedullary femoral referencing in the conventional jig-based TKA group, which has been shown to induce a systemic inflammatory response.

Robotic-arm assisted TKA was associated with reduced overall periarticular soft tissue injury and reduced bone trauma compared to conventional jig-based TKA. These findings are consistent with a cadaveric study performed by Khlopas et al in which blinded observers graded iatrogenic periarticular soft tissue injury in six specimens undergoing conventional TKA on one side and robotic TKA on the contralateral side. The study found that robotic TKA was associated with reduced PCL injury, decreased tibial subluxation, and reduced patella eversion compared to conventional TKA. In chapter 3, we conducted a prospective cohort study in 60 patients undergoing primary TKA, and found robotic-arm assisted TKA reduced periarticular soft tissue injury in both correctible and non-correctible coronal plane deformities compared to conventional jig-based TKA. Robotic TKA uses stereotactic boundaries to limit sawblade action to the confines of the preoperative surgical plan and optical motion capture technology to fine-tune bone resection and implant positioning. This limits the need for controlled soft tissue releases for flexion-extension gap balancing and inadvertent iatrogenic sawblade injury to the periarticular soft tissue envelope. Improved intraoperative preservation of the periarticular soft tissue envelope with robotic TKA may have helped to reduce soft tissue irritation during postoperative rehabilitation and limit the early (day 7) systemic inflammatory response compared to conventional TKA. Robotic TKA was associated with reduced levels IL-6, TNF-α, CRP, LDH, ESR, and CK at postoperative day 7 compared to conventional TKA. Levels of IL-6 and TNF-α have been previously negatively correlated to postoperative pain, swelling, and rehabilitation time following TKA, and robotic TKA shown to reduce postoperative pain scores, decrease opiate analgesia consumption and improve range of motion during postoperative rehabilitation compared to conventional TKA. Our study found robotic-arm assisted TKA reduced bone trauma and improved periarticular soft tissue preservation but there but there was no gross ligamentous disruption in either treatment group and the long-term clinical significance of these statistical differences in soft tissue injury outcomes remains unknown.
IL-6 helps to stimulate hepatic CRP synthesis and therefore the serum profiles and levels of these two cytokines are usually synchronised during the postoperative systemic inflammatory response. However, this study found that although there was a similar trend in the serum profiles of these two cytokines, CRP levels remained higher than IL-6 levels during the study period, and CRP levels increased between postoperative day 1 and day 2, whereas IL-6 levels decreased over this time period in both treatment groups. These findings may be attributable to IL-6 having a much shorter half-life, which led to more rapid fluctuations in its serum concentration compared to CRP during the postoperative inflammatory phase. IL-6 is known to peak during the first 12-24 hours after surgery and fall back to baseline at 48-72 hours, whereas CRP remains elevated during this time frame. Another plausible explanation for these findings is that pre-existing medical conditions, such as malignancies, cardiovascular disease or diabetes mellitus may have induced a direct hepatic acute phase response, and therefore increased CRP production without corresponding serum changes in IL-6 levels. It has been previously suggested that an increase in one of these two cytokines may reflect an acute phase response, whereas an increase in both of these cytokines may reflect a more valid measure of subclinical inflammation. This study recorded ASA scores in all study patients but did not record specific comorbidities that may have acted as confounders and affected serum cytokine levels in both treatment groups.

Robotic-arm assisted TKA was associated with improved accuracy of implant positioning and limb alignment compared to conventional jig-based TKA. Our findings are consistent with previous studies showing that robotic technology improves surgical precision and reduces outliers in femoral and tibial implant positioning. Bellemans et al reviewed outcomes in 25 patients undergoing robotic TKA and found femoral and tibial implant alignment within 1° of the planned positions in all three planes. Song et al conducted a prospective randomised study on 100 patients undergoing primary TKA and found robotic TKA improved accuracy in achieving the planned limb alignment, and reduced outliers of greater than 3° from neutral alignment (0 versus 24% respectively, p <0.001) compared to conventional manual TKA. Accuracy of achieving these radiological objectives has been shown to affect functional recovery, clinical outcomes, and long-term implant survivorship. Robotic technology helped to produce more pristine bone resections with reduced residual femoral and tibial surface irregularities compared to conventional jig-based TKA. This technology may offer an avenue for improving implant survivorship by reducing surgeon-controlled errors in implant positioning and facilitate the implementation of cementless components in future TKA implant designs. The high-levels of precision offered by robotic technology also enable non-neutral alignment targets to achieved with increased reproducibility, which decreases the risks of producing significant outliers from the safe ranges of alignment. This may help to subsequently establish new safe ranges for limb alignment based on patient-specific knee anatomy and kinematics, as guided by the periarticular soft tissue envelope.

The main strengths of this study are that patients were prospectively randomised to their treatment groups, preoperative surgical planning was undertaken using the same templating system, surgical intervention was performed using a standardised surgical approach, identical implant designs were used in both treatment groups, blinded observers graded soft tissue injury and bone trauma using a validated classification system, and a comprehensive, objective range of serum markers of inflammation were collected at predefined intervals after surgery. This study provides a unique profile of the postoperative systemic inflammatory response after TKA and is the first study to compare the systemic surgical insult of conventional TKA versus robotic TKA. However, there are certain limitations of this study that must be appreciated when understanding the findings. The current study reports on statistical differences in systemic inflammatory markers but the
long-term clinical significance or acceptable cut-off values for these outcomes remains unknown. The patients in this study will be followed up and the effects of the systemic inflammatory response and soft tissue injury on long-term clinical and functional outcomes reported in due course. In addition, femoral and tibial registration pins may have induced an inflammatory response and affected the study outcomes obtained in the robotic TKA group. The study may have been affected by the Hawthorne effect. The operating surgeons may have modified their surgical practices and behaviours in response to the awareness that the results were going to be analysed for the study. This may be overcome in future studies by undertaking studies with hidden observation in both conventional and robotic TKA.

**Conclusion:**

Robotic-arm assisted TKA was associated with a transient reduction in the early (day 7) inflammatory response with reduced levels of IL-6, TNF-α, CRP, ESR, LDH, and CK compared to conventional jig-based TKA. However, there was no difference in the immediate (<48 hours) or late (day 28) postoperative systemic inflammatory reaction or localised thermal response between the two treatment groups. Robotic-arm assisted TKA was associated with decreased iatrogenic periarticular soft tissue injury, reduced bone trauma and improved accuracy of implant positioning compared to conventional jig-based TKA. In the following chapter, we assess how these differences in perioperative outcomes relating to implant positioning, soft tissue injury and the systemic inflammatory response between the two groups translate to early postoperative functional rehabilitation.

**My role in this study:**

- Identified gap in the scientific literature on postoperative systemic inflammatory response after robotic TKA
- Generated study hypothesis
- Identified study outcomes
- Wrote study protocol and case report forms
- Completed Integrated Research Application System (IRAS) application
- Attended meetings with Research Ethics committee, Health Regulation Authority and sponsors
- Attended meetings with Research and Design team at UCL
- Recruited study patients
- Recorded intraoperative and postoperative data
- Collated study samples for analysis
- Performed statistical analysis
- Wrote manuscript for publication
Chapter 7

Postoperative functional rehabilitation in conventional jig-based total knee arthroplasty versus robotic-arm assisted total knee arthroplasty
Abstract

Robotic technology has been used to enhance postoperative rehabilitation in several surgical specialties, but the effects of this technology on early functional rehabilitation following TKA remain unknown. The objective of this study was to compare early postoperative functional rehabilitation and time to hospital discharge in conventional jig-based TKA versus robotic-arm assisted TKA. This study included 40 consecutive patients undergoing conventional jig-based TKA followed by 40 consecutive patients receiving robotic-arm assisted TKA. All surgical procedures were performed by a single surgeon using the medial parapatellar approach with identical implant designs and standardised postoperative inpatient rehabilitation in all patients. Inpatient functional outcomes and time to hospital discharge were collected in all study patients. This study found that robotic-arm assisted TKA was associated with reduced postoperative pain ($p<0.001$), decreased opiate analgesia requirements ($p<0.001$), decreased reduction in postoperative haemoglobin levels ($p<0.001$), shorter time to straight leg raise ($p<0.001$), decreased number of physiotherapy sessions ($p<0.001$) and improved maximum knee flexion at discharge ($p<0.001$) compared with conventional jig-based TKA. Median time to hospital discharge in robotic-arm assisted TKA was 77 hours (interquartile range (IQR) 74 to 81) compared with 105 hours (IQR 98 to 126) in conventional jig-based TKA ($p<0.001$). The findings of this study suggest that robotic technology may offer an avenue for further enhancing postoperative rehabilitation and facilitating earlier hospital discharge following TKA.
Background
In the previous chapters, we established that robotic-arm assisted TKA improves accuracy of implant positioning and reduces periarticular soft tissue injury compared to conventional jig-based TKA. However, it remains unclear how this translates to differences in postoperative functional recovery and time to hospital discharge between the two treatment techniques. In this chapter, we explore the effect of transitioning from conventional jig-based TKA to robotic-arm assisted TKA on postoperative functional outcomes and time to hospital discharge. All surgical procedures were performed by a single surgeon using the same surgical approach and all patients received a standardised rehabilitation programme.

Robotic technology has been used to perform several surgical procedures including cholecystectomy, hysterectomy, lobectomy, mitral valve replacement, coronary artery bypass grafting, and prostatectomy. In these surgical procedures, the use of robotics has been associated with smaller skin incisions, improved precision of soft tissue dissection, and better visualisation of the surgical field compared to open surgery or laparoscopic surgery.23,24 Clinically, this has translated to robotic surgery enabling faster postoperative rehabilitation and decreased length of hospital stay compared to conventional and laparoscopic surgery for these procedures.23-25 In TKA, robotic TKA improves the accuracy of implant positioning, reduces periarticular soft tissue injury, and decreases bone trauma compared to conventional jig-based techniques.31,32,61,63,146 However, the effect of robotic technology on early functional rehabilitation and time to hospital discharge in TKA has not been previously reported.

The primary objective of this study was to determine differences in postoperative pain scores in conventional jig-based TKA versus robotic-arm assisted TKA. The study hypothesis was that postoperative pain scores were comparable in conventional jig-based TKA versus robotic-arm assisted TKA. Secondary objectives were to compare opiate analgesia consumption, inpatient physiotherapy utilisation, time to straight leg raise, maximum knee flexion, and time to hospital discharge between the two treatment groups.

Methods
Patient selection.
This study included 80 patients with symptomatic knee osteoarthritis undergoing primary TKA, which included 40 consecutive conventional jig-based TKAs and the following 40 consecutive robotic-arm assisted TKAs. Patients were allocated to their treatment group based on the date of their surgery relative to installation of the robotic device into our institution. Conventional jig-based TKA was performed prior to installation of the robotic device, and robotic-arm assisted TKA performed after its installation. All operative procedures were performed by a single surgeon (F.S.H) with extensive experience in conventional jig-based TKA and previous cadaveric training in robotic-arm assisted TKA. Inclusion criteria for this study included the following: patients with knee osteoarthritis undergoing primary TKA; patients between 18 and 80 years of age; surgery using the conventional jig-based or robotic-arm assisted technique; surgery performed by a single surgeon (F.S.H). Exclusion criteria included the following: conversion of unicompartmental to TKA; prior infection of knee joint; arthroplasty for fracture or previous osteotomy; underlying neurological dysfunction compromising mobility; and/or the use of other surgical techniques such as computer navigation for TKA. There were no differences in systemic baseline and demographic characteristic in patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA (Table 7a). Written informed consent was obtained from all study patients. Hospital review board approval was acquired before commencement of the study.
Table 7a: Demographic and baseline measurements for patients undergoing conventional TKA versus robotic TKA

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Category</th>
<th>Conventional TKA (n=40)</th>
<th>Robotic TKA (n=40)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-</td>
<td>71.4 (range, 54.2 – 87.1)</td>
<td>69.7 (range, 53.1 – 85.3)</td>
<td>0.32</td>
</tr>
<tr>
<td>Gender</td>
<td>Female</td>
<td>25 (62%)</td>
<td>22 (55%)</td>
<td>0.50</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>15 (38%)</td>
<td>18 (45%)</td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>-</td>
<td>26.7 (range, 20.3 – 36.0)</td>
<td>27.9 (range, 21.8 - 37.1)</td>
<td>0.17</td>
</tr>
<tr>
<td>ASA score</td>
<td>I</td>
<td>7 (18%)</td>
<td>8 (20%)</td>
<td>0.88</td>
</tr>
<tr>
<td></td>
<td>II</td>
<td>29 (72%)</td>
<td>27 (67%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>III</td>
<td>4 (10%)</td>
<td>5 (13%)</td>
<td></td>
</tr>
<tr>
<td>Side of intervention</td>
<td>Left</td>
<td>20 (50%)</td>
<td>18 (45%)</td>
<td>0.65</td>
</tr>
<tr>
<td></td>
<td>Right</td>
<td>20 (50%)</td>
<td>22 (55%)</td>
<td></td>
</tr>
<tr>
<td>Mean preoperative Hb (g/L)</td>
<td></td>
<td>132.7 (95.1 to 164.3)</td>
<td>133.3 (113.2 to 154.6)</td>
<td>0.82</td>
</tr>
</tbody>
</table>

Summary statistics are: N (percentage) or mean with standard deviation, BMI=Body Mass Index, ASA score = American Society of Anaesthesiologists score.

Preoperative imaging and templating
All patients underwent routine preoperative anteroposterior weight-bearing knee radiographs, lateral knee radiographs, and full-length hip-to-ankle radiographs. In patients undergoing conventional jig-based TKA, the operating surgeon used Traumacad software (Traumacad, Petach-Tikva, Israel) with plain radiographs to preoperatively template optimal bone resection, implant sizes, and implant positioning. In patients undergoing robotic-arm assisted TKA, computer software (Mako system software, Stryker Limited, Kalamazoo, MI) was used to translate the preoperative CT scan into a patient-specific virtual 3D computer-aided design (CAD) model of the knee joint. The operating surgeon used the preoperative CT scan and CAD to template optimal bone resection, implant positioning and implant sizes. Preoperative imaging and templating in conventional jig-based TKA and robotic-arm assisted TKA are discussed in further detail in appendix section 10.1.

Surgical technique:
All operative procedures were performed under general anaesthesia. The surgical techniques for conventional jig-based TKA and robotic-arm assisted TKA are described in detail in appendix section 10.2. In both treatments groups, the
standard medial parapatellar approach was used with implantation of the cemented Stryker Triathlon (Stryker Navigation, Kalamazoo, Michigan, USA) cruciate substituting knee system with patella resurfacing using asymmetrical components.

**Postoperative inpatient care:**
All patients received postoperative patient-controlled analgesia (PCA) with a background intravenous morphine infusion rate of 0.5 mg/hour, and bolus doses of 2mg with lockout period of ten minutes. If the patient required additional analgesia then the nursing staff administered oral paracetamol and ibuprofen over this time. The PCA was stopped 24 hours postoperatively and converted to an oral regimen of regular paracetamol, ibuprofen and dihydrocodeine, with oral morphine available for breakthrough pain. All TKAs were performed at the same time of day and the first physiotherapy session was undertaken at six hours postoperatively. Patients underwent a standardised postoperative rehabilitation programme with full weight-bearing and active range of movement exercises commenced from day of surgery. Each physiotherapy session lasted 25 minutes in total and all rehabilitation was performed by the same team in both treatment groups. Patients were discharged home after adequate pain control, knee flexion to a minimum of 90°, independent mobilization with the use of crutches and independent ascent and descent of stairs.

**Outcomes:**
Two observers (B.K and J.R.T.P) blinded to each other’s recordings, collected all study outcomes. Findings were compared to establish any baseline differences between the two treatment groups. The following postoperative outcomes were prospectively collected in all study patients: operating time (minutes); assessment of the intraoperative blood loss based on the difference in pre- and postoperative haemoglobin concentration (g/l); postoperative pain score on the numerical rating scale (0 to 10) at days 0 to 3; opiate analgesia (mg) requirements at days 0 to 3; range of movement at discharge (); time from completion of operation to independent straight leg raise in the supine position (hours); number of inpatient physiotherapy sessions; use of inpatient continuous passive motion machine; time to hospital discharge (hours); and complications for 30 days following surgery. Study outcomes were selected based on previous studies showing that these early functional outcomes in TKA affect time to hospital discharge or long-term clinical outcomes.6,191-193

**Power calculation:**
The primary outcome measure in this study was the pain score on the numerical rating scale (NRS) at 48 hours after surgery. A sample size calculation was performed using a previously published study reporting the mean postoperative pain score at 48 hours after TKA as 4.19 with standard deviation of 1.37, and the minimum clinically important difference was set at one point.194 Using a two-tailed, two-sample t-test with power of 80% and an alpha value of 0.05, this study needed to recruit a minimum of 72 patients to detect this difference between the two treatment groups. The assumption of a 10% drop-out rate within the 30 days follow-up period resulted in a net sample size of 80 patients (40 patients in each treatment group).

**Statistical analysis:**
When comparing baseline and outcome measures between the two treatment groups, continuous variables with normal distributions were compared using the independent t-test, whilst the Mann–Whitney U test was used to compare continuous variables that were not normally distributed. One categorical outcome (use of continuous passive motion
machine) was analysed using Fisher’s exact test, due to the small number of occurrences of this outcome. Continuous variables found to be normally distributed were displayed with the mean and range, whilst the median and interquartile range (IQR) were presented for factors not found to follow a normal distribution. Categorical variables were shown by the number and percentage of patients where the outcome occurred. Statistical significance was set at a p-value < 0.05 for all analyses and all statistical analysis was performed using SPSS software version 21 (SPSS Inc., Chicago, Illinois, USA).

**Results**

Interobserver correlation coefficient was 0.90 (95% CI: 0.88 to 0.92) for all postoperative outcomes recorded suggesting good interobserver agreement between the two independent observers. Study outcomes are displayed in Table 7b. Patients undergoing robotic-arm assisted TKA had significantly reduced pain scores at all four-time intervals following surgery compared with conventional jig-based TKA (Figure 7a). In both groups, pain scores were greatest at day one, which reflected the day that the PCA was converted to oral analgesia. Opiate analgesia requirements were also significantly reduced in the robotic group compared with the conventional group and this was found to be statistically significant at all four time points (Figure 7b).

**Table 7b: Study outcomes for patients undergoing conventional jig-based TKA and robotic-arm assisted TKA**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Conventional TKA (n=40)</th>
<th>Robotic TKA (n=40)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating time (mins)</td>
<td>61.2 (range, 54.6 – 83.1)</td>
<td>74 (range, 59.2 – 91.7)</td>
<td>0.34</td>
</tr>
<tr>
<td>Fall in Hb (g/L)</td>
<td>26.1 (range, 5.1 - 49.6)</td>
<td>18.7 (range, 8.0 – 37.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-op Hb (g/L)</td>
<td>106.7 (range, 77.3 to 138.4)</td>
<td>114.7 (range, 86.4 – 139.1)</td>
<td>0.01</td>
</tr>
<tr>
<td>Pain score (NRS) – Day 0</td>
<td>5.4 (range, 3.0 – 7.0)</td>
<td>3.1 (range, 2.0 – 5.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pain score (NRS) – Day 1</td>
<td>6.3 (range, 4.0 – 8.0)</td>
<td>3.6 (range, 2.0 – 6.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pain score (NRS) – Day 2</td>
<td>6.1 (range, 3.0 – 8.0)</td>
<td>3.3 (range, 1.0 – 5.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pain score (NRS) – Day 3</td>
<td>4.5 (range, 2.0 – 7.0)</td>
<td>2.6 (range, 1.0 – 5.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Analgesia (mg) – Day 0</td>
<td>36.0 [IQR, 29.0 – 51.3]</td>
<td>20.0 [IQR, 16.0 - 28.5]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Analgesia (mg) – Day 1</td>
<td>10.0 [IQR, 10.0 – 20.0]</td>
<td>10.0 [IQR, 0.0 - 10.0]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Analgesia (mg) – Day 2</td>
<td>10.0 [IQR, 10.0 – 20.0]</td>
<td>10.0 [IQR, 0.0 - 10.0]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Analgesia (mg) – Day 3</td>
<td>10.0 [IQR, 0.0 – 10.0]</td>
<td>0.0 [IQR, 0.0 - 5.0]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time to SLR (hours)</td>
<td>31.0 [IQR, 24.0 – 44.0]</td>
<td>20.0 [IQR, 18.0 – 21.0]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Knee extension (degrees)</td>
<td>93.3 (range, 90.0 – 110.0)</td>
<td>104.1 (range, 90.0 - 120.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Number physio sessions</td>
<td>11.0 [IQR, 9.0 – 11.0]</td>
<td>5.0 [IQR, 5.0 – 6.0]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CPM sessions</td>
<td>5 (12.5%)</td>
<td>2 (5.0%)</td>
<td>0.43</td>
</tr>
<tr>
<td>Time to discharge (hours)</td>
<td>105.0 [IQR, 98.0 – 126.0]</td>
<td>77.0 [IQR, 74.0 – 81.0]</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Summary statistics are: N (percentage), mean with range, or median with interquartile range [IQR], NRS - Numerical Rating Scale, Hb - Haemoglobin concentration, SLR = Straight leg raise, CPM – Continuous Passive Motion Machine.
Figure 7a: Boxplot showing pain scores as measured using the numerical rating scale in conventional jig-based TKA versus robotic-arm assisted TKA.

Figure 7b: Boxplot showing opiate analgesia requirements in conventional jig-based TKA versus robotic-arm assisted TKA.
There was no significant difference in preoperative haemoglobin concentration between the two treatment groups, but patients undergoing conventional jig-based TKA had a significantly greater reduction in postoperative haemoglobin concentration compared with those undergoing robotic-arm assisted TKA. The pneumatic tourniquet was not inflated in any study patient. Two patients (5%) in the robotic-arm assisted TKA group each received two units of red blood cells compared with four patients (10%) in the conventional jig-based TKA group. Attainment of physiotherapy targets, including time to straight leg raise and maximum knee flexion at discharge, followed the same trend with significantly improved outcomes in robotic-arm assisted TKA compared with conventional jig-based TKA (Figures 7c-f).

*Figure 7c: Boxplot showing time to straight leg raise in conventional jig-based TKA versus robotic-arm assisted TKA*
Figure 7d: Boxplot showing maximum knee flexion at discharge in conventional jig-based TKA versus robotic-arm assisted TKA

Figure 7e: Boxplot showing number of inpatient physiotherapy sessions in conventional jig-based TKA versus robotic-arm assisted TKA
Each boxplot graphically displays the respective study outcome with the transverse line showing the median value and the box part representing the interquartile range. The whiskers extend to the minimum and maximum value, except for values more than $1.5 \times$ interquartile range width from the lower or upper quartiles, which are plotted separately. There were two inpatient complications in this study, which included one patient from each treatment group. In the conventional jig-based TKA, one patient had minor wound dehiscence from the distal part of the midline incision, which was treated with prophylactic antibiotics and adhesive skin strips to approximate the wound edges. In the robotic-arm assisted TKA group, one patient had minor wound dehiscence over the incision for the proximal tibial registration pins. This was treated with regular dressings and prophylactic oral antibiotics. Both patients made a satisfactory recovery with no further complications.

**Discussion**

In this study, there were no systematic differences in baseline characteristics between the two treatment groups, surgery was undertaken by a single surgeon using the same approach with identical implant designs, and inpatient rehabilitation performed using a standardised programme with the same rehabilitation team for all study patients. Robotic-arm assisted TKA was associated with reduced postoperative pain, decreased analgesia requirements, shorter time to be able to perform a straight leg raise, improved maximum knee flexion at discharge and decreased length of stay compared with conventional jig-based TKA. Our findings suggest that implementation of robotic-arm assisted surgery may help to further improve early functional rehabilitation and reduce time to hospital discharge in patients undergoing TKA.

Persistent pain following TKA is the strongest predictor of patient dissatisfaction, reduced mobility and poor functional outcomes.\(^{195}\) Regression analysis has also shown that postoperative pain is the most important prognostic indicator for
long-term patient dissatisfaction following TKA. Our study showed reduced pain and opiate analgesia requirements at each of the four time points in patients undergoing robotic-arm assisted surgery compared with conventional jig-based TKA. These findings are similar to those of Marchand et al that compared outcomes in 28 robotic-arm assisted TKAs matched with 20 conventional jig-based TKAs and found that pain, physical function scores and patient satisfaction as measured using the WOMAC criteria were better in the robotic group compared with the conventional group at six months after surgery. Our data shows important differences in pain and analgesia requirements in the early postoperative period, but the long-term clinical significance of these remain unknown. The present data will be subsequently correlated to long-term clinical outcomes.

Robotic-arm assisted TKA uses intraoperative motion capture technology to assess flexion-extension gaps, mediolateral soft tissue tension, range of motion and limb alignment. Using this intraoperative data, the surgeon is able to manipulate bone resections and fine-tune implant positioning to achieve the desired knee biomechanics, which limits the need for additional soft tissue releases. Robotic-arm assisted also confines bone resection to the stereotactic boundaries of the surgical plan, which helps to limit inadvertent sawblade injury to the periartrial soft tissue envelope as compared with a manual sawblade in conventional jig-based TKA. In the previous chapters, we found that robotic-arm assisted TKA reduced periartrial soft tissue injury, decreased bone trauma and reduced the early postoperative inflammatory response compared to conventional TKA. Existing studies comparing conventional versus minimally-invasive surgical approaches for THA and TKA have also found positive correlations between iatrogenic soft tissue injury and the systemic inflammatory response. Siebert et al conducted a retrospective study on 70 patients undergoing robotic-arm assisted TKA versus a matched historical cohort of 50 patients receiving conventional jig-based TKAs, and observed reduced postoperative soft-tissue swelling in the robotic-group. In the current study, improved preservation of the periartrial soft-tissue envelope and reduced iatrogenic bone trauma in the robotic group may have helped to limit postoperative pain and enhance early functional recovery compared to the conventional manual group.

In this study, there was a trend towards increased operating time in the robotic group but this was not statistically significant. Our findings are consistent with a previous study by Song et al who conducted a prospective study on 30 patients undergoing sequential TKA, which included conventional jig-based TKA on one side followed by robotic-arm assisted TKA on the contralateral side. The authors reported no difference in operating time between the two treatment groups, with mean operating time in the robotic-arm assisted of 95 minutes (SD 18). Park and Lee reported on the learning curve of robotic-arm assisted TKA and showed that six of their 32 robotic-arm assisted TKAs had short-term complications, including superficial infection, patellar ligament rupture, patellar dislocation, supracondylar fracture, patellar fracture and common peroneal injury during the learning phase. The reduced operating time and absence of intraoperative complications in our cohort of patients compared with these previous studies may be due to the operating surgeon in this study having extensive training in robotic-arm assisted TKA in cadaveric workshops and prior experience in performing computer navigated arthroplasty. As such, progression along the learning curve for some aspects of robotic-assisted surgery may have already been achieved. The surgical team’s learning curve with robotic-arm assisted TKA is explored in more detail in chapter 2. Although a financial analysis has not been undertaken, our findings do show important differences in inpatient rehabilitation and hospital stay, which will aid healthcare policy makers in the allocation of medical resources and cost planning for the implementation of this technology into clinical practice.
There are several limitations of this study that need to be considered when interpreting the findings. All study patients received general anaesthetic, which is not consistent with current trends in enhanced recovery programmes and this may have reduced the overall rehabilitation time in both treatment groups. Patients and observers recording study outcomes could not be blinded as patients in the robotic group had additional incisions over the proximal tibia for the insertion of the tibial registration pins. Robotic TKA had been recently introduced into the hospital as the latest technology in TKA, which may have influenced patient and observer perceptions about the robotic procedure. This may have introduced reporter bias and observer bias into the study. Furthermore, the effects of grade of arthritis, comorbidities, radiological deformity, and preadmission analgesia use were not analysed in this study. This study found an important difference in early functional rehabilitation between conventional jig-based TKA and robotic-arm assisted TKA but these findings need to be interpreted with these limitations in mind. Further studies with more robust methodology and longer-term follow-up are required to better understand the clinical significance of these early differences in functional rehabilitation between the two treatment groups.

**Conclusion**

Robotic-arm assisted TKA was associated with reduced postoperative pain, decreased analgesia requirements, smaller decline in postoperative haemoglobin levels, shorter time to perform a straight leg raise, decreased length of stay, and improved maximum knee flexion at discharge compared with conventional jig-based TKA. There was no additional risk of inpatient complications in patients undergoing robotic-arm assisted TKA compared with conventional jig-based TKA. In the following chapter, we use the various findings from the prospective cohort studies undertaken within this thesis to establish a prospective double-blinded randomised control trial comparing patient satisfaction, functional outcomes, implant survivorship and cost-effectiveness in robotic mechanically-aligned TKA versus robotic functionally-aligned TKA.

**My role in this study:**

- Identified gap in the scientific literature on postoperative outcomes after robotic TKA
- Generated study hypothesis
- Identified study outcomes
- Recorded intraoperative data
- Collated study outcomes and performed statistical analysis
- Wrote manuscript for publication

Robotic-arm assisted total knee arthroplasty is associated with improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based total knee arthroplasty.

Kayani B, Konan S, Tahmassebi J, Pietrzak JRT, Haddad FS.

Bone Joint J. 2018 Jul;100-B(7):930-937. PMID: 29954217
Chapter 8

A prospective double-blinded randomised controlled trial comparing robotic-arm assisted functionally aligned total knee arthroplasty versus robotic-arm assisted mechanically aligned total knee arthroplasty

(Study Protocol)
Abstract

Total knee arthroplasty with mechanical alignment (MA TKA) aims to achieve neutral overall limb alignment. Total knee arthroplasty with functional alignment (FA TKA) aims to restore the native joint line height and obliquity, and achieve the planned knee biomechanics by manipulating implant positioning as guided by the soft tissue envelope. The chapter describes the protocol for a prospective double-blinded randomised controlled trial comparing a comprehensive range of clinical, functional and radiological outcomes in MA TKA vs FA TKA. This study will include 100 patients with symptomatic knee osteoarthritis undergoing primary robotic-arm assisted TKA. Robotic technology will be used to execute the planned alignment technique and implant positions with high levels of accuracy and reproducibility. Following informed consent, patients will be randomised to MA TKA (control group) or FA TKA (investigation group). Blinded observers will review patients at regular intervals to record predefined study outcomes for two-years after surgery. The findings of this study will enable an improved understanding of the optimal alignment technique in TKA for achieving high-levels of patient satisfaction, improving functional outcomes, increasing implant survivorship, improving cost-effectiveness, and reducing complications.
Background

In chapter 2, we found that robotic-arm assisted TKA was associated with improved accuracy of implant positioning and limb alignment compared to conventional jig-based TKA, and robotic-arm assisted TKA did not have a learning curve effect for achieving the planned implant positioning. In chapter 3, we developed the MASTI classification system and found that robotic-arm assisted TKA was associated with reduced iatrogenic soft tissue injury and bone trauma compared to conventional jig-based TKA. In chapters 4 and 5, we validated the use of optical motion capture technology as an investigative tool for assessing knee biomechanics and used this to quantify the effects of ACL and PCL release on knee kinematics during TKA. In chapters 6 and 7, we found that robotic-arm assisted TKA limited the early postoperative systemic inflammatory response and enhanced postoperative rehabilitation compared to conventional jig-based TKA. In this chapter, we use the pertinent findings from the aforementioned studies in this thesis to develop and establish a prospective double-blinded randomised controlled trial to determine the optical alignment technique in TKA. The planned study will include a more comprehensive range of study outcomes and use more robust scientific methodology to help overcome the potential limitations and bias from the previous prospective cohort studies described in this thesis.

Total knee arthroplasty with mechanical alignment (MA TKA) aims to restore neutral alignment of the limb. This is achieved by placing implants perpendicular to the mechanical axis of the femur and tibia, and externally rotating the femoral component to obtain a rectangular, balanced flexion-extension gap, which also aids patella tracking. The principle of neutral mechanical alignment is to distribute load evenly across the implants, which provides a mechanical advantage in flexion and limits asymmetrical bearing surface wear. However, recent studies have shown that there are large variations in native knee anatomy with most patients having a mild native varus limb alignment. Therefore, in the large majority of patients undergoing MA TKA, the knee is forced into an unnatural position with resultant changes in knee biomechanics that may alter the native femoral flexion axis, ligament tension, quadriceps function, patella tracking and overall knee kinematics.

Total knee arthroplasty with functional alignment (FA TKA) aims to restore the native joint line height and obliquity, and achieve the planned knee biomechanics by manipulating implant positioning as guided by the soft tissue envelope. The goal is to place the components in the positions that least compromises the soft-tissue envelope by restoring the plane and obliquity of the joint line as dictated by the soft tissues. This is most commonly achieved using robotic technology, which uses optical motion capture tracking to provide objective intraoperative data on limb alignment, mediolateral soft tissue tension, flexion-extension gaps, and range of motion. The robotic arm with sawblade action confined to the stereotactic boundaries is used to intraoperatively modify bone resections in the coronal, sagittal, and axial plane to execute individualised patient-specific limb alignment and knee kinematics, whilst ensuring limb alignment is achieved within the predefined safe zones. Robotic TKA with functional alignment aims to reduce the need for controlled soft tissue releases to achieve the planned knee biomechanics compared to MA TKA. There is optimism that TKA with functional alignment will enable better restoration of patient-specific knee biomechanics and further improve patient satisfaction and functional outcomes in TKA.
Objectives
The primary objective of this study is to compare the WOMAC score in MA TKA versus FA TKA at two years after surgery. The study hypothesis is that WOMAC scores will be superior in patients undergoing FA TKA compared to MA TKA at two years follow-up.

The secondary objectives are to compare the following outcomes between the two treatment groups:
1. Accuracy of implant positioning and limb alignment
2. Surgical efficiency
3. Postoperative functional rehabilitation
4. Functional outcomes
5. Quality of life
6. Implant migration
7. Gait
8. Resource use and cost effectiveness
9. Complications

Methods
Trial design
This study is a prospective, single-centre, double-blinded, randomised controlled trial. The study will be undertaken in the department of trauma and orthopaedics, University College Hospital, 235 Euston Road, London NW1 2PG, UK. The study will include 100 patients randomly allocated to either MA TKA (control group) or FA TKA (investigation group). All patients will undergo robotic-arm assisted TKA to improve the accuracy of achieving the planned implant positioning and limb alignment. The study commenced patient recruitment in January 2019 and is expected to complete patient recruitment in January 2021. All patients will be followed up for two years after surgery and therefore the anticipated completion date for the study is January 2023. The study is sponsored by University College London, UK. The patient enrolment flowchart is presented in figure 8a. The schedule of enrolment, interventions, and assessments for all study patients is shown in figure 8b.
Patient with knee osteoarthritis require total knee arthroplasty

Assessed for eligibility

Excluded: either ineligible or declined participation

Consent & Randomisation

Allocated to robotic-arm assisted TKA with functional alignment (TKA FA)

Baseline data; gait analysis; operation; operative data collected; routine knee radiograph; CT scan

2 weeks clinical review; outpatient physiotherapy commences; RSA radiographs

6 weeks routine outpatient follow-up; clinical data collected; CT scanogram and RSA radiographs

6 months routine outpatient follow-up; clinical data collected; gait analysis; RSA radiographs

1-year routine outpatient follow-up; clinical data collected; gait analysis; RSA radiographs

2 years routine outpatient follow-up; clinical data collected; RSA radiographs; ends participation in study

Allocated to robotic-arm assisted TKA with Mechanical alignment (TKA MA)

Baseline data; gait analysis; operation; operative data collected; routine knee radiograph; CT scan

2 weeks clinical review; outpatient physiotherapy commences; RSA radiographs

6 weeks routine outpatient follow-up; clinical data collected; CT scanogram and RSA radiographs

6 months routine outpatient follow-up; clinical data collected; gait analysis; RSA radiographs

1-year routine outpatient follow-up; clinical data collected; gait analysis; RSA radiographs

2 years routine outpatient follow-up; clinical data collected; RSA radiographs; ends participation in study
### Eligibility criteria

The inclusion criteria for this study is as follows: Patient has symptomatic knee osteoarthritis requiring primary TKA; patient fit for surgical intervention following review by surgeon and anaesthetist; patient aged between 18-80 years at time of surgery; Patient able to give informed consent and agrees to comply with the postoperative review program;
Patient has sufficient mobility to attend follow-up clinics. The exclusion criteria for this study is as follows: patient undergoing revision surgery or second stage TKA; patient not suitable for study implants (e.g. patient requires a constrained prosthesis); patient is immobile or has another neurological condition affecting musculoskeletal function; patient already enrolled on another concurrent clinical trial; patient unable or unwilling to sign the informed consent form specific to this study; patient unable to attend the study follow-up programme.

Recruitment
Patients will be recruited from the orthopaedic outpatient clinic at University College Hospital, 235 Euston Road, London NW1 2PG, UK. All patients will be screened by the clinical team (orthopaedic consultant surgeon, clinical research fellow, and orthopaedic registrar) for study participation based on the predefined inclusion and exclusion criteria listed above. Patients that fulfil the eligibility criteria and express an interest to participate in the study will be provided with a Research Ethics Committee approved patient information sheet. This provides details about the study, treatment, follow-up and contact details for further information. All members of the clinical team are familiar with the study and will address any preliminary questions about the study. Details of those patients expressing an interest to participate in the study will be recorded in the patient contact form and forwarded to the research physiotherapist. The research physiotherapist will phone the patient four weeks after this consultation to discuss any further questions and confirm if the patient would like to participate in the study.

Consent
Informed consent will be obtained by the chief investigator or principal investigator when the patient attends for the preoperative planning CT scan. This is six weeks after the initial consultation to book the patient for TKA and two weeks before surgery. It is important for the data collection scheme that patients are able to follow commands, read and interpret questions via questionnaires. For those who cannot hear, read or understand English, an interpreter will be provided. The operating surgeon will use the preoperative CT scan to create a patient-specific CAD model and create a surgical plan for executing neutral mechanical alignment in both treatment groups. Intraoperatively, this will be further modified to execute the designated alignment technique within each group. Further details on preoperative templating are provided in appendix section 10.1

Allocation
After informed consent has been obtained, the research physiotherapist will randomise the patient into one of the two treatment groups using an online random number generator (www.random.org). A number from 1 to 100 will be randomly generated and will allocate a patient to one of the two arms of the study: 1-50 inclusive for the control group, 51-100 inclusive for the investigation group. The research physiotherapist will perform the randomisation procedure and store the designated treatment group for each patient on a password-encrypted file on the hospital computer. The operating surgeon will have this information communicated to them on the morning of surgery.

Surgical Intervention
In patients undergoing MA TKA, femoral and tibial bone implant positioning will be used to achieve neutral overall limb alignment. In the coronal plane, femoral implant positioning will be set at 5-7 valgus in relation to the anatomical axis of the femur. In the sagittal plane, femoral component positioning will be set at 0-5 degrees of flexion to optimise implant
positioning whilst preventing notching. In the axial plane, femoral component will be aligned to the surgical transepicondylar axis, which is approximately 3 degrees externally rotated to the posterior condylar axis (PCA). The size of the femoral implant will be selected using posterior referencing with the largest size that does not overhang the femur, notch the anterior femur, or overhang the mediolateral bone edges, and avoids overstuffing the patellofemoral joint. The femoral implant will be positioned at the centre of the mediolateral cortical bone edges. In the coronal plane, tibial implant position will be aligned to the tibial mechanical axis. In the sagittal plane, tibial implant position will be set to 0-3 degrees of posterior tibial slope. In the axial plane, tibial implant will be positioned at 0-5 degrees of external rotation to Akagi’s line. Tibial implant size will be selected with the largest size that does not overhang the anteroposterior or mediolateral bone coverage. The implant will be positioned in the centre between the anteroposterior and mediolateral cortical bone edges.

In patients undergoing FA TKA, the implants will be positioned to optimise soft tissue tension through achieving balanced flexion-extension gaps and equal mediolateral soft tissue tension by altering bone resections and implant positions rather than through soft tissue releases. This will be achieved when possible within strict alignment limits, and where not achievable because of the magnitude of a fixed deformity, by balancing after bone cuts with limited soft tissue releases. In the coronal plane, femoral implant positioning will be modified from a starting point of 0 degrees to the mechanical axis to balance the extension gap. In the sagittal plane, femoral component positioning will be set to optimise component sizing whilst avoiding notching by flexing up to 5 degrees. In the axial plane, the femoral component will be aligned to the surgical transepicondylar axis and modified by up to 3 degrees to balance the flexion gap. The size of the femoral implant will be selected using posterior referencing with the smallest size that does not overhang the femur, notch the anterior femur, or overhang mediolateral bone edges, and avoids overstuffing the patellofemoral joint. The femoral implant will be positioned at the centre of the mediolateral cortical bone edges, favouring a lateral position if necessary. In the coronal plane, tibial implant position will be aligned to the tibial mechanical axis and then modified to balance flexion-extension gaps by up to 3 degrees of varus. Valgus tibial position will be avoided. In the sagittal plane, tibial implant position will be set to match the patient’s native posterior tibial slope, and modified to balance the flexion gap if necessary. In the axial plane, the tibial implant will be positioned to match Akagi’s line. Tibial implant size will be selected with the largest size that does not overhang the anteroposterior and mediolateral bone coverage whilst achieving the correct rotation. The implant will be positioned in the centre between the anteroposterior and mediolateral cortical bone edges.

All operative procedures will be undertaken using the Mako robotic-arm interactive orthopaedic system (Stryker Limited, Kalamazoo, MI, USA) under the direct supervision of one arthroplasty surgeons (F.S.H). The cemented Stryker Triathlon (Stryker Navigation, Kalamazoo, Michigan, USA) cruciate substituting knee system with patella resurfacing will be used in all study patients.

Outcomes:
All study patients will undergo review by two blinded observers (one orthopaedic registrar and one clinical research fellow) at 2 weeks, 6 weeks, 6 months, 1 year and 2 years following surgery. During these follow-up times, predefined clinical, functional and radiological outcomes will be recorded by these observers using case report forms (CRFs). The following outcomes will be recorded in all study patients:
1. Accuracy of implant positioning and limb alignment as assessed using CT scan postoperatively at 6 weeks.
2. Operating time (minutes)
3. Time to hospital discharge (hours)
4. Analgesia requirements during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year and 2 years
5. Patient reported outcome measures including the Forgotten Joint Score (FJS), Oxford Knee Score (OKS), Short form health survey of 12 items (SF-12), Knee injury and osteoarthritis outcome score (KOOS), WOMAC, University of California at Los Angeles knee (UCLA), and University College Hospital knee (UCH) scores preoperatively and postoperatively at 6 weeks, 6 months, 1 year and 2 years
6. Health-related quality of life as measured using European Quality of Life questionnaire with 5 dimensions for adults (EQ-5D) preoperatively and postoperatively at 6 weeks, 6 months, 1 year and 2 years
7. Mobilisation distance (metres) and use of mobility aids during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year and 2 years
8. Range of movement (degrees) in knee joint during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year and 2 years
9. Femoral and tibial implant early migration as assessed using RSA performed postoperatively at 2 weeks, 6 weeks, 6 months, 1 year, and 2 years
10. Gait analysis performed postoperatively at 6 months and 1 year postoperatively using an instrumented treadmill with force plates
11. Resource use and cost effectiveness including comparisons between the two treatment groups relating to: Operating time, theatre efficiency, equipment and sterilisation costs, analgesia requirements, inpatient rehabilitation, time to discharge, outpatient follow-up, additional imaging costs, and need for further surgery.
12. Complications

The FJS, UCLA, WOMAC, OKS, KOOS, SF-12, and EQ-5D are validated tools for the clinical assessment of patients after knee arthroplasty.\textsuperscript{200-202} In addition, the blinded observer will record the UCH functional knee score to assess overall pain, function and mobility. All study patients will undergo gait analysis using an instrumented treadmill with force plates (Kistler Gaitway, Kistler Instrument Corporation, Amherst, New York, USA) on a level platform. Gait analysis will be performed at the patient’s self-selected comfortable speed and maximum speed without running. Vertical ground reaction forces and spatiotemporal data will be obtained from force plates built into the treadmill. RSA radiographs will be performed at regular postoperative follow-up intervals to quantify motion between the implant and host bone, which is highly predictive of long-term implant survival.\textsuperscript{203,204}

**Blinding**

All patients and clinical staff recording postoperative study outcomes will remain blinded to the treatment group. Study patients will be identifiable with a unique study number. Only the research physiotherapist will have the key to identify individual patients and their respective treatment arm. Any documents related to the study will be archived directly at the study site by the research physiotherapist within a locked filing cabinet in a locked research office. This office has swipe card access with onsite security and 24-hour CCTV surveillance. Patient data will be logged electronically using each patient’s unique identification number with computer software on an encrypted, password-protected research computer.
Sample size
The sample size calculation was performed using the WOMAC score as the primary outcome measure. A recently published study reported the mean WOMAC score was 20.4 ± 1.8 in robotic TKA with mechanical alignment and 19.3 ± 1.9 in robotic TKA with kinematic alignment at median 8 years (range; 8.0 to 9.4 years) follow-up. Assuming similar postoperative WOMAC scores in this study, and using a two-tailed, two-sample t test with a power of 80% and significance level of 5%, a sample size of 92 patients (46 patients in each treatment group) was required to detect this difference between the two groups. To account for 10% sample size attrition during follow-up, 100 patients will be recruited into this study.

Statistical methods
The analysis of the per-protocol population will be considered the primary analysis. The differences between the MA TKA and FA TKA groups will be analysed by calculating the difference from baseline, per patient, and a two-sided confidence interval for the difference between the changes from baseline will be calculated. This confidence interval will cover the true difference in the percentage change from baseline with a probability of 95%. The following statistical methods will be employed to analyse the data: descriptive statistics, independent t-test, paired t-test, analysis of variance, Fisher exact test, Chi-square test, and graphical displays. Assumptions of normality will be tested with the D’Agostino test. Assumptions of homogeneity of variance will be tested with Levene’s test. If the distributional assumptions are (severely) violated, non-parametric techniques, such as Mann-Whitney’s test will be employed. In the event that FA TKA is converted to MA TKA intraoperatively, analysis will be performed using the intention-to-treat population and the treatment actually received by the patients. Intra-operative conversion from FA TKA to MA TKA will be documented and published as part of the study. Statistical significance is set at a p-value < 0.05 for all analyses and all statistical analysis will be performed using SPSS software version 21 (SPSS Inc., Chicago, Illinois).

Adverse events
Adverse events are defined as any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved. A serious adverse event (SAE) is an adverse event that results in hospitalisation or prolongation of existing hospitalisation; persistent or significant disability or incapacity; life-threatening clinical sequelae; or death. All SAEs during the protocol treatment will be reported directly to the sponsor using the SAE web form. The chief investigator will also assess the SAE for severity, causality, seriousness and expectedness using pre-existing criteria provided by the sponsor and inform the Data Safety Monitoring Board (DSMB) within three days of the initial observation of the event. The protocol treatment period is defined as the period from the day that the first study patient is recruited into the trial to the day that the final study patient has completed two years follow-up. The chief investigator will also inform the London-Surrey Research Ethics Committee and local Health Research Authority within three days of the SAE taking place. Safety aspects of the study are closely monitored by the sponsor and DSMB using unblinded data for its judgment. In cases where the SAE arises due to a problem with the robotic device, Stryker Limited will also be notified within two days of the event taking place. The chief investigator will record the following: onset date, complete description of the event, severity, duration, action taken, and outcome for each SAE. The chief investigator will also provide regular updates of all SAEs to the London-Surrey Research Ethics Committee, local Health Research Authority, DSMB, and sponsor.
Data Management
On-site monitoring visits shall occur throughout the course of the clinical study by the chief investigator. The chief investigator shall permit and assist the sponsor (should they choose to monitor the study) to carry out verification of all study forms against data in the source documents, which shall occur as per the departmental policy for undertaking such activities. University College Hospital recognises that there is an obligation to archive study-related documents at the end of the study. The study master file will be archived at University College London in accordance with the University College Hospital Standard Operating Procedure for Archiving of Investigator Site File (ISF) and Pharmacy Site File (PSF). It will be archived for a minimum of 5 years from the study end, and no longer than 30 years from study end.

End of protocol treatment
Reasons for going off study protocol include:
- Completion of last follow-up visit at two years after surgery
- Patient non-compliance or withdrawal (the reason for discontinuation will be recorded in the case report form)
- Intercurrent death

All patients included into this study are free to withdraw from the study at any time without compromise to their future treatment. On withdrawal, patients will revert to the standard follow-up regimen for routine (non-study) TKA at the study site. The end of study form will be completed and the reason for withdrawal documented. This form will also be completed if the patient is lost to follow-up or dies during the course of the study. Data to the point of discontinuation will be used for analysis.

Monitoring
The chief investigator will monitor the progress of the clinical study in the form of monthly research meetings for those involved in the trial. The chief investigator will be responsible for the day to day monitoring and management of the study. The UCLH/UCL/Joint Research Office, on behalf of UCL as Sponsor, will monitor and conduct random audits on a selection of studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the Department of Health Research Governance Framework for Health & Social Care (April, 2005), and in accordance with the sponsor’s monitoring and audit policies and procedures. As per the protocol, the principal investigator will email the sponsor twice yearly with the following: delegation log, adverse event log, deviation log, and any annual progress reports sent to the Ethics committee.

Ethics and dissemination of findings
The findings of this study will be published in peer-review journals. There are no terms or conditions to the funding that may impact upon publication and dissemination. Authorship will reflect the amount of time spent designing the study, collating the data, analysing the results, and writing the manuscript.

Funding
The study is investigator initiated. Funding was obtained from Stryker Limited. University College London is the sponsor.
Ethics Approval
London-Surrey Research Ethics Committee, UK

Peer review
The study protocol was reviewed by two external reviewers. The suggestions and recommendations for improvement to the study design were implemented. The reviewers and sponsor reviewed the revised protocol documents and confirmed that all queries and suggestions had been fully addressed.

My role in this study:
- Identified gap in the scientific literature with studies comparing robotic neutral mechanical alignment versus robotic functional alignment in TKA
- Generated study hypothesis
- Identified study outcomes
- Wrote study protocol and case report forms
- Completed Integrated Research Application System (IRAS) application
- Attended meetings with Research Ethics committee, Health Regulation Authority and sponsors
- Attended meetings with Research and Design team at UCL
- Recruited study patients
- Recorded intraoperative and postoperative data
- Collated study samples for analysis
- Performed statistical analysis
- Wrote manuscript for publication

The study commenced patient recruitment in January 2019 and is expected to complete patient recruitment in January 2021. All patients will be followed up for two years after surgery and therefore the anticipated completion date for the study is January 2023.

A prospective double-blinded randomised control trial comparing robotic arm-assisted functionally aligned total knee arthroplasty versus robotic arm-assisted mechanically aligned total knee arthroplasty.

Kayani B, Konan S, Tahmassebi J, Oussedik S, Moriarty PD, Haddad FS.
Trials. 2020 Feb 18;21(1):194. PMID: 32070406
Chapter 9

Discussion
Abstract

This chapter discusses the evolution of computer technology within the healthcare industry and the development of robotic technology in TKA. The pertinent findings from this research thesis are revisited and their clinical relevance to current practice highlighted. Further gaps in the existing medical literature are discussed and areas for future research and development are highlighted.
**Computer technology in industry**

During the course of my lifetime, computer technology has transformed the development and manufacturing process of almost every industry worldwide. Experts from a range of industries, including aviation, military, engineering, architecture, and healthcare have shown that each industry moves through five distinct phases: 1. consideration of the industry as an art by specialists within the field; 2. development of specific rules and instruments; 3. creation of standardised protocols and procedures; 4. automation; and 5. integration of computer technology.\(^{16,20}\) During the final phase, computer systems provide accurate, objective, real-time data to optimise efficiency, increase accuracy, decrease wastage, and minimise system error. Computer systems have enabled industries to achieve high levels of performance and sustained productivity that were simply not attainable with a manual human workforce. Further evolution in computer technology has led to the development of robotic machines, which help to execute predefined tasks with improved accuracy and reliability, and artificial intelligence, which apply specific computer algorithms to replicate human intelligence and perform tasks. Within each of these industries that have integrated computer technology into their workforce, the use of this technology has never diminished or exited from the industry.\(^{16}\)

In my opinion, the aviation industry best exemplifies how computer systems have been incorporated into the fabric of an industry to enhance human performance, increase efficiency, and reduce human error. Current aircraft autopilot systems use real-time data related to wind-speed, humidity, barometric pressure, altitude, weight-distribution, turbulence, moments of inertia, and numerous electronic and system setting combinations to determine how to follow a flight path that is changing in real-time. The computer systems are calculating how these variables will affect the aircraft in its current position, and calculating where it will be in the future, across all the other possible flight paths.\(^{20}\) The aircraft autopilot system provides the pilot with live in-flight feedback with recommendations to improve fuel efficiency and passenger comfort. In the automobile industry, computer systems have been used to develop inbuilt parking sensors, night vision with pedestrian detection, automatic high-beam control, parental control, satellite navigation, parking cameras, inbuilt electronic fuel sensors/temperature sensors/tyre pressure sensors, keyless entry, smartphone integration, heated seats, adaptive cruise control, and self-parking cars. In the construction industry, computer technology has been used to improve efficiency, provide live feedback of on-field progress, and reduce overall costs. Computer-aided design software handles engineering input data including design criteria and methodology, drafting, and preparation of plans and specifications. The software also prepares materials and quantity lists, estimates costs, workflow, inventory requirements, machine tool loading, and shop floor control.\(^{16,206}\)

**Computer technology in medicine**

Computer technology is routinely used in the healthcare industry by many medical professionals. In my own experience, computer systems are used on a daily basis to access patient notes, review blood tests, assess patient images, and electronically log patient reports. Anaesthetists routinely use intraoperative computer technology to measure, record, analyse, and fine-tune the administration of medication. The anaesthetic monitor displays a continuous ECG waveform, blood oxygen saturation, heart rate, blood pressure, capnogram waveform through the breathing cycle with digital values for inspiration and expiration, and body temperature. If a central venous or arterial catheter is inserted, the monitor presents a continuous waveform with readings of systolic, diastolic and mean blood pressure values. If a neuromuscular monitor is used, the values of the muscle strength in response to an electrical stimulus applied to the nerve supplying that muscle are displayed. This assists the anaesthetist in deciding when to give more muscle relaxant and when to reverse the
relaxant, and provides the concentrations of the volatile agent in each breath at the beginning of inspiration and at the end of expiration. Computer technology in anaesthesia has now become an integral part of patient safety and the “anaesthetic machine check” has been implemented into the World Health Organisation’s (WHO) checklist before the induction of anaesthesia.²⁰ I strongly believe that our anaesthetic colleagues are far more advanced with the routine use of computer technology to augment and fine-tune their clinical practice than other medical and surgical specialties. This may be surprising as surgeons are often viewed as being at the forefront of medical engineering and technology to improve patient care. Plausible explanations for the lag of computer technology in surgical specialties may be the prolonged training and experience to develop fine motor skills and manual dexterity, lack of exposure, time and resources for additional training with computer technology, and/or the lack of high-quality studies showing any improvements in clinical outcomes compared to conventional manual surgical techniques.

Robotic technology in general surgery

The most commonly adopted robotic surgical device is the Da Vinci Robotic platform (Intuitive Surgical, Sunnyvale, California), which uses an intraoperative computer console to control miniaturised instruments mounted onto three robotic arms.²²-²⁴ The surgeon looks through a 3D camera attached to a fourth robotic arm, which magnifies the surgical site to increase the visual field compared to a conventional 2D camera used in laparoscopy. The surgeon’s hand, wrist and finger movements are transmitted through the computer console to the instruments attached to the robotic arms, which enables greater range of motion and increased precision compared to open or laparoscopic surgery. I first came across the Da Vinci robotic device at Imperial college in 2007, where the robotic machine was installed in a virtual-reality research laboratory. As aspiring surgeons, we used to play with the robotic platform to stack sugar cubes or ligate leaking blood vessels displayed on a computer screen in the shortest time possible. The Da Vinci robotic device was regarded as an advanced computer console from a science fiction movie, with very limited clinical evidence to support its use in surgery. However, over the following 10 years, the Da Vinci robotic platform was used to perform over six million procedures worldwide including coronary artery bypass grafting, mitral valve surgery, colectomy, rectal resection, lobectomy, prostatectomy, partial nephrectomy, and hysterectomy.²²-²⁴ As robotic surgery is undertaken through smaller surgical incisions, reduced soft tissue trauma, and more accurate resection of diseased tissue, the procedure enables faster rehabilitation, reduced need for analgesia, reduced hospital length of stay, and decreased risk of long-term complications compared to open and laparoscopic surgery.²³-²⁵

Robotic technology in orthopaedics

Robotic technology has recently regained momentum as an avenue for improving the accuracy of implant positioning and limb alignment in TKA compared to conventional jig-based based techniques. TKA is an effective and cost-efficient procedure with implant survivorship, as assessed with revision as the primary endpoint, greater than 90% at ten years’ follow-up.³ However, despite developments in minimally invasive surgery, pain management, regional anaesthesia, deep vein thrombosis prophylaxis, antibiotic prophylaxis, implant design, and enhanced postoperative rehabilitation, patient satisfaction and functional outcomes in TKA remain inferior to THA.²-⁷,¹² Recent studies have shown that up to 20% of patients remain dissatisfied following TKA despite an otherwise uncomplicated procedure.²,⁷-¹² In my opinion, patient dissatisfaction following TKA is likely to be multifactorial but variables such as accuracy of implant positioning and periarticular soft tissue tensioning are important surgeon-controlled variables that may be modified to improve patient outcomes. Previous studies have shown accurate implant positioning, balanced flexion-extension gaps, and proper
ligament tensioning are important variables that affect functional outcomes, implant stability, and long-term implant survivorship in TKA. 6,13,18,20 If surgical technology can help us surgeons to achieve the technical objectives of TKA with greater accuracy and reproducibility, this may help to improve outcomes in TKA further.

**Reducing surgical error in TKA**

As a trauma and orthopaedic registrar, I rotate across several hospitals and view operative procedures undertaken by surgeons with varying levels of skill and experience. Although the intraoperative steps for most surgical procedures are standardised, there is marked variation in the skill and expertise with which these are executed by the operating surgeon. Conventional jig-based TKA uses preoperative radiographic films, intraoperative anatomical landmarks, and manually-positioned alignment jigs to guide bone resection and implant positioning. However, these handheld techniques are associated with poor reproducibility of alignment-guide positioning, inadvertent sawblade injury to the periarticular soft tissue envelope, and limited intraoperative data on gap measurements or ligamentous tensioning to fine-tune implant positioning. 33-37 Suboptimal implant positioning or gap balancing may lead to poor functional recovery, reduce clinical outcomes, increase instability, and reduce implant survivorship. 104,122-127 The National Joint Registry of the United Kingdom has shown marked variations in implant survivorship and revision rates between different operating surgeons and arthroplasty hospitals. 3 It seems logical to use technology to limit manual errors in implant positioning and help standardise the quality of TKA procedures. In my opinion, robotic technology has the potential for inexperienced or low-volume arthroplasty surgeons to execute the planned technical objectives relating to component positioning, flexion-extension gap balancing, mediolateral ligamentous tensioning, and periarticular soft tissue preservation with greater precision and reduced outliers. This may help to reduce surgeon-controlled errors and reduce the burden of premature implant failure and revision surgery in TKA.

**Separating science and marketing**

Robotic-arm assisted TKA uses a preoperative CT scan and patient-specific CAD models to plan optimal bone resection and implant positioning. An intraoperative robotic arm helps to execute this plan with a high level of accuracy. 26-32 Haptic boundaries limit the action of the sawblade to the confines of the preoperative surgical plan to limit iatrogenic soft tissue injury. 63,146 Optical motion technology enables live onscreen assessments of knee biomechanics, which enables intraoperative modifications to bone resection and implant positioning to achieve the desired flexion-extension gaps, mediolateral soft tissue balance, limb alignment, and range of motion. 64,84,146,185 I believe the recent resurgence in robotic-arm assisted TKA is attributable to advances in surgical technology and the ease with which modifications may be made to computer navigated TKA. However, there is also a significant marketing drive from the manufacturers of the robotic device as each company aims to gain a larger market share of the robotic TKA marketplace. Although many companies now have robotic booths at most arthroplasty conferences and free training courses with their respective devices, there is limited clinical evidence to support the widespread implementation of this technology for TKA. Many of these companies also target lay members of the public and patients with advertisements and promotions of the robotic device and often overinflate findings from existing cadaveric or clinical trials. I believe it is important for clinicians to explain the potential benefits of this technology but also the limitations of the existing studies and paucity of any long-term data comparing clinical outcomes to conventional jig-based TKA.
Research overview

This research thesis consists of a series of prospective cohort studies that compare radiological objectives and perioperative outcomes in conventional jig-based TKA versus robotic-arm assisted TKA. We validated and utilised intraoperative optical motion capture technology during robotic-arm assisted TKA to quantify the effects of ACL and PCL resections on knee biomechanics. All study outcomes were selected based on existing studies showing their relevance to long-term clinical outcomes and implant survivorship following TKA.\textsuperscript{1,2,6,16,49,150,164,191-194,197,209-212} The findings of the various prospective cohort studies undertaken within this research fill important gaps in the existing medical literature comparing conventional jig-based TKA versus robotic-arm assisted TKA. We have revisited the pertinent findings from each study and discussed how these may affect clinical practice. We have also provided a breakdown of the limitations of each study and explored how we aim to overcome these within the prospective randomised controlled trials in progress.

Learning curve of robotic TKA

Robotic-arm assisted TKA has been implemented into many arthroplasty centres worldwide but the surgical team’s learning curve for integrating this procedure into the operative workflow was unknown.\textsuperscript{129,213,214} We explored the surgical team’s learning curve with robotic-arm assisted TKA through assessments of operative times, surgical team comfort levels, accuracy of implant positioning and complications, and used CUSUM analysis to assess incremental changes in study outcomes until predefined levels of surgical proficiency were achieved. We found that robotic-arm assisted TKA had a learning curve of seven operative cases for achieving operative times and surgical team comfort levels comparable to conventional jig-based TKA but there was no learning curve effect for accuracy of implant positioning or limb alignment. There was no additional risk of complications during the learning phase of robotic-arm assisted TKA. The findings of this study are clinically relevant as they provide an improved understanding of the effects of implementing robotic-arm assisted TKA on the surgical workflow. Theatre planning and scheduling of operative cases should consider increased operative times and heightened levels of anxiety amongst the surgical team during this initial learning phase. The learning curve did not impact the accuracy of implant positioning or increase the risk of complications, which are important findings for the safe implementation of this procedure into routine practice. The main limitations of this study are that learning outcomes were recorded in a surgical team with experience in performing both conventional and computer navigated TKA, and therefore the findings may not be directly generalisable to all other surgical teams. Furthermore, the learning curve of the preoperative planning and segmenting process was not recorded. In the ongoing prospective randomised controlled trial (chapter 8), we will be assessing the learning curve for preoperative planning and templating, recording learning curve outcomes in independent surgeons, and correlating these findings to longer-term clinical and functional outcomes.

Accuracy of Implant Positioning

This research supports several previous studies showing robotic-arm assisted TKA is associated with improved accuracy of implant positioning compared to conventional jig-based TKA.\textsuperscript{27,32,53} We found that robotic-arm assisted TKA enabled the planned limb alignment, native joint line height, and posterior tibial slope to be executed with greater precision than conventional jig-based TKA. Improved accuracy in achieving these radiological objectives during TKA has been previously associated with improved functional outcomes, increased implant survivorship and reduced complications.\textsuperscript{31,32,89,91,96,97} Postoperative malalignment of greater than 3 degrees may lead to greater eccentric stresses on load-bearing surfaces, increased shear forces at the bone-prosthesis interface, and reduced implant
The main limitations of this study were that plain radiographs were used to assess component positioning instead of CT scans, accuracy of achieving the planned implant position in the axial plane was not assessed, and implant survivorship was not assessed due to the limited follow-up times. In the ongoing study comparing robotic MA TKA versus FA TKA (chapter 8), accuracy of implant positioning will be assessed using pre- and post-operative CT scans by blinded observers, and RSA will be used to assess implant micromotion and predict survivorship in both treatment groups.

**MASTI Classification System**

The technical objectives of TKA are to replace diseased bone with artificial implants, restore limb alignment, preserve the joint line, balance flexion-extension gaps, and maintain the normal Q angle for patella tracking. In order to achieve these objectives, preservation of the surrounding soft tissue envelope during TKA is essential. We wanted to compare periarticular soft tissue injury and bone trauma in conventional jig-based TKA versus robotic-arm assisted TKA but we could not identify any existing classification systems for grading intraoperative soft tissue injury or bone trauma. We developed the MASTI classification system for stratifying intraoperative periarticular soft tissue injury and grading bone trauma during TKA. Intraoperative photos were graded by six independent observers and the MASTI classification system validated for high interobserver and intraobserver reliability. This classification system grades iatrogenic periarticular soft tissue injury in the anterior (extensor), posterior, medial, and lateral compartments to provide an overall score for the injury to the periarticular soft tissue envelope. Femoral and tibial surfaces are also graded for iatrogenic sawblade trauma. The MASTI classification system offers a unique grading system for reporting periarticular soft tissue injury and bone trauma during TKA. This may be used in further studies comparing the invasiveness of different surgical approaches or trials correlating intraoperative soft tissue findings during TKA to long-term functional outcomes. The main limitation of the MASTI classification system is that the overall score is not currently correlated to any long-term clinical or functional outcomes. In the ongoing prospective randomised control trial comparing conventional jig-based TKA versus robotic-arm assisted TKA (chapter 6), the MASTI scores will be correlated to predefined patient-reported outcome scores at one- and two-years follow-up.

**Periarticular Soft Tissue Injury**

Blinded observers used the MASTI classification system to grade iatrogenic periarticular soft tissue injury and bone trauma using intraoperative photographs from both treatment groups. Robotic-arm assisted total knee arthroplasty was found to have reduced periarticular soft tissue injury with decreased femoral and tibial bone trauma compared conventional jig-based TKA. Robotic-arm assisted TKA uses optical motion capture technology to fine-tune bone resection and implant positioning to achieve balanced flexion-extension gaps and proper mediolateral soft tensioning. This reduces the need for controlled soft tissue releases compared to conventional jig-based TKA. Furthermore, stereotactic boundaries confine the action of the sawblade to the haptic bone resection windows, which may have helped to reduce inadvertent sawblade injury to the periarticular soft tissue envelope. We found the results of this study surprising as the operating surgeon was a high-volume arthroplasty surgeon with over 25 years of experience in conventional jig-based TKA. Differences in periarticular soft tissue injury and bone trauma between conventional jig-based TKA and robotic-arm assisted may be even more marked in arthroplasty surgeons with less experience or with residents in training. I believe that more pristine femoral and tibial bone resections with robotic-arm assisted TKA may also facilitate the future implementation of cementless components in TKA.
Effects of anterior and posterior cruciate ligament resection on knee biomechanics

Optical motion capture technology during robotic-arm assisted TKA was validated and used to assess the effects of ACL and PCL resection on knee biomechanics. We found that ACL resection created flexion-extension mismatch by increasing the extension gap more than the flexion gap but did not affect mediolateral soft tissue balance, maximum knee extension or overall limb alignment. PCL resection created flexion-extension mismatch by increasing the flexion gap more than the extension gap. The increase in the lateral flexion gap was greater than the increase in the medial flexion gap, which created mediolateral soft tissue imbalance in flexion but not in extension. Improvements in FFD following PCL resection were dependent on the degree of FFD prior to PCL resection. Bone resection, implant positioning, and periarticular soft-tissue balancing should account for these biomechanical changes following ACL and PCL resection during TKA. The main limitations of these studies were that valgus and varus forces applied to the medial and lateral soft tissues were not standardised, outcomes were recorded under general anaesthesia in the supine position without defined compression forces in a load-bearing joint, and rotation of the tibia relative to the femur may have affected the gap values recorded. Future studies should use dynamometers or force sensors to help apply more standardised forces to the medial and lateral soft tissue structures, assess rotation and translation of the tibia relative to the femur, and assess study outcomes at smaller increments through the arc of knee flexion.

Systemic inflammatory response

Measurements of serum markers of inflammation and muscle damage offer an objective method for assessing the invasiveness of a surgical procedure. This method has been previously used to quantify the surgical insult of minimally-invasive surgery, synovectomy, and intraoperative tourniquet application in TKA. We were interested to understand how reduced soft tissue injury and decreased bone trauma with robotic-arm assisted TKA would translate to the systemic inflammatory cascade and localised thermal response compared to conventional jig-based TKA. We therefore conducted a prospective randomised controlled trial comparing biochemical, thermal, and macroscopic soft tissue injury outcomes in conventional jig-based TKA versus robotic-arm assisted TKA. We found that robotic-arm assisted TKA was associated with a transient reduction in the early (day 7) inflammatory response with reduced levels of IL-6, TNF-α, CRP, ESR, LDH, and CK compared to conventional jig-based TKA. However, there was no difference in the immediate (<48 hours) or late (day 28) postoperative systemic inflammatory reaction or localised thermal response between the two treatment groups. Robotic-arm assisted TKA was associated with decreased iatrogenic periarticular soft tissue injury, reduced bone trauma and improved accuracy of implant positioning compared to conventional jig-based TKA. The main limitations of this study were the small sample size, potential Hawthorne effect with the operating surgeons’ modifying their behaviours in awareness of the study, and the lack of correlation to long-term clinical outcomes. The biochemical, thermal, and macroscopic soft tissue outcomes in this study will be subsequently correlated to middle- and long-term functional outcomes.

Early functional rehabilitation

Robotic technology has been used to limit the insult of operative intervention and enhance postoperative rehabilitation compared to open and laparoscopic surgery in a range of surgical specialties. We were curious to assess how improved accuracy of bone resection and reduced periarticular soft tissue injury in robotic-arm assisted TKA would translate to postoperative functional rehabilitation compared to conventional jig-based TKA. There were no systematic differences
in baseline characteristics between the two treatment groups, surgery was undertaken by a single surgeon using the medial parapatellar approach with identical implant designs, and inpatient rehabilitation performed using a standardised programme by the same rehabilitation team. Robotic-arm assisted TKA was associated with reduced pain, decreased opiate analgesia consumption, reduced inpatient physiotherapy, shorter time to straight leg raise, and improved range of movement compared to conventional jig-based TKA. Robotic-arm assisted TKA also reduced time to hospital discharge compared to conventional jig-based TKA. These findings of this study are clinically relevant as they demonstrate how robotic technology affects early postoperative recovery, and suggest that his technology may be used as an avenue for further enhancing postoperative rehabilitation following TKA. As many arthroplasty centres move towards day case TKA, robotic technology may help to facilitate this practice through improved pain control, enhanced functional rehabilitation, reduced need for physiotherapy, and earlier time to hospital discharge. The main limitations of this study were that we it a historical cohort as a control group, patients and observers recording outcomes were not blinded, and outcomes were recorded for only 30 days after surgery. In the current study comparing conventional jig-based TKA versus robotic-arm assisted TKA (chapter 6), we aim to overcome these limitations by prospectively randomising patients to their two treatment groups, applying dressing over the operated leg to blind patients and observers during the inpatient episode, and recording clinical and functional outcomes for minimum two-years after surgery.

Robotic neutral mechanical alignment versus robotic functional alignment
There is no uniform consensus on the optimal alignment technique for TKA. MA TKA aims to achieve neutral limb alignment using either measured resection or gap balancing techniques. Further, periarticular soft tissue releases are often required to balance flexion-extension gaps and optimise mediolateral soft tissue tension. FA TKA aims to restore joint line height, preserve native obliquity, balance flexion-extension gaps, and optimise mediolateral soft tissue tension by manipulating bone resections and implant positioning as guided by the soft tissue envelope. This limits the need for intraoperative periarticular soft tissue releases. Previous studies exploring outcomes in outcomes with different alignment techniques have used pre-planned bone resections and/or patient-specific implants to achieve the planned limb alignment. The main limitations of these existing studies were that different implant designs were used within each treatment group, manually-positioned cutting blocks with poor reproducibility were used to achieve the planned limb alignment, intraoperative limb alignment was not assessed, and limited data on functional outcomes or implant survivorship was reported. Robotic technology offers an opportunity to execute the planned implant positioning and limb alignment with improved accuracy, facilitates manipulation of bone cuts and implant positioning to achieve the desired limb alignment with limited soft tissue releases, and intraoperative optical motion capture tracking to confirm the planned alignment has been achieved. This thesis includes a study protocol (chapter 8) for a prospective double-blinded randomised controlled trial in 100 patients with symptomatic knee osteoarthritis undergoing primary robotic-arm assisted MA TKA versus robotic-arm assisted FA TKA. Blinded observers will review patients at regular intervals for two years after surgery to record predefined outcomes relating to postoperative rehabilitation, clinical progress, functional outcomes, accuracy of implant positioning and limb alignment, gait, implant stability, cost-effectiveness, and complications. The findings of this study will enable an improved understanding of the optimal alignment technique in TKA for achieving high levels of patient satisfaction, improving functional outcomes, increasing implant survivorship, improving cost-effectiveness, and reducing complications.
Risk of error

Type I error (false positive) occurs when a researcher incorrectly rejects a true null hypothesis. We tried to limit the risk of committing a type I error by limiting multiple testing and selecting an alpha level (α) of 0.05, and thereby accepting a 5% probability of incorrectly rejecting the null hypothesis. We could have used a smaller alpha level to further reduce the risk of type I error but this would have increased the risk of type II error. A type II error (false negative) occurs when a researcher fails to reject a null hypothesis that is really false. To limit the risk of committing a type II error, we selected a power (1-ß) of 80% and using the minimal clinically important difference where possible for the sample size calculation.

Limitations of robotic TKA

Robotic-arm assisted TKA requires additional radiation exposure from preoperative imaging, more time for preoperative segmenting and surgical planning, and extra incisions for femoral and tibial registration pins. Fully automated robotic TKA systems have also been associated with periarticular soft tissue injury and machine dysfunction that may require intraoperative conversion to conventional jig-based TKA. In my opinion, further higher quality multi-centre studies are required to determine the effect of this technology on longer term patient satisfaction, clinical outcomes, and implant survivorship. Big data generated from National Joint Registries will enable more comprehensive analyses of long-term outcomes and complications with robotic-arm assisted TKA compared to TKA with patient-specific implants, computer navigation, and conventional jig-based TKA. I would also advise caution when translating our research findings directly to all other robotic devices. Our studies were undertaken using the Mako Robotic Arm Interactive Orthopaedic System (Stryker Ltd, Kalamazoo, Michigan, USA), which is a CT-based, semi-active robotic platform. Study outcomes may be different with other robotic devices such as the Navio Surgical system (Smith & Nephew, Andover, Texas), which is an imageless, handheld platform without haptic boundaries, or the Rosa Knee System (Zimmer Biomet, Warsaw, Indiana), which uses computer technology to help position femoral and tibial cutting blocks. Future registry data should stratify outcomes for robotic TKA designs based on the use of image-guidance, active versus semi-active systems, and motor constraints of the robotic device.

Cost effectiveness

Assessments of cost-effectiveness and resource use are important prior to the implementation of any surgical intervention into routine NHS care. State-based systems often use quality-adjusted life-years (QALYs) to assess cost-effectiveness, and the National Institute for Health and Care Excellence (NICE) has a clear threshold on the 12-month short-form six-dimensional index above which cost-effectiveness is accepted. Robotic-arm assisted TKA is associated with substantial costs associated with purchasing the robotic device, service contracts and maintenance, preoperative imaging, and training the surgical team to become proficient with the procedure. Additional service contracts may be required for applications to THA and UKA, and increased operative times will affect overall theatre case-volume during the learning phase of the procedure. These costs may be partially offset by improved accuracy in predicting the correct implant sizes, decreased opiate analgesia consumption, faster postoperative rehabilitation, reduced need for physiotherapy, and earlier hospital discharge compared to conventional jig-based TKA. Improvements in accuracy of implant positioning and reduced periarticular soft tissue injury may also increase implant survivorship and reduce long-term costs associated with treatment of instability and revision surgery. Due to the novelty of robotic-arm assisted TKA, there is very limited long-term data on how this technology effects functional outcomes, QALYs, implant survivorship, and cumulative revision rates compared to conventional jig-based TKA.
We were unable to assess the cost-effectiveness of conventional jig-based TKA versus robotic-arm assisted TKA within this research thesis. However, we have performed a comprehensive literature search and identified several key outcome measures related to cost-effectiveness and human resource use that will be collected in the ongoing prospective randomised controlled trials comparing conventional jig-based TKA versus robotic-arm assisted TKA (chapter 6) and robotic MA TKA versus robotic FA TKA (chapter 8). These outcomes will include the following: Operating time; theatre efficiency; equipment and sterilisation costs; analgesia requirements; inpatient rehabilitation; time to hospital discharge; outpatient follow-up visits; additional imaging costs; need for further surgery; patient-reported outcome measures including the FJS, OKS, SF-12, KOOS, WOMAC, UCLA knee score and UCH knee score; and Health-related quality of life as measured using EQ-5D. In the study comparing robotic MA TKA versus FA TKA, RSA will also be used to assess component micromotion and stability, which will help to determine implant survivorship and time to revision surgery.204,225,226 These findings will help to determine the optimal surgical technique and limb alignment in TKA for optimising cost effectiveness and resource use, and enable clinicians and healthcare policy makers to make better informed decisions about the implementation of this technology into routine arthroplasty practice in the NHS.

**Future work**
The various prospective studies undertaken within this research thesis fill important gaps in the existing medical literature on robotic TKA relating to the learning curve of this technology, accuracy of implant positioning, limb alignment, periarticular soft tissue injury, early functional rehabilitation and the systemic inflammatory response compared to conventional jig-based TKA. We have developed and validated the MASTI classification system for grading intraoperative periarticular soft tissue injury, and used optical motion capture technology during robotic TKA as a research tool to assess the effects of controlled ligamentous releases on knee biomechanics. However, it is important to appreciate that this research thesis focuses on perioperative outcomes and there are several limitations to the study designs that have been highlighted within each respective chapter. Further studies assessing a more comprehensive range of study outcomes with more robust scientific methodology and longer term follow up are required before this technology can be considered for mainstream TKA in the NHS. Future studies should assess the effects of robotic TKA on patient satisfaction, functional outcomes, implant survivorship, gait, cost-effectiveness, and complications compared to conventional jig-based TKA. Multi-centre studies would enable larger numbers of patients to be recruited from different geographic locations, and enable findings between centres to be compared to improve the generalisability of the findings. National joint registries will subsequently provide big data relating to implant survival and revision rates with robotic TKA but it is important for this data to be stratified according to the type (fully active versus semi-active systems or image-based versus imageless systems) of robotic device used. Further studies using optical motion capture technology should assess native flexion-extension gaps and mediolateral soft tissue tension, tibial translation and rotation relative to the femur through the arc of knee flexion, and compartment pressures with different alignment techniques using pressure-sensor technology. These studies will enable us to develop the optimal TKA procedure with high levels of patient satisfaction, improved functional outcomes and longer implant survival.

**Robotic total knee arthroplasty: Clinical outcomes and direction for future research**

Kayani B, Haddad FS.

*Bone Joint Res 2019;8:438–442. PMID: 31728181*
Conclusion

TKA is an established and highly-effective treatment for patients with symptomatic end-stage knee osteoarthritis. Conventional jig-based TKA uses preoperative radiographic films, intraoperative anatomical landmarks, and manually-positioned alignment jigs to guide bone resection and implant positioning. However, these techniques have limited accuracy and reproducibility, and are highly-dependent on the skill and expertise of the operating surgeon. Additional soft tissue releases are often needed to achieve the planned knee biomechanics and intraoperative gap assessments are performed using manually-positioned tensioning devices. Robotic-arm assisted TKA uses preoperative CT scans and patient-specific CAD models to plan optimal bone resection and implant positioning. An intraoperative robotic-arm helps to execute this plan with a high level of accuracy, and stereotactic windows limit sawblade action to the confines of the surgical plan. Optical motion capture technology may be used to assess flexion-extension gaps, mediolateral soft tissue tension, limb alignment, and range of motion, which are then used to manipulate bone resections and fine-tune implant positioning to achieve the desired knee biomechanics.

The studies within this research thesis have shown that robotic-arm assisted TKA is associated with improved accuracy of implant positioning, reduced periarticular soft tissue injury, decreased bone trauma, reduced early systemic inflammatory response and faster postoperative functional rehabilitation compared to conventional-jig-based TKA. Robotic-arm assisted TKA had a learning curve of seven cases for operative times but there was no learning curve effect for achieving the planned implant positioning. The Macroscopic Soft Tissue Injury (MASTI) was developed and validated for grading intraoperative periarticular soft tissue injury and bone trauma during TKA. Optical motion capture technology during robotic-arm assisted TKA was used to quantify the effects of controlled ligamentous releases on knee biomechanics. ACL resection created flexion-extension mismatch by increasing the extension gap more than the flexion gap, whilst PCL resection increased the flexion gap more than the extension gap and created mediolateral soft tissue imbalances in knee flexion.

This research thesis makes several important contributions to the existing literature on robotic TKA relating to the learning curve of this procedure, intraoperative periarticular soft tissue injury, early functional rehabilitation, and the postoperative systemic inflammatory response compared to conventional jig-based TKA. The MASTI classification system may be used in further trials assessing periarticular soft tissue injury during TKA, and optical motion capture technology during robotic TKA may be used to assess the effects of further ligamentous releases on knee biomechanics. The studies within this research thesis are limited to perioperative outcomes with short-term follow-up. Future studies should assess the effects of robotic TKA on patient satisfaction, functional outcomes, implant survivorship, gait, cost-effectiveness, and complications compared to conventional jig-based TKA with longer-term follow-up.
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Appendices
| 10.1 | Preoperative templating |
| 10.2 | Surgical techniques |
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| 10.5 | Publications during completion of research thesis |
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| 10.8 | Published manuscripts during completion of research thesis |
10.1 Preoperative templating

All patients underwent routine preoperative anteroposterior weight-bearing knee radiographs, lateral knee radiographs, and full-length hip-to-ankle radiographs. The operating surgeon used Traumacad software (Traumacad, Petach-Tikva, Israel) with plain radiographs to preoperatively template optimal bone resections, implant positions, and implant sizes. Full-length hip-to-ankle radiographs were used to guide femoral and tibial resection angles to achieve neutral mechanical alignment. Lateral knee radiographs were used to select the femoral component size and position to restore the patient’s native posterior condylar offset ratio whilst avoiding overhang or notching of the femur. Tibial implant position and size were selected to restore native posterior tibial slope and avoid any anteroposterior overhang. On the anteroposterior knee radiograph, femoral and tibial implant positions and sizes were selected to achieve maximum mediolateral contact whilst avoiding overhang. In patients undergoing robotic-arm assisted TKA, computer software (Mako system software, Stryker Limited, Kalamazoo, MI) was used to convert the preoperative CT scan of the knee joint into a patient-specific virtual three-dimensional (3D) computer-aided design (CAD) model. The preoperative scan CT and CAD model were used to plan bone resection and implant positioning for achieving the planned bone coverage, component position, and limb alignment.

10.2 Surgical technique

All patients received general anaesthesia with a standardised regimen of fentanyl, morphine, clonidine, paracetamol and diclofenac at induction by the same consultant anaesthetist. In conventional jig-based TKA, the patient was positioned supine on the operating table with a lateral thigh support and foot bolster to enable flexion and extension of the knee joint. In robotic-arm assisted TKA, the patient was positioned supine with the proximal tibia and foot of the operated limb in the mobile leg holder boot. As per the surgeon’s routine practice, a pneumatic tourniquet was applied but not inflated unless there was intraoperative difficulty in achieving haemostasis or compromise to the bone-cement interface. All study patients received one gram of intravenous tranexamic acid on induction and diathermy was used to help control intraoperative bleeding in all operative procedures.

The standard medial parapatellar approach was used in all study patients. A midline longitudinal incision was made over the knee joint with the knee in flexion. The initial incision extended proximally from the tibial tubercle for approximately 10-15cm and further proximal extension was undertaken to improve exposure and reduce skin stretching if required. Dissection was continued in the midline until the quadriceps tendon was identified. The medial parapatellar incision was extended through the medial parapatellar retinaculum and along the medial border of the patella tendon distally. A 3mm cuff of quadriceps tendon was left attached to vastus medialis and a cuff of medial retinaculum attached to the patella to aid surgical closure. The medial capsule was released subperiosteally off the proximal tibia to gain exposure to the medial compartment. In patients with a varus deformity, the dissection was extended to include the deep medial collateral ligament and posteromedial corner if required. In patients with a valgus knee, the medial release was minimised to the anteromedial corner. The knee was then extended, the patella everted, and retropatellar fat partially excised. The remnants of the menisci were excised, and the ACL and PCL both resected. Osteophytes were resected at this stage. The synovial membrane at the anterior cortex of the distal femur was subperiosteally undermined in order to seat the anterior flange of the femoral component.
Conventional jig-based TKA was performed with the aim of achieving neutral mechanical alignment. Tibial bone resection was performed perpendicular to the mechanical axis of the tibia in the coronal plane with the aim of matching the anatomical anteroposterior slope in the sagittal plane. Extramedullary referencing was used for the tibial bone cuts with the alignment rod positioned in line with the anterior tibial spine and distally just medial to the centre of the ankle joint and second metatarsal. The tibia was externally rotated and subluxed anteriorly to allow exposure of the entire articular surface of the tibia. The tibial cut was performed using an angle cutting block and oscillating sawblade with protection of the surrounding soft tissues using blunt Hohmann retractors. The tibial component was sized following trial of the components, and the tibia prepared to accept the stem. The tibial component was positioned in slight internal rotation on the tibia and the midpoint of the tibial baseplate positioned in line with the medial third of the patella tendon to optimise patella tracking. The femur was prepared using an intramedullary alignment jig. A drill was used to create an entry point in the distal femoral canal at a point approximately 1 cm anterior to the insertion of the PCL in the trochlea. The intramedullary rod was inserted into the canal and distal cutting jig positioned so that the distal femoral cut was at 5-9° valgus angle. The exact value of this valgus angle was selected to match the anatomical axis on the contralateral limb. The distal cutting jig was secured with three pins and an initial distal femoral resection of 9 mm performed. The distal femur was sized using anterior femoral referencing. The distal femoral cutting block was positioned in 3° of external rotation using the transepicondylar axis. The anterior cut was performed first and then the posterior condyles, anterior chamfer, and finally the posterior chamfer cuts. A Mikhail retractor was used to protect the posterior structures, and blunt Hohmann retractors were used to protect the medial and lateral soft tissue structures during bone resection. The femur was lifted anteriorly and any residual posterior osteophytes excised. Flexion-extension gaps were checked and further soft tissue releases performed as described by Whiteside to ensure balanced flexion-extension gaps and proper mediolateral soft tissue tensioning. Polyethylene thickness was selected to maximise range of motion whilst avoiding hyperextension and ligament laxity.

Robotic-arm assisted TKA was performed with the aim of achieving functional alignment. The surgeon reviewed the preoperative surgical plan on the CT scan and CAD model with the Mako product specialist and confirmed the planned bone section, implant positioning, and limb alignment. Two intra-incisional femoral registration pins and two extra-incisional tibial registration pins were inserted four finger breadths below the tibial tubercle. Fixed arrays were mounted onto these to enable optical motion capture tracking during surgery. Bone registration was performed by intraoperatively mapping radiological landmarks displayed on the computer screen to verify anatomy and establish bone geometry. Joint balancing captured femoral and tibial poses with corrective forces, assessed kinematics through the arc of motion, and enabled fine-tuning of implant positioning based on laxity of the soft tissue envelope. The Mako Robotic Arm Interactive Orthopaedic system (Stryker Ltd, Kalamazoo, MI, USA) with visual, tactile, and audio feedback was used to execute the planned femoral and tibial bone resections within the confines of the stereotactic boundaries. Tibial and femoral osteotomies in the coronal plane were performed perpendicular to the tibial and femoral mechanical axes respectively to achieve neutral overall alignment. In the sagittal plane, 0°-5° of femoral component flexion were used to optimise implant sizing whilst preventing notching. The tibial slope was initially set to zero degrees and then adjusted as required based on intraoperative assessment of the flexion gap and range of motion. A Mikhail retractor was used to protect the posterior structures, and blunt Hohmann retractors were used to protect the medial and lateral soft tissue structures during bone resection.
Functional alignment was performed in all robotic TKA cases with implant position manipulated in all three planes to restore the plane and obliquity of the joint as dictated by the periarticular soft tissues. Joint line obliquity was restored by applying valgus correction to the distal femoral resection and varus correction to the proximal tibial resection, and retaining overall limb alignment within the 0° to 3° safe zone of coronal alignment. Over-resection of the distal femur was avoided to maintain joint line height and minimise the risk of mid-flexion instability, whilst under-resection of the distal femur was avoided to minimise the use of thinner polyethylene inserts that may induce flexion instability. Tibial slope was revised based on intraoperative assessments to within 7° of combined femoral and tibial component flexion, as per implant recommendations. The revised bone resections were then executed, and the flexion-extension gaps, range of motion, and limb alignment reassessed using the aforementioned technique with corrective varus and valgus strains. Further periarticular soft tissue releases as described by Whiteside could be undertaken at this stage if required. The remaining femoral bone resections were performed using the robotic arm. The femoral box cut was performed with manual instrumentation, and the polyethylene insert selected after assessing flexion-extension gaps, mediolateral soft tissue tension, alignment and range of motion with trial femoral and tibial components in place.

All patients underwent patella resurfacing with asymmetrical components. The surgical site was washed and a layered closure of the medial retinaculum, quadriceps tendon, subcutaneous tissue, and skin performed with absorbable sutures. All patients received an intraarticular vacuum drain with a silicon tube extending from a 1cm incision over the anterolateral aspect of the knee joint. All patients received 40ml of 0.25% Marcaine into the joint capsule prior to wound closure.

10.3 Surgical devices
The cemented Stryker Triathlon (Stryker Navigation, Kalamazoo, Michigan, USA) cruciate-substituting knee system with asymmetrical patellar resurfacing was used in both groups.

10.4 Postoperative rehabilitation and care
All patients had routine postoperative neurovascular, cardiovascular, and respiratory observations. Vital signs, urine output, temperature and drainage output were recorded by the nursing staff. Mechanical and chemical prophylaxis were commenced on the day of surgery and continued for two weeks after surgery. Two further doses of intravenous antibiotics were administered at 8 hours and 16 hours after surgery. The intraarticular drain was removed at 24 hours after surgery and all epidural lines, cannulae and catheters removed within the first 48 hours to reduce portals of infection. Pressure dressings were reduced and ice applied at 24 hours. All patients underwent undergo routine inpatient and outpatient rehabilitation with full weight-bearing and active range of motion exercises commenced as soon as possible.

10.5 Publications during completion of research thesis

Direct publications

The effect of anterior cruciate ligament resection on knee biomechanics.
Kayani B, Konan S, Ahmed SS, Chang JS, Ayuob A, Haddad FS.
A prospective double-blinded randomised control trial comparing robotic arm-assisted functionally aligned total knee arthroplasty versus robotic arm-assisted mechanically aligned total knee arthroplasty.
Kayani B, Konan S, Tahmassebi J, Oussedik S, Moriarty PD, Haddad FS.
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Kayani B, Konan S, Pietrzak JRT, Haddad FS.

Indirect publications


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Management of hamstring injuries: current concepts review.
Chang JS, Kayani B, Plastow R, Singh S, Magan A, Haddad FS.

Computerised tomography-based planning with conventional total hip arthroplasty versus robotic-arm assisted total hip arthroplasty: study protocol for a prospective randomised controlled trial.
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Al-Jabri T, Tan JYQ, Tong GY, Shenoy R, Kayani B, Parratt T, Khan T.  

Prevention of limb length discrepancy in total hip arthroplasty.  
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10.6 Presentations during completion of research thesis

Direct presentations


Can robotic technology take enhanced recovery arthroplasty one step further? A Prospective cohort study. Kayani B, Konan S, Ayuob A, Tahmassebi J, Haddad FS. SICOT Orthopaedic World Congress. Muscat, Oman, 4-7th December 2019.


Iatrogenic Bone and Soft Tissue Trauma in Robotic Total Knee Arthroplasty Compared with Conventional Jig-Based Total Knee Arthroplasty: A Prospective Cohort Study and Validation of a New Classification System. Kayani B, Konan


Cumulative Summation (CUSUM) Analysis to Assess the Surgical Team’s Learning Curve with Robotic Assisted Total Knee Arthroplasty. Kayani B, Konan S, SS Huq, Tahmassebi , Haddad FS. EFORT, Lisbon, Portugal, 5-7\textsuperscript{th} June 2019.

Robotic-arm assisted total knee arthroplasty is associated with improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based total knee arthroplasty: A prospective cohort study. Kayani B, Konan S, J Tahmassebi, Pietrzak JRT, Haddad FS. 30\textsuperscript{th} Annual Meeting of the European Society of Paediatric and Neonatal Intensive Care, Salzburg, Austria, June 18-21\textsuperscript{st} 2019.


Posterior Cruciate Ligament Resection in Total Knee Arthroplasty: Effect on Flexion-Extension Gaps, Mediolateral Laxity, and Fixed Flexion Deformity. Kayani B, Konan S, Haddad FS. 12\textsuperscript{th} Biennial ISAKOS Congress, Cancun, Mexico, 12-16\textsuperscript{th} May 2019.

Robotic-Arm Assisted Total Knee Arthroplasty Has a Learning Curve of Seven Cases for Integration into the Surgical Workflow but No Learning Curve Effect for Accuracy of Implant Positioning. Kayani B, Konan S, Huq SS, Tahmassebi J, Haddad FS. 12\textsuperscript{th} Biennial ISAKOS Congress, Cancun, Mexico, 12-16\textsuperscript{th} May 2019.
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Reduced Iatrogenic Bone and Soft Tissue Trauma in Robotic-Arm Assisted Total Knee Arthroplasty Compared to Conventional Jig-Based Total Knee Arthroplasty: A Prospective Single-Surgeon Comparison. Kayani B, Konan S, Pietrzak JRT, Haddad FS. European Federation of National Associations of Orthopaedics and Traumatology (EFORT), Barcelona, Spain, 30th May-1st June 2018.

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**Indirect Presentations**


Does Robotic Unicompartmental Knee Arthroplasty have a learning curve for accuracy of implant positioning? A Prospective Cohort Study. Kayani B, Konan S, Ayuob A, Tahmassebi J, Huq SS Haddad FS. SICOT Orthopaedic World Congress. Muscat, Oman, 4-7th December 2019.


Surgical management of distal hamstring non-avulsion T-junction tears. Kayani B, Ayuob A, Haddad FS. SICOT Orthopaedic World Congress. Muscat, Oman, 4-7th December 2019.


Early Functional Rehabilitation and Hospital Discharge in Unicompartmental Knee Arthroplasty with Conventional Jig-Based Technique versus Robotic-Arm Assistance: A Prospective Cohort Study. Kayani B, Konan S, J Tahmassebi, Rowan FE, Haddad FS. 12th Biennial ISAKOS Congress, Cancun, Mexico, 12-16th May 2019.

Early Experience of Reduced Soft Tissue Damage and Better Early Functional Outcomes with MAKO UKA and TKA. Kayani B, Haddad FS. 12th Biennial ISAKOS Congress, Cancun, Mexico, 12-16th May 2019.


Improved Accuracy and Reduced Outliers in Robotic-Arm Assisted Unicompartmental Knee Arthroplasty Compared to Conventional Jig-Based Technique: Early Results of a Prospective Single-Surgeon Series. Kayani B, Konan S, Tahmassebi J, Pietrzak JRT, Haddad FS. European Federation of National Associations of Orthopaedics and Traumatology (EFORT), Barcelona, Spain, 30th May-1st June 2018.


The learning curve associated with the CT planned, robotic-guided unicompartmental knee arthroplasty

11.7 Prizes/Grants list during completion of research thesis

Royal College of Surgeons - One-Year Research fellowship (2018-2019) - £50,000

University College London Hospitals NHS Trust (2019) - Clinical Research Fellowship - £50,000


Charles Fixsen prize 2018 – Best original scientific paper - Robotic-arm assisted total knee arthroplasty has a learning curve of seven cases for integration into the surgical workflow but no learning curve effect for accuracy of implant positioning. Kayani B, Konan S, Huq SS, Tahmassebi J, Haddad FS. Percival Pott Meeting, Royal London Hospital, UK, 9th November 2018.

International Society for Technology in Arthroplasty Young Investigator Scholarship (2018) - Iatrogenic Bone and Soft Tissue Trauma in Robotic-Arm Assisted Total Knee Arthroplasty Compared with Conventional Jig-Based Total Knee Arthroplasty: A Prospective Cohort Study and Validation of a New Classification System.
Kayani B, Konan S, Pietrzak JRT, Haddad FS.

11.8 Published manuscripts during completion of research thesis
The role of electrical stimulation in the management of avascular necrosis of the femoral head in adults: a systematic review

Talal Al-Jabri, Jessica Yan Qi Tan, Gabriel Yihan Tong, Ravikiran Shenoy, Babar Kayani, Timothy Parratt and Tahir Khan

Abstract

Background: Avascular necrosis of the femoral head causes significant morbidity and occurs in up to 20,000 people per year. A variety of nonoperative and operative measures have been trialled however a definitive treatment algorithm is yet to be established. Young adults in many cases have undergone multiple surgical procedures in their lifetime with increasing risks of complications. Less invasive techniques may help reduce the number of operations required and positively influence the natural history of the disease process. Our aim was to navigate the literature and examine the results of electrical stimulation of the femoral head in avascular necrosis.

Methods: The following defined search strategy was used to perform a systematic review using MEDLINE and Google Scholar databases: ((avascular necrosis) OR (osteonecrosis)) AND (femoral head) AND ((electrical stimulation) OR (capacitive coupling) OR (pulsed electromagnetic fields)). Articles were reviewed and data compiled into tables for analysis.

Results: Forty six articles were identified with a total of 10 articles meeting the inclusion criteria. 8 articles were prospective studies and 2 were retrospective. Early Ficat stages showed the best responses to treatment via pulsed electromagnetic fields with improvements in both clinical and radiographic parameters. Direct current and capacitative coupling have had a more ambiguous outcome.

Conclusions: Pulsed electromagnetic fields may have a role in the management of early avascular necrosis. The paucity of clinical studies into this technique indicates a need for further studies.

Keywords: Avascular necrosis, Osteonecrosis, Hip, Femoral head, Electrical stimulation

Background

Avascular necrosis (AVN) of the femoral head is a debilitating, progressive condition which occurs in up to 20,000 people in the United States per year [1–3]. It can occur at any age however, typically adults in their third and fourth decades are affected. It frequently results in subchondral collapse and secondary osteoarthritis as the disease process progresses limiting the treatment options available and ultimately, necessitating a total hip arthroplasty. The pathophysiology has not been clearly defined however various mechanisms have been implicated and specific risk factors have been associated with the development of AVN. These include smoking, corticosteroid administration, diabetes mellitus, systemic lupus erythematosus, rheumatoid arthritis and sickle cell disease amongst others [3–6].

Both nonsurgical and surgical treatment options have been used with varying rates of success nonetheless a specific algorithm for the various options has not yet been established. Importantly, young adult patients would in many cases require more than one arthroplasty procedure in their lifetime [7, 8] and as such interest in less invasive techniques aimed at slowing or preventing disease progression have gained the interest of clinicians involved in the management of AVN.
Electrical fields in bone known as strain related potentials arise from mechanical deformation of bone. These strain related potentials transfer information to the osteocyte regarding its biophysical environment. The use of exogenous electrical currents of the correct amplitude and frequency have been shown to have positive effects on bone formation, bone graft incorporation and bone repair in in vivo and in vitro models [6, 9]. Pulsed electromagnetic fields have been shown to decrease parathyroid hormone receptor activity on osteoblasts and to reduce the lysosomal content of osteoclasts thereby suppressing bone resorption and increasing bone mass [9].

Noninvasive techniques of applying electric fields include inductive or capacitive coupling. Capacitive coupling involves centring skin electrodes posteriorly and anteriorly to the femoral head. Inductive coupling involves pulsed, time-varied electromagnetic fields created by an external generator and a current carrying coil. Invasive techniques whereby an implantable current generating unit supplies a constant direct current (DC) have been described in the literature and often these involve implanting the cathode to the site of bone repair and the anode in the nearby soft tissues. This is usually done in conjunction with a core decompression and necessitates surgical removal following treatment is accomplished [6, 10, 11].

Aims and objectives
The aim of this systematic review is to examine the published clinical and radiographic outcomes following the use of electrical stimulation in the management of avascular necrosis of the femoral head in adults.

Methods
This systematic review was completed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) reporting guidelines for the meta-analysis of intervention trials [12]. The protocol was not registered and ethical approval was not required as this was a small study involving review of existing, published literature and did not involve the handling of new patient data.

The following search strategy was used to complete a search on MEDLINE and Google Scholar from 1928 to April 2016: (avascular necrosis OR osteonecrosis) AND (femoral head) AND ((electrical stimulation) OR (capacitive coupling) OR (pulsed electromagnetic fields)). Journals in all languages were included, and there were no limitations on the search strategy. Abstracts were screened and articles relevant to the role of electrical stimulation for avascular necrosis were selected and included. Exclusion criteria included studies which did not separate Perthe's disease from avascular necrosis of the femoral head in adults. Letters, editorials and review articles were excluded.

The technique of electrical stimulation used, duration of treatment, staging of avascular necrosis, follow-up period and complication rates were extracted from each article and compiled into a database. References of selected full text articles were screened for the inclusion of additional articles. Recorded data was extracted and entered into an excel spreadsheet (Microsoft Office Excel, 2007). The references were independently reviewed by 2 of the authors and any ambiguity was resolved through discussion. Bias was assessed and its influence if any included within the analysis as laid out by the Critical Appraisal Skills Programme [13]. Outcome measures have been summarized alongside individual studies in this systematic review as studies on this topic are limited in number, size, quality of research methodology and there is heterogeneity in the methodology used.

Results
The role of electrical stimulation in femoral heads with avascular necrosis is a subject that has not been widely investigated. Of the 46 articles identified in our search, 36 did not meet our inclusion criteria or were duplicates, letters, editorials or review articles. Of the 10 papers included, 2 were retrospective studies, 8 were prospective studies (Table 1, Fig.1).

Retrospective studies
In the two retrospective studies, a total of 117 patients or 146 hips with symptomatic, non-collapsed avascular necrosis of the femoral head were included [2, 3]. In both studies, patients were treated with PEMF for 8 h a day for 6 months. Cebrian et al. demonstrated that electromagnetic stimulation in femoral heads of ARCO stages I and II led to a survival percentage of 88.57% of the heads on radiographic assessment [3]. Similarly, the paper by Cadossi et al. revealed that PEMF preserved 90% of the femoral heads of Ficat I, 75% of Ficat II and 50% of Ficat III; there were even improvements in the staging of 45% of Ficat I hips to stage 0 and 35% of Ficat II hips to stage I. Functionally, 46% of patients achieved normal hip function and 39% achieved sufficient hip joint function at the end of treatment. As for pain scores, the study found that 53% of patients were pain free after treatment with PEMF while 26% had pain of moderate intensity [2]. Likewise, Cebrian et al. also noted improvement on the D'Aubigne pain scale in 78.57% of the hips [3]. Nevertheless, in both studies, there were some hips that eventually progressed to collapse. Cebrian's study had a total of eight femoral head collapses, all of which were of ARCO stage II (n = 50) whereas Cadossi found that 15 (three Ficat II and 12 Ficat III initially) of the 76 hips had radiographic...
Table 1 Summary of results

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study type</th>
<th>Number of patients</th>
<th>Stage</th>
<th>Pre-treatment hip outcome score</th>
<th>Aetiology</th>
<th>Clinical technique</th>
<th>Additional management</th>
<th>Results</th>
<th>Post-treatment Hip outcome score</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>J. L. Cebrián et al. [3]</td>
<td>Retrospective</td>
<td>51 (70 hips)</td>
<td>ARCO staging used.</td>
<td>1.20</td>
<td>I: 30</td>
<td>Symptomatic, AVN no collapse on MRI and X-ray</td>
<td>Idiopathic: 40 Steroids: 26 Alcohol: 4</td>
<td>1 pair of coils attached anteriorly &amp; posteriorly, held in place over greater trochanter on molded splint. Single pulse of Frequency: 75 Hz; Intensity: 400 mA; Time: 1 at 3 ms. Duration of each coil worn for 8 h/day for 6 months.</td>
<td>Follow up at 3, 6, 12, 24, 48 months. Mean follow-up = 26 months.</td>
<td>Progression = ARCO stage or collapse &gt;2 mm compared to pre-treatment.</td>
</tr>
<tr>
<td>L. Massari et al. [4]</td>
<td>Prospective</td>
<td>68</td>
<td>Steinberg staging used</td>
<td>-</td>
<td>Primary: 34 Steroids: 17 Trauma: 5</td>
<td>SPT BOSTIM pulse generator used</td>
<td>Core decompression and autologous bone graft from proximal metaphysis and femoral neck</td>
<td>Core decompression and autologous bone graft from proximal metaphysis and femoral neck</td>
<td>X-ray and MRI at 1, 3, 6, 12, 24 months from surgery. After, X-ray yearly and MRI every 2 or 3 yr. Mean follow-up = 5.8 yrs. Steinberg I: 81% no pain and limping, good radiographic results. Steinberg II: 70% success. Steinberg III: 53% good clinical results. 27% good radiographic results.</td>
<td>15 of 76 hips progressed.</td>
</tr>
<tr>
<td>L. Massari et al. [2]</td>
<td>Retrospective</td>
<td>66 (76 hips)</td>
<td>Ficat staging used.</td>
<td>I: 31</td>
<td>II: 22</td>
<td>III: 23</td>
<td>1/3 were Ficat stage III Intense pain and significant functional restriction</td>
<td>Primary: 51 Secondary (alcohol), trauma, steroids: 15</td>
<td>SPT BOSTIM pulse generator used</td>
<td>Core decompression and autologous bone graft from proximal metaphysis and femoral neck</td>
</tr>
<tr>
<td>C. Windisch et al. [5]</td>
<td>Prospective</td>
<td>35</td>
<td>ARCO staging used. Group 1: 3/19 pts. had bilateral involvement. Group 2: 2/16 had bilateral involvement</td>
<td>I: 4</td>
<td>II: 9</td>
<td>III: 2</td>
<td>Group 2 (non-PMEF): I: 4</td>
<td>Magnetodyn – external magnetic field coil and an invasive bipolar induction screw. Frequency: sinus shaped external magnetic field of ~20 Hz. Magnetic flux density ~5mT. Voltage: ~700 mV induced. Electric field strength: 50-700 mV/cm.</td>
<td>Corecttage, autologous bone grafting (from greater trochanter and proximal femur).</td>
<td>Follow-up checks at 6 and 12 months. Clinical exam, clinical evaluation modified Harris Hip score, Meets D’Aubigné hip score, VAS imaging – X-ray with pelvic view and axial projection of hips, bilateral MRI. Group 1: - 2 stage: 2C patients had THA. - 2 stage: 3C patients had THA Group 2: - 1 stage: 28 patients had THA. - 1 stage: 3B patient had THA. - 2 stage: 3C patients had THA. Comparing clinical outcomes of group 1 and 2:</td>
</tr>
</tbody>
</table>
Table 1 Summary of results (Continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Prospective + historical control</th>
<th>116 hips 55 hips for disease progression (separate studies)</th>
<th>95 (118 hips)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steinberg et al. [11]</td>
<td>Steinberg staging used. Mean stages: Non-stimulated: IIA Stimulated: IIb</td>
<td>Non-stimulated: IIA Stimulated: IIb</td>
<td>Steinberg modification of Merle D'Aubigne Postel system Mean scores = Pain:3.9 Function: 3.7 Mobility: 5.2 Total: 12.8</td>
</tr>
<tr>
<td>Steinberg et al. [15]</td>
<td>-</td>
<td>Non-stimulated: IIb Stimulated: IIb</td>
<td>Charnley modification of Merle D'Aubigne-Postel system Mean scores = Pain:3.9 Function: 3.7 Mobility: 5.2 Total: 12.8</td>
</tr>
<tr>
<td>Bassett et al. [10]</td>
<td>-</td>
<td>Non-stimulated: IIa Stimulated: IIb</td>
<td>Charnley modification of Merle D'Aubigne-Postel system Mean scores = Pain:3.9 Function: 3.7 Mobility: 5.2 Total: 12.8</td>
</tr>
</tbody>
</table>

- Steinberg staging used. I: 133 II: 13 III: 85 IV: 4
- Primary: 10% Steroids: 36% Alcohol: 37%
- Group 1: Constant DC via cathode wire coiled about the graft and attached to an Osteostem/Orthofuse
- Group 2: Capacitive coupling via surface electrodes applied anteriorly and posteriorly to the skin over the femoral head and connected to a portable power unit.

Core decompression and bone grafting

Post-operative evaluation by Harris Hip score, AP + lateral X-rays, taken at 3, 6, 12, 18, 24 months and then yearly/two yearly thereafter.

Mean follow-up = 46 months

DC group
- Radiographic progression in 70%
- Mean progression: 2/3 stage
- Mean 5 point improvement in HHS (64%) improved or remained unchanged
- 41% needed THA

Control
- 79% radiographic progression
- Mean progression: 1 1/3 a stage
- Mean 3 point drop in HHS
- 43% improved or unchanged
- 37% needed THA

Capacitive coupling
- Clinically and radiographically, 45% improved or remained unchanged
- 25% needed THA

Control
- Radiographically and clinically, 50% improved or remained unchanged
- 20% needed THA

Electrical stimulation gave better Harris scores, less roentgenographic progression, but similar need for arthroplasty. No fractures or complications

No electricity: IVB Electricity: IVA
Mean Harris scores No electricity: 62 Electricity: 70

One year: 15 Most recent: 15.8
20 required surgical procedures

Table 1 (Continued)
Table 1 Summary of results (Continued)

<table>
<thead>
<tr>
<th>Study (Ref)</th>
<th>Study Design</th>
<th>Patients</th>
<th>Steinberg Staging</th>
<th>Treatment Details</th>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>R.K. Aaron et al. [6]</td>
<td>Prospective 77 (106 hips)</td>
<td>Ficat staging used: PEMF II: 23 III: 33 Core decompression II: 26 III: 24</td>
<td>Modified D’Aubigne scale, actual scores not given</td>
<td>Duration: 8–10 h/day, discontinued 4–1 year. No changes with weight-bearing</td>
<td>Joint space width increased on average 1 mm in 17 of these 19, but most of these showed clinical improvement</td>
</tr>
<tr>
<td>Steinberg et al. [14]</td>
<td>Prospective + historical control 40 (40 hips) 55 control hips</td>
<td>Steinberg staging used: Stimulated I: 3 II: 16 Unstimulated I: 4 II: 16</td>
<td>Harris score: Stimulated: 94 Unstimulated: 75 Mean stage: Stimulated: 1B Unstimulated: IIA</td>
<td>2 capacitive-coupling units (self-adhering electrodes) over femoral head Frequency: 5 V Intensity: 5 V peak-peak amplitude.</td>
<td>All 40 patients had core decompression + grafting</td>
</tr>
<tr>
<td>R.K. Aaron et al. [2, 6]</td>
<td>Prospective 264 (373 hips)</td>
<td>Steinberg staging</td>
<td>Radiographic progression</td>
<td>PEMF</td>
<td>Mean follow-up = 3 years Percentage demonstrating both clinical &amp; roentgenographic success PEMF: 52% Core: 20%</td>
</tr>
</tbody>
</table>

AVN Avascular Necrosis, ARCO Association Research Circulation Osseous, CD Core Decompression, PEMF Pulsed Electromagnetic Field, DC Direct Current, NSAIDs Non-steroidal Anti-Inflammatory Drugs
progression that led to the development of severe osteoarthritis requiring hip arthroplasty [2, 3].

**Prospective studies**

**PEMF**

In six prospective studies, the effect of PEMF therapy as an adjunct to other treatments (core decompression and bone grafting) was evaluated.

In an Italian study conducted by Massari et al., 68 patients with ONFH were treated with core decompression, autologous bone grafts and PEMF. Of those with Steinberg stage II scores, 81% had good results radiographically and clinically had no pain or limp. Similar results were seen in stage III patients but only in 70%. This is further reduced in stage IV patients where only 27% had good radiographic outcomes and 53% had good clinical results. Two patients (one stage III and one stage IV) required total hip arthroplasty (THA) [4].

Windisch et al. divided 35 patients into two groups, one treated with curettage, bone grafting and PEMF ($n = 19$) and one with curettage and bone grafting without PEMF ($n = 16$). In the group that underwent PEMF, four patients in total (18%) had to have THA — two of these patients were ARCO stage II C and the other two were stage III C. On the other hand, the non-PEMF group also had four patients (22%) who required THA. However, one was stage II B, one stage III B and two stage III C. However, interestingly, clinical evaluation of both arms revealed no significant difference in pain and functional scores [5].

In another prospective study, Aaron et al. compared the effectiveness of PEMF against core decompression in Ficat stages II and III hips. Based on clinical response (using a modified D'Aubigne scale), clinical success was determined as marginal pain with retention of the femoral head. They found that 68% of those treated with PEMF were clinically successful, compared to 44% of those treated with core decompression. Roentgenographically, 39% showed progression in those treated with PEMF, versus 64% of those treated with core decompression [6].

Aaron et al. compared patients with stage II and III lesions receiving core decompression and PEMF as adjunct therapy, to core decompression alone. They although there was no difference in joint survival, radiographically, stage II hips showed a significant increase in joint stabilisation with PEMF therapy (77% versus 44% in core decompression alone). Stage III hips receiving PEMF also demonstrated clinical improvement [1, 2, 6].
In two prospective studies, the use of pulsed electromagnetic field therapy in the treatment of osteonecrosis of the femoral head without use of or comparison to additional management (eg: core decompression, bone grafts) was examined [2, 10]. Aaron et al. found that based on need for subsequent joint replacement, the greatest advantage was seen in Steinberg Stage I hips, where none required surgery. 77% of stage II hips were conserved, although there was no statistically significant difference between these and stage I hips. However, of the stage III hips, only 53% were conserved, showing a statistically significant decrease compared to stage II hips. Radiologically, the effect of electrical stimulation was less pronounced. In stage I hips, 75% showed progression, notably more than in stage II and III, where 54% and 68% demonstrated progression [2, 6]. In the other study, Bassett et al. quantified the response to PEMF therapy using the Steinberg staging method. They found that 9 hips showed improvement, and they were all in stages II to III, demonstrating a 60% improvement rate. Of these 9 hips, 3 of these returned to a normal structure. 90 hips across all stages (76%) showed no improvement or deterioration, while 19 hips (16%) showed a deterioration of <2 mm further femoral head collapse [10].

Direct current stimulation and capacitive coupling
Steinberg et al. conducted several studies comparing the outcome of hips that received electrical stimulation, and those that did not [11, 14, 15]. In one paper, he looked at two groups of patients, one who received direct current (DC) stimulation and one who had capacitive coupling (CC) [11], both in addition to core decompression and grafting. The results of the former group showed radiographic progression in 70% compared to 79% in control hips; there was a mean 5 point improvement in the Harris Hip score whereas the control group had a mean 3 point drop instead; however, 41% of hips treated with DC required THA compared to 37% of control hips. The CC group showed less promising results, with 42% of hips either clinically and radiographically improving or remaining unchanged compared to 50% in the control group; 25% of stimulated hips eventually needed THA versus 20% of unstimulated hips [11].

Steinberg et al. also compared non-operative management with core decompression and grafting alone, and with DC as adjunct. They found that electrical stimulation showed an improvement in number of hips and average extent of roentgenographic progression, albeit not a significant difference. Electrical stimulation also gave better Harris scores, with 64% showing improvement or remained unchanged, versus 43% in the core decompression alone group. Requirement for hip replacement was similar with or without electrical stimulation. Both groups were superior in all aspects compared to non-operative management [15].

In another similar study, Steinberg et al. compared non-operative management, core decompression with grafting, and CC as adjunct to decompression and grafting. They found that no significant difference was found when CC was used, based on roentgenographic progression, clinical evaluation, and hips requiring replacement. However both groups were superior to non-operative management [14].

Discussion
Osteonecrosis of the femoral head is a debilitating disease which generally occurs in the younger population. Multiple studies have shown that once the roentgenographic changes are established, the disease normally progresses to femoral head collapse requiring joint replacement. Since the group of individuals affected by this condition is usually active, hip replacement in these placements are widely regarded as a last resort as the long term outcomes are less than ideal. Therefore, the general clinical approach to these patients is femoral head preservation and various methods have been sought out. Amongst these methods, core decompression (CD) stands out as a conservative technique that has greater success rates in early disease. The principle behind CD is to lower the intraosseous pressure which has been found to be raised. Theoretically this addresses the relative ischaemia while simultaneously stimulating a vascularized healing response [16]. Two of the Steinberg studies analysed in this review showed that CD demonstrated an improvement in outcome over non-operative treatment [14, 15].

The other method evaluated in the studies is biophysical stimulation (either by PEMF or electrical stimulation via DC or CC). The rationale behind the use of biophysical stimulation is its anti-inflammatory actions which prevent cartilage breakdown and promote angiogenesis, thus limiting the extent of necrosis [2, 4]. Moreover, it encourages bone formation via stimulation of osteoblasts and inhibition of osteoclasts [2, 4], thus slowing the breakdown of structural integrity [6]. In particular, PEMF has been proposed to exert its effects based on the following three concepts: Wolff’s law, the piezoelectric effect and streaming potentials [17].

Wolff’s law states that bones respond to mechanical loads under which they are placed; compression results in osteogenesis on the side compressed and simultaneous resorption on the contralateral side [18]. This occurs via a process called mechanotransduction whereby mechanical signals are transformed into biochemical ones [19].

The piezoelectric effect describes the phenomenon where certain materials demonstrate an ability to generate negative and positive potentials when subjected to
mechanical strain. In bone, the piezoelectric nature of hydroxyapatite and collagen results in a negative potential generated during compression and a positive one when the stress is relieved. Notably, the piezoelectric effect is reversible, hence the mechanical stress can be induced with the application of an electric field [20].

In cartilage, streaming potentials refer to the movement of positively charged ions across negatively charged proteoglycans during mechanical stress, generating an electric current which may stimulate chondrocytes [21].

Therefore, a possible mechanism of PEMF application is the induction of a mechanical strain via the converse piezoelectric effect, thus inducing osteogenesis via Wolff’s law, as well as chondrocyte stimulation [17].

**PEMF**

In the present review, studies examining the effect of PEMF, whether alone or in combination with other treatments, generally showed some benefit when PEMF was administered. As a treatment used on its own, PEMF was shown to preserve majority of femoral heads (80.2% by Cadossi [2], 88.57% by Cebrian [3], 83.9% by Bassett [10]) with these benefits being more pronounced in hips of earlier stages, namely Ficat I and II and Steinberg II and III, and decreasing as severity increased. Remarkably, PEMF has also been shown to reverse the disease progression across 2 of these studies; Bassett et al. found 9 hips demonstrated improvements with 3 of these even returning to normal [10], while Cadossi et al. showed improvements in Ficat stages [2].

Additionally, it was found that PEMF was also effective in improving symptoms of osteonecrosis. Cebrian and Cadossi both found that significant proportions of patients who received PEMF therapy eventually experienced an improvement in pain or even became pain free [2, 3]. Moreover, Massari et al. found that though the efficacy of PEMF decreased overall with increased Steinberg staging, there was greater clinical than radiographic benefit seen in those with Steinberg IV hips [4], further reinforcing the potential of PEMF to alleviate pain in these patients. Conversely, Windisch et al. showed that there was no difference in clinical outcomes between patients who received PEMF and those who didn’t. However, unlike the other papers, the method of inducing the electromagnetic field in this study was an invasive one via a bipolar induction screw through the femoral head [5]. This may have contributed to the discrepancy, as discussed later in the section on DC therapy.

A notable limitation to these studies is the lack of comparison to pain outcomes in non-operative management, hence making it difficult to ascertain the actual degree of improvement. However, Aaron et al. found that more patients who received PEMF alone experienced less pain than patients who received core decompression alone [6]. This is significant as it is the only study that directly compared outcomes of PEMF therapy to the current most widely-accepted conservative treatment method, and it showed a clear advantage of PEMF over core decompression.

These findings show that PEMF therapy is a promising technique, especially for the management of early stage disease.

**Direct current stimulation**

Two studies examined the effect of electrical stimulation as an adjunct to core decompression and grafting with varying results. One study showed improvements in Harris Hip scores and less roentgenographic progression in electrically stimulated hips via DC, although the percentage of patients needing THA in both groups was the same [15]. Similarly, in another study, femoral heads that were treated with DC had better radiological and clinical outcomes than the control group, with an average progression of two thirds a stage compared to one and a third a stage respectively [11]. However, surprisingly, more hips from the DC group eventually required THA (41% vs 37%) [11]. Although there appears to be a small benefit with DC stimulation, its efficacy should be considered in the context of it being an invasive procedure. Due to the study designs, DC application was only evaluated as an adjunct therapy to core decompression and grafting, where it showed no extra benefit. Therefore, more research is required to assess its efficacy as a technique alone. Yet, randomised double-blind controlled trials may not be suitable in this instance, as the control group would likely have to receive insertion of a placebo device, which is ethically problematic [22]. As such, future trials should compare DC therapy alone to other techniques alone, or vary the protocols used in terms of voltage and length of stimulation.

**Capacitive coupling**

Patients who received CC fared worse than those who did not. In one study, hips that were stimulated showed poorer outcomes in all parameters: roentgenographic progression, HHS and Steinberg staging [14]. The other study also revealed comparable findings with unstimulated hips faring better [11]. This is noteworthy because CC is another non-invasive method of applying electric fields, yet the results yielded are significantly worse than those of PEMF. One interesting difference we identified between the PEMF and CC groups is the duration of stimulation: all the patients who were treated with PEMF had it administered 8 h a day whereas those who received CC in one of the studies had their affected hips stimulated nearly 24 h a day [14]. This may explain the large discrepancy in results between the two modalities; it may be that CC would have similar effects to PEMF if
the protocols used were more similar. This difference also makes it difficult to directly compare these studies, hence, more controlled clinical trials are needed before any concrete conclusion can be made about the effectiveness of CC compared to PEMF, with emphasis on evaluating the optimal protocol for CC application.

Prognostic factors
In the paper by Cebrian et al., it was noted that in addition to the presence of certain radiological features, having a femoral head with a greater than 15% necrotic area influenced the likelihood of progression as well. Moreover, they identified that all of the femoral heads that went on to have roentgenographic progression had predominantly lateral involvement [3]. Similarly, Steinberg et al. noted that hips with small lesions fared significantly better than those with intermediate and large lesions [11]. As such, lesion size and its location may be important prognostic markers, and are parameters that haven’t been addressed in other papers.

Finally, another important point to note is that many of these papers either did not take into consideration the aetiologies of the disease, or did not evaluate the outcomes according to aetiologies. With regards to PEMF therapy, Bassett et al. noted that corticosteroid use as an aetiology may have influenced response [10], while Cadossi et al. proposed that idiopathic lesions may be more sensitive [2]. Steinberg et al. mentioned that patients who have had alcohol and steroid use as disease aetiologies may have had poorer outcomes, although the difference was not statistically significant [11]. Causes of the disease may be a confounding factor; secondary lesions may be less responsive to treatment due to their ongoing nature, for example steroid use for treatment of another disease should not be interrupted [4]. Studies to date on this topic are limited in number, size, and quality of research methodology. There is heterogeneity in the methodology used (eg: dosage of electrical stimulation and follow up period) so a meta-analysis would not yield any meaningful data on the outcomes of interest. Hence this article shows the best available evidence on the disease may be a confounding factor; secondary lesions may be less responsive to treatment due to their ongoing nature, for example steroid use for treatment of another disease should not be interrupted [4]. Studies to date on this topic are limited in number, size, and quality of research methodology. There is heterogeneity in the methodology used (eg: dosage of electrical stimulation and follow up period) so a meta-analysis would not yield any meaningful data on the outcomes of interest. Hence this article shows the best available evidence on the outcomes and disease aetiologies.

Conclusion
The outcomes of stimulated femoral heads with osteonecrosis with PEMF have been encouraging, with the improvement in both radiographic and clinical parameters, especially in early Ficat stages. Given its non-invasive nature and potential to stop or reverse the disease process, PEMF is an especially promising area of research. However, the technique is perhaps hindered by the fact that its application is generally cumbersome and requires significant compliance on the part of the patients; the devices often require long hours of use for many months (e.g. 8 h a day for 6 months [2, 3, 4, 6, 10], and precise placement of the coils, typically requiring splints [3, 4, 6, 10]. On the other hand, other techniques of electrical stimulation such as with DC or CC have shown equivocal results. In essence, more trials need to be completed to ascertain the indications for and complications of the use of electrical stimulation in avascular necrosis of femoral heads, and thus derive an optimal protocol.

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TAJ devised the project and was the lead investigator. TAJ, JYQT, GYT, RS, BK, TP and TR helped in reviewing studies and drafting the manuscript. All authors read, edited and approved the final manuscript.

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This was not required for this article.

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Robotic-arm assisted total knee arthroplasty is associated with improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based total knee arthroplasty

**A PROSPECTIVE COHORT STUDY**

**Aims**

The objective of this study was to compare early postoperative functional outcomes and time to hospital discharge between conventional jig-based total knee arthroplasty (TKA) and robotic-arm assisted TKA.

**Patients and Methods**

This prospective cohort study included 40 consecutive patients undergoing conventional jig-based TKA followed by 40 consecutive patients receiving robotic-arm assisted TKA. All surgical procedures were performed by a single surgeon using the medial parapatellar approach with identical implant designs and standardized postoperative inpatient rehabilitation. Inpatient functional outcomes and time to hospital discharge were collected in all study patients.

**Results**

There were no systematic differences in baseline characteristics between the conventional jig-based TKA and robotic-arm assisted TKA treatment groups with respect to age (p = 0.32), gender (p = 0.50), body mass index (p = 0.17), American Society of Anesthesiologists score (p = 0.88), and preoperative haemoglobin level (p = 0.82). Robotic-arm assisted TKA was associated with reduced postoperative pain (p < 0.001), decreased analgesia requirements (p < 0.001), decreased reduction in postoperative haemoglobin levels (p < 0.001), shorter time to straight leg raise (p < 0.001), decreased number of physiotherapy sessions (p < 0.001) and improved maximum knee flexion at discharge (p < 0.001) compared with conventional jig-based TKA. Median time to hospital discharge in robotic-arm assisted TKA was 77 hours (interquartile range (IQR) 74 to 81) compared with 105 hours (IQR 98 to 126) in conventional jig-based TKA (p < 0.001).

**Conclusion**

Robotic-arm assisted TKA was associated with decreased pain, improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based TKA.

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Total knee arthroplasty (TKA) is an established and highly effective procedure that is performed in over 90 000 patients per year within the United Kingdom. The demand for TKA has grown rapidly over the last two decades during which time the overall costs have risen. To control this expenditure optimization of postoperative recovery and reducing length of hospital stay, whilst preserving the quality of care, is required. Developments in minimally invasive surgery, pain management, anaesthesia, deep vein thrombosis prophylaxis, antibiotic prophylaxis, implant design and manufacturing and enhanced rehabilitation techniques, have all ultimately focussed on optimizing postoperative recovery and duration of inpatient stay following TKA. Robotic-arm assisted technology has been used to enhance inpatient recovery and expedite discharge in gastrointestinal, urological, gynaecological surgery, and over the last decade in arthroplasty surgery.
Robotic-arm assisted TKA uses preoperative imaging to create a 3D reconstruction of the patient’s native knee anatomy. This patient-specific model is then used to calculate a haptic window for bone resection, and select optimal implant sizing and positioning for the desired postoperative bone coverage and limb alignment. An interactive robotic-arm with visual, audio and tactile resistive feedback then guides intraoperative bone resection within this predefined haptic window. Saw blade action outside of this stereotactic window is limited, which conceptually helps to preserve native bone stock and minimize periarticular soft-tissue injury. Dynamic referencing is used to assess intraoperative flexion and extension gaps, joint stability, range of movement and limb alignment, enabling the surgeon to perform on-table modifications to bone resection, soft-tissue releases and implant positioning. Studies have shown that robotic-arm assisted TKA is associated with improved accuracy of implant positioning and reduced outliers compared with conventional jig-based TKA, but to our knowledge, there are no existing studies exploring how this translates into differences in early postoperative recovery and hospital discharge.

The objective of this prospective cohort study was to determine differences in early postoperative recovery and time to hospital discharge between patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA. The primary outcome measure in this study was pain score on the numerical rating scale at 24 hours following surgery. The hypothesis was that no difference exists between the two groups relating to pain scores at 24 hours as all operative procedures were performed through the same surgical approach with a standardized rehabilitation programme.

**Patients and Methods**

**Patient selection.** This study included 80 patients with symptomatic knee osteoarthritis undergoing primary TKA at the same treatment centre between January 2016 and September 2017. This included 40 consecutive robotic-arm assisted TKAs and the preceding 40 consecutive conventional jig-based TKAs. All operative procedures were performed by the senior author (FSH) who was experienced in performing conventional jig-based and computer-navigated TKA, and had undergone cadaveric training on robotic-arm assisted TKA. The robotic group was the first cohort of patients undergoing robotic-arm assisted TKA under the operating surgeon. Inclusion criteria for this study included the following: patients with knee osteoarthritis undergoing primary TKA; patient between 18 and 80 years of age; surgery using the conventional jig-based or robotic-arm assisted technique; surgery performed by the senior author (FSH). Exclusion criteria included the following: conversion of unicompartmental to TKA; prior infection of knee joint; arthroplasty for fracture or previous osteotomy; underlying neurological dysfunction compromising mobility; and/or the use of other surgical techniques such as computer navigation for TKA. The study was assessed by the hospital review board who advised that further institutional review board assessment for ethical approval was not required. Patients were allocated to their treatment group based on the date of their surgery relative to installation of the robotic device into our institution (Princess Grace Hospital, London, United Kingdom) in September 2016. Conventional jig-based techniques were used prior to installation of the robotic device, and robotic-arm assisted surgery performed after installation.

**Surgical technique.** All patients received general anaesthesia with a standardized regimen of fentanyl, morphine, clonidine, paracetamol and diclofenac at induction by the same consultant anaesthetist. In conventional jig-based TKA, the patient was positioned supine on the operating table with a lateral thigh support and foot bolster to enable flexion and extension of the knee joint. In robotic-guided TKA, the patient was positioned supine with the proximal tibia and foot of the operated limb in the mobile leg holder boot. As per the surgeon’s routine practice, a pneumatic tourniquet was applied but not inflated unless there was intraoperative difficulty in achieving haemostasis or compromise to the bone-cement interface. All study patients received one gram of intravenous tranexamic acid on induction and diathermy was used to help control intraoperative bleeding in all operative procedures. A conventional medial parapatellar approach was used in all patients. In both treatment groups, the objective was to achieve neutral mechanical alignment.

In conventional jig-based TKA, extramedullary referencing was used to perform tibial bone resection perpendicular to the mechanical axis of the tibia in the coronal plane with the aim of matching anatomical anteroposterior slope in the sagittal plane. The femur was prepared using an intramedullary alignment jig with the distal cutting block positioned so that the distal femoral cut was at 5° to 7° valgus angle depending on the pre-existing deformity. The distal femoral cutting block was positioned in 3° or greater of external rotation using the transepicondyral axis. Appropriate soft tissue releases were performed to ensure symmetrical and balanced flexion and extension gaps. In robotic-arm assisted TKA, the patient-specific computer aided design model of the patient’s knee joint was used to create a virtual plan for optimal bone resection and implant positioning. The RIO robotic interactive orthopaedic arm system (Mako Surgical Corporation, Kalamazoo, Michigan) was then used to execute this plan intraoperatively and achieve the planned bone coverage and limb alignment. Femoral registration pins were placed through the midline incision whilst tibial registration pins were placed through a separate 3 cm longitudinal incision over the proximal anteromedial tibia. Intraoperative dynamic tracking markers were used to assess alignment, flexion and extension gaps, and range of movement, enabling on-table modifications to bone resection and implant positioning. Tibial and femoral osteotomies in the coronal plane were performed perpendicular to the tibial and femoral mechanical axes respectively to achieve neutral overall alignment. In the sagittal plane, 0° to 5° of femoral component flexion were used to optimize implant sizing whilst preventing notching. The tibial slope was initially set to 0° and then adjusted as required based on intraoperative assessment of the flexion gap and range of movement.

The cemented Triathlon Posterior Stabilized (PS) implant (Stryker, Mahwah, New Jersey), knee system with an asymmetrical patellar resurfacing button was used in both treatment groups. Polyethylene thickness was selected to maximize range of
movement whilst avoiding hyperextension and ligament laxity. Patients in both treatment groups received 40 ml of 0.25% bupivacaine into the joint capsule prior to wound closure.

**Postoperative inpatient care.** All patients received postoperative patient-controlled analgesia (PCA) with the background intravenous morphine infusion rate set at 0.5 mg/hour, a bolus dose of 2 mg and lockout period of ten minutes. If the patient required additional analgesia then the nursing staff administered oral paracetamol and ibuprofen over this time. The PCA was stopped 24 hours postoperatively and converted to an oral regimen of regular paracetamol, ibuprofen and dihydrocodeine, with oral morphine available for breakthrough pain. All TKAs were performed at the same time of day and the first physiotherapy session was undertaken at six hours postoperatively. Patients underwent a standardized postoperative rehabilitation programme with full weight-bearing and active range of movement exercises commenced from day of surgery. Each physiotherapy session lasted 25 minutes in total and all rehabilitation was performed by the same team in both treatment groups. Patients were discharged home after adequate pain control, knee flexion to a minimum of 90°, independent mobilization with the use of crutches and independent ascent and descent of stairs.

**Outcomes.** All demographic data and patient outcomes were prospectively collected by two independent fellowship trained surgeons (JRTP and SK). Baseline measurements included the following: age at time of surgery (years); gender (male/female); body mass index (kg/m²); American Society of Anesthesiologists (ASA) grade (I to IV);⁻ side of intervention (right/left); and preoperative haemoglobin concentration (g/l). Findings were compared to establish any baseline differences between the two treatment groups. The following postoperative outcomes were also prospectively collected in all study patients: operating time (minutes); assessment of the intraoperative blood loss based on the difference in pre- and postoperative haemoglobin concentration (g/l); postoperative pain score on the numerical rating scale (0 to 10) at days 0 to 3; opiate analgesia (mg) requirements at days 0 to 3; range of movement at discharge (°); time from completion of operation to independent straight leg raise in the supine position (hours); number of inpatient physiotherapy sessions; use of inpatient continuous passive motion machine; time to hospital discharge (hours); and complications for 30 days following surgery. Study outcomes were selected based on previous studies showing that these early functional parameters influence time to hospital discharge and mid- to long-term clinical outcomes following TKA.¹¹⁻¹⁴

**Statistical analysis.** A sample size calculation was made based on a published mean postoperative score on the numerical rating scale following TKA of 4.19 (standard deviation (SD) 1.37),¹⁵ and a minimum clinically important difference in the numerical rating scale of one point. To achieve a minimum power of 80% in detecting this difference using a two-sample *t*-test at the level of 5% significance, the study needed to recruit a minimum of 72 patients. The assumption of a 10% drop-out rate within the 30 days follow-up period resulted in a net sample size of 80 patients (40 patients in each group). When comparing baseline and outcome measures between the two treatment groups, continuous variables with normal distributions were compared using the unpaired *t*-test, whilst the Mann–Whitney U test was used to compare continuous variables that were not normally distributed. One categorical outcome (use of continuous passive motion machine) was analysed using Fisher’s exact test, due to the small number of occurrences of this outcome. Continuous variables found to be normally distributed were displayed with the mean and range, whilst the median and interquartile range (IQR) were presented for factors not found to follow a normal distribution. Categorical variables were shown by the number and percentage of patients where the outcome occurred. Statistical significance was set at a p-value < 0.05 for all analyses and all statistical analysis was performed using SPSS software version 12 (SPSS Inc., Chicago, Illinois).

**Results**

There was no statistical difference in relation to baseline characteristics recorded between conventional jig-based TKA and robotic-arm assisted TKA (Table I). Interclass correlation coefficient was above 0.8 (0.88 to 0.92) for all postoperative outcomes recorded suggesting good interobserver agreement between the two independent observers. Study outcomes are displayed in Table II.

Patients undergoing robotic-arm assisted surgery had reduced pain scores at each of the four time intervals following surgery compared with conventional jig-based surgery (*p* < 0.001, unpaired *t*-test). In both groups, pain scores were greatest at day one, which reflected the day that the PCA was converted to oral analgesia (Fig. 1). Opiate analgesia requirements were also reduced in the robotic-group compared with the conventional group and this was found to be statistically significant at all four time points (*p* < 0.001, Mann–Whitney U test) (Fig. 2). There was no significant difference in preoperative haemoglobin concentration between the two treatment groups but patients undergoing conventional TKA had a greater reduction postoperatively compared with those undergoing robotic-arm assisted TKA (*p* < 0.001, unpaired *t*-test). The pneumatic tourniquet was not inflated in any study patient. Two patients in the robotic-arm assisted TKA group each received two units of red blood cells compared with four patients (10%) in the conventional jig-based TKA group. Attainment of physiotherapy targets including time to straight leg raise (*p* < 0.001, Mann–Whitney U test) and maximum knee flexion at discharge (*p* < 0.001, unpaired *t*-test) followed the same trend with improved outcomes in the robotic-arm assisted TKA group compared with the conventional jig-based TKA group (Figs 3 to 6). Each boxplot graphically displays the respective study outcome with the transverse line showing the median value and the box part representing the interquartile range. The whiskers extend to the minimum and maximum value, except for values more than 1.5 × interquartile range width from the lower or upper quartiles, which are plotted separately. There was a tendency towards to increased operating time in robotic-arm assisted TKA but overall hospital discharge was reduced in the robotic group (*p* < 0.001).

There were two inpatient complications in this study, which included one patient from each treatment group. In the conventional jig-based TKA, one patient had minor wound dehiscence from the distal part of the midline incision, which was treated...
with prophylactic antibiotics and adhesive skin strips to approximate the wound edges. In the robotic-arm assisted TKA group, one patient had minor wound dehiscence over the incision for the proximal tibial registration pins. This was treated with regular dressings and prophylactic oral antibiotics. Both patients made a satisfactory recovery with no further complications.

**Discussion**

In this prospective cohort study, there were no systematic differences in baseline characteristics between the two treatment groups, surgery was undertaken by a single surgeon using the same approach with identical implant designs, and inpatient rehabilitation performed using a standardized programme with the same rehabilitation team. Robotic-arm assisted TKA was associated with reduced postoperative pain, decreased analgesia requirements, smaller drop in haemoglobin concentration, shorter time to be able to perform a straight leg raise, improved maximum knee flexion at discharge and decreased length of stay compared with conventional jig-based TKA. Our findings suggest that implementation of robotic-arm assisted surgery may help to further improve early functional recovery and reduce time to hospital discharge in patients undergoing TKA.

Analysis of data from the National Joint Registry of England and Wales showed that persistent pain following TKA is the strongest predictor of patient dissatisfaction and reduced functional outcomes including the Oxford Hip Score. Regression analysis has also shown that postoperative pain is the most important prognostic indicator for long-term dissatisfaction following TKA. Our study showed reduced pain and opiate analgesia requirements at each of the four time points in patients undergoing TKA.

**Table I.** Demographic and baseline measurements for study patients undergoing conventional jig-based total knee arthroplasty (TKA) and robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Category</th>
<th>Conventional (n = 40)</th>
<th>Robotic (n = 40)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (yrs)</td>
<td></td>
<td>71.4 (54.2 to 87.1)</td>
<td>69.7 (53.1 to 85.3)</td>
<td>0.32†</td>
</tr>
<tr>
<td>Gender (%)</td>
<td>Female</td>
<td>25 (62)</td>
<td>22 (55)</td>
<td>0.50†</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>15 (38)</td>
<td>18 (45)</td>
<td></td>
</tr>
<tr>
<td>Mean BMI (kg/m²)</td>
<td></td>
<td>26.7 (20.3 to 36.0)</td>
<td>27.9 (21.8 to 37.1)</td>
<td>0.17†</td>
</tr>
<tr>
<td>ASA score (%)</td>
<td>I</td>
<td>7 (18)</td>
<td>8 (20)</td>
<td>0.88†</td>
</tr>
<tr>
<td></td>
<td>II</td>
<td>29 (72)</td>
<td>27 (67)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>III</td>
<td>4 (10)</td>
<td>5 (13)</td>
<td></td>
</tr>
<tr>
<td>Side intervention (%)</td>
<td>Left</td>
<td>20 (50)</td>
<td>18 (45)</td>
<td>0.65†</td>
</tr>
<tr>
<td></td>
<td>Right</td>
<td>20 (50)</td>
<td>22 (55)</td>
<td></td>
</tr>
<tr>
<td>Mean preoperative Hb (g/L)</td>
<td></td>
<td>132.7 (95.1 to 164.3)</td>
<td>133.3 (113.2 to 154.6)</td>
<td>0.82*</td>
</tr>
</tbody>
</table>

*BMI, body mass index; ASA, American Society of Anesthesiologists; Hb, Haemoglobin

**Table II.** Study outcomes for patients undergoing conventional jig-based total knee arthroplasty (TKA) and robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Conventional (n = 40)</th>
<th>Robotic (n = 40)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean operating time (mins)</td>
<td>61.2 (54.6 to 83.1)</td>
<td>70.4 (59.2 to 91.7)</td>
<td>0.34</td>
</tr>
<tr>
<td>Mean fall in Hb (g/L)</td>
<td>26.1 (5.1 to 49.6)</td>
<td>18.7 (8.0 to 37.2)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Mean postoperative Hb (g/L)</td>
<td>106.7 (77.3 to 138.4)</td>
<td>114.7 (86.4 to 139.1)</td>
<td>0.01†</td>
</tr>
<tr>
<td>Mean pain score (NRS) – Day 0</td>
<td>5.4 (3.0 to 7.0)</td>
<td>3.1 (2.0 to 5.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Mean pain score (NRS) – Day 1</td>
<td>6.3 (4.0 to 8.0)</td>
<td>3.6 (2.0 to 6.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Mean pain score (NRS) – Day 2</td>
<td>6.1 (3.0 to 8.0)</td>
<td>3.3 (1.0 to 5.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Mean pain score (NRS) – Day 3</td>
<td>4.5 (2.0 to 7.0)</td>
<td>2.6 (1.0 to 5.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median analgesia (mg) – Day 0</td>
<td>36.0 (IQR 29.0 to 51.3)</td>
<td>20.0 (IQR 16.0 to 28.5)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median analgesia (mg) – Day 1</td>
<td>10.0 (IQR 10.0 to 20.0)</td>
<td>10.0 (IQR 0.0 to 10.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median analgesia (mg) – Day 2</td>
<td>10.0 (IQR 10.0 to 20.0)</td>
<td>10.0 (IQR 0.0 to 10.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median analgesia (mg) – Day 3</td>
<td>10.0 (IQR 0.0 to 10.0)</td>
<td>0.0 (IQR 0.0 to 5.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median time to SLR (hrs)</td>
<td>31.0 (IQR 24.0 to 44.0)</td>
<td>20.0 (IQR 18.0 to 21.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median knee extension (*)</td>
<td>0.0 (IQR 0.0 to 0.0)</td>
<td>0.0 (IQR 0.0 to 0.0)</td>
<td>0.08†</td>
</tr>
<tr>
<td>Mean knee flexion (°)</td>
<td>93.3 (90.0 to 110.0)</td>
<td>104.1 (90.0 to 120.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median physiotherapy sessions (n)</td>
<td>11.0 (IQR 9.0 to 11.0)</td>
<td>5.0 (IQR 5.0 to 6.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>CPM sessions, n (%)</td>
<td>5 (12.6)</td>
<td>2 (5.0)</td>
<td>0.43‡</td>
</tr>
<tr>
<td>Median time to discharge (hrs)</td>
<td>105.0 (IQR 98.0 to 126.0)</td>
<td>77.0 (IQR 74.0 to 81.0)</td>
<td>&lt; 0.001†</td>
</tr>
</tbody>
</table>

*Unpaired t-test
†Mann-Whitney U test
‡Fisher’s exact test
NRS, numerical rating scale; Hb, haemoglobin concentration; IQR, interquartile range; SLR, straight leg raise; CPM, continuous passive motion machine
robotic-arm assisted surgery compared with conventional jig-based TKA, which we hope would lead to improved long-term patient satisfaction and functional outcomes in the robotic TKA group. Marchand et al. compared outcomes in 28 robotic-arm assisted TKAs matched with 20 conventional jig-based TKAs and showed that pain, physical function scores and patient satisfaction measured using Western Ontario and McMaster Universities Arthritis Index were better in the robotic group compared with the conventional group at six months after surgery. Our data shows important differences in pain and analgesia requirements in the early postoperative period but the long-term clinical significance of these remains unknown. The present data will be subsequently correlated to validated long-term clinical and functional outcome measures.
Robotic-arm assisted TKA uses dynamic referencing to assess intraoperative knee stability, alignment and range of movement, enabling on-table adjustments to bone resection and implant positioning to be performed. The surgeon is able manipulate bone cuts to achieve the desired flexion and extension gaps without having to perform extensive soft-tissue releases. No additional soft-tissue releases for knee balancing were performed in the robotic-arm assisted group in this study. Reduced soft-tissue dissection and muscle trauma may have helped to reduce the local inflammatory response and time to attainment of physiotherapy targets such as straight leg raise in the robotic-group compared with patients undergoing conventional jig-based TKA.

Siebert et al. conducted a retrospective study on 70 patients undergoing robotic-arm assisted TKA versus a matched historic cohort of 50 conventional TKAs, and observed reduced postoperative soft-tissue swelling in the robotic-group but the size or difference in the effect was not quantified. There are no existing studies comparing the local or systemic inflammatory response to hip and knee arthroplasty have shown that the extent of soft-tissue release was associated with the magnitude of the inflammatory cytokine response and signal changes visible on postoperative MRI.

The technical objectives of TKA are to restore mechanical alignment, preserve the joint line, balance flexion and extension gaps and maintain the normal Q angle for correct patella tracking. In order to achieve these objectives, preservation of the surrounding soft-tissue envelope is essential. Compromise to the periarticular soft-tissue structures such as the collateral ligaments, posterior cruciate ligament or extensor mechanism, may compromise postoperative clinical and functional recovery, reduce stability and decrease implant survivorship. Manual based techniques may lead to inadvertent disruption of the periarticular soft-tissue injuries. Robotic-arm assisted TKA limits saw blade action to within the fixed stereotactic field, which conceptually helps to reduce iatrogenic bone and soft-tissue injury.

In this study, no intraoperative macroscopic soft-tissue complications were identified but previous cadaveric reports have shown that robotic-arm assisted technology can reduce more discrete periarticular soft-tissue injuries. Khlopa et al. conducted a prospective non-randomized study comparing soft-tissue injury in six cadaveric knees undergoing robotic-
The authors found mild posterior cruciate ligament injury in two of the seven conventional jig-based TKAs compared with none of the six robotic-arm assisted TKAs, with more extensive soft-tissue disruption in the conventional group on careful visual evaluation and palpation. In the current study, improved preservation of the periarticular soft-tissue envelope and reduced iatrogenic trauma in the robotic-arm assisted group may have helped to limit pain and enhance early functional recovery.

In this study, there was a trend towards increased operating time in the robotic group but this was not statistically significant. Our findings are consistent with a previous study by Song et al., who conducted a prospective study on 30 patients undergoing sequential TKA, which included conventional jig-based TKA on one side followed by robotic-arm assisted TKA on the contra-lateral side. The authors reported no difference in operating time between the two treatment groups, with mean operating time in the robotic-arm assisted of 95 minutes (SD 18). Park and Lee reported on the learning curve of robotic-arm assisted TKA and showed that six of their 32 robotic-arm assisted TKAs had short-term complications, including superficial infection, patellar ligament rupture, patellar dislocation, supracondylar fracture, patellar fracture and common peroneal injury during the learning phase. The reduced operating time and absence of intraoperative complications in our cohort of patients compared with these previous studies may be due to the operating surgeon in this study having extensive training in robotic-arm assisted TKA in cadaver-workshops and prior experience in performing computer navigated arthroplasty. As such progression along the learning curve for some aspects of robotic-assisted surgery may have already been achieved.

There is growing literature showing that robotic-arm assisted knee arthroplasty is associated with improved accuracy of implant positioning, better short- to mid-term functional scores and reduced revision rates compared with conventional jig-based TKA. Although a financial analysis has not been undertaken, our findings do show important differences in inpatient rehabilitation and hospital stay, which will aid healthcare policy makers in the allocation of medical resources and cost planning for the implementation of this technology into clinical practice.

There are several limitations of this study that need to be considered when interpreting the findings. First, all patients received general anaesthetic, which is not keeping in with current trends in enhanced recovery programmes and this may have reduced the overall rehabilitation time in both treatment groups. Second, the reported early functional outcome measures were not correlated to long-term clinical outcomes or implant survivorship. Third, patients and observers recording outcomes of interest could not be blinded as patients in the robotic group had an additional incision over the proximal tibia for the insertion of the registration pins. Fourth, the use of historical controls may have introduced bias into the study due to increasing drive for faster rehabilitation and reduced length of stay. Improved outcomes in the robotic group may therefore not be exclusively due to surgical technique. Fifth, preoperative grading of the arthritis and radiological outcomes were not analysed in this study. Despite these limitations, this prospective single surgeon study used the same surgical approach, implant design and rehabilitation programme in two systemically matched treatment groups, and showed improved early functional recovery and time to hospital discharge with no additional risk of complications in robotic-arm assisted TKA compared with conventional jig-based TKA.

Robotic-arm assisted TKA was associated with reduced postoperative pain, decreased analgesia requirements, less reduction in postoperative haemoglobin levels, shorter time to perform a straight leg raise, decreased length of stay, and improved maximum knee flexion at discharge compared with conventional jig-based TKA. There was no additional risk of inpatient complications in patients undergoing robotic-arm assisted TKA compared with conventional jig-based TKA.

Take home message:
- Robotic-arm assisted TKA is associated with reduced postoperative pain and analgesia requirements compared with conventional jig-based TKA.
- Robotic-arm assisted TKA is associated with improved early functional recovery compared with conventional jig-based TKA.
- Robotic-arm assisted TKA is associated with reduced time to hospital discharge compared with conventional jig-based TKA.

References
ROBOTIC-ARM ASSISTED TKA ASSOCIATED WITH IMPROVED EARLY FUNCTIONAL RECOVERY AND REDUCED TIME TO HOSPITAL DISCHARGE


Author contributions:
B. Kayani: Hypothesis generation, Data interpretation, Manuscript preparation.
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J. Tahmassebi: Data collection, Data analysis.

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This article was primary edited by G. Scott.
Robotic-arm assisted total knee arthroplasty has a learning curve of seven cases for integration into the surgical workflow but no learning curve effect for accuracy of implant positioning

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Abstract
Purpose The primary objective of this study was to determine the surgical team’s learning curve for robotic-arm assisted TKA through assessments of operative times, surgical team comfort levels, accuracy of implant positioning, limb alignment, and postoperative complications. Secondary objectives were to compare accuracy of implant positioning and limb alignment in conventional jig-based TKA versus robotic-arm assisted TKA.

Methods This prospective cohort study included 60 consecutive conventional jig-based TKAs followed by 60 consecutive robotic-arm assisted TKAs performed by a single surgeon. Independent observers recorded surrogate markers of the learning curve including operative times, stress levels amongst the surgical team using the state-trait anxiety inventory (STAI) questionnaire, accuracy of implant positioning, limb alignment, and complications within 30 days of surgery. Cumulative summation (CUSUM) analyses were used to assess learning curves for operative time and STAI scores in robotic TKA.

Results Robotic-arm assisted TKA was associated with a learning curve of seven cases for operative times (p = 0.01) and surgical team anxiety levels (p = 0.02). Cumulative robotic experience did not affect accuracy of implant positioning (n.s.) limb alignment (n.s.) posterior condylar offset ratio (n.s.) posterior tibial slope (n.s.) and joint line restoration (n.s.). Robotic TKA improved accuracy of implant positioning (p < 0.001) and limb alignment (p < 0.001) with no additional risk of post-operative complications compared to conventional manual TKA.

Conclusion Implementation of robotic-arm assisted TKA led to increased operative times and heightened levels of anxiety amongst the surgical team for the initial seven cases but there was no learning curve for achieving the planned implant positioning. Robotic-arm assisted TKA improved accuracy of implant positioning and limb alignment compared to conventional jig-based TKA. The findings of this study will enable clinicians and healthcare professionals to better understand the impact of implementing robotic TKA on the surgical workflow, assist the safe integration of this procedure into surgical practice, and facilitate theatre planning and scheduling of operative cases during the learning phase.

Level of evidence II.

Keywords Implant positioning · Learning curve · Operative time · Robotics · TKA · Total knee arthroplasty · Total knee replacement

Introduction

Total knee arthroplasty (TKA) is an established and cost-effective treatment for patients with symptomatic end-stage knee osteoarthritis [7]. However, recent studies have shown that 20% of patients still remain dissatisfied following TKA [1, 18]. Accuracy of implant positioning and limb alignment are important prognostic factors that influence patient satisfaction, clinical outcomes, and long-term implant survivorship following TKA [8, 17, 18, 22]. Evolution in surgical technology has led to the development of robotic-arm assisted TKA, which
uses a preoperative computerised tomography (CT) scan to create a patient-specific computer-aided design (CAD) model of the patient’s unique knee anatomy. The surgeon is able to virtually select the desired implant position and alignment, and an intraoperative robotic arm helps to execute this plan with a high degree of accuracy [11, 12]. Robotic-arm assisted TKA improves the accuracy of bone resection, reduces outliers in postoperative limb alignment, and decreases iatrogenic bone and periarticular soft tissue injury compared to conventional manual TKA [11, 12, 21, 22].

Existing studies on the learning curve of robotic-arm assisted TKA have used operative times as exclusive markers of surgical competence, and found surgical proficiency may be achieved by high-volume arthroplasty surgeons within a few months [4, 20]. It is possible to improve on these existing studies by comparing a more comprehensive range of learning outcome measures including operative times of individual stages of the robotic procedure, surgical team comfort levels, accuracy of implant positioning, restoration of limb alignment, and postoperative complications. In this study, cumulative summation (CUSUM) analyses will be used to assess incremental changes in these study outcomes during progression of the robotic TKA learning curve [13], and the findings compared to baseline values from a cohort of patients undergoing conventional manual TKA by the same operating surgeon. This data will be used to ascertain inflexion points at which the surgeon transitions from the learning phase to the proficiency phase in more detail. The findings of this study will enable clinicians and healthcare professionals to better understand the impact of implementing robotic TKA on the surgical workflow, facilitate theatre planning and scheduling of operative cases, and understand any additional risks or complications during the acquisition of surgical proficiency.

The primary objective of this study was to determine the surgical team’s learning curve for robotic-arm assisted TKA through assessments of operative times, surgical team comfort levels, accuracy of implant positioning, limb alignment, and postoperative complications. The hypothesis was that cumulative experience with robotic-arm assisted TKA would lead to improved operative times and surgical team comfort levels but there would be no learning effect for accuracy of implant positioning or limb alignment. The secondary objectives were to compare accuracy of implant positioning and limb alignment in patients undergoing robotic-arm assisted TKA versus conventional jig-based TKA.

**Materials and methods**

This prospective cohort study included 120 patients with symptomatic knee osteoarthritis undergoing primary TKA between 2016 and 2017. This included 60 consecutive patients undergoing conventional jig-based TKA followed by 60 consecutive patients receiving robotic-arm assisted TKA. Patients were allocated to their treatment group based on the date of their surgery relative to installation of the robotic device into the study institution. Conventional jig-based TKA was performed prior to installation of the robotic device, and robotic-arm assisted TKA performed after its installation. Patients were not randomized but this enabled assessment of learning curves associated with complete transition from conventional jig-based TKA to robotic-arm assisted TKA. All operative procedures were performed by the senior author who is experienced in performing conventional jig-based TKA and had undergone cadaveric training on robotic-arm assisted TKA. The robotic group was the first cohort of patients undergoing robotic-arm assisted TKA under the operating surgeon.

Inclusion criteria for this study included the following: Patients with knee osteoarthritis undergoing primary total knee arthroplasty; patients between 18 and 80 years of age; surgery undertaken using the conventional jig-based or robotic-arm assisted technique; surgery performed by the senior author. Exclusion criteria included the following: conversion of unicompartmental knee arthroplasty to TKA ($n = 6$); prior infection of knee joint ($n = 1$); arthroplasty for fracture or previous osteotomy ($n = 2$); and underlying neurological dysfunction compromising mobility ($n = 1$). Patients undergoing conventional jig-based TKA and robotic-arm assisted TKA were well matched for baseline characteristics (Table 1). In both treatment groups, the standard medial parapatellar approach was used with implantation of the cemented Stryker Triathlon (Stryker Navigation, Kalamazoo, Michigan, USA), cruciate substituting knee system and asymmetrical patella resurfacing. Two independent observers collected all study outcomes and both were blinded to each other’s recordings. These observers were not involved in the surgical planning, operative procedure, or postoperative treatment process. Written informed consent was obtained from all study participants.

All patients underwent routine preoperative anteroposterior weight-bearing knee radiographs, lateral knee radiographs, and full-length hip-to-ankle weight-bearing radiographs. In both treatment groups, the operating surgeon used Traumacad software (Traumacad, Petach-Tikva, Israel) with plain radiographs to preoperatively template implant sizes and positions. Full-length hip-to-ankle radiographs were used to guide femoral and tibial resection angles to achieve neutral mechanical alignment. Lateral knee radiograph was used to select the femoral component size and position to restore the patient’s native posterior condylar offset ratio whilst avoiding overhang or notching of the femur. Tibial implant position and size were selected to restore native posterior tibial slope and avoid any anteroposterior overhang. On the anteroposterior knee radiograph, femoral and
tibial implant positons and sizes were selected to achieve maximum mediolateral contact whilst avoiding overhang. In patients undergoing robotic-arm assisted TKA, preoperative CT scan and CAD model were used to select the optimal implant positioning and implant sizes for achieving the desired bone coverage and limb alignment.

**Surgical technique**

Conventional jig-based TKA was performed using standard instrumentation with alignment jigs to guide bone resection. Extramedullary referencing was used to perform tibial bone resection perpendicular to the mechanical axis of the tibia in the coronal plane with the aim of matching anatomical anteroposterior slope in the sagittal plane. The femur was prepared using an intramedullary alignment jig with the distal cutting block positioned so that the distal femoral cut was at $5^\circ$–$7^\circ$ valgus angle depending on the pre-existing deformity. The distal femoral cutting block was positioned in $3^\circ$ or greater of external rotation using the transepicondylar axis. Flexion and extension gaps were checked and appropriate soft tissue releases performed to ensure the knee was balanced. No further intraoperative adjustments or tailoring of implant positioning were performed to account for individual patient anatomy.

In patients undergoing robotic-arm assisted TKA, distal femoral and proximal tibial bicortical registration pins were inserted and fixed arrays mounted onto these to enable intraoperative dynamic referencing. Bone registration was performed by intraoperatively mapping radiological landmarks displayed on the computer screen to verify anatomy and establish bone geometry. Joint balancing captured femoral and tibial poses with corrective forces, assessed kinematics through the arc of motion, and enabled fine tuning of implant positioning based on laxity of the soft tissue envelope. An intraoperative surgeon-controlled robotic arm with visual, tactile, and audio feedback was then used to execute the preoperative plan to within 2 mm of the planned bone resection. Tibial and femoral osteotomies in the coronal plane were performed perpendicular to the tibial and femoral mechanical axes, respectively, to achieve neutral overall alignment. In the sagittal plane, $0^\circ$–$5^\circ$ of femoral component flexion were used to optimise implant sizing whilst preventing notching. The tibial slope was initially set to zero degrees and then adjusted as required based on intraoperative assessment of the flexion gap and range of motion. Optical motion capture technology was used to assess limb alignment, range of motion, flexion and extension gaps, and arc of motion with trial implants prior to definitive selection and cement implantation of final components.

**Outcome measures**

**Interclass correlation coefficient**

All radiological measurements were recorded by each observer at 28 days apart and findings compared to assess for intra-observer agreement. Radiological measurements were compared between the two observers to assess for inter-observer agreement. Interclass correlation coefficient was 0.9 (95% CI 0.8–1.0) for intra-observer agreement and 0.9 (95% CI 0.8–0.9) for inter-observer agreement in all study outcomes, which indicated good agreement on all radiological parameters assessed by the two independent observers.

**Operative time**

Operative time was defined as time from initial surgical incision to final wound closure. In robotic-arm assisted TKA, surgical times for the following parts of the procedure were recorded: Setup of surgical tray, robotic device, and instruments; surgical approach and insertion of registration pins; bone registration; joint balancing; bone preparation; implant...
trailing; cement implantation of final prosthesis; and overall operative time.

Surgical team anxiety levels

The Spielberger State-Trait Anxiety Inventory (STAI) questionnaire is a validated subjective assessment tool for quantifying an individual’s stress levels with individual traits arising from the clinical environment [14]. The six-item questionnaire has a 4-point rating scale and total scores range from 6 to 24, with higher values indicating higher levels of stress. The STAI questionnaire was completed by each member of the surgical team prior to the surgical time-out in all study patients. The surgical team included the operating surgeon, two consultant anaesthetists, two senior scrub nurses, one operating department practitioner (ODP), and one circulating nurse.

Implant positioning and limb alignment

All patients underwent postoperative anteroposterior weight-bearing and lateral knee radiographs, and full-length hip-to-ankle weight-bearing radiographs. Accuracy of implant positioning and limb alignment were assessed by comparing the values achieved in the postoperative radiographs to the planned values in the corresponding preoperative radiographs. Femoral and tibial axes were used as reference markers as described by Bell et al. [2]. Accuracy of achieving the planned femoral and tibial implant positioning were assessed using the techniques described by Moon et al. [15]. The femoral coronal implant alignment was measured as the medial angle subtended by the femoral mechanical axis and the line connecting the distal points of the medial and lateral condyles of the femoral component. The femoral sagittal implant alignment was calculated as the angle subtended between the perpendicular line running proximally from the distal femoral surface in contact with the femoral component and the femoral mechanical axis. The tibial coronal implant alignment was measured as the medial angle subtended by the tibial mechanical axis and the line connecting the distal points of the medial and lateral condyles of the tibial component. The tibial sagittal alignment was calculated as the angle between the tibial mechanical axis and posterior to anterior axis of the tibial implant. Anteroposterior plain knee radiographs were used to measure the joint line height by calculating the perpendicular distance from a line extending through the distal points of the femoral condyles and a parallel line extending to the fibular head. True lateral knee radiographs were used to calculate the posterior tibial slope and posterior condylar offset ratio (PCOR) using the methods described by Gaudiani et al. [6] and Johal et al. [9] respectively.

Complications

All patients were reviewed in outpatient clinic at 30 days following surgery by the independent observers for clinical assessment and full weight-bearing radiographs performed. Any postoperative complications and their respective treatments during this follow-up period were recorded for analysis.

Hospital review board approval was acquired from the host institution (Reference: 241413, Princess Grace Hospital, 42–52 Nottingham place, Marylebone, London, W1U 5NY, UK) before commencement of the study. Further Research Ethics Committee (REC) or Health Research Authority (HRA) approval was not required for this study.

Statistical analysis

Sample size calculation was performed using operative time as the primary outcome measure and published data on operative times with similar surgical techniques for TKA. The minimal clinical difference was set at 5 min and standard deviation at 10 min [19]. This study required 60 patients in each arm to detect this minimum difference in operative time using a two-tailed, two-sample t tests with a power of 80% and significance level of 5%. Due to the limited follow-up time, no further adjustments were made to the sample size calculation to account for sample size attrition during follow-up.

The CUSUM sequential analysis tool was used to assess learning curves in robotic-arm assisted TKA for operative time and surgical team stress levels as assessed using the STAI questionnaire. Standardised target values for the CUSUM analyses were set using the overall mean values for these outcome measures from the robotic-arm assisted TKA group. CUSUM values represent a running total of the differences between the value of each data point and the standardised target values for each outcome. Learning curves for accuracy of implant position and limb alignment in robotic-arm assisted TKA were assessed by calculating root mean square error values for radiological outcomes and assessing progression in groups of ten patients. Categorical data were compared using the chi square test and Fisher’s exact test where greater than 25% of cells had less than five cases. Normally distributed continuous variables were compared using independent t tests for unpaired variables, paired t test for paired (matched) variables, and one-way ANOVA for multiple variables. The Mann–Whitney test was used for non-parametric data. Statistical significance was set at \( p < 0.05 \) for all statistical tests. All statistical analyses were performed using SPSS software version 21 (SPSS Inc., Chicago, IL, USA).
Results

Operative times

In robotic-arm assisted TKAs, CUSUM analysis for operative times revealed a sharp inflexion point after the initial seven cases, which helped to identify two distinct phases in the learning curve (Fig. 1). Phase 1 represents the initial learning segment and phase 2 represents the proficiency stage in robotic-arm assisted TKA. Comparison of the two phases demonstrated phase 1 procedures to be significantly longer \((p = 0.01)\) with no differences in baseline characteristics compared to phase 2 (Tables 2, 3).

Surgical team anxiety levels

CUSUM analysis of preoperative stress levels as assessed using the STAI questionnaire revealed an inflexion point after seven robotic cases \((p = 0.02)\) in a pattern similar to operative times in robotic-arm assisted TKA (Fig. 2). Further analysis revealed STAI scores to be significantly higher

![CUSUM analysis charts demonstrating the learning curve for operative time in patients undergoing robotic-arm assisted TKA.](image)
in phase 1 than in phase 2 for all members of the surgical team (Fig. 3).

**Implant positioning and limb alignment**

There was no learning curve effect of robotic-arm assisted TKA on accuracy of achieving the planned implant position and limb alignment (Table 4; Figs. 4, 5). Robotic-arm assisted TKA improved accuracy in achieving the planned implant positions compared to conventional jig-based TKA (Table 5).

**Complications**

There were two inpatient complications in this study, which included one patient from each treatment group. In conventional jig-based TKA, one patient had minor wound dehiscence from the distal part of the midline incision, which was treated with adhesive skin strips to approximate the wound edges and prophylactic antibiotics. In the robotic-arm assisted TKA group, one patient had minor wound dehiscence over the incision for the proximal tibial registration pins. This was treated with regular dressings and prophylactic oral antibiotics. Both patients made a satisfactory recovery with no further complications.
Discussion

The most pertinent findings from this study are that robotic-arm assisted TKA was associated with a learning curve of seven cases for operative times and surgical team comfort levels but there was no learning curve for accuracy of implant positioning, limb alignment, posterior condylar offset ratio, posterior tibial slope, and joint line preservation. Robotic-arm assisted TKA was associated with improved accuracy of implant positioning and limb alignment with no additional risk of complications compared to conventional jig-based TKA.

The operative time in robotic-arm assisted TKA progressively decreased over the initial seven cases as the surgical team became increasingly familiar with robotic technology and accustomed to the stages of robotic TKA. Most marked time improvements occurred with bone registration and operative times for this stage of the procedure decreased by over 50% during the initial learning phase. Intraoperative anatomical landmarks for bone registration were similar in

Table 4  Accuracy of implant positioning and limb alignment in patients undergoing robotic-arm assisted TKA

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Mechanical alignment RMSE (degrees)</td>
<td>1.6 ± 0.8</td>
<td>1.8 ± 1.0</td>
<td>1.7 ± 1.2</td>
<td>1.1 ± 0.6</td>
<td>1.6 ± 0.9</td>
<td>1.3 ± 1.0</td>
<td>n.s.</td>
</tr>
<tr>
<td>PCOR RMSE</td>
<td>0.2 ± 0.1</td>
<td>0.2 ± 0.1</td>
<td>0.2 ± 0.1</td>
<td>0.2 ± 0.1</td>
<td>0.2 ± 0.1</td>
<td>0.2 ± 0.1</td>
<td>n.s.</td>
</tr>
<tr>
<td>Posterior tibial slope RMSE (degrees)</td>
<td>1.4 ± 0.7</td>
<td>1.4 ± 0.9</td>
<td>1.3 ± 0.6</td>
<td>1.5 ± 0.7</td>
<td>1.3 ± 0.6</td>
<td>1.4 ± 0.7</td>
<td>n.s.</td>
</tr>
<tr>
<td>Joint line RMSE (mm)</td>
<td>1.0 ± 0.4</td>
<td>1.0 ± 0.6</td>
<td>1.1 ± 0.6</td>
<td>0.9 ± 0.6</td>
<td>1.1 ± 0.7</td>
<td>1.0 ± 0.6</td>
<td>n.s.</td>
</tr>
<tr>
<td>Femoral coronal RMSE (degrees)</td>
<td>1.0 ± 0.4</td>
<td>1.0 ± 0.3</td>
<td>0.9 ± 0.4</td>
<td>1.0 ± 0.4</td>
<td>0.9 ± 0.5</td>
<td>1.0 ± 0.4</td>
<td>n.s.</td>
</tr>
<tr>
<td>Femoral sagittal RMSE (degrees)</td>
<td>2.1 ± 0.8</td>
<td>2.0 ± 0.7</td>
<td>2.1 ± 0.5</td>
<td>2.0 ± 0.5</td>
<td>2.0 ± 1.0</td>
<td>1.9 ± 0.5</td>
<td>n.s.</td>
</tr>
<tr>
<td>Tibial coronal RMSE (degrees)</td>
<td>0.9 ± 0.3</td>
<td>1.0 ± 0.5</td>
<td>1.0 ± 0.7</td>
<td>0.9 ± 0.5</td>
<td>1.1 ± 0.4</td>
<td>1.0 ± 0.5</td>
<td>n.s.</td>
</tr>
<tr>
<td>Tibial sagittal RMSE (degrees)</td>
<td>2.0 ± 0.5</td>
<td>2.1 ± 0.5</td>
<td>1.9 ± 0.7</td>
<td>2.1 ± 0.7</td>
<td>1.9 ± 0.8</td>
<td>2.2 ± 0.5</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

Summary statistics are: RMSE (root mean square error) with standard deviation

Fig. 3  Chart comparing STAI scores between learning phases for all members of the surgical team in robotic-arm assisted TKA

Fig. 4  Bar chart showing changes in root mean square error (RMSE) for accuracy in femoral and tibial implant positioning (degrees) in consecutive patient groups undergoing robotic-arm assisted TKA
all patients, and therefore, with increasing surgical experience, the surgeon was able to predict and pre-emptively place the bovie tip over the appropriate bone landmark for registration. More moderate improvements were observed in time for bone resection as the surgeon became progressively more responsive to feedback from the saw blade. As the surgeon became more adept with fine movements of the robotic arm and more receptive to the audio, visual, and tactile feedback, he was able to better control the movements of the arm and perform bone cuts with greater efficiency.

This study also found that mean time for joint balancing during the proficiency stage was 8.9 min (range 7–12 min). During this stage, the surgeon assessed knee kinematics through the arc of motion, flexion and extension gaps, range of movement, and stability using optical motion technology. Using this intraoperative data, the surgeon was able to fine-tune femoral and tibial bone resections to balance flexion and extension gaps without having to perform more extensive soft tissue releases as may often be required in conventional jig-based TKA [7, 8]. This may have helped to limit the overall observed difference in operative times between conventional TKA versus robotic TKA.

The findings of this study complement those of Sodhi et al. [20] that explored the learning curve of robotic TKA using operative time as an exclusive marker of surgical proficiency. The authors reviewed operative times in two different surgeons and found mean operative times in the first 20 robotic cases were increased compared to each surgeon’s

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**Table 5** Study outcomes in patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Conventional jig-based TKA (n=60)</th>
<th>Robotic-arm assisted TKA (n=60)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative time (mins)</td>
<td>62.1 ± 5.7</td>
<td>69.4 ± 8.1</td>
<td>n.s.</td>
</tr>
<tr>
<td>Preoperative STAI score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating surgeon</td>
<td>12.1 ± 3.4</td>
<td>13.0 ± 4.1</td>
<td>n.s.</td>
</tr>
<tr>
<td>Anaesthetist</td>
<td>9.1 ± 2.5</td>
<td>9.7 ± 2.5</td>
<td>n.s.</td>
</tr>
<tr>
<td>Scrub nurse</td>
<td>12.8 ± 3.1</td>
<td>13.3 ± 2.6</td>
<td>n.s.</td>
</tr>
<tr>
<td>Circulating nurse</td>
<td>11.1 ± 2.1</td>
<td>10.2 ± 2.9</td>
<td>n.s.</td>
</tr>
<tr>
<td>ODP</td>
<td>8.6 ± 3.1</td>
<td>7.6 ± 2.4</td>
<td>n.s.</td>
</tr>
<tr>
<td>Postoperative radiological outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical alignment RMSE (degrees)</td>
<td>3.2 ± 1.2</td>
<td>1.5 ± 0.9</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>PCOR</td>
<td>0.3 ± 0.1</td>
<td>0.2 ± 0.1</td>
<td>n.s.</td>
</tr>
<tr>
<td>Posterior tibial slope RMSE (degrees)</td>
<td>3.4 ± 1.1</td>
<td>1.4 ± 0.6</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Joint line RMSE (mm)</td>
<td>2.9 ± 1.4</td>
<td>1.0 ± 0.6</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Femoral coronal alignment RMSE (degrees)</td>
<td>4.1 ± 1.1</td>
<td>1.0 ± 0.4</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Femoral sagittal alignment RMSE (degrees)</td>
<td>4.2 ± 0.8</td>
<td>2.1 ± 0.7</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Tibial coronal alignment RMSE (degrees)</td>
<td>3.6 ± 0.8</td>
<td>1.0 ± 0.5</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Tibial sagittal alignment RMSE (degrees)</td>
<td>3.9 ± 1.0</td>
<td>2.0 ± 0.6</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

Summary statistics are: mean with standard deviation
mean operative time for conventional jig-based TKA [20]. Operative times for the initial 20 robotic TKA cases ranged from 71 to 104 min for surgeon 1, and ranged from 74 to 142 min in surgeon 2. The wide variation in operative times over the first 20 cases suggest that the learning curve may have already been in effect and operative times comparable to those of conventional TKA may have been observed much earlier than reported. The authors also reported that after the initial learning phase, operative times in robotic-arm assisted TKA were comparable to those of conventional jig-based TKA, which is consistent with the findings of this study. In theory, robotic-arm assisted surgery helps to produce a more streamlined surgical procedure by reducing the need for instrument trays, alignment guides, and cutting blocks, enabling more rapid computer-guided bone resections, and reducing need for trialling due to the high accuracy of preoperative surgical planning [21]. However, in this study, these potential benefits with robotic TKA did not translate to faster operative times compared to conventional jig-based TKA.

Implementation of robotic-arm assisted TKA was associated with heightened levels of anxiety amongst the surgical team during the initial learning phase. This is important as higher levels of stress and mental strain are associated with diminished operative performance, poor decision-making, and reduced technical skills [14]. In this study, improvements in the surgical team’s anxiety levels with robotic-arm assisted TKA followed in a trend similar to that of operative times with baseline STAI scores reached after seven cases. Progressive improvements in anxiety scores during this initial learning phase correlated with the surgical team becoming more proficient with setting up the new trays and instruments, positioning the robotic machine in theatre, attaching the burr to the robotic arm, and proactively preparing the registration pins, check points, and arrays. As the team became more confident with these steps, subjective anxiety levels and operative times diminished. The highest anxiety levels were observed in the operating surgeon and scrub nurse during the initial learning phase but these did not translate into any differences in accuracy of implant positioning or limb alignment.

Cumulative robotic experience did not impact the accuracy of achieving the planned implant positioning, limb alignment, posterior condylar offset ratio, posterior tibial slope, or native joint line restoration. Robotic-arm assisted TKA uses bone registration to confirm intraoperative spatial orientation of the limb and fixed arrays accurately track the femoral and tibial bone resection windows throughout the procedure. Stereotactic boundaries also confine bone resection to the limits of the haptic windows, which helps to reduce manual errors in bone resection and iatrogenic soft tissue injury from the handheld sawblade used in conventional TKA [11, 12]. The robotic procedure, therefore, limits bone resection to the preoperative surgical plan and this may have helped to limit any surgeon-induced errors in implant positioning during the learning phase.

Robotic-arm assisted TKA was associated with improved accuracy in implant positioning and limb alignment compared to conventional jig-based TKA, which is important as these outcomes affect functional recovery, clinical outcomes, and long-term implant survivorship [8, 18, 19, 22]. The findings of this study are consistent with those of Song et al. who performed a prospective randomized study on 100 patients undergoing primary TKA and found robotic-arm assisted surgery improved accuracy of mechanical alignment with reduced outliers of greater than 3° in planned alignment compared to conventional manual TKA (0 versus 24%, p < 0.001) [22]. Bellemans et al. reviewed outcomes in 25 patients undergoing robotic-arm assisted TKA and found femoral and tibial implant alignment within 1° of the planned positions in all three planes [3]. Improved accuracy in preserving the native posterior tibial slope and joint line within the robotic group in this study are also significant findings as previous studies have shown that these radiological outcomes correlate with improved patient satisfaction, stability, and kinematics through the arc of motion following TKA [5, 10].

There are several limitations of this study that must be appreciated when interpreting the findings. First, accuracy of implant positioning and limb alignment was measured using plain radiographs, which are not as accurate as CT scans. Second, different preoperative planning techniques were used in each treatment group, which may have affected the accuracy of implant positioning achieved with each treatment technique. Third, the surgical team in this study are all experienced in working with both conventional and navigated TKA in a high-volume arthroplasty centre, and therefore, their learning curve may not be directly transferrable to other less experienced teams. Fourth, follow-up time was limited to 30 days following surgery and so long-term data on functional outcomes, implant survivorship and revision rates were not available. Fifth, additional costs and impact on other operative cases due to increased operating times during the learning phase were not assessed.

The findings of this study will enable healthcare professionals to better understand the impact of implementing robotic-arm assisted TKA on the surgical workflow. Theatre planning and scheduling of operative cases should consider increased operative times and heightened levels of anxiety amongst the surgical team during this initial learning phase. As team members become more familiar and adept with robotic technology, comfort levels improve and theatre efficiency increases thereafter. After the initial learning phase of robotic-arm assisted TKA, operative times with robotic TKA will be comparable to those with conventional manual TKA. There is no impact of cumulative experience with robotic-arm assisted TKA on accuracy of implant
positioning or limb alignment, which is important for the safe implementation of this procedure into routine surgical practice. Robotic-arm assisted TKA improves accuracy of implant positioning with no additional risk of postoperative complications at short-term follow-up compared to conventional manual TKA.

**Conclusion**

Implementation of robotic-arm assisted TKA alters the surgical workflow with increased operative times and heightened levels of anxiety amongst the surgical team for the initial seven cases but this does not translate to any compromise in the accuracy of implant positioning. Robotic-arm assisted TKA improved accuracy of implant positioning and limb alignment compared to conventional jig-based TKA.

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**Compliance with ethical standards**

**Conflict of interest** The author F.S. Haddad is a paid consultant that receives royalties from Stryker Limited. The other authors have no conflicts of interest to declare in relation to this study.

**Ethical approval** Hospital board approval was obtained from the host institution (Reference: 241413, Princess Grace Hospital, 42–52 Nottingham place, Marylebone, London, W1U 5NY, UK). No further REC or HRA approval was required for this study.

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**References**

The management of prosthetic joint infection (PJI) following total hip (THA) and knee arthroplasty (TKA) remains challenging. Although rare, with an incidence as low as 0.39% after TKA and higher (0.97%) in revision cases, PJIs are associated with significant morbidity and socioeconomic burden.

Whether operative management should be undertaken as a single- or two-stage procedure remains controversial. Routine surgical treatment for a chronic PJI currently in the United Kingdom and North America involves a two-stage approach. However, this requires long periods of time in hospital and considerable functional morbidity and socioeconomic burden. Since early descriptions of single-staged exchange arthroplasty for infection, in the 1980s, this approach has slowly gained popularity for use in selected patients, potentially allowing less morbidity and better functional outcomes. As it involves fewer procedures, it is also more cost-effective, with a shorter period of hospitalization and reduced use of antibiotics. However, aggressive debridement of bone and soft tissue with removal of components and cement is required, which can result in significant bone loss requiring expert reconstructive surgery.

**Indications for a single-stage exchange arthroplasty for chronic prosthetic joint infection**

**A SYSTEMATIC REVIEW**

**Aims**

Prosthetic joint infections (PJIs) of the hip and knee are associated with significant morbidity and socioeconomic burden. We undertook a systematic review of the current literature with the aim of proposing criteria for the selection of patients for a single-stage exchange arthroplasty in the management of a PJI.

**Material and Methods**

A comprehensive review of the current literature was performed using the OVID-MEDLINE, EMBASE, and Cochrane Library databases and the search terms: infection and knee arthroplasty OR knee revision OR hip arthroplasty OR hip revision, and one stage OR single stage OR direct exchange. All studies involving fewer than ten patients and follow-up of less than two years in the study group were excluded as also were systematic reviews, surgical techniques, and expert opinions.

**Results**

The initial search revealed 875 potential articles of which 22 fulfilled the inclusion and exclusion criteria. There were 16 case series and six comparative studies; five were prospective and 14 were retrospective. The studies included 962 patients who underwent single stage revision arthroplasty of an infected hip or knee joint. The rate of recurrent infection ranged from 0% to 18%, at a minimum of two years’ follow-up. The rate was lower in patients who were selected on the basis of factors relating to the patient and the local soft-tissue and bony conditions.

**Conclusion**

We conclude that single-stage revision is an acceptable form of surgical treatment for the management of a PJI in selected patients. The indications for this approach include the absence of severe immunocompromise and significant soft-tissue or bony compromise and concurrent acute sepsis. We suggest that a two-stage approach should be used in patients with multidrug resistant or atypical organisms such as fungus.

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In 2013, the proceedings of an International Consensus Meeting on PJI concluded that single-stage arthroplasty was a reasonable option in certain circumstances, with 78% of delegates voting in favour of this conclusion. Four years later, we aimed, in this study, to provide an update of this statement by performing a systematic review looking at the indications for single stage revision THA and TKA for PJI, with the specific aim of proposing criteria for selecting patients for this form of treatment. In particular, we wished to consider how factors such as the immunological status of the patient, the condition of the soft tissues, and the microbiological profile have on the rate of recurrent infection after single-stage exchange arthroplasty.

Materials and Methods
The review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for systematic reviews. Patients with an infected THA or TKA who were treated with a single-stage exchange procedure were to be compared with those who were treated with a two-stage procedure. The outcome measure was recurrent infection following surgery.

A comprehensive literature search was performed in February 2018 looking at single stage revision arthroplasty for PJI in the last 20 years. OVID-EMBASE, MEDLINE, and Cochrane Library databases were used and the reference lists of all relevant publications were examined and appropriate studies included in the final analysis. The search strategy was developed by the first author (RRT) and a literature search was performed using: infection and knee arthroplasty OR knee revision OR hip arthroplasty OR hip revision and one stage OR single stage OR direct exchange. All prospective and retrospective cohort and case control studies and case series were included. The absence of randomized controlled trials (RCTs) dealing with this issue has previously been described. Studies with less than ten patients in the study group, those with a minimum follow-up of less than two years, and those reporting operative management other than a single-stage revision were excluded. Only studies available in English were analyzed. Further exclusion criteria included: review articles, surgical techniques, and expert opinions; publications involving only abstracts; publications without microbiological details; and publications reporting operations for indications other than a confirmed PJI. Following the initial search, abstracts were independently screened for eligibility by two authors (RRT and SH). Discrepancies were referred to the senior author (FSH) if a consensus was not achieved. The full texts were then examined to identify the studies that were to be included in the analysis.

The study protocol was designed to identify criteria contributing to recurrent infection after single-stage revision for PJI. The data that were extracted included year of publication, type of arthroplasty (THA or TKA), the number of patients in the single-stage revision arm of the study, the number with microbiology results, and whether immunocompromised patients and those with soft-tissue/bony defects were included. The individual papers’ descriptions of extent of lesion were used; in many cases, there was limited information in the results from the studies to allow us to classify the extent of the soft-tissue/bony lesions. Finally, the rate of recurrent infection was identified.

Results
The preliminary search produced 875 studies (Fig. 1), of which 111 were potentially relevant to the study. The texts were scrutinized independently and, based on the inclusion and exclusion criteria, 22 studies involving 962 patients were included in the review (Table I). A total of 15 studies included PJI after THA, six studies included PJI after TKA, and one study included both.

There were five prospective studies, one comparative and four case series, and 14 retrospective studies. In three of the studies, it was not apparent from the methodology as to whether the study was conducted retrospectively or prospectively. As predicted, there were no RCTs, but six comparative studies and 16 case series in total. The rate of recurrence was between 0% and 18%, and a total of 62 patients (6%) had a recurrent PJI.

Looking at the microbiological profile of the patients, in 15 out of the 22 studies, a coagulase-negative staphylococcus, including S. epidermidis, was the most common causative organism for the index infection, followed by S. aureus (4/22 studies).

Five studies excluded immunocompromised patients and those with soft-tissue compromise or a bony defect, as being unsuitable for a single-stage revision. The rate of recurrence in this group of studies was within the lowest, between 0% and 8.9%. Patients with soft-tissue compromise or a bony defect only were excluded from a single-stage revision in a further five studies with a rate of recurrent infection of between 0% and 10%. Although another two studies also excluded such patients and reported low recurrence rates, 0% and 5%, they failed to comment on the immunological status of the patients. Immunocompromised patients with soft-tissue compromise or a bony defect were included in seven studies; the rate of recurrent infection in this group was the highest, between 4.2% and 18%.

Fig. 1
Flow diagram of the study.
Discussion

The evidence for best practice in the management of PJIs is evolving. Single-stage revision has become more popular in recent years, following the publication of a number of studies reporting comparable, if not better, outcomes of single stage compared with two-stage procedures with an associated reduction in morbidity, mortality, and financial and sociological burden. What appears to be evident from our review is that outcomes following a single-stage procedure are affected by many factors based on the immunological status of the patient, the local soft-tissue and bony characteristics, and the microbiological profile. Promising infection-free outcomes have been reported when strict criteria for the selection of patients are applied.

In 2015, Haddad et al described a series of 28 patients who underwent single stage revision of a chronically infected TKA without a recurrence, at a minimum follow-up of three years. Their cohort accurately matched the patients’ local and microbiological criteria used in this study, concluding that a single-stage revision strategy may be utilized in the absence of significant soft-tissue/bony defects, significant host immunocompromise, and unknown microbiology or atypical multiresistant organisms. In 2010, Oussedik et al reported a similarly successful infection-free survival following a single-stage revision for patients with an infected THA at a mean follow-up of seven years. These studies, however, had short to medium term follow-up only. The study with the longest mean follow-up that echoed these results in our review was by Ure et al, who described 20 infected THAs with no recurrence at a mean follow-up of 9.9 years.

During our literature search, we identified one study that reported that patient selection had no impact on outcome following single-stage exchange arthroplasty. Jenny et al retrospectively compared outcomes between two centres performing single-stage revision for infected TKAs. One centre performed the procedure without patient selection, the other only included patients based on specific criteria, with rates of recurrent infection of 17% and 21%, respectively. Although the authors drew strong conclusions, in the absence of a surgical protocol guiding the type of implant and antibiotic impregnated cement that were used, there remains the potential of bias. Furthermore, the overall rate of recurrent infection in their study was comparably higher as compared with the aforementioned studies in which patient-selection criteria were used.

Role of preoperative microbiological profile on outcomes of OSEA. Early experience of single-staged exchange arthroplasty

Table I. Details of the studies

<table>
<thead>
<tr>
<th>Study (year)</th>
<th>Patients included in review, n</th>
<th>Mean follow-up, yrs</th>
<th>Patients with microbiological results, n</th>
<th>Immuno-compromised host</th>
<th>Compromised soft-tissue/bone defect</th>
<th>Reinfection, n (%)</th>
<th>Level of evidence</th>
<th>Revised arthroplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bori et al (2018)</td>
<td>17</td>
<td>3</td>
<td>12</td>
<td>Included</td>
<td>Included</td>
<td>1 (5.8)</td>
<td>IV (Retros)</td>
<td>THA</td>
</tr>
<tr>
<td>Lange et al (2017)</td>
<td>56</td>
<td>4</td>
<td>41</td>
<td>Excluded</td>
<td>Excluded</td>
<td>5 (8.9)</td>
<td>IV (Pros)</td>
<td>THA</td>
</tr>
<tr>
<td>Born et al (2016)</td>
<td>28</td>
<td>7</td>
<td>27</td>
<td>Included</td>
<td>Excluded</td>
<td>0 (0)</td>
<td>III</td>
<td>THA</td>
</tr>
<tr>
<td>Jenny et al (2016)</td>
<td>54 (study group)</td>
<td>3</td>
<td>53</td>
<td>Included</td>
<td>Included</td>
<td>9 (17)</td>
<td>III (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Ilchmann et al (2016)</td>
<td>39</td>
<td>6</td>
<td>39</td>
<td>N/A</td>
<td>Excluded sinus/abscess</td>
<td>0 (0)</td>
<td>IV (Retros)</td>
<td>THA</td>
</tr>
<tr>
<td>Zahar et al (2016)</td>
<td>70</td>
<td>10</td>
<td>70</td>
<td>Included</td>
<td>Included</td>
<td>5 (7)</td>
<td>IV (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Jenny et al (2014)</td>
<td>65</td>
<td>5</td>
<td>62</td>
<td>N/A</td>
<td>N/A</td>
<td>11 (16)</td>
<td>IV</td>
<td>TKA</td>
</tr>
<tr>
<td>Haddad et al (2015)</td>
<td>28</td>
<td>6</td>
<td>28</td>
<td>Excluded</td>
<td>Excluded</td>
<td>0 (0)</td>
<td>III (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Tibrewal et al (2014)</td>
<td>50</td>
<td>10</td>
<td>50</td>
<td>Included</td>
<td>Excluded</td>
<td>1 (2)</td>
<td>IV (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Zeller et al (2014)</td>
<td>157</td>
<td>3</td>
<td>157</td>
<td>Included</td>
<td>Severe bone defect excluded</td>
<td>8 (5)</td>
<td>IV (Pros)</td>
<td>THA</td>
</tr>
<tr>
<td>Klatte et al (2014)</td>
<td>10</td>
<td>7</td>
<td>10 (fungal infection)</td>
<td>Included</td>
<td>Excluded</td>
<td>1 (10)</td>
<td>IV (Retros)</td>
<td>THA/TKA</td>
</tr>
<tr>
<td>Klatte et al (2014)</td>
<td>100</td>
<td>3</td>
<td>100</td>
<td>Included</td>
<td>Included</td>
<td>4 (4)</td>
<td>III (Retros)</td>
<td>THA</td>
</tr>
<tr>
<td>Bori et al (2014)</td>
<td>24</td>
<td>4</td>
<td>24</td>
<td>Included</td>
<td>Included</td>
<td>1 (4.2)</td>
<td>IV (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Choi et al (2013)</td>
<td>17</td>
<td>5</td>
<td>15</td>
<td>Included</td>
<td>Included</td>
<td>2 (18)</td>
<td>III (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Jenny et al (2013)</td>
<td>47</td>
<td>3</td>
<td>47</td>
<td>Included</td>
<td>Included</td>
<td>6 (13)</td>
<td>IV (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Klouche et al (2012)</td>
<td>38</td>
<td>3</td>
<td>38</td>
<td>Included</td>
<td>Severe bone defect excluded</td>
<td>0 (0)</td>
<td>III (Pros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Singer et al (2012)</td>
<td>63</td>
<td>3</td>
<td>63 (excluded MRSA, MRSE)</td>
<td>N/A</td>
<td>Excluded</td>
<td>3 (5)</td>
<td>IV (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Oussedik et al (2010)</td>
<td>11</td>
<td>7</td>
<td>11</td>
<td>Excluded</td>
<td>Excluded</td>
<td>0 (0)</td>
<td>IV (Pros)</td>
<td>THA</td>
</tr>
<tr>
<td>Rudelli et al (2008)</td>
<td>32</td>
<td>8</td>
<td>29</td>
<td>Excluded</td>
<td>Included</td>
<td>2 (6.2)</td>
<td>IV</td>
<td>THA</td>
</tr>
<tr>
<td>Yoo et al (2009)</td>
<td>12</td>
<td>7</td>
<td>12</td>
<td>Excluded</td>
<td>Excluded</td>
<td>1 (8.3)</td>
<td>V (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Callaghan et al (1999)</td>
<td>24</td>
<td>11</td>
<td>24</td>
<td>Excluded</td>
<td>Severe bone defect excluded</td>
<td>2 (8.3)</td>
<td>IV</td>
<td>THA</td>
</tr>
<tr>
<td>Ure et al (1998)</td>
<td>20</td>
<td>9.9</td>
<td>20</td>
<td>N/A</td>
<td>Included</td>
<td>0 (0)</td>
<td>IV (Pros)</td>
<td>THA</td>
</tr>
</tbody>
</table>

Retros, retrospective; Pros, prospective; THA, total hip arthroplasty; TKA, total knee arthroplasty; N/A, not available; MRSA, methicillin-resistant Staphylococcus aureus; MRSE, methicillin-resistant Staphylococcus epidermidis
by Buchholz et al27 in 1981, reported an overall success rate of 77% in a series of 583 patients. They noted that the microbiological profile was important in determining outcome, with polymicrobial infections and atypical and gram-negative organisms being associated with a higher failure rate. These findings have later been confirmed by Jackson et al,28 in 2000, in a review of the literature. These authors concluded that in addition to these factors, infection with MRSA or MRSE resistant organisms was associated with a poor outcome.

Excellent results have been reported in a number of series, with infection free survival of between 92% and 100% in patients in whom the microbiological details were established preoperatively,14,17,18,21,25,39 supporting previous guidance from the International Consensus Meeting on Periprosthetic Joint Infection9 and the Infectious Disease Society of America.40 More recently, however, Ichmann et al32 reported no recurrent infections following single-stage revision of 39 infected THAs, despite six patients having a negative preoperative culture. The importance of predetermined microbiology has also been indirectly questioned by some recent studies. Lange et al29 in a series of 56 patients, reported a 91% infection-free rate, despite 15 having negative preoperative cultures. Only one of the five failures had a negative culture. Bori et al25, in 2014, reported a series of 24 infected THAs; five patients did not have preoperative aspiration and a further three had a negative growth. All patients had positive intraoperative cultures and, despite this, there was no adverse effect on the rate of recurrent infection, which was 4.2% (1/24).

On this basis, it seems that the lack of a preoperative microbiological diagnosis may be a relative, rather than an absolute contraindication, to a single stage revision. What appears to be more important is the identification of the microorganism perioperatively with available information on sensitivities to allow early appropriate antibiotic treatment. Fungal PJIs present particular challenges. They often present in immunocompromised patients against a background of previous complex surgery and, hence, a two-stage procedure has traditionally been used.41 In 2014, the ENDO-Klinik published their experience in the management of fungal PJIs using a single-stage approach. Klatte et al30 reported a retrospective series of ten patients with six THAs and four TKAs, with a single recurrent infection requiring further surgery. Their approach included preoperative identification of the causative organism and appropriate antibiotic and antifungal treatment postoperatively. Neither immunocompromised patients nor those with a sinus tract were excluded, and five patients were diabetic and five had a soft-tissue lesion. The single recurrence was in a severely immunocompromised diabetic patient on long-term steroid treatment. Their results suggest that where a fungal infection is identified preoperatively, single-stage revision surgery may be considered.

The effect of host immunity on OSEA. Host and local factors have also been highlighted as important determinants of outcome of single-stage revision.42 In particular, the integrity of the patient’s immune system appears to play a role when deciding on single-stage versus two-stage surgery.43 The term ‘immunocompromised’ can be applied to any patient with a defect in their defences against infection. We found this term to be somewhat heterogeneously used to describe drug-induced compromise such as by steroids or disease modifying antirheumatic drugs, malignancy, diabetes, or HIV disease. Patients with severe inflammatory arthropathy and conditions such as hepatitis were also often grouped into this category, probably due to their medication.44 Göksan et al,45 in 1992, described a small series of 18 patients who underwent single-stage revision of an infected TKA, with eradication of infection in 16 (94%), at a mean follow-up of five years. The profile of the patients in this series matched some of the criteria set out by the International Consensus Meeting9 in 2013 to include absence of systemic sepsis and gross tissue inflammation. Both the patients with recurrent infection had severe immunosuppression.

In a retrospective study, Wolf et al46 classified their patients using the McPherson staging system. They concluded that the eradication of infection was better following two-stage compared with single-stage revision procedures when the patient’s status (McPherson type B + C patients) was compromised (95% eradication for two-stage vs 33% for one-stage). A similar result was observed in the presence of significant local soft-tissue and bony compromise (McPherson Grade 3) factors (95% eradication for two-stage vs 0% for one-stage). More recently, Bori et al34 described 19 consecutive single stage revision THAs with a 95% cure rate at a follow-up of one year. They noted an absence of significant bony defects intraoperatively, with only four patients requiring bone grafting, as a potential contributing factor to a successful outcome.

The effect of the presence of a sinus tract on outcomes of OSEA. The presence of a sinus tract appears to adversely affect the outcome in some studies. In a series by Jenny et al,31 of the 11 cases of recurrent infection reported, six patients (55%) originally presented with a sinus tract as their index symptom. Similarly, of the five recurrent infections in a series reported by Lange et al,13 involving 56 patients, three had a sinus tract at the time of presentation and one had an abscess. Despite these findings, however, Jenny et al,28 in their earlier series of 47 patients with an infected TKA, recorded that 41 (87%) were infection-free at a minimum follow-up of three years despite the fact that 20 (43%) presented with a sinus. Only two of those with a sinus at presentation had a recurrent infection. In 2008, Rudelli et al32 drew a similar conclusion based on a series of 32 patients who underwent single-stage revision THA; two (6%) had recurrent infection at a mean follow-up of 8.5 years. It therefore seems that a discharging sinus is, in itself, not an absolute contraindication to a single-stage revision, a conclusion also drawn in an earlier study by Raut et al.47

In conclusion, single-stage exchange arthroplasty remains an acceptable form of surgical treatment for the management of a chronic PJI in selected patients with the prospect of promising infection-free survival. The lowest reinfection rates after this procedure are in patients without immune compromise and significant soft-tissue and bony defects. Much of this evidence, however, is based on the analysis of retrospective observational studies. There remains little high-quality evidence addressing this issue. A limitation of this review is the absence of RCTs. Our conclusions have been drawn from the analysis of prospective and retrospective studies, level 3 evidence, and level 4
Evidence. Selection bias, therefore, is unavoidable, due to the nature of these studies. Stronger conclusions may be drawn in the future following the results of RCTs such as the Infection Orthopaedic Management (INFORM) trial and the recently registered multicentre study by Fehring et al. 

None the less, this review represents a summary of the best available current evidence and on this basis, it may be suggested that single-stage exchange arthroplasty be undertaken in the absence of the following features: severe immunosuppression or without significant systemic disease; concurrent acute local sepsis and soft-tissue or bony compromise not amenable to primary wound closure; and multidrug resistant, polymicrobial or atypical organisms. The lack of preoperatively identified infective organisms seems to represent a relative contraindication to this procedure.

Take home message
- Single-stage revision is a plausible option for the management of prosthetic joint infections in a selected group of individuals.
- Indications include an absence of concurrent sepsis, host immunocompromise, and soft-tissue or bony compromise.
- Knowledge of microbiological profile in the perioperative period is also associated with a more favourable outcome.

References


**Author contributions:**
R. R. Thakrar: Designing the study, Literature search, Analyzing the data, Preparing the manuscript.
S. Horriat: Literature search, Analyzing the data, Preparing the manuscript.
B. Kayani: Preparing the manuscript.
F. S. Haddad: Preparing the manuscript, Supervising the study.

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Robotic unicompartmental knee arthroplasty
CURRENT CHALLENGES AND FUTURE PERSPECTIVES

B. Kayani, F. S. Haddad

Unicompartmental knee arthroplasty (UKA) is an established and highly effective treatment for patients with end-stage disease affecting one compartment of the knee joint. The procedure accounts for between 8% and 10% of all knee arthroplasty procedures performed in the United Kingdom and United States. There are several advantages of performing UKA over total knee arthroplasty (TKA), including reduced operating time, decreased intraoperative blood loss, reduced periarticular soft-tissue trauma, improved preservation of bone stock, better restoration of native kinematics, increased patient satisfaction, and improved functional outcomes. However, UKA is associated with decreased implant survivorship and increased revision rates compared with TKA. Accuracy of component positioning and limb alignment are important prognostic variables that affect implant survival and time to revision surgery following UKA. Consequently, techniques that improve the accuracy of implant positioning and limb alignment in UKA may help to improve long-term survivorship and reduce the burden of revision disease.

Experts from a range of industries, including aviation training, military activity, financial services, and medical care, have shown that each industry moves through five distinct phases: 1) consideration of the industry as an art by specialists within the field; 2) development of specific rules and instruments; 3) creation of standardized protocols and procedures; 4) automation; and 5) integration of computer technology. During the final phase, accurate objective real-time data provided by computerized systems help to minimize the risk of system error, improve efficiency, and optimize productivity. Within the healthcare industry, robotic technology has been implemented in general surgery, urology, cardiology, ophthalmology, and gynaecology to minimize human error, improve surgical precision, enhance postoperative rehabilitation, and improve long-term clinical outcomes.

Over the last decade, robotic technology has gained momentum as an avenue for improving accuracy of implant positioning and limb alignment compared with conventional jig-based techniques for UKA.

Cobb et al conducted a prospective randomized study on 27 patients with medial compartment knee osteoarthritis undergoing conventional jig-based UKA versus robotic UKA. The authors reported that all patients undergoing robotic UKA had tibiofemoral alignment in the coronal plane within 2° of the planned position, compared with only 40% in those undergoing conventional jig-based UKA. Bell et al performed a prospective randomized controlled study assessing accuracy of implant positioning using postoperative CT scans in 62 robotic UKAs versus 58 conventional UKAs, and found that robotic UKA reduced root mean square errors in achieving planned femoral and tibial implant positioning. Herry et al retrospectively reviewed plain radiographs in 40 conventional jig-based UKAs versus 40 robotic UKAs, and found improved restoration of the native joint line with robotic-guided surgery. Improved accuracy of implant position with robotic UKA may help to improve long-term implant survivorship and facilitate implementation of cementless implants for future UKA implant designs.

Studies using data from three separate national joint registries have demonstrated a relationship between the surgical (or unit)
case-load and revision rate following UKA. Surgeon-controlled errors in implant positioning are the most common reason for implant failure, and low case volume has been identified as a risk factor for early revision surgery following UKA. Liddle et al reviewed outcomes of 41,986 UKAs from the National Joint Registry for England and Wales, and found that optimal outcomes (as assessed using revision rates) were achieved with UKA usage in between 40% and 60% of a surgeon’s practice. Acceptable revision rates were achieved with UKA usage in 20% or more of UKA practice, while surgeons with the lowest usage (less than 5%) had the highest revision rates. However, achieving optimal UKA usage is challenging, owing to the limited number of patients with single compartment disease and strict inclusion criteria for conventional UKA.

Robotic UKA uses a preoperative CT scan (image-guided) or intraoperative osseous registration (imageless) to create a patient-specific virtual 3D reconstruction of the knee joint. The surgeon uses this virtual model to plan optimal bone coverage, implant positioning, and limb alignment for each patient’s unique knee anatomy. An intraoperative robotic arm then helps to execute this plan with a high level of accuracy, and stereotactic boundaries limit bone resection to the predefined femoral and tibial haptic windows. There is no learning curve effect in robotic UKA for accuracy of achieving the planned femoral or tibial implant positioning, posterior condylar offset ratio, limb alignment, and restoration of native joint line. Robotic technology offers an opportunity for low-volume UKA surgeons to achieve high levels of accuracy in implant positioning. Robotic UKA may thus help overcome the current challenges of surgeons or units/departments needing to achieve minimum UKA case volumes to minimize the risk of surgeon-induced errors in implant positioning.

Achieving proper soft-tissue tensioning and ligamentous balancing are important technical objectives for optimizing stability and long-term functional outcomes in UKA. In conventional jig-based surgery, assessment of the periarrticular soft-tissue tension and limb alignment are performed manually, which is dependent on the skill and expertise of the operating surgeon. Robotic UKA uses optical motion capture technology to provide real-time medial and lateral gap measurements while applying valgus/varus strain to appropriately tension the ligaments through the arc of flexion. These patient-specific intraoperative data may be used to fine-tune implant positioning to achieve the desired ligamentous tension and limb alignment. Intraoperative data on the ‘tightness’ and ‘looseness’ of the knee joint through the arc of flexion may be used to further adjust bone resection, implant sizes, and implant positions to achieve the desired knee kinematics. Further studies are required to establish if the improved ligament tensioning in robotic UKA translates to differences in knee kinematics, implant stability, and range of movement compared with conventional manual UKA.

Bone resection in robotic knee arthroplasty is restricted to the confines of the stereotactic boundaries, which may help to reduce periarticular soft-tissue injury and enhance postoperative rehabilitation compared with conventional manual knee arthroplasty. Kayani et al conducted a prospective cohort study on 146 patients showing robotic UKA was associated with reduced postoperative pain, decreased opiate analgesia consumption, reduced inpatient physiotherapy, and decreased mean time to hospital discharge compared with conventional manual UKA (42.5 hours (SD 5.9) vs 71.1 hours (SD 14.6), respectively; p < 0.001). Blyth et al performed a prospective randomized control trial on 139 patients and reported robotic UKA reduced median pain scores by 55.4% compared with conventional manual UKA from postoperative day one to week eight after surgery. As many arthroplasty centres move towards day case UKA, robotic UKA may help to facilitate this practice through improved pain control, enhanced functional rehabilitation, reduced need for physiotherapy, and earlier time to hospital discharge.

Improved accuracy of implant positioning in robotic UKA has not been shown to improve mid-term to long-term clinical or functional outcomes compared with conventional jig-based UKA. Blyth et al reported that robotic UKA was associated with improved American Knee Society Score for three months following surgery, but there was no difference in functional outcomes observed between conventional and robotic UKA at one year after surgery. Subgroup analysis of the 35 most active patients revealed robotic UKA improved Knee Society Scores, Oxford Knee Scores, and Forgotten Joint Scores compared with conventional manual UKA at two years’ follow-up. More recently, Canetti et al reviewed outcomes in 28 highly active patients undergoing lateral compartment UKA, and found that robotic UKA enabled markedly earlier mean return to sporting activity compared with conventional UKA (4.2 months (SD 1.8) vs 10.5 months (SD 6.7), respectively; p < 0.01). These studies suggest that robotic UKA enables improved short-term functional outcomes in highly active patients, although overall functional outcomes are comparable to those of conventional jig-based UKA. Many studies have shown excellent functional outcomes with both treatment techniques for UKA and therefore subgroup analysis is essential for overcoming the ceiling effect with routine patient-reported outcome measures.

Aseptic loosening and progression of osteoarthritis in the remaining native knee compartments are common reasons for failure in UKA. Robotic technology enables accurate intraoperative assessment of limb alignment to avoid overcorrection, which may help to limit disease.
progression in the other compartments and improve time to revision surgery compared with conventional manual UKA. Pearle et al. conducted a prospective, multicentre review of 1135 robotic UKAs and found implant survivorship was 98.8% at a minimum of 22 months’ follow-up, which is superior to the survival rates of conventional UKA reported in the national joint registries of the United Kingdom (95.6%), Sweden (95.3%), Australia (95.1%), and New Zealand (96.1%). Batailler et al. compared outcomes in 80 conventional UKAs versus 80 robotic UKAs, and found revision rates in robotic UKA were 5% compared with 9% in conventional manual UKA, although this difference was not statistically significant. Importantly, 86% of revisions in the conventional group were secondary to component malposition or limb malalignment, compared with none in the robotic group.

Moschetti et al. used a Markov decision analysis tool to compare cost-effectiveness of conventional UKA versus robotic UKA. Using a two-year failure rate of 1.2% for robotic UKA and 3.1% for manual UKA, the authors reported that robotic UKA was a cost-effective procedure compared with manual UKA if robotic UKA case volume exceeded 94 cases per year. However, these findings should be interpreted with caution as several additional costs with robotic technology were overlooked. Robotic UKA is also associated with substantial costs for installation of the robotic device, additional preoperative CT scanning, further training for surgical staff, and increased operative times during the initial learning phase. Many robotic devices are also only compatible with specific implants and therefore additional costs for purchasing equipment and implants must be considered in any future cost analysis. Further studies on resource use and cost-effectiveness on conventional versus robotic UKA are required before this technology can be implemented into mainstream UKA practice.

Overall, robotic UKA improves accuracy of implant positioning, enhances postoperative functional rehabilitation, and improves early functional outcomes in highly active individuals compared with conventional jig-based UKA. Robotic technology also provides live intraoperative data on knee kinematics through the arc of flexion that can be used to fine-tune implant positioning and optimize soft-tissue tensioning. Robotic UKA offers a unique opportunity for low-volume arthroplasty surgeons to achieve high levels of accuracy in implant positioning, which may help to improve implant survivorship and reduce the burden of revision disease. However, further studies are required to assess the effect of robotic UKA on long-term functional outcomes, implant survivorship, cost-effectiveness, and complications compared with conventional jig-based UKA.

References


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Acute Surgical Excision of a Traumatic Fat Fracture in a Professional Soccer Player

Babar Kayani\(^1\), Atif Ayub\(^1\), Elliot Onochie\(^1\), Fares S Haddad\(^1\)\(^2\)

**Learning Point of the Article:**
Acute surgical excision of a traumatic fat fracture may be used as an avenue for reducing pain, enhancing functional rehabilitation, and facilitating early return to pre-injury level of function.

**Abstract**

**Introduction:** Surgical excision of fat fractures is often reserved for patients with large chronic deformities to improve cosmetic appearance. To our knowledge, the acute surgical management of a traumatic fat fracture has not been previously reported.

**Case Report:** This case report describes the management of a professional soccer player that developed a traumatic fat fracture over the lateral thigh. The patient presented with persistent pain, reduced range of movement, and inability to participate in sporting activity. Symptoms were refractory to non-operative treatment. Following acute surgical excision of the fat fracture, the patient was able to make an early return to sporting activity with no complications at short-term follow-up.

**Conclusion:** Acute surgical excision of a traumatic fat fracture may be used as an avenue for improving pain, enhancing functional rehabilitation, and facilitating early return to pre-injury level of function.

**Keywords:** Acute, fat fracture, pain, trauma, surgery

**Introduction**

Fat fractures occur when blunt trauma leads to disruption in the architectural morphology of adipose tissue [1]. Although the term “fracture” usually describes discontinuation in the integrity of cartilage or bone, fat fractures represent a similar pathological process that leads to distortion of the organized septa within fat lobules [1, 2, 3]. Patients often present with persistent pain and localized tenderness over the affected region [1, 2, 3]. Adipose tissue over bone prominences of the gluteal region and knee joints is most commonly affected [1, 3]. Initial treatment consists of conservative management with avoidance of any exacerbating factors and progressive rehabilitation, but this is associated with significant delays in returning to pre-injury level of function and high risk of recurrence with further trauma [1,2]. Surgical treatment is often reserved for patients with persistent pain or large chronic deformities to improve the cosmetic appearance of the affected region [1,4,5, 6, 7]. To our knowledge, the early surgical treatment of a traumatic fat fracture has not been previously reported. This case report describes the acute surgical excision of a fat fracture in a professional soccer player, which enabled the patient to make an early return to sporting activity without any evidence of recurrence or complications at short-term follow-up. This case report will enable patients and health-care professionals to better understand the potential role of acute surgical excision of traumatic fat fractures in enhancing rehabilitation and restoring activity in patients with high functional demands.

**Case Report**

A 27-year-old professional soccer goalkeeper sustained blunt trauma to his left thigh while diving to catch a football. He immediately developed pain and swelling over the lateral aspect
of his left thigh below the greater trochanter. The pain was exacerbated by weight-bearing on the affected limb, radiated into the left gluteal region, and was associated with subjectively reduced range of movement in the left hip joint. He struggled with sprinting, jumping, and diving onto the affected side for the remainder of the match but managed to walk independently off the field of play after finishing the game. There was also an associated swelling over the zone of injury, which progressively increased in size in the hours following the match. The player did not have any other concurrent injuries and did not have any significant medical history. Clinical examination revealed a soft, fluctuant, lobulated mass measuring 5.0 cm × 4.0 cm approximately three finger breadths below the left greater trochanter. The mass was exquisitely tender to touch and located in the plane between the skin and underlying fascia. There was an associated effusion around the mass but no overlying erythema or breach in skin integrity. The skin was not warm to touch compared to the right side. There was no tenderness over the bony prominences of the anterior superior iliac supine, ischial tuberosity, greater trochanter, or iliac crest and no snapping of the iliotibial band over the greater trochanter. The patient had full active range of motion in the left hip and knee joints. Specialist hip tests including flexion abduction and internal rotation, flexion abduction and external rotation, Thomas test, and Ober’s test were negative. The patient had a normal gait and did not require any walking aids. Plain anteroposterior and lateral radiographs of the left hip joint and left femur were unremarkable. Magnetic resonance imaging (MRI) of the left thigh revealed a well-circumscribed, lobulated mass measuring 5.2 cm × 4.3 cm × 3.2 cm in size. This was arising from the adipose tissue located between the subcutaneous tissue and fascia immediately inferior to the left greater trochanter (Figs. 1 and 2) and was associated with a surrounding effusion (Fig. 3). There was no other bone or soft-tissue pathology identified on the MRI scan. These clinical and radiological findings were consistent with an acute traumatic fat fracture. The differential diagnosis included the following: Fat fracture, benign tumor (e.g., lipoma), malignant tumor (e.g., liposarcoma), abscess, and hematoma. The patient was reviewed by the team doctor and sports physiotherapist on the day of injury and commenced onto a supervised physiotherapy program the following day. Initial treatment consisted of resting the affected limb, avoiding any exacerbating positions or maneuvers, and limiting any pressure (e.g., laying on the affected side, tight clothing) over the zone of injury. The patient was commenced on regular non-steroidal anti-inflammatory medication. Physiotherapy consisted of isometric muscle exercises, core strengthening, neuromuscular control activities, cryotherapy, and hydrotherapy. After 3 weeks of conservative treatment, the patient still had persistent pain and tenderness over the lateral aspect of his left thigh and could not participate in any level of training or competitive sporting activity. The patient was further counseled about the likely diagnosis and further management options. These included continuing conservative treatment, acute surgical excision, or delayed surgical excision if symptoms persisted despite further rehabilitation. As a professional soccer goalkeeper, his main treatment priorities were early return to sporting activity and minimal risk of recurrence with diving onto the affected side in the future. The patient elected to undergo acute surgical excision of the traumatic fat fracture. The procedure was performed under general anesthetic with the patient in the lateral decubitus position. A longitudinal incision measuring 6 cm in length was centered over the soft-tissue mass, and dissection performed through the subcutaneous tissue down to the underlying capsule of the fat fracture. Finger dissection was performed between the underlying muscular fascia and the capsule of the fat fracture. Electrocautery was used to dissect fibrous bands adhering the cystic mass to the underlying fascia. The mass was excised with the surrounding capsule intact (Fig. 4). Hemostasis was performed and the wound closed with absorbable sutures. Histological analysis of the excised specimen revealed lobulated and focally degenerate adipose tissue. This was covered by a thick layer of inflamed fibrous tissue which extended into the lesion. There was no evidence of fat necrosis or any neoplastic process. The findings were consistent with the working diagnosis of a fat fracture. The patient was followed up in clinic at 2 weeks after surgery. The pain over
the left lateral thigh had completely resolved, and the patient had discontinued all analgesia. The patient had returned to his pre-injury level of sporting function without any problems. On examination, the wound was clean and wellhealed without any evidence of infection. There was no underlying collection or mass palpable, and he had full active range of motion in the left hip and knee joints. He did not require any walking aids and had a normal gait. The patient remained asymptomatic and continued to participate in full sporting activity without any complications at 1-year follow-up and was discharged from clinic at this time point.

Discussion
To our knowledge, this is the first report on the acute surgical excision of a traumatic fat fracture. The patient was a professional soccer goalkeeper that made an early return to his pre-injury level of sporting activity without any complications at short-term follow-up. Fat fractures were first described in 1972 as the “battered buttock syndrome” in a series of 12 female patients with chronic traumatic injuries leading to deformities in the gluteal region [1]. Of these, five patients were managed conservatively with improvements in pain and tenderness over the gluteal region reported at 3 months to 2 years follow-up. The remaining seven patients underwent successful surgical excision of large cosmetically deforming fat fractures causing chronic pain and/or long-standing disfigurement around the gluteal region. Individual case reports have also described ultrasound or MRI findings of fat fractures from the deltot, quadriceps, and Achilles tendon following blunt trauma [2, 3, 5]. More recently, a case report described the surgical management of a large chronic fat fracture of the lateral thigh with surgical excision, extensive rigotomy, and fat transfer from the inner thigh [4]. The initial blunt trauma occurred 2 years before surgical excision, and the patient did not have any pain or restriction in function from the fat fracture. Surgical excision was undertaken exclusively to improve the cosmetic appearance of the thigh. The indications, timing of surgery, and surgical technique were different from those in the current study. Fat fractures arise when blunt trauma to adipose tissue leads to changes in the vascularity and/or disruptions to the architecture of fat lobules, which are conventionally arranged in tiers and supported by horizontal and vertical fibrous septa [1]. Normal physiological forces cause the lobules to flatten and dissipate the energy through the septa into the tiers. However, excessive loads may sheer these septa and disrupt these fat lobules, which creates irregularity in the layer between the epidermis and the fascia [8, 9, 10]. Fat fractures are often managed conservatively with activity modification, isometric muscle exercises, core strengthening, and neuromuscular control activities [1, 2, 3]. Symptomatic relief may also be gained by the application of topical non-steroidal anti-inflammatory agents and/or adjuvant treatment with hydrotherapy and cryotherapy [1, 3, 4]. Surgical intervention is often reserved for patients with chronic pain or significant cosmetic deformity. In our study, the patient received only 3 weeks of conservative treatment but made very limited progress with pain and function over this time frame. Furthermore, he was professional soccer goalkeeper and therefore delays in returning to sporting activity, and future recurrences were of significant concern to his playing career. Acute surgical intervention enabled the fat fracture to be excised and the patient to make a rapid return to his pre-injury level of function without any complications at short-term follow-up.

Conclusion
Fat fracture is an important differential diagnosis in patients with soft-tissue injury after blunt trauma. MRI facilitates diagnosis of fat fractures and aids planning of any subsequent surgical intervention. Acute surgical excision of a traumatic fat fracture may be used as an avenue for reducing pain, enhancing functional rehabilitation, and facilitating early return to pre-injury level of function.

Clinical Message
Fat fractures are rare diagnoses that may lead to persistent pain and significant impairment in physical performance. Acute surgical excision of a traumatic fat fracture should be considered as a treatment option to enhance rehabilitation and restore early functional performance.

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How to Cite This Article
Total hip arthroplasty in patients with chronic liver disease: A systematic review

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Abstract – 

Introduction: Chronic liver disease (CLD) is a significant and increasingly prevalent co-morbidity in patients undergoing total hip arthroplasty (THA). These patients may develop metabolic bone disease (MBD) and systemic dysfunction, which pose challenges to THA surgery. This systematic review of literature aims to examine clinical outcomes and complications in patients with CLD undergoing THA and provide evidence-based approaches as to the optimization of their perioperative care.

Methods: A Pubmed search was performed, identifying eight studies on 28,514 THAs for inclusion. Two additional studies reported on 44 patients undergoing THA post liver transplant. These were reviewed separately.

Results: Increased early perioperative complications are reported recurrently. Review of long-term complications demonstrates an increased postoperative infection rate of 0.5% (p < 0.001) and perioperative mortality of 4.1% (p < 0.001). The need for revision surgery is more frequent at 4% (p < 0.001). Aetiology of need for revision surgery included; periprosthetic infection (70%), aseptic loosening (13%), instability (13%), periprosthetic fracture (2%) and liner wear (2%). THA in patients with liver transplants seems to offer functional improvement; however, no studies have formally assessed functional outcomes in the patient with active CLD.

Discussion: A multidisciplinary perioperative approach is suggested in order to minimize increased complication risks. Specific measures include optimizing haemoglobin and taking measures to reduce infection. This review also highlights gaps in available literature and guides future research to appraise functional outcomes, further detail long-term failure reasons and study any differences in outcomes and complications based on the range of operative approaches and available implant choices.

Key words: Hip arthroplasty, Hip replacement, Liver disease, Cirrhosis, Outcomes, Complications.

Introduction

Chronic liver disease (CLD) is the fifth most common cause of mortality worldwide and its prevalence is increasing [1]. Hepatitis B and C viruses are the most common causes of CLD. Other causes include alcohol, drugs, hereditary and autoimmune diseases. Improvements in medical care have meant that patients with CLD are also surviving longer. Total hip arthroplasty (THA) is indicated to treat debilitating symptoms of hip osteoarthritis, including in those patients with CLD, this following lifestyle modifications and medical management. Several causes of CLD such as Sarcoidosis and Haemochromatosis are themselves associated with joint pathology, which may require THA. Patients whose CLD is secondary to chronic alcohol excess, or who are on long-term corticosteroids to treat CLD, are at an increased risk of developing avascular necrosis of the femoral head, which again may necessitate THA.

Performing THA in patients with CLD is challenging as the disease process induces biological and structural changes in bone, termed metabolic bone disease (MBD), whilst there is also systemic dysfunction [2]. The precise aetiology of bone disorders is thought to differ across the various causes of CLD, and indeed most pathological processes described are still somewhat conjectural [3]. MBD leads to osteopaenia and osteoporosis [4], whilst abnormal bone remodelling leads to bowing of the proximal femur with thinning of the cortices and widening of the medullary canal [5]. These morphological changes increase the technical challenges of performing THA. In press-fit implants, poor bone quality and unusual morphology means an increased risk of intraoperative fractures, subsidence of the femoral stem and postoperative periprosthetic fractures.
In cemented implants, these abnormalities may lead to inadequate cement mantles and an increased risk of aseptic loosening [7]. Coagulopathies in CLD may impair visualization of the surgical field, challenging surgical approach, implant positioning and wound closure. Coagulopathies increase intraoperative blood loss and also compromise the ability to achieve well-prepared, dry bone for bone-cement interdigitation. The use of tranexamic acid in THA has been shown to reduce bleeding without increasing thromboembolic risk [8]. Acetabular THA components have shown good results with both cemented and uncemented techniques in osteoporotic bone [9]. Finally, diminished hepatic biosynthetic and reticulo-endothelial capabilities together with depleted nutritional reserves, increase the risk of poor wound healing, superficial and deep infections.

With regard to the CLD patient, studies in English literature have reviewed surgical outcomes when performing general surgeries, and cumulating mixed arthroplasty cases, with reports of increased morbidity and mortality [10]. However, there are limited data in English literature on the specific risks for CLD patients undergoing THA. The objective of this study was to gather and systematically review available evidence in this area, summating the risks that a medical team must be aware of when considering THA in the patient with CLD. In addition, this review aims to evaluate functional outcomes in this patient group to assess whether the known technical challenges in this patient group are being successfully overcome.

Materials and methods

Search strategy

Databases PUBMED, MEDLINE and EMBASE were searched to identify relevant studies in English literature that addressed the results of THA in patients with CLD between 1980 and August 2019. This was performed in line with the PRISMA statement. Keywords used for the searches were “hip arthroplasty” OR “total hip arthroplasty” OR “total hip replacement” AND “Chronic Liver disease” OR “Liver Failure”, OR “Cirrhosis” OR “Hepatitis”. The bibliographies of included studies and relevant foundation materials were reviewed judiciously to identify any supplementary studies for the review and for pertinent background materials.

Eligibility criteria

Inclusion criteria included all papers, describing the results of THA in patients with CLD published in the English language. Isolated case reports/series with five or less patients were excluded. The included articles met the PICO criteria (Population, Intervention, Comparison and Outcomes) for systematic reviews. Figure 1 is the PRISMA flowchart illustrating the systematic search and screening strategy resulting in the final number of records included.

Data extraction

One reviewer extracted data through a standardized data collection form, and then another reviewer checked the data for accuracy. Any issues flagged up, or discrepancies in results were resolved by discussion. Data on the number of patients, age, follow-up period, type of implant, type of fixation, complications, re-operations, revision rate and functional outcomes were extracted and entered in a spreadsheet.

Statistical analysis

All analyses compared CLD and non-CLD (control) patients, and all outcomes were binary in nature. The Chi-square test was used to compare groups for the majority of outcomes. The exception was for outcomes where the dataset was small in which Fisher’s exact test was performed. A p value of <0.05 was considered statistically significant.

Results

Search results

A total of 26 relevant article titles were identified. After application of eligibility criteria described, eight studies [11–18] qualified for inclusion. Two further studies [19, 20] reported on outcomes of THA in patients post liver transplantation for CLD, and this was deemed an interesting group for comment separately.

Quality assessment

The included studies were small-to-large size retrospective case series (n = 19–27 401). The range of follow-up in the studies was 1–144 months. There was a significant heterogeneity between studies in terms of outcome recording.

Cohort characteristics

The studies included 28 514 THAs performed in patients with a mean age of 57.3 years and mean follow up period of 13.5 months (range 1–144 months). Only two studies [12, 17] documented the types of implant used. There were an additional 44 THAs performed in patients post liver transplant with a mean age of 51.7 and mean follow up of 40.3 months [19, 20] 42 uncemented THAs (95%) and two cemented THAs (5%) were included in this subgroup of patients.

Outcome analysis

Functional outcome

Both studies in patients with liver transplant patients reported significant improvements in patient satisfaction and hip function following THA [19, 20]. The remaining studies did not report on functional outcome scores following THA.

Aseptic loosening

Two studies reported on rates of aseptic loosening [12, 17]. There was an increased risk of aseptic loosening at 7% (6/85 THAs) compared with 0% in controls (p = 0.03). There was
no comment on the mean timing of implant loosening. In patients with liver transplantation, there was one case of aseptic loosening in 44 THAs (2%), this at 39 months of follow-up. Further stratification based on cemented or uncemented prostheses was not recorded.

**Revisions rate**

Six studies reported on implant failure and revision rates [11–13, 16–18]. There was an increased rate of revision surgery at 4% (46/1083 THAs) compared with 0.2% in controls ($p < 0.001$). Time to implant failure was not reported. Reasons for implant failure included periprosthetic infection or septic loosening in 70% ($n = 32$), aseptic loosening in 13% ($n = 6$), instability in 13% ($n = 6$), periprosthetic fracture in 2% ($n = 1$), and polyethylene liner wear with osteolysis in 2% ($n = 1$). In liver transplant patients, implant failure occurred in three of the 44 patients (7%) at a mean time of 7.1 months. In these patients, implant failure secondary to instability with dislocation occurred in 67% ($n = 2$), and aseptic loosening in 33% ($n = 1$). Further stratification of implant failure based on the type of implant or revision surgery was not recorded.
Infection rate

Infection rate was reported in seven studies [12–18], which included 28,495 THAs. There was an increased infection rate in CLD patients, at 0.5% (range 0.3%–15.4%) compared with 0.15% in controls (p < 0.001). Two studies recorded separate infection rates for elective arthroplasty cases versus emergency cases [13, 18]. This amounted to 954 THAs, including 803 elective cases and 151 urgent procedures. There was an increased mean infection rate for elective cases at 4.1% (n = 33, p < 0.001) and for urgent cases at 8.6% (n = 13, p < 0.001). In patients with liver transplants, the mean infection rate was 1% [19, 20].

Mortality

Perioperative mortality rates were documented in five studies [11–14, 18] amounting to 1048 THAs. The mean perioperative mortality rate was increased in CLD patients at 4.1% compared with 0.2% in controls (p < 0.001). No perioperative mortality was reported in patients with liver transplants. Table 1 summarizes the demographics and key findings of each study included in this systematic review.

Discussion

Anecdotal evidence suggests that THA in patients with CLD is a generally successful procedure. However, this review highlights that there are no objective data within English literature that documents functional outcomes in this patient group, despite the fact that it is accepted that there are increased technical challenges. Indeed this study has found increased infection rates, mortality rates, rates of revision surgery and aseptic loosening in patients with CLD undergoing THA.

Long-term outcome measures are somewhat heterogeneously reported in current literature. These were examined during this study. This review found a revision surgery rate of 4%, with the majority of revisions being for periprosthetic infection/septic loosening of prosthesis (70%). The National Joint Registry (NJR) of England and Wales in 2016 reports a revision rate of 2.6% in THAs, and accordingly the suggestion is that THA revision rates are higher in patients with CLD.

In addition, the most common underlying reason for revisions in NJR data was aseptic loosening at 24.2%, with infection only accounting for 13.8%. The limited numbers and heterogeneity of reporting, limit the ability to draw conclusions; however, there is a suggestion that infection may play a larger role in THA failures in patients with CLD. When considering THA in liver transplant patients, functional outcomes were shown to improve following surgery, with a 2% incidence of aseptic loosening, and a 7% need for revision surgery. Supporting this, Leviatsky et al. (2003) [21] conducted a small review of arthroplasty cases in liver transplant patients (eight knee, three hip and one ankle). They found no deaths or major complications. These positive trends offer a faint suggestion that some aspects of MBD associated with CLD might be reversed after liver transplantation; however, the small numbers mean that drawing firm conclusions is not advisable. Indeed Cavanaugh et al. (2015) [22] conducted a retrospective study between 1993 and 2011 of 787 liver transplant patients who had undergone THA or Total Knee Arthroplasty (TKA) finding a higher risk of surgical site infection, renal and cardiorespiratory complications.

The inferences of this review are that there is an increased risk of general surgical and medical complications in patients with CLD undergoing THA. These findings are supported by previous research that has reviewed surgical outcomes in patients with CLD. Ziser et al. (1999) [10] conducted a review of 733 mixed surgeries at the Mayo clinic in 1999. This study reported significantly increased perioperative complications at 30.1%, increased mortality rate at 11.6%, and noted increased mortality with higher Child’s Pugh scores. The study also included a small number of hip and pelvic surgeries, and showed that these patients had significantly higher complication rates than other types of surgery (53% vs. 29.4%, p = 0.008). There are several studies that have looked at the outcomes of arthroplasty in patients with CLD, when combining THA and TKA. Deleuran et al. (2015) [23], retrospectively reviewed 363 THA and TKA cases in patients with CLD between 1995 and 2011. Patients with CLD had increased odds of mortality within 30 days (OR 3.9, 95% CI 1.5–10), deep infection (3.1% vs. 1.4%), and need for revision surgery (3.7% vs. 1.7%) compared to the control group. Tiberi et al. (2014) [24] reviewed clinical outcomes of 115 THA and TKA cases in patients with CLD between 2000 and 2012. This study showed

### Table 1. Demographics and key findings of studies included in this systematic review.

<table>
<thead>
<tr>
<th>Study, Country</th>
<th>Age (mean)</th>
<th>Follow up (mean) months</th>
<th>No. of THAs</th>
<th>Revision rate (%)</th>
<th>Mortality rate (%)</th>
<th>Infection rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohen [11], USA</td>
<td>Elective: 65.7</td>
<td>1</td>
<td>19</td>
<td>5</td>
<td>5.3</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Urgent: 68.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hsieh [12], Taiwan</td>
<td>55.2</td>
<td>84</td>
<td>45</td>
<td>37.8</td>
<td>11.1</td>
<td>24.4</td>
</tr>
<tr>
<td>Jiang [13], USA</td>
<td>62.3</td>
<td>6</td>
<td>878</td>
<td>1.2</td>
<td>1.1</td>
<td>4.0</td>
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<tr>
<td>Moon [14], Korea</td>
<td>60</td>
<td>1</td>
<td>30</td>
<td>0.3</td>
<td>0.15</td>
<td>10.0</td>
</tr>
<tr>
<td>Newman [15], USA</td>
<td>57.1</td>
<td>Until discharge</td>
<td>27 401</td>
<td>–</td>
<td>–</td>
<td>0.3</td>
</tr>
<tr>
<td>Orozco [16], USA</td>
<td>59</td>
<td>35</td>
<td>25</td>
<td>–</td>
<td>–</td>
<td>8.0</td>
</tr>
<tr>
<td>Pour [17], USA</td>
<td>55</td>
<td>101</td>
<td>40</td>
<td>8</td>
<td>–</td>
<td>15.0</td>
</tr>
<tr>
<td>Seol [18], South Korea</td>
<td>Elective: 61.9</td>
<td>Until discharge</td>
<td>76</td>
<td>Elective 13.5</td>
<td>3.9</td>
<td>14.5</td>
</tr>
<tr>
<td></td>
<td>Urgent: 75.5</td>
<td></td>
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</tbody>
</table>

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patients with CLD had increased risk of urinary tract infection ($p < 0.01$), acute kidney injury ($p < 0.03$), need for transfusion ($p < 0.01$), dislocation ($p = 0.01$), infection ($p = 0.02$), 90-day revision surgery ($p = 0.04$) and 1 year mortality ($p = 0.01$) compared to the matched control group. Poulsides et al. (2013) [25] retrospectively reviewed 412 356 THA and 784 335 TKA between 1998 and 2007. Liver disease was found to be an independent risk factor for developing surgical site infection (OR = 2.53, $p = 0.0001$).

Worldwide, increasing numbers of THAs are being performed annually. It is reasonable to infer that arthroplasty surgeons will be performing THAs in patients with CLD with increasing frequency. It is thus essential to appreciate the medical and surgical issues unique to this patient-group, and particularly how to optimize controllable factors. Patel (1999) [26] discusses in detail systematic approaches to assess and optimize the patient with CLD for surgery. A multi-disciplinary approach is recommended. In line with this paper and other relevant evidence, the following pre-, intra- and post-operative considerations should be addressed:

**Pre-operative considerations/requirements**

Advice may be sought from haematologists and/or hepatologists as to optimization strategies. The input of microbiologists may be sought on an individual case basis. Preoperative workup should aim to optimize haemoglobin levels. The cause for anaemia should be assessed and treated accordingly. Treatment may include nutritional supplementation such as with iron, or Erythropoietin where there is anaemia of chronic disease [27]. Pre-operative blood transfusion should not be considered a first-line option. It is important to obtain and review good quality radiographic studies of the pelvis and femur to assess bone morphology and quality, and plan surgery including selection of the most appropriate implants. Bisphosphonates have been shown to reduce periprosthetic bone loss and improve implant integration in those with osteoporotic bone [28] and thus should be considered.

**Intra-operative considerations**

Surgery should be carried out with a focus on minimizing blood loss with vigilant haemostasis and the use of tranexamic acid [8]. Implant choice in THA in patients with CLD is complex. In osteoporotic bone, the surgeon may consider cemented femoral implants to reduce intraoperative fracture rates and aseptic loosening. With uncemented implants, the surgeon must appreciate general recommendations for implant preparation and fixation in osteoporotic bone.

This includes achieving good rim fit and using acetabular screws to enhance fixation in uncemented shells, and cautious femoral preparation and sizing choices.

**Postoperative considerations**

Vigilant clinical assessment should be made with particular watchfulness for bleeding and infection as well other medical complications. Long-term follow up should include careful clinical and radiographic review for prosthesis loosening.

**Limitations**

The results of this review must be interpreted with the limitations of this study in mind. All of the studies included in this review article are retrospective studies with their inherent limitations. There is non-uniform reporting of long-term complications, with some studies only reviewing short-term measures. Subgroup analysis has not been performed and confounding variables may have affected the outcomes recorded, for example, the use of immunosuppressant medication or steroids. With only two studies reporting on the type of implant used, it was not possible to draw conclusions or make recommendations as to the optimal implant properties for patients with CLD. The extent of CLD was also not stratified. Despite these limitations, this systematic review provides timely and important information for the medical community in clinical decision making and offering informed patient choices.

**Recommendations for research**

There is a need for further large studies on patients with CLD undergoing THA. It is important to review functional outcomes so that patients can be fully informed when undertaking the decision to proceed with THA. With the availability of radiographic classifications such as by Dorr et al. (1993), it would be useful to study whether these influence outcomes, and whether this can be related to implant choices.

**Conclusion**

A multidisciplinary perioperative approach is recommended in order to minimize increased complication risks, in particular infection, mortality, aseptic loosening and need for revision surgery. Infection may need heightened consideration when trying to avoid the serious complication of need for revision surgery. This review guides future research to appraise functional outcomes of THA in patients with active CLD, further detail long-term failure reasons, and review any differences in outcomes and complications based on various operative approaches and available implants.

**Conflicts of interest**

All the authors declare that they have no competing interests.

**References**


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EDITORIAL

Robotic total knee arthroplasty
CLINICAL OUTCOMES AND DIRECTIONS FOR FUTURE RESEARCH

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The term ‘robot’ originates from the Czech word ‘robota’, which means forced labour or activity. Karel Capek first used the term in his 1921 play Rossum’s Universal Robots, in which robots were a series of factory-manufactured artificial people made from synthetic material that undertook mundane tasks for their human masters. The robots eventually became frustrated with their roles and masterminded a robotic rebellion, leading to the extinction of the human race. Since then, robotics has evolved to describe an array of computer machines that perform programmed, precise, and repetitive procedures. These computer machines have now become integrated into the routine workforce of several industries, including aviation, military, healthcare, finance, construction, and engineering.1,2 Robotic technology has helped each of these sectors to achieve and sustain levels of precision, productivity, and efficiency that were not possible with humans alone. Within each of these sectors that have integrated robotic technology into the workforce, the use of this technology has never diminished or exited from the industry.2

The first robotic surgical procedure was performed by Kwoh et al3 in 1988 using the PUMA 560 robotic system (Westinghouse Electric, Pittsburgh, Pennsylvania) to undertake neurosurgical biopsies with improved precision. The same robotic platform was used by Davies et al4 in 1991 to undertake transurethral resections of the prostate with greater accuracy and reduced iatrogenic soft-tissue injury. Over the following two decades, several other surgical robotic devices were developed, including the Zeus (Computer Motion, Inc., Goleta, California) and Da Vinci (Intuitive Surgical, Sunnyvale, California) robotic platforms, which enabled a variety of surgical procedures to be performed remotely using robotically controlled arms and a 3D camera to improve the visual field.5,6 These robotic devices have been used to perform cholecystectomy, hysterectomy, lobectomy, mitral valve replacement, coronary artery bypass grafting, and prostatectomy. Compared with conventional open surgery or laparoscopic surgery, robotic surgery with these devices is associated with smaller skin incisions, improved precision of soft-tissue dissection, better visualization of the surgical field, and more comprehensive data capture for surgical training.6,7 Clinically, this has translated to robotic surgery enabling faster postoperative rehabilitation and decreased length of hospital stay compared with conventional and laparoscopic surgery for these procedures.5-8

Total knee arthroplasty (TKA) is an effective and cost-efficient procedure that is performed in over 90,000 patients per year in the United Kingdom.9 Implant survivorship, assessed with revision as the primary endpoint, is greater than 90% at ten years’ follow-up.10,11 However, patient satisfaction and functional outcomes remain inferior to total hip arthroplasty, with up to 20% of patients remaining dissatisfied following TKA.12,13 Accurate implant positioning, balanced flexion-extension gaps, proper ligament tensioning, and preservation of the periarticular soft-tissue envelope are important surgeon-controlled variables that affect functional outcomes, implant stability, and long-term implant survivorship.14-16 Conventional jig-based TKA uses preoperative radiographic films, intraoperative anatomical landmarks, and manually positioned alignment jigs to guide bone resection and implant positioning. However, these handheld techniques are associated with poor reproducibility of alignment-guide positioning, inadvertent sawblade injury to the periarticular soft-tissue envelope, and limited intraoperative data on gap measurements or ligamentous tensioning to

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Robotic TKA uses computer software to convert anatomical information into a virtual patient-specific 3D reconstruction of the knee joint. The anatomical information may be obtained using preoperative CT (image-based) or a combination of preoperative radiographs and intraoperative osseous mapping (imageless). The surgeon uses this virtual model to plan optimal bone resection, implant positioning, bone coverage, and limb alignment based on the patient’s unique anatomy. An intraoperative robotic device helps to execute this preoperative patient-specific plan with a high level of accuracy.20,26 The action of the sawblade is confined to the preoperative surgical plan for femoral and tibial resection, which limits iatrogenic periarticular soft-tissue injury and bone trauma.27,28 Although the first robotic TKA was performed in 1988 using the ACROBOT robotic system (Imperial College, London, United Kingdom), there has been a surge in robotic TKA over the last decade.29 This has been attributed to recent developments in computer software and technology, and the ease with which modifications can be made to existing technology such as computer navigation.1,2 Computer-navigated TKA provides patient-specific anatomical data with recommendations for bone resection and optimal component positioning. Robotic TKA takes this one step further by actively controlling and/or restraining the surgeon’s motor function to improve the accuracy of achieving the planned bone resection and implant positioning.

There are a variety of robotic TKA devices, some of which actively perform all parts of femoral and tibial bone resections (fully active), while others enable the surgeon to undertake the procedure while providing live intraoperative feedback to help control bone resection to the confines of the preoperative surgical plan (semi-active). ROBODOC (THINK Surgical Inc., Fremont, California) is an example of a fully active robotic TKA application system.30 The surgeon performs the surgical approach, positions retractors to protect the periarticular soft tissues, and then secures the limb into a fixed device. The robotic device then independently executes the planned bone resections. The Mako Robotic Arm Interactive Orthopaedic System (Stryker Ltd, Kalamazoo, Michigan) is an example of an image-guided semi-active robotic system for robotic TKA.31 The robotic arm has visual, tactile, and audio feedback that help the surgeon to control the force and direction of saw blade action within the confines of the femoral and tibial bone resection windows. The Navio Surgical system (Smith & Nephew, Andover, Texas) is an imageless semi-active robotic system that uses a handheld platform to intraoperatively map osseous anatomy and guide bone resection.32 The Rosa Knee System (Zimmer Biomet, Warsaw, Indiana) offers a computer software program to convert 2D knee radiographs into a 3D patient-specific bone model, and a robotic device to help position the cutting blocks and execute the planned bone resections with greater accuracy.33 Omnibotic (OMNIlife Science Inc., East Taunton, Massachusetts) is a robotic device that uses patented intraoperative Bone Morphin technology to create a 3D model of the osseous anatomy using plain radiographs.34 This may be combined with the BalanceBot Ligament Balancer (OMNIlife Science Inc.), which uses an intraoperative robotic device to balance the soft tissues. Together, these technologies may help surgeons place implants anatomically while minimizing the need for soft-tissue releases.34

Robotic TKA is associated with improved accuracy of achieving the planned femoral and tibial implant positioning, joint line restoration, limb alignment, and posterior tibial slope compared with conventional jig-based TKA.20,24 This has been attributed to the stereotactic boundaries that confine the action of the sawblade to the preplanned haptic femoral and tibial windows. Song et al20,21 performed a prospective randomized study on 100 patients undergoing primary TKA, and found that robotic TKA was associated with improved accuracy and reduced outliers in achieving the planned alignment compared with conventional manual TKA. Bellemans et al22 reviewed outcomes in 25 patients undergoing robotic TKA and reported femoral and tibial implant positioning within 1° of the planned positions in all three planes. Hampp et al23 performed a study on six cadaveric specimens and found that robotic TKA was associated with improved accuracy of femoral and tibial implant positioning in the coronal, sagittal, and axial planes compared with conventional manual TKA. Improved accuracy in achieving these radiological outcomes has been previously correlated to increased patient satisfaction, greater stability, and improved kinematics through the arc of motion following TKA.1,25,26 Furthermore, robotic TKA is associated with a learning curve of six to 20 cases for operative times, but there is no learning curve for achieving the planned femoral or tibial implant positioning.35,36 This is important for the safe implementation of this technology to routine arthroplasty practice and offers an avenue for low-volume arthroplasty surgeons to achieve high levels of accuracy in implant positioning. Balanced flexion-extension gaps and proper mediolateral ligamentous tensioning are important technical objectives in TKA for optimizing knee kinematics, stability, and long-term implant survivorship.14,16 Conventional jig-based TKA techniques often utilize controlled soft-tissue releases to achieve balanced flexion-extension gaps and mediolateral soft-tissue tension. Assessing intraoperative gap measurements and periarticular soft-tissue laxity is challenging, and is often dependent on the skill and
expertise of the operating surgeon. Robotic TKA uses optical motion capture technology to assess intraoperative alignment, component positioning, range of movement, flexion-extension gaps, and mediolateral laxity. This real-time intraoperative data can then be used to fine-tune bone resection and guide implant positioning, in order to achieve the desired knee kinematics and limit the need for additional soft-tissue releases. Kayani et al. conducted a prospective cohort study comparing bone trauma and periarticular soft tissue injury in 30 patients undergoing conventional jig-based TKA versus 30 patients receiving robotic TKA. The study found that robotic TKA enabled better preservation of the periarticular soft tissue envelope in both correctible and non-correctible coronal plane deformities, and robotic TKA was associated with less trauma to the residual femoral and tibial bone resection surfaces. Khlopas et al. conducted a cadaveric study in which six blinded observers reported soft-tissue trauma following bone resection in cruciate-retaining TKAs, and found that robotic TKA was associated with reduced posterior cruciate ligament injury, decreased tibial subluxation, and reduced patella eversion compared with conventional jig-based TKA.

Improved preservation of the periarticular soft envelope secondary to reduced iatrogenic periarticular soft-tissue injury in robotic TKA may help to limit the local inflammatory response, decrease pain, and reduce postoperative swelling compared with conventional jig-based TKA. Siebert et al. conducted a retrospective study on 70 patients undergoing robotic TKA versus a matched historic cohort of 50 conventional jig-based TKAs, and observed reduced postoperative soft-tissue swelling in the robotic group. Kayani et al. conducted a prospective cohort study comparing early functional outcomes in 40 conventional manual UKAs followed by 40 robotic TKAs. The authors found that robotic TKA was associated with reduced postoperative pain, decreased analgesia requirements, shorter time to straight leg raise, increased knee flexion at discharge, and reduced need for inpatient physiotherapy compared with conventional jig-based TKA. Median time to hospital discharge in robotic-arm assisted TKA was 77 hours (interquartile range (IQR) 74 to 81) compared with 105 hours (IQR 98 to 126) in conventional jig-based TKA (p < 0.001). Marchand et al. compared outcomes in 28 robotic TKAs matched with 20 conventional jig-based TKAs and showed that pain, patient satisfaction, and physical function scores, as measured using Western Ontario and McMaster Universities Arthritis Index (WOMAC), were better in the robotic group compared with the conventional group at six months after surgery.

Improved accuracy of implant positioning and enhanced postoperative rehabilitation in robotic TKA have not translated to any differences in middle- to long-term functional outcomes compared with conventional jig-based TKA. Song et al. reported no difference in Hospital for Special Surgery (HSS) or WOMAC scores between 50 conventional jig-based TKAs and 50 robotic TKAs at two years’ follow-up. Liow et al. conducted a prospective randomized trial in 29 conventional jig-based TKAs versus 31 robotic TKAs, and found that there was no difference between the two treatment groups with respect to the Oxford Knee Score (OKS) and KSS at two years’ follow-up. Yang et al. conducted a prospective cohort study on 71 robotic TKAs versus 42 conventional jig-based TKAs, and found no difference in HSS and WOMAC scores at a minimum of ten years’ follow-up. As with all new technology in medicine and surgery, there is a paucity of prospective randomized controlled trials reporting on longer-term outcomes.

Fixed femoral and tibial arrays provide novel intraoperative data on fixed flexion deformity, range of movement, limb alignment, flexion-extension gaps, and mediolateral ligamentous laxity, which may be used for research and development purposes. For example, existing studies assessing functional alignment in TKA have used patient-specific implants or alignment guides to achieve the preplanned alignment. Robotic technology offers an opportunity to accurately execute the planned bone resection and implant positioning to achieve functional alignment, and fixed intraoperative femoral and tibial arrays enable the surgeon to confirm that this alignment has been achieved. Similarly, changes in gap measurements and alignment following specific ligamentous resection may provide data on ligament biomechanics and kinematics. In anterior and posterior cruciate ligament reconstructions, robotic technology potentially offers an avenue to improve accuracy and reduce outliers in correct femoral and tibial tunnel positioning. Robotic technology may minimize human error and provide objective, real-time data for scientists, clinicians, and engineers to accurately record changes in knee kinematics and function. Intraoperative data on the various stages of robotic TKA may also be used for teaching purposes to improve surgical proficiency.

Robotic technology is associated with several limitations that must be acknowledged when understanding the current role and future potential of this technology in TKA. The robotic device is expensive to install and separate applications may need to be required for total hip arthroplasty, TKA, and unicompartmental knee arthroplasty. The robotic device is only compatible with a limited number of implants from the manufacturer of the robotic device, and additional costs are incurred for preoperative imaging, increased operating times during the learning phase, training the surgical team, updating of computer software and servicing contracts, and consumables. Image-guided robotic TKA requires preoperative CT scans that require extra time and radiation exposure. Additional time is also required for remote preoperative
planning and segmentation using the patient-specific virtual models, and a robotic product specialist is required in the operating room to capture data and facilitate the operative procedure. Fully active robotic TKA systems have also been reported to cause periarticular soft-tissue injury, and technical issues with robotic device have required intraoperative conversion to conventional jig-based TKA.\(^1\)\(^,\)\(^1^7\)

Overall, robotic technology enables TKA to be undertaken with improved accuracy of implant positioning and reduced periarticular soft-tissue injury compared with conventional jig-based TKA. This has translated to improved inpatient functional rehabilitation and earlier time to hospital discharge compared with conventional jig-based TKA. Robotic technology offers potential for further research by providing objective data on gap measurements and knee kinematics following specific ligamentous releases, and provides an avenue for executing preplanned implant positioning and alignment with greater precision and reproducibility for study purposes. These advantages must be acknowledged while respecting the limitations of robotic TKA, which include additional costs for installation and maintenance of the robotic machine, additional radiation exposure, and paucity of long-term data showing any functional benefit over conventional jig-based TKA. The results of further high-quality studies with longer term follow-up on functional outcomes, implant survivorship, complications, and cost-effectiveness are awaited.

References


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Robotic technology in total knee arthroplasty: a systematic review

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Talal Al-Jabri¹
Fares S. Haddad¹,²

- Robotic total knee arthroplasty (TKA) improves the accuracy of implant positioning and reduces outliers in achieving the planned limb alignment compared to conventional jig-based TKA.
- Robotic TKA does not have a learning curve effect for achieving the planned implant positioning. The learning curve for achieving operative times comparable to conventional jig-based TKA is 7–20 robotic TKA cases.
- Cadaveric studies have shown robotic TKA is associated with reduced iatrogenic injury to the periarticular soft tissue envelope compared to conventional jig-based TKA.
- Robotic TKA is associated with decreased postoperative pain, enhanced early functional rehabilitation, and decreased time to hospital discharge compared to conventional jig-based TKA. However, there are no differences in medium- to long-term functional outcomes between conventional jig-based TKA and robotic TKA.
- Limitations of robotic TKA include high installation costs, additional radiation exposure, learning curves for gaining surgical proficiency, and compatibility of the robotic technology with a limited number of implant designs.
- Further higher quality studies are required to compare differences in conventional TKA versus robotic TKA in relation to long-term functional outcomes, implant survivorship, time to revision surgery, and cost-effectiveness.

Keywords: functional outcomes; robotic; total knee arthroplasty

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Introduction

Total knee arthroplasty (TKA) is an established and highly effective treatment for patients with symptomatic end-stage knee osteoarthritis.¹,² The procedure is performed in over 90,000 patients per year in the United Kingdom.³ Pooled registry data has shown that implant survivorship, assessed with revision as the primary endpoint, is approximately 82% at 25 years follow-up.⁴,⁵ However, patient satisfaction and functional outcomes remain inferior to those for total hip arthroplasty.³ Despite advances in implant design, implant material, enhanced recovery programmes, thromboembolic prophylaxis, antibiotic prophylaxis, patient-specific implants, and computer navigation, recent studies have shown that up to 20% of patients remain dissatisfied following TKA.²,⁶–¹¹ Accurate implant positioning, balanced flexion-extension gaps, proper ligament tensioning, and preservation of the periarticular soft tissue envelope are important surgeon-controlled variables that affect functional outcomes, implant stability, and long-term implant survivorship.¹²–¹⁹ Conceptually, technology that enables these technical objectives to be delivered with greater accuracy and reproducibility may help to further improve outcomes in TKA.

Robotic technology has been used to improve the accuracy of soft tissue dissection and enhance postoperative rehabilitation in general surgery, cardiology, obstetrics and gynaecology, and ophthalmology.¹⁶ Over the last decade, robotic TKA has gathered momentum as an avenue for improving the accuracy of implant positioning and reducing outliers in limb alignment compared to conventional jig-based TKA.²⁰–²⁶ However, many clinicians remain sceptical about robotic TKA owing to the substantive setup costs and limited long-term evidence.
Comparing clinical and functional outcomes to conventional manual TKA.

This article discusses the current role of robotic technology in TKA, explores the benefits of this technology on accuracy of implant positioning and periarticular soft tissue preservation, and highlights the limitations of robotic TKA compared to conventional jig-based TKA.

**Limitations of conventional jig-based TKA**

Conventional jig-based TKA uses preoperative radiographic films, intraoperative anatomical landmarks, and manually positioned alignment jigs to guide bone resection and implant positioning. However, these techniques are poorly reproducible and accuracy of achieving the planned implant position is dependent on the skill and expertise of the operating surgeon. Achieving balanced flexion-extension gaps and proper mediolateral ligamentous tensioning is dependent on subjective intraoperative gap assessments with limited capacity for fine-tuning bone resection and implant positioning. Intraoperative tensioning devices may help to guide soft tissue releases but there is often inter-surgeon heterogeneity with their positioning in the joint and overall distraction forces applied. Conventional jig-based TKA also uses a manually controlled sawblade to perform bone resection and handheld instruments to protect the periarticular soft tissue envelope. This manual technique for bone resection may lead to inadvertent injury to the supporting ligamentous structures, which may compromise postoperative clinical and functional recovery, reduce stability, and decrease implant survivorship.

Conventional jig-based TKA does not provide real-time feedback on the thickness or orientation of the bone cuts. The use of intramedullary referencing guides for bone resection during conventional jig-based TKA may also increase the risk of thromboembolic events and cardiorespiratory complications.

**Computer-navigated versus robotic TKA**

Computer-navigated TKA involves the use of computer systems that provide live on-screen information on patient anatomy and knee kinematics during surgery. This osseous anatomical map of the patient’s knee joint may be obtained using preoperative computerized tomography (CT) scans (image-based navigation) or intraoperative mapping of bony anatomical landmarks on a generic model of the knee joint (non-image-based navigation). Computer navigation provides patient-specific anatomical data with recommendations for bone resection and optimal implant positioning, but the computer system does not actively control or restrain the motor function of the operating surgeon. Robotic TKA uses computer software to convert anatomical information into a virtual patient-specific three-dimensional (3D) reconstruction of the knee joint, which the operating surgeon uses to calculate optimal bone resection and implant positioning. An intraoperative robotic device helps to execute this preoperative patient-specific plan with a high level of accuracy. Depending on the degree of control that the robotic device provides the operating surgeon, robotic assistants are classified as either fully active or semi-active systems.

**Fully active versus semi-active robotic TKA systems**

Fully active robotic systems work autonomously to perform the planned femoral and tibial bone resections. The surgeon oversees the bone resection and may activate an emergency deactivation switch if required. ROBODOC (THINK Surgical Inc., Fremont, California, USA) is an example of a fully active robotic TKA application system. The surgeon performs the surgical approach, positions retractor to protect the periarticular soft tissues, and then secures the limb into a fixed device. The robotic device then independently executes the planned bone resections. There has been limited uptake of fully active robotic TKA systems owing to substantial robotic device installation costs and increased risk of complications during the learning phase of this procedure. Park and Lee reported six of their initial 32 fully active robotic TKA procedures had short-term complications including superficial infection, patellar ligament rupture, patellar dislocation, supracondylar fracture, patellar fracture, and common peroneal injury.

Semi-active robotic systems enable the surgeon to maintain overall control over bone resection and implant positioning but provide live intraoperative feedback to limit deviation from the preoperative surgical plan. The Mako Robotic Arm Interactive Orthopaedic system (Stryker Ltd, Kalamazoo, MI, USA) is an example of an image-guided semi-active robotic system for robotic TKA. The robotic arm has visual, tactile, and audio feedback that help the surgeon to control the force and direction of saw blade action within the confines of the femoral and tibial bone resection windows. The patient’s limb is secured within a mobile leg holder boot that can be adjusted during bone resection to improve visualization of the operative field. Rapid or jerking movements deactivate the robotic device to help limit iatrogenic bone and soft tissue injury. The Navio Surgical System (Smith & Nephew, Andover, Texas, USA) is an imageless semi-active robotic system that uses a handheld platform to intraoperatively map osseous anatomy and guide bone resection without the haptic boundaries. More recently, the Rosa Knee System (Zimmer-Biomet, Warsaw, Indiana, USA) has gained FDA approval. This robotic system offers a
computer software program to convert two-dimensional knee radiographs into a three-dimensional patient-specific bone model. Virtual plans on implant positioning and ligament balancing are created before execution of the desired patient-specific plan using the robotically positioned cutting blocks.

**Stages of robotic TKA**

Robotic TKA uses computerized systems at five distinct stages for accurate execution of the patient-specific surgical plan. First, preoperative plain radiographs or CT scans of the knee joint are used to create a virtual three-dimensional reconstruction of the patient’s native knee anatomy. Second, the surgeon uses this patient-specific virtual model to plan optimal implant positioning, alignment, and sizing to achieve the desired bone coverage, component position, and limb alignment. Computer software uses this virtual data to calculate femoral and tibial bone resection windows for accomplishing this surgical plan with a high level of precision. Third, intraoperative bone registration and verification of bony landmarks are used to confirm the patient’s osseous knee anatomy prior to bone resection. In CT-free robotic application systems, registration is performed by mapping the patient’s osseous anatomy onto a generic virtual model of the knee joint, and planning of implant positioning and bone resection is performed intraoperatively. In CT-based robotic knee systems, a patient-specific model of the knee joint is created and osseous anatomy is mapped intraoperatively to confirm bone geometry. Fourth, the surgeon uses the robotic device to perform the bone resections within the pre-planned boundaries of the femoral and tibial bone windows. Fifth, optical motion capture technology is used to re-assess intraoperative flexion and extension gaps, joint stability, range of movement, and limb alignment. The surgeon is able to perform live on-table modifications to bone resection, adjust implant positioning, and fine-tune soft tissue releases to achieve the desired bone coverage, component positioning, knee kinematics, and limb alignment.

**Accuracy of implant positioning**

Robotic TKA is associated with improved accuracy in implant positioning and limb alignment compared to conventional jig-based TKA. Sawblade action is limited to the confines of the preoperative surgical plan, which helps to execute the planned femoral and tibial bone resections with a high level of precision. Song et al conducted a prospective randomized study on 50 conventional manual TKA versus 50 robotic TKA, and found robotic TKA improved accuracy of mechanical alignment and reduced outliers of greater than 3° in planned alignment compared to conventional manual TKA. Bellemans et al reviewed outcomes in 25 patients undergoing robotic TKA and reported femoral and tibial implant positioning within 1° of the planned positions in all three planes. Hampp et al performed a cadaveric study on six specimens undergoing conventional manual TKA on one side and robotic TKA on the contralateral side. The authors found that robotic TKA was associated with improved accuracy of femoral and tibial implant positioning in the coronal, sagittal, and axial planes compared to conventional manual TKA, and there was no learning effect for accuracy of implant positioning in the robotic group. Moon et al also conducted a cadaveric study using CT scans to assess the accuracy of implant positioning and limb alignment in 10 conventional jig-based TKAs versus 10 robotic TKAs. The authors found that robotic TKA was associated with high levels of precision in achieving the planned component positioning and reduced outliers in limb alignment compared to conventional jig-based TKA. Robotic TKA has also been shown to more accurately restore the native joint line, posterior condylar offset ratio, and Insall-Salvati ratio compared to conventional jig-based TKA. Improved accuracy in achieving these radiological outcomes has been previously correlated to increased patient satisfaction, greater stability, and improved kinematics through the arc of motion following TKA.

**Learning curve of robotic TKA**

The learning curve of robotic TKA is important for understanding the impact of this procedure on the surgical workflow, scheduling of operative cases and theatre lists, and establishing any additional risks or complications during the acquisition of surgical proficiency. Kayani et al assessed the learning curve of robotic TKA by assessing surrogate operative and radiological markers of the learning curve in 60 consecutive conventional manual TKAs followed by 60 robotic TKAs. Using cumulative summative analysis, the authors reported that the learning curve for operative times and surgical team confidence levels with robotic TKA was seven cases. There was no learning curve effect in robotic TKA for achieving the planned femoral and tibial implant positioning, limb alignment, posterior condylar offset ratio, and native joint restoration. Sodhi et al explored the learning curve of robotic TKA in two different surgeons, and found operative times were increased for an initial 20 robotic TKA cases. Thereafter, operative times in robotic TKA were comparable to those of conventional manual TKA in both surgeons. Proponents of robotic TKA claim that this technology helps to produce a more streamlined procedure than conventional jig-based TKA by reducing the need for instrument trays, alignment guides, and cutting blocks, enabling more rapid computer-guided bone resections, and reducing the
need for trialling due to the high accuracy of preoperative surgical planning. However, existing studies show that operative times are increased in the learning phase of robotic TKA, and comparable between the two treatment techniques after the proficiency phase for robotic TKA has been achieved.42,43

**Periarticular soft tissue injury**

Balanced flexion-extension gaps and proper mediolateral ligamentous tensioning are essential for optimizing knee kinematics, stability, and long-term implant survivorship.35–38 In conventional jig-based TKA, controlled soft tissue releases are performed in 50–76% of patients to balance mediolateral laxity, with some authors advocating for all non-navigated TKAs to undergo ligamentous releases.17,20,38–40 Robotic TKA uses optical motion capture technology to assess intraoperative alignment, component positioning, range of motion, flexion-extension gaps, and mediolateral laxity. This real-time intraoperative data can then be used to fine-tune bone resection and guide implant positioning to achieve the desired kinematics, and limit the need for additional soft tissue releases.42,44 Robotic TKA also utilizes haptic boundaries that limit the action of the sawblade to the confines of the preoperative surgical plans for femoral and tibial resections, and therefore limit iatrogenic periarticular soft tissue injury. Khlopas et al conducted a cadaveric study in which six blinded observers reported soft tissue trauma following bone resection in cruciate-retaining TKAs with either conventional jig-based TKA or robotic TKA. The authors found that robotic TKA was associated with reduced posterior cruciate ligament (PCL) injury, tibial subluxation, and patella eversion compared with conventional manual TKA.44

**Early functional outcomes and time to hospital discharge**

Improved preservation of the periarticular soft envelope secondary to reduced intentional soft tissue releases and decreased iatrogenic periarticular soft tissue injury in robotic TKA may help to limit the local inflammatory response, decrease pain, and reduce postoperative swelling compared to conventional jig-based TKA. Siebert et al conducted a retrospective study on 70 patients undergoing robotic TKA versus a matched historic cohort of 50 conventional jig-based TKAs, and observed reduced postoperative soft-tissue swelling in the robotic group.45 Kayani et al conducted a prospective cohort study comparing early functional outcomes in 40 conventional manual TKAs followed by 40 robotic TKAs.46 The authors found that robotic TKA was associated with reduced postoperative pain, decreased analgesia requirements, shorter time to straight leg raise, increased knee flexion at discharge, and reduced need for inpatient physiotherapy compared to conventional jig-based TKA. Median time to hospital discharge in robotic-arm-assisted TKA was 77 hours (interquartile range (IQR) 74 to 81) compared with 105 hours (IQR 98 to 126) in conventional jig-based TKA (p < 0.001). Marchand et al compared outcomes in 28 robotic TKAs matched with 20 conventional jig-based TKAs and showed that pain, patient satisfaction, and physical function scores as measured using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) were better in the robotic group compared with the conventional group at six months after surgery.47 Khlopas et al conducted a prospective non-randomized multi-centre trial comparing 102 conventional jig-based TKAs with 150 robotic TKAs, and found robotic TKA was associated with greater improvements in walking and standing at 4–6 weeks and three months after surgery compared to conventional manual TKA.48 Ren et al recently conducted a meta-analysis of five studies with 323 robotic TKAs and 251 conventional jig-based TKAs, and reported improved Knee Society Score (KSS) functional score and WOMAC scores in the robotic group at six months follow-up.49

**Medium- to long-term functional outcomes**

Improved accuracy of implant positioning and enhanced postoperative rehabilitation in robotic TKA have not translated to any differences in medium-to-long-term functional outcomes compared to conventional jig-based TKA. Song et al reported no difference in Hospital for Special Surgery (HSS) or WOMAC scores between 50 conventional jig-based TKAs and 50 robotic TKAs at two years follow-up.25,26 Liow et al conducted a prospective randomized trial in 29 conventional jig-based TKAs versus 31 robotic TKAs, and found there was no difference between the two treatment groups with respect to the Oxford Knee Score (OKS) and KSS at two years follow-up.50 Yang conducted a prospective cohort study on 71 robotic TKAs versus 42 conventional jig-based TKAs, and found no difference in HSS or WOMAC scores at minimum 10 years follow-up.51 Cho et al recently reported outcomes in 155 robotic TKAs versus 196 conventional jig-based TKAs, and also found no difference in WOMAC, OKS, KSS, or SF-12 at minimum 10 years follow-up.52

**Limitations of robotic TKA**

Robotic technology is associated with substantial installation and maintenance costs for the robotic device. Further costs are incurred with additional preoperative imaging, increased operating times during the learning phase, training the surgical team, updating of computer software and servicing contracts, and consumables. Many robotic
devices are also only compatible with a limited number of implant designs, and different application systems need to be purchased for total hip arthroplasty, TKA, and unicompartamental knee arthroplasty. The cost of purchasing the robotic device ranges between $600 k to $1.5 million US dollars depending on the specification of the robotic machine, support and upgrade agreements, and category of application systems included. These costs may be partially offset as robotic TKA is associated with reduced operative analgesia consumption, decreased need for inpatient physiotherapy, earlier time to hospital discharge, reduced readmission rates, and fewer discharges to rehabilitation units or skilled nursing facilities compared to conventional jig-based TKA. \(^3\) Robotic TKA requires additional incisions for insertion of the femoral and tibial registration pins to enable optical motion-capture tracking, and image-guided robotic TKA increases radiation exposure to the patient. There are additional time delays for the remote planning team to template the optimal implant size and positioning on the patient-specific virtual model, which then requires further fine-tuning by the surgeon before surgery. Fully active robotic TKA systems have been reported to cause periarticular soft tissue injury and technical issues with robotic devices have required intraoperative conversion to conventional jig-based TKA. \(^3\) The robotic device, computer screens, and infrared sensors reduce the intraoperative working space, and additional instruments and surgical trays may cause instrument crowding.

**Conclusion**

Robotic TKA uses preoperative imaging or intraoperative bone mapping to create a patient-specific virtual reconstruction of the knee joint. The surgeon uses this model to plan optimal bone resection and implant positioning, and an intraoperative robotic device to execute this plan with a high level of accuracy. Intraoperative optical motion capture technology enables accurate assessment of ligamentous laxity, which enables the surgeon to fine-tune bone resection and guide implant positioning whilst limiting the need for soft tissue releases. Haptic boundaries also limit the action of the saw to the confines of the preoperative surgical plan to limit iatrogenic soft tissue injury. There is no learning curve for achieving the planned implant position and operative times are equivalent to those for conventional jig-based TKA after the initial learning phase. However, improved radiological outcomes in robotic TKA have not translated to any differences in long-term functional outcomes compared to conventional jig-based TKA. Limitations of robotic TKA include substantial installation and maintenance costs, additional radiation exposure with image-based platforms, and increased operative times during the learning phase.

Further high-quality studies with longer-term follow-up on functional outcomes, implant survivorship, complications, and cost-effectiveness are required before this technique is adopted into mainstream TKA practice.

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**ICMJE CONFLICT OF INTEREST STATEMENT**

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The current role of robotics in total hip arthroplasty

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- Robotic total hip arthroplasty (THA) improves accuracy in achieving the planned acetabular cup positioning compared to conventional manual THA.
- Robotic THA improves precision and reduces outliers in restoring the planned centre of hip rotation compared to conventional manual THA.
- Improved accuracy in restoring hip biomechanics and acetabular cup positioning in robotic THA have not translated to any differences in early functional outcomes, correction of leg-length discrepancy, or postoperative complications compared to conventional manual THA.
- Limitations of robotic THA include substantive installation costs, additional radiation exposure, steep learning curves for gaining surgical proficiency, and compatibility of the robotic technology with a limited number of implant designs.
- Further higher quality studies are required to compare differences in conventional versus robotic THA in relation to long-term functional outcomes, implant survivorship, time to revision surgery, and cost-effectiveness.

Keywords: functional outcomes; hip biomechanics; implant positioning; robotics; total hip arthroplasty/replacement

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Introduction

The surgical treatment of symptomatic end-stage hip osteoarthritis has evolved over the last three hundred years from rudimentary excision surgery to modern robotic total hip arthroplasty (THA).1 Prior to the advent of modern anaesthesia, surgical treatment of hip osteoarthritis included proximal femoral resection or limb amputation.1,2 Increasing functional demands of patients and development in general anaesthesia led to the creation of interposition arthroplasty in which skin, fascia lata, or submucosa from porcine bladder were placed between the articulating surfaces of the hip joint.1 Further advancements in the understanding of hip anatomy and joint biomechanics led to partial arthroplasties of the femoral head or native acetabulum with alloys of chromium, cobalt, and molybdenum.2 These procedures were associated with high risk of failure owing to poor implant designs and suboptimal mechanical properties of the metal components.2,3 In 1971, Charnley revolutionized THA through the introduction of low-friction arthroplasty, and his subsequent developments of acrylic cement to fix implants to living bone and high-density polyethylene as a bearing material.1 Analysis of these implants, using revision of either component as the endpoint, found implant survivorship of 77–82% at 20 years follow-up, and led to many surgeons heralding THA as the ‘operation of the century’.1,2

Since Charnley’s low-friction arthroplasty, there have been several further advancements in implant design and material for THA including cementless technology to promote bone ingrowth, modular femoral components to restore native hip kinematics, larger femoral heads to reduce impingement-related wear, and improvements in bearing surfaces such as highly cross-linked polyethylene and modern ceramics.4–17 Robotic technology is routinely used in general surgery, cardiothoracic surgery, gynaecology, and urology to improve surgical precision, reduce iatrogenic soft tissue injury, and enhance postoperative functional rehabilitation. Over the last decade, robotic THA has gained momentum as an avenue for reducing surgical error and improving the accuracy of implant positioning compared to conventional manual THA.18,19 Conceptually, improved accuracy of implant positioning and greater precision in restoring hip biomechanics with robotic THA will translate to further improvements in
functional outcomes and implant survivorship. However, despite the recent surge in publications on robotic THA, many surgeons remain sceptical about introducing this unproven and costly technology to improve an already highly successful and cost-efficient manual THA procedure. Implant survivorship with conventional manual THA is now over 90% at 10 years follow-up and over 80% at 25 years follow-up. This article discusses the current role of robotic technology in THA, provides an overview of how this technology affects functional and radiological outcomes, and explores the limitations of robotic THA compared to conventional manual THA.

Conventional manual techniques for THA

Accurate implant positioning and restoration of native hip biomechanics are important surgeon-controlled factors that influence postoperative acetabular bone stock, abductor function, joint stability, soft tissue injury, impingement, bearing surface wear, and long-term implant survival. Conventional manual techniques for THA use radiographic templating, surgical alignment guides, and intraoperative landmarks such as the transverse acetabular ligament, acetabular notch, and anterior superior iliac spine with the sciatic notch to help guide acetabular reaming and implant positioning in THA. However, only 38–47% of acetabular components are within the desired safe ranges of anteversion and inclination using these manual handheld techniques, and low surgeon volume has been identified as a risk factor for errors in implant positioning. Patients with hip osteoarthritis and/or spinal deformities also often have abnormal spinopelvic alignment or sagittal imbalances, which lead to patient-specific changes in the relationship of the pelvis, femur, and spine with functional activities of daily living. Conventional preoperative two-dimensional (2D) templating of the pelvis with the patient in the standing position may therefore not account for patient-specific safe zones for implant positioning. Suboptimal implant positioning in THA leads to increased risk of hip instability, accelerated wear of the bearing surface, and reduced long-term implant survivorship.

Computer-navigated versus robotic THA

Computer-navigated THA refers to the use of computer systems that provide the operating surgeon with information on patient anatomy and implant position during surgery. This anatomical information may be obtained using preoperative CT scans (imaged-based navigation) or intraoperative mapping of osseous anatomical landmarks on a generic model of the pelvis (non-image-based navigation). Computer navigation provides patient-specific anatomical data with recommendations for bone resection and optimal implant positioning, but the computer system does not actively control or restrain the motor function of the operating surgeon. Robotic THA uses computer software to convert anatomical information into a virtual patient-specific three-dimensional (3D) reconstruction of the pelvis, which the operating surgeon uses to calculate and plan optimal implant positioning. An intraoperative robotic device helps to execute this preoperative patient-specific plan with a high level of accuracy. Depending on the degree of control that the robotic device provides the operating surgeon, robotic systems are classified as either fully active or semi-active assistants.

Fully active versus semi-active THA systems

Fully active robotic assistants work autonomously to execute the planned bone resection and implant position during THA. The surgeon oversees the surgical procedure and may activate an emergency shut-off switch if required. An example of a fully active robotic system is ROBOTODOC (Curexo Technology Corporation, Fremont, California), which has been shown to improve the accuracy, alignment, and fit of the femoral stem during THA. However, fully active robotic THA systems have been associated with inadvertent soft tissue injury to the abductor mechanism and femoral fractures, which have led to several lawsuits against the manufacturers and resistance to the uptake of this technology for THA. Furthermore, this technology has not been established for acetabular reaming or acetabular cup placement and its impact on achieving the planned combined version or inclination remains unknown.

Semi-active robotic systems enable the surgeon to maintain overall control over bone resection and implant positioning, but provide live intraoperative feedback to limit deviation from the preoperative surgical plan. The Mako Robotic Arm Interactive Orthopaedic System (Stryker Ltd, Kalamazoo, Michigan, USA) is an example of a semi-active robotic system used to perform robotic THA. Acetabular reaming is confined to a haptic tunnel with stereotactic boundaries and the robotic arm has tactile, audio, and visual feedback, which help the surgeon to control the force and direction of acetabular reaming to execute the preoperative plan with a high level of accuracy. Femoral osteotomy site and angle may also be marked prior to femoral bone resection and stem preparation, and live onscreen changes in bone coverage, implant position, offset, and leg length are checked prior to definitive implant selection and positioning.

Stages of robotic THA

Robotic THA uses four distinct stages for accurate execution of the patient-specific surgical plan. First, preoperative
CT scans of the pelvis and proximal femur are used to create a patient-specific virtual 3D model of the native hip anatomy. This model accounts for pelvic orientation in the axial, sagittal, and coronal planes, which enables accurate assessment and planning for restoration of hip biomechanics. Second, the surgeon uses this virtual 3D reconstruction to template the optimal implant positions and sizes for achieving the desired bone coverage, restoration of hip biomechanics, component version, component inclination, and leg-length correction. Computer software calculates the depth of acetabular bone resection, femoral osteotomy site and angle, and component positioning for accurate execution of this surgical plan. Third, the surgeon intraoperatively maps the osseous anatomy of the acetabulum and proximal femur to establish bone geometry and confirm pelvic position prior to bone resection (Fig. 1). Fourth, a robotic device is used to execute the planned bone resection and guide final implant positioning with live onscreen changes in bone coverage, implant inclination, implant version, offset, and leg-length correction displayed throughout the procedure (Figs. 2–5).

**Accuracy of implant positioning**

Data from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man has shown that instability is the leading complication in both primary and revision THA within the first year of surgery. To minimize the risk of instability and its associated problems, many surgeons use predefined safe zones, such as those of Lewinnek et al (5–25° anteversion, 30–50° inclination) to guide acetabular cup positioning during THA. However, achieving implant positioning within these safe zones is challenging owing to intraoperative pelvic tilt, distorted anatomical landmarks, and limited accuracy and reproducibility of the alignment guides. Robotic THA uses intraoperative mapping of osseous landmarks with fixed femoral and acetabular registration pins to confirm hip anatomy and establish pelvic tilt, which helps to reduce manual subjective errors in achieving the planned implant positioning. El Bitar et al followed 61 patients undergoing robotic THA and reported overall mean acetabular cup inclination of 38.9° ± 3.2° and anteversion of 20.3° ± 2.8°.
Illgen et al. reviewed outcomes in 200 consecutive conventional manual THAs followed by 100 consecutive robotic THAs, and found robotic THA was associated with an additional 71% improvement in the accuracy of acetabular implant positioning compared with manual THA in the first year of use. Acetabular implant positioning within Lewinnek’s safe zones was achieved in 30% of the first 100 consecutive conventional THAs, 45% of the last 100 consecutive conventional THAs, and 77% in the first 100 consecutive robotic-arm-assisted THAs. Nawabi et al. showed manual THA was associated with root mean square error values that were five times higher for cup inclination and 3.4 times higher for cup anteversion compared to robotic THA.

**Accuracy of restoring hip biomechanics**

Robotic THA uses the preoperative CT scan and virtual 3D reconstruction to calculate the optimal femoral and acetabular bone resection levels for accurate execution of the surgical plan. Semi-active robotic devices enable the femoral resection site to be marked prior to femoral osteotomy with a manual saw blade whilst fully active robotic devices autonomously resect at the planned femoral osteotomy level. Acetabular reaming is controlled by the robotic device to ensure the desired depth is reached for accurate restoration of the hip offset and centre of rotation. Adverse outcomes have been reported in THA in which the centre of rotation is shifted medially by more than 5 mm or superiorly by greater than 3 mm. Nawabi et al. conducted a cadaveric study in which six conventional manual THAs were performed on one side and six robotic THAs on the contralateral side. Nawabi et al. showed that the robotic THA reduced root mean square error values in achieving both planned horizontal (1.5 mm vs. 2.0 mm respectively), anteroposterior (1.2 mm vs. 2.8 mm respectively) and vertical (1.9 mm vs. 2.2 mm respectively) centres of rotation compared to conventional THA. Tsai et al. reviewed radiological outcomes in 14 conventional THA versus 12 robotic THA, and found robotic technology improved the accuracy of achieving the planned vertical centre of rotation (0.7 mm ± 4.4 mm vs. 4.0 mm ± 4.7 mm respectively) compared to conventional manual THA. Nodzo et al. followed 20 patients undergoing robotic THA, and reported intraoperative robotic measurement of the hip centre of rotation had a mean mediolateral error of 1.0 mm ± 0.79 mm, anteroposterior error of 1.2 mm ± 0.8 mm, and superoinferior error of 1.6 mm ± 0.8 mm in planned acetabular component position compared to postoperative CT-measured values. The authors also showed that there was no significant difference in the postoperatively measured mean change in hip offset compared to the preoperatively planned mean change in hip offset (0.5 mm ± 3.0 mm vs. 1.4 mm ± 4.0 mm respectively).

Lewinnek’s safe zones provide the most commonly adopted range of angles for acceptable acetabular component positioning. Acetabular cup angles that stray...
Outside of these safe ranges may lead to increased risk of dislocation, liner fracture, impingement, edge-loading, and wear.\textsuperscript{22–24} There are several factors that may influence cup positioning within these predefined safe zones. Callanan et al reviewed outcomes in 1,823 THAs and found that only 917 (50\%) were within Lewinnek’s safe ranges for both inclination and version.\textsuperscript{36} Factors correlated to malpositioned cups included minimally invasive surgical approach, low surgeon volume, and obesity (BMI > 30 Kg/m\textsuperscript{2}). Esposito et al reviewed implant positioning in 147 patients that had dislocation within six months of primary THA, and found no differences in radiographic zones (± 5°, ± 10°, ± 15° boundaries) within the dislocated hips.\textsuperscript{37} The authors concluded that acetabular component position alone did not predict instability. More recently, patient-specific safe zones based on preoperative assessments of pelvic kinematics have gathered momentum as a route for improving stability and reducing complications in THA. Pierrepont et al assessed pelvic tilt in 1,517 patients undergoing THA in the supine, standing, and flexed-seated positions, and found mean pelvic tilt was 4.2° (range: −20.5° to 24.5°), −1.3° (range: −30.2° to 27.9°) and 0.6° (range: −42.0° to 41.3°) respectively in the three positions.\textsuperscript{38} Mean sagittal pelvic rotation from supine to standing was −5.5° (range: −21.8° to 8.4°), from supine to flexed seated was −3.7° (range: 48.3° to 38.6°) and from standing to flexed seated was 1.8° (range: −51.8° to 39.5°)). Preoperative spinopelvic radiographs or CT scans to assess individualized pelvic kinematics during functional activities could help to determine patient-specific safe zones for implant positioning. Robotic technology may offer an avenue for executing implant positioning into these patient-specific safe zones with a high level of accuracy.

**Functional outcomes**

Improved accuracy of implant positioning and restoration of hip biomechanics in robotic THA has not translated to differences in short-term functional outcomes compared to conventional manual THA.\textsuperscript{39–42} Perets et al followed 162 patients with hip osteoarthritis undergoing robotic THA and reported reduced pain, increased patient satisfaction, and improved functional outcomes as assessed using the Harris Hip Score and Forgotten Joint Score at minimum two years follow-up.\textsuperscript{39} However, there was no control group undergoing conventional manual THA in this study. Siebel et al conducted a prospective randomized study on 36 robotic THAs versus 35 conventional manual THAs and found no difference in Harris Hip Scores between the two groups at an average of 18 months follow-up after surgery.\textsuperscript{40} The authors reported that Merle d’Aubigné and Postel scores and hip abductor function were better in the conventional THA group compared to the robotic THA group at an average of 18 months follow-up. Bukowski et al compared outcomes in 100 conventional THAs versus 100 robotic THAs and found improved University of California Los Angeles (UCLA) scores in the robotic group but no difference in Short-Form 12 Health Survey (SF-12), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, or postoperative complications at minimum one year after surgery.\textsuperscript{31} Banchetti et al retrospectively reviewed outcomes in 56 robotic-arm-assisted THAs and 51 conventional manual THAs, and found no difference in the pain score on the numerical rating scale, WOMAC score, Harris Hip Scores, or postoperative complications between the two treatment groups at minimum 24 months follow-up.\textsuperscript{42} Chen et al recently conducted a meta-analysis of 994 conventional manual THAs versus 522 robotic THAs and found no difference in functional outcomes, leg-length discrepancy, stress shielding, or rates of revision surgery between the two treatment techniques.\textsuperscript{43} Karunaratne et al performed a meta-analysis of patient-reported outcome measures using data from seven studies reporting on 755 THAs, and found no differences in the modified Harris Hip Score, Harris Hip Score or Mayo Clinical Hip Scores between conventional and robotic THA at short-term follow-up.\textsuperscript{44} At long-term follow-up, pooled estimates of function using the Merle d’Aubigné Score, and combined modified Harris Hip Score and Harris Hip Score showed no difference in outcomes between conventional and robotic THA, though the evidence levels of the studies used for analysis were classified as low-quality.
Limitations of robotic THA

Robotic THA is associated with substantive costs for installation of the robotic device, updating and servicing the computer software, and training the surgical team to become familiar with the new instruments and workflow. The robotic technology is also only compatible with a select number of implant designs from the manufacturer. There is a steep learning curve for the operating surgeon with additional operative times and surgical delays until surgical proficiency is reached. Preoperative CT scans for surgical planning are associated with additional radiation exposure and extra time is required for segmenting and templating with the 3D virtual reconstruction. Complications reported with robotic THA include injury to soft tissues of the abductor mechanism, heterotrophic ossification, milling defects in the femur, and technical issues such as robotic device dysfunction. Mechanical issues with the robotic device have led to conversion from fully active robotic THA to conventional manual THA in up to 18% of patients. Patients with advanced osteoarthritis also often have abnormal spino-pelvic alignment or sagittal imbalances through the arc of flexion, which creates patient-specific safe zones for optimal implant positioning. Robotic THA does not currently use dynamic preoperative imaging to assess the relationship of the pelvis, femur, and spine through these functional activities. However, if preoperative dynamic imaging were used to determine patient-specific safe zones for implant positioning then robotic technology could offer an avenue for executing this surgical plan with a high level of accuracy.

Conclusion

Robotic THA uses preoperative imaging to create a patient-specific surgical plan and an intraoperative robotic device to execute this plan with a high level of accuracy. Preliminary studies have shown that robotic technology improves the accuracy of acetabular cup positioning within Lewinnek’s safe zones and enables more precise restoration of the planned centre of hip rotation compared to conventional manual THA. However, improved radiological outcomes in robotic THA have not translated to differences in short-term functional outcomes, correction of leg-length discrepancy, or postoperative complications compared to conventional manual THA. Limitations of robotic THA include additional radiation exposure, substantive installation costs, and the lack of long-term data showing improved clinical outcomes or implant survival compared to manual techniques. The deficiency of long-term clinical and radiological data on robotic THA has restricted the uptake of this technology to routine arthroplasty practice. Robotic technology offers promise in the early stages but further studies reporting on long-term functional outcomes, implant survivorship, complications, and cost-effectiveness are required before this technique may be adopted into mainstream THA practice.

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The learning curve of robotic-arm assisted acetabular cup positioning during total hip arthroplasty

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Abstract

Background: Robotic-arm assisted surgery aims to reduce manual errors and improve the accuracy of implant positioning and orientation during total hip arthroplasty (THA). The objective of this study was to assess the surgical team’s learning curve for robotic-arm assisted acetabular cup positioning during THA.

Methods: This prospective cohort study included 100 patients with symptomatic hip osteoarthritis undergoing primary total THA performed by a single surgeon. This included 50 patients receiving conventional manual THA and 50 patients undergoing robotic-arm assisted acetabular cup positioning during THA. Independent observers recorded surrogate markers of the learning curve including operative times, confidence levels amongst the surgical team using the state-trait anxiety inventory (STAI) questionnaire, accuracy in restoring native hip biomechanics, acetabular cup positioning, leg-length discrepancy, and complications within 90 days of surgery.

Results: Cumulative summation (CUSUM) analysis revealed robotic-arm assisted acetabular cup positioning during THA was associated with a learning curve of 12 cases for achieving operative times (p < 0.001) and surgical team confidence levels (p < 0.001) comparable to conventional manual THA. There was no learning curve of robotic-arm assisted THA for accuracy of achieving the planned horizontal (p = 0.83) and vertical (p = 0.71) centres of rotation, combined offset (p = 0.67), cup inclination (p = 0.68), cup anteverision (p = 0.72), and correction of leg-length discrepancy (p = 0.61). There was no difference in postoperative complications between the two treatment groups.

Conclusions: Integration of robotic-arm assisted acetabular cup positioning during THA was associated with a learning curve of 12 cases for operative times and surgical team confidence levels but there was no learning curve effect for accuracy in restoring native hip biomechanics or achieving planned acetabular cup positioning and orientation.

Keywords

Biomechanics, cup position, learning curve, operating time, robotics, total hip replacement

Date received: 16 December 2018; accepted: 16 August 2019

Introduction

Accurate implant positioning and restoration of native hip biomechanics in total hip arthroplasty (THA) are important technical objectives that directly affect residual acetabular bone stock, abductor function, joint stability, soft tissue injury, impingement, bearing surface wear, and long-term implant survival.¹⁻⁵ However, recent studies have shown that acetabular cup positioning within the desired safe zones of cup inclination and anteverision is achieved in only 38–47% of conventional manual THAs.⁶⁻⁸ Robotic-arm assisted THA uses preoperative computerised tomography (CT) scans of the pelvis and proximal femur to create a virtual reconstruction of the patient’s native hip anatomy. The surgeon uses this 3-dimensional model to create a preoperative patient-specific surgical plan for bone resection and implant positioning. An intraoperative robotic device then helps to execute this plan with a high-level of accuracy. Preliminary studies have shown that
robotic THA improves accuracy of restoring native hip biomechanics and reduces outliers in acetabular cup positioning compared to conventional manual THA. Understanding the learning curve of this procedure is important for optimising theatre efficiency and ensuring its safe implementation into surgical practice.

Recent studies on the learning curve of robotic THA have found improved operative times and reduced outliers in acetabular cup positioning with increasing robotic THA experience. It is possible to improve on these existing studies by assessing a more comprehensive and robust range of learning outcome measures including operative times of individual stages of the procedure, surgical team confidence levels, accuracy in restoring native hip biomechanics, correction of leg-length discrepancy, and postoperative complications. Furthermore, cumulative summation (CUSUM) analyses may be used to assess incremental changes in study outcomes during the progression of the learning curve and these outcome measures compared to the surgeon’s baseline values from conventional manual THA. This analytical technique will provide more accurate inflexion points at which the surgeon transitions from the learning phase to the proficiency phase of robotic THA.

The objective of this study was to assess the surgical team’s learning curve for robotic-arm assisted acetabular cup positioning during THA through analysis of operative times, surgical team confidence levels, accuracy in restoring native hip biomechanics, acetabular cup positioning, correction of leg-length discrepancy, and postoperative complications. The hypothesis was that cumulative experience with robotic-arm assisted THA would reduce operative times and improve surgical team confidence levels but there would be no learning curve effect for accuracy of restoring planned hip biomechanics and acetabular cup positioning.

**Methods**

**Patient selection**

This study included 100 patients with symptomatic hip osteoarthritis undergoing primary THA between September 2016 and August 2018. This included 50 patients undergoing conventional manual THA and 50 patients receiving robotic-arm assisted acetabular cup positioning during THA (robotic-arm assisted THA). Patients were allocated to their respective treatment groups based on availability of the robotic device within the hospital on the day of surgery. The robotic device is routinely used for unicompartmental and total knee arthroplasty at the treatment centre and was therefore not available for all THA procedures. No other preoperative clinical or radiological data were used for patient allocation to the treatment groups. All operative procedures were performed by the senior author (FSH) who had extensive experience with conventional manual THA and previous cadaveric training with robotic-arm assisted THA. The robotic-arm assisted THA group was the first cohort of patients undergoing robotic THA by the operating surgeon. All surgical procedures were performed using the posterior approach in the lateral decubitus position. Informed consent was obtained from all study patients. Institutional review board approval was obtained prior to commencement of the study.

**Inclusion criteria**

Inclusion criteria for this study included the following: diagnosis of primary osteoarthritis or osteoarthritis secondary to osteonecrosis or rheumatoid arthritis; patients undergoing primary THA; patients between 18–80 years of age; and patients judged suitable for the planned study implants. Exclusion criteria included the following: patients in which the planned hip biomechanics were in a different position to the contralateral side (e.g. developmental dysplasia of the hip or protrusio acetabuli); patients requiring revision surgery following previously failed THA; patients that were immobile or had another neurological condition affecting musculoskeletal function; and patients not suitable for the planned study implants (e.g. patient required dual-mobility cup or cemented implants). Patients undergoing conventional manual THA and robotic-arm assisted THA were not preoperatively matched but had comparable baseline demographic characteristics (Table 1).

**Preoperative imaging and templating**

The operating surgeon performed preoperative templating on all study patients using standing plain anteroposterior pelvic radiographs with Traumacad software (Traumacad, Petach-Tikva, Israel). Patients in both treatment groups also had preoperative CT scans of the pelvis and proximal femur to create patient-specific CAD models to guide implant positioning using the MAKOplasty total hip application system (Mako surgical corporation, Kalamazoo, MI, USA). Preoperative templating was performed to restore the native centre of rotation and combined offset to that of the contralateral side. Planned acetabular cup position was 40° inclination and 20° anteversion in both treatment groups. In all study patients, preoperative templating was performed to fully correct for any pre-existing leg-length discrepancy.

**Surgical technique**

Conventional manual THA was performed using the standard handheld reaming technique with manual implantation of the acetabular cup. The transverse acetabular ligament, anterior and posterior acetabular walls, and anterior superior iliac spine were used as fixed intraoperative anatomical landmarks to help guide position of the acetabular component. An external alignment guide was attached to
the cutting-edge reamer handle to achieve cup position with 40 degrees inclination and 20 degrees anteversion. Robotic-arm assisted THA was undertaken with the RIO robotic arm interactive orthopaedic system using the Mako robotic hip system (Mako surgical, Kalamazoo, MI, USA) to guide acetabular bone reaming and acetabular cup positioning based on the preoperative surgical plan. An electrocardiogram (ECG) lead over the inferior pole of the patella was used as a fixed reference point to display live on-screen changes in leg-length. These measurements guided intraoperative adjustments to bone resection, implant position, and implant size to achieve the desired leg-length correction. Patients in both treatment groups received the Accolade II femoral stem (Stryker, Mahwah, NJ, USA) and trident acetabular shell (Stryker, Mahwah, NJ, USA). In both treatment groups, the femur was prepared manually. Hip stability was tested through the full range of movement and leg-length discrepancy confirmed clinically before selection and insertion of final femoral stem and head sizes. Intraoperative image intensifier was not used in any study patients.

**Outcome measures**

All study outcomes were recorded by two independent fellowship-trained surgeons that were blinded to each other’s findings. Total operative times were collected in both treatment groups and individual stages of the robotic procedure in the robotic-arm assisted THA group. Preoperative confidence levels amongst the surgical team were recorded using the Spielberger State-Trait Anxiety Inventory (STAI) questionnaire, which is a validated subjective assessment tool for quantifying an individual’s stress levels with individual traits arising from the clinical environment. The 6-item questionnaire has a 4-point rating scale and total scores range from 6 to 24, with higher values indicating higher levels of stress. The STAI questionnaire has been previously used to assess the learning curves of robotic-arm assisted total knee and unicompartmental knee arthroplasty. This questionnaire was completed by each member of the surgical team prior to the surgical time-out in all study patients. The surgical team included the operating surgeon, two consultant anaesthetists, two senior scrub nurses, one operating department practitioner (ODP), and one circulating nurse.

Radiological outcomes were recorded using standing anteroposterior pelvic radiographs at 6 weeks after surgery. Measurements were recorded twice by each observer at 28 days apart to assess for intra-observer agreement. All root mean square error values were assessed by calculating the difference in the achieved radiological outcome measure on the postoperative pelvic radiograph versus the planned radiological outcome measure on the preoperative pelvic radiographic template. Accuracy of achieving the planned centres of horizontal and vertical rotation were assessed using the method described by Meermans et al. Acetabular cup inclination and version were calculated using the method described by Murray. Combined offset was calculated by summing the value of the acetabular offset and femoral offset as described by Fletcher et al. Leg-length discrepancy was calculated using the technique described by Woolson et al. Lewinnek’s safe zones were defined as 30–50° inclination and 5–25° anteversion, and Callanan’s safe zones defined as 30–45° inclination and 5–25° anteversion. Accuracy of the Traumacad system for measuring radiological parameters has previously been reported. Complications within 90 days following surgery were recorded.

### Power calculation

A sample size calculation was performed using operative time as the primary outcome measure. Using an effect size of 0.6 based on previously published data on operative times in conventional THA versus robotic-arm assisted THA, this study required 90 patients (45 patients in each

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**Table 1. Baseline demographic characteristics in patients undergoing conventional manual THA versus robotic-arm assisted acetabular cup positioning during THA.**

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Conventional manual THA (n = 50)</th>
<th>Robotic THA (n = 50)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>68.5 ± 5.4</td>
<td>67.1 ± 5.3</td>
<td>0.23&lt;sup&gt;*&lt;/sup&gt;</td>
</tr>
<tr>
<td>Gender (male/female)</td>
<td>Male – 25 (50%)</td>
<td>Male – 23 (46%)</td>
<td>0.82&lt;sup&gt;o&lt;/sup&gt;</td>
</tr>
<tr>
<td>Laterality (right/left)</td>
<td>Female – 25 (50%)</td>
<td>Female – 27 (54%)</td>
<td>0.34&lt;sup&gt;o&lt;/sup&gt;</td>
</tr>
<tr>
<td>Laterality (right/left)</td>
<td>Right – 27 (54%)</td>
<td>Right – 26 (52%)</td>
<td>0.74&lt;sup&gt;y&lt;/sup&gt;</td>
</tr>
<tr>
<td>Laterality (right/left)</td>
<td>Left – 23 (46%)</td>
<td>Left – 24 (48%)</td>
<td>0.30&lt;sup&gt;o&lt;/sup&gt;</td>
</tr>
<tr>
<td>Body mass index (kg/m&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>26.1 ± 2.7</td>
<td>25.8 ± 2.2</td>
<td>0.34&lt;sup&gt;o&lt;/sup&gt;</td>
</tr>
<tr>
<td>ASA score (I–IV)</td>
<td>I – 0</td>
<td>I – 0</td>
<td>0.74&lt;sup&gt;o&lt;/sup&gt;</td>
</tr>
<tr>
<td>ASA score (I–IV)</td>
<td>II – 40 (80%)</td>
<td>II – 42 (84%)</td>
<td>0.30&lt;sup&gt;o&lt;/sup&gt;</td>
</tr>
<tr>
<td>ASA score (I–IV)</td>
<td>III – 10 (20%)</td>
<td>III – 8 (16%)</td>
<td>0.30&lt;sup&gt;o&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Summary statistics are: mean ± standard deviation or number (percentage).

<sup>*</sup>Independent t-test.
<sup>o</sup>chi-squared test.
treatment arm) to detect a significant difference in operative time using a two-tailed, two-sample *t*-tests with a power of 80% and alpha value of 5%. To account for 10% sample size attrition at 90 days follow-up, 100 patients were recruited into this study.

**Statistical analysis**

The CUSUM sequential analysis tool was used to assess learning curves in robotic-arm assisted THA for operative times and surgical team confidence levels with standardised target values for these outcome measures from the conventional THA group. Accuracy of restoring native hip biomechanics and achieving planned acetabular cup positioning in robotic-arm assisted THA were assessed by calculating root mean square error values in consecutive groups of ten patients. Categorical data was compared using the chi square test and Fisher’s exact test. Normally distributed continuous variables were compared using independent *t*-tests for unpaired variables and paired *t*-test for matched (paired) variables. Multiple variables were assessed using one-way ANOVA and Kruskal–Wallis tests. The Mann–Whitney test was used for non-parametric data. Statistical significance was set at *p* < 0.05 for all statistical tests. All statistical analyses were performed using SPSS software version 21 (SPSS Inc., Chicago, IL, USA).

**Results**

**Interclass correlation coefficient**

Interclass correlation coefficient was 0.85 (95% CI, 0.82–0.91) for intra-observer agreement and 0.87 (95% CI, 0.84–0.92) for inter-observer agreement in all study outcomes, which indicated good agreement on all parameters assessed by the two independent observers.

**Operative times**

CUSUM analysis for operative times in robotic-arm assisted THA revealed an inflexion point after the initial 12 cases, which helped to identify two distinct phases in the learning curve (Figure 1). Phase 1 represents the initial learning stage and Phase 2 represents the proficiency stage with robotic-arm assisted THA. Analysis of individual phases in the robotic group showed most marked decreases in time for surgical tray, robotic device, and instrument set up (<0.001), bone registration (<0.001), and acetabular reaming (<0.001) (Table 2). Overall, robotic-arm assisted THA was not associated with increased operative times compared to conventional manual THA (*p* = 0.14) (Table 3).

**Surgical team confidence levels**

Preoperative confidence levels as assessed using the STAI questionnaire revealed an inflexion point after the initial

![Figure 1. Charts displaying cumulative summation (CUSUM) analysis for operative times in all study patients undergoing](image)
Figure 1. (Continued)

robotic-arm assisted during THA. (a) Chart plotting CUSUM analysis for operative times in consecutive robotic-arm assisted THA procedures. The dashed line represents the division between the learning phase (Phase 1, n = 12) and proficiency phase (Phase 2, n = 38) of the learning curve associated with robotic-arm assisted THA. (b) Chart plotting CUSUM analysis for cases within Phase 1 of the learning curve in robotic-arm assisted THA. (c) Chart plotting CUSUM analysis for cases within Phase 2 of the learning curve with robotic-arm assisted THA.

12 cases \( p < 0.001 \) in a pattern similar to operative times in robotic-arm assisted THA (Figure 2). There was no difference in the overall STAI scores amongst team members between conventional manual THA and robotic-arm assisted THA (Table 3).

Implant positioning and orientation

Robotic-arm assisted THA did not have a learning curve for accuracy in achieving the planned hip biomechanics, acetabular cup positioning and orientation, and correction of leg-length discrepancy (Table 4). Patient number 21 in the robotic group had acetabular cup positioning outside of Lewinnek’s safe zone, and patients number 12 and 21 had acetabular cup positioning outside of Callanan’s safe zones. No other outliers were identified in the robotic-arm assisted THA group. Robotic-arm assisted THA improved accuracy in restoration of native hip biomechanics, acetabular cup position, and acetabular cup orientation compared to conventional manual THA (Table 3).

Complications

No complications were reported in either treatment group within 90 days of follow-up.

Discussion

Robotic-arm assisted acetabular cup positioning during THA was associated with a learning curve of 12 cases for achieving operative times and surgical team confidence levels comparable to conventional manual THA. There was no learning curve effect for achieving the planned centre of rotation, combined offset, acetabular cup position and orientation, and correction of limb-length discrepancy.

Operative time is commonly used as a surrogate marker of surgical proficiency. Total operative time decreased with consecutive robotic cases during the initial learning phase as the surgical team became increasing familiar with individual stages of robotic-arm assisted THA and accustomed to the new instrumentation. Most marked improvements were observed in time for acetabular bone resection during the learning phase, which reflects the surgeon becoming progressively more adept with fine movements of the robotic arm and inbuilt audio, visual, and tactile inhibitory feedback. As the surgeon became more practiced with the robotic arm, he was able to better adjust the force and direction of the remaining process to ensure more controlled and efficient acetabular bone resection. More moderate time improvements were observed in bone registration. The acetabular landmarks for bone registration and verification are standardised and therefore with increasing surgical experience, the surgeon was able to predict and proactively position the bovie tip over the appropriate anatomical landmark before it was displayed on the computer screen.

Our findings support existing data showing that operative times in robotic-arm assisted THA decrease with cumulative experience. Redmond et al.\(^{18}\) conducted a prospective study on the learning curve of robotic-arm assisted THA by comparing outcomes in three consecutive groups of 35 patients. The authors reported that the mean

Table 2. Operative data in patients undergoing robotic-arm assisted total hip arthroplasty.

<table>
<thead>
<tr>
<th>Operative stage (mins)</th>
<th>Cases 1–10</th>
<th>Cases 11–20</th>
<th>Cases 21–30</th>
<th>Cases 31–40</th>
<th>Cases 41–50</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical tray, robotic device, and instrument set up</td>
<td>22.9 ± 7.4</td>
<td>12.4 ± 4.0</td>
<td>9.4 ± 3.6</td>
<td>10.1 ± 3.8</td>
<td>9.7 ± 3.9</td>
<td>&lt;0.001(^b)</td>
</tr>
<tr>
<td>Surgical approach/pin insertion</td>
<td>6.6 ± 1.4</td>
<td>6.2 ± 1.0</td>
<td>6.4 ± 1.1</td>
<td>6.8 ± 1.2</td>
<td>6.7 ± 1.5</td>
<td>0.61(^b)</td>
</tr>
<tr>
<td>Bone registration</td>
<td>17.1 ± 4.8</td>
<td>8.2 ± 2.7</td>
<td>6.1 ± 1.4</td>
<td>7.1 ± 1.3</td>
<td>6.7 ± 1.7</td>
<td>&lt;0.001(^b)</td>
</tr>
<tr>
<td>Assess hip biomechanics, leg-length, and perform femoral osteotomy</td>
<td>7.2 ± 3.5</td>
<td>6.9 ± 3.3</td>
<td>6.7 ± 3.1</td>
<td>6.6 ± 3.4</td>
<td>7.2 ± 3.1</td>
<td>0.13(^b)</td>
</tr>
<tr>
<td>Acetabular reaming</td>
<td>14.3 ± 3.9</td>
<td>7.7 ± 2.1</td>
<td>5.8 ± 1.0</td>
<td>5.7 ± 0.8</td>
<td>6.1 ± 1.0</td>
<td>&lt;0.001(^b)</td>
</tr>
<tr>
<td>Femoral stem preparation</td>
<td>6.2 ± 2.1</td>
<td>5.4 ± 2.5</td>
<td>7.1 ± 3.2</td>
<td>6.2 ± 2.1</td>
<td>7.3 ± 2.3</td>
<td>0.56(^b)</td>
</tr>
<tr>
<td>Implant Trialling</td>
<td>7.2 ± 3.6</td>
<td>6.9 ± 3.5</td>
<td>7.3 ± 3.4</td>
<td>7.2 ± 3.7</td>
<td>6.9 ± 3.2</td>
<td>0.67(^b)</td>
</tr>
<tr>
<td>Implant insertion</td>
<td>7.4 ± 1.4</td>
<td>8.1 ± 0.7</td>
<td>7.7 ± 0.9</td>
<td>6.9 ± 0.6</td>
<td>7.3 ± 1.9</td>
<td>0.41(^b)</td>
</tr>
<tr>
<td>Closure</td>
<td>6.7 ± 0.8</td>
<td>8.1 ± 1.2</td>
<td>8.4 ± 1.4</td>
<td>7.9 ± 0.9</td>
<td>8.2 ± 1.2</td>
<td>0.67(^b)</td>
</tr>
<tr>
<td>Overall operating time</td>
<td>72.7 ± 6.4</td>
<td>57.5 ± 3.7</td>
<td>55.7 ± 2.8</td>
<td>54.4 ± 5.1</td>
<td>54.9 ± 2.9</td>
<td>&lt;0.001(^b)</td>
</tr>
</tbody>
</table>

Summary statistics are: Mean value and standard deviation. P-value for trend.
\(^a\)one-way analysis of variance (ANOVA) test.
\(^b\)one-way analysis of variance (ANOVA) test with Welch test.
\(^c\)Kruskall–Wallace test.
operative time in the first robotic cohort was 79.8 ± 27 minutes, compared to 63.2 ± 14.2 minutes and 69.4 ± 16.3 minutes respectively in the last two robotic cohorts (p = 0.02). In our study, CUSUM analysis enabled more accurate assessment of transition from the learning phase to the proficiency phase, and the accumulative robotic experience required for the surgeon to become "time even" to conventional THA. However, this finding should be interpreted with caution as robotic-arm assisted THA was performed using the express workflow system in which the robotic device does not help to execute the planned femoral osteotomy or femoral stem preparation. The enhanced workflow may also further influence accuracy of restoring the native centre of rotation and combined offset in the robotic-arm assisted THA group.

Increased levels of stress and mental strain during surgery are associated with diminished operative performance, poor decision making, and reduced technical skills. In this study, improvements in the surgical team’s confidence levels during the initial learning phase followed a similar trend to operative times. This was associated with objective improvements in time for set-up of the robotic device, fixed arrays, and surgical instruments during

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Table 3. Study outcomes in patients undergoing conventional manual total hip arthroplasty (THA) versus robotic-arm assisted THA.

<table>
<thead>
<tr>
<th></th>
<th>Conventional manual THA (n = 50)</th>
<th>Robotic THA (n = 50)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Horizontal centre of rotation (mm) RMSE</strong></td>
<td>3.7 ± 1.7</td>
<td>1.7 ± 1.2</td>
<td>&lt;0.001α</td>
</tr>
<tr>
<td><strong>Vertical centre of rotation (mm) RMSE</strong></td>
<td>2.2 ± 0.9</td>
<td>0.8 ± 0.8</td>
<td>&lt;0.001α</td>
</tr>
<tr>
<td><strong>Combined offset (mm) RMSE</strong></td>
<td>2.6 ± 0.9</td>
<td>1.6 ± 1.1</td>
<td>&lt;0.001α</td>
</tr>
<tr>
<td><strong>Cup inclination</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Within Lewinnek’s safe zone</td>
<td>40 (80%)</td>
<td>49 (98%)</td>
<td>&lt;0.001α</td>
</tr>
<tr>
<td>– Within Callanan’s safe zone</td>
<td>38 (76%)</td>
<td>48 (98%)</td>
<td>&lt;0.001α</td>
</tr>
<tr>
<td><strong>Cup Anteversion</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Within Lewinnek’s safe zone</td>
<td>44 (88%)</td>
<td>50 (100%)</td>
<td>0.03β</td>
</tr>
<tr>
<td>– Within Callanan’s safe zone</td>
<td>44 (88%)</td>
<td>50 (100%)</td>
<td>0.02β</td>
</tr>
<tr>
<td><strong>Overall cup position</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Within Lewinnek’s safe zone</td>
<td>34 (68%)</td>
<td>49 (98%)</td>
<td>&lt;0.001α</td>
</tr>
<tr>
<td>– Within Callanan’s safe zone</td>
<td>32 (64%)</td>
<td>48 (96%)</td>
<td>&lt;0.001α</td>
</tr>
<tr>
<td><strong>Leg-length discrepancy (mm) RMSE</strong></td>
<td>2.6 ± 3.1</td>
<td>1.4 ± 1.2</td>
<td>0.23γ</td>
</tr>
<tr>
<td><strong>Operative time (mins)</strong></td>
<td>54.7 ± 2.6</td>
<td>59.0 ± 4.2</td>
<td>0.14δ</td>
</tr>
<tr>
<td><strong>STAI scores</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Operating surgeon</td>
<td>12.6 ± 1.8</td>
<td>13.1 ± 3.2</td>
<td>0.45ο</td>
</tr>
<tr>
<td>– Consultant anaesthetist</td>
<td>11.2 ± 2.1</td>
<td>11.6 ± 3.1</td>
<td>0.68ο</td>
</tr>
<tr>
<td>– Scrub nurse</td>
<td>10.5 ± 1.5</td>
<td>10.7 ± 2.4</td>
<td>0.41ο</td>
</tr>
<tr>
<td>– ODP</td>
<td>9.2 ± 1.1</td>
<td>9.9 ± 2.6</td>
<td>0.26ο</td>
</tr>
<tr>
<td>– Circulating nurse</td>
<td>12.0 ± 1.9</td>
<td>11.0 ± 2.8</td>
<td>0.30ο</td>
</tr>
</tbody>
</table>

RMSE, Root mean square error; STAI, State-trait anxiety inventory score (6-24); ODP, Operating department practitioner.

Summary statistics are: mean ± standard deviation or number (percentage). Lewinnek’s safe zone - inclination 30–50°; anteversion 5–25°; Callanan’s safe zone - Inclination 30–45°; anteversion 5–25°.α

Independent t-test.

βChi-squared test.

γKruskall–Wallace test.

δMann–Whitney test.

οPaired t-test.

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Figure 2. Chart displaying CUSUM analysis for STAI scores amongst surgical team members in all robotic-arm assisted THA procedures.
this learning phase. The highest STAI score was observed in the operating surgeon but this did not translate to any differences in accuracy of implant positioning or restoration of native hip biomechanics. Robotic-arm assisted THA is undertaken with the assistance of a trained robotic technician that aids preoperative surgical planning, facilitates intraoperative data capture, physical movement of the robotic device around the operating room, and advises on optimal bone resection and implant positioning. The level of training and experience of this robotic technician may also influence the surgical team’s learning curve.

There was no learning curve effect for achieving the planned centre of rotation and combined offset in patients undergoing robotic-arm assisted THA, which enabled accurate restoration of native hip biomechanics during both learning and proficiency phases. Robotic-arm assisted THA uses stereotactic boundaries to control acetabular reaming within the predefined haptic tunnel, which helps to reduce technical errors in the direction and depth of acetabular bone reaming. Nawabi et al.\(^1\) performed a cadaveric study with 12 conventional manual THAs on one side and 12 robotic THAs on the contralateral side, and found reduced root mean square errors in achieving the planned horizontal and vertical centres of rotation in the robotic group. The root mean square error values for accuracy in restoring the native centre of hip rotations in conventional and robotic THA were similar to those reported in this study. Although, robotic THA improves accuracy of implant positioning and reduces outliers in acetabular cup positioning, there remains a paucity of data on how these improved radiological outcomes translate to differences in clinical recovery, functional outcomes, implant survivorship, and long-term complications compared to conventional manual THA. Robotic THA has substantial installation costs for the robotic device and compatible implants, and image-guided robotic THA requires additional preoperative radiation exposure.

Hip instability and mechanical loosening secondary to suboptimal implant positioning are the most common reasons for revision THA.\(^3\)\(^1\)\(^2\)\(^3\)\(^1\)\(^3\)\(^1\) Robotic-arm assisted THA uses computer software to assess the patient’s pelvic tilt in the supine position during CT scan, and then guides acetabular cup positioning based on the functional (coronal) plane of Murray instead of the anatomical plane.\(^1\)\(^3\) Intraoperative bone registration also enables the surgeon to intraoperatively confirm the acetabular bony anatomy of the CT scan prior to acetabular reaming and cup positioning.\(^2\) These factors may have helped to limit surgical errors in acetabular cup positioning during the initial learning phase, and improve the overall accuracy of cup positioning within the safe zones compared to the manual THA group. Our findings are consistent with Domb et al.\(^1\)\(^3\) who found that cup positioning within Lewinnek’s safe zone was achieved in 50/50 (100%) robotic THAs compared to 40/50 (80%) conventional THAs (\(p = 0.001\)). The authors also reported that cup positioning within Callanan’s safe zone was achieved in 46/50 (92%) robotic THAs but only 31/50 (62%) conventional THAs (\(p = 0.001\)).

The findings of this study will enable healthcare professionals to better understand the impact of implementing robotic-arm assisted acetabular cup positioning during THA on the surgical workflow. Theatre planning and scheduling of operative cases should consider increased operative times and heightened levels of anxiety amongst the surgical team during this initial learning phase. As team members become more familiar and adept with robotic technology, confidence levels improve, and theatre efficiency increases thereafter. There is no effect of cumulative experience with robotic-arm assisted acetabular cup positioning during THA on accuracy of restoring native hip biomechanics, acetabular cup positioning, and acetabular cup orientation, which are important for the safe implementation of this procedure into routine surgical practice.

There are several limitations of the study design that must be appreciated when interpreting the findings of this study. First, this study was undertaken on a single surgeon within a surgical team that was experienced with conventional and computer navigated THA in a high-volume arthroplasty centre. The learning curve may therefore not be directly transferable to other surgeons or surgical teams with less experience. However, this study design did enable us to better understand how cumulative robotic experience in a

**Table 4.** Accuracy of restoring native hip biomechanics and acetabular cup positioning in patients undergoing robotic-arm assisted total hip arthroplasty.

<table>
<thead>
<tr>
<th>Radiological outcome</th>
<th>Cases 1–10</th>
<th>Cases 11–20</th>
<th>Cases 21–30</th>
<th>Cases 31–40</th>
<th>Cases 41–50</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RMSE Horizontal centre of rotation, mm</td>
<td>1.4 ± 0.8</td>
<td>1.8 ± 1.2</td>
<td>2.0 ± 1.6</td>
<td>1.7 ± 1.5</td>
<td>1.8 ± 1.3</td>
<td>0.83(^a)</td>
</tr>
<tr>
<td>RMSE Vertical centre of rotation, mm</td>
<td>0.9 ± 0.8</td>
<td>0.8 ± 0.6</td>
<td>0.9 ± 0.5</td>
<td>0.7 ± 1.1</td>
<td>0.7 ± 0.8</td>
<td>0.71(^b)</td>
</tr>
<tr>
<td>RMSE Combined offset, mm</td>
<td>1.6 ± 1.1</td>
<td>1.8 ± 1.4</td>
<td>1.4 ± 1.2</td>
<td>1.7 ± 0.9</td>
<td>1.5 ± 0.9</td>
<td>0.67(^a)</td>
</tr>
<tr>
<td>Mean acetabular cup inclination, °</td>
<td>37.7 ± 2.9</td>
<td>37.1 ± 5.6</td>
<td>38.9 ± 4.6</td>
<td>39.1 ± 6.1</td>
<td>37.1 ± 5.0</td>
<td>0.68(^b)</td>
</tr>
<tr>
<td>Mean acetabular cup version, °</td>
<td>18.1 ± 2.4</td>
<td>18.4 ± 2.7</td>
<td>17.1 ± 4.9</td>
<td>18.0 ± 2.5</td>
<td>17.3 ± 3.9</td>
<td>0.72(^a)</td>
</tr>
<tr>
<td>Leg-length discrepancy, mm</td>
<td>1.5 ± 1.3</td>
<td>1.1 ± 1.5</td>
<td>1.6 ± 1.3</td>
<td>1.4 ± 0.8</td>
<td>1.4 ± 1.2</td>
<td>0.61(^a)</td>
</tr>
</tbody>
</table>

Summary statistics are: RMSE (root mean square error) with standard deviation. \(p\)-value for trend.

\(^a\)Kruskal–Wallace test.

\(^b\)Kruskal–Wallace test.
single surgical team impacts operative times, confidence levels, and accuracy of implant positioning. Second, radiological analysis of implant positioning was undertaken using plain radiographs, which are not as accurate as CT scan. Third, patient allocation using randomisation instead of availability of the robotic device would have helped to better reduce any potential confounding or bias in the study. Fourth, follow-up time was limited to 90 days after surgery and therefore long-term data on functional outcomes, implant survivorship and revision rates was not available.

**Conclusion**

Implementation of robotic-arm assisted acetabular cup positioning during THA was associated with a learning curve of 12 cases for operative times and surgical team confidence but there was no learning effect for accuracy in restoring native hip centre of rotation, preservation of combined offset, acetabular cup position and orientation, and correction of leg-length discrepancy. There was no difference in postoperative complications between conventional manual THA and robotic-arm assisted acetabular cup positioning during THA within 90 days follow-up.

**Declaration of conflicting interests**

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**References**

A prospective double-blinded randomised control trial comparing robotic arm-assisted functionally aligned total knee arthroplasty versus robotic arm-assisted mechanically aligned total knee arthroplasty

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Abstract

Background: Total knee arthroplasty (TKA) with mechanical alignment (MA) aims to achieve neutral limb alignment in all patients, whereas TKA with functional alignment (FA) aims to restore native, patient-specific anatomy and knee kinematics by manipulating bone resections and fine-tuning implant positioning. The objective of this study is to determine the optimal alignment technique in TKA by comparing patient satisfaction, functional outcomes, implant survivorship, complications, and cost-effectiveness in MA TKA versus FA TKA. Robotic technology will be used to execute the planned implant positioning and limb alignment with high-levels of accuracy in all study patients.

Methods and analysis: This prospective double-blinded randomised control trial will include 100 patients with symptomatic knee osteoarthritis undergoing primary robotic arm-assisted TKA. Following informed consent, patients will be randomised to MA TKA (the control group) or FA TKA (the investigation group) at a ratio of 1:1 using an online random number generator. Blinded observers will review patients at regular intervals for 2 years after surgery to record predefined study outcomes relating to postoperative rehabilitation, clinical progress, functional outcomes, accuracy of implant positioning and limb alignment, gait, implant stability, cost-effectiveness, and complications. A superiority study design will be used to evaluate whether FA TKA provides superior outcomes compared to MA TKA. Primary and secondary objectives will be used to quantify and draw inferences on differences in the efficacy of treatment between the two groups. Intention-to-treat and per-protocol population analysis will be undertaken. The following statistical methods will be employed to analyse the data: descriptive statistics, independent t test, paired t test, analysis of variance, Fisher exact test, chi-square test, and graphical displays. Ethical approval was obtained from the London-Surrey Research Ethics Committee, UK. The study is sponsored by University College London, UK.

Discussion: This is the first study to describe the use of robotic technology to achieve FA TKA, and the only existing clinical trial comparing robotic MA TKA versus robotic FA TKA. The findings of this study will enable an improved understanding of the optimal alignment technique in TKA for achieving high-levels of patient satisfaction, improving functional outcomes, increasing implant survivorship, improving cost-effectiveness, and reducing complications.

Registration: Clinical Trials.gov, NCT04092153. Registered on 17 September 2019.
Background

Total knee arthroplasty (TKA) is an established and highly effective treatment for patients with symptomatic end-stage knee osteoarthritis. The procedure is performed in over 90,000 patients per year in the UK [1]. Middle- to long-term follow-up studies have shown good clinical outcomes following TKA [20, 22, 39], and the 10-year revision rate for cemented, unconstrained, fixed bearing TKA is 3% [1]. Despite these results, there is a higher incidence of patient dissatisfaction compared to total hip arthroplasty, with up to 20% of patients reporting dissatisfaction in an otherwise uncomplicated TKA [5, 9, 10, 35]. The exact aetiology of this is not clear but recent studies have shown one possible reason to be suboptimal limb alignment, which may adversely affect postoperative knee biomechanics and kinematic function [4, 7, 9–11, 35, 44]. Conceptually, an improved understanding and execution of the optimal alignment in TKA may help to increase patient satisfaction, improve functional outcomes and reduce long-term complications.

Total knee arthroplasty with mechanical alignment (MA) aims to achieve neutral alignment of the limb. This is achieved by placing implants perpendicular to the mechanical axis of the femur and tibia, and externally rotating the femoral component to obtain a rectangular, balanced flexion-extension gap, which also aids patella tracking [11]. Measured bone resections or gap balancing techniques with controlled periarticular soft tissue releases help to achieve balanced flexion-extension gaps and restore equal mediolateral soft tissue tension. The principle of neutral mechanical alignment is to distribute load evenly across the implants, which provides a mechanical advantage in flexion and limits asymmetrical bearing surface wear [44]. However, recent studies have shown that there are large variations in native knee anatomy with only 5–5.5% of the general population having natural neutral mechanical alignment [4, 6]. Therefore, in the large majority of patients undergoing MA TKA, the knee is forced into an unnatural position with resultant changes in knee biomechanics that alter the native femoral flexion axis, ligament tension, quadriceps function, patella tracking and overall knee kinematics [4, 6, 17, 18].

Total knee arthroplasty with functional alignment (FA) aims to restore joint line height, preserve native obliquity, and achieve balanced flexion-extension gaps with equal mediolateral soft tissue tension by manipulating bone resections and fine-tuning implant positioning. Conceptually, FA TKA reduces the need for intraoperative periarticular soft tissue releases while restoring the patient’s native pre-arthritic knee kinematics. This technique is a modification of TKA with kinematic alignment, in which bone resections and implant positioning are undertaken to restore the patient’s natural distal and femoral joint lines, tibial joint line and limb alignment. Patient-specific implants, computer navigation and three-dimensional printed cutting blocks have been used to help achieve kinematic alignment in TKA. Studies have demonstrated that TKA with kinematic alignment reproduces more natural knee kinematics including medial pivot movement and femoral rollback compared to MA TKA [14, 34, 15, 26, 29]. Preserving patient-specific alignment and knee kinematics in TKA with kinematic alignment may also decrease the risk of common peroneal nerve palsy, which is associated with forcing the limb into neutral alignment with extensive bone resections and periarticular releases in MA TKA [23, 25]. Early clinical and functional outcome studies have reported promising outcomes in TKA with kinematic alignment [14, 27, 28], but results of longer-term studies have yet to be published.

There is no uniform consensus on the optimal alignment technique for TKA [8, 12, 16, 19, 30, 33, 36–38, 41]. Some studies have shown improved clinical outcomes with TKA with kinematic alignment compared to MA TKA at short-term follow-up, while other systematic reviews and meta-analyses have shown no difference in outcomes between the two alignment techniques [14, 27, 28, 34, 44]. The main limitations of these existing studies are that different implant designs were used within each treatment group, manually positioned cutting blocks with poor reproducibility were used to achieve the planned limb alignment, intraoperative limb alignment was not assessed, and limited data on functional outcomes or implant survivorship were reported. It is possible to improve on these existing studies by assessing a more comprehensive range of validated clinical and functional outcome measures, blinding both patients and observers recording outcomes, and using radiostereometric analysis (RSA) to assess implant micromotion for long-term implant survivorship [32, 42, 43]. Importantly, FA TKA offers an avenue for achieving patient-specific kinematics with balanced flexion-extension gaps and equal mediolateral soft tissue tension by manipulating bone resections and fine-tuning implant positioning, while limiting the need for periaxial soft tissue releases. Robotic technology also offers an avenue for executing the planned MA TKA or FA TKA with greater accuracy and reduced outliers. The findings of this study will enable an improved understanding of the optimal alignment technique in TKA for achieving high levels of patient satisfaction, improving functional outcomes, increasing implant survivorship, improving cost-effectiveness and reducing complications.

Methods/design

Objectives

The primary objective of this study is to compare the total Western Ontario and McMaster Universities Arthritis Index (WOMAC) score in MA TKA versus FA TKA at 2
years after surgery. As FA TKA enables improved restoration of native, patient-specific knee kinematics [15, 26, 29], the study hypothesis is that total WOMAC scores will be superior in patients undergoing FA TKA compared to MA TKA at 2 years follow-up.

The secondary objectives are to compare the following outcomes between the two treatment groups:

1. Accuracy of implant positioning and limb alignment
2. Surgical efficiency
3. Postoperative functional rehabilitation
4. Functional outcomes
5. Quality of life
6. Implant migration
7. Gait
8. Resource use and cost-effectiveness
9. Complications

Trial design
This study is a prospective, single-centre, double-blinded, randomised control trial. The study will be undertaken in the Department of Trauma and Orthopaedics, University College Hospital, London, UK. The study will include 100 patients randomly allocated to either MA TKA (the control group) or FA TKA (the investigation group). All patients will undergo robotic arm-assisted TKA to improve the accuracy of achieving the planned implant positioning and limb alignment. The study commenced patient recruitment in December 2018 and is expected to complete patient recruitment in December 2020. All patients will be followed up for 2 years after surgery and therefore the anticipated completion date for the study is December 2022. The study is sponsored by University College London, UK. The patient enrolment flowchart is presented in Fig. 1. The schedule of enrolment, interventions, and assessments for all study patients is shown in Fig. 2. This study followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (Additional file 1).

Eligibility criteria
The inclusion criteria for this study are as follows: 1) the participant has symptomatic knee osteoarthritis requiring primary TKA; 2) the participant is fit for surgical intervention following a review by the surgeon and anaesthetist; 3) the participant is aged between 18 and 80 years at the time of surgery; 4) the participant is able to give informed consent and agrees to comply with the postoperative review programme; and 5) the participant has sufficient mobility to attend follow-up clinics. The exclusion criteria for this study are as follows: 1) the participant is undergoing revision surgery or second-stage TKA; 2) the participant is not suitable for study implants (e.g. requires a constrained prosthesis); 3) the participant is immobile or has another neurological condition affecting musculoskeletal function; 4) the participant is already enrolled on another concurrent clinical trial; 5) the participant is unable or unwilling to sign the informed consent form specific to this study; and 6) the participant is unable to attend the study follow-up programme.

Recruitment
Participants will be recruited from the orthopaedic outpatient clinic at University College Hospital, London, UK. All patients will be screened by the clinical team (orthopaedic consultant surgeon, clinical research fellow, and orthopaedic registrar) for study participation based on the predefined inclusion and exclusion criteria listed above. Patients that fulfil the eligibility criteria and express an interest in participating in the study will be provided with an Ethics Committee-approved patient information sheet. This provides details about the study, treatment, follow-up and contact details for further information. All members of the clinical team are familiar with the study and will address any preliminary questions about the study. Details of those patients expressing an interest to participate in the study will be recorded in the patient contact form and forwarded to the research physiotherapist. The research physiotherapist will telephone the patient 4 weeks after this consultation to discuss any further questions and confirm if the patient would like to participate in the study.

Consent
Informed consent will be obtained by the chief investigator or principal investigator when the patient attends for the preoperative planning computerised tomography (CT) scan. This is 6 weeks after the outpatient consultation for agreement to TKA and 2 weeks before surgery. It is important to the data collection scheme that patients are able to follow commands and read and interpret questions via questionnaires. For those who cannot hear, read or understand English, an interpreter will be provided. The operating surgeon will use the preoperative CT scan to create a patient-specific computer-aided design model and create a surgical plan for executing both MA TKA and FA TKA in all study patients.

Allocation
After informed consent has been obtained, the research physiotherapist will randomise the patient into one of the two groups using an online random number generator (www.random.org). A number from 1 to 100 will be randomly generated and will allocate a patient to one of the two arms of the study: 1–50 inclusive for the control group, 51–100 inclusive for the investigation group. The research physiotherapist will perform the randomisation procedure and store the designated treatment group for each patient on a password-encrypted file on the hospital
The operating surgeon will have this information communicated to him on the morning of surgery.

**Surgical intervention**

In patients undergoing MA TKA, femoral and tibial bone implant positioning will be used to achieve neutral limb alignment. In the coronal plane, femoral implant positioning will be set at 5–7° valgus in relation to the anatomical axis of the femur. In the sagittal plane, femoral component positioning will be set at 0–5° of flexion to optimise implant positioning while preventing notching. In the axial plane, the femoral component will be
aligned to the surgical transepicondylar axis, which is approximately 3° externally rotated to the posterior condylar axis [2, 3]. The size of the femoral implant will be selected using posterior referencing with the largest size that does not overhang the femur, notch the anterior femur, or overhang the mediolateral bone edges, and avoids overstuffing the patellofemoral joint. The femoral implant will be positioned at the centre of the mediolateral cortical bone edges. In the coronal plane, tibial implant position will be aligned to the tibial mechanical axis. In the sagittal plane, tibial implant position will be set to 0–3° of posterior tibial slope. In the axial plane, tibial implant will be positioned at 0–5° of external rotation to Akagi’s line [2, 3, 45]. Tibial implant size will be selected with the largest size that does not overhang the anteroposterior or mediolateral bone coverage. The implant will be positioned in the centre between the anteroposterior and mediolateral cortical bone edges.

In patients undergoing FA TKA, implants will be positioned to optimise soft tissue tension through achieving...
balanced flexion–extension gaps and equal mediolateral soft tissue tension by altering bone resections and implant positions rather than through soft tissue releases. This will be achieved when possible within strict alignment limits, and where not achievable because of the magnitude of a fixed deformity by balancing after bone cuts with limited soft tissue releases. The preoperative surgical plan will be used to fix a specific point on the tibia and the gaps balanced to restore the obliquity of the native joint line. In the coronal plane, femoral implant positioning will be modified from a starting point of 0° to the mechanical axis to balance the extension gap. In the sagittal plane, femoral component positioning will be set to optimise component sizing while avoiding notching by flexing up to 5°. In the axial plane, the femoral component will be aligned to the surgical trans-epicondylar axis and modified by up to 3° to balance the flexion gap. The size of the femoral implant will be selected using posterior referencing with the smallest size that does not overhang the femur, notch the anterior femur, or overhang mediolateral bone edges, and avoids overstuffing the patellofemoral joint. The femoral implant will be positioned at the centre of the mediolateral cortical bone edges, favouring a lateral position if necessary. In the coronal plane, tibial implant position will be aligned to the tibial mechanical axis and then modified to balance flexion and extension gaps by up to 3° of varus. Valgus tibial position will be avoided. In the sagittal plane, tibial implant position will be set to match the patient’s native posterior tibial slope, modified to balance the flexion gap if necessary. In the axial plane, the tibial implant will be positioned using Akagi’s line [2, 3, 45]. Tibial implant size will be selected with the largest size that does not overhang the anteroposterior and mediolateral bone coverage while achieving the correct rotation. The implant will be positioned in the centre between the anteroposterior and mediolateral cortical bone edges.

All operative procedures will be undertaken using the Mako robotic arm interactive orthopaedic system (Stryker Limited, Kalamazoo, MI, USA) under the direct supervision of one arthroplasty surgeon (FSH). The cemented Stryker Triathlon (Stryker Navigation, Kalamazoo, MI, USA) cruciate-retaining knee system with asymmetrical patellar resurfacing will be used in both groups. All bone resections, implant positioning and limb alignment will be within regulatory approval for the Triathlon cruciate-retaining knee system. Overall limb alignment, defined as the sum of the femoral and tibial coronal rotations, will range from 3° of varus to 3° of valgus.

**Outcomes**

All study patients will undergo review by two blinded observers (one orthopaedic registrar and one clinical research fellow) at 2 weeks, 6 weeks, 6 months, 1 year and 2 years following surgery. During these follow-up times, predefined clinical, functional and radiological outcomes will be recorded by these observers using case report forms. The following outcomes will be recorded in all study patients:

1. Accuracy of implant positioning and limb alignment as assessed using CT scans of the knee joint performed postoperatively at 6 weeks.
2. Operating time (minutes)
3. Time to hospital discharge (hours)
4. Analgesia requirements during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year and 2 years
5. Patient-reported outcome measures including Forgotten Joint Score (FJS), Oxford Knee Score (OKS), short-form health survey of 12 items (SF-12), Knee Injury and Osteoarthritis Outcome Score (KOOS), WOMAC, University of California at Los Angeles score and University College Hospital functional knee score preoperatively and postoperatively at 6 weeks, 6 months, 1 year and 2 years
6. Health-related quality of life as measured using the European Quality of Life questionnaire with five dimensions for adults (EQ-5D) preoperatively and postoperatively at 6 weeks, 6 months, 1 year and 2 years
7. Mobilisation distance (metres) and use of mobility aids during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year and 2 years
8. Range of movement (degrees) in knee joint during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year and 2 years
9. Femoral and tibial implant early migration as assessed using RSA performed postoperatively at 2 weeks, 6 weeks, 6 months, 1 year, and 2 years
10. Gait analysis performed postoperatively at 6 months and 1 year using an instrumented treadmill with force plates
11. Resource use and cost-effectiveness, including comparisons between the two treatment groups relating to operating time, theatre efficiency, equipment and sterilisation costs, analgesia requirements, inpatient rehabilitation, time to discharge, outpatient follow-up, additional imaging costs and need for further surgery.
12. Complications

The FJS, University of California at Los Angeles knee score, WOMAC, OKS, KOOS, SF-12 and EQ-5D are validated tools for the clinical assessment of patients after knee arthroplasty [21, 24, 31]. In addition, the blinded observer will record the University College Hospital functional knee score to assess overall pain, function and
mobility. All study patients will undergo gait analysis using an instrumented treadmill with force plates (Kistler Gateway, Kistler Instrument Corporation, Amherst, NY, USA) on a level platform. Gait analysis will be performed at the patient’s self-selected comfortable speed and maximum speed without running. Vertical ground reaction forces and spatiotemporal data will be obtained from force plates built into the treadmill. RSA radiographs will be performed at regular postoperative follow-up intervals to quantify motion between the implant and host bone, which is highly predictive of long-term implant survival [32, 40].

**Blinding**

All patients and clinical staff recording postoperative study outcomes will remain blinded to the treatment group. Study patients will be identifiable with a unique study number. Only the research physiotherapist will have the key to identify individual patients and their respective treatment arm. Any documents related to the study will be archived directly at the study site by the research physiotherapist within a secure filing cabinet in a locked research office. This office has swipe card access with onsite security and 24-h closed-circuit television surveillance. Patient data will be logged electronically using each patient’s unique identification number with computer software on an encrypted, password-protected research computer.

**Sample size**

Using data from a previous study recording functional outcomes, the mean WOMAC score at 2 years using MA TKA was 26 (standard deviation 22.6) and using TKA with kinematic alignment was 15 (standard deviation 20.3) [14]. Using a two-tailed, two-sample t test with an effect size of 0.35, power of 90% with significance level of 5%, and accounting for an expected drop-out rate of 10% during the 2-year follow-up period, the study requires 100 patients to detect a minimal clinically important difference of 11 points in the total WOMAC score between the two treatment groups [13].

**Statistical analysis**

The analysis of the per-protocol population will be considered the primary analysis. The differences between the MA TKA and FA TKA groups will be analysed by calculating the difference from baseline per patient, and a two-sided confidence interval for the difference between the changes from baseline values will be calculated. This confidence interval will cover the true difference in the percentage change from baseline with a probability of 95%. The following statistical methods will be employed to analyse the data: descriptive statistics, independent t test, paired t test, analysis of variance, Fisher exact test, chi-square test and graphical displays. Assumptions of normality will be tested with the D’Agostino test. Assumptions of homogeneity of variance will be tested with Levene’s test. If the distributional assumptions are (severely) violated, non-parametric techniques such as the Mann-Whitney test will be employed. In the event that FA TKA is converted to MA TKA intraoperatively, analysis will be performed using the intention-to-treat population and the treatment actually received by the patients. Intraoperative conversion from FA TKA to MA TKA will be documented and presented as part of the study. Statistical significance is set at a P value <0.05 for all analyses and all statistical analyses will be performed using SPSS software version 25 (SPSS Inc., Chicago, IL, USA). The Bonferroni correction will be used to adjust P values to reduce the risk of type I error with performing multiple statistical comparisons.

**Adverse events**

Adverse events are defined as any untoward medical occurrence in a patient or study participant that does not necessarily have a causal relationship with the procedure involved. A serious adverse event (SAE) is an adverse event that results in hospitalisation or prolongation of existing hospitalisation, persistent or significant disability or incapacity, life-threatening clinical sequelae, or death. All SAEs during the protocol treatment will be reported directly to the sponsor using the SAE web form. The chief investigator will also assess the SAE for severity, causality, seriousness and expectedness using pre-existing criteria provided by the sponsor and will inform the Data Safety Monitoring Board (DSMB) within 3 days of the initial observation of the event. The protocol treatment period is defined as the period from the day that the first study patient is recruited into the trial to the day that the final study patient has completed 2 years follow-up. The chief investigator will also inform the London-Surrey Research Ethics Committee and local Health Research Authority within 3 days of the SAE taking place. Safety aspects of the study are closely monitored by the sponsor and DSMB using unblinded data for its judgment. In cases where the SAE arises due to a problem with the robotic device, Stryker Limited will also be notified within 2 days of the event taking place. The chief investigator will record the following: onset date, complete description of the event, severity, duration, action taken and outcome for each SAE. The chief investigator will also provide regular updates of all SAEs to the London-Surrey Research Ethics Committee, local Health Research Authority, DSMB, and sponsor.

**Data management**

On-site monitoring visits shall occur throughout the course of the clinical study by the chief investigator. The
chief investigator shall permit and assist the sponsor (should they chose to monitor the study) to carry out verification of all study forms against data in the source documents, which shall occur as per the departmental policy for undertaking such activities. University College Hospital recognises that there is an obligation to archive study-related documents at the end of the study. The study master file will be archived at University College London in accordance with the University College Hospital Standard Operating Procedure for Archiving of Investigator Site File and Pharmacy Site File. It will be archived for a minimum of 5 years from the study end, and for no longer than 30 years from the study end.

End-of-protocol treatment
Reasons for going off study protocol include:

1. Completion of last follow-up visit 2 years after surgery
2. Patient non-compliance or withdrawal (the reason for discontinuation will be recorded in the case report form)
3. Intercurrent death

All patients included in this study are free to withdraw from the study at any time without compromise to their future treatment. On withdrawal, patients will revert to the standard follow-up regimen for routine (non-study) TKA at the study site. The end-of-study form will be completed and the reason for withdrawal documented. This form will also be completed if the patient is lost to follow-up or dies during the course of the study. Data to the point of discontinuation will be used for analysis.

Monitoring
The chief investigator will monitor the progress of the clinical study in the form of monthly research meetings for those involved in the trial. The chief investigator will be responsible for the day-to-day monitoring and management of the study. The University College Hospital/University College London/Joint Research Office, on behalf of University College London as Sponsor, will monitor and conduct random audits on a selection of studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the Department of Health Research Governance Framework for Health and Social Care (April 2005), and in accordance with the sponsor’s monitoring and audit policies and procedures. As per the protocol, the principal investigator will email the sponsor twice yearly with the following information: delegation log, adverse event log, deviation log, and any annual progress reports sent to the Ethics Committee.

Peer review
The study protocol was reviewed by two external reviewers. The suggestions and recommendations for improvement to the study design were implemented. The reviewers and sponsor reviewed the revised protocol documents and confirmed that all queries and suggestions had been fully addressed.

Discussion
The concept of MA TKA is to distribute load evenly across the components to optimise implant survivorship and balance forces through the periarticular soft tissue envelope for proper functioning of the knee joint. However, in the majority of patients this forces the knee into an unnatural position with altered knee kinematics through the arc of flexion [4, 6, 17, 18]. FA TKA aims to restore joint line height, preserve native obliquity, and achieve balanced flexion-extension gaps with equal mediolateral soft tissue tension by manipulating bone resections and fine-tuning implant positioning, which reduces the need for soft tissue releases. To our knowledge, this prospective randomised control trial is the first study to compare MA TKA with FA TKA. Robotic technology will be used in both treatment groups, which will enable accurate execution of the preoperative surgical plan and help preserve the double-blinded nature of this study. Furthermore, RSA will be used to compare micromotion and implant survivorship between the two treatment groups. The findings of this study will enable an improved understanding of the optimal alignment technique in TKA for achieving high-levels of patient satisfaction, improving functional outcomes, increasing implant survivorship, improving cost-effectiveness and reducing complications.

Trial status
This is protocol version 3.0, 1 June 2018. Patient recruitment started on 28 December 2018. The estimated date for completion of recruitment is 28 December 2020. The estimated date for completion of the final follow-up is 28 December 2012.

Supplementary information
Supplementary information accompanies this paper at https://doi.org/10.1186/s13063-020-4123-8.


Abbreviations
DSMB: Data Safety Monitoring Board; EQ-5D: European Quality of Life questionnaire with five dimensions for adults; FA: Functional alignment; FJS: Forgotten Joint Score; KOOS: Knee Injury and Osteoarthritis Outcome Score; MA: Mechanical alignment; OKS: Oxford Knee Score; RSA: Radiosteriometric analysis; SAE: Serious adverse event; SF-12: Short-form health survey

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health survey of 12 items; TKA: Total knee arthroplasty; WOMAC: Western Ontario and McMaster Universities Arthritis Index

Acknowledgements
None.

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Authors’ contributions
BK, JT and FSH performed background research, identified gaps in the medical literature, created the study objectives, designed the trial, created the case report forms, attended Research Ethics Committee meetings, helped write the study protocol and prepared the National Institute for Health Research Clinical Research Network costing template. PM, SO and SK helped write the study protocol. All authors read and approved the final manuscript.

Funding
Funding was obtained from Stryker Limited. There are no terms or conditions to the funding that will impact the study design, data collection, analysis, interpretation of data, or writing the manuscript.

Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate
The study has been reviewed and approved for patient recruitment by the London-Surrey Research Ethics Committee, United Kingdom (reference 18/LO/0783). Written informed consent will be obtained from participants during recruitment on site and prior to data collection. Consent to use the data collected for scientific reporting and publication will also be obtained at the same time as the consent to participate.

Consent for publication
The findings of this research will be published in peer-reviewed journals. All study patients will provide informed consent for publication of anonymised patient data and study findings. Authorship will reflect the amount of time spent designing the study, collating the data, analysing the results, and writing the manuscript.

Competing interests
FSH reports Board membership of The Bone and Joint Journal and the Annals of the Royal College of Surgeons, has acted as a consultant for Smith & Nephew, Corin, MatOrtho and Stryker, has received payment for lectures including service on speakers’ bureaus for Smith & Nephew and Stryker, and has received royalties paid by Smith & Nephew, MatOrtho, Corin and Stryker, all outside the submitted work. SK reports consultancy, payment for lectures including service on speakers’ bureaus, payment for development of education presentations and travel/accommodations/meeting expenses for Smith & Nephew and AO, all outside the submitted work. The remaining authors declare no competing interests.

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References

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Surgical Management of Chronic Incomplete Proximal Hamstring Avulsion Injuries

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Investigation performed at Trauma and Orthopaedic Department at University College London Hospital, London, United Kingdom, and Department of Orthopaedic Surgery, The Princess Grace Hospital, London, United Kingdom

Background: Chronic incomplete proximal hamstring avulsion injuries are debilitating injuries associated with prolonged periods of convalescence and poor return to preinjury level of function. This study explores the efficacy of operative intervention for these injuries on patient satisfaction, muscle strength, range of motion, functional performance, return to preinjury level of sporting activity, and injury recurrence.

Hypothesis: Surgical intervention of chronic incomplete proximal hamstring avulsion injuries enables return to preinjury level of sporting function with low risk of clinical recurrence.

Study Design: Case series: Level of evidence, 4.

Methods: This prospective single-surgeon study included 41 patients with incomplete proximal hamstring avulsion injuries refractory to 6 months of nonoperative treatment. All study patients underwent primary operative repair of the avulsed proximal hamstring tendon and received standardized postoperative rehabilitation. Predefined outcomes were recorded at regular intervals after surgery. Mean follow-up time was 28.2 months (range, 25.0-35.0 months) from date of surgery.

Results: All patients returned to their preinjury level of sporting activity. Mean ± SD time from surgery to return to full sporting activity was 22.2 ± 6.7 weeks. There were no episodes of clinical recurrence. At 3 months after surgery, 39 patients (95.1%) were satisfied/very satisfied with the outcomes of their surgery, and as compared with preoperative values, improvements were recorded in isometric hamstring muscle strength at 0° (84.9% ± 10.9% vs 40.4% ± 8.8%; P < .001), 15° (89.6% ± 7.6% vs 44.2% ± 11.1%; P < .001), and 45° (94.1% ± 5.1% vs 66.4% ± 9.0%; P < .001); mean passive straight leg raise angle (71.2° ± 13.5° vs 45.4° ± 11.9°; P < .001); mean lower extremity functional score (70.9 ± 5.1 vs 48.4 ± 5.2; P < .001); and mean Marx activity rating score (5.6 ± 2.8 vs 2.7 ± 1.0; P < .001). High patient satisfaction and functional outcome scores were maintained at 1- and 2-year follow-up.

Conclusion: Operative repair of chronic incomplete proximal hamstring avulsion injuries enabled return to preoperative level of sporting function with no episodes of clinical recurrence at short-term follow-up. Surgical intervention was associated with high patient satisfaction and improved isometric hamstring muscle strength, range of motion, and functional outcome scores as compared with preoperative values. High patient satisfaction and improved functional outcomes were sustained at 2-year follow-up.

Keywords: hamstrings; chronic avulsion; partial avulsion; surgical repair

The hamstrings are the most commonly injured muscle group in professional athletes and account for 12% to 26% of all injuries sustained during sporting activities.2,8,13,29 Incomplete proximal hamstring avulsion injuries most commonly occur during explosive movements that involve combined ipsilateral hip flexion and knee extension10,11,17 or repetitive low-force trauma that causes localized proximal hamstring tendon attrition and surrounding tendinopathy.14,18 High-speed running requires eccentric muscle strength as the hamstrings are lengthened across the hip and knee articulations. Previous hamstring injuries may lead to poor hamstring muscle strength during the lengthened state and predispose to recurrent injury.13,25,29 Additional risk factors for hamstring injuries include reduced flexibility, muscle weakness, poor core stability, muscle fatigue, and poor lumbar posture.2,8,18,25,29 Patients may have a variety of clinical symptoms, ranging from acute, sharp, sudden-onset gluteal pain during exertional sporting activity to more chronic, generalized...
prolonged hamstring discomfort with progressive limb weakness and instability.\textsuperscript{16,18} Hamstring muscle contractions may also lead to reduced hip flexibility and decreased straight leg raise as compared with the contralateral limb.\textsuperscript{23,27} These injuries often occur in professional athletes and are regarded as career-threatening injuries in most sporting activities.

Patients with incomplete proximal hamstring avulsion injuries are often initially managed with nonoperative treatment, including rest, nonsteroidal anti-inflammatory drugs, protected range of movement, eccentric muscle exercises, and ultrasound-guided injections of corticosteroids or plasma-rich protein.\textsuperscript{5,15-18,21} However, nonoperative treatment of these injuries is associated with poor return to preinjury level of sporting function, variable times for convalescence, and high risk of recurrence.\textsuperscript{15,16,20,21,24} Patients may develop chronic symptoms owing to delays in presentation, referral for appropriate imaging, and transfer to suitable treatment centers. Chronic proximal hamstring avulsion injuries are associated with worse patient satisfaction, poorer functional outcomes, and longer time to return to sporting activity as compared with acute proximal hamstring avulsion injuries.\textsuperscript{3} Although surgical repair of chronic proximal hamstring avulsion injuries may facilitate restoration to preinjury level of sporting activity,\textsuperscript{3,12} the efficacy of surgical treatment for these injuries on muscle strength, range of motion, functional outcomes, and recurrence remains unknown.

The primary objective of this study was to assess the effect of operative repair for chronic incomplete hamstring avulsion injuries on return to preinjury level of sporting function and clinical recurrence. The study hypothesis was that surgical repair of chronic incomplete hamstring avulsion injuries would enable return to preinjury level of function with low risk of clinical recurrence at short-term follow-up. Secondary objectives were to assess the effect of surgical intervention on patient satisfaction, hamstring muscle strength, range of motion, straight leg raise, functional performance, and complications.

**METHODS**

**Patient Selection**

This prospective study included 41 patients (31 males and 10 females) undergoing operative repair of chronic incomplete proximal hamstring avulsion injuries. All operative procedures were performed by a single surgeon (F.S.H.) between September 2014 and September 2016. Of the 41 study patients, 14 were active or retired professional athletes: 6 rugby players, 5 soccer players, and 3 sprinters. A further 27 patients were nonprofessional athletes who indulged in regular sporting activities, such as running, soccer, badminton, and tennis. Baseline characteristics for study patients are presented in Table 1.

All patients had a recall of a specific event that led to the injury but were treated nonoperatively as the first line of treatment for a minimum 6 months. Mean ± SD time from injury to surgery was 8.2 ± 1.8 months (range, 6-14 months). Preoperative magnetic resonance imaging (MRI) was undertaken at the study center to confirm diagnosis, assess for any concurrent injury, and plan operative intervention (Figure 1).

Inclusion criteria for study participation included the following: onset of symptoms >6 months before date of surgery, MRI to confirm incomplete proximal hamstring

### TABLE 1

Baseline Characteristics for All Study Patients Undergoing Surgical Repair of Chronic Incomplete Proximal Hamstring Avulsion Injuries* (N = 41)

<table>
<thead>
<tr>
<th>Characteristic: Category</th>
<th>Mean ± SD (Range) or No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>38.7 ± 7.2</td>
</tr>
<tr>
<td>Female (n = 10)</td>
<td>39.4 ± 8.3</td>
</tr>
<tr>
<td>Male (n = 31)</td>
<td>38.5 ± 6.9</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>10 (24.4)</td>
</tr>
<tr>
<td>Male</td>
<td>31 (75.6)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>24.7 ± 3.2</td>
</tr>
<tr>
<td>ASA score</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>41 (100)</td>
</tr>
<tr>
<td>II</td>
<td>0 (0)</td>
</tr>
<tr>
<td>III</td>
<td>0 (0)</td>
</tr>
<tr>
<td>IV</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Laterality</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>24 (58.5)</td>
</tr>
<tr>
<td>Left</td>
<td>17 (41.5)</td>
</tr>
<tr>
<td>Sporting activity</td>
<td></td>
</tr>
<tr>
<td>Amateur</td>
<td></td>
</tr>
<tr>
<td>Running</td>
<td>19 (46.3)</td>
</tr>
<tr>
<td>Soccer</td>
<td>5 (12.2)</td>
</tr>
<tr>
<td>Badminton</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Tennis</td>
<td>2 (4.9)</td>
</tr>
<tr>
<td>Professional</td>
<td></td>
</tr>
<tr>
<td>Soccer</td>
<td>5 (12.2)</td>
</tr>
<tr>
<td>Rugby</td>
<td>6 (14.6)</td>
</tr>
<tr>
<td>Sprinting</td>
<td>3 (7.3)</td>
</tr>
<tr>
<td>Time from onset of symptoms to surgery, mo</td>
<td>8.2 ± 1.8 (6-14)</td>
</tr>
<tr>
<td>Time from surgery to return to sporting activity, wk</td>
<td>22.3 ± 6.9 (12-42)</td>
</tr>
</tbody>
</table>

*ASA, American Society of Anesthesiologists.

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avulsion injury, patient symptomatic despite nonoperative management, and operative intervention undertaken by the senior author. Exclusion criteria included the following: complete proximal hamstring avulsion injury (n = 62), partial avulsion injury sustained within 6 months of date of surgery (n = 2), recurrent injury after previous surgical intervention (n = 2), and patient living abroad or not available for follow-up (n = 5). Presenting complaint was gluteal pain (n = 31), muscle weakness (n = 5), reduced range of motion (n = 2), and paresthesia in the distribution of the sciatic nerve (n = 3). The study was prospectively reviewed by the hospital review board, which advised that further research ethics committee approval was not required. Informed consent for participation was obtained from all study patients.

Surgical Technique

All operative procedures were performed with the patient in the prone position under general anesthesia. The affected hip was flexed and the gluteal skin crease marked. In patients without neurological symptoms (n = 38), a transverse incision measuring 8 to 10 cm was performed through this skin crease. In patients with sciatic nerve impingement symptoms (n = 3), a longitudinal incision measuring 7 to 8 cm was performed distal to the skin crease instead of the transverse incision. The underlying subcutaneous tissue and gluteal fascia were divided by electrocautery, exposing the inferior border of the gluteus maximus muscle. The posterior cutaneous nerve of the thigh was identified and protected. The gluteus maximus was then retracted superiorly to expose the underlying fascia over the hamstrings. Caution was taken not to place the retractor too deep on the ischium to minimize risk of inferior gluteal nerve injury.

A longitudinal incision was performed through the hamstring fascia, and the hamstrings tendons were traced proximally to the ischial tuberosity. The hamstring tendons were identified and the sciatic nerve palpated to confirm its position deep and lateral relative to the hamstring complex and ischial tuberosity. The hamstring tendons were explored and the bare area from the avulsed ischial tuberosity identified. Blunt finger dissection and electrocautery were used to carefully dissect any scar tissue, and the fibrotic end of the retracted proximal tendon was excised. The sciatic nerve was palpated to ensure that it was tension-free. Six patients had adhesions to the adjacent sciatic nerve that were dissected with blunt finger dissection and electrocautery. Two TWINFIX 5.0-mm suture anchors (Smith & Nephew Limited) were inserted into the ischial tuberosity under direct vision. Each suture anchor had 2 nonabsorbable ultrahigh molecular weight polyethylene fiber sutures, which were stitched into the free end of the partially avulsed tendons with a modified Kessler technique. The knee was flexed to 30°, and the avulsed tendon was parachuted down to the tendon bed under direct vision. The knee was then fully extended to ensure satisfactory tension in the repair throughout the arc of motion. The wound was copiously irrigated with normal saline. The overlying fascia, subcutaneous tissue, and skin were closed in layers with absorbable sutures and a pressure dressing applied to the wound. All patients wore a hinged knee brace.

Postoperative Rehabilitation

All patients received a standardized milestone-based rehabilitation program, which was supervised by an experienced sports physiotherapist. The rehabilitation program was divided into 4 distinct phases:

**Phase 1**: RICE (rest, ice, compression, and elevation), aspirin (75 mg once daily), limit excessive combined hip flexion and knee extension, knee range of motion restricted from 60° to 120°.

**Phase 2**: Regain full pain-free hip and knee range of motion, full weightbearing, concentric and eccentric training, core strengthening.

**Phase 3**: Muscle strengthening with resistance exercises, double- and single-leg squats, quadriceps extension, and hamstring curls. Aerobic conditioning with light jogging, cycling, and swimming. Sport-specific training.

**Phase 4**: Return to full sporting activity with full pain-free range of motion, muscle strength 90% of uninjured limb, and no concerns with sport-specific training.

Outcome Measures

All study patients were clinically reviewed by the operating surgeon at regular intervals until return to play. Study outcomes were recorded by a specialist nurse practitioner preoperatively and at predefined intervals after surgery.
All outcomes at 3 months and 1 year after surgery were collected during clinical consultation, and outcomes at 2-year follow-up were collated by telephone conversation, given the wide geographic location of study patients.

Patient Satisfaction. Patient satisfaction was recorded at 3 months, 1 year, and 2 years after surgery via the Musculoskeletal Outcomes Data Evaluation and Management System, which scores patient satisfaction on a scale of 1 to 5 (1, very unsatisfied; 2, unsatisfied; 3, neutral; 4, satisfied; 5, very satisfied).

Hamstring Strength. Isometric hamstring strength was tested pre- and postoperatively at 3 months and 1 year. The patient was placed in the prone position and a handheld dynamometer (Hoggan Scientific LLC) positioned over the ipsilateral calcaneus. Maximum resisted knee flexion force (newtons) was recorded at 0°, 15°, 45°, and 90°. This technique was repeated 3 times and the mean flexion force at each angle in the injured limb calculated. All values were compared with those of the contralateral uninjured limb to calculate the percentage of normal hamstring muscle strength.

Passive Straight Leg Raise. Maximum angle of passive straight leg raise (PSLR) was tested pre- and postoperatively at 3 months and 1 year. With the patient in the supine position, the uninjured limb was passively elevated, inducing flexion at the hip while maintaining extension at the knee joint to the point of failure secondary to pain or elastic limit of the limb. The maximum attainable PSLR (degrees) was measured with a standard goniometer and compared with the maximum PSLR in the contralateral injured limb. The deficit in PSLR between the limbs was recorded.

Functional Progress and Return to Function. All study patients completed the Lower Extremity Functional Scale (LEFS) and Marx Activity Rating Scale (MARS) preoperatively and at 3 months, 1 year, and 2 years after surgery.4,19 The LEFS is a validated and effective questionnaire for assessing specific lower limb function. It is an 80-point scale with 20 questions (4 points per question) and a minimum clinical difference of 9 points.4 The MARS measures patient activity level and knee function independently of age, sex, and type of sporting activity. Scores of 0 to 4 are assigned to 4 activities—running, changing direction, decelerating, and pivoting—with a total score of 16.19 Time from surgical intervention to full return to sporting activity was collected in all study patients.

Complications. All complications within 2 years of the surgery were recorded. All patients recruited into this study completed follow-up. Mean follow-up time was 28.2 months (range, 25.0-35.0 months) from date of surgery.

Statistical Analysis

Paired t tests were used to compare study outcomes found to be normally distributed, while the Mann-Whitney U test was used for continuous outcomes found not to be normally distributed. Categorical outcomes were compared with the Fisher exact test. Statistical significance was set at P < .05 for all analyses, and all statistical analysis was performed with SPSS software (v 24; IBM Corp).

RESULTS

Return to Function and Clinical Recurrence

All study patients returned to their preinjury level of sporting activity. Mean time from surgical intervention to return to sporting activity was 22.3 ± 6.9 weeks. The overall range for time from surgical intervention to return to sporting activity was 12 to 42 weeks. At 1- and 2-year follow-up, all study patients were still participating at their preinjury level of sporting activity. No study patients had clinical recurrence of their primary injury.

Patient Satisfaction

Operative repair of chronic incomplete proximal hamstring avulsion injuries was associated with high levels of patient satisfaction. At 3 months after surgery, 39 patients (95.1%) were satisfied/very satisfied with the outcomes of their surgery, and 2 patients were unsatisfied (Table 2). Of the 2 unsatisfied patients, 1 was disappointed with the speed of postoperative recovery. He was a professional soccer player who returned to preinjury level of sporting activity at 34 weeks after surgery. The second patient was a professional rugby player who developed postoperative complex regional pain syndrome around the operated limb. He was successfully treated with analgesia and physiotherapy and made a return to full sporting activity at 42 weeks. At 2 years after surgery, 38 patients (92.7%) were very satisfied and 3 (7.3%) were satisfied with the outcomes of their surgery.

Hamstring Strength

Surgical intervention was associated with improved hamstring muscle strength at 3 months after surgery as compared with presurgery (Table 3, Figure 2). At 1-year follow-up, all patients had restored hamstring muscle strength to >90% of the contralateral side.

<table>
<thead>
<tr>
<th>TABLE 2</th>
<th>Patient Satisfaction Scores at Predefined Study Intervals After Surgical Repair of Chronic Incomplete Hamstring Avulsion Injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patients, No. (%)</td>
</tr>
<tr>
<td>3 mo</td>
<td>1 y</td>
</tr>
<tr>
<td>Very unsatisfied: 1</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Unsatisfied: 2</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Neutral: 3</td>
<td>0</td>
</tr>
<tr>
<td>Satisfied: 4</td>
<td>19 (46.3)</td>
</tr>
<tr>
<td>Very satisfied: 5</td>
<td>20 (48.8)</td>
</tr>
</tbody>
</table>
Passive Straight Leg Raise

Operative repair of chronic incomplete proximal hamstring avulsion injuries was associated with improved PSLR and decreased PSLR deficit at 3-month follow-up as compared with preoperative values (Table 4, Figure 3). Further improvements in PSLR were observed at 1 year after surgery as compared with 3 months. Two patients had maximum PSLR ≤50 at 3-month follow-up, which included 1 patient with chronic regional pain syndrome and 1 patient with chronic back pain. In both patients, PSLR improved to 80° at 1-year follow-up after surgery.

Functional Progress and Return to Function

At 3 months after surgery, mean LEFS score markedly improved as compared with the preoperative value. At 3-month follow-up, 12 patients (29.2%) had an LEFS score of 80 (out of 80), and 24 (58.5%) had a score >75. Further incremental improvements in LEFS scores were observed at 1 and 2 years after surgery (Table 5, Figure 4). At 2-year follow-up, 16 patients (39.0%) had an LEFS score of 80, and 21 (51.2%) had a score >75. MARS scores followed a similar trend with statistically improved scores at each follow-up interval after surgery. At 2-year follow-up, 35 patients (85.3%) had a minimum MARS score of 12 (out of 16), which included 9 (22.0%) with a score of 16.

Complications

There were no intraoperative complications. In addition to the 1 patient who developed chronic regional pain syndrome described earlier, 4 patients had extensive bruising distal to the operative site, all of which was managed nonoperatively. One patient developed a superficial wound infection that was successfully treated with a 1-week course of oral antibiotics. No other complications occurred within 2 years of surgery.

DISCUSSION

This study found that surgical repair of chronic incomplete proximal hamstring avulsion injuries enabled return to preoperative level of sporting function with no episodes of clinical...
of operative intervention in 71 proximal hamstring injuries, which included 7 proximal partial avulsion injuries treated with bone anchors. All patients made a full return to sporting activity with high patient satisfaction at 6-month follow-up. Barnett et al\(^6\) performed operative repair on 34 patients with chronic partial hamstring avulsion injuries and found that only 60% of patients were able to return to their preinjury level of function and 26% labeled their surgical outcomes as moderate. The mean time from initial injury to operative intervention was 510 days (2.5 times the mean time from injury to surgical intervention in our study), and patients did not have standardized postoperative rehabilitation, which may have contributed to the less favorable outcomes as compared with those observed in the current study.

Delays in operative treatment may lead to muscle weakness and fibrosis of scar tissue to the sciatic nerve and then to neurological complications, such as foot drop or paresis of the lower limb.\(^9,18,22,24\) In the current study, 3 patients had paresthesia in the distribution of the sciatic nerve, which resolved after operative intervention. In these patients, the proximal avulsed portion of the retracted hamstring was scarred and adhered to the adjacent sciatic nerve. The scar tissue was dissected and the sciatic nerve freed to minimize any tension. Bowman et al\(^5\) reported outcomes in 17 patients undergoing surgical repair of partial proximal hamstring injuries refractory to 6 months of nonoperative treatment and found that 5 of these patients developed postoperative paresthesia. Sarimo et al\(^24\) reviewed the outcomes of surgical treatment in 41 patients with acute or chronic complete proximal hamstring avulsion injuries and found that chronic cases were associated with the torn muscle having a macroscopically abnormal appearance with a hardened fibrotic texture. The authors reported that time from injury to operative intervention was 2.4 months in patients reporting good and excellent results but 11.7 months in patients with poor or moderate outcomes (\(P < .001\)).

Operative repair of chronic proximal incomplete hamstring avulsion injuries enabled improvements in isometric

---

**TABLE 4**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Preoperative</th>
<th>3 mo</th>
<th>Improvement in PSLR, MD (95% CI)</th>
<th>(P) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSLR, deg</td>
<td>45.4 ± 11.9</td>
<td>71.2 ± 13.5</td>
<td>25.9 ± 10.0 (22.7 to 29.0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PSLR deficit, deg(^b)</td>
<td>38.5 ± 9.6</td>
<td>12.7 ± 10.5</td>
<td>−25.9 ± 10.0 (−22.7 to −29.0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Preoperative</td>
<td></td>
<td>1 y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSLR, deg</td>
<td>45.4 ± 11.9</td>
<td>77.8 ± 7.9</td>
<td>32.2 ± 9.8 (29.7 to 34.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PSLR deficit, deg(^b)</td>
<td>38.5 ± 9.6</td>
<td>6.1 ± 6.7</td>
<td>−32.2 ± 9.8 (−29.7 to −34.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 mo 1 y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSLR, deg</td>
<td>71.2 ± 13.5</td>
<td>77.8 ± 7.9</td>
<td>6.6 ± 11.3 (3.1 to 10.1)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PSLR deficit, deg(^b)</td>
<td>12.7 ± 10.5</td>
<td>6.1 ± 6.7</td>
<td>−6.6 ± 11.3 (−3.1 to −10.1)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

\(^b\)MD, mean difference; PSLR, passive straight leg raise.

\(^b\)Compared with contralateral limb.
hamstring muscle strength through the arc of flexion. Maximum hamstring strength deficit was seen in the range of 0° to 45° of flexion with the least strength deficit at 90° of flexion. These findings are consistent with those of Young et al, who assessed hamstring muscle strength in 41 of 47 patients using a subjective measure of clinical weakness of hamstrings. The authors found that proximal hamstring insufficiency resulted in maximum hamstring strength deficit in the first 45° of knee flexion. Improvements in isometric muscle hamstring strength observed in our study are consistent with those reported by Barnett et al. In their study, surgical repair of partial hamstring avulsion injuries resulted in improvements in hamstring muscle strength from 53.6% preoperatively to 84.1% postoperatively as compared with the contralateral side. Aldridge et al reported outcomes in 23 consecutive patients with chronic partial hamstring avulsion injuries who were undergoing surgical repair via reattachment with bone anchors. The authors found that mean isometric strength improved from 64% to 88% of the contralateral side at 6-month follow-up.

Operative intervention for chronic incomplete proximal hamstring avulsion injuries in our study was associated with improvements in functional outcomes. Although pre-injury scores were not available for comparison, 12 patients (29.2%) from this study had an LEFS score of 80 (out of 80), and 24 patients (58.5%) had a score >75 at 3 months after surgery. Statistically significant incremental improvements in LEFS and MARS scores were observed over 2 years after surgery, which suggests progressive improvements in confidence with sporting activity and daily functional activities over this period. In this study, observed improvements in objective functional outcome scores after surgical repair are consistent with existing literature on surgical repair of acute and chronic hamstring injuries. Sonnery-Cottet et al found that surgical repair of proximal or distal hamstring injuries in 10 professional athletes was associated with return to preinjury level of sporting activity at 3.4 months (range, 2-5 months). Cohen et al followed 52 patients undergoing suture anchor repair of proximal hamstring avulsion injuries and found a mean LEFS score of 75 (range, 50-80) at a follow-up of 33 months (range, 12-76 months).

The main clinical significance of this study is that it provides important prognostic information on muscle strength, range of motion, functional progress, and time to return to preinjury level of function after operative repair of chronic incomplete proximal hamstring avulsion injuries. The findings will facilitate postoperative rehabilitation and planning for return to sporting activity. This study supports existing literature showing that chronic proximal hamstring avulsion injuries may lead to fibrosis of the avulsed tendon and tethering to the adjacent sciatic nerve. These fibrotic adhesions may require intraoperative division to release the sciatic nerve and improve any distal neurological compromise. Operative intervention also enabled all study patients to return to preinjury level of sporting function. Although it remains unclear how the time to return to sporting function compares with a standardized nonoperative rehabilitation program, there was no clinical recurrence of the primary symptoms at short-term follow-up. This information should be included in any discussion between medical professionals and patients when deciding between nonoperative and operative intervention.

There are several limitations of this study that need to be considered when interpreting the findings. There was no control group of patients undergoing nonoperative management; therefore, it is difficult to ascertain the effect of

### Table 5

<table>
<thead>
<tr>
<th>Outcome: Time</th>
<th>Mean ± SD</th>
<th>Improvement in Scores, MD (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEFS</td>
<td>Preoperative</td>
<td>48.4 ± 5.2</td>
<td>22.4 ± 6.5 (20.4-24.4)</td>
</tr>
<tr>
<td></td>
<td>3 mo</td>
<td>70.9 ± 5.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 y</td>
<td>75.2 ± 2.7</td>
<td>4.3 ± 3.8 (3.1-5.5)</td>
</tr>
<tr>
<td></td>
<td>2 y</td>
<td>77.0 ± 3.0</td>
<td>1.9 ± 3.0 (0.9-2.8)</td>
</tr>
<tr>
<td>MARS</td>
<td>Preoperative</td>
<td>2.7 ± 1.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 mo</td>
<td>5.6 ± 2.8</td>
<td>3.1 ± 2.1 (2.2-4.0)</td>
</tr>
<tr>
<td></td>
<td>1 y</td>
<td>9.4 ± 1.5</td>
<td>3.8 ± 3.3 (2.8-4.9)</td>
</tr>
<tr>
<td></td>
<td>2 y</td>
<td>12.4 ± 2.4</td>
<td>3.0 ± 2.5 (2.2-3.8)</td>
</tr>
</tbody>
</table>

*LEFS, lower extremity function scale; MARS, Marx Activity Rating Scale; MD, mean difference.*
surgical repair as compared with nonoperative treatment with the standardized rehabilitation program. Patient recruitment with prospective randomization to operative treatment or further nonoperative treatment is challenging in highly active patients who have already failed a minimum 6 months of nonoperative management. Furthermore, although all patients received a minimum 6 months of nonoperative treatment, the overall time from injury to surgical intervention was not correlated with study outcomes. Stratification of patients based on duration of nonoperative management may help to provide more detailed information about optimal time for surgical repair and prognostic outcomes. Repeat imaging with MRI was not used to assess healing at the operative site; therefore, asymptomatic recurrent injuries may not have been detected. Finally, study outcomes were not correlated with preoperative clinical findings or radiological grade of injury, and follow-up was limited to 2 years after surgery.

CONCLUSION
Operative repair of chronic incomplete proximal hamstring avulsion injuries enabled return to preoperative level of sporting function with no episodes of clinical recurrence at short-term follow-up. Surgical intervention was associated with high patient satisfaction and improved isometric hamstring muscle strength, range of motion, and functional outcome scores as compared with preoperative values. High patient satisfaction and improved functional outcomes were maintained at 2 years after surgery.

REFERENCES
The role of electrical stimulation in the management of avascular necrosis of the femoral head in adults: a systematic review

Talal Al-Jabri, Jessica Yan Qi Tan, Gabriel Yihan Tong, Ravikiran Shenoy, Babar Kayani, Timothy Parratt and Tahir Khan

Abstract

Background: Avascular necrosis of the femoral head causes significant morbidity and occurs in up to 20,000 people per year. A variety of nonoperative and operative measures have been trialled however a definitive treatment algorithm is yet to be established. Young adults in many cases have undergone multiple surgical procedures in their lifetime with increasing risks of complications. Less invasive techniques may help reduce the number of operations required and positively influence the natural history of the disease process. Our aim was to navigate the literature and examine the results of electrical stimulation of the femoral head in avascular necrosis.

Methods: The following defined search strategy was used to perform a systematic review using MEDLINE and Google Scholar databases: ((vascular necrosis) OR (osteonecrosis)) AND (femoral head) AND ((electrical stimulation) OR (capacitive coupling) OR (pulsed electromagnetic fields)). Articles were reviewed and data compiled into tables for analysis.

Results: Forty six articles were identified with a total of 10 articles meeting the inclusion criteria. 8 articles were prospective studies and 2 were retrospective. Early Ficat stages showed the best responses to treatment via pulsed electromagnetic fields with improvements in both clinical and radiographic parameters. Direct current and capacitative coupling have had a more ambiguous outcome.

Conclusions: Pulsed electromagnetic fields may have a role in the management of early avascular necrosis. The paucity of clinical studies into this technique indicates a need for further studies.

Keywords: Avascular necrosis, Osteonecrosis, Hip, Femoral head, Electrical stimulation

Background

Avascular necrosis (AVN) of the femoral head is a debilitating, progressive condition which occurs in up to 20,000 people in the United States per year [1–3]. It can occur at any age however, typically adults in their third and fourth decades are affected. It frequently results in subchondral collapse and secondary osteoarthritis as the disease process progresses limiting the treatment options available and ultimately, necessitating a total hip arthroplasty. The pathophysiology has not been clearly defined however various mechanisms have been implicated and specific risk factors have been associated with the development of AVN. These include smoking, corticosteroid administration, diabetes mellitus, systemic lupus erythematosus, rheumatoid arthritis and sickle cell disease amongst others [3–6].

Both nonsurgical and surgical treatment options have been used with varying rates of success nonetheless a specific algorithm for the various options has not yet been established. Importantly, young adult patients would in many cases require more than one arthroplasty procedure in their lifetime [7, 8] and as such interest in less invasive techniques aimed at slowing or preventing disease progression have gained the interest of clinicians involved in the management of AVN.
Electrical fields in bone known as strain related potentials arise from mechanical deformation of bone. These strain related potentials transfer information to the osteocyte regarding its biophysical environment. The use of exogenous electrical currents of the correct amplitude and frequency have been shown to have positive effects on bone formation, bone graft incorporation and bone repair in in vivo and in vitro models [6, 9]. Pulsed electromagnetic fields have been shown to decrease parathyroid hormone receptor activity on osteoblasts and to reduce the lysosomal content of osteoclasts thereby suppressing bone resorption and increasing bone mass [9].

Noninvasive techniques of applying electric fields include inductive or capacitive coupling. Capacitive coupling involves centring skin electrodes posteriorly and anteriorly to the femoral head. Inductive coupling involves pulsed, time-varied electromagnetic fields created by an external generator and a current carrying coil. Invasive techniques whereby an implantable current generating unit supplies a constant direct current (DC) have been described in the literature and often these involve implanting the cathode to the site of bone repair and the anode in the nearby soft tissues. This is usually done in conjunction with a core decompression and necessitates surgical removal following treatment is accomplished [6, 10, 11].

Aims and objectives
The aim of this systematic review is to examine the published clinical and radiographic outcomes following the use of electrical stimulation in the management of avascular necrosis of the femoral head in adults.

Methods
This systematic review was completed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) reporting guidelines for the meta-analysis of intervention trials [12]. The protocol was not registered and ethical approval was not required as this was a small study involving review of existing, published literature and did not involve the handling of new patient data.

The following search strategy was used to complete a search on MEDLINE and Google Scholar from 1928 to April 2016: (vascular necrosis) OR (osteonecrosis) AND (femoral head) AND ((electrical stimulation) OR (capacitive coupling) OR (pulsed electromagnetic fields)). Journals in all languages were included, and there were no limitations on the search strategy. Abstracts were screened and articles relevant to the role of electrical stimulation for avascular necrosis were selected and included. Exclusion criteria included studies which did not separate Perthe's disease from avascular necrosis of the femoral head in adults. Letters, editorials and review articles were excluded.

The technique of electrical stimulation used, duration of treatment, staging of avascular necrosis, follow-up period and complication rates were extracted from each article and compiled into a database. References of selected full text articles were screened for the inclusion of additional articles. Recorded data was extracted and entered into an excel spreadsheet (Microsoft Office Excel, 2007). The references were independently reviewed by 2 of the authors and any ambiguity was resolved through discussion. Bias was assessed and its influence if any included within the analysis as laid out by the Critical Appraisal Skills Programme [13]. Outcome measures have been summarized alongside individual studies in this systematic review as studies on this topic are limited in number, size, quality of research methodology and there is heterogeneity in the methodology used.

Results
The role of electrical stimulation in femoral heads with avascular necrosis is a subject that has not been widely investigated. Of the 46 articles identified in our search, 36 did not meet our inclusion criteria or were duplicates, letters, editorials or review articles. Of the 10 papers included, 2 were retrospective studies, 8 were prospective studies (Table 1, Fig.1).

Retrospective studies
In the two retrospective studies, a total of 117 patients or 146 hips with symptomatic, non-collapsed avascular necrosis of the femoral head were included [2, 3]. In both studies, patients were treated with PEMF for 8 h a day for 6 months. Cebrian et al. demonstrated that electromagnetic stimulation in femoral heads of ARCO stages I and II led to a survival percentage of 88.57% of the heads on radiographic assessment [3]. Similarly, the paper by Cadossi et al. revealed that PEMF preserved 90% of the femoral heads of Ficat I, 75% of Ficat II and 50% of Ficat III; there were even improvements in the staging of 45% of Ficat I hips to stage 0 and 35% of Ficat II hips to stage I. Functionally, 46% of patients achieved normal hip function and 39% achieved sufficient hip joint function at the end of treatment. As for pain scores, the study found that 53% of patients were pain free after treatment with PEMF while 26% had pain of moderate intensity [2]. Likewise, Cebrian et al. also noted improvement on the D'Aubigne pain scale in 78.57% of the hips [3]. Nevertheless, in both studies, there were some hips that eventually progressed to collapse. Cebrian's study had a total of eight femoral head collapses, all of which were of ARCO stage II (n = 50) whereas Cadossi found that 15 (three Ficat II and 12 Ficat III initially) of the 76 hips had radiographic
**Table 1 Summary of results**

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study type</th>
<th>Number of patients</th>
<th>Stage</th>
<th>Pre-treatment hip outcome score</th>
<th>Aetiology</th>
<th>Clinical technique</th>
<th>Additional management</th>
<th>Results</th>
<th>Post-treatment hip outcome score</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>J.L. Gobin et al. [3]</td>
<td>Retrospective</td>
<td>51 (70 hips)</td>
<td>ARCO staging used.</td>
<td>1.20</td>
<td></td>
<td>Symptomatic: AIN + no collapse on MRI and X-ray</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>40 Steroids: 26 Alcohol: 4</td>
<td>1 pair of coils attached anteriorly &amp; posteriorly held in place over greater trochanter on molded splint. Single pulse of Frequency: 75 Hz Intensity: 400 mA Time: 1 at 3 ms Duration of tx: Coils worn for 8 h/day for 6 months</td>
<td>-</td>
<td>Follow up at 3, 6, 12, 24, 48 months with AP + Axial X-ray and MRI. Mean follow-up = 26 months.</td>
<td></td>
<td>80% had radiological success. 88.57% had no progression. 11.43% collapsed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L. Massari et al. [4]</td>
<td>Prospective</td>
<td>68</td>
<td>Steinberg staging used</td>
<td>-</td>
<td>Primary: 34 Steroids: 17 Trauma: 5</td>
<td>SPT BOSTIM pulse generator used. Single voltage pulses Frequency: 75 Hz Time each pulse at 1.3 ms Duration of tx: 8 h/day for 6 months</td>
<td>Core decompression and autologous bone graft from proximal metaphysis and femoral neck</td>
<td>-</td>
<td>X-ray and MRI at 1, 3, 6, 12, 24 months from surgery. After, X-ray yearly and MRI every 2 or 3 yr. Mean follow-up = 5.8 yrs. Steinberg I: 81% no pain and limping, good radiographic results. Steinberg II: 70% success Steinberg III: 53% good clinical results. 27% good radiographic results.</td>
<td>2 patients needed total hip arthroplasty: - Bilateral in 1 patient (Steinberg III) - Unilateral in 1 patient (Steinberg IV)</td>
</tr>
<tr>
<td>L. Massari et al. [2]</td>
<td>Retrospective</td>
<td>66 (76 hips)</td>
<td>Ficat staging used</td>
<td>1-3: 1</td>
<td>Intense pain and significant functional restriction</td>
<td>SPT BOSTIM pulse generator used. Duration of tx: 8 h/day for 6 months (mean duration = 5+/−2 months)</td>
<td>NSAIDS for pain. Non-weight bearing advised but only 50% complied.</td>
<td>Mean follow-up = 28 months X-ray at follow-up with CT and MRI confirmation if available. Ficat I: 50/53 hips preserved; 3 Ficat II: 12 hips had progression Ficat I: 45% improved to stage 0; 45% unchanged; 10% worsened to stage II Ficat II: 35% improved to stage I; 50% unchanged; 25% worsened to stage III Ficat III: 0% improved; 50% unchanged; 50% worsened to stage IV</td>
<td>15 of 76 hips progressed. Pain - 35 were pain free after 60 days of treatment. - 17 had pain of moderate intensity. - 14 still had intense pain. Hip joint function - Normal in 46% - Sufficient in 39% - Insufficient in 15%</td>
<td></td>
</tr>
<tr>
<td>C. Windisch et al. [5]</td>
<td>Prospective</td>
<td>35</td>
<td>ARCO staging used. Group 1: 3/19 pts. had bilateral involvement. Group 2: 2/16 had bilateral involvement</td>
<td>-</td>
<td></td>
<td>Magnetodyn – external magnetic field coil and an invasive bipolar induction screw. Frequency: Sinus shaped external magnetic field of ~20 Hz. Magnetic flux density ~5 mT. Voltage: ~700 mV induced. Electric field strength: 50-700 mV/cm</td>
<td>Grafting, autologous bone grafting (from greater trochanter and proximal femur).</td>
<td>Follow-up checks at 6 and 12 months: clinical exam, clinical evaluation– modified Harris Hip score, Merle D’Aubigné hip score, VAS; imaging – X-ray with pelvic view and axial projection of hip, bilateral MRI. Group 1: - 2 stage 2C patients had THA - 2 stage 3C patients had THA Group 2: - 1 stage 2B patient had THA - 1 stage 3B patient had THA - 2 stage 3C patients had THA Comparing clinical outcomes of group 1 and 2:</td>
<td>18% of patients in Group 1 had to have THA. 22% of patients in Group 2 had to have THA.</td>
<td></td>
</tr>
</tbody>
</table>

*Table adapted from Al-Jabri et al. BMC Musculoskeletal Disorders (2017) 18:319*
### Table 1: Summary of results (Continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th>Sample Size</th>
<th>Staging Used</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>ME, Steinberg et al. [11]</td>
<td>Prospective + historical control</td>
<td>116 hips</td>
<td>Steinberg staging used: Mean stages</td>
<td>Non-stimulated: IIA Stimulated: IIIB</td>
</tr>
<tr>
<td>Bassett et al. [10]</td>
<td>Prospective</td>
<td>95 (118 hips)</td>
<td>Steinberg staging used:</td>
<td>Chanley modification of Merle D'Aubigne - Postel system Mean scores = Pain:3.9 Function: 3.7 Mobility: 5.2 Total: 12.8</td>
</tr>
</tbody>
</table>

**Post-operative evaluation by Harris Hip score, AP + lateral X-rays, taken at 3, 6, 12, 18, 24 months and then yearly/two yearly thereafter. Mean follow-up = 46 months**

**DC group**
- Radiographic progression in 70%
- Mean progression: 2/3 stage
- Mean 5 point improvement in HHS (64%) improved or remained unchanged
- 41% needed THA

**Control**
- Radiographically and clinically, 45% improved or remained unchanged
- 25% needed THA

**Capacitive coupling**
- Clinically and radiographically, 45% improved or remained unchanged
- 15% needed THA

**Core decompression and bone grafting**
- Mean follow-up time = Non-stimulated: 33 months Stimulated: 44 months
- Electrical stimulation gave better Harris scores, less roentgenographic progression, but similar need for arthroplasty. No fractures or complications

**Results**
- No significant difference between groups for D'Aubigne score.
- No significant difference in Harris Hip score.
- No significant difference in VAS.
- No significant improvements/deterioration as a result of the procedure in group 1.
- Both procedures promising up to stage 2A.

### Steinberg staging used.

- I: 133
- II: 13
- III: 65
- IV: 85
- V: 4

- Group 1: Constant DC via cathode wire coiled about the graft and attached to an Osteostem/Orthofuse
- Group 2: Capacitative coupling via surface electrodes applied anteriorly and posteriorly to the skin over the femoral head and connected to a portable power unit.

- Core decompression and bone grafting

- Mean follow-up = 46 months

**DC group**
- Radiographic progression in 70%
- Mean progression: 2/3 stage
- Mean 5 point improvement in HHS (64%) improved or remained unchanged
- 41% needed THA

**Control**
- Radiographically and clinically, 50% improved or remained unchanged
- 20% needed THA
### Table 1 Summary of results (Continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>N (Total Hips)</th>
<th>Staging (Artemia)</th>
<th>Treatment</th>
<th>Duration</th>
<th>Joint Space Width</th>
<th>Clinical Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>R.K. Aaron et al. [6]</td>
<td>Prospective</td>
<td>77 (106 hips)</td>
<td>Penetrating Ficat I-III</td>
<td>PEMF II: 23, III: 33, Core decompression II: 26, III: 24</td>
<td>8-10 h/day, discontinued *1 year</td>
<td>Joint space width increased on average 1 mm in 17 of these 19, but most of these showed clinical improvement</td>
<td>Mean follow-up = 3 years, Percentage demonstrating both clinical &amp; roentgenographic success: PEMF: 52%, Core: 20%</td>
</tr>
<tr>
<td>Steinberg et al. [14]</td>
<td>Prospective + Historical control</td>
<td>40 (40 hips) 55 control hips</td>
<td>Steinberg staging I-III</td>
<td>Stimulated: 94, Unstimulated: 75</td>
<td>Single pulse, Frequency: 72 Hz, quasirectangular, 380 microsec, Duration: 8 h/day, 12-18 months</td>
<td>All 40 patients had core decompression + grafting</td>
<td>Harris score Stimulated: 82, Unstimulated: 76</td>
</tr>
<tr>
<td>R.K. Aaron et al. [2, 6].</td>
<td>Prospective</td>
<td>264 (373 hips)</td>
<td>Steinberg staging</td>
<td>PEMF</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Notes:**
- AVN: Avascular Necrosis
- ARCO: Association Research Circulation Osseous
- CD: Core Decompression
- PEMF: Pulsed Electromagnetic Field
- DC: Direct Current
- NSAIDs: Non-steroidal Anti-Inflammatory Drugs

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*Al-Jabri et al. BMC Musculoskeletal Disorders (2017) 18:319*
progression that led to the development of severe osteoarthritis requiring hip arthroplasty [2, 3].

Prospective studies

**PEMF**

In six prospective studies, the effect of PEMF therapy as an adjunct to other treatments (core decompression and bone grafting) was evaluated.

In an Italian study conducted by Massari et al., 68 patients with ONFH were treated with core decompression, autologous bone grafts and PEMF. Of those with Steinberg stage II scores, 81% had good results radiographically and clinically had no pain or limp. Similar results were seen in stage III patients but only in 70%. This is further reduced in stage IV patients where only 27% had good radiographic outcomes and 53% had good clinical results. Two patients (one stage III and one stage IV) required total hip arthroplasty (THA) [4].

Windisch et al. divided 35 patients into two groups, one treated with curettage, bone grafting and PEMF ($n = 19$) and one with curettage and bone grafting without PEMF ($n = 16$). In the group that underwent PEMF, four patients in total (18%) had to have THA — two of these patients were ARCO stage II C and the other two were stage III C. On the other hand, the non-PEMF group also had four patients (22%) who required THA. However, one was stage II B, one stage III B and two stage III C. However, interestingly, clinical evaluation of both arms revealed no significant difference in pain and functional scores [5].

In another prospective study, Aaron et al. compared the effectiveness of PEMF against core decompression in Ficat stages II and III hips. Based on clinical response (using a modified D’Aubigne scale), clinical success was determined as marginal pain with retention of the femoral head. They found that 68% of those treated with PEMF were clinically successful, compared to 44% of those treated with core decompression. Roentgenographically, 39% showed progression in those treated with PEMF, versus 64% of those treated with core decompression [6].

Aaron et al. compared patients with stage II and III lesions receiving core decompression and PEMF as adjunct therapy, to core decompression alone. They although there was no difference in joint survival, radiographically, stage II hips showed a significant increase in joint stabilisation with PEMF therapy (77% versus 44% in core decompression alone). Stage III hips receiving PEMF also demonstrated clinical improvement [1, 2, 6].
In two prospective studies, the use of pulsed electromagnetic field therapy in the treatment of osteonecrosis of the femoral head without use of or comparison to additional management (eg: core decompression, bone grafts) was examined [2, 10]. Aaron et al. found that based on need for subsequent joint replacement, the greatest advantage was seen in Steinberg Stage I hips, where none required surgery. 77% of stage II hips were conserved, although there was no statistically significant difference between these and stage I hips. However, of the stage III hips, only 53% were conserved, showing a statistically significant decrease compared to stage II hips. Radiologically, the effect of electrical stimulation was less pronounced. In stage I hips, 75% showed progression, notably more than in stage II and III, where 54% and 68% demonstrated progression [2, 6]. In the other study, Bassett et al. quantified the response to PEMF therapy using the Steinberg staging method. They found that 9 hips showed improvement, and they were all in stages II to III, demonstrating a 60% improvement rate. Of these 9 hips, 3 of these returned to a normal structure. 90 hips across all stages (76%) showed no improvement or deterioration, while 19 hips (16%) showed a deterioration of <2 mm further femoral head collapse [10].

**Direct current stimulation and capacitive coupling**

Steinberg et al. conducted several studies comparing the outcome of hips that received electrical stimulation, and those that did not [11, 14, 15]. In one paper, he looked at two groups of patients, one who received direct current (DC) stimulation and one who had capacitive coupling (CC) [11], both in addition to core decompression and grafting. The results of the former group showed radiographic progression in 70% compared to 79% in control hips; there was a mean 5 point improvement in the Harris Hip score whereas the control group had a mean 3 point drop instead; however, 41% of hips treated with DC required THA compared to 37% of control hips. The CC group showed less promising results, with 42% of hips either clinically and radiographically improving or remaining unchanged compared to 50% in the control group; 25% of stimulated hips eventually needed THA versus 20% of unstimulated hips [11].

Steinberg et al. also compared non-operative management with core decompression and grafting alone, and with DC as adjunct. They found that electrical stimulation showed an improvement in number of hips and average extent of roentgenographic progression, albeit not a significant difference. Electrical stimulation also gave better Harris scores, with 64% showing improvement or remained unchanged, versus 43% in the core decompression alone group. Requirement for hip replacement was similar with or without electrical stimulation. Both groups were superior in all aspects compared to non-operative management [15].

In another similar study, Steinberg et al. compared non-operative management, core decompression with grafting, and CC as adjunct to decompression and grafting. They found that no significant difference was found when CC was used, based on roentgenographic progression, clinical evaluation, and hips requiring replacement. However both groups were superior to non-operative management [14].

**Discussion**

Osteonecrosis of the femoral head is a debilitating disease which generally occurs in the younger population. Multiple studies have shown that once the roentgenographic changes are established, the disease normally progresses to femoral head collapse requiring joint replacement. Since the group of individuals affected by this condition is usually active, hip replacement in these placements are widely regarded as a last resort as the long term outcomes are less than ideal. Therefore, the general clinical approach to these patients is femoral head preservation and various methods have been sought out. Amongst these methods, core decompression (CD) stands out as a conservative technique that has greater success rates in early disease. The principle behind CD is to lower the intraosseous pressure which has been found to be raised. Theoretically this addresses the relative ischaemia while simultaneously stimulating a vascularized healing response [16]. Two of the Steinberg studies analysed in this review showed that CD demonstrated an improvement in outcome over non-operative treatment [14, 15].

The other method evaluated in the studies is biophysical stimulation (either by PEMF or electrical stimulation via DC or CC). The rationale behind the use of biophysical stimulation is its anti-inflammatory actions which prevent cartilage breakdown and promote angiogenesis, thus limiting the extent of necrosis [2, 4]. Moreover, it encourages bone formation via stimulation of osteoblasts and inhibition of osteoclasts [2, 4], thus slowing the breakdown of structural integrity [6]. In particular, PEMF has been proposed to exert its effects based on the following three concepts: Wolff’s law, the piezoelectric effect and streaming potentials [17].

Wolff’s law states that bones respond to mechanical loads under which they are placed; compression results in osteogenesis on the side compressed and simultaneous resorption on the contralateral side [18]. This occurs via a process called mechanotransduction whereby mechanical signals are transformed into biochemical ones [19].

The piezoelectric effect describes the phenomenon where certain materials demonstrate an ability to generate negative and positive potentials when subjected to
mechanical strain. In bone, the piezoelectric nature of hydroxyapatite and collagen results in a negative potential generated during compression and a positive one when the stress is relieved. Notably, the piezoelectric effect is reversible, hence the mechanical stress can be induced with the application of an electric field [20].

In cartilage, streaming potentials refer to the movement of positively charged ions across negatively charged proteoglycans during mechanical stress, generating an electric current which may stimulate chondrocytes [21]. Therefore, a possible mechanism of PEMF application is the induction of a mechanical strain via the converse piezoelectric effect, thus inducing osteogenesis via Wolff’s law, as well as chondrocyte stimulation [17].

**PEMF**

In the present review, studies examining the effect of PEMF, whether alone or in combination with other treatments, generally showed some benefit when PEMF was administered. As a treatment used on its own, PEMF was shown to preserve majority of femoral heads (80.2% by Cadossi [2], 88.57% by Cebrian [3], 83.9% by Bassett [10]) with these benefits being more pronounced in hips of earlier stages, namely Ficat I and II and Steinberg II and III, and decreasing as severity increased. Remarkably, PEMF has also been shown to reverse the disease progression across 2 of these studies; Bassett et al. found 9 hips demonstrated improvements with 3 of these even returning to normal [10], while Cadossi et al. showed improvements in Ficat stages [2].

Additionally, it was found that PEMF was also effective in improving symptoms of osteonecrosis. Cebrian and Cadossi both found that significant proportions of patients who received PEMF therapy eventually experienced an improvement in pain or even became pain free [2, 3]. Moreover, Massari et al. found that though the efficacy of PEMF decreased overall with increased Steinberg staging, there was greater clinical than radiographic benefit seen in those with Steinberg IV hips [4], further reinforcing the potential of PEMF to alleviate pain in these patients. Conversely, Windisch et al. showed that there was no difference in clinical outcomes between patients who received PEMF and those who didn’t. However, unlike the other papers, the method of inducing the electromagnetic field in this study was an invasive one via a bipolar induction screw through the femoral head [5]. This may have contributed to the discrepancy, as discussed later in the section on DC therapy.

A notable limitation to these studies is the lack of comparison to pain outcomes in non-operative management, hence making it difficult to ascertain the actual degree of improvement. However, Aaron et al. found that more patients who received PEMF alone experienced less pain than patients who received core decompression alone [6]. This is significant as it is the only study that directly compared outcomes of PEMF therapy to the current most widely-accepted conservative treatment method, and it showed a clear advantage of PEMF over core decompression. These findings show that PEMF therapy is a promising technique, especially for the management of early stage disease.

**Direct current stimulation**

Two studies examined the effect of electrical stimulation as an adjunct to core decompression and grafting with varying results. One study showed improvements in Harris Hip scores and less roentgenographic progression in electrically stimulated hips via DC, although the percentage of patients needing THA in both groups was the same [15]. Similarly, in another study, femoral heads that were treated with DC had better radiological and clinical outcomes than the control group, with an average progression of two thirds a stage compared to one and a third a stage respectively [11]. However, surprisingly, more hips from the DC group eventually required THA (41% vs 37%) [11]. Although there appears to be a small benefit with DC stimulation, its efficacy should be considered in the context of it being an invasive procedure. Due to the study designs, DC application was only evaluated as an adjunct therapy to core decompression and grafting, where it showed no extra benefit. Therefore, more research is required to assess its efficacy as a technique alone. Yet, randomised double-blind controlled trials may not be suitable in this instance, as the control group would likely have to receive insertion of a placebo device, which is ethically problematic [22]. As such, future trials should compare DC therapy alone to other techniques alone, or vary the protocols used in terms of voltage and length of stimulation.

**Capacitive coupling**

Patients who received CC fared worse than those who did not. In one study, hips that were stimulated showed poorer outcomes in all parameters: roentgenographic progression, HHS and Steinberg staging [14]. The other study also revealed comparable findings with unstimulated hips faring better [11]. This is noteworthy because CC is another non-invasive method of applying electric fields, yet the results yielded are significantly worse than those of PEMF. One interesting difference we identified between the PEMF and CC groups is the duration of stimulation: all the patients who were treated with PEMF had it administered 8 h a day whereas those who received CC in one of the studies had their affected hips stimulated nearly 24 h a day [14]. This may explain the large discrepancy in results between the two modalities; it may be that CC would have similar effects to PEMF if...
the protocols used were more similar. This difference also makes it difficult to directly compare these studies, hence, more controlled clinical trials are needed before any concrete conclusion can be made about the effectiveness of CC compared to PEMF, with emphasis on evaluating the optimal protocol for CC application.

**Prognostic factors**
In the paper by Cebrian et al., it was noted that in addition to the presence of certain radiological features, having a femoral head with a greater than 15% necrotic area influenced the likelihood of progression as well. Moreover, they identified that all of the femoral heads that went on to have roentgenographic progression had predominantly lateral involvement [3]. Similarly, Steinberg et al. noted that hips with small lesions fared significantly better than those with intermediate and large lesions [11]. As such, lesion size and its location may be important prognostic markers, and are parameters that haven’t been addressed in other papers.

Finally, another important point to note is that many of these papers either did not take into consideration the aetiologies of the disease, or did not evaluate the outcomes according to aetiologies. With regards to PEMF therapy, Bassett et al. noted that corticosteroid use as an aetiology may have influenced response [10], while Cadossi et al. proposed that idiopathic lesions may be more sensitive [2]. Steinberg et al. mentioned that patients who have had alcohol and steroid use as disease aetiologies may have had poorer outcomes, although the difference was not statistically significant [11]. Causes of the disease may be a confounding factor; secondary lesions may be less responsive to treatment due to their ongoing nature, for example steroid use for treatment of another disease should not be interrupted [4]. Studies to date on this topic are limited in number, size, and quality of research methodology. There is heterogeneity in the methodology used (e.g. dosage of electrical stimulation and follow up period) so a meta-analysis would not yield any meaningful data on the outcomes of interest. Hence this article shows the best available evidence on aetiologies. With regards to PEMF, as noted by Cebrian et al. BMC Musculoskeletal Disorders (2017) 18:319

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**Conclusion**
The outcomes of stimulated femoral heads with osteonecrosis with PEMF have been encouraging, with the improvement in both radiographic and clinical parameters, especially in early Ficat stages. Given its non-invasive nature and potential to stop or reverse the disease process, PEMF is an especially promising area of research. However, the technique is perhaps hindered by the fact that its application is generally cumbersome and requires significant compliance on the part of the patients; the devices often require long hours of use for many months (e.g. 8 h a day for 6 months [2, 3, 4, 6, 10], and precise placement of the coils, typically requiring splints [3, 4, 6, 10]. On the other hand, other techniques of electrical stimulation such as with DC or CC have shown equivocal results. In essence, more trials need to be completed to ascertain the indications for and complications of the use of electrical stimulation in avascular necrosis of femoral heads, and thus derive an optimal protocol.

**Abbreviations**
ARCO: Association Research Circulation Osseous; AVN: Avascular necrosis; CD: Core Decompression; CT: Computed tomogram; DC: Direct current; NSAIDs: Non-steroidal Anti-Inflammatory Drugs; PEMF: Pulsed Electromagnetic Field

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Authors original submitted files are included in this manuscript.

**Authors’ contributions**
TAJ devised the project and was the lead investigator. TAJ, JYQT, GYT, RS, BK, TP and TR helped in reviewing studies and drafting the manuscript. All authors read, edited and approved the final manuscript.

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This was not required for this article.

**Consent for publication**
Not applicable.

**Competing interests**
The authors declare that they do not have any competing interests.

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**References**


Robotic-arm assisted total knee arthroplasty is associated with improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based total knee arthroplasty

**A PROSPECTIVE COHORT STUDY**

**Aims**

The objective of this study was to compare early postoperative functional outcomes and time to hospital discharge between conventional jig-based total knee arthroplasty (TKA) and robotic-arm assisted TKA.

**Patients and Methods**

This prospective cohort study included 40 consecutive patients undergoing conventional jig-based TKA followed by 40 consecutive patients receiving robotic-arm assisted TKA. All surgical procedures were performed by a single surgeon using the medial parapatellar approach with identical implant designs and standardized postoperative inpatient rehabilitation. Inpatient functional outcomes and time to hospital discharge were collected in all study patients.

**Results**

There were no systematic differences in baseline characteristics between the conventional jig-based TKA and robotic-arm assisted TKA treatment groups with respect to age (p = 0.32), gender (p = 0.50), body mass index (p = 0.17), American Society of Anesthesiologists score (p = 0.88), and preoperative haemoglobin level (p = 0.82). Robotic-arm assisted TKA was associated with reduced postoperative pain (p < 0.001), decreased analgesia requirements (p < 0.001), decreased reduction in postoperative haemoglobin levels (p < 0.001), shorter time to straight leg raise (p < 0.001), decreased number of physiotherapy sessions (p < 0.001) and improved maximum knee flexion at discharge (p < 0.001) compared with conventional jig-based TKA. Median time to hospital discharge in robotic-arm assisted TKA was 77 hours (interquartile range (IQR) 74 to 81) compared with 105 hours (IQR 98 to 126) in conventional jig-based TKA (p < 0.001).

**Conclusion**

Robotic-arm assisted TKA was associated with decreased pain, improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based TKA.

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Total knee arthroplasty (TKA) is an established and highly effective procedure that is performed in over 90,000 patients per year within the United Kingdom. The demand for TKA has grown rapidly over the last two decades during which time the overall costs have risen. To control this expenditure optimization of postoperative recovery and reducing length of hospital stay, whilst preserving the quality of care, is required. Developments in minimally invasive surgery, pain management, anaesthesia, deep vein thrombosis prophylaxis, antibiotic prophylaxis, implant design and manufacturing and enhanced rehabilitation techniques, have all ultimately focussed on optimizing postoperative recovery and duration of inpatient stay following TKA. Robotic-arm assisted technology has been used to enhance inpatient recovery and expedite discharge in gastrointestinal, urological, gynaecological surgery, and over the last decade in arthroplasty surgery.
Robotic-arm assisted TKA uses preoperative imaging to create a 3D reconstruction of the patient’s native knee anatomy. This patient-specific model is then used to calculate a haptic window for bone resection, and select optimal implant sizing and positioning for the desired postoperative bone coverage and limb alignment.\(^4\,5\) An interactive robotic-arm with visual, audio and tactile resistive feedback then guides intraoperative bone resection within this predefined haptic window. Saw blade action outside of this stereotactic window is limited, which conceptually helps to preserve native bone stock and minimize periarticular soft-tissue injury.\(^6\) Dynamic referencing is used to assess intraoperative flexion and extension gaps, joint stability, range of movement and limb alignment, enabling the surgeon to perform on-table modifications to bone resection, soft-tissue releases and implant positioning. Studies have shown that robotic-arm assisted TKA is associated with improved accuracy of implant positioning and reduced outliers compared with conventional jig-based TKA\(^2\,4\,8\) but to our knowledge, there are no existing studies exploring how this translates into differences in early postoperative recovery and hospital discharge.

The objective of this prospective cohort study was to determine differences in early postoperative recovery and time to hospital discharge between patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA. The primary outcome measure in this study was pain score on the numerical rating scale at 24 hours following surgery. The hypothesis was that no difference exists between the two groups relating to pain scores at 24 hours as all operative procedures were performed through the same surgical approach with a standardized rehabilitation programme.

**Patients and Methods**

**Patient selection.** This study included 80 patients with symptomatic knee osteoarthritis undergoing primary TKA at the same treatment centre between January 2016 and September 2017. This included 40 consecutive robotic-arm assisted TKAs and the preceding 40 consecutive conventional jig-based TKAs. All operative procedures were performed by the senior author (FSH) who was experienced in performing conventional jig-based and computer-navigated TKA, and had undergone cadaveric training on robotic-arm assisted TKA. The robotic group was the first cohort of patients undergoing robotic-arm assisted TKA under the operating surgeon. Inclusion criteria for this study included the following: patients with knee osteoarthritis undergoing primary TKA; patient between 18 and 80 years of age; surgery using the conventional jig-based or robotic-arm assisted technique; surgery performed by the senior author (FSH). Exclusion criteria included the following: conversion of unicompartmental to TKA; prior infection of knee joint; arthroplasty for fracture or previous osteotomy; underlying neurological dysfunction compromising mobility; and/or the use of other surgical techniques such as computer navigation for TKA. The study was assessed by the hospital review board who advised that further institutional review board assessment for ethical approval was not required. Patients were allocated to their treatment group based on the date of their surgery relative to installation of the robotic device into our institution (Princess Grace Hospital, London, United Kingdom) in September 2016. Conventional jig-based techniques were used prior to installation of the robotic device, and robotic-arm assisted surgery performed after installation.

**Surgical technique.** All patients received general anaesthesia with a standardized regimen of fentanyl, morphine, clonidine, paracetamol and diclofenac at induction by the same consultant anaesthetist. In conventional jig-based TKA, the patient was positioned supine on the operating table with a lateral thigh support and foot bolster to enable flexion and extension of the knee joint. In robotic-guided TKA, the patient was positioned supine with the proximal tibia and foot of the operated limb in the mobile leg holder boot. As per the surgeon’s routine practice, a pneumatic tourniquet was applied but not inflated unless there was intraoperative difficulty in achieving haemostasis or compromise to the bone-cement interface. All study patients received one gram of intravenous tranexamic acid on induction and diathermy was used to help control intraoperative bleeding in all operative procedures. A conventional medial parapatellar approach was used in all patients. In both treatment groups, the objective was to achieve neutral mechanical alignment.

In conventional jig-based TKA, extramedullary referencing was used to perform tibial bone resection perpendicular to the mechanical axis of the tibia in the coronal plane with the aim of matching anatomical anteroposterior slope in the sagittal plane. The femur was prepared using an intramedullary alignment jig with the distal cutting block positioned so that the distal femoral cut was at 5° to 7° valgus angle depending on the pre-existing deformity. The distal femoral cutting block was positioned in 3° or greater of external rotation using the transepicondylar axis. Appropriate soft tissue releases were performed to ensure symmetrical and balanced flexion and extension gaps. In robotic-arm assisted TKA, the patient-specific computer aided design model of the patient’s knee joint was used to create a virtual plan for optimal bone resection and implant positioning. The RIO robotic interactive orthopaedic arm system (Mako Surgical Corporation, Kalamazoo, Michigan) was then used to execute this plan intraoperatively and achieve the planned bone coverage and limb alignment. Femoral registration pins were placed through the midline incision whilst tibial registration pins were placed through a separate 3 cm longitudinal incision over the proximal anteromedial tibia. Intraoperative dynamic tracking markers were used to assess alignment, flexion and extension gaps, and range of movement, enabling on-table modifications to bone resection and implant positioning. Tibial and femoral osteotomies in the coronal plane were performed perpendicular to the tibial and femoral mechanical axes respectively to achieve neutral overall alignment. In the sagittal plane, 0° to 5° of femoral component flexion were used to optimize implant sizing whilst preventing notching. The tibial slope was initially set to 0° and then adjusted as required based on intraoperative assessment of the flexion gap and range of movement.

The cemented Triathlon Posterior Stabilized (PS) implant (Stryker, Mahwah, New Jersey), knee system with an asymmetrical patellar resurfacing button was used in both treatment groups. Polyethylene thickness was selected to maximize range of
movement whilst avoiding hyperextension and ligament laxity. Patients in both treatment groups received 40 ml of 0.25% bupivacaine into the joint capsule prior to wound closure.

**Postoperative inpatient care.** All patients received postoperative patient-controlled analgesia (PCA) with the background intravenous morphine infusion rate set at 0.5 mg/hour, a bolus dose of 2 mg and lockout period of ten minutes. If the patient required additional analgesia then the nursing staff administered oral paracetamol and ibuprofen over this time. The PCA was stopped 24 hours postoperatively and converted to an oral regimen of regular paracetamol, ibuprofen and dihydrocodeine, with oral morphine available for breakthrough pain. All TKAs were performed at the same time of day and the first physiotherapy session was undertaken at six hours postoperatively. Patients underwent a standardized postoperative rehabilitation programme with full weight-bearing and active range of movement exercises commenced from day of surgery. Each physiotherapy session lasted 25 minutes in total and all rehabilitation was performed by the same team in both treatment groups. Patients were discharged home after adequate pain control, knee flexion to a minimum of 90°, independent mobilization with the use of crutches and independent ascent and descent of stairs.

**Outcomes.** All demographic data and patient outcomes were prospectively collected by two independent fellowship trained surgeons (JRTP and SK). Baseline measurements included the operative haemoglobin concentration (g/l). Findings were compared with normal distributions were compared using the unpaired *t*-test, whilst the Mann–Whitney U test was used to compare continuous variables that were not normally distributed.

One categorical outcome (use of continuous passive motion machine) was analysed using Fisher’s exact test, due to the small number of occurrences of this outcome. Continuous variables found to be normally distributed were displayed with the mean and range, whilst the median and interquartile range (IQR) were presented for factors not found to follow a normal distribution. Categorical variables were shown by the number and percentage of patients where the outcome occurred. Statistical significance was set at a *p*-value < 0.05 for all analyses and all statistical analysis was performed using SPSS software version 12 (SPSS Inc., Chicago, Illinois).

**Results**

There was no statistical difference in relation to baseline characteristics recorded between conventional jig-based TKA and robotic-arm assisted TKA (Table I). Interclass correlation coefficient was above 0.8 (0.88 to 0.92) for all postoperative outcomes recorded suggesting good interobserver agreement between the two independent observers. Study outcomes are displayed in Table II.

Patients undergoing robotic-arm assisted surgery had reduced pain scores at each of the four time intervals following surgery compared with conventional jig-based surgery (*p* < 0.001, unpaired *t*-test). In both groups, pain scores were greatest at day one, which reflected the day that the PCA was converted to oral analgesia (Fig. 1). Opiate analgesia requirements were also reduced in the robotic-group compared with the conventional group and this was found to be statistically significant at all four time points (*p* < 0.001, Mann–Whitney U test) (Fig. 2). There was no significant difference in preoperative haemoglobin concentration between the two treatment groups but patients undergoing conventional TKA had a greater reduction postoperatively compared with those undergoing robotic-arm assisted TKA (*p* < 0.001, unpaired *t*-test). The pneumatic tourniquet was not inflated in any study patient. Two patients in the robotic-arm assisted TKA group each received two units of red blood cells compared with four patients (10%) in the conventional jig-based TKA group. Attainment of physiotherapy targets including time to straight leg raise (*p* < 0.001, Mann–Whitney U test) and maximum knee flexion at discharge (*p* < 0.001, unpaired *t*-test) followed the same trend with improved outcomes in the robotic-arm assisted TKA group compared with the conventional jig-based TKA group (Figs 3 to 6). Each boxplot graphically displays the respective study outcome with the transverse line showing the median value and the box representing the interquartile range. The whiskers extend to the minimum and maximum value, except for values more than 1.5 × interquartile range width from the lower or upper quartiles, which are plotted separately. There was a tendency towards to increased operating time in robotic-arm assisted TKA but overall hospital discharge was reduced in the robotic group (*p* < 0.001).

There were two inpatient complications in this study, which included one patient from each treatment group. In the conventional jig-based TKA, one patient had minor wound dehiscence from the distal part of the midline incision, which was treated
Discussion

In this prospective cohort study, there were no systematic differences in baseline characteristics between the two treatment groups, surgery was undertaken by a single surgeon using the same approach with identical implant designs, and inpatient rehabilitation performed using a standardized programme with the same rehabilitation team. Robotic-arm assisted TKA was associated with reduced postoperative pain, decreased analgesia requirements, smaller drop in haemoglobin concentration, shorter time to be able to perform a straight leg raise, improved maximum knee flexion at discharge and decreased length of stay compared with conventional jig-based TKA. Our findings suggest that implementation of robotic-arm assisted surgery may help to further improve early functional recovery and reduce time to hospital discharge in patients undergoing TKA.

Analysis of data from the National Joint Registry of England and Wales showed that persistent pain following TKA is the strongest predictor of patient dissatisfaction and reduced functional outcomes including the Oxford Hip Score.16 Regression analysis has also shown that postoperative pain is the most important prognostic indicator for long-term dissatisfaction following TKA.11 Our study showed reduced pain and opiate analgesia requirements at each of the four time points in patients undergoing

with prophylactic antibiotics and adhesive skin strips to approximate the wound edges. In the robotic-arm assisted TKA group, one patient had minor wound dehiscence over the incision for the proximal tibial registration pins. This was treated with regular dressings and prophylactic oral antibiotics. Both patients made a satisfactory recovery with no further complications.

Table I. Demographic and baseline measurements for study patients undergoing conventional jig-based total knee arthroplasty (TKA) and robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Conventional (n = 40)</th>
<th>Robotic (n = 40)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (yrs)</td>
<td>71.4 (54.2 to 87.1)</td>
<td>69.7 (53.1 to 85.3)</td>
<td>0.32†</td>
</tr>
<tr>
<td>Gender (%)</td>
<td>Female 25 (62)</td>
<td>22 (55)</td>
<td>0.50†</td>
</tr>
<tr>
<td></td>
<td>Male 15 (38)</td>
<td>18 (45)</td>
<td></td>
</tr>
<tr>
<td>Mean BMI (kg/m²)</td>
<td>26.7 (20.3 to 36.0)</td>
<td>27.9 (21.8 to 37.1)</td>
<td>0.17†</td>
</tr>
<tr>
<td>ASA score (%)</td>
<td>I 7 (18)</td>
<td>8 (20)</td>
<td>0.88†</td>
</tr>
<tr>
<td></td>
<td>II 29 (72)</td>
<td>27 (67)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>III 4 (10)</td>
<td>5 (13)</td>
<td></td>
</tr>
<tr>
<td>Side intervention (%)</td>
<td>Left 20 (50)</td>
<td>18 (45)</td>
<td>0.65†</td>
</tr>
<tr>
<td></td>
<td>Right 20 (50)</td>
<td>22 (55)</td>
<td></td>
</tr>
<tr>
<td>Mean preoperative Hb (g/L)</td>
<td>-</td>
<td>132.7 (95.1 to 164.3)</td>
<td>133.3 (113.2 to 154.6)</td>
</tr>
</tbody>
</table>

‡Chi-squared test
*Unpaired t-test
†Fisher’s exact test
BMI, body mass index; ASA, American Society of Anesthesiologists; Hb, Haemoglobin

Table II. Study outcomes for patients undergoing conventional jig-based total knee arthroplasty (TKA) and robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Conventional (n = 40)</th>
<th>Robotic (n = 40)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean operating time (mins)</td>
<td>61.2 (54.6 to 83.1)</td>
<td>70.4 (59.2 to 91.7)</td>
<td>0.34†</td>
</tr>
<tr>
<td>Mean fall in Hb (g/L)</td>
<td>26.1 (5.1 to 49.6)</td>
<td>18.7 (8.0 to 37.2)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>Mean postoperative Hb (g/L)</td>
<td>106.7 (77.3 to 138.4)</td>
<td>114.7 (86.4 to 139.1)</td>
<td>0.01†</td>
</tr>
<tr>
<td>Mean pain score (NRS) – Day 0</td>
<td>5.4 (3.0 to 7.0)</td>
<td>3.1 (2.0 to 5.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Mean pain score (NRS) – Day 1</td>
<td>6.3 (4.0 to 8.0)</td>
<td>3.6 (2.0 to 6.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Mean pain score (NRS) – Day 2</td>
<td>6.1 (3.0 to 8.0)</td>
<td>3.3 (1.0 to 5.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Mean pain score (NRS) – Day 3</td>
<td>4.5 (2.0 to 7.0)</td>
<td>2.6 (1.0 to 5.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median analgesia (mg) – Day 0</td>
<td>36.0 (IQR 29.0 to 51.3)</td>
<td>20.0 (IQR 16.0 to 28.5)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median analgesia (mg) – Day 1</td>
<td>10.0 (IQR 10.0 to 20.0)</td>
<td>10.0 (IQR 0.0 to 10.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median analgesia (mg) – Day 2</td>
<td>10.0 (IQR 10.0 to 20.0)</td>
<td>10.0 (IQR 0.0 to 10.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median analgesia (mg) – Day 3</td>
<td>10.0 (IQR 0.0 to 10.0)</td>
<td>0.0 (IQR 0.0 to 5.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median time to SLR (hrs)</td>
<td>31.0 (IQR 24.0 to 44.0)</td>
<td>20.0 (IQR 18.0 to 21.0)</td>
<td>&lt; 0.001†</td>
</tr>
<tr>
<td>Median knee flexion (°)</td>
<td>0.0 (IQR 0.0 to 0.0)</td>
<td>0.0 (IQR 0.0 to 0.0)</td>
<td>0.08†</td>
</tr>
<tr>
<td>CPM sessions, n (%)</td>
<td>5 (12.6)</td>
<td>2 (5.0)</td>
<td>0.43†</td>
</tr>
<tr>
<td>Median time to discharge (hrs)</td>
<td>105.0 (IQR 98.0 to 126.0)</td>
<td>77.0 (IQR 74.0 to 81.0)</td>
<td>&lt; 0.001†</td>
</tr>
</tbody>
</table>

†Unpaired t-test
‡Mann-Whitney U test
*Fisher’s exact test
NRS, numerical rating scale; Hb, haemoglobin concentration; IQR, interquartile range; SLR, straight leg raise; CPM, continuous passive motion machine
robotic-arm assisted surgery compared with conventional jig-based TKA, which we hope would lead to improved long-term patient satisfaction and functional outcomes in the robotic TKA group. Marchand et al. 17 compared outcomes in 28 robotic-arm assisted TKAs matched with 20 conventional jig-based TKAs and showed that pain, physical function scores and patient satisfaction measured using Western Ontario and McMaster Universities Arthritis Index 18 were better in the robotic group compared with the conventional group at six months after surgery. Our data shows important differences in pain and analgesia requirements in the early postoperative period but the long-term clinical significance of these remains unknown. The present data will be subsequently correlated to validated long-term clinical and functional outcome measures.
Robotic-arm assisted TKA uses dynamic referencing to assess intraoperative knee stability, alignment and range of movement, enabling on-table adjustments to bone resection and implant positioning to be performed. The surgeon is able manipulate bone cuts to achieve the desired flexion and extension gaps without having to perform extensive soft-tissue releases. No additional soft-tissue releases for knee balancing were performed in the robotic-arm assisted group in this study. Reduced soft-tissue dissection and muscle trauma may have helped to reduce the local inflammatory response and time to attainment of physiotherapy targets such as straight leg raise in the robotic-group compared with patients undergoing conventional jig-based TKA.

Siebert et al. conducted a retrospective study on 70 patients undergoing robotic-arm assisted TKA versus a matched historic cohort of 50 conventional TKAs, and observed reduced postoperative soft-tissue swelling in the robotic-group but the size or difference in the effect was not quantified. There are no existing studies comparing the local or systemic inflammatory response in conventional versus robotic arm assisted surgery but existing studies comparing conventional versus minimally invasive surgical approaches for hip and knee arthroplasty have shown that the extent of soft-tissue release was associated with the magnitude of the inflammatory cytokine response and signal changes visible on postoperative MR.

The technical objectives of TKA are to restore mechanical alignment, preserve the joint line, balance flexion and extension gaps and maintain the normal Q angle for correct patella tracking. In order to achieve these objectives, preservation of the surrounding soft-tissue envelope is essential. Compromise to the periarticular soft-tissue structures such as the collateral ligaments, posterior cruciate ligament or extensor mechanism, may compromise postoperative clinical and functional recovery, reduce stability and decrease implant survivorship. Manual based techniques may lead to inadvertent disruption of the periarticular soft-tissue injuries, and in many cases these ligamentous and soft-tissue injuries are underreported. Robotic-arm assisted TKA limits saw blade action to within the fixed stereotactic field, which conceptually helps to reduce iatrogenic bone and soft-tissue injury.
arm assisted TKA versus seven conventional jig-based TKA. The authors found mild posterior cruciate ligament injury in two of the seven conventional jig-based TKAs compared with none of the six robotic-arm assisted TKAs, with more extensive soft-tissue disruption in the conventional group on careful visual evaluation and palpation. In the current study, improved preservation of the periarticular soft-tissue envelope and reduced iatrogenic trauma in the robotic-arm assisted group may have helped to limit pain and enhance early functional recovery.

In this study, there was a trend towards increased operating time in the robotic group but this was not statistically significant. Our findings are consistent with a previous study by Song et al, who conducted a prospective study on 30 patients undergoing sequential TKA, which included conventional jig-based TKA on one side followed by robotic-arm assisted TKA on the contralateral side. The authors reported no difference in operating time between the two treatment groups, with mean operating time in the robotic-arm assisted of 95 minutes (SD 18). Park and Lee reported on the learning curve of robotic-assisted TKA and showed that six of their 32 robotic-arm assisted TKAs had short-term complications, including superficial infection, patellar ligament rupture, patellar dislocation, supracondylar fracture, patellar fracture and common peroneal injury during the learning phase. The reduced operating time and absence of intraoperative complications in our cohort of patients compared with these previous studies may be due to the operating surgeon in this study having extensive training in robotic-assisted TKA in cadaver-workshops and prior experience in performing computer navigated arthroplasty. As such progression along the learning curve for some aspects of robotic-assisted surgery may have already been achieved.

There is growing literature showing that robotic-arm assisted knee arthroplasty is associated with improved accuracy of implant positioning, better short- to mid-term functional scores and reduced revision rates compared with conventional jig-based TKA. Although a financial analysis has not been undertaken, our findings do show important differences in inpatient rehabilitation and hospital stay, which will aid healthcare policy makers in the allocation of medical resources and cost planning for the implementation of this technology into clinical practice.

There are several limitations of this study that need to be considered when interpreting the findings. First, all patients received general anaesthetic, which is not keeping in with current trends in enhanced recovery programmes and this may have reduced the overall rehabilitation time in both treatment groups. Second, the reported early functional outcome measures were not correlated to long-term clinical outcomes or implant survivorship. Third, patients and observers recording outcomes of interest could not be blinded as patients in the robotic group had an additional incision over the proximal tibia for the insertion of the registration pins. Fourth, the use of historical controls may have introduced bias into the study due to increasing drive for faster rehabilitation and reduced length of stay. Improved outcomes in the robotic group may therefore not be exclusively due to surgical technique. Fifth, preoperative grading of the arthritis and radiological outcomes were not analysed in this study. Despite these limitations, this prospective single surgeon study used the same surgical approach, implant design and rehabilitation programme in two systemically matched treatment groups, and showed improved early functional recovery and time to hospital discharge with no additional risk of complications in robotic-arm assisted TKA compared with conventional jig-based TKA.

Robotic-arm assisted TKA was associated with reduced postoperative pain, decreased analgesia requirements, less reduction in postoperative haemoglobin levels, shorter time to perform a straight leg raise, decreased length of stay, and improved maximum knee flexion at discharge compared with conventional jig-based TKA. There was no additional risk of inpatient complications in patients undergoing robotic-arm assisted TKA compared with conventional jig-based TKA.

**Take home message:**
- Robotic-arm assisted TKA is associated with reduced postoperative pain and analgesia requirements compared with conventional jig-based TKA.
- Robotic-arm assisted TKA is associated with improved early functional recovery compared with conventional jig-based TKA.
- Robotic-arm assisted TKA is associated with reduced time to hospital discharge compared with conventional jig-based TKA.

**References**

Author contributions:
B. Kayani: Hypothesis generation, Data interpretation, Manuscript preparation.
S. Konan: Hypothesis generation, Data collection, Manuscript preparation.
J. R. T. Pietrzak: Data collection, Data analysis.
J. Tahmassebi: Data collection, Data analysis.

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Robotic-arm assisted total knee arthroplasty has a learning curve of seven cases for integration into the surgical workflow but no learning curve effect for accuracy of implant positioning

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Abstract

Purpose The primary objective of this study was to determine the surgical team’s learning curve for robotic-arm assisted TKA through assessments of operative times, surgical team comfort levels, accuracy of implant positioning, limb alignment, and postoperative complications. Secondary objectives were to compare accuracy of implant positioning and limb alignment in conventional jig-based TKA versus robotic-arm assisted TKA.

Methods This prospective cohort study included 60 consecutive conventional jig-based TKAs followed by 60 consecutive robotic-arm assisted TKAs performed by a single surgeon. Independent observers recorded surrogate markers of the learning curve including operative times, stress levels amongst the surgical team using the state-trait anxiety inventory (STAI) questionnaire, accuracy of implant positioning, limb alignment, and complications within 30 days of surgery. Cumulative summation (CUSUM) analyses were used to assess learning curves for operative time and STAI scores in robotic TKA.

Results Robotic-arm assisted TKA was associated with a learning curve of seven cases for operative times (p = 0.01) and surgical team anxiety levels (p = 0.02). Cumulative robotic experience did not affect accuracy of implant positioning (n.s.) limb alignment (n.s.) posterior condylar offset ratio (n.s.) posterior tibial slope (n.s.) and joint line restoration (n.s.). Robotic TKA improved accuracy of implant positioning (p < 0.001) and limb alignment (p < 0.001) with no additional risk of postoperative complications compared to conventional manual TKA.

Conclusion Implementation of robotic-arm assisted TKA led to increased operative times and heightened levels of anxiety amongst the surgical team for the initial seven cases but there was no learning curve for achieving the planned implant positioning. Robotic-arm assisted TKA improved accuracy of implant positioning and limb alignment compared to conventional jig-based TKA. The findings of this study will enable clinicians and healthcare professionals to better understand the impact of implementing robotic TKA on the surgical workflow, assist the safe integration of this procedure into surgical practice, and facilitate theatre planning and scheduling of operative cases during the learning phase.

Level of evidence II.

Keywords Implant positioning · Learning curve · Operative time · Robotics · TKA · Total knee arthroplasty · Total knee replacement

Introduction

Total knee arthroplasty (TKA) is an established and cost-effective treatment for patients with symptomatic end-stage knee osteoarthritis [7]. However, recent studies have shown that 20% of patients still remain dissatisfied following TKA [1, 18]. Accuracy of implant positioning and limb alignment are important prognostic factors that influence patient satisfaction, clinical outcomes, and long-term implant survivorship following TKA [8, 17, 18, 22]. Evolution in surgical technology has led to the development of robotic-arm assisted TKA, which
uses a preoperative computerised tomography (CT) scan to create a patient-specific computer-aided design (CAD) model of the patient’s unique knee anatomy. The surgeon is able to virtually select the desired implant position and alignment, and an intraoperative robotic arm helps to execute this plan with a high degree of accuracy [11, 12]. Robotic-arm assisted TKA improves the accuracy of bone resection, reduces outliers in postoperative limb alignment, and decreases iatrogenic bone and periarticular soft tissue injury compared to conventional manual TKA [11, 12, 21, 22].

Existing studies on the learning curve of robotic-arm assisted TKA have used operative times as exclusive markers of surgical competence, and found surgical proficiency may be achieved by high-volume arthroplasty surgeons within a few months [4, 20]. It is possible to improve on these existing studies by comparing a more comprehensive range of learning outcome measures including operative times of individual stages of the robotic procedure, surgical team comfort levels, accuracy of implant positioning, restoration of limb alignment, and postoperative complications. In this study, cumulative summation (CUSUM) analyses will be used to assess incremental changes in these study outcomes during progression of the robotic TKA learning curve [13], and the findings compared to baseline values from a cohort of patients undergoing conventional manual TKA by the same operating surgeon. This data will be used to ascertain inflexion points at which the surgeon transitions from the learning phase to the proficiency phase in more detail. The findings of this study will enable clinicians and healthcare professionals to better understand the impact of implementing robotic TKA on the surgical workflow, facilitate theatre planning and scheduling of operative cases, and understand any additional risks or complications during the acquisition of surgical proficiency.

The primary objective of this study was to determine the surgical team’s learning curve for robotic-arm assisted TKA through assessments of operative times, surgical team comfort levels, accuracy of implant positioning, limb alignment, and postoperative complications. The hypothesis was that cumulative experience with robotic-arm assisted TKA would lead to improved operative times and surgical team comfort levels but there would be no learning effect for accuracy of implant positioning or limb alignment. The secondary objectives were to compare accuracy of implant positioning and limb alignment in patients undergoing robotic-arm assisted TKA versus conventional jig-based TKA.

Materials and methods

This prospective cohort study included 120 patients with symptomatic knee osteoarthritis undergoing primary TKA between 2016 and 2017. This included 60 consecutive patients undergoing conventional jig-based TKA followed by 60 consecutive patients receiving robotic-arm assisted TKA. Patients were allocated to their treatment group based on the date of their surgery relative to installation of the robotic device into the study institution. Conventional jig-based TKA was performed prior to installation of the robotic device, and robotic-arm assisted TKA performed after its installation. Patients were not randomized but this enabled assessment of learning curves associated with complete transition from conventional jig-based TKA to robotic-arm assisted TKA. All operative procedures were performed by the senior author who is experienced in performing conventional jig-based TKA and had undergone cadaveric training on robotic-arm assisted TKA. The robotic group was the first cohort of patients undergoing robotic-arm assisted TKA under the operating surgeon.

Inclusion criteria for this study included the following: Patients with knee osteoarthritis undergoing primary total knee arthroplasty; patients between 18 and 80 years of age; surgery undertaken using the conventional jig-based or robotic-arm assisted technique; surgery performed by the senior author. Exclusion criteria included the following: conversion of unicompartmental knee arthroplasty to TKA (n = 6); prior infection of knee joint (n = 1); arthroplasty for fracture or previous osteotomy (n = 2); and underlying neurological dysfunction compromising mobility (n = 1). Patients undergoing conventional jig-based TKA and robotic-arm assisted TKA were well matched for baseline characteristics (Table 1). In both treatment groups, the standard medial parapatellar approach was used with implantation of the cemented Stryker Triathlon (Stryker Navigation, Kalamazoo, Michigan, USA), cruciate substituting knee system and asymmetrical patella resurfacing. Two independent observers collected all study outcomes and both were blinded to each other’s recordings. These observers were not involved in the surgical planning, operative procedure, or postoperative treatment process. Written informed consent was obtained from all study participants.

All patients underwent routine preoperative anteroposterior weight-bearing knee radiographs, lateral knee radiographs, and full-length hip-to-ankle weight-bearing radiographs. In both treatment groups, the operating surgeon used Traumacad software (Traumacad, Petach-Tikva, Israel) with plain radiographs to preoperatively template implant sizes and positions. Full-length hip-to-ankle radiographs were used to guide femoral and tibial resection angles to achieve neutral mechanical alignment. Lateral knee radiograph was used to select the femoral component size and position to restore the patient’s native posterior condylar offset ratio whilst avoiding overhang or notching of the femur. Tibial implant position and size were selected to restore native posterior tibial slope and avoid any anteroposterior overhang. On the anteroposterior knee radiograph, femoral and
tibial implant positions and sizes were selected to achieve maximum mediolateral contact whilst avoiding overhang. In patients undergoing robotic-arm assisted TKA, preoperative CT scan and CAD model were used to select the optimal implant positioning and implant sizes for achieving the desired bone coverage and limb alignment.

**Surgical technique**

Conventional jig-based TKA was performed using standard instrumentation with alignment jigs to guide bone resection. Extramedullary referencing was used to perform tibial bone resection perpendicular to the mechanical axis of the tibia in the coronal plane with the aim of matching anatomical anteroposterior slope in the sagittal plane. The femur was prepared using an intramedullary alignment jig with the distal cutting block positioned so that the distal femoral cut was at $5^\circ$–$7^\circ$ valgus angle depending on the pre-existing deformity. The distal femoral cutting block was positioned in $3^\circ$ or greater of external rotation using the transepicondylar axis. Flexion and extension gaps were checked and appropriate soft tissue releases performed to ensure the knee was balanced. No further intraoperative adjustments or tailoring of implant positioning were performed to account for individual patient anatomy.

In patients undergoing robotic-arm assisted TKA, distal femoral and proximal tibial bicortical registration pins were inserted and fixed arrays mounted onto these to enable intraoperative dynamic referencing. Bone registration was performed by intraoperatively mapping radiological landmarks displayed on the computer screen to verify anatomy and establish bone geometry. Joint balancing captured femoral and tibial poses with corrective forces, assessed kinematics through the arc of motion, and enabled fine tuning of implant positioning based on laxity of the soft tissue envelope. An intraoperative surgeon-controlled robotic arm with visual, tactile, and audio feedback was then used to execute the preoperative plan to within 2 mm of the planned bone resection. Tibial and femoral osteotomies in the coronal plane were performed perpendicular to the tibial and femoral mechanical axes, respectively, to achieve neutral overall alignment. In the sagittal plane, $0^\circ$–$5^\circ$ of femoral component flexion were used to optimise implant sizing whilst preventing notching. The tibial slope was initially set to zero degrees and then adjusted as required based on intraoperative assessment of the flexion gap and range of motion. Optical motion capture technology was used to assess limb alignment, range of motion, flexion and extension gaps, and arc of motion with trial implants prior to definitive selection and cement implantation of final components.

**Outcome measures**

**Interclass correlation coefficient**

All radiological measurements were recorded by each observer at 28 days apart and findings compared to assess for intra-observer agreement. Radiological measurements were compared between the two observers to assess for inter-observer agreement. Interclass correlation coefficient was 0.9 (95% CI 0.8–1.0) for intra-observer agreement and 0.9 (95% CI 0.8–0.9) for inter-observer agreement in all study outcomes, which indicated good agreement on all radiological parameters assessed by the two independent observers.

**Operative time**

Operative time was defined as time from initial surgical incision to final wound closure. In robotic-arm assisted TKA, surgical times for the following parts of the procedure were recorded: Set up of surgical tray, robotic device, and instruments; surgical approach and insertion of registration pins; bone registration; joint balancing; bone preparation; implant

### Table 1

Baseline characteristics in patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Conventional jig-based TKA ($n=60$)</th>
<th>Robotic-arm assisted TKA ($N=60$)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>68.7 ± 6.1</td>
<td>67.6 ± 7.6</td>
<td>n.s.</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>26.1 ± 3.6</td>
<td>27.2 ± 3.6</td>
<td>n.s.</td>
</tr>
<tr>
<td>Gender (female/male)</td>
<td>F 33 (55%)</td>
<td>F 32 (53%)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td>M 27 (45%)</td>
<td>M 28 (46.7%)</td>
<td></td>
</tr>
<tr>
<td>ASA grade</td>
<td>I—24 (40.0%)</td>
<td>I—21 (35.0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>II—32 (53.7%)</td>
<td>II—33 (55.0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>III—4 (6.7%)</td>
<td>III—6 (10.0%)</td>
<td></td>
</tr>
<tr>
<td>Side intervention (right/left)</td>
<td>R 29 (48.3%)</td>
<td>R 33 (55.0%)</td>
<td>n.s.</td>
</tr>
<tr>
<td></td>
<td>L 31 (51.7%)</td>
<td>L 27 (45.0%)</td>
<td></td>
</tr>
</tbody>
</table>

Summary statistics are: $N$ (percentage) or mean with standard deviation.

*BMI* body mass index, *ASA score* American Society of Anaesthesiologists score.
trailing; cement implantation of final prosthesis; and overall operative time.

**Surgical team anxiety levels**

The Spielberger State-Trait Anxiety Inventory (STAI) questionnaire is a validated subjective assessment tool for quantifying an individual’s stress levels with individual traits arising from the clinical environment [14]. The six-item questionnaire has a 4-point rating scale and total scores range from 6 to 24, with higher values indicating higher levels of stress. The STAI questionnaire was completed by each member of the surgical team prior to the surgical time-out in all study patients. The surgical team included the operating surgeon, two consultant anaesthetists, two senior scrub nurses, one operating department practitioner (ODP), and one circulating nurse.

**Implant positioning and limb alignment**

All patients underwent postoperative anteroposterior weight-bearing and lateral knee radiographs, and full-length hip-to-ankle weight-bearing radiographs. Accuracy of implant positioning and limb alignment were assessed by comparing the values achieved in the postoperative radiographs to the planned values in the corresponding preoperative radiographs. Femoral and tibial axes were used as reference markers as described by Bell et al. [2]. Accuracy of achieving the planned femoral and tibial implant positioning were assessed using the techniques described by Moon et al. [15]. The femoral coronal implant alignment was measured as the medial angle subtended by the femoral mechanical axis and the line connecting the distal points of the medial and lateral condyles of the femoral component. The femoral sagittal implant alignment was calculated as the angle subtended between the perpendicular line running proximally from the distal femoral surface in contact with the femoral component and the femoral mechanical axis. The tibial coronal implant alignment was measured as the medial angle subtended by the tibial mechanical axis and the medial to lateral axis of the tibial implant. The tibial sagittal alignment was calculated as the angle between the tibial mechanical axis and anterior to posterior axis of the tibial implant. Anteroposterior plain knee radiographs were used to measure the joint line height by calculating the perpendicular distance from a line extending through the distal points of the femoral condyles and a parallel line extending to the fibular head. True lateral knee radiographs were used to calculate the posterior tibial slope and posterior condylar offset ratio (PCOR) using the methods described by Gaudiani et al. [6] and Johal et al. [9] respectively.

**Complications**

All patients were reviewed in outpatient clinic at 30 days following surgery by the independent observers for clinical assessment and full weight-bearing radiographs performed. Any postoperative complications and their respective treatments during this follow-up period were recorded for analysis.

Hospital review board approval was acquired from the host institution (Reference: 241413, Princess Grace Hospital, 42–52 Nottingham place, Marylebone, London, W1U 5NY, UK) before commencement of the study. Further Research Ethics Committee (REC) or Health Research Authority (HRA) approval was not required for this study.

**Statistical analysis**

Sample size calculation was performed using operative time as the primary outcome measure and published data on operative times with similar surgical techniques for TKA. The minimal clinical difference was set at 5 min and standard deviation at 10 min [19]. This study required 60 patients in each arm to detect this minimum difference in operative time using a two-tailed, two-sample t-tests with a power of 80% and significance level of 5%. Due to the limited follow-up time, no further adjustments were made to the sample size calculation to account for sample size attrition during follow-up.

The CUSUM sequential analysis tool was used to assess learning curves in robotic-arm assisted TKA for operative time and surgical team stress levels as assessed using the STAI questionnaire. Standardised target values for the CUSUM analyses were set using the overall mean values for these outcome measures from the robotic-arm assisted TKA group. CUSUM values represent a running total of the differences between the value of each data point and the standardised target values for each outcome. Learning curves for accuracy of implant position and limb alignment in robotic-arm assisted TKA were assessed by calculating root mean square error values for radiological outcomes and assessing progression in groups of ten patients. Categorical data were compared using the chi square test and Fisher’s exact test where greater than 25% of cells had less than five cases. Normally distributed continuous variables were compared using independent t-tests for unpaired variables, paired t test for paired (matched) variables, and one-way ANOVA for multiple variables, The Mann–Whitney test was used for non-parametric data. Statistical significance was set at p < 0.05 for all statistical tests. All statistical analyses were performed using SPSS software version 21 (SPSS Inc., Chicago, IL, USA).
Results

Operative times

In robotic-arm assisted TKAs, CUSUM analysis for operative times revealed a sharp inflexion point after the initial seven cases, which helped to identify two distinct phases in the learning curve (Fig. 1). Phase 1 represents the initial learning segment and phase 2 represents the proficiency stage in robotic-arm assisted TKA. Comparison of the two phases demonstrated phase 1 procedures to be significantly longer \((p = 0.01)\) with no differences in baseline characteristics compared to phase 2 (Tables 2, 3).

Surgical team anxiety levels

CUSUM analysis of preoperative stress levels as assessed using the STAI questionnaire revealed an inflexion point after seven robotic cases \((p = 0.02)\) in a pattern similar to operative times in robotic-arm assisted TKA (Fig. 2). Further analysis revealed STAI scores to be significantly higher.

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Fig. 1 CUSUM analysis charts demonstrating the learning curve for operative time in patients undergoing robotic-arm assisted TKA. a CUSUM chart for operative times in consecutive robotic-arm assisted TKA cases. Dashed vertical line represents the inflexion point at which the learning curve transitions from the learning phase (phase 1) to the proficiency phase (phase 2). b CUSUM chart for phase 1 robotic-arm assisted TKA cases. c CUSUM chart for phase 2 robotic-arm assisted TKA cases.
in phase 1 than in phase 2 for all members of the surgical team (Fig. 3).

**Implant positioning and limb alignment**

There was no learning curve effect of robotic-arm assisted TKA on accuracy of achieving the planned implant position and limb alignment (Table 4; Figs. 4, 5). Robotic-arm assisted TKA improved accuracy in achieving the planned implant positions compared to conventional jig-based TKA (Table 5).

**Complications**

There were two inpatient complications in this study, which included one patient from each treatment group. In conventional jig-based TKA, one patient had minor wound dehiscence from the distal part of the midline incision, which was treated with adhesive skin strips to approximate the wound edges and prophylactic antibiotics. In the robotic-arm assisted TKA group, one patient had minor wound dehiscence over the incision for the proximal tibial registration pins. This was treated with regular dressings and prophylactic oral antibiotics. Both patients made a satisfactory recovery with no further complications.
Discussion

The most pertinent findings from this study are that robotic-arm assisted TKA was associated with a learning curve of seven cases for operative times and surgical team comfort levels but there was no learning curve for accuracy of implant positioning, limb alignment, posterior condylar offset ratio, posterior tibial slope, and joint line preservation. Robotic-arm assisted TKA was associated with improved accuracy of implant positioning and limb alignment with no additional risk of complications compared to conventional jig-based TKA.

The operative time in robotic-arm assisted TKA progressively decreased over the initial seven cases as the surgical team became increasingly familiar with robotic technology and accustomed to the stages of robotic TKA. Most marked time improvements occurred with bone registration and operative times for this stage of the procedure decreased by over 50% during the initial learning phase. Intraoperative anatomical landmarks for bone registration were similar in

![Fig. 3 Chart comparing STAI scores between learning phases for all members of the surgical team in robotic-arm assisted TKA](image)

**Table 4** Accuracy of implant positioning and limb alignment in patients undergoing robotic-arm assisted TKA

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical alignment RMSE (degrees)</td>
<td>1.6 ± 0.8</td>
<td>1.8 ± 1.0</td>
<td>1.7 ± 1.2</td>
<td>1.1 ± 0.6</td>
<td>1.6 ± 0.9</td>
<td>1.3 ± 1.0</td>
<td>n.s.</td>
</tr>
<tr>
<td>PCOR RMSE</td>
<td>0.2 ± 0.1</td>
<td>0.2 ± 0.1</td>
<td>0.2 ± 0.1</td>
<td>0.2 ± 0.1</td>
<td>0.2 ± 0.1</td>
<td>0.2 ± 0.1</td>
<td>n.s.</td>
</tr>
<tr>
<td>Posterior tibial slope RMSE (degrees)</td>
<td>1.4 ± 0.7</td>
<td>1.4 ± 0.9</td>
<td>1.3 ± 0.6</td>
<td>1.5 ± 0.7</td>
<td>1.3 ± 0.6</td>
<td>1.4 ± 0.7</td>
<td>n.s.</td>
</tr>
<tr>
<td>Joint line RMSE (mm)</td>
<td>1.0 ± 0.4</td>
<td>1.0 ± 0.6</td>
<td>1.1 ± 0.6</td>
<td>0.9 ± 0.6</td>
<td>1.1 ± 0.7</td>
<td>1.0 ± 0.6</td>
<td>n.s.</td>
</tr>
<tr>
<td>Femoral coronal RMSE (degrees)</td>
<td>1.0 ± 0.4</td>
<td>1.0 ± 0.3</td>
<td>0.9 ± 0.4</td>
<td>1.0 ± 0.4</td>
<td>0.9 ± 0.5</td>
<td>1.0 ± 0.4</td>
<td>n.s.</td>
</tr>
<tr>
<td>Femoral sagittal RMSE (degrees)</td>
<td>2.1 ± 0.8</td>
<td>2.0 ± 0.7</td>
<td>2.1 ± 0.5</td>
<td>2.0 ± 0.5</td>
<td>2.0 ± 1.0</td>
<td>1.9 ± 0.5</td>
<td>n.s.</td>
</tr>
<tr>
<td>Tibial coronal RMSE (degrees)</td>
<td>0.9 ± 0.3</td>
<td>1.0 ± 0.5</td>
<td>1.0 ± 0.7</td>
<td>0.9 ± 0.5</td>
<td>1.1 ± 0.4</td>
<td>1.0 ± 0.5</td>
<td>n.s.</td>
</tr>
<tr>
<td>Tibial sagittal RMSE (degrees)</td>
<td>2.0 ± 0.5</td>
<td>2.1 ± 0.5</td>
<td>1.9 ± 0.7</td>
<td>2.1 ± 0.7</td>
<td>1.9 ± 0.8</td>
<td>2.2 ± 0.5</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

Summary statistics are: RMSE (root mean square error) with standard deviation

![Fig. 4 Bar chart showing changes in root mean square error (RMSE) for accuracy in femoral and tibial implant positioning (degrees) in consecutive patient groups undergoing robotic-arm assisted TKA](image)
all patients, and therefore, with increasing surgical experience, the surgeon was able to predict and pre-emptively place the bovie tip over the appropriate bone landmark for registration. More moderate improvements were observed in time for bone resection as the surgeon became progressively more responsive to feedback from the saw blade. As the surgeon became more adept with fine movements of the robotic arm and more receptive to the audio, visual, and tactile feedback, he was able to better control the movements of the arm and preform bone cuts with greater efficiency.

This study also found that mean time for joint balancing during the proficiency stage was 8.9 min (range 7–12 min). During this stage, the surgeon assessed knee kinematics through the arc of motion, flexion and extension gaps, range of movement, and stability using optical motion technology. Using this intraoperative data, the surgeon was able to fine-tune femoral and tibial bone resections to balance flexion and extension gaps without having to perform more extensive soft tissue releases as may often be required in conventional jig-based TKA [7, 8]. This may have helped to limit the overall observed difference in operative times between conventional TKA versus robotic TKA.

The findings of this study complement those of Sodhi et al. [20] that explored the learning curve of robotic TKA using operative time as an exclusive marker of surgical proficiency. The authors reviewed operative times in two different surgeons and found mean operative times in the first 20 robotic cases were increased compared to each surgeon’s

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**Fig. 5** Bar chart showing changes in root mean square error (RMSE) for accuracy in achieving planned mechanical alignment (degree), posterior condylar offset ratio (PCOR), posterior tibial slope (degrees), and joint line restoration (mm) in consecutive patient groups undergoing robotic-arm assisted TKA

**Table 5** Study outcomes in patients undergoing conventional jig-based TKA versus robotic-arm assisted TKA

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Conventional jig-based TKA ( (n=60) )</th>
<th>Robotic-arm assisted TKA ( (n=60) )</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative time (mins)</td>
<td>62.1 ± 5.7</td>
<td>69.4 ± 8.1</td>
<td>n.s.</td>
</tr>
<tr>
<td>Preoperative STAI score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating surgeon</td>
<td>12.1 ± 3.4</td>
<td>13.0 ± 4.1</td>
<td>n.s.</td>
</tr>
<tr>
<td>Anaesthetist</td>
<td>9.1 ± 2.5</td>
<td>9.7 ± 2.5</td>
<td>n.s.</td>
</tr>
<tr>
<td>Scrub nurse</td>
<td>12.8 ± 3.1</td>
<td>13.3 ± 2.6</td>
<td>n.s.</td>
</tr>
<tr>
<td>Circulating nurse</td>
<td>11.1 ± 2.1</td>
<td>10.2 ± 2.9</td>
<td>n.s.</td>
</tr>
<tr>
<td>ODP</td>
<td>8.6 ± 3.1</td>
<td>7.6 ± 2.4</td>
<td>n.s.</td>
</tr>
<tr>
<td>Postoperative radiological outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical alignment RMSE (degrees)</td>
<td>3.2 ± 1.2</td>
<td>1.5 ± 0.9</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>PCOR</td>
<td>0.3 ± 0.1</td>
<td>0.2 ± 0.1</td>
<td>n.s.</td>
</tr>
<tr>
<td>Posterior tibial slope RMSE (degrees)</td>
<td>3.4 ± 1.1</td>
<td>1.4 ± 0.6</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Joint line RMSE (mm)</td>
<td>2.9 ± 1.4</td>
<td>1.0 ± 0.6</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Femoral coronal alignment RMSE (degrees)</td>
<td>4.1 ± 1.1</td>
<td>1.0 ± 0.4</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Femoral sagittal alignment RMSE (degrees)</td>
<td>4.2 ± 0.8</td>
<td>2.1 ± 0.7</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Tibial coronal alignment RMSE (degrees)</td>
<td>3.6 ± 0.8</td>
<td>1.0 ± 0.5</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Tibial sagittal alignment RMSE (degrees)</td>
<td>3.9 ± 1.0</td>
<td>2.0 ± 0.6</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

Summary statistics are: mean with standard deviation
mean operative time for conventional jig-based TKA [20].
Operative times for the initial 20 robotic TKA cases ranged
from 71 to 104 min for surgeon 1, and ranged from 74 to
142 min in surgeon 2. The wide variation in operative
times over the first 20 cases suggest that the learning curve may
have already been in effect and operative times comparable
to those of conventional TKA may have been observed much
earlier than reported. The authors also reported that after the
initial learning phase, operative times in robotic-arm assisted
TKA were comparable to those of conventional jig-based
TKA, which is consistent with the findings of this study.
In theory, robotic-arm assisted surgery helps to produce a
more streamlined surgical procedure by reducing the need
for instrument trays, alignment guides, and cutting blocks,
reducing need for trialling due to the high accuracy of preop-
erative surgical planning [21]. However, in this study, these
potential benefits with robotic TKA did not translate to faster
operative times compared to conventional jig-based TKA.
Implementation of robotic-arm assisted TKA was associ-
ated with heightened levels of anxiety amongst the surgical
team during the initial learning phase. This is important as
higher levels of stress and mental strain are associated with
diminished operative performance, poor decision-making,
and reduced technical skills [14]. In this study, improve-
ments in the surgical team’s anxiety levels with robotic-arm
assisted TKA followed in a trend similar to that of opera-
tive times with baseline STAI scores reached after seven
cases. Progressive improvements in anxiety scores during
this initial learning phase correlated with the surgical team
becoming more proficient with setting up the new trays and
instruments, positioning the robotic machine in theatre,
attaching the burr to the robotic arm, and proactively pre-
paring the registration pins, check points, and arrays. As the
team became more confident with these steps, subjective
anxiety levels and operative times diminished. The high-
est anxiety levels were observed in the operating surgeon
and scrub nurse during the initial learning phase but these
did not translate into any differences in accuracy of implant
positioning or limb alignment.
Cumulative robotic experience did not impact the accu-
ry of achieving the planned implant positioning, limb
alignment, posterior condylar offset ratio, posterior tibial
slope, or native joint line restoration. Robotic-arm assisted
TKA uses bone registration to confirm intraoperative spa-
tial orientation of the limb and fixed arrays accurately track
the femoral and tibial bone resection windows throughout
the procedure. Stereotactic boundaries also confine bone
resection to the limits of the haptic windows, which helps
to reduce manual errors in bone resection and iatrogenic soft
tissue injury from the handheld sawblade used in conven-
tional TKA [11, 12]. The robotic procedure, therefore, limits
bone resection to the preoperative surgical plan and this may
have helped to limit any surgeon-induced errors in implant
positioning during the learning phase.
Robotic-arm assisted TKA was associated with improved
accuracy in implant positioning and limb alignment com-
pared to conventional jig-based TKA, which is important
as these outcomes affect functional recovery, clinical out-
comes, and long-term implant survivorship [8, 18, 19, 22].
The findings of this study are consistent with those of Song
et al. who performed a prospective randomized study on 100
patients undergoing primary TKA and found robotic-arm
assisted surgery improved accuracy of mechanical align-
ment with reduced outliers of greater than 3° in planned
alignment compared to conventional manual TKA (0 versus
24%, \( p < 0.001 \)) [22]. Bellemans et al. reviewed outcomes
in 25 patients undergoing robotic-arm assisted TKA and
found femoral and tibial implant alignment within 1° of the
planned positions in all three planes [3]. Improved accuracy
in preserving the native posterior tibial slope and joint line
within the robotic group in this study are also significant
findings as previous studies have shown that these radiologi-
cal outcomes correlate with improved patient satisfaction,
stability, and kinematics through the arc of motion following
TKA [5, 10].
There are several limitations of this study that must be
appreciated when interpreting the findings. First, accuracy
of implant positioning and limb alignment was measured
using plain radiographs, which are not as accurate as CT
scans. Second, different preoperative planning techniques
were used in each treatment group, which may have affected
the accuracy of implant positioning achieved with each treat-
ment technique. Third, the surgical team in this study are all
experienced in working with both conventional and navi-
gated TKA in a high-volume arthroplasty centre, and there-
fore, their learning curve may not be directly transferrable
to other less experienced teams. Fourth, follow-up time was
limited to 30 days following surgery and so long-term data
on functional outcomes, implant survivorship and revision
rates were not available. Fifth, additional costs and impact
on other operative cases due to increased operating times
during the learning phase were not assessed.
The findings of this study will enable healthcare pro-
essionals to better understand the impact of implement-
ing robotic-arm assisted TKA on the surgical workflow.
Theatre planning and scheduling of operative cases should
consider increased operative times and heightened levels of
anxiety amongst the surgical team during this initial learning
phase. As team members become more familiar and adept
with robotic technology, comfort levels improve and thea-
tre efficiency increases thereafter. After the initial learning
phase of robotic-arm assisted TKA, operative times with
robotic TKA will be comparable to those with conventional
manual TKA. There is no impact of cumulative experience
with robotic-arm assisted TKA on accuracy of implant
positioning or limb alignment, which is important for the safe implementation of this procedure into routine surgical practice. Robotic-arm assisted TKA improves accuracy of implant positioning with no additional risk of postoperative complications at short-term follow-up compared to conventional manual TKA.

**Conclusion**

Implementation of robotic-arm assisted TKA alters the surgical workflow with increased operative times and heightened levels of anxiety amongst the surgical team for the initial seven cases but this does not translate to any compromise in the accuracy of implant positioning. Robotic-arm assisted TKA improved accuracy of implant positioning and limb alignment compared to conventional jig-based TKA.

**Funding**

None.

**Compliance with ethical standards**

**Conflict of interest** The author F.S. Haddad is a paid consultant that receives royalties from Stryker Limited. The other authors have no conflicts of interest to declare in relation to this study.

**Ethical approval** Hospital board approval was obtained from the host institution (Reference: 241413, Princess Grace Hospital, 42–52 Nottingham place, Marylebone, London, W1U 5NY, UK). No further REC or HRA approval was required for this study.

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**References**

Indications for a single-stage exchange arthroplasty for chronic prosthetic joint infection
A SYSTEMATIC REVIEW

Aims
Prosthetic joint infections (PJIs) of the hip and knee are associated with significant morbidity and socioeconomic burden. We undertook a systematic review of the current literature with the aim of proposing criteria for the selection of patients for a single-stage exchange arthroplasty in the management of a PJI.

Material and Methods
A comprehensive review of the current literature was performed using the OVID-MEDLINE, EMBASE, and Cochrane Library databases and the search terms: infection and knee arthroplasty OR knee revision OR hip arthroplasty OR hip revision, and one stage OR single stage OR direct exchange. All studies involving fewer than ten patients and follow-up of less than two years in the study group were excluded as also were systematic reviews, surgical techniques, and expert opinions.

Results
The initial search revealed 875 potential articles of which 22 fulfilled the inclusion and exclusion criteria. There were 16 case series and six comparative studies; five were prospective and 14 were retrospective. The studies included 962 patients who underwent single stage revision arthroplasty of an infected hip or knee joint. The rate of recurrent infection ranged from 0% to 18%, at a minimum of two years’ follow-up. The rate was lower in patients who were selected on the basis of factors relating to the patient and the local soft-tissue and bony conditions.

Conclusion
We conclude that single-stage revision is an acceptable form of surgical treatment for the management of a PJI in selected patients. The indications for this approach include the absence of severe immunocompromise and significant soft-tissue or bony compromise and concurrent acute sepsis. We suggest that a two-stage approach should be used in patients with multidrug resistant or atypical organisms such as fungus.

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The management of prosthetic joint infection (PJI) following total hip (THA) and knee arthroplasty (TKA) remains challenging. Although rare, with an incidence as low as 0.39% after TKA and higher (0.97%) in revision cases, PJIs are associated with significant morbidity and socioeconomic burden. 4 Since early descriptions of single-staged exchange arthroplasty for infection, in the 1980s, 5,6 this approach has slowly gained popularity for use in selected patients, potentially allowing less morbidity and better functional outcomes. 7 As it involves fewer procedures, it is also more cost-effective, with a shorter period of hospitalization and reduced use of antibiotics. 8 However, aggressive debridement of bone and soft tissue with removal of components and cement is required, which can result in significant bone loss requiring expert reconstructive surgery.
In 2013, the proceedings of an International Consensus Meeting on PJI concluded that single-stage arthroplasty was a reasonable option in certain circumstances, with 78% of delegates voting in favour of this conclusion. Four years later, we aimed, in this study, to provide an update of this statement by performing a systematic review looking at the indications for single stage revision THA and TKA for PJI, with the specific aim of proposing criteria for selecting patients for this form of treatment. In particular, we wished to consider how factors such as the immunological status of the patient, the condition of the soft tissues, and the microbiological profile have on the rate of recurrent infection after single-stage exchange arthroplasty.

Materials and Methods

The review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for systematic reviews. Patients with an infected THA or TKA who were treated with a single-stage exchange procedure were to be compared with those who were treated with a two-stage procedure. The outcome measure was recurrent infection following surgery.

A comprehensive literature search was performed in February 2018 looking at single stage revision arthroplasty for PJI in the last 20 years. OVID-EMBASE, MEDLINE, and Cochrane Library databases were used and the reference lists of all relevant publications were examined and appropriate studies included in the final analysis. The search strategy was developed by the first author (RRT) and a literature search was performed using: infection and knee arthroplasty OR knee revision OR hip arthroplasty OR hip revision and one stage OR single stage OR direct exchange. All prospective and retrospective cohort and case control studies and case series were included. The absence of randomized controlled trials (RCTs) dealing with this issue has previously been described. Studies with less than ten patients in the study group, those with a minimum follow-up of less than two years, and those reporting operative management other than a single-stage revision were excluded. Only studies available in English were analyzed. Further exclusion criteria included: review articles, surgical techniques, and expert opinions; publications involving only abstracts; publications without microbiological details; and publications reporting operations for indications other than a confirmed PJI. Following the initial search, abstracts were independently screened for eligibility by two authors (RRT and SH). Discrepancies were referred to the senior author (FSH) if a consensus was not achieved. The full texts were then examined to identify the studies that were to be included in the analysis.

The study protocol was designed to identify criteria contributing to recurrent infection after single-stage revision for PJI. The data that were extracted included year of publication, type of arthroplasty (THA or TKA), the number of patients in the single-stage revision arm of the study, the number with microbiology results, and whether immunocompromised patients and those with soft-tissue/bony defects were included. The individual papers’ descriptions of extent of lesion were used; in many cases, there was limited information in the results from the studies to allow us to classify the extent of the soft-tissue/bony lesions. Finally, the rate of recurrent infection was identified.

The Oxford Centre of Evidence-based Medicine levels of evidence classification was used to assess the quality of the studies.

Results

The preliminary search produced 875 studies (Fig. 1), of which 111 were potentially relevant to the study. The texts were scrutinized independently and, based on the inclusion and exclusion criteria, 22 studies involving 962 patients were included in the review (Table I). A total of 15 studies included PJI after THA, six studies included PJI after TKA, and one study included both.

There were five prospective studies, one comparative and four case series, and 14 retrospective studies. In three of the studies, it was not apparent from the methodology as to whether the study was conducted retrospectively or prospectively. As predicted, there were no RCTs, but six comparative studies and 16 case series in total. The rate of recurrence was between 0% and 18%, and a total of 62 patients (6%) had a recurrent PJI.

Looking at the microbiological profile of the patients, in 15 out of the 22 studies, a coagulase-negative staphylococcus, including S. epidermidis, was the most common causative organism for the index infection, followed by S. aureus (4/22 studies).

Five studies excluded immunocompromised patients and those with soft-tissue compromise or a bony defect, as being unsuitable for a single-stage revision. The rate of recurrence in this group of studies was within the lowest, between 0% and 8.9%. Patients with soft-tissue compromise or a bony defect only were excluded from a single-stage revision in a further five studies with a rate of recurrent infection of between 0% and 10%. Although another two studies also excluded such patients and reported low recurrence rates, 0% and 5%, they failed to comment on the immunological status of the patients. Immunocompromised patients with soft-tissue compromise or a bony defect were included in seven studies; the rate of recurrent infection in this group was the highest, between 4.2% and 18%.

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**Table I. Details of the studies**

<table>
<thead>
<tr>
<th>Study (year)</th>
<th>Patients included in review, n</th>
<th>Mean follow-up yrs</th>
<th>Patients with microbiological results, n</th>
<th>Immuno-compromised host</th>
<th>Compromised soft-tissue/bone defect</th>
<th>Reinfection, n (%)</th>
<th>Level of evidence</th>
<th>Revised arthroplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bori et al(^a) (2018)</td>
<td>17</td>
<td>3</td>
<td>12</td>
<td>Included</td>
<td>Included</td>
<td>1 (5.8)</td>
<td>IV (Retros)</td>
<td>THA</td>
</tr>
<tr>
<td>Lange et al(^a) (2017)</td>
<td>56</td>
<td>4</td>
<td>41</td>
<td>Excluded</td>
<td>Excluded</td>
<td>5 (8.9)</td>
<td>IV (Pros)</td>
<td>THA</td>
</tr>
<tr>
<td>Born et al(^a) (2016)</td>
<td>28</td>
<td>7</td>
<td>27</td>
<td>Excluded</td>
<td>Excluded</td>
<td>0 (0)</td>
<td>III</td>
<td>THA</td>
</tr>
<tr>
<td>Jenny et al(^a) (2016)</td>
<td>54 (study group)</td>
<td>3</td>
<td>53</td>
<td>Included</td>
<td>Included</td>
<td>9 (17)</td>
<td>III (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Ilchmann et al(^b) (2016)</td>
<td>39</td>
<td>6</td>
<td>39</td>
<td>N/A</td>
<td>Excluded sinus/abscess</td>
<td>0 (0)</td>
<td>IV (Retros)</td>
<td>THA</td>
</tr>
<tr>
<td>Zahar et al(^c) (2016)</td>
<td>70</td>
<td>10</td>
<td>70</td>
<td>Included</td>
<td>Included</td>
<td>5 (7)</td>
<td>IV (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Jenny et al(^d) (2014)</td>
<td>65</td>
<td>5</td>
<td>62</td>
<td>N/A</td>
<td>Excluded</td>
<td>11 (16)</td>
<td>IV (Retros)</td>
<td>THA</td>
</tr>
<tr>
<td>Haddad et al(^e) (2015)</td>
<td>28</td>
<td>6</td>
<td>28</td>
<td>Excluded</td>
<td>Excluded</td>
<td>0 (0)</td>
<td>III (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Tibrewal et al(^f) (2014)</td>
<td>50</td>
<td>10</td>
<td>50</td>
<td>Included</td>
<td>Excluded</td>
<td>1 (2)</td>
<td>IV (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Zeller et al(^g) (2014)</td>
<td>157</td>
<td>3</td>
<td>157</td>
<td>Included</td>
<td>Severe bone defect excluded</td>
<td>8 (5)</td>
<td>IV (Pros)</td>
<td>THA</td>
</tr>
<tr>
<td>Klatte et al(^h) (2014)</td>
<td>10</td>
<td>7</td>
<td>10 (funga l infection)</td>
<td>Included</td>
<td>Excluded</td>
<td>1 (10)</td>
<td>IV (Retros)</td>
<td>THA/TKA</td>
</tr>
<tr>
<td>Klatte et al(^i) (2014)</td>
<td>100</td>
<td>3</td>
<td>100</td>
<td>Included</td>
<td>Included</td>
<td>4 (4)</td>
<td>III (Retros)</td>
<td>THA</td>
</tr>
<tr>
<td>Bori et al(^j) (2014)</td>
<td>24</td>
<td>5</td>
<td>24</td>
<td>Included</td>
<td>Included</td>
<td>1 (4.2)</td>
<td>IV (Retros)</td>
<td>THA</td>
</tr>
<tr>
<td>Choi et al(^k) (2013)</td>
<td>17</td>
<td>5</td>
<td>15</td>
<td>Included</td>
<td>Included</td>
<td>2 (18)</td>
<td>III (Retros)</td>
<td>THA</td>
</tr>
<tr>
<td>Jenny et al(^l) (2013)</td>
<td>47</td>
<td>3</td>
<td>47</td>
<td>Included</td>
<td>Included</td>
<td>6 (13)</td>
<td>IV (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Klouche et al(^m) (2012)</td>
<td>38</td>
<td>3</td>
<td>38</td>
<td>Included</td>
<td>Severe bone defect excluded</td>
<td>0 (0)</td>
<td>III (Pros)</td>
<td>THA</td>
</tr>
<tr>
<td>Singer et al(^n) (2012)</td>
<td>63</td>
<td>3</td>
<td>63 (excluded MRSA, MRSE)</td>
<td>N/A</td>
<td>Excluded</td>
<td>3 (5)</td>
<td>IV (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Oussedik et al(^o) (2010)</td>
<td>11</td>
<td>7</td>
<td>11</td>
<td>Excluded</td>
<td>Excluded</td>
<td>0 (0)</td>
<td>IV (Pros)</td>
<td>THA</td>
</tr>
<tr>
<td>Rudelli et al(^p) (2008)</td>
<td>32</td>
<td>8</td>
<td>29</td>
<td>Excluded</td>
<td>Included</td>
<td>2 (6.2)</td>
<td>IV</td>
<td>THA</td>
</tr>
<tr>
<td>Yoo et al(^q) (2009)</td>
<td>12</td>
<td>7</td>
<td>12</td>
<td>Excluded</td>
<td>Excluded</td>
<td>1 (8.3)</td>
<td>V (Retros)</td>
<td>TKA</td>
</tr>
<tr>
<td>Callaghan et al(^r) (1999)</td>
<td>24</td>
<td>11</td>
<td>24</td>
<td>Excluded</td>
<td>Severe bone defect excluded</td>
<td>2 (8.3)</td>
<td>IV</td>
<td>THA</td>
</tr>
<tr>
<td>Ure et al(^s) (1998)</td>
<td>20</td>
<td>9.9</td>
<td>20</td>
<td>N/A</td>
<td>Included</td>
<td>0 (0)</td>
<td>IV (Pros)</td>
<td>THA</td>
</tr>
</tbody>
</table>

Retros, retrospective; Pros, prospective; THA, total hip arthroplasty; TKA, total knee arthroplasty; N/A, not available; MRSA, methicillin-resistant *Staphylococcus aureus*; MRSE, methicillin-resistant *Staphylococcus epidermidis*

**Discussion**

The evidence for best practice in the management of PJIs is evolving. Single-stage revision has become more popular in recent years, following the publication of a number of studies reporting comparable,\(^{33,34}\) if not better,\(^{14}\) outcomes of single stage compared with two-stage procedures with an associated reduction in morbidity, mortality, and financial and sociological burden.\(^{7,20,35,36}\)

What appears to be evident from our review is that outcomes following a single-stage procedure are affected by many factors based on the immunological status of the patient, the local soft-tissue and bony characteristics, and the microbiological profile. Promising infection-free outcomes have been reported when strict criteria for the selection of patients are applied.

In 2015, Haddad et al\(^{14}\) described a series of 28 patients who underwent single stage revision of a chronically infected TKA without a recurrence, at a minimum follow-up of three years. Their cohort accurately matched the patients’ local and microbiological criteria used in this study, concluding that a single-stage revision strategy may be utilized in the absence of significant soft-tissue/bony defects, significant host immune-compromise, and unknown microbiology or atypical multiresistant organisms. In 2010, Oussedik et al\(^{1}\) reported a similarly successful infection-free survival following a single-stage revision for patients with an infected THA at a mean follow-up of seven years. These studies, however, had short to medium term follow-up only. The study with the longest mean follow-up that echoed these results in our review was by Ure et al,\(^{30}\) who described 20 infected THAs with no recurrence at a mean follow-up of 9.9 years.

During our literature search, we identified one study that reported that patient selection had no impact on outcome following single-stage exchange arthroplasty. Jenny et al\(^{33}\) retrospectively compared outcomes between two centres performing single-stage revision for infected TKAs. One centre performed the procedure without patient selection, the other only included patients based on specific criteria, with rates of recurrent infection of 17% and 21%, respectively. Although the authors drew strong conclusions, in the absence of a surgical protocol guiding the type of implant and antibiotic impregnated cement that were used, there remains the potential of bias. Furthermore, the overall rate of recurrent infection in their study was comparably higher as compared with the aforementioned studies in which patient-selection criteria were used.

**Role of preoperative microbiological profile on outcomes of OSEA.** Early experience of single-staged exchange arthroplasty...
by Buchholz et al\textsuperscript{37} in 1981, reported an overall success rate of 77% in a series of 583 patients. They noted that the microbiological profile was important in determining outcome, with polymicrobial infections and atypical and gram-negative organisms being associated with a higher failure rate. These findings have later been confirmed by Jackson et al\textsuperscript{39} in 2000, in a review of the literature. These authors concluded that in addition to these factors, infection with MRSA or MRSE resistant organisms was associated with a poor outcome.

Excellent results have been reported in a number of series, with infection free survival of between 92% and 100% in patients in whom the microbiological details were established preoperatively,\textsuperscript{14,17,18,21,25,39} supporting previous guidance from the International Consensus Meeting on Periprosthetic Joint Infection \textsuperscript{9} and the Infectious Disease Society of America.\textsuperscript{40} More recently, however, Ilichmann et al\textsuperscript{32} reported no recurrent infections following single-stage revision of 39 infected THAs, despite six patients having a negative preoperative culture. The importance of predetermined microbiology has also been indirectly questioned by some recent studies. Lange et al\textsuperscript{13} in a series of 56 patients, reported a 91% infection-free rate, despite 15 having negative preoperative cultures. Only one of the five failures had a negative culture. Bori et al\textsuperscript{26}, in 2014, reported a series of 24 infected THAs; five patients did not have preoperative aspiration and a further three had a negative growth. All patients had positive intraoperative cultures and, despite this, there was no adverse effect on the rate of recurrent infection, which was 4.2% (1/24).

On this basis, it seems that the lack of a preoperative microbiological diagnosis may be a relative, rather than an absolute contraindication, to a single stage revision. What appears to be more important is the identification of the microorganism perioperatively with available information on sensitivities to allow early appropriate antibiotic treatment. Fungal PJIs present particular challenges. They often present in immunocompromised patients against a background of previous complex surgery and, hence, a two-stage procedure has traditionally been used.\textsuperscript{41} In 2014, the ENDO-Klinik published their experience in the management of fungal PJIs using a single-stage approach. Klatte et al\textsuperscript{19} reported a retrospective series of ten patients with six THAs and four TKAs, with a single recurrent infection requiring further surgery. Their approach included preoperative identification of the causative organism and appropriate antibiotic and antifungal treatment postoperatively. Neither immunocompromised patients nor those with a sinus tract were excluded, and five patients were diabetic and five had a soft-tissue lesion. The single recurrence was in a severely immunocompromised diabetic patient on long-term steroid treatment. Their results suggest that where a fungal infection is identified preoperatively, single-stage revision surgery may be considered.

The effect of host immunity on OSEA. Host and local factors have also been highlighted as important determinants of outcome of single-stage revision.\textsuperscript{42} In particular, the integrity of the patient’s immune system appears to play a role when deciding on single-stage versus two-stage surgery.\textsuperscript{43} The term ‘immunocompromised’ can be applied to any patient with a defect in their defences against infection. We found this term to be somewhat heterogeneously used to describe drug-induced compromise such as by steroids or disease modifying antirheumatic drugs, malignancy, diabetes, or HIV disease. Patients with severe inflammatory arthropathy and conditions such as hepatitis were also often grouped into this category, probably due to their medication.\textsuperscript{44} Goksan et al\textsuperscript{45} in 1992, described a small series of 18 patients who underwent single-stage revision of an infected TKA, with eradication of infection in 16 (94%), at a mean follow-up of five years. The profile of the patients in this series matched some of the criteria set out by the International Consensus Meeting\textsuperscript{9} in 2013 to include absence of systemic sepsis and gross tissue inflammation. Both the patients with recurrent infection had severe immunosuppression.

In a retrospective study, Wolf et al\textsuperscript{46} classified their patients using the McPherson staging system. They concluded that the eradication of infection was better following two-stage compared with single-stage revision procedures when the patient’s status (McPherson type B + C patients) was compromised (95% eradication for two-stage vs 33% for one-stage). A similar result was observed in the presence of significant local soft-tissue and bony compromising (McPherson Grade 3) factors (95% eradication for two-stage vs 0% for one-stage). More recently, Bori et al\textsuperscript{26} described 19 consecutive single stage revision THAs with a 95% cure rate at a follow-up of one year. They noted an absence of significant bony defects intraoperatively, with only four patients requiring bone grafting, as a potential contributing factor to a successful outcome.

The effect of the presence of a sinus tract on outcomes of OSEA. The presence of a sinus tract appears to adversely affect the outcome in some studies. In a series by Jenny et al\textsuperscript{31} of the 11 cases of recurrent infection reported, six patients (55%) originally presented with a sinus tract as their index symptom. Similarly, of the five recurrent infections in a series reported by Lange et al\textsuperscript{13} involving 56 patients, three had a sinus tract at the time of presentation and one had an abscess. Despite these findings, however, Jenny et al\textsuperscript{28} in their earlier series of 47 patients with an infected TKA, recorded that 41 (87%) were infection-free at a minimum follow-up of three years despite the fact that 20 (43%) presented with a sinus. Only two of those with a sinus at presentation had a recurrent infection. In 2008, Rudelli et al\textsuperscript{22} drew a similar conclusion based on a series of 32 patients who underwent single-stage revision THA; two (6%) had recurrent infection at a mean follow-up of 8.5 years. It therefore seems that a discharging sinus is, in itself, not an absolute contraindication to a single-stage revision, a conclusion also drawn in an earlier study by Raut et al\textsuperscript{47}.

In conclusion, single-stage exchange arthroplasty remains an acceptable form of surgical treatment for the management of a chronic PJI in selected patients with the prospect of promising infection-free survival. The lowest reinfection rates after this procedure are in patients without immune compromise and significant soft-tissue and bony defects. Much of this evidence, however, is based on the analysis of retrospective observational studies. There remains little high-quality evidence addressing this issue. A limitation of this review is the absence of RCTs. Our conclusions have been drawn from the analysis of prospective and retrospective studies, level 3 evidence, and level 4
Take home message

- Single-stage revision is a plausible option for the management of prosthetic joint infections in a selected group of individuals.
- Indications include an absence of concurrent sepsis, host immunocompromise, and soft-tissue or bony compromise.
- Knowledge of microbiological profile in the perioperative period is also associated with a more favourable outcome.

References


Author contributions:
R. R. Thakrar: Designing the study, Literature search, Analyzing the data, Preparing the manuscript.
S. Horriat: Literature search, Analyzing the data, Preparing the manuscript.
B. Kayani: Preparing the manuscript.
F. S. Haddad: Preparing the manuscript, Supervising the study.

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Robotic unicompartmental knee arthroplasty
CURRENT CHALLENGES AND FUTURE PERSPECTIVES

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Unicompartmental knee arthroplasty (UKA) is an established and highly effective treatment for patients with end-stage disease affecting one compartment of the knee joint. The procedure accounts for between 8% and 10% of all knee arthroplasty procedures performed in the United Kingdom and United States. There are several advantages of performing UKA over total knee arthroplasty (TKA), including reduced operating time, decreased intraoperative blood loss, reduced periarticular soft-tissue trauma, improved preservation of bone stock, better restoration of native kinematics, increased patient satisfaction, and improved functional outcomes. However, UKA is associated with decreased implant survivorship and increased revision rates compared with TKA. Accuracy of component positioning and limb alignment are important prognostic variables that affect implant survival and time to revision surgery following UKA. Consequently, techniques that improve the accuracy of implant positioning and limb alignment in UKA may help to improve long-term survivorship and reduce the burden of revision disease.

Experts from a range of industries, including aviation training, military activity, financial services, and medical care, have shown that each industry moves through five distinct phases: 1) consideration of the industry as an art by specialists within the field; 2) development of specific rules and instruments; 3) creation of standardized protocols and procedures; 4) automation; and 5) integration of computer technology. During the final phase, accurate objective real-time data provided by computerized systems help to minimize the risk of system error, improve efficiency, and optimize productivity. Within the healthcare industry, robotic technology has been implemented in general surgery, urology, cardiology, ophthalmology, and gynaecology to minimize human error, improve surgical precision, enhance postoperative rehabilitation, and improve long-term clinical outcomes. Over the last decade, robotic technology has gained momentum as an avenue for improving accuracy of implant positioning and limb alignment compared with conventional jig-based techniques for UKA.

Cobb et al conducted a prospective randomized study on 27 patients with medial compartment knee osteoarthritis undergoing conventional jig-based UKA versus robotic UKA. The authors reported that all patients undergoing robotic UKA had tibiofemoral alignment in the coronal plane within 2° of the planned position, compared with only 40% in those undergoing conventional jig-based UKA. Bell et al performed a prospective randomized controlled study assessing accuracy of implant positioning using postoperative CT scans in 62 robotic UKAs versus 58 conventional UKAs, and found that robotic UKA reduced root mean square errors in achieving planned femoral and tibial implant positioning. Herry et al retrospectively reviewed plain radiographs in 40 conventional jig-based UKAs versus 40 robotic UKAs, and found improved restitution of the native joint line with robotic-guided surgery. Improved accuracy of implant position with robotic UKA may help to improve long-term implant survivorship and facilitate implementation of cementless implants for future UKA implant designs.

Studies using data from three separate national joint registries have demonstrated a relationship between the surgical (or unit)
case-load and revision rate following UKA.\textsuperscript{19-21} Surgeon-controlled errors in implant positioning are the most common reason for implant failure, and low case volume has been identified as a risk factor for early revision surgery following UKA.\textsuperscript{18,19} Liddle et al\textsuperscript{19} reviewed outcomes of 41,986 UKAs from the National Joint Registry for England and Wales, and found that optimal outcomes (as assessed using revision rates) were achieved with UKA usage in between 40% and 60% of a surgeon’s practice. Acceptable revision rates were achieved with UKA usage in 20% or more of UKA practice, while surgeons with the lowest usage (less than 5%) had the highest revision rates. However, achieving optimal UKA usage is challenging, owing to the limited number of patients with single compartment disease and strict inclusion criteria for conventional UKA.

Robotic UKA uses a preoperative CT scan (image-guided) or intraoperative osseous registration (imageless) to create a patient-specific virtual 3D reconstruction of the knee joint. The surgeon uses this virtual model to plan optimal bone coverage, implant positioning, and limb alignment for each patient’s unique knee anatomy. An intraoperative robotic arm then helps to execute this plan with a high level of accuracy, and stereotactic boundaries limit bone resection to the predefined femoral and tibial haptic windows. There is no learning curve effect in robotic UKA for accuracy of achieving the planned femoral or tibial implant positioning, posterior condylar offset ratio, limb alignment, and restoration of native joint line.\textsuperscript{16} Robotic technology offers an opportunity for low-volume UKA surgeons to achieve high levels of accuracy in implant positioning. Robotic UKA may thus help overcome the current challenges of surgeons or units/departments needing to achieve minimum UKA case volumes to minimize the risk of surgeon-induced errors in implant positioning.

Achieving proper soft-tissue tensioning and ligamentous balancing are important technical objectives for optimizing stability and long-term functional outcomes in UKA. In conventional jig-based surgery, assessment of the periarticular soft-tissue tension and limb alignment are performed manually, which is dependent on the skill and expertise of the operating surgeon. Robotic UKA uses optical motion capture technology to provide real-time medial and lateral gap measurements while applying valgus/varus strain to appropriately tension the ligaments through the arc of flexion. These patient-specific intraoperative data may be used to fine-tune implant positioning to achieve the desired ligamentous tension and limb alignment.\textsuperscript{22} Intraoperative data on the ‘tightness’ and ‘looseness’ of the knee joint through the arc of flexion may be used to further adjust bone resection, implant sizes, and implant positions to achieve the desired knee kinematics. Further studies are required to establish if the improved ligament tensioning in robotic UKA translates to differences in knee kinematics, implant stability, and range of movement compared with conventional manual UKA.

Bone resection in robotic knee arthroplasty is restricted to the confines of the stereotactic boundaries, which may help to reduce periarticular soft-tissue injury and enhance postoperative rehabilitation compared with conventional manual knee arthroplasty. Kayani et al\textsuperscript{23} conducted a prospective cohort study on 146 patients showing robotic UKA was associated with reduced postoperative pain, decreased opiate analgesia consumption, reduced inpatient physiotherapy, and decreased mean time to hospital discharge compared with conventional manual UKA (42.5 hours (sd 5.9) vs 71.1 hours (sd 14.6), respectively; p < 0.001). Blyth et al\textsuperscript{24} performed a prospective randomized control trial on 139 patients and reported robotic UKA reduced median pain scores by 55.4% compared with conventional manual UKA from postoperative day one to week eight after surgery. As many arthroplasty centres move towards day case UKA, robotic UKA may help to facilitate this practice through improved pain control, enhanced functional rehabilitation, reduced need for physiotherapy, and earlier time to hospital discharge.\textsuperscript{25}

Improved accuracy of implant positioning in robotic UKA has not been shown to improve mid-term to long-term clinical or functional outcomes compared with conventional jig-based UKA. Blyth et al\textsuperscript{24} reported that robotic UKA was associated with improved American Knee Society Score for three months following surgery, but there was no difference in functional outcomes observed between conventional and robotic UKA at one year after surgery. Subgroup analysis of the 35 most active patients revealed robotic UKA improved Knee Society Scores, Oxford Knee Scores, and Forgotten Joint Scores compared with conventional manual UKA at two years’ follow-up.\textsuperscript{26} More recently, Canetti et al\textsuperscript{27} reviewed outcomes in 28 highly active patients undergoing lateral compartment UKA, and found that robotic UKA enabled markedly earlier mean return to sporting activity compared with conventional UKA (4.2 months (sd 1.8) vs 10.5 months (sd 6.7), respectively; p < 0.01). These studies suggest that robotic UKA enables improved short-term functional outcomes in highly active patients, although overall functional outcomes are comparable to those of conventional jig-based UKA. Many studies have shown excellent functional outcomes with both treatment techniques for UKA and therefore subgroup analysis is essential for overcoming the ceiling effect with routine patient-reported outcome measures.

Aseptic loosening and progression of osteoarthritis in the remaining native knee compartments are common reasons for failure in UKA.\textsuperscript{3,4} Robotic technology enables accurate intraoperative assessment of limb alignment to avoid overcorrection, which may help to limit disease
progression in the other compartments and improve time to revision surgery compared with conventional manual UKA. Pearle et al 28 conducted a prospective, multicentre review of 1135 robotic UKAs and found implant survivorship was 98.8% at a minimum of 22 months’ follow-up, which is superior to the survival rates of conventional UKA reported in the national joint registries of the United Kingdom (95.6%), Sweden (95.3%), Australia (95.1%), and New Zealand (96.1%).28-32 Batailler et al 33 compared outcomes in 80 conventional UKAs versus 80 robotic UKAs, and found revision rates in robotic UKA were 5% compared with 9% in conventional manual UKA, although this difference was not statistically significant. Importantly, 86% of revisions in the conventional group were secondary to component malposition or limb malalignment, compared with none in the robotic group.33

Moschetti et al 34 used a Markov decision analysis tool to compare cost-effectiveness of conventional UKA versus robotic UKA. Using a two-year failure rate of 1.2% for robotic UKA and 3.1% for manual UKA, the authors reported that robotic UKA was a cost-effective procedure compared with manual UKA if robotic UKA case volume exceeded 94 cases per year. However, these findings should be interpreted with caution as several additional costs with robotic technology were overlooked. Robotic UKA is also associated with substantial costs for installation of the robotic device, additional preoperative CT scanning, further training for surgical staff, and increased operative times during the initial learning phase. Many robotic devices are also only compatible with specific implants and therefore additional costs for purchasing equipment and implants must be considered in any future cost analysis. Further studies on resource use and cost-effectiveness on conventional versus robotic UKA are required before this technology can be implemented into mainstream UKA practice.

Overall, robotic UKA improves accuracy of implant positioning, enhances postoperative functional rehabilitation, and improves early functional outcomes in highly active individuals compared with conventional jig-based UKA. Robotic technology also provides live intraoperative data on knee kinematics through the arc of flexion that can be used to fine-tune implant positioning and optimize soft-tissue tensioning. Robotic UKA offers a unique opportunity for low-volume arthroplasty surgeons to achieve high levels of accuracy in implant positioning, which may help to improve implant survivorship and reduce the burden of revision disease. However, further studies are required to assess the effect of robotic UKA on long-term functional outcomes, implant survivorship, cost-effectiveness, and complications compared with conventional jig-based UKA.

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Acute Surgical Excision of a Traumatic Fat Fracture in a Professional Soccer Player

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Learning Point of the Article:
Acute surgical excision of a traumatic fat fracture may be used as an avenue for reducing pain, enhancing functional rehabilitation, and facilitating early return to pre-injury level of function.

Abstract

Introduction: Surgical excision of fat fractures is often reserved for patients with large chronic deformities to improve cosmetic appearance. To our knowledge, the acute surgical management of a traumatic fat fracture has not been previously reported.

Case Report: This case report describes the management of a professional soccer player that developed a traumatic fat fracture over the lateral thigh. The patient presented with persistent pain, reduced range of movement, and inability to participate in sporting activity. Symptoms were refractory to non-operative treatment. Following acute surgical excision of the fat fracture, the patient was able to make an early return to sporting activity with no complications at short-term follow-up.

Conclusion: Acute surgical excision of a traumatic fat fracture may be used as an avenue for improving pain, enhancing functional rehabilitation, and facilitating early return to pre-injury level of function.

Keywords: Acute, fat fracture, pain, trauma, surgery

Introduction

Fat fractures occur when blunt trauma leads to disruption in the architectural morphology of adipose tissue [1]. Although the term “fracture” usually describes discontinuation in the integrity of cartilage or bone, fat fractures represent a similar pathological process that leads to distortion of the organized septa within fat lobules [1, 2, 3]. Patients often present with persistent pain and localized tenderness over the affected region [1, 2, 3]. Adipose tissue over bone prominences of the gluteal region and knee joints is most commonly affected [1, 3]. Initial treatment consists of conservative management with avoidance of any exacerbating factors and progressive rehabilitation, but this is associated with significant delays in returning to pre-injury level of function and high risk of recurrence with further trauma [1,2]. Surgical treatment is often reserved for patients with persistent pain or large chronic deformities to improve the cosmetic appearance of the affected region [1,4,5, 6, 7]. To our knowledge, the early surgical treatment of a traumatic fat fracture has not been previously reported. This case report describes the acute surgical excision of a fat fracture in a professional soccer player, which enabled the patient to make an early return to sporting activity without any evidence of recurrence or complications at short-term follow-up. This case report will enable patients and health-care professionals to better understand the potential role of acute surgical excision of traumatic fat fractures in enhancing rehabilitation and restoring activity in patients with high functional demands.

Case Report

A 27-year-old professional soccer goalkeeper sustained blunt trauma to his left thigh while diving to catch a football. He immediately developed pain and swelling over the lateral aspect...
of his left thigh below the greater trochanter. The pain was exacerbated by weight-bearing on the affected limb, radiated into the left gluteal region, and was associated with subjectively reduced range of movement in the left hip joint. He struggled with sprinting, jumping, and diving onto the affected side for the remainder of the match but managed to walk independently off the field of play after finishing the game. There was also an associated swelling over the zone of injury, which progressively increased in size in the hours following the match. The player did not have any other concurrent injuries and did not have any significant medical history. Clinical examination revealed a soft, fluctuant, lobulated mass measuring 5.0 cm × 4.0 cm approximately three finger breadths below the left greater trochanter. The mass was exquisitely tender to touch and located in the plane between the skin and underlying fascia. There was an associated effusion around the mass but no overlying erythema or breach in skin integrity. The skin was not warm to touch compared to the right side. There was no tenderness over the bony prominences of the anterior superior iliac spine, ischial tuberosity, greater trochanter, or iliac crest and no snapping of the iliobibial band over the greater trochanter. The patient had full active range of motion in the left hip and knee joints. Specialist hip tests including flexion abduction and internal rotation, flexion abduction and external rotation, Thomas test, and Ober’s test were negative. The patient had a normal gait and did not require any walking aids. Plain anteroposterior and lateral radiographs of the left hip joint and left femur were unremarkable. Magnetic resonance imaging (MRI) of the left thigh revealed a well-circumscribed, lobulated mass measuring 5.2 cm × 4.3 cm × 3.2 cm in size. This was arising from the adipose tissue located between the subcutaneous tissue and fascia immediately inferior to the left greater trochanter (Figs. 1 and 2) and was associated with a surrounding effusion (Fig. 3). There was no other bone or soft-tissue pathology identified on the MRI scan. These clinical and radiological findings were consistent with an acute traumatic fat fracture. The differential diagnosis included the following: Fat fracture, benign tumor (e.g., lipoma), malignant tumor (e.g., liposarcoma), abscess, and hematoma. The patient was reviewed by the team doctor and sports physiotherapist on the day of injury and commenced onto a supervised physiotherapy program the following day. Initial treatment consisted of resting the affected limb, avoiding any exacerbating positions or maneuvers, and limiting any pressure (e.g., laying on the affected side, tight clothing) over the zone of injury. The patient was commenced on regular non-steroidal anti-inflammatory medication. Physiotherapy consisted of isometric muscle exercises, core strengthening, neuromuscular control activities, cryotherapy, and hydrotherapy. After 3 weeks of conservative treatment, the patient still had persistent pain and tenderness over the lateral aspect of his left thigh and could not participate in any level of training or competitive sporting activity. The patient was further counseled about the likely diagnosis and further management options. These included continuing conservative treatment, acute surgical excision, or delayed surgical excision if symptoms persisted despite further rehabilitation. As a professional soccer goalkeeper, his main treatment priorities were early return to sporting activity and minimal risk of recurrence with diving onto the affected side in the future. The patient elected to undergo acute surgical excision of the traumatic fat fracture. The procedure was performed under general anesthetic with the patient in the lateral decubitus position. A longitudinal incision measuring 6 cm in length was centered over the soft-tissue mass, and dissection performed through the subcutaneous tissue down to the underlying capsule of the fat fracture. Finger dissection was performed between the underlying muscular fascia and the capsule of the fat fracture. Electrocautery was used to dissect fibrous bands adhering the cystic mass to the underlying fascia. The mass was excised with the surrounding capsule intact (Fig. 4). Hemostasis was performed and the wound closed with absorbable sutures. Histological analysis of the excised specimen revealed lobulated and focally degenerate adipose tissue. This was covered by a thick layer of inflamed fibrous tissue which extended into the lesion. There was no evidence of fat necrosis or any neoplastic process. The findings were consistent with the working diagnosis of a fat fracture. The patient was followed up in clinic at 2 weeks after surgery. The pain over
the left lateral thigh had completely resolved, and the patient had discontinued all analgesia. The patient had returned to his pre-injury level of sporting function without any problems. On examination, the wound was clean and wellhealed without any evidence of infection. There was no underlying collection or mass palpable, and he had full active range of motion in the left hip and knee joints. He did not require any walking aids and had a normal gait. The patient remained asymptomatic and continued to participate in full sporting activity without any complications at 1-year follow-up and was discharged from clinic at this time point.

**Discussion**

To our knowledge, this is the first report on the acute surgical excision of a traumatic fat fracture. The patient was a professional soccer goalkeeper that made an early return to his pre-injury level of sporting activity without any complications at short-term follow-up. Fat fractures were first described in 1972 as the “battered buttock syndrome” in a series of 12 female patients with chronic traumatic injuries leading to deformities in the gluteal region [1]. Of these, five patients were managed conservatively with improvements in pain and tenderness over the gluteal region reported at 3 months to 2 years follow-up. The remaining seven patients underwent successful surgical excision of large cosmetically deforming fat fractures causing chronic pain and/or long-standing disfigurement around the gluteal region. Individual case reports have also described ultrasound or MRI findings of fat fractures from the deltoid, quadriceps, and Achilles tendon following blunt trauma [2, 3, 5]. More recently, a case report described the surgical management of a large chronic fat fracture of the lateral thigh with surgical excision, extensive rigotomy, and fat transfer from the inner thigh [4]. The initial blunt trauma occurred 2 years before surgical excision, and the patient did not have any pain or restriction in function from the fat fracture. Surgical excision was undertaken exclusively to improve the cosmetic appearance of the thigh. The indications, timing of surgery, and surgical technique were different from those in the current study. Fat fractures arise when blunt trauma to adipose tissue leads to changes in the vascularity and/or disruptions to the architecture of fat lobules, which are conventionally arranged in tiers and supported by horizontal and vertical fibrous septa[1]. Normal physiological forces cause the lobules to flatten and dissipate the energy through the septa into the tiers. However, excessive loads may shear these septa and disrupt these fat lobules, which creates irregularity in the layer between the epidermis and the fascia [8, 9, 10]. Fat fractures are often managed conservatively with activity modification, isometric muscle exercises, core strengthening, and neuromuscular control activities [1, 2, 3]. Symptomatic relief may also be gained by the application of topical non-steroidal anti-inflammatory agents and/or adjuvant treatment with hydrotherapy and cryotherapy[1,3,4]. Surgical intervention is often reserved for patients with chronic pain or significant cosmetic deformity. In our study, the patient received only 3 weeks of conservative treatment but made very limited progress with pain and function over this time frame. Furthermore, he was professional soccer goalkeeper and therefore delays in returning to sporting activity, and future recurrences were of significant concern to his playing career. Acute surgical intervention enabled the fat fracture to be excised and the patient to make a rapid return to his pre-injury level of function without any complications at short-term follow-up.

**Conclusion**

Fat fracture is an important differential diagnosis in patients with soft-tissue injury after blunt trauma. MRI facilitates diagnosis of fat fractures and aids planning of any subsequent surgical intervention. Acute surgical excision of a traumatic fat fracture may be used as an avenue for reducing pain, enhancing functional rehabilitation, and facilitating early return to pre-injury level of function.

**Clinical Message**

Fat fractures are rare diagnoses that may lead to persistent pain and significant impairment in physical performance. Acute surgical excision of a traumatic fat fracture should be considered as a treatment option to enhance rehabilitation and restore early functional performance.

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**How to Cite This Article**

Total hip arthroplasty in patients with chronic liver disease: A systematic review

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Abstract — Introduction: Chronic liver disease (CLD) is a significant and increasingly prevalent co-morbidity in patients undergoing total hip arthroplasty (THA). These patients may develop metabolic bone disease (MBD) and systemic dysfunction, which pose challenges to THA surgery. This systematic review of literature aims to examine clinical outcomes and complications in patients with CLD undergoing THA and provide evidence-based approaches as to the optimization of their perioperative care.

Methods: A Pubmed search was performed, identifying eight studies on 28 514 THAs for inclusion. Two additional studies reported on 44 patients undergoing THA post liver transplant. These were reviewed separately.

Results: Increased early perioperative complications are reported recurrently. Review of long-term complications demonstrates an increased postoperative infection rate of 0.5% ($p < 0.001$) and perioperative mortality of 4.1% ($p < 0.001$). The need for revision surgery is more frequent at 4% ($p < 0.001$). Aetiology of need for revision surgery included; periprosthestic infection (70%), aseptic loosening (13%), instability (13%), periprosthetic fracture (2%) and liner wear (2%). THA in patients with liver transplants seems to offer functional improvement; however, no studies have formally assessed functional outcomes in the patient with active CLD.

Discussion: A multidisciplinary perioperative approach is suggested in order to minimize increased complication risks. Specific measures include optimizing haemoglobin and taking measures to reduce infection. This review also highlights gaps in available literature and guides future research to appraise functional outcomes, further detail long-term failure reasons and study any differences in outcomes and complications based on the range of operative approaches and available implant choices.

Key words: Hip arthroplasty, Hip replacement, Liver disease, Cirrhosis, Outcomes, Complications.

Introduction

Chronic liver disease (CLD) is the fifth most common cause of mortality worldwide and its prevalence is increasing [1]. Hepatitis B and C viruses are the most common causes of CLD. Other causes include alcohol, drugs, hereditary and autoimmune diseases. Improvements in medical care have meant that patients with CLD are also surviving longer. Total hip arthroplasty (THA) is indicated to treat debilitating symptoms of hip osteoarthritis, including in those patients with CLD, this following lifestyle modifications and medical management. Several causes of CLD such as Sarcoidosis and Haemochromatosis are themselves associated with joint pathology, which may require THA. Patients whose CLD is secondary to chronic alcohol excess, or who are on long-term corticosteroids to treat CLD, are at an increased risk of developing avascular necrosis of the femoral head, which again may necessitate THA.

Performing THA in patients with CLD is challenging as the disease process induces biological and structural changes in bone, termed metabolic bone disease (MBD), whilst there is also systemic dysfunction [2]. The precise aetiology of bone disorders is thought to differ across the various causes of CLD, and indeed most pathological processes described are still somewhat conjectural [3]. MBD leads to osteopaenia and osteoporosis [4], whilst abnormal bone remodelling leads to bowing of the proximal femur with thinning of the cortices and widening of the medullary canal [5]. These morphological changes increase the technical challenges of performing THA. In press-fit implants, poor bone quality and unusual morphology means an increased risk of intraoperative fractures, subsidence of the femoral stem and postoperative periprosthetic fractures.
In cemented implants, these abnormalities may lead to inadequate cement mantles and an increased risk of aseptic loosening [7]. Coagulopathies in CLD may impair visualization of the surgical field, challenging surgical approach, implant positioning and wound closure. Coagulopathies increase intraoperative blood loss and also compromise the ability to achieve well-prepared, dry bone for bone-cement interdigitation. The use of tranexamic acid in THA has been shown to reduce bleeding without increasing thromboembolic risk [8]. Acetabular THA components have shown good results with both cemented and uncemented techniques in osteoporotic bone [9]. Finally, diminished hepatic biosynthetic and reticuloendothelial capabilities together with depleted nutritional reserves, increase the risk of poor wound healing, superficial and deep infections.

With regard to the CLD patient, studies in English literature have reviewed surgical outcomes when performing general surgeries, and cumulating mixed arthroplasty cases, with reports of increased morbidity and mortality [10]. However, there are limited data in English literature on the specific risks for CLD patients undergoing THA. The objective of this study was to gather and systematically review available evidence in this area, summating the risks that a medical team must be aware of when considering THA in the patient with CLD. In addition, this review aims to evaluate functional outcomes in this patient group to assess whether the known technical challenges in this patient group are being successfully overcome.

Materials and methods

Search strategy

Databases PUBMED, MEDLINE and EMBASE were searched to identify relevant studies in English literature that addressed the results of THA in patients with CLD between 1980 and August 2019. This was performed in line with the PRISMA statement. Keywords used for the searches were “hip arthroplasty” OR “total hip arthroplasty” OR “total hip replacement” AND “Chronic Liver disease” OR “Liver Failure”, OR “Cirrhosis” OR “Hepatitis”. The bibliographies of included studies and relevant foundation materials were reviewed judiciously to identify any supplementary studies for the review and for pertinent background materials.

Eligibility criteria

Inclusion criteria included all papers, describing the results of THA in patients with CLD published in the English language. Isolated case reports/series with five or less patients were excluded. The included articles met the PICO criteria (Population, Intervention, Comparison and Outcomes) for systematic reviews. Figure 1 is the PRISMA flowchart illustrating the systematic search and screening strategy resulting in the final number of records included.

Data extraction

One reviewer extracted data through a standardized data collection form, and then another reviewer checked the data for accuracy. Any issues flagged up, or discrepancies in results were resolved by discussion. Data on the number of patients, age, follow-up period, type of implant, type of fixation, complications, re-operations, revision rate and functional outcomes were extracted and entered in a spreadsheet.

Statistical analysis

All analyses compared CLD and non-CLD (control) patients, and all outcomes were binary in nature. The Chi-square test was used to compare groups for the majority of outcomes. The exception was for outcomes where the dataset was small in which Fisher’s exact test was performed. A p value of <0.05 was considered statistically significant.

Results

Search results

A total of 26 relevant article titles were identified. After application of eligibility criteria described, eight studies [11–18] qualified for inclusion. Two further studies [19, 20] reported on outcomes of THA in patients post liver transplantation for CLD, and this was deemed an interesting group for comment separately.

Quality assessment

The included studies were small-to-large size retrospective case series (n=19–27 401). The range of follow-up in the studies was 1–144 months. There was a significant heterogeneity between studies in terms of outcome recording.

Cohort characteristics

The studies included 28 514 THAs performed in patients with a mean age of 57.3 years and mean follow up period of 13.5 months (range 1–144 months). Only two studies [12, 17] documented the types of implant used. There were an additional 44 THAs performed in patients post liver transplant with a mean age of 51.7 and mean follow up of 40.3 months [19, 20] 42 uncemented THAs (95%) and two cemented THAs (5%) were included in this subgroup of patients.

Outcome analysis

Functional outcome

Both studies in patients with liver transplant patients reported significant improvements in patient satisfaction and hip function following THA [19, 20]. The remaining studies did not report on functional outcome scores following THA.

Aseptic loosening

Two studies reported on rates of aseptic loosening [12, 17]. There was an increased risk of aseptic loosening at 7% (6/85 THAs) compared with 0% in controls (p = 0.03). There was
no comment on the mean timing of implant loosening. In patients with liver transplantation, there was one case of aseptic loosening in 44 THAs (2%), this at 39 months of follow-up. Further stratification based on cemented or uncemented prostheses was not recorded.

Revisions rate

Six studies reported on implant failure and revision rates [11–13, 16–18]. There was an increased rate of revision surgery at 4% (46/1083 THAs) compared with 0.2% in controls ($p < 0.001$). Time to implant failure was not reported. Reasons for implant failure included periprosthetic infection or septic loosening in 70% ($n = 32$), aseptic loosening in 13% ($n = 6$), instability in 13% ($n = 6$), periprosthetic fracture in 2% ($n = 1$), and polyethylene liner wear with osteolysis in 2% ($n = 1$). In liver transplant patients, implant failure occurred in three of the 44 patients (7%) at a mean time of 7.1 months. In these patients, implant failure secondary to instability with dislocation occurred in 67% ($n = 2$), and aseptic loosening in 33% ($n = 1$). Further stratification of implant failure based on the type of implant or revision surgery was not recorded.
Infection rate

Infection rate was reported in seven studies [12–18], which included 28 495 THAs. There was an increased infection rate in CLD patients, at 0.5% (range 0.3%–15.4%) compared with 0.15% in controls (p < 0.001). Two studies recorded separate infection rates for elective arthroplasty cases versus emergency cases [13, 18]. This amounted to 954 THAs, including 803 elective cases and 151 urgent procedures. There was an increased mean infection rate for elective cases at 4.1% (n = 33, p < 0.001) and for urgent cases at 8.6% (n = 13, p < 0.001). In patients with liver transplants, the mean infection rate was 1% [19, 20].

Mortality

Perioperative mortality rates were documented in five studies [11–14, 18] amounting to 1048 THAs. The mean perioperative mortality rate was increased in CLD patients at 4.1% compared with 0.2% in controls (p < 0.001). No perioperative mortality was reported in patients with liver transplants. Table 1 summarizes the demographics and key findings of each study included in this systematic review.

Discussion

Anecdotal evidence suggests that THA in patients with CLD is a generally successful procedure. However, this review highlights that there are no objective data within English literature that documents functional outcomes in this patient group, despite the fact that it is accepted that there are increased technical challenges. Indeed this study has found increased infection rates, mortality rates, rates of revision surgery and aseptic loosening in patients with CLD undergoing THA.

Long-term outcome measures are somewhat heterogeneously reported in current literature. These were examined during this study. This review found a revision surgery rate of 4%, with the majority of revisions being for periprosthetic infection/septic loosening of prosthesis (70%). The National Joint Registry (NJR) of England and Wales in 2016 reports a revision rate of 2.6% in THAs, and accordingly the suggestion is that THA revision rates are higher in patients with CLD.

In addition, the most common underlying reason for revisions in NJR data was aseptic loosening at 24.2%, with infection only accounting for 13.8%. The limited numbers and heterogeneity of reporting, limit the ability to draw conclusions; however, there is a suggestion that infection may play a larger role in THA failures in patients with CLD. When considering THA in liver transplant patients, functional outcomes were shown to improve following surgery, with a 2% incidence of aseptic loosening, and a 7% need for revision surgery. Supporting this, Levitsky et al. (2003) [21] conducted a small review of arthroplasty cases in liver transplant patients (eight knee, three hip and one ankle). They found no deaths or major complications. These positive trends offer a faint suggestion that some aspects of MBD associated with CLD might be reversed after liver transplantation; however, the small numbers mean that drawing firm conclusions is not advisable. Indeed Cavanaugh et al. (2015) [22] conducted a retrospective study between 1993 and 2011 of 787 liver transplant patients who had undergone THA or Total Knee Arthroplasty (TKA) finding a higher risk of surgical site infection, renal and cardiorespiratory complications.

The inferences of this review are that there is an increased risk of general surgical and medical complications in patients with CLD undergoing THA. These findings are supported by previous research that has reviewed surgical outcomes in patients with CLD. Ziser et al. (1999) [10] conducted a review of 733 mixed surgeries at the Mayo clinic in 1999. This study reported significantly increased perioperative complications at 30.1%, increased mortality rate at 11.6%, and noted increased mortality with higher Child’s Pugh scores. The study also included a small number of hip and pelvic surgeries, and showed that these patients had significantly higher complication rates than other types of surgery (53% vs. 29.4%, p = 0.008). There are several studies that have looked at the outcomes of arthroplasty in patients with CLD, when combining THA and TKA. Deleuran et al. (2015) [23], retrospectively reviewed 363 THA and TKA cases in patients with CLD between 1995 and 2011. Patients with CLD had increased odds of mortality within 30 days (OR 3.9, 95% CI 1.5–10), deep infection (3.1% vs. 1.4%), and need for revision surgery (3.7% vs. 1.7%) compared to the control group. Tiberi et al. (2014) [24] reviewed clinical outcomes of 115 THA and TKA cases in patients with CLD between 2000 and 2012. This study showed

<table>
<thead>
<tr>
<th>Study, Country</th>
<th>Age (mean)</th>
<th>Follow up (mean) months</th>
<th>No. of THAs</th>
<th>Revision rate (%)</th>
<th>Mortality rate (%)</th>
<th>Infection rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohen [11], USA</td>
<td>Elective: 65.7</td>
<td>1</td>
<td>19</td>
<td>5</td>
<td>5.3</td>
<td>–</td>
</tr>
<tr>
<td>Hsieh [12], Taiwan</td>
<td>55.2</td>
<td>84</td>
<td>45</td>
<td>37.8</td>
<td>11.1</td>
<td>24.4</td>
</tr>
<tr>
<td>Jiang [13], USA</td>
<td>62.3</td>
<td>6</td>
<td>878</td>
<td>1.2</td>
<td>4</td>
<td>0.0</td>
</tr>
<tr>
<td>Moon [14], Korea</td>
<td>60</td>
<td>1</td>
<td>30</td>
<td>6.7</td>
<td>10.0</td>
<td>0.3</td>
</tr>
<tr>
<td>Newman [15], USA</td>
<td>57.1</td>
<td>Until discharge</td>
<td>27 401</td>
<td>–</td>
<td>–</td>
<td>8.0</td>
</tr>
<tr>
<td>Orozco [16], USA</td>
<td>59</td>
<td>35</td>
<td>25</td>
<td>–</td>
<td>–</td>
<td>0.15</td>
</tr>
<tr>
<td>Pour [17], USA</td>
<td>55</td>
<td>101</td>
<td>40</td>
<td>8</td>
<td>–</td>
<td>15.0</td>
</tr>
<tr>
<td>Seol [18], South Korea</td>
<td>Elective: 61.9</td>
<td>Until discharge</td>
<td>76</td>
<td>Elective 13.5</td>
<td>3.9</td>
<td>14.5</td>
</tr>
</tbody>
</table>
patients with CLD had increased risk of urinary tract infection ($p < 0.01$), acute kidney injury ($p < 0.03$), need for transfusion ($p < 0.01$), dislocation ($p = 0.01$), infection ($p = 0.02$), 90-day revision surgery ($p = 0.04$) and 1 year mortality ($p = 0.01$) compared to the matched control group. Poultsides et al. (2013) retrospectively reviewed 412 356 THA and 784 335 TKA between 1998 and 2007. Liver disease was found to be an independent risk factor for developing surgical site infection (OR = 2.53, $p = 0.0001$).

Worldwide, increasing numbers of THAs are being performed annually. It is reasonable to infer that arthroplasty surgeons will be performing THAs in patients with CLD with increasing frequency. It is thus essential to appreciate the medical and surgical issues unique to this patient-group, and particularly how to optimize controllable factors. Patel (1999) discusses in detail systematic approaches to assess and optimize the patient with CLD for surgery. A multi-disciplinary approach is recommended. In line with this paper and other relevant evidence, the following pre-, intra- and post-operative considerations should be addressed:

**Pre-operative considerations/requirements**

Advice may be sought from haematologists and/or hepatologists as to optimization strategies. The input of microbiologists may be sought on an individual case basis. Preoperative workup should aim to optimize haemoglobin levels. The cause for anaemia should be assessed and treated accordingly. Treatment may include nutritional supplementation such as with iron, or Erythropoietin where there is anaemia of chronic disease [27]. Pre-operative blood transfusion should not be considered a first-line option. It is important to obtain and review good quality radiographic studies of the pelvis and femur to assess bone morphology and quality, and plan surgery including selection of the most appropriate implants. Bisphosphonates have been shown to reduce periprosthetic bone loss and improve implant integration in those with osteoporotic bone [28] and thus should be considered.

**Intra-operative considerations**

Surgery should be carried out with a focus on minimizing blood loss with vigilant haemostasis and the use of tranexamic acid [8]. Implant choice in THA in patients with CLD is complex. In osteoporotic bone, the surgeon may consider cemented femoral implants to reduce intraoperative fracture rates and aseptic loosening. With uncemented implants, the surgeon must appreciate general recommendations for implant preparation and fixation in osteoporotic bone.

This includes achieving good rim fit and using acetabular screws to enhance fixation in uncemented shells, and cautious femoral preparation and sizing choices.

**Postoperative considerations**

Vigilant clinical assessment should be made with particular watchfulness for bleeding and infection as well other medical complications. Long-term follow up should include careful clinical and radiographic review for prosthesis loosening.

**Limitations**

The results of this review must be interpreted with the limitations of this study in mind. All of the studies included in this review article are retrospective studies with their inherent limitations. There is non-uniform reporting of long-term complications, with some studies only reviewing short-term measures. Subgroup analysis has not been performed and confounding variables may have affected the outcomes recorded, for example, the use of immunosuppressant medication or steroids. With only two studies reporting on the type of implant used, it was not possible to draw conclusions or make recommendations as to the optimal implant properties for patients with CLD. The extent of CLD was also not stratified. Despite these limitations, this systematic review provides timely and important information for the medical community in clinical decision making and offering informed patient choices.

**Recommendations for research**

There is a need for further large studies on patients with CLD undergoing THA. It is important to review functional outcomes so that patients can be fully informed when undertaking the decision to proceed with THA. With the availability of radiographic classifications such as by Dorr et al. (1993), it would be useful to study whether these influence outcomes, and whether this can be related to implant choices.

**Conclusion**

A multidisciplinary perioperative approach is recommended in order to minimize increased complication risks, in particular infection, mortality, aseptic loosening and need for revision surgery. Infection may need heightened consideration when trying to avoid the serious complication of need for revision surgery. This review guides future research to appraise functional outcomes of THA in patients with active CLD, further detail long-term failure reasons, and review any differences in outcomes and complications based on various operative approaches and available implants.

**Conflicts of interest**

All the authors declare that they have no competing interests.

**References**


EDITORIAL

Robotic total knee arthroplasty

CLINICAL OUTCOMES AND DIRECTIONS FOR FUTURE RESEARCH

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The term ‘robot’ originates from the Czech word ‘robota’, which means forced labour or activity. Karel Capek first used the term in his 1921 play Rossum’s Universal Robots, in which robots were a series of factory-manufactured artificial people made from synthetic material that undertook mundane tasks for their human masters. The robots eventually became frustrated with their roles and masterminded a robotic rebellion, leading to the extinction of the human race. Since then, robotics has evolved to describe an array of computer machines that perform programmed, precise, and repetitive procedures. These computer machines have now become integrated into the routine workforce of several industries, including aviation, military, healthcare, finance, construction, and engineering.1,2 Robotic technology has helped each of these sectors to achieve and sustain levels of precision, productivity, and efficiency that were not possible with humans alone. Within each of these sectors that have integrated robotic technology into the workforce, the use of this technology has never diminished or exited from the industry.2

The first robotic surgical procedure was performed by Kwoh et al3 in 1988 using the PUMA 560 robotic system (Westinghouse Electric, Pittsburgh, Pennsylvania) to undertake neurosurgical biopsies with improved precision. The same robotic platform was used by Davies et al4 in 1991 to undertake transurethral resections of the prostate with greater accuracy and reduced iatrogenic soft-tissue injury. Over the following two decades, several other surgical robotic devices were developed, including the Zeus (Computer Motion, Inc., Goleta, California) and Da Vinci (Intuitive Surgical, Sunnyvale, California) robotic platforms, which enabled a variety of surgical procedures to be performed remotely using robotically controlled arms and a 3D camera to improve the visual field.5-6 These robotic devices have been used to perform cholecystectomy, hysterectomy, lobectomy, mitral valve replacement, coronary artery bypass grafting, and prostatectomy. Compared with conventional open surgery or laparoscopic surgery, robotic surgery with these devices is associated with smaller skin incisions, improved precision of soft-tissue dissection, better visualization of the surgical field, and more comprehensive data capture for surgical training.6,7 Clinically, this has translated to robotic surgery enabling faster postoperative rehabilitation and decreased length of hospital stay compared with conventional and laparoscopic surgery for these procedures.5-8

Total knee arthroplasty (TKA) is an effective and cost-efficient procedure that is performed in over 90,000 patients per year in the United Kingdom.9 Implant survivorship, assessed with revision as the primary endpoint, is greater than 90% at ten years’ follow-up.10,11 However, patient satisfaction and functional outcomes remain inferior to total hip arthroplasty, with up to 20% of patients remaining dissatisfied following TKA.12,13 Accurate implant positioning, balanced flexion-extension gaps, proper ligament tensioning, and preservation of the periarticular soft-tissue envelope are important surgeon-controlled variables that affect functional outcomes, implant stability, and long-term implant survivorship.14-16 Conventional jig-based TKA uses preoperative radiographic films, intraoperative anatomical landmarks, and manually positioned alignment jigs to guide bone resection and implant positioning. However, these handheld techniques are associated with poor reproducibility of alignment-guide positioning, inadvertent sawblade injury to the periarticular soft-tissue envelope, and limited intraoperative data on gap measurements or ligamentous tensioning to...
fine-tune implant positioning. Suboptimal implant positioning or gap balancing may lead to poor functional recovery, reduced clinical outcomes, increased instability, and reduced implant survivorship.

Robotic TKA uses computer software to convert anatomical information into a virtual patient-specific 3D reconstruction of the knee joint. The anatomical information may be obtained using preoperative CT (image-based) or a combination of preoperative radiographs and intraoperative osseous mapping (imageless). The surgeon uses this virtual model to plan optimal bone resection, implant positioning, bone coverage, and limb alignment based on the patient’s unique anatomy. An intraoperative robotic device helps to execute this preoperative patient-specific plan with a high level of accuracy. The action of the sawblade is confined to the preoperative surgical plan for femoral and tibial resection, which limits iatrogenic periarticular soft-tissue injury and bone trauma. Although the first robotic TKA was performed in 1988 using the ACRobot robotic system (Imperial College, London, United Kingdom), there has been a surge in robotic TKA over the last decade. This has been attributed to recent developments in computer software and technology, and the ease with which modifications can be made to existing technology such as computer navigation. Computer-navigated TKA provides patient-specific anatomical data with recommendations for bone resection and optimal component positioning. Robotic TKA takes this one step further by actively controlling and/or restraining the surgeon’s motor function to improve the accuracy of achieving the planned bone resection and implant positioning.

There are a variety of robotic TKA devices, some of which actively perform all parts of femoral and tibial bone resections (fully active), while others enable the surgeon to undertake the procedure while providing live intraoperative feedback to help control bone resection to the confines of the preoperative surgical plan (semi-active). ROBODOC (THINK Surgical Inc., Fremont, California) is an example of a fully active robotic TKA application system. The surgeon performs the surgical approach, positions retractors to protect the periarticular soft tissues, and then secures the limb into a fixed device. The robotic device then independently executes the planned bone resections. The Mako Robotic Arm Interactive Orthopaedic System (Stryker Ltd, Kalamazoo, Michigan) is an example of an image-guided semi-active robotic system for robotic TKA. The robotic arm has visual, tactile, and audio feedback that help the surgeon to control the force and direction of saw blade action within the confines of the femoral and tibial bone resection windows. The Navio Surgical system (Smith & Nephew, Andover, Texas) is an imageless semi-active robotic system that uses a handheld platform to intraoperatively map osseous anatomy and guide bone resection. The Rosa Knee System (Zimmer Biomet, Warsaw, Indiana) offers a computer software program to convert 2D knee radiographs into a 3D patient-specific bone model, and a robotic device to help position the cutting blocks and execute the planned bone resections with greater accuracy. Omnibot (OMNIlife Science Inc., East Taunton, Massachusetts) is a robotic device that uses patented intraoperative Bone Morphin technology to create a 3D model of the osseous anatomy using plain radiographs. This may be combined with the BalanceBot Ligament Balancer (OMNIlife Science Inc.), which uses an intraoperative robotic device to balance the soft tissues. Together, these technologies may help surgeons place implants anatomically while minimizing the need for soft-tissue releases.

Robotic TKA is associated with improved accuracy of achieving the planned femoral and tibial implant positioning, joint line restoration, limb alignment, and posterior tibial slope compared with conventional jig-based TKA. This has been attributed to the stereotactic boundaries that confine the action of the sawblade to the preplanned haptic femoral and tibial windows. Song et al. performed a prospective randomized study on 100 patients undergoing primary TKA, and found that robotic TKA was associated with improved accuracy and reduced outliers in achieving the planned alignment compared with conventional manual TKA. Bellemans et al. reviewed outcomes in 25 patients undergoing robotic TKA and reported femoral and tibial implant positioning within 1° of the planned positions in all three planes. Hampp et al. performed a study on six cadaveric specimens and found that robotic TKA was associated with improved accuracy of femoral and tibial implant positioning in the coronal, sagittal, and axial planes compared with conventional manual TKA. Improved accuracy in achieving these radiological outcomes has been previously correlated to increased patient satisfaction, greater stability, and improved kinematics through the arc of motion following TKA. Furthermore, robotic TKA is associated with a learning curve of six to 20 cases for operative times, but there is no learning curve for achieving the planned femoral or tibial implant positioning. This is important for the safe implementation of this technology into routine arthroplasty practice and offers an avenue for low-volume arthroplasty surgeons to achieve high levels of accuracy in implant positioning.

Balanced flexion-extension gaps and proper mediolateral ligamentous tensioning are important technical objectives in TKA for optimizing knee kinematics, stability, and long-term implant survivorship. Conventional jig-based TKA techniques often utilize controlled soft-tissue releases to achieve balanced flexion-extension gaps and mediolateral soft-tissue tension. Assessing intraoperative gap measurements and periarticular soft-tissue laxity is challenging, and is often dependent on the skill and
Robotic TKA uses optical motion capture technology to assess intraoperative alignment, component positioning, range of movement, flexion-extension gaps, and mediolateral laxity. This real-time intraoperative data can then be used to fine-tune bone resection and guide implant positioning, in order to achieve the desired knee kinematics and limit the need for additional soft-tissue releases. Kayani et al conducted a prospective cohort study comparing bone trauma and periarticular soft tissue injury in 30 patients undergoing conventional jig-based TKA versus 30 patients receiving robotic TKA. The study found that robotic TKA enabled better preservation of the periarticular soft-tissue envelope in both correctible and non-correctible coronal plane deformities, and robotic TKA was associated with less trauma to the residual femoral and tibial bone resection surfaces. Khlopas et al conducted a cadaveric study in which six blinded observers reported soft-tissue trauma following bone resection in cruciate-retaining TKAs, and found that robotic TKA was associated with reduced posterior cruciate ligament injury, decreased tibial subluxation, and reduced patella eversion compared with conventional jig-based TKA.

Improved preservation of the periarticular soft envelope secondary to reduced iatrogenic periarticular soft-tissue injury in robotic TKA may help to limit the local inflammatory response, decrease pain, and reduce postoperative swelling compared with conventional jig-based TKA. Siebert et al conducted a retrospective study on 70 patients undergoing robotic TKA versus a matched historic cohort of 50 conventional jig-based TKAs, and observed reduced postoperative soft-tissue swelling in the robotic group. Kayani et al conducted a prospective cohort study comparing early functional outcomes in 40 conventional manual UKAs followed by 40 robotic TKAs. The authors found that robotic TKA was associated with reduced postoperative pain, decreased analgesia requirements, shorter time to straight leg raise, increased knee flexion at discharge, and reduced need for inpatient physiotherapy compared with conventional jig-based TKA. Median time to hospital discharge in robotic-arm assisted TKA was 77 hours (interquartile range (IQR) 74 to 81) compared with 105 hours (IQR 98 to 126) in conventional jig-based TKA ($p < 0.001$). Marchand et al compared outcomes in 28 robotic TKAs matched with 20 conventional jig-based TKAs and showed that pain, patient satisfaction, and physical function scores, as measured using Western Ontario and McMaster Universities Arthritis Index (WOMAC), were better in the robotic group compared with the conventional group at six months after surgery.

Improved accuracy of implant positioning and enhanced postoperative rehabilitation in robotic TKA have not translated to any differences in middle- to long-term functional outcomes compared with conventional jig-based TKA. Song et al reported no difference in Hospital for Special Surgery (HSS) or WOMAC scores between 50 conventional jig-based TKAs and 50 robotic TKAs at two years’ follow-up. Liow et al conducted a prospective randomized trial in 29 conventional jig-based TKAs versus 31 robotic TKAs, and found that there was no difference between the two treatment groups with respect to the Oxford Knee Score (OKS) and KSS at two years’ follow-up. Yang et al conducted a prospective cohort study on 71 robotic TKAs versus 42 conventional jig-based TKAs, and found no difference in HSS and WOMAC scores at a minimum of ten years’ follow-up. As with all new technology in medicine and surgery, there is a paucity of prospective randomized controlled trials reporting on longer-term outcomes.

Fixed femoral and tibial arrays provide novel intraoperative data on fixed flexion deformity, range of movement, limb alignment, flexion-extension gaps, and mediolateral ligamentous laxity, which may be used for research and development purposes. For example, existing studies assessing functional alignment in TKA have used patient-specific implants or alignment guides to achieve the preplanned alignment. Robotic technology offers an opportunity to accurately execute the planned bone resection and implant positioning to achieve functional alignment, and fixed intraoperative femoral and tibial arrays enable the surgeon to confirm that this alignment has been achieved. Similarly, changes in gap measurements and alignment following specific ligamentous resection may provide data on ligament biomechanics and kinematics. In anterior and posterior cruciate ligament reconstructions, robotic technology potentially offers an avenue to improve accuracy and reduce outliers in correct femoral and tibial tunnel positioning. Robotic technology may minimize human error and provide objective, real-time data for scientists, clinicians, and engineers to accurately record changes in knee kinematics and function. Intraoperative data on the various stages of robotic TKA may also be used for teaching purposes to improve surgical proficiency.

Robotic technology is associated with several limitations that must be acknowledged when understanding the current role and future potential of this technology in TKA. The robotic device is expensive to install and separate applications may need to be required for total hip arthroplasty, TKA, and unicompartmental knee arthroplasty. The robotic device is only compatible with a limited number of implants from the manufacturer of the robotic device, and additional costs are incurred for preoperative imaging, increased operating times during the learning phase, training the surgical team, updating of computer software and servicing contracts, and consumables. Image-guided robotic TKA requires preoperative CT scans that require extra time and radiation exposure. Additional time is also required for remote preoperative
planning and segmentation using the patient-specific virtual models, and a robotic product specialist is required in the operating room to capture data and facilitate the operative procedure. Fully active robotic TKA systems have also been reported to cause periarticular soft-tissue injury, and technical issues with robotic device have required intraoperative conversion to conventional jig-based TKA.\(^1\)\(^1\)\(^7\)

Overall, robotic technology enables TKA to be undertaken with improved accuracy of implant positioning and reduced periarticular soft-tissue injury compared with conventional jig-based TKA. This has translated to improved inpatient functional rehabilitation and earlier time to hospital discharge compared with conventional jig-based TKA. Robotic technology offers potential for further research by providing objective data on gap measurements and knee kinematics following specific ligamentous releases, and provides an avenue for executing preplanned implant positioning and alignment with greater precision and reproducibility for study purposes. These advantages must be acknowledged while respecting the limitations of robotic TKA, which include additional costs for installation and maintenance of the robotic machine, additional radiation exposure, and paucity of long-term data showing any functional benefit over conventional jig-based TKA. The results of further high-quality studies with longer term follow-up on functional outcomes, implant survivorship, complications, and cost-effectiveness are awaited.

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Robotic technology in total knee arthroplasty: a systematic review

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Fares S. Haddad1,2

Introduction

Total knee arthroplasty (TKA) is an established and highly effective treatment for patients with symptomatic end-stage knee osteoarthritis.1,2 The procedure is performed in over 90,000 patients per year in the United Kingdom.3 Pooled registry data has shown that implant survivorship, assessed with revision as the primary endpoint, is approximately 82% at 25 years follow-up.4,5 However, patient satisfaction and functional outcomes remain inferior to those for total hip arthroplasty.3 Despite advances in implant design, implant material, enhanced recovery programmes, thromboembolic prophylaxis, antibiotic prophylaxis, patient-specific implants, and computer navigation, recent studies have shown that up to 20% of patients remain dissatisfied following TKA.2,6–11 Accurate implant positioning, balanced flexion-extension gaps, proper ligament tensioning, and preservation of the periarticular soft tissue envelope are important surgeon-controlled variables that affect functional outcomes, implant stability, and long-term implant survivorship.12–19 Conceptually, technology that enables these technical objectives to be delivered with greater accuracy and reproducibility may help to further improve outcomes in TKA.

Robotic technology has been used to improve the accuracy of soft tissue dissection and enhance postoperative rehabilitation in general surgery, cardiology, obstetrics and gynaecology, and ophthalmology.16 Over the last decade, robotic TKA has gathered momentum as an avenue for improving the accuracy of implant positioning and reducing outliers in limb alignment compared to conventional jig-based TKA.20–26 However, many clinicians remain sceptical about robotic TKA owing to the substantive set-up costs and limited long-term evidence.
comparing clinical and functional outcomes to conventional manual TKA.

This article discusses the current role of robotic technology in TKA, explores the benefits of this technology on accuracy of implant positioning and periarticular soft tissue preservation, and highlights the limitations of robotic TKA compared to conventional jig-based TKA.

Limitations of conventional jig-based TKA

Conventional jig-based TKA uses preoperative radiographic films, intraoperative anatomical landmarks, and manually positioned alignment jigs to guide bone resection and implant positioning. However, these techniques are poorly reproducible and accuracy of achieving the planned implant position is dependent on the skill and expertise of the operating surgeon. Achieving balanced flexion-extension gaps and proper mediolateral ligamentous tensioning is dependent on subjective intraoperative gap assessments with limited capacity for fine-tuning bone resection and implant positioning. Intraoperative tensioning devices may help to guide soft tissue releases but there is often inter-surgeon heterogeneity in their positioning in the joint and overall distraction forces applied. Conventional jig-based TKA also uses a manually controlled sawblade to perform bone resection and handheld instruments to protect the periarticular soft tissue envelope. This manual technique for bone resection may lead to inadvertent injury to the supporting ligamentous structures, which may compromise postoperative clinical and functional recovery, reduce stability, and decrease implant survivorship. Conventional jig-based TKA does not provide real-time feedback on the thickness or orientation of the bone cuts. The use of intramedullary referencing guides for bone resection during conventional jig-based TKA may also increase the risk of thromboembolic events and cardiorespiratory complications.

Computer-navigated versus robotic TKA

Computer-navigated TKA involves the use of computer systems that provide live on-screen information on patient anatomy and knee kinematics during surgery. This osseous anatomical map of the patient’s knee joint may be obtained using preoperative computerized tomography (CT) scans (image-based navigation) or intraoperative mapping of bony anatomical landmarks on a generic model of the knee joint (non-image-based navigation). Computer navigation provides patient-specific anatomical data with recommendations for bone resection and optimal implant positioning, but the computer system does not actively control or restrain the motor function of the operating surgeon. Robotic TKA uses computer software to convert anatomical information into a virtual patient-specific three-dimensional (3D) reconstruction of the knee joint, which the operating surgeon uses to calculate optimal bone resection and implant positioning. An intraoperative robotic device helps to execute this preoperative patient-specific plan with a high level of accuracy. Depending on the degree of control that the robotic device provides the operating surgeon, robotic assistants are classified as either fully active or semi-active systems.

Fully active versus semi-active robotic TKA systems

Fully active robotic systems work autonomously to perform the planned femoral and tibial bone resections. The surgeon oversees the bone resection and may activate an emergency deactivation switch if required. ROBODOC (THINK Surgical Inc., Fremont, California, USA) is an example of a fully active robotic TKA application system. The surgeon performs the surgical approach, positions retractors to protect the periarticular soft tissues, and then secures the limb into a fixed device. The robotic device then independently executes the planned bone resections. There has been limited uptake of fully active robotic TKA systems owing to substantial robotic device installation costs and increased risk of complications during the learning phase of this procedure. Park and Lee reported six of their initial 32 fully active robotic TKA procedures had short-term complications including superficial infection, patellar ligament rupture, patellar dislocation, supracondylar fracture, patellar fracture, and common peroneal injury.

Semi-active robotic systems enable the surgeon to maintain overall control over bone resection and implant positioning but provide live intraoperative feedback to limit deviation from the preoperative surgical plan. The Mako Robotic Arm Interactive Orthopaedic system (Stryker Ltd, Kalamazoo, MI, USA) is an example of an image-guided semi-active robotic system for robotic TKA. The robotic arm has visual, tactile, and audio feedback that help the surgeon control the force and direction of saw blade action within the confines of the femoral and tibial bone resection windows. The patient’s limb is secured within a mobile leg holder boot that can be adjusted during bone resection to improve visualization of the operative field. Rapid or jerking movements deactivate the robotic device to help limit iatrogenic bone and soft tissue injury. The Navio Surgical System (Smith & Nephew, Andover, Texas, USA) is an imageless semi-active robotic system that uses a handheld platform to intraoperatively map osseous anatomy and guide bone resection without the haptic boundaries. More recently, the Rosa Knee System (Zimmer-Biomet, Warsaw, Indiana, USA) has gained FDA approval. This robotic system offers a
computer software program to convert two-dimensional knee radiographs into a three-dimensional patient-specific bone model. Virtual plans on implant positioning and ligament balancing are created before execution of the desired patient-specific plan using the robotically positioned cutting blocks.

Stages of robotic TKA

Robotic TKA uses computerized systems at five distinct stages for accurate execution of the patient-specific surgical plan. First, preoperative plain radiographs or CT scans of the knee joint are used to create a virtual three-dimensional reconstruction of the patient’s native knee anatomy. Second, the surgeon uses this patient-specific virtual model to plan optimal implant positioning, alignment, and sizing to achieve the desired bone coverage, component position, and limb alignment. Computer software uses this virtual data to calculate femoral and tibial bone resection windows for accomplishing this surgical plan with a high level of precision. Third, intraoperative bone registration and verification of bony landmarks are used to confirm the patient’s osseous knee anatomy prior to bone resection. In CT-free robotic application systems, registration is performed by mapping the patient’s osseous anatomy onto a generic virtual model of the knee joint, and planning of implant positioning and bone resection is performed intraoperatively. In CT-based robotic knee systems, a patient-specific model of the knee joint is created and osseous anatomy is mapped intraoperatively to confirm bone geometry. Fourth, the surgeon uses the robotic device to perform the bone resections within the pre-planned boundaries of the femoral and tibial bone windows. Fifth, optical motion capture technology is used to re-assess intraoperative flexion and extension gaps, joint stability, range of movement, and limb alignment. The surgeon is able to perform live on-table modifications to bone resection, adjust implant positioning, and fine-tune soft tissue releases to achieve the desired bone coverage, component positioning, knee kinematics, and limb alignment.

Accuracy of implant positioning

Robotic TKA is associated with improved accuracy in implant positioning and limb alignment compared to conventional jig-based TKA. Sawblade action is limited to the confines of the preoperative surgical plan, which helps to execute the planned femoral and tibial bone resections with a high level of precision. Song et al conducted a prospective randomized study on 50 conventional manual TKA versus 50 robotic TKA, and found robotic TKA improved accuracy of mechanical alignment and reduced outliers of greater than 3° in planned alignment compared to conventional manual TKA. Bellemans et al reviewed outcomes in 25 patients undergoing robotic TKA and reported femoral and tibial implant positioning within 1° of the planned positions in all three planes. Hampp et al performed a cadaveric study on six specimens undergoing conventional manual TKA on one side and robotic TKA on the contralateral side. The authors found that robotic TKA was associated with improved accuracy of femoral and tibial implant positioning in the coronal, sagittal, and axial planes compared to conventional manual TKA, and there was no learning effect for accuracy of implant positioning in the robotic group. Moon et al also conducted a cadaveric study using CT scans to assess the accuracy of implant positioning and limb alignment in 10 conventional jig-based TKAs versus 10 robotic TKAs. The authors found that robotic TKA was associated with high levels of precision in achieving the planned component positioning and reduced outliers in limb alignment compared to conventional jig-based TKA. Robotic TKA has also been shown to more accurately restore the native joint line, posterior condylar offset ratio, and Insall-Salvati ratio compared to conventional jig-based TKA. Improved accuracy in achieving these radiological outcomes has been previously correlated to increased patient satisfaction, greater stability, and improved kinematics through the arc of motion following TKA.

Learning curve of robotic TKA

The learning curve of robotic TKA is important for understanding the impact of this procedure on the surgical workflow, scheduling of operative cases and theatre lists, and establishing any additional risks or complications during the acquisition of surgical proficiency. Kayani et al assessed the learning curve of robotic TKA by assessing surrogate operative and radiological markers of the learning curve in 60 consecutive conventional manual TKAs followed by 60 robotic TKAs. Using cumulative summative analysis, the authors reported that the learning curve for operative times and surgical team confidence levels with robotic TKA was seven cases. There was no learning curve effect in robotic TKA for achieving the planned femoral and tibial implant positioning, limb alignment, posterior condylar offset ratio, and native joint restoration. Sodhi et al explored the learning curve of robotic TKA in two different surgeons, and found operative times were increased for an initial 20 robotic TKA cases. Thereafter, operative times in robotic TKA were comparable to those of conventional manual TKA in both surgeons. Proponents of robotic TKA claim that this technology helps to produce a more streamlined procedure than conventional jig-based TKA by reducing the need for instrument trays, alignment guides, and cutting blocks, enabling more rapid computer-guided bone resections, and reducing the
need for trialling due to the high accuracy of preoperative surgical planning. However, existing studies show that operative times are increased in the learning phase of robotic TKA, and comparable between the two treatment techniques after the proficiency phase for robotic TKA has been achieved.42,43

Periarticular soft tissue injury

Balanced flexion-extension gaps and proper mediolateral ligamentous tensioning are essential for optimizing knee kinematics, stability, and long-term implant survivorship.35–38 In conventional jig-based TKA, controlled soft tissue releases are performed in 50–76% of patients to balance mediolateral laxity, with some authors advocating for all non-navigated TKAs to undergo ligamentous releases.17,20,38–40 Robotic TKA uses optical motion capture technology to assess intraoperative alignment, component positioning, range of motion, flexion-extension gaps, and mediolateral laxity. This real-time intraoperative data can then be used to fine-tune bone resection and guide implant positioning to achieve the desired kinematics, and limit the need for additional soft tissue releases.42,44

Robotic TKA also utilizes haptic boundaries that limit the action of the sawblade to the confines of the preoperative surgical plans for femoral and tibial resections, and therefore limit iatrogenic periarticular soft tissue injury. Khlopas et al conducted a cadaveric study in which six blinded observers reported soft tissue trauma following bone resection in cruciate-retaining TKAs with either conventional jig-based TKA or robotic TKA. The authors found that robotic TKA was associated with reduced posterior cruciate ligament (PCL) injury, tibial subluxation, and patella ever sion compared with conventional manual TKA.44

Early functional outcomes and time to hospital discharge

Improved preservation of the periarticular soft envelope secondary to reduced intentional soft tissue releases and decreased iatrogenic periarticular soft tissue injury in robotic TKA may help to limit the local inflammatory response, decrease pain, and reduce postoperative swelling compared to conventional jig-based TKA. Siebert et al conducted a retrospective study on 70 patients undergoing robotic TKA versus a matched historic cohort of 50 conventional jig-based TKAs, and observed reduced postoperative soft-tissue swelling in the robotic group.45 Kayani et al conducted a prospective cohort study comparing early functional outcomes in 40 conventional manual TKAs followed by 40 robotic TKAs.46 The authors found that robotic TKA was associated with reduced postoperative pain, decreased analgesia requirements, shorter time to straight leg raise, increased knee flexion at discharge, and reduced need for inpatient physiotherapy compared to conventional jig-based TKA. Median time to hospital discharge in robotic-arm-assisted TKA was 77 hours (inter-quartile range (IQR) 74 to 81) compared with 105 hours (IQR 98 to 126) in conventional jig-based TKA (p < 0.001). Marchand et al compared outcomes in 28 robotic TKAs matched with 20 conventional jig-based TKAs and showed that pain, patient satisfaction, and physical function scores as measured using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) were better in the robotic group compared with the conventional group at six months after surgery.47 Khlopas et al conducted a prospective non-randomized multi-centre trial comparing 102 conventional jig-based TKAs with 150 robotic TKAs, and found robotic TKA was associated with greater improvements in walking and standing at 4–6 weeks and three months after surgery compared to conventional manual TKA.48 Ren et al recently conducted a meta-analysis of five studies with 323 robotic TKAs and 251 conventional jig-based TKAs, and reported improved Knee Society Score (KSS) functional score and WOMAC scores in the robotic group at six months follow-up.49

Medium- to long-term functional outcomes

Improved accuracy of implant positioning and enhanced postoperative rehabilitation in robotic TKA have not translated to any differences in medium- to long-term functional outcomes compared to conventional jig-based TKA. Song et al reported no difference in Hospital for Special Surgery (HSS) or WOMAC scores between 50 conventional jig-based TKAs and 50 robotic TKAs at two years follow-up.25,26 Liow et al conducted a prospective randomized trial in 29 conventional jig-based TKAs versus 31 robotic TKAs, and found there was no difference between the two treatment groups with respect to the Oxford Knee Score (OKS) and KSS at two years follow-up.50 Yang conducted a prospective cohort study on 71 robotic TKAs versus 42 conventional jig-based TKAs, and found no difference in HSS or WOMAC scores at minimum 10 years follow-up.51 Cho et al recently reported outcomes in 155 robotic TKAs versus 196 conventional jig-based TKAs, and also found no difference in WOMAC, OKS, KSS, or SF-12 at minimum 10 years follow-up.52

Limitations of robotic TKA

Robotic technology is associated with substantial installation and maintenance costs for the robotic device. Further costs are incurred with additional preoperative imaging, increased operating times during the learning phase, training the surgical team, updating of computer software and servicing contracts, and consumables. Many robotic
devices are also only compatible with a limited number of implant designs, and different application systems need to be purchased for total hip arthroplasty, TKA, and unicompartmental knee arthroplasty. The cost of purchasing the robotic device ranges between $600 k to $1.5 million US dollars depending on the specification of the robotic machine, support and upgrade agreements, and category of application systems included. These costs may be partially offset as robotic TKA is associated with reduced operative analgesia consumption, decreased need for inpatient physiotherapy, earlier time to hospital discharge, reduced readmission rates, and fewer discharges to rehabilitation units or skilled nursing facilities compared to conventional jig-based TKA. Robotic TKA requires additional incisions for insertion of the femoral and tibial registration pins to enable optical motion-capture tracking, and image-guided robotic TKA increases radiation exposure to the patient. There are additional time delays for the remote planning team to template the optimal implant size and positioning on the patient-specific virtual model, which then requires further fine-tuning by the surgeon before surgery. Fully active robotic TKA systems have been reported to cause periarticular soft tissue injury and technical issues with robotic devices have required intraoperative conversion to conventional jig-based TKA. The robotic device, computer screens, and infrared sensors reduce the intraoperative working space, and additional instruments and surgical trays may cause instrument crowding.

Conclusion

Robotic TKA uses preoperative imaging or intraoperative bone mapping to create a patient-specific virtual reconstruction of the knee joint. The surgeon uses this model to plan optimal bone resection and implant positioning, and an intraoperative robotic device to execute this plan with a high level of accuracy. Intraoperative optical motion capture technology enables accurate assessment of ligamentous laxity, which enables the surgeon to fine-tune bone resection and guide implant positioning whilst limiting the need for soft tissue releases. Haptic boundaries also limit the action of the saw to the confines of the preoperative surgical plan to limit iatrogenic soft tissue injury. There is no learning curve for achieving the planned implant position and operative times are equivalent to those for conventional jig-based TKA after the initial learning phase. However, improved radiological outcomes in robotic TKA have not translated to any differences in long-term functional outcomes compared to conventional jig-based TKA. Limitations of robotic TKA include substantial installation and maintenance costs, additional radiation exposure with image-based platforms, and increased operative times during the learning phase. Further high-quality studies with longer-term follow-up on functional outcomes, implant survivorship, complications, and cost-effectiveness are required before this technique is adopted into mainstream TKA practice.


Robotic total hip arthroplasty (THA) improves accuracy in achieving the planned acetabular cup positioning compared to conventional manual THA.

Robotic THA improves precision and reduces outliers in restoring the planned centre of hip rotation compared to conventional manual THA.

Improved accuracy in restoring hip biomechanics and acetabular cup positioning in robotic THA have not translated to any differences in early functional outcomes, correction of leg-length discrepancy, or postoperative complications compared to conventional manual THA.

Limitations of robotic THA include substantive installation costs, additional radiation exposure, steep learning curves for gaining surgical proficiency, and compatibility of the robotic technology with a limited number of implant designs.

Further higher quality studies are required to compare differences in conventional versus robotic THA in relation to long-term functional outcomes, implant survivorship, time to revision surgery, and cost-effectiveness.

**Keywords:** functional outcomes; hip biomechanics; implant positioning; robotics; total hip arthroplasty/replacement

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**Introduction**

The surgical treatment of symptomatic end-stage hip osteoarthritis has evolved over the last three hundred years from rudimentary excision surgery to modern robotic total hip arthroplasty (THA). Prior to the advent of modern anaesthesia, surgical treatment of hip osteoarthritis included proximal femoral resection or limb amputation.

Increasing functional demands of patients and developments in general anaesthesia led to the creation of interposition arthroplasty in which skin, fascia lata, or submucosa from porcine bladder were placed between the articulating surfaces of the hip joint. Further advancements in the understanding of hip anatomy and joint biomechanics led to partial arthroplasties of the femoral head or native acetabulum with alloys of chromium, cobalt, and molybdenum. These procedures were associated with high risk of failure owing to poor implant designs and suboptimal mechanical properties of the metal components. In 1971, Charnley revolutionized THA through the introduction of low-friction arthroplasty, and his subsequent developments of acrylic cement to fix implants to living bone and high-density polyethylene as a bearing material. Analysis of these implants, using revision of either component as the endpoint, found implant survivorship of 77–82% at 20 years follow-up, and led to many surgeons heralding THA as the ‘operation of the century’.

Since Charnley’s low-friction arthroplasty, there have been several further advancements in implant design and material for THA including cementless technology to promote bone ingrowth, modular femoral components to restore native hip kinematics, larger femoral heads to reduce impingement-related wear, and improvements in bearing surfaces such as highly cross-linked polyethylene and modern ceramics. Robotic technology is routinely used in general surgery, cardiothoracic surgery, gynaecology, and urology to improve surgical precision, reduce iatrogenic soft tissue injury, and enhance postoperative functional rehabilitation. Over the last decade, robotic THA has gained momentum as an avenue for reducing surgical error and improving the accuracy of implant positioning compared to conventional manual THA. Conceptually, improved accuracy of implant positioning and greater precision in restoring hip biomechanics with robotic THA will translate to further improvements in

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Conventional manual techniques for THA

Accurate implant positioning and restoration of native hip biomechanics are important surgeon-controlled factors that influence postoperative acetabular bone stock, abductor function, joint stability, soft tissue injury, impingement, bearing surface wear, and long-term implant survival. Conventional manual techniques for THA use radiographic templating, surgical alignment guides, and intraoperative landmarks such as the transverse acetabular ligament, acetabular notch, and anterior superior iliac spine with the sciatic notch to help guide acetabular reaming and implant positioning in THA. However, only 38–47% of acetabular components are within the desired safe ranges of anteversion and inclination using these manual handheld techniques, and low surgeon volume has been identified as a risk factor for errors in implant positioning. Patients with hip osteoarthritis and/or spinal deformities also often have abnormal spinopelvic alignment or sagittal imbalances, which lead to patient-specific changes in the relationship of the pelvis, femur, and spine with functional activities of daily living. Conventional preoperative two-dimensional (2D) templating of the pelvis with the patient in the standing position may therefore not account for patient-specific safe zones for implant positioning. Suboptimal implant positioning in THA leads to increased risk of hip instability, accelerated wear of the bearing surface, and reduced long-term implant survivorship.

Computer-navigated versus robotic THA

Computer-navigated THA refers to the use of computer systems that provide the operating surgeon with information on patient anatomy and implant position during surgery. This anatomical information may be obtained using preoperative CT scans (imaged-based navigation) or intraoperative mapping of osseous anatomical landmarks on a generic model of the pelvis (non-image-based navigation). Computer navigation provides patient-specific anatomical data with recommendations for bone resection and optimal implant positioning, but the computer system does not actively control or restrain the motor function of the operating surgeon. Robotic THA uses computer software to convert anatomical information into a virtual patient-specific three-dimensional (3D) reconstruction of the pelvis, which the operating surgeon uses to calculate and plan optimal implant positioning. An intraoperative robotic device helps to execute this preoperative patient-specific plan with a high level of accuracy. Depending on the degree of control that the robotic device provides the operating surgeon, robotic systems are classified as either fully active or semi-active assistants.

Fully active versus semi-active THA systems

Fully active robotic assistants work autonomously to execute the planned bone resection and implant position during THA. The surgeon oversees the surgical procedure and may activate an emergency shut-off switch if required. An example of a fully active robotic system is ROBOTOD (Curexo Technology Corporation, Fremont, California), which has been shown to improve the accuracy, alignment, and fit of the femoral stem during THA. Semi-active robotic systems enable the surgeon to maintain overall control over bone resection and implant positioning, but provide live intraoperative feedback to limit deviation from the preoperative surgical plan. The Mako Robotic Arm Interactive Orthopaedic System (Stryker Ltd, Kalamazoo, Michigan, USA) is an example of a semi-active robotic system used to perform robotic THA. Acetabular reaming is confined to a haptic tunnel with stereotactic boundaries and the robotic arm has tactile, audio, and visual feedback, which help the surgeon to control the force and direction of acetabular reaming to execute the preoperative plan with a high level of accuracy. Femoral osteotomy site and angle may also be marked prior to femoral bone resection and stem preparation, and live onscreen changes in bone coverage, implant position, offset, and leg length are checked prior to definitive implant selection and positioning.

Stages of robotic THA

Robotic THA uses four distinct stages for accurate execution of the patient-specific surgical plan. First, preoperative
CT scans of the pelvis and proximal femur are used to create a patient-specific virtual 3D model of the native hip anatomy. This model accounts for pelvic orientation in the axial, sagittal, and coronal planes, which enables accurate assessment and planning for restoration of hip biomechanics. Second, the surgeon uses this virtual 3D reconstruction to template the optimal implant positions and sizes for achieving the desired bone coverage, restoration of hip biomechanics, component version, component inclination, and leg-length correction. Computer software calculates the depth of acetabular bone resection, femoral osteotomy site and angle, and component positioning for accurate execution of this surgical plan. Third, the surgeon intraoperatively maps the osseous anatomy of the acetabulum and proximal femur to establish bone geometry and confirm pelvic position prior to bone resection (Fig. 1). Fourth, a robotic device is used to execute the planned bone resection and guide final implant positioning with live onscreen changes in bone coverage, implant inclination, implant version, offset, and leg-length correction displayed throughout the procedure (Figs. 2–5).

**Accuracy of implant positioning**

Data from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man has shown that instability is the leading complication in both primary and revision THA within the first after year of surgery. To minimize the risk of instability and its associated problems, many surgeons use predefined safe zones, such as those of Lewinnek et al (5°–25° anteversion, 30°–50° inclination) to guide acetabular cup positioning during THA. However, achieving implant positioning within these safe zones is challenging owing to intraoperative pelvic tilt, distorted anatomical landmarks, and limited accuracy and reproducibility of the alignment guides. Robotic THA uses intraoperative mapping of osseous landmarks with fixed femoral and acetabular registration pins to confirm hip anatomy and establish pelvic tilt, which helps to reduce manual subjective errors in achieving the planned implant positioning. El Bitar et al followed 61 patients undergoing robotic THA and reported overall mean acetabular cup inclination of 38.9° ± 3.2° and anteversion of 20.3° ± 2.8°.
Illgen et al. reviewed outcomes in 200 consecutive conventional manual THAs followed by 100 consecutive robotic THAs, and found robotic THA was associated with an additional 71% improvement in the accuracy of acetabular implant positioning compared with manual THA in the first year of use. Acetabular implant positioning within Lewinnek’s safe zones was achieved in 30% of the first 100 consecutive conventional THAs, 45% of the last 100 consecutive conventional THAs, and 77% in the first 100 consecutive robotic-arm-assisted THAs. Nawabi et al. showed manual THA was associated with root mean square error values that were five times higher for cup inclination and 3.4 times higher for cup anteversion compared to robotic THA.

### Accuracy of restoring hip biomechanics

Robotic THA uses the preoperative CT scan and virtual 3D reconstruction to calculate the optimal femoral and acetabular bone resection levels for accurate execution of the surgical plan. Semi-active robotic devices enable the femoral resection site to be marked prior to femoral osteotomy with a manual saw blade whilst fully active robotic devices autonomously resect at the planned femoral osteotomy level. Acetabular reaming is controlled by the robotic device to ensure the desired depth is reached for accurate restoration of the hip offset and centre of rotation. Adverse outcomes have been reported in THA in which the centre of rotation is shifted medially by more than 5 mm or superiorly by greater than 3 mm. Nawabi et al. conducted a cadaveric study in which six conventional manual THAs were performed on one side and six robotic THAs on the contralateral side. Robotic THA reduced root mean square error values in achieving both planned horizontal (1.5 mm vs. 2.0 mm respectively), anteroposterior (1.2 mm vs. 2.8 mm respectively) and vertical (1.9 mm vs. 2.2 mm respectively) centres of rotation compared to conventional THA. Tsai et al. reviewed radiological outcomes in 14 conventional THA versus 12 robotic THA, and found robotic technology improved the accuracy of achieving the planned vertical centre of rotation (0.7 mm ± 4.4 mm vs. 4.0 mm ± 4.7 mm respectively) compared to conventional manual THA. Nodzo et al. followed 20 patients undergoing robotic THA, and reported intraoperative robotic measurement of the hip centre of rotation had a mean mediolateral error of 1.0 mm ± 0.79 mm, anteroposterior error of 1.2 mm ± 0.8 mm, and superoinferior error of 1.6 mm ± 0.8 mm in planned acetabular component position compared to postoperative CT-measured values. The authors also showed that there was no significant difference in the postoperatively measured mean change in hip offset compared to the preoperatively planned mean change in hip offset (0.5 mm ± 3.0 mm vs. 1.4 mm ± 4.0 mm respectively).

Lewinnek’s safe zones provide the most commonly adopted range of angles for acceptable acetabular component positioning. Acetabular cup angles that stray
Factors correlated to malpositioned cups included minimally invasive surgical approach, low surgeon volume, and obesity (BMI > 30 Kg/m²). Esposito et al reviewed implant positioning in 147 patients that had dislocation within six months of primary THA, and found no differences in radiographic zones (± 5°, ± 10°, ± 15° boundaries) within the dislocated hips. The authors concluded that acetabular component position alone did not predict instability. More recently, patient-specific safe zones based on preoperative assessments of pelvic kinematics have gathered momentum as a route for improving stability and reducing complications in THA. Pierrepont et al assessed pelvic tilt in 1,517 patients undergoing THA in the supine, standing, and flexed-seated positions, and found mean pelvic tilt was 4.2° (range: −20.5° to 24.5°), −1.3° (range: −30.2° to 27.9°) and 0.6° (range: −42.0° to 41.3°) respectively in the three positions. Mean sagittal pelvic rotation from supine to standing was −5.5° (range: −21.8° to 8.4°), from supine to flexed seated was −3.7° (range: 48.3° to 38.6°) and from standing to flexed seated was 1.8° (range: −51.8° to 39.5°). Preoperative spinopelvic radiographs or CT scans to assess individualized pelvic kinematics during functional activities could help to determine patient-specific safe zones for implant positioning. Robotic technology may offer an avenue for executing implant positioning into these patient-specific safe zones with a high level of accuracy.

**Functional outcomes**

Improved accuracy of implant positioning and restoration of hip biomechanics in robotic THA has not translated to differences in short-term functional outcomes compared to conventional manual THA. Perets et al followed 162 patients with hip osteoarthritis undergoing robotic THA and reported reduced pain, increased patient satisfaction, and improved functional outcomes as assessed using the Harris Hip Score and Forgotten Joint Score at minimum two years follow-up. However, there was no control group undergoing conventional manual THA in this study. Siebel et al conducted a prospective randomized study on 36 robotic THAs versus 35 conventional manual THAs and found no difference in Harris Hip Scores between the two groups at an average of 18 months follow-up after surgery. The authors reported that Merle d’Aubigné and Postel scores and hip abductor function were better in the conventional THA group compared to the robotic THA group at an average of 18 months follow-up. Bukowski et al compared outcomes in 100 conventional THAs versus 100 robotic THAs and found improved University of California Los Angeles (UCLA) scores in the robotic group but no difference in Short-Form 12 Health Survey (SF-12), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, or postoperative complications at minimum one year after surgery. Banchetti et al retrospectively reviewed outcomes in 56 robotic-arm-assisted THAs and 51 conventional manual THAs, and found no difference in the pain score on the numerical rating scale, WOMAC score, Harris Hip Scores, or postoperative complications between the two treatment groups at minimum 24 months follow-up. Chen et al recently conducted a meta-analysis of 994 conventional manual THAs versus 522 robotic THAs and found no difference in functional outcomes, leg-length discrepancy, stress shielding, or rates of revision surgery between the two treatment techniques. Karunaratne et al performed a meta-analysis of patient-reported outcome measures using data from seven studies reporting on 755 THAs, and found no differences in the modified Harris Hip Score, Harris Hip Score or Mayo Clinical Hip Scores between conventional and robotic THA at short-term follow-up. At long-term follow-up, pooled estimates of function using the Merle d’Aubigné Score, and combined modified Harris Hip Score and Harris Hip Score showed no difference in outcomes between conventional and robotic THA, though the evidence levels of the studies used for analysis were classified as low-quality.
Limitations of robotic THA

Robotic THA is associated with substantive costs for installation of the robotic device, updating and servicing the computer software, and training the surgical team to become familiar with the new instruments and workflow. The robotic technology is also only compatible with a select number of implant designs from the manufacturer. There is a steep learning curve for the operating surgeon with additional operative times and surgical delays until surgical proficiency is reached. Preoperative CT scans for surgical planning are associated with additional radiation exposure and extra time is required for segmenting and templating with the 3D virtual reconstruction. Complications reported with robotic THA include injury to soft tissues of the abductor mechanism, heterotrophic ossification, milling defects in the femur, and technical issues such as robotic device dysfunction. Mechanical issues with the robotic device have led to conversion from fully active robotic THA to conventional manual THA in up to 18% of patients. Patients with advanced osteoarthritis also often have abnormal spino-pelvic alignment or sagittal imbalances through the arc of flexion, which creates patient-specific safe zones for optimal implant positioning. Robotic THA does not currently use dynamic preoperative imaging to assess the relationship of the pelvis, femur, and spine through these functional activities. However, if preoperative dynamic imaging were used to determine patient-specific safe zones for implant positioning then robotic technology could offer an avenue for executing this surgical plan with a high level of accuracy.

Conclusion

Robotic THA uses preoperative imaging to create a patient-specific surgical plan and an intraoperative robotic device to execute this plan with a high level of accuracy. Preliminary studies have shown that robotic technology improves the accuracy of acetabular cup positioning within Lewinnek’s safe zones and enables more precise restoration of the planned centre of hip rotation compared to conventional manual THA. However, improved radiological outcomes in robotic THA have not translated to differences in short-term functional outcomes, correction of leg-length discrepancy, or postoperative complications compared to conventional manual THA. Limitations of robotic THA include additional radiation exposure, substantive installation costs, and the lack of long-term data showing improved clinical outcomes or implant survival compared to manual techniques. The deficiency of long-term clinical and radiological data on robotic THA has restricted the uptake of this technology to routine arthroplasty practice. Robotic technology offers promise in the early stages but further studies reporting on long-term functional outcomes, implant survivorship, complications, and cost-effectiveness are required before this technique may be adopted into mainstream THA practice.

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All other authors declare no conflicts of interest.

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The learning curve of robotic-arm assisted acetabular cup positioning during total hip arthroplasty

Babar Kayani¹,², Sujith Konan¹,², Sumon S Huq¹,², Mazin S Ibrahim¹,², Atif Ayuob¹,², Fares S Haddad¹,²

Abstract
Background: Robotic-arm assisted surgery aims to reduce manual errors and improve the accuracy of implant positioning and orientation during total hip arthroplasty (THA). The objective of this study was to assess the surgical team’s learning curve for robotic-arm assisted acetabular cup positioning during THA.
Methods: This prospective cohort study included 100 patients with symptomatic hip osteoarthritis undergoing primary total THA performed by a single surgeon. This included 50 patients receiving conventional manual THA and 50 patients undergoing robotic-arm assisted acetabular cup positioning during THA. Independent observers recorded surrogate markers of the learning curve including operative times, confidence levels amongst the surgical team using the state-trait anxiety inventory (STAI) questionnaire, accuracy in restoring native hip biomechanics, acetabular cup positioning, leg-length discrepancy, and complications within 90 days of surgery.
Results: Cumulative summation (CUSUM) analysis revealed robotic-arm assisted acetabular cup positioning during THA was associated with a learning curve of 12 cases for achieving operative times (p < 0.001) and surgical team confidence levels (p < 0.001) comparable to conventional manual THA. There was no learning curve of robotic-arm assisted THA for accuracy of achieving the planned horizontal (p = 0.83) and vertical (p = 0.71) centres of rotation, combined offset (p = 0.67), cup inclination (p = 0.68), cup anteversion (p = 0.72), and correction of leg-length discrepancy (p = 0.61). There was no difference in postoperative complications between the two treatment groups.
Conclusions: Integration of robotic-arm assisted acetabular cup positioning during THA was associated with a learning curve of 12 cases for operative times and surgical team confidence levels but there was no learning curve effect for accuracy in restoring native hip biomechanics or achieving planned acetabular cup positioning and orientation.

Keywords
Biomechanics, cup position, learning curve, operating time, robotics, total hip replacement

Introduction
Accurate implant positioning and restoration of native hip biomechanics in total hip arthroplasty (THA) are important technical objectives that directly affect residual acetabular bone stock, abductor function, joint stability, soft tissue injury, impingement, bearing surface wear, and long-term implant survival.¹⁻⁵ However, recent studies have shown that acetabular cup positioning within the desired safe zones of cup inclination and anteversion is achieved in only 38–47% of conventional manual THAs.⁶⁻⁹ Robotic-arm assisted THA uses preoperative computerised tomography (CT) scans of the pelvis and proximal femur to create a virtual reconstruction of the patient’s native hip anatomy. The surgeon uses this 3-dimensional model to create a preoperative patient-specific surgical plan for bone resection and implant positioning. An intraoperative robotic device then helps to execute this plan with a high-level of accuracy. Preliminary studies have shown that
robotic THA improves accuracy of restoring native hip biomechanics and reduces outliers in acetabular cup positioning compared to conventional manual THA.\textsuperscript{10–14} Understanding the learning curve of this procedure is important for optimising theatre efficiency and ensuring its safe implementation into surgical practice.\textsuperscript{15–17}

Recent studies on the learning curve of robotic THA have found improved operative times and reduced outliers in acetabular cup positioning with increasing robotic THA experience.\textsuperscript{18,19} It is possible to improve on these existing studies by assessing a more comprehensive and robust range of learning outcome measures including operative times of individual stages of the procedure, surgical team confidence levels, accuracy in restoring native hip biomechanics, correction of leg-length discrepancy, and postoperative complications. Furthermore, cumulative summation (CUSUM) analyses may be used to assess incremental changes in study outcomes during the progression of the learning curve and these outcome measures compared to the surgeon’s baseline values from conventional manual THA. This analytical technique will provide more accurate inflexion points at which the surgeon transitions from the learning phase to the proficiency phase of robotic THA.\textsuperscript{20–22}

The objective of this study was to assess the surgical team’s learning curve for robotic-arm assisted acetabular cup positioning during THA through analysis of operative times, surgical team confidence levels, accuracy in restoring native hip biomechanics, acetabular cup positioning, correction of leg-length discrepancy, and postoperative complications. The hypothesis was that cumulative experience with robotic-arm assisted THA would reduce operative times and improve surgical team confidence levels but there would be no learning curve effect for accuracy of restoring planned hip biomechanics and acetabular cup positioning.

\section*{Methods}

\textbf{Patient selection}

This study included 100 patients with symptomatic hip osteoarthritis undergoing primary THA between September 2016 and August 2018. This included 50 patients undergoing conventional manual THA and 50 patients receiving robotic-arm assisted acetabular cup positioning during THA (robotic-arm assisted THA). Patients were allocated to their respective treatment groups based on availability of the robotic device within the hospital on the day of surgery. The robotic device is routinely used for unicondylar and total knee arthroplasty at the treatment centre and was therefore not available for all THA procedures. No other preoperative clinical or radiological data were used for patient allocation to the treatment groups. All operative procedures were performed by the senior author (FSH) who had extensive experience with conventional manual THA and previous cadaveric training with robotic-arm assisted THA. The robotic-arm assisted THA group was the first cohort of patients undergoing robotic THA by the operating surgeon. All surgical procedures were performed using the posterior approach in the lateral decubitus position. Informed consent was obtained from all study patients. Institutional review board approval was obtained prior to commencement of the study.

\section*{Inclusion criteria}

Inclusion criteria for this study included the following: diagnosis of primary osteoarthritis or osteoarthritis secondary to osteonecrosis or rheumatoid arthritis; patients undergoing primary THA; patients between 18–80 years of age; and patients judged suitable for the planned study implants. Exclusion criteria included the following: patients in which the planned hip biomechanics were in a different position to the contralateral side (e.g. developmental dysplasia of the hip or protrusio acetabuli); patients requiring revision surgery following previously failed THA; patients that were immobile or had another neurological condition affecting musculoskeletal function; and patients not suitable for the planned study implants (e.g. patient required dual-mobility cup or cemented implants). Patients undergoing conventional manual THA and robotic-arm assisted THA were not preoperatively matched but had comparable baseline demographic characteristics (Table 1).

\section*{Preoperative imaging and templating}

The operating surgeon performed preoperative templating on all study patients using standing plain anteroposterior pelvic radiographs with Traumacad software (Traumacad, Petach-Tikva, Israel). Patients in both treatment groups also had preoperative CT scans of the pelvis and proximal femur to create patient-specific CAD models to guide implant positioning using the MakoPlasty total hip application system (Mako surgical corporation, Kalamazoo, MI, USA). Preoperative templating was performed to restore the native centre of rotation and combined offset to that of the contralateral side. Planned acetabular cup position was 40° inclination and 20° anteversion in both treatment groups. In all study patients, preoperative templating was performed to fully correct for any pre-existing leg-length discrepancy.

\section*{Surgical technique}

Conventional manual THA was performed using the standard handheld reaming technique with manual implantation of the acetabular cup. The transverse acetabular ligament, anterior and posterior acetabular walls, and anterior superior iliac spine were used as fixed intraoperative anatomical landmarks to help guide position of the acetabular component. An external alignment guide was attached to
the cutting-edge reamer handle to achieve cup position with 40 degrees inclination and 20 degrees anteversion. Robotic-arm assisted THA was undertaken with the RIO robotic arm interactive orthopaedic system using the Mako robotic hip system (Mako surgical, Kalamazoo, MI, USA) to guide acetabular bone reaming and acetabular cup positioning based on the preoperative surgical plan. An electrocardiogram (ECG) lead over the inferior pole of the patella was used as a fixed reference point to display live on-screen changes in leg-length. These measurements guided intraoperative adjustments to bone resection, implant position, and implant size to achieve the desired leg-length correction. Patients in both treatment groups received the Accolade II femoral stem (Stryker, Mahwah, NJ, USA) and trident acetabular shell (Stryker, Mahwah, NJ, USA). In both treatment groups, the femur was prepared manually. Hip stability was tested through the full range of movement and leg-length discrepancy confirmed clinically before selection and insertion of final femoral stem and head sizes. Intraoperative image intensifier was not used in any study patients.

**Outcome measures**

All study outcomes were recorded by two independent fellowship-trained surgeons that were blinded to each other’s findings. Total operative times were collected in both treatment groups and individual stages of the robotic procedure in the robotic-arm assisted THA group. Preoperative confidence levels amongst the surgical team were recorded using the Spielberger State-Trait Anxiety Inventory (STAI) questionnaire, which is a validated subjective assessment tool for quantifying an individual’s stress levels with individual traits arising from the clinical environment. The STAI questionnaire has previously been used to assess the learning curves of robotic-arm assisted total knee and unicompartmental knee arthroplasty. This questionnaire was completed by each member of the surgical team prior to the surgical time-out in all study patients. The surgical team included the operating surgeon, two consultant anaesthetists, two senior scrub nurses, one operating department practitioner (ODP), and one circulating nurse.

Radiological outcomes were recorded using standing anteroposterior pelvic radiographs at 6 weeks after surgery. Measurements were recorded twice by each observer at 28 days apart to assess for intra-observer agreement. All root mean square error values were assessed by calculating the difference in the achieved radiological outcome measure on the postoperative pelvic radiograph versus the planned radiological outcome measure on the preoperative pelvic radiographic template. Accuracy of achieving the planned centres of horizontal and vertical rotation were assessed using the method described by Meermans et al. Acetabular cup inclination and version were calculated using the method described by Murray. Combined offset was calculated by summating the value of the acetabular offset and femoral offset as described by Fletcher et al. Leg-length discrepancy was calculated using the technique described by Woolson et al. Lewinnek’s safe zones were defined as 30–50° inclination and 5–25° anteversion, and Callanan’s safe zones defined as 30–45° inclination and 5–25° anteversion. Accuracy of the Traumacad system for measuring radiological parameters has previously been reported. Complications within 90 days following surgery were recorded.

**Power calculation**

A sample size calculation was performed using operative time as the primary outcome measure. Using an effect size of 0.6 based on previously published data on operative times in conventional THA versus robotic-arm assisted THA, this study required 90 patients (45 patients in each

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Table 1. Baseline demographic characteristics in patients undergoing conventional manual THA versus robotic-arm assisted acetabular cup positioning during THA.

<table>
<thead>
<tr>
<th></th>
<th>Conventional manual THA (n = 50)</th>
<th>Robotic THA (n = 50)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>68.5 ± 5.4</td>
<td>67.1 ± 5.3</td>
<td>0.23^a</td>
</tr>
<tr>
<td>Gender (male/female)</td>
<td>Male – 25 (50%)</td>
<td>Male – 23 (46%)</td>
<td>0.82^a</td>
</tr>
<tr>
<td>Female – 25 (50%)</td>
<td>Female – 27 (54%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laterality (right/left)</td>
<td>Right – 27 (54%)</td>
<td>Right – 26 (52%)</td>
<td>0.34^a</td>
</tr>
<tr>
<td>Left – 23 (46%)</td>
<td>Left – 24 (48%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body mass index (kg/m^2)</td>
<td>26.1 ± 2.7</td>
<td>25.8 ± 2.2</td>
<td>0.74^a</td>
</tr>
<tr>
<td>ASA score (I–IV)</td>
<td>I – 0</td>
<td>I – 0</td>
<td>0.30^a</td>
</tr>
<tr>
<td>II – 40 (80%)</td>
<td>II – 42 (84%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>III – 10 (20%)</td>
<td>III – 8 (16%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Summary statistics are: mean ± standard deviation or number (percentage).

^aIndependent t-test.

^bChi-squared test.
treatment arm) to detect a significant difference in operative time using a two-tailed, two-sample t-tests with a power of 80% and alpha value of 5%. To account for 10% sample size attrition at 90 days follow-up, 100 patients were recruited into this study.

Statistical analysis
The CUSUM sequential analysis tool was used to assess learning curves in robotic-arm assisted THA for operative times and surgical team confidence levels with standardised target values for these outcome measures from the conventional THA group. Accuracy of restoring native hip biomechanics and achieving planned acetabular cup positioning in robotic-arm assisted THA were assessed by calculating root mean square error values in consecutive groups of ten patients. Categorical data was compared using the chi square test and Fisher’s exact test. Normally distributed continuous variables were compared using independent t-tests for unpaired variables and paired t-test for matched (paired) variables. Multiple variables were assessed using one-way ANOVA and Kruskal–Wallis tests. The Mann–Whitney test was used for non-parametric data. Statistical significance was set at $p < 0.05$ for all statistical tests. All statistical analyses were performed using SPSS software version 21 (SPSS Inc., Chicago, IL, USA).

Results

Interclass correlation coefficient
Interclass correlation coefficient was 0.85 (95% CI, 0.82–0.91) for intra-observer agreement and 0.87 (95% CI, 0.84–0.92) for inter-observer agreement in all study outcomes, which indicated good agreement on all parameters assessed by the two independent observers.

Operative times
CUSUM analysis for operative times in robotic-arm assisted THA revealed an inflexion point after the initial 12 cases, which helped to identify two distinct phases in the learning curve (Figure 1). Phase 1 represents the initial learning stage and Phase 2 represents the proficiency stage with robotic-arm assisted THA. Analysis of individual phases in the robotic group showed most marked decreases in time for surgical tray, robotic device, and instrument setup ($<0.001$), bone registration ($<0.001$), and acetabular reaming ($<0.001$) (Table 2). Overall, robotic-arm assisted THA was not associated with increased operative times compared to conventional manual THA ($p = 0.14$) (Table 3).

Surgical team confidence levels
Preoperative confidence levels as assessed using the STAI questionnaire revealed an inflexion point after the initial

Figure 1. Charts displaying cumulative summation (CUSUM) analysis for operative times in all study patients undergoing (Continued)
Figure 1. (Continued)

Robotic-arm assisted during THA. (a) Chart plotting CUSUM analysis for operative times in consecutive robotic-arm assisted THA procedures. The dashed line represents the division between the learning phase (Phase 1, n = 12) and proficiency phase (Phase 2, n = 38) of the learning curve associated with robotic-arm assisted THA. (b) Chart plotting CUSUM analysis for cases within Phase 1 of the learning curve in robotic-arm assisted THA. (c) Chart plotting CUSUM analysis for cases within Phase 2 of the learning curve with robotic-arm assisted THA.

12 cases p < 0.001) in a pattern similar to operative times in robotic-arm assisted THA (Figure 2). There was no difference in the overall STAI scores amongst team members between conventional manual THA and robotic-arm assisted THA (Table 3).

Implant positioning and orientation

Robotic-arm assisted THA did not have a learning curve for accuracy in achieving the planned hip biomechanics, acetabular cup positioning and orientation, and correction of leg-length discrepancy (Table 4). Patient number 21 in the robotic group had acetabular cup positioning outside of Lewinnek’s safe zone, and patients number 12 and 21 had acetabular cup positioning outside of Callanan’s safe zones. No other outliers were identified in the robotic-arm assisted THA group. Robotic-arm assisted THA improved accuracy in restoration of native hip biomechanics, acetabular cup position, and acetabular cup orientation compared to conventional manual THA (Table 3).

Complications

No complications were reported in either treatment group within 90 days of follow-up.

Discussion

Robotic-arm assisted acetabular cup positioning during THA was associated with a learning curve of 12 cases for achieving operative times and surgical team confidence levels comparable to conventional manual THA. There was no learning curve effect for achieving the planned centre of rotation, combined offset, acetabular cup position and orientation, and correction of limb-length discrepancy.

Operative time is commonly used as a surrogate marker of surgical proficiency. Total operative time decreased with consecutive robotic cases during the initial learning phase as the surgical team became increasing familiar with individual stages of robotic-arm assisted THA and accustomed to the new instrumentation. Most marked improvements were observed in time for acetabular bone resection during the learning phase, which reflects the surgeon becoming progressively more adept with fine movements of the robotic arm and inbuilt audio, visual, and tactile inhibitory feedback. As the surgeon became more practiced with the robotic arm, he was able to better adjust the force and direction of the remaining process to ensure more controlled and efficient acetabular bone resection. More moderate time improvements were observed in bone registration. The acetabular landmarks for bone registration and verification are standardised and therefore with increasing surgical experience, the surgeon was able to predict and proactively position the bovie tip over the appropriate anatomical landmark before it was displayed on the computer screen.

Our findings support existing data showing that operative times in robotic-arm assisted THA decrease with cumulative experience. Redmond et al.16 conducted a prospective study on the learning curve of robotic-arm assisted THA by comparing outcomes in three consecutive groups of 35 patients. The authors reported that the mean

Table 2. Operative data in patients undergoing robotic-arm assisted total hip arthroplasty.

<table>
<thead>
<tr>
<th>Operative stage (mins)</th>
<th>Cases 1–10</th>
<th>Cases 11–20</th>
<th>Cases 21–30</th>
<th>Cases 31–40</th>
<th>Cases 41–50</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical tray, robotic device, and instrument set up</td>
<td>22.9 ± 7.4</td>
<td>12.4 ± 4.0</td>
<td>9.4 ± 3.6</td>
<td>10.1 ± 3.8</td>
<td>9.7 ± 3.9</td>
<td>&lt;0.001²</td>
</tr>
<tr>
<td>Surgical approach/pin insertion</td>
<td>6.6 ± 1.4</td>
<td>6.2 ± 1.0</td>
<td>6.4 ± 1.1</td>
<td>6.8 ± 1.2</td>
<td>6.7 ± 1.5</td>
<td>0.61³</td>
</tr>
<tr>
<td>Bone registration</td>
<td>17.1 ± 4.8</td>
<td>8.2 ± 2.7</td>
<td>6.1 ± 1.4</td>
<td>7.1 ± 1.3</td>
<td>6.7 ± 1.7</td>
<td>&lt;0.001β</td>
</tr>
<tr>
<td>Assess hip biomechanics, leg-length, and perform femoral osteotomy</td>
<td>7.2 ± 3.5</td>
<td>6.9 ± 3.3</td>
<td>6.7 ± 3.1</td>
<td>6.6 ± 3.4</td>
<td>7.2 ± 3.1</td>
<td>0.13²</td>
</tr>
<tr>
<td>Acetabular reaming</td>
<td>14.3 ± 3.9</td>
<td>7.7 ± 2.1</td>
<td>5.8 ± 1.0</td>
<td>5.7 ± 0.8</td>
<td>6.1 ± 1.0</td>
<td>&lt;0.001β</td>
</tr>
<tr>
<td>Femoral stem preparation</td>
<td>6.2 ± 2.1</td>
<td>5.4 ± 2.5</td>
<td>7.1 ± 3.2</td>
<td>6.2 ± 2.1</td>
<td>7.3 ± 2.3</td>
<td>0.56⁵</td>
</tr>
<tr>
<td>Implant Trialling</td>
<td>7.2 ± 3.6</td>
<td>6.9 ± 3.5</td>
<td>7.3 ± 3.4</td>
<td>7.2 ± 3.7</td>
<td>6.9 ± 3.2</td>
<td>0.67⁵</td>
</tr>
<tr>
<td>Implant Trialling</td>
<td>7.4 ± 1.4</td>
<td>8.1 ± 0.7</td>
<td>7.7 ± 0.9</td>
<td>6.9 ± 0.6</td>
<td>7.3 ± 1.9</td>
<td>0.41⁶</td>
</tr>
<tr>
<td>Closure</td>
<td>6.7 ± 0.8</td>
<td>8.1 ± 1.2</td>
<td>8.4 ± 1.4</td>
<td>7.9 ± 0.9</td>
<td>8.2 ± 1.2</td>
<td>0.67⁶</td>
</tr>
<tr>
<td>Overall operating time</td>
<td>72.7 ± 6.4</td>
<td>57.5 ± 3.7</td>
<td>55.7 ± 2.8</td>
<td>54.4 ± 5.1</td>
<td>54.9 ± 2.9</td>
<td>&lt;0.001β</td>
</tr>
</tbody>
</table>

Summary statistics are: Mean value and standard deviation. P-value for trend.

¹one-way analysis of variance (ANOVA) test.
²one-way analysis of variance (ANOVA) test with Welch test.
³Kruskall–Wallace test.
⁴Kruskall–Wallace test.
operative time in the first robotic cohort was 79.8 ± 27 minutes, compared to 63.2 ± 14.2 minutes and 69.4 ± 16.3 minutes respectively in the last two robotic cohorts (p = 0.02). In our study, CUSUM analysis enabled more accurate assessment of transition from the learning phase to the proficiency phase, and the accumulative robotic experience required for the surgeon to become “time even” to conventional THA. However, this finding should be interpreted with caution as robotic-arm assisted THA was performed using the express workflow system in which the robotic device does not help to execute the planned femoral osteotomy or femoral stem preparation. The enhanced workflow may also further influence accuracy of restoring the native centre of rotation and combined offset in the robotic-arm asssisted THA group.

Increased levels of stress and mental strain during surgery are associated with diminished operative performance, poor decision making, and reduced technical skills. In this study, improvements in the surgical team’s confidence levels during the initial learning phase followed a similar trend to operative times. This was associated with objective improvements in time for set-up of the robotic device, fixed arrays, and surgical instruments during

Table 3. Study outcomes in patients undergoing conventional manual total hip arthroplasty (THA) versus robotic-arm assisted THA.

<table>
<thead>
<tr>
<th></th>
<th>Conventional manual THA (n = 50)</th>
<th>Robotic THA (n = 50)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horizontal centre of rotation (mm) RMSE</td>
<td>3.7 ± 1.7</td>
<td>1.7 ± 1.2</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Vertical centre of rotation (mm) RMSE</td>
<td>2.2 ± 0.9</td>
<td>0.8 ± 0.8</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Combined offset (mm) RMSE</td>
<td>2.6 ± 0.9</td>
<td>1.6 ± 1.1</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Cup inclination</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Within Lewinnek’s safe zone</td>
<td>40 (80%)</td>
<td>49 (98%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>– Within Callanan’s safe zone</td>
<td>38 (76%)</td>
<td>48 (96%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Cup Anteversion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Within Lewinnek’s safe zone</td>
<td>44 (88%)</td>
<td>50 (100%)</td>
<td>0.03*</td>
</tr>
<tr>
<td>– Within Callanan’s safe zone</td>
<td>44 (88%)</td>
<td>50 (100%)</td>
<td>0.02*</td>
</tr>
<tr>
<td>Overall cup position</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Within Lewinnek’s safe zone</td>
<td>34 (68%)</td>
<td>49 (98%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>– Within Callanan’s safe zone</td>
<td>32 (64%)</td>
<td>48 (96%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Leg-length discrepancy (mm) RMSE</td>
<td>2.6 ± 3.1</td>
<td>1.4 ± 1.2</td>
<td>0.23*</td>
</tr>
<tr>
<td>Operative time (mins)</td>
<td>54.7 ± 2.6</td>
<td>59.0 ± 4.2</td>
<td>0.14*</td>
</tr>
<tr>
<td>STAI scores</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Operating surgeon</td>
<td>12.6 ± 1.8</td>
<td>13.1 ± 3.2</td>
<td>0.45*</td>
</tr>
<tr>
<td>– Consultant anaesthetist</td>
<td>11.2 ± 2.1</td>
<td>11.6 ± 3.1</td>
<td>0.68*</td>
</tr>
<tr>
<td>– Scrub nurse</td>
<td>10.5 ± 1.5</td>
<td>10.7 ± 2.4</td>
<td>0.41*</td>
</tr>
<tr>
<td>– ODP</td>
<td>9.2 ± 1.1</td>
<td>9.9 ± 2.6</td>
<td>0.26*</td>
</tr>
<tr>
<td>– Circulating nurse</td>
<td>12.0 ± 1.9</td>
<td>11.0 ± 2.8</td>
<td>0.30*</td>
</tr>
</tbody>
</table>

RMSE, Root mean square error; STAI, State-trait anxiety inventory score (6-24); ODP, Operating department practitioner.

Summary statistics are: mean ± standard deviation or number (percentage). Lewinnek’s safe zone - inclination 30–50°; anteversion 5–25°; Callanan’s safe zone - Inclination 30–45°; anteversion 5–25°.7

*Independent t-test.
*Chi-squared test.
*Kruskall–Wallace test.
*Mann–Whitney test.
Paired t-test.

Figure 2. Chart displaying CUSUM analysis for STAI scores amongst surgical team members in all robotic-arm assisted THA procedures.
this learning phase. The highest STAI score was observed in the operating surgeon but this did not translate to any differences in accuracy of implant positioning or restoration of native hip biomechanics. Robotic-arm assisted THA is undertaken with the assistance of a trained robotic technician that aids preoperative surgical planning, facilitates intraoperative data capture, physical movement of the robotic device around the operating room, and advises on optimal bone resection and implant positioning. The level of training and experience of this robotic technician may also influence the surgical team’s learning curve.

There was no learning curve effect for achieving the planned centre of rotation and combined offset in patients undergoing robotic-arm assisted THA, which enabled accurate restoration of native hip biomechanics during both learning and proficiency phases. Robotic-arm assisted THA uses stereotactic boundaries to control acetabular reaming within the predefined haptic tunnel, which helps to reduce technical errors in the direction and depth of acetabular bone reaming. Nawabi et al. performed a cadaveric study with 12 conventional manual THAs on one side and 12 robotic THAs on the contralateral side, and found reduced root mean square errors in achieving the planned horizontal and vertical centres of rotation in the robotic group. The root mean square error values for accuracy in restoring the native centre of hip rotations in conventional and robotic THA were similar to those reported in this study. Although, robotic THA improves accuracy of implant positioning and reduces outliers in acetabular cup positioning, there remains a paucity of data on how these improved radiological outcomes translate to differences in clinical recovery, functional outcomes, implant survivorship, and long-term complications compared to conventional manual THA. Robotic THA has substantial installation costs for the robotic device and compatible implants, and image-guided robotic THA requires additional preoperative radiation exposure.

Hip instability and mechanical loosening secondary to suboptimal implant positioning are the most common reasons for revision THA. Robotic-arm assisted THA uses computer software to assess the patient’s pelvic tilt in the supine position during CT scan, and then guides acetabular cup positioning based on the functional (coronal) plane of Murray instead of the anatomical plane. Intraoperative bone registration also enables the surgeon to intraoperatively confirm the acetabular bony anatomy of the CT scan prior to acetabular reaming and cup positioning. These factors may have helped to limit surgical errors in acetabular cup positioning during the initial learning phase, and improve the overall accuracy of cup positioning within the safe zones compared to the manual THA group. Our findings are consistent with Domb et al. who found that cup positioning within Lewinnek’s safe zone was achieved in 50/50 (100%) robotic THAs compared to 40/50 (80%) conventional THAs (p = 0.001). The authors also reported that cup positioning within Callanan’s safe zone was achieved in 46/50 (92%) robotic THAs but only 31/50 (62%) conventional THAs (p = 0.001).

The findings of this study will enable healthcare professionals to better understand the impact of implementing robotic-arm assisted acetabular cup positioning during THA on the surgical workflow. Theatre planning and scheduling of operative cases should consider increased operative times and heightened levels of anxiety amongst the surgical team during this initial learning phase. As team members become more familiar and adept with robotic technology, confidence levels improve, and theatre efficiency increases thereafter. There is no effect of cumulative experience with robotic-arm assisted acetabular cup positioning during THA on accuracy of restoring native hip biomechanics, acetabular cup positioning, and acetabular cup orientation, which are important for the safe implementation of this procedure into routine surgical practice.

There are several limitations of the study design that must be appreciated when interpreting the findings of this study. First, this study was undertaken on a single surgeon within a surgical team that was experienced with conventional and computer navigated THA in a high-volume arthroplasty centre. The learning curve may therefore not be directly transferable to other surgeons or surgical teams with less experience. However, this study design did enable us to better understand how cumulative robotic experience in a
single surgical team impacts operative times, confidence levels, and accuracy of implant positioning. Second, radiological analysis of implant positioning was undertaken using plain radiographs, which are not as accurate as CT scan. Third, patient allocation using randomisation instead of availability of the robotic device would have helped to better reduce any potential confounding or bias in the study. Fourth, follow-up time was limited to 90 days after surgery and therefore long-term data on functional outcomes, implant survivorship and revision rates was not available.

Conclusion

Implementation of robotic-arm assisted acetabular cup positioning during THA was associated with a learning curve of 12 cases for operative times and surgical team confidence but there was no learning effect for accuracy in restoring native hip centre of rotation, preservation of combined offset, acetabular cup position and orientation, and correction of leg-length discrepancy. There was no difference in postoperative complications between conventional manual THA and robotic-arm assisted acetabular cup positioning during THA within 90 days follow-up.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: FSH: is a paid consultant and receives royalties from Stryker, Smith & Nephew, Corin, and Matortho.

All other authors declare that there is no conflict of interest.

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References


A prospective double-blinded randomised control trial comparing robotic arm-assisted functionally aligned total knee arthroplasty versus robotic arm-assisted mechanically aligned total knee arthroplasty

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**Abstract**

**Background:** Total knee arthroplasty (TKA) with mechanical alignment (MA) aims to achieve neutral limb alignment in all patients, whereas TKA with functional alignment (FA) aims to restore native, patient-specific anatomy and knee kinematics by manipulating bone resections and fine-tuning implant positioning. The objective of this study is to determine the optimal alignment technique in TKA by comparing patient satisfaction, functional outcomes, implant survivorship, complications, and cost-effectiveness in MA TKA versus FA TKA. Robotic technology will be used to execute the planned implant positioning and limb alignment with high-levels of accuracy in all study patients.

**Methods and analysis:** This prospective double-blinded randomised control trial will include 100 patients with symptomatic knee osteoarthritis undergoing primary robotic arm-assisted TKA. Following informed consent, patients will be randomised to MA TKA (the control group) or FA TKA (the investigation group) at a ratio of 1:1 using an online random number generator. Blinded observers will review patients at regular intervals for 2 years after surgery to record predefined study outcomes relating to postoperative rehabilitation, clinical progress, functional outcomes, accuracy of implant positioning and limb alignment, gait, implant stability, cost-effectiveness, and complications. A superiority study design will be used to evaluate whether FA TKA provides superior outcomes compared to MA TKA. Primary and secondary objectives will be used to quantify and draw inferences on differences in the efficacy of treatment between the two groups. Intention-to-treat and per-protocol population analysis will be undertaken. The following statistical methods will be employed to analyse the data: descriptive statistics, independent t test, paired t test, analysis of variance, Fisher exact test, chi-square test, and graphical displays. Ethical approval was obtained from the London-Surrey Research Ethics Committee, UK. The study is sponsored by University College London, UK.

**Discussion:** This is the first study to describe the use of robotic technology to achieve FA TKA, and the only existing clinical trial comparing robotic MA TKA versus robotic FA TKA. The findings of this study will enable an improved understanding of the optimal alignment technique in TKA for achieving high-levels of patient satisfaction, improving functional outcomes, increasing implant survivorship, improving cost-effectiveness, and reducing complications.

**Registration:** Clinical Trials.gov, NCT04092153. Registered on 17 September 2019.
Background

Total knee arthroplasty (TKA) is an established and highly effective treatment for patients with symptomatic end-stage knee osteoarthritis. The procedure is performed in over 90,000 patients per year in the UK [1]. Middle- to long-term follow-up studies have shown good clinical outcomes following TKA [20, 22, 39], and the 10-year revision rate for cemented, unconstrained, fixed bearing TKA is 3% [1]. Despite these results, there is a higher incidence of patient dissatisfaction compared to total hip arthroplasty, with up to 20% of patients reporting dissatisfaction in an otherwise uncomplicated TKA [5, 9, 10, 35]. The exact aetiology of this is not clear but recent studies have shown one possible reason to be suboptimal limb alignment, which may adversely affect postoperative knee biomechanics and kinematic function [4, 7, 9–11, 35, 44]. Conceptually, an improved understanding and execution of the optimal alignment in TKA may help to increase patient satisfaction, improve functional outcomes and reduce long-term complications.

Total knee arthroplasty with mechanical alignment (MA) aims to achieve neutral alignment of the limb. This is achieved by placing implants perpendicular to the mechanical axis of the femur and tibia, and externally rotating the femoral component to obtain a rectangular, balanced flexion-extension gap, which also aids patella tracking [11]. Measured bone resections or gap balancing techniques with controlled periarticular soft tissue releases help to achieve balanced flexion-extension gaps and restore equal mediolateral soft tissue tension. The principle of neutral mechanical alignment is to distribute load evenly across the implants, which provides a mechanical advantage in flexion and limits asymmetrical bearing surface wear [44]. However, recent studies have shown that there are large variations in native knee anatomy with only 5–5.5% of the general population having natural neutral mechanical alignment [4, 6]. Therefore, in the large majority of patients undergoing MA TKA, the knee is forced into an unnatural position with resultant changes in knee biomechanics that alter the native femoral flexion axis, ligament tension, quadriceps function, patella tracking and overall knee kinematics [4, 6, 17, 18].

Total knee arthroplasty with functional alignment (FA) aims to restore joint line height, preserve native obliquity, and achieve balanced flexion-extension gaps with equal mediolateral soft tissue tension by manipulating bone resections and fine-tuning implant positioning. Conceptually, FA TKA reduces the need for intraoperative periarticular soft tissue releases while restoring the patient’s native pre-arthritic knee kinematics. This technique is a modification of TKA with kinematic alignment, in which bone resections and implant positioning are undertaken to restore the patient’s natural distal and femoral joint lines, tibial joint line and limb alignment. Patient-specific implants, computer navigation and three-dimensional printed cutting blocks have been used to help achieve kinematic alignment in TKA. Studies have demonstrated that TKA with kinematic alignment reproduces more natural knee kinematics including medial pivot movement and femoral rollback compared to MA TKA [14, 34, 15, 26, 29]. Preserving patient-specific alignment and knee kinematics in TKA with kinematic alignment may also decrease the risk of common peroneal nerve palsy, which is associated with forcing the limb into neutral alignment with extensive bone resections and periarticular releases in MA TKA [23, 25]. Early clinical and functional outcome studies have reported promising outcomes in TKA with kinematic alignment [14, 27, 28], but results of longer-term studies have yet to be published.

There is no uniform consensus on the optimal alignment technique for TKA [8, 12, 16, 19, 30, 33, 36–38, 41]. Some studies have shown improved clinical outcomes with TKA with kinematic alignment compared to MA TKA at short-term follow-up, while other systematic reviews and meta-analyses have shown no difference in outcomes between the two alignment techniques [14, 27, 28, 34, 44]. The main limitations of these existing studies are that different implant designs were used within each treatment group, manually positioned cutting blocks with poor reproducibility were used to achieve the planned limb alignment, intraoperative limb alignment was not assessed, and limited data on functional outcomes or implant survivorship were reported. It is possible to improve on these existing studies by assessing a more comprehensive range of validated clinical and functional outcome measures, blinding both patients and observers recording outcomes, and using radiostereometric analysis (RSA) to assess implant micromotion for long-term implant survivorship [32, 42, 43]. Importantly, FA TKA offers an avenue for achieving patient-specific kinematics with balanced flexion-extension gaps and equal mediolateral soft tissue tension by manipulating bone resections and fine-tuning implant positioning, while limiting the need for periarticular soft tissue releases. Robotic technology also offers an avenue for executing the planned MA TKA or FA TKA with greater accuracy and reduced outliers. The findings of this study will enable an improved understanding of the optimal alignment technique in TKA for achieving high levels of patient satisfaction, improving functional outcomes, increasing implant survivorship, improving cost-effectiveness and reducing complications.

Methods/design

Objectives

The primary objective of this study is to compare the total Western Ontario and McMaster Universities Arthritis Index (WOMAC) score in MA TKA versus FA TKA at 2
years after surgery. As FA TKA enables improved restoration of native, patient-specific knee kinematics [15, 26, 29], the study hypothesis is that total WOMAC scores will be superior in patients undergoing FA TKA compared to MA TKA at 2 years follow-up.

The secondary objectives are to compare the following outcomes between the two treatment groups:

1. Accuracy of implant positioning and limb alignment
2. Surgical efficiency
3. Postoperative functional rehabilitation
4. Functional outcomes
5. Quality of life
6. Implant migration
7. Gait
8. Resource use and cost-effectiveness
9. Complications

Trial design
This study is a prospective, single-centre, double-blinded, randomised control trial. The study will be undertaken in the Department of Trauma and Orthopaedics, University College Hospital, London, UK. The study will include 100 patients randomly allocated to either MA TKA (the control group) or FA TKA (the investigation group). All patients will undergo robotic arm-assisted TKA to improve the accuracy of achieving the planned implant positioning and limb alignment. The study commenced patient recruitment in December 2018 and is expected to complete patient recruitment in December 2020. All patients will be followed up for 2 years after surgery and therefore the anticipated completion date for the study is December 2022. The study is sponsored by University College London, UK. The patient enrolment flowchart is presented in Fig. 1. The schedule of enrolment, interventions, and assessments for all study patients is shown in Fig. 2. This study follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (Additional file 1).

Eligibility criteria
The inclusion criteria for this study are as follows: 1) the participant has symptomatic knee osteoarthritis requiring primary TKA; 2) the participant is fit for surgical intervention following a review by the surgeon and anesthetist; 3) the participant is aged between 18 and 80 years at the time of surgery; 4) the participant is able to give informed consent and agrees to comply with the postoperative review programme; and 5) the participant has sufficient mobility to attend follow-up clinics. The exclusion criteria for this study are as follows: 1) the participant is undergoing revision surgery or second-stage TKA; 2) the participant is not suitable for study implants (e.g. requires a constrained prosthesis); 3) the participant is immobile or has another neurological condition affecting musculoskeletal function; 4) the participant is already enrolled on another concurrent clinical trial; 5) the participant is unable or unwilling to sign the informed consent form specific to this study; and 6) the participant is unable to attend the study follow-up programme.

Recruitment
Participants will be recruited from the orthopaedic outpatient clinic at University College Hospital, London, UK. All patients will be screened by the clinical team (orthopaedic consultant surgeon, clinical research fellow, and orthopaedic registrar) for study participation based on the predefined inclusion and exclusion criteria listed above. Patients that fulfil the eligibility criteria and express an interest in participating in the study will be provided with an Ethics Committee-approved patient information sheet. This provides details about the study, treatment, follow-up and contact details for further information. All members of the clinical team are familiar with the study and will address any preliminary questions about the study. Details of those patients expressing an interest to participate in the study will be recorded in the patient contact form and forwarded to the research physiotherapist. The research physiotherapist will telephone the patient 4 weeks after this consultation to discuss any further questions and confirm if the patient would like to participate in the study.

Consent
Informed consent will be obtained by the chief investigator or principal investigator when the patient attends for the preoperative planning computerised tomography (CT) scan. This is 6 weeks after the outpatient consultation for agreement to TKA and 2 weeks before surgery. It is important to the data collection scheme that patients are able to follow commands and read and interpret questions via questionnaires. For those who cannot hear, read or understand English, an interpreter will be provided. The operating surgeon will use the preoperative CT scan to create a patient-specific computer-aided design model and create a surgical plan for executing both MA TKA and FA TKA in all study patients.

Allocation
After informed consent has been obtained, the research physiotherapist will randomise the patient into one of the two groups using an online random number generator (www.random.org). A number from 1 to 100 will be randomly generated and will allocate a patient to one of the two arms of the study: 1–50 inclusive for the control group, 51–100 inclusive for the investigation group. The research physiotherapist will perform the randomisation procedure and store the designated treatment group for each patient on a password-encrypted file on the hospital computer.
computer. The operating surgeon will have this information communicated to him on the morning of surgery.

**Surgical intervention**

In patients undergoing MA TKA, femoral and tibial bone implant positioning will be used to achieve neutral limb alignment. In the coronal plane, femoral implant positioning will be set at 5–7° valgus in relation to the anatomical axis of the femur. In the sagittal plane, femoral component positioning will be set at 0–5° of flexion to optimise implant positioning while preventing notching. In the axial plane, the femoral component will be
aligned to the surgical transepicondylar axis, which is approximately 3° externally rotated to the posterior condylar axis [2, 3]. The size of the femoral implant will be selected using posterior referencing with the largest size that does not overhang the femur, notch the anterior femur, or overhang the mediolateral bone edges, and avoids overstuffing the patellofemoral joint. The femoral implant will be positioned at the centre of the mediolateral cortical bone edges.

In patients undergoing FA TKA, implants will be positioned to optimise soft tissue tension through achieving...
balanced flexion-extension gaps and equal mediolateral soft tissue tension by altering bone resections and implant positions rather than through soft tissue releases. This will be achieved when possible within strict alignment limits, and where not achievable because of the magnitude of a fixed deformity by balancing after bone cuts with limited soft tissue releases. The preoperative surgical plan will be used to fix a specific point on the tibia and the gaps balanced to restore the obliquity of the native joint line. In the coronal plane, femoral implant positioning will be modified from a starting point of 0° to the mechanical axis to balance the extension gap. In the sagittal plane, femoral component positioning will be set to optimise component sizing while avoiding notching by flexing up to 5°. In the axial plane, the femoral component will be aligned to the surgical transepicondylar axis and modified by up to 3° to balance the flexion gap. The size of the femoral implant will be selected using posterior referencing with the smallest size that does not overhang the femur, notch the anterior femur, or overhang mediolateral bone edges, and avoids overstuffing the patellofemoral joint. The femoral implant will be positioned at the centre of the mediolateral cortical bone edges, favouring a lateral position if necessary. In the coronal plane, tibial implant position will be aligned to the tibial mechanical axis and then modified to balance flexion and extension gaps by up to 3° of varus. Valgus tibial position will be avoided. In the sagittal plane, tibial implant position will be set to match the patient’s native posterior tibial slope, modified to balance the flexion gap if necessary. In the axial plane, the tibial implant will be positioned using Akagi’s line [2, 3, 45]. Tibial implant size will be selected with the largest size that does not overhang the anteroposterior and mediolateral bone coverage while achieving the correct rotation. The implant will be positioned in the centre between the anteroposterior and mediolateral cortical bone edges.

All operative procedures will be undertaken using the Mako robotic arm interactive orthopaedic system (Stryker Limited, Kalamazoo, MI, USA) under the direct supervision of one arthroplasty surgeon (FSH). The cemented Stryker Triathlon (Stryker Navigation, Kalamazoo, MI, USA) cruciate-retaining knee system with asymmetrical patellar resurfacing will be used in both groups. All bone resections, implant positioning and limb alignment will be within regulatory approval for the Triathlon cruciate-retaining knee system. Overall limb alignment, defined as the sum of the femoral and tibial coronal rotations, will range from 3° of varus to 3° of valgus.

Outcomes

All study patients will undergo review by two blinded observers (one orthopaedic registrar and one clinical research fellow) at 2 weeks, 6 weeks, 6 months, 1 year and 2 years following surgery. During these follow-up times, predefined clinical, functional and radiological outcomes will be recorded by these observers using case report forms. The following outcomes will be recorded in all study patients:

1. Accuracy of implant positioning and limb alignment as assessed using CT scans of the knee joint performed postoperatively at 6 weeks.
2. Operating time (minutes)
3. Time to hospital discharge (hours)
4. Analgesia requirements during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year and 2 years
5. Patient-reported outcome measures including Forgotten Joint Score (FJS), Oxford Knee Score (OKS), short-form health survey of 12 items (SF-12), Knee Injury and Osteoarthritis Outcome Score (KOOS), WOMAC, University of California at Los Angeles score and University College Hospital functional knee score preoperatively and postoperatively at 6 weeks, 6 months, 1 year and 2 years
6. Health-related quality of life as measured using the European Quality of Life questionnaire with five dimensions for adults (EQ-5D) preoperatively and postoperatively at 6 weeks, 6 months, 1 year and 2 years
7. Mobilisation distance (metres) and use of mobility aids during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year and 2 years
8. Range of movement (degrees) in knee joint during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year and 2 years
9. Femoral and tibial implant early migration as assessed using RSA performed postoperatively at 2 weeks, 6 weeks, 6 months, 1 year, and 2 years
10. Gait analysis performed postoperatively at 6 months and 1 year using an instrumented treadmill with force plates
11. Resource use and cost-effectiveness, including comparisons between the two treatment groups relating to operating time, theatre efficiency, equipment and sterilisation costs, analgesia requirements, inpatient rehabilitation, time to discharge, outpatient follow-up, additional imaging costs and need for further surgery.
12. Complications

The FJS, University of California at Los Angeles knee score, WOMAC, OKS, KOOS, SF-12 and EQ-5D are validated tools for the clinical assessment of patients after knee arthroplasty [21, 24, 31]. In addition, the blinded observer will record the University College Hospital functional knee score to assess overall pain, function and
mobility. All study patients will undergo gait analysis using an instrumented treadmill with force plates (Kistler Gaitway, Kistler Instrument Corporation, Amherst, NY, USA) on a level platform. Gait analysis will be performed at the patient’s self-selected comfortable speed and maximum speed without running. Vertical ground reaction forces and spatiotemporal data will be obtained from force plates built into the treadmill. RSA radiographs will be performed at regular postoperative follow-up intervals to quantify motion between the implant and host bone, which is highly predictive of long-term implant survival [32, 40].

Blinding
All patients and clinical staff recording postoperative study outcomes will remain blinded to the treatment group. Study patients will be identifiable with a unique study number. Only the research physiotherapist will have the key to identify individual patients and their respective treatment arm. Any documents related to the study will be archived directly at the study site by the research physiotherapist within a secure filing cabinet in a locked research office. This office has swipe card access with onsite security and 24-h closed-circuit television surveillance. Patient data will be logged electronically using each patient’s unique identification number with computer software on an encrypted, password-protected research computer.

Sample size
Using data from a previous study recording functional outcomes, the mean WOMAC score at 2 years using MA TKA was 26 (standard deviation 22.6) and using TKA with kinematic alignment was 15 (standard deviation 20.3) [14]. Using a two-tailed, two-sample $t$ test with an effect size of 0.35, power of 90% with significance level of 5%, and accounting for an expected drop-out rate of 10% during the 2-year follow-up period, the study requires 100 patients to detect a minimal clinically important difference of 11 points in the total WOMAC score between the two treatment groups [13].

Statistical analysis
The analysis of the per-protocol population will be considered the primary analysis. The differences between the MA TKA and FA TKA groups will be analysed by calculating the difference from baseline per patient, and a two-sided confidence interval for the difference between the changes from baseline values will be calculated. This confidence interval will cover the true difference in the percentage change from baseline with a probability of 95%. The following statistical methods will be employed to analyse the data: descriptive statistics, independent $t$ test, paired $t$ test, analysis of variance, Fisher exact test, chi-square test and graphical displays. Assumptions of normality will be tested with the D’Agostino test. Assumptions of homogeneity of variance will be tested with Levene’s test. If the distributional assumptions are (severely) violated, non-parametric techniques such as the Mann–Whitney test will be employed. In the event that FA TKA is converted to MA TKA intraoperatively, analysis will be performed using the intention-to-treat population and the treatment actually received by the patients. Intraoperative conversion from FA TKA to MA TKA will be documented and presented and published as part of the study. Statistical significance is set at a $P$ value <0.05 for all analyses and all statistical analyses will be performed using SPSS software version 25 (SPSS Inc., Chicago, IL, USA). The Bonferroni correction will be used to adjust $P$ values to reduce the risk of type I error with performing multiple statistical comparisons.

Adverse events
Adverse events are defined as any untoward medical occurrence in a patient or study participant that does not necessarily have a causal relationship with the procedure involved. A serious adverse event (SAE) is an adverse event that results in hospitalisation or prolongation of existing hospitalisation, persistent or significant disability or incapacity, life-threatening clinical sequelae, or death. All SAEs during the protocol treatment will be reported directly to the sponsor using the SAE web form. The chief investigator will also assess the SAE for severity, causality, seriousness and expectedness using pre-existing criteria provided by the sponsor and will inform the Data Safety Monitoring Board (DSMB) within 3 days of the initial observation of the event. The protocol treatment period is defined as the period from the day that the first study patient is recruited into the trial to the day that the final study patient has completed 2 years follow-up. The chief investigator will also inform the London-Surrey Research Ethics Committee and local Health Research Authority within 3 days of the SAE taking place. Safety aspects of the study are closely monitored by the sponsor and DSMB using unblinded data for its judgment. In cases where the SAE arises due to a problem with the robotic device, Stryker Limited will also be notified within 2 days of the event taking place. The chief investigator will record the following: onset date, complete description of the event, severity, duration, action taken and outcome for each SAE. The chief investigator will also provide regular updates of all SAEs to the London-Surrey Research Ethics Committee, local Health Research Authority, DSMB, and sponsor.

Data management
On-site monitoring visits shall occur throughout the course of the clinical study by the chief investigator. The
chief investigator shall permit and assist the sponsor (should they chose to monitor the study) to carry out verification of all study forms against data in the source documents, which shall occur as per the departmental policy for undertaking such activities. University College Hospital recognises that there is an obligation to archive study-related documents at the end of the study. The study master file will be archived at University College London in accordance with the University College Hospital Standard Operating Procedure for Archiving of Investigator Site File and Pharmacy Site File. It will be archived for a minimum of 5 years from the study end, and for no longer than 30 years from the study end.

**End-of-protocol treatment**

Reasons for going off study protocol include:

1. Completion of last follow-up visit 2 years after surgery
2. Patient non-compliance or withdrawal (the reason for discontinuation will be recorded in the case report form)
3. Intercurrent death

All patients included in this study are free to withdraw from the study at any time without compromise to their future treatment. On withdrawal, patients will revert to the standard follow-up regimen for routine (non-study) TKA at the study site. The end-of-study form will be completed and the reason for withdrawal documented. This form will also be completed if the patient is lost to follow-up or dies during the course of the study. Data to the point of discontinuation will be used for analysis.

**Peer review**

The study protocol was reviewed by two external reviewers. The suggestions and recommendations for improvement to the study design were implemented. The reviewers and sponsor reviewed the revised protocol documents and confirmed that all queries and suggestions had been fully addressed.

**Discussion**

The concept of MA TKA is to distribute load evenly across the components to optimise implant survivorship and balance forces through the periarticular soft tissue envelope for proper functioning of the knee joint. However, in the majority of patients this forces the knee into an unnatural position with altered knee kinematics through the arc of flexion [4, 6, 17, 18]. FA TKA aims to restore joint line height, preserve native obliquity, and achieve balanced flexion-extension gaps with equal mediolateral soft tissue tension by manipulating bone resections and fine-tuning implant positioning, which reduces the need for soft tissue releases. To our knowledge, this prospective randomised control trial is the first study to compare MA TKA with FA TKA. Robotic technology will be used in both treatment groups, which will enable accurate execution of the preoperative surgical plan and help preserve the double-blinded nature of this study. Furthermore, RSA will be used to compare micromotion and implant survivorship between the two treatment groups. The findings of this study will enable an improved understanding of the optimal alignment technique in TKA for achieving high-levels of patient satisfaction, improving functional outcomes, increasing implant survivorship, improving cost-effectiveness and reducing complications.

**Trial status**

This is protocol version 3.0, 1 June 2018. Patient recruitment started on 28 December 2018. The estimated date for completion of recruitment is 28 December 2020. The estimated date for completion of the final follow-up is 28 December 2012.

**Supplementary information**

Supplementary information accompanies this paper at https://doi.org/10.1186/s13063-020-4123-8.

**Additional file 1.** Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 checklist—recommended items to address in a clinical trial protocol and related documents.

**Abbreviations**

DSMB: Data Safety Monitoring Board; EQ-5D: European Quality of Life questionnaire with five dimensions for adults; FA: Functional alignment; FJS: Forgotten Joint Score; KOOS: Knee Injury and Osteoarthritis Outcome Score; MA: Mechanical alignment; OKS: Oxford Knee Score; RSA: Radiosteriometric analysis; SAE: Serious adverse event; SF-12: Short-form health status survey
health survey of 12 items; TKA: Total knee arthroplasty; WOMAC: Western Ontario and McMaster Universities Arthritis Index

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Authors’ contributions
BK, JT and FSH performed background research, identified gaps in the medical literature, created the study objectives, designed the trial, created the case report forms, attended Research Ethics Committee meetings, helped write the study protocol and prepared the National Institute for Health Research Clinical Research Network costing template. PM, SO and SK helped write the study protocol. All authors read and approved the final manuscript.

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Funding was obtained from Stryker Limited. There are no terms or conditions to the funding that will impact the study design, data collection, analysis, interpretation of data, or writing the manuscript.

Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate
The study has been reviewed and approved for patient recruitment by the Ethics approval and consent to participate. The study has been reviewed and approved for patient recruitment by the Ethics approval and consent to participate. The study has been reviewed and approved for patient recruitment by the Ethics approval and consent to participate. The study has been reviewed and approved for patient recruitment by the Ethics approval and consent to participate.

Consent for publication
The findings of this research will be published in peer-reviewed journals. All study patients will provide informed consent for publication of anonymised patient data and study findings. Authorship will reflect the amount of time spent designing the study, collating the data, analysing the results, and writing the manuscript.

Competing interests
The findings of this research will be published in peer-reviewed journals. All study patients will provide informed consent for publication of anonymised patient data and study findings. Authorship will reflect the amount of time spent designing the study, collating the data, analysing the results, and writing the manuscript.

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Surgical Management of Chronic Incomplete Proximal Hamstring Avulsion Injuries

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Investigation performed at Trauma and Orthopaedic Department at University College London Hospital, London, United Kingdom, and Department of Orthopaedic Surgery, The Princess Grace Hospital, London, United Kingdom

Background: Chronic incomplete proximal hamstring avulsion injuries are debilitating injuries associated with prolonged periods of convalescence and poor return to preinjury level of function. This study explores the efficacy of operative intervention for these injuries on patient satisfaction, muscle strength, range of motion, functional performance, return to preinjury level of sporting activity, and injury recurrence.

Hypothesis: Surgical intervention of chronic incomplete proximal hamstring avulsion injuries enables return to preinjury level of sporting function with low risk of clinical recurrence.

Study Design: Case series: Level of evidence, 4.

Methods: This prospective single-surgeon study included 41 patients with incomplete proximal hamstring avulsion injuries refractory to 6 months of nonoperative treatment. All study patients underwent primary operative repair of the avulsed proximal hamstring tendon and received standardized postoperative rehabilitation. Predefined outcomes were recorded at regular intervals after surgery. Mean follow-up time was 28.2 months (range, 25.0-35.0 months) from date of surgery.

Results: All patients returned to their preinjury level of sporting activity. Mean ± SD time from surgery to return to full sporting activity was 22.2 ± 6.7 weeks. There were no episodes of clinical recurrence. At 3 months after surgery, 39 patients (95.1%) were satisfied/very satisfied with the outcomes of their surgery, and as compared with preoperative values, improvements were recorded in isometric hamstring muscle strength at 0° (84.9% ± 10.9% vs 40.4% ± 8.8%; P < .001), 15° (89.6% ± 7.6% vs 44.2% ± 11.1%; P < .001), and 45° (94.1% ± 5.1% vs 66.4% ± 9.0%; P < .001); mean passive straight leg raise angle (71.2° ± 13.5° vs 45.4° ± 11.9°; P < .001); mean lower extremity functional score (70.9 ± 5.1 vs 48.4 ± 5.2; P < .001); and mean Marx activity rating score (5.6 ± 2.8 vs 2.7 ± 1.0; P < .001). High patient satisfaction and functional outcome scores were maintained at 1- and 2-year follow-up.

Conclusion: Operative repair of chronic incomplete proximal hamstring avulsion injuries enabled return to preoperative level of sporting function with no episodes of clinical recurrence at short-term follow-up. Surgical intervention was associated with high patient satisfaction and improved isometric hamstring muscle strength, range of motion, and functional outcome scores as compared with preoperative values. High patient satisfaction and improved functional outcomes were sustained at 2-year follow-up.

Keywords: hamstrings; chronic avulsion; partial avulsion; surgical repair

The hamstrings are the most commonly injured muscle group in professional athletes and account for 12% to 26% of all injuries sustained during sporting activities.2,8,13,29 Incomplete proximal hamstring avulsion injuries most commonly occur during explosive movements that involve combined ipsilateral hip flexion and knee extension10,11,17 or repetitive low-force trauma that causes localized proximal hamstring tendon attrition and surrounding tendinopathy.14,18 High-speed running requires eccentric muscle strength as the hamstrings are lengthened across the hip and knee articulations. Previous hamstring injuries may lead to poor hamstring muscle strength during the lengthened state and predispose to recurrent injury.13,25,29 Additional risk factors for hamstring injuries include reduced flexibility, muscle weakness, poor core stability, muscle fatigue, and poor lumbar posture.2,8,18,25,29 Patients may have a variety of clinical symptoms, ranging from acute, sharp, sudden-onset gluteal pain during exertional sporting activity to more chronic, generalized
proximal hamstring discomfort with progressive limb weakness and instability.16,18 Hamstring muscle contractions may also lead to reduced hip flexibility and decreased straight leg raise as compared with the contralateral limb.23,27 These injuries often occur in professional athletes and are regarded as career-threatening injuries in most sporting activities.

Patients with incomplete proximal hamstring avulsion injuries are often initially managed with nonoperative treatment, including rest, nonsteroidal anti-inflammatory drugs, protected range of movement, eccentric muscle exercises, and ultrasound-guided injections of corticosteroids or plasma-rich protein.5,15-18,21 However, nonoperative treatment of these injuries is associated with poor return to preinjury level of sporting function, variable times for convalescence, and high risk of recurrence.15,16,20,21,24 Patients may develop chronic symptoms owing to delays in presentation, referral for appropriate imaging, and transfer to suitable treatment centers. Chronic proximal hamstring avulsion injuries are associated with worse patient satisfaction, poorer functional outcomes, and longer time to return to sporting activity as compared with acute proximal hamstring avulsion injuries.3 Although surgical repair of chronic proximal hamstring avulsion injuries may facilitate restoration to preinjury level of sporting activity,3,12 the efficacy of surgical treatment for these injuries on muscle strength, range of motion, functional outcomes, and recurrence remains unknown.

The primary objective of this study was to assess the effect of operative repair for chronic incomplete hamstring avulsion injuries on return to preinjury level of sporting function and clinical recurrence. The study hypothesis was that surgical repair of chronic incomplete hamstring avulsion injuries would enable return to preinjury level of function with low risk of clinical recurrence at short-term follow-up. Secondary objectives were to assess the effect of surgical intervention on patient satisfaction, hamstring muscle strength, range of motion, straight leg raise, functional performance, and complications.

**METHODS**

**Patient Selection**

This prospective study included 41 patients (31 males and 10 females) undergoing operative repair of chronic incomplete proximal hamstring avulsion injuries. All operative procedures were performed by a single surgeon (F.S.H.) between September 2014 and September 2016. Of the 41 study patients, 14 were active or recently retired professional athletes: 6 rugby players, 5 soccer players, and 3 sprinters. A further 27 patients were nonprofessional athletes who indulged in regular sporting activities, such as running, soccer, badminton, and tennis. Baseline characteristics for study patients are presented in Table 1.

All patients had a recall of a specific event that led to the injury but were treated nonoperatively as the first line of treatment for a minimum 6 months. Mean ± SD time from injury to surgery was 8.2 ± 1.8 months (range, 6-14 months). Preoperative magnetic resonance imaging (MRI) was undertaken at the study center to confirm diagnosis, assess for any concurrent injury, and plan operative intervention (Figure 1).

Inclusion criteria for study participation included the following: onset of symptoms >6 months before date of surgery, MRI to confirm incomplete proximal hamstring

### TABLE 1
Baseline Characteristics for All Study Patients Undergoing Surgical Repair of Chronic Incomplete Proximal Hamstring Avulsion Injuriesa (N = 41)

<table>
<thead>
<tr>
<th>Characteristic: Category</th>
<th>Mean ± SD (Range) or No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>38.7 ± 7.2</td>
</tr>
<tr>
<td>Male (n = 31)</td>
<td>38.5 ± 6.9</td>
</tr>
<tr>
<td>Female (n = 10)</td>
<td>39.4 ± 8.3</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>10 (24.4)</td>
</tr>
<tr>
<td>Male</td>
<td>31 (75.6)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>24.7 ± 3.2</td>
</tr>
<tr>
<td>ASA score</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>41 (100)</td>
</tr>
<tr>
<td>II</td>
<td>0 (0)</td>
</tr>
<tr>
<td>III</td>
<td>0 (0)</td>
</tr>
<tr>
<td>IV</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Laterality</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>24 (58.5)</td>
</tr>
<tr>
<td>Left</td>
<td>17 (41.5)</td>
</tr>
<tr>
<td>Sporting activity</td>
<td></td>
</tr>
<tr>
<td>Amateur</td>
<td></td>
</tr>
<tr>
<td>Running</td>
<td>19 (46.3)</td>
</tr>
<tr>
<td>Soccer</td>
<td>5 (12.2)</td>
</tr>
<tr>
<td>Badminton</td>
<td>1 (2.4)</td>
</tr>
<tr>
<td>Tennis</td>
<td>2 (4.9)</td>
</tr>
<tr>
<td>Professional</td>
<td></td>
</tr>
<tr>
<td>Soccer</td>
<td>5 (12.2)</td>
</tr>
<tr>
<td>Rugby</td>
<td>6 (14.6)</td>
</tr>
<tr>
<td>Sprinting</td>
<td>3 (7.3)</td>
</tr>
<tr>
<td>Time from onset of symptoms to surgery, mo</td>
<td>8.2 ± 1.8 (6-14)</td>
</tr>
<tr>
<td>Time from surgery to return to sporting activity, wk</td>
<td>22.3 ± 6.9 (12-42)</td>
</tr>
</tbody>
</table>

*ASA, American Society of Anesthesiologists.

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avulsion injury, patient symptomatic despite nonoperative management, and operative intervention undertaken by the senior author. Exclusion criteria included the following: complete proximal hamstring avulsion injury (n = 62), partial avulsion injury sustained within 6 months of date of surgery (n = 2), recurrent injury after previous surgical intervention (n = 2), and patient living abroad or not available for follow-up (n = 5). Presenting complaint was gluteal pain (n = 31), muscle weakness (n = 5), reduced range of motion (n = 2), and paresthesia in the distribution of the sciatic nerve (n = 3). The study was prospectively reviewed by the hospital review board, which advised that further research ethics committee approval was not required. Informed consent for participation was obtained from all study patients.

Surgical Technique

All operative procedures were performed with the patient in the prone position under general anesthesia. The affected hip was flexed and the gluteal skin crease marked. In patients without neurological symptoms (n = 38), a transverse incision measuring 8 to 10 cm was performed through this skin crease. In patients with sciatic nerve impingement symptoms (n = 3), a longitudinal incision measuring 7 to 8 cm was performed distal to the skin crease instead of the transverse incision. The underlying subcutaneous tissue and gluteal fascia were divided by electrocautery, exposing the inferior border of the gluteus maximus muscle. The posterior cutaneous nerve of the thigh was identified and protected. The gluteus maximus was then retracted superiorly to expose the underlying fascia over the hamstrings. Caution was taken not to place the retractor too deep on the ischium to minimize risk of inferior gluteal nerve injury.

A longitudinal incision was performed through the hamstring fascia, and the hamstrings tendons were traced proximally to the ischial tuberosity. The hamstring tendons were identified and the sciatic nerve palpated to confirm its position deep and lateral relative to the hamstring complex and ischial tuberosity. The hamstring tendons were explored and the bare area from the avulsed ischial tuberosity identified. Blunt finger dissection and electrocautery were used to carefully dissect any scar tissue, and the fibrotic end of the retracted proximal tendon was excised. The sciatic nerve was palpated to ensure that it was tension-free. Six patients had adhesions to the adjacent sciatic nerve that were dissected with blunt finger dissection and electrocautery. Two TWINFIX 5.0-mm suture anchors (Smith & Nephew Limited) were inserted into the ischial tuberosity under direct vision. Each suture anchor had 2 nonabsorbable ultrahigh molecular weight polyethylene fiber sutures, which were stitched into the free end of the partially avulsed tendons with a modified Kessler technique. The knee was flexed to 30°, and the avulsed tendon was parachuted down to the tendon bed under direct vision. The knee was then fully extended to ensure satisfactory tension in the repair throughout the arc of motion. The wound was copiously irrigated with normal saline. The overlying fascia, subcutaneous tissue, and skin were closed in layers with absorbable sutures and a pressure dressing applied to the wound. All patients wore a hinged knee brace.

Postoperative Rehabilitation

All patients received a standardized milestone-based rehabilitation program, which was supervised by an experienced sports physiotherapist. The rehabilitation program was divided into 4 distinct phases:

- **Phase 1**: RICE (rest, ice, compression, and elevation), aspirin (75 mg once daily), limit excessive combined hip flexion and knee extension, knee range of motion restricted from 60° to 120°.
- **Phase 2**: Regain full pain-free hip and knee range of motion, full weightbearing, concentric and eccentric training, core strengthening.
- **Phase 3**: Muscle strengthening with resistance exercises, double- and single-leg squats, quadriceps extension, and hamstring curls. Aerobic conditioning with light jogging, cycling, and swimming. Sport-specific training.
- **Phase 4**: Return to full sporting activity with full pain-free range of motion, muscle strength 90% of uninjured limb, and no concerns with sport-specific training.

Outcome Measures

All study patients were clinically reviewed by the operating surgeon at regular intervals until return to play. Study outcomes were recorded by a specialist nurse practitioner preoperatively and at predefined intervals after surgery.
All outcomes at 3 months and 1 year after surgery were collected during clinical consultation, and outcomes at 2-year follow-up were collated by telephone conversation, giving the wide geographic location of study patients.

**Patient Satisfaction.** Patient satisfaction was recorded at 3 months, 1 year, and 2 years after surgery via the Musculoskeletal Outcomes Data Evaluation and Management System, which scores patient satisfaction on a scale of 1 to 5 (1, very unsatisfied; 2, unsatisfied; 3, neutral; 4, satisfied; 5, very satisfied).

**Hamstring Strength.** Isometric hamstring strength was tested pre- and postoperatively at 3 months and 1 year. The patient was placed in the prone position and a handheld dynamometer (Hoggan Scientific LLC) positioned over the ipsilateral calcaneus. Maximum resisted knee flexion force (newtons) was recorded at 0°, 15°, 45°, and 90°. This technique was repeated 3 times and the mean flexion force at each angle in the injured limb calculated. All values were compared with those of the contralateral uninjured limb to calculate the percentage of normal hamstring muscle strength.

**Passive Straight Leg Raise.** Maximum angle of passive straight leg raise (PSLR) was tested pre- and postoperatively at 3 months and 1 year. With the patient in the supine position, the uninjured limb was passively elevated, inducing flexion at the hip while maintaining extension at the knee joint to the point of failure secondary to pain or elastic limit of the limb. The maximum attainable PSLR (degrees) was measured with a standard goniometer and compared with the maximum PSLR in the contralateral injured limb. The deficit in PSLR between the limbs was recorded.

**Functional Progress and Return to Function.** All study patients completed the Lower Extremity Functional Scale (LEFS) and Marx Activity Rating Scale (MARS) preoperatively and at 3 months, 1 year, and 2 years after surgery. The LEFS is a validated and effective questionnaire for assessing specific lower limb function. It is an 80-point scale with 20 questions (4 points per question) and a minimum clinical difference of 9 points. The MARS measures patient activity level and knee function independently of age, sex, and type of sporting activity. Scores of 0 to 4 are assigned to 4 activities—running, changing direction, decelerating, and pivoting—with a total score of 16. Time from surgical intervention to full return to sporting activity was collected in all study patients.

**Complications.** All complications within 2 years of the surgical intervention were recorded. All patients recruited into this study completed follow-up. Mean follow-up time was 28.2 months (range, 25.0-35.0 months) from date of surgery.

### Statistical Analysis

Paired t tests were used to compare study outcomes found to be normally distributed, while the Mann-Whitney U test was used for continuous outcomes found not to be normally distributed. Categorical outcomes were compared with the Fisher exact test. Statistical significance was set at $P < .05$

### RESULTS

**Return to Function and Clinical Recurrence**

All study patients returned to their preinjury level of sporting activity. Mean time from surgical intervention to return to sporting activity was 22.3 ± 6.9 weeks. The overall range for time from surgical intervention to return to sporting activity was 12 to 42 weeks. At 1- and 2-year follow-up, all study patients were still participating at their preinjury level of sporting activity. No study patients had clinical recurrence of their primary injury.

**Patient Satisfaction**

Operative repair of chronic incomplete proximal hamstring avulsion injuries was associated with high levels of patient satisfaction. At 3 months after surgery, 39 patients (95.1%) were satisfied/very satisfied with the outcomes of their surgery, and 2 patients were unsatisfied (Table 2). Of the 2 unsatisfied patients, 1 was disappointed with the speed of postoperative recovery. He was a professional soccer player who returned to preinjury level of sporting activity at 34 weeks after surgery. The second patient was a professional rugby player who developed postoperative complex regional pain syndrome around the operated limb. He was successfully treated with analgesia and physiotherapy and made a return to full sporting activity at 42 weeks. At 2 years after surgery, 38 patients (92.7%) were very satisfied and 3 (7.3%) were satisfied with the outcomes of their surgery.

### Hamstring Strength

Surgical intervention was associated with improved hamstring muscle strength at 3 months after surgery as compared with presurgery (Table 3, Figure 2). At 1-year follow-up, all patients had restored hamstring muscle strength to >90% of the contralateral side.

### Table 2

<table>
<thead>
<tr>
<th></th>
<th>3 mo</th>
<th>1 y</th>
<th>2 y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very unsatisfied</td>
<td>1 (2.4)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unsatisfied</td>
<td>2 (2.4)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Neutral</td>
<td>3</td>
<td>1 (2.4)</td>
<td>0</td>
</tr>
<tr>
<td>Satisfied</td>
<td>4 (46.3)</td>
<td>7 (17.1)</td>
<td>3 (7.3)</td>
</tr>
<tr>
<td>Very satisfied</td>
<td>5 (48.8)</td>
<td>33 (80.5)</td>
<td>38 (92.7)</td>
</tr>
</tbody>
</table>

for all analyses, and all statistical analysis was performed with SPSS software (v 24; IBM Corp).
Passive Straight Leg Raise

Operative repair of chronic incomplete proximal hamstring avulsion injuries was associated with improved PSLR and decreased PSLR deficit at 3-month follow-up as compared with preoperative values (Table 4, Figure 3). Further improvements in PSLR were observed at 1 year after surgery as compared with 3 months. Two patients had maximum PSLR $\leq 50^\circ$ at 3-month follow-up, which included 1 patient with chronic regional pain syndrome and 1 patient with chronic back pain. In both patients, PSLR improved to $80^\circ$ at 1-year follow-up after surgery.

Functional Progress and Return to Function

At 3 months after surgery, mean LEFS score markedly improved as compared with the preoperative value. At 3-month follow-up, 12 patients (29.2%) had an LEFS score of 80 (out of 80), and 24 (58.5%) had a score $\geq 75$. Further incremental improvements in LEFS scores were observed at 1 and 2 years after surgery (Table 5, Figure 4). At 2-year follow-up, 16 patients (39.0%) had an LEFS score of 80, and 21 (51.2%) had a score $\geq 75$. MARS scores followed a similar trend with statistically improved scores at each follow-up interval after surgery. At 2-year follow-up, 35 patients (85.3%) had a minimum MARS score of 12 (out of 16), which included 9 (22.0%) with a score of 16.

Complications

There were no intraoperative complications. In addition to the 1 patient who developed chronic regional pain syndrome described earlier, 4 patients had extensive bruising distal to the operative site, all of which was managed nonoperatively. One patient developed a superficial wound infection that was successfully treated with a 1-week course of oral antibiotics. No other complications occurred within 2 years of surgery.

DISCUSSION

This study found that surgical repair of chronic incomplete proximal hamstring avulsion injuries enabled return to preoperative level of sporting function with no episodes of clinical

![Figure 2. Boxplots show hamstring muscle strength (vs the contralateral limb) in study patients undergoing surgical repair of chronic incomplete proximal hamstring avulsion injuries. Values are presented as mean ($\bar{x}$), median (line), interquartile range (box), range (error bars), and outliers more than 1.5 times the interquartile range width from the lower or upper quartiles (circles).](image)

### TABLE 3

Hamstring Muscle Strength vs Contralateral Limb in Patients Undergoing Surgical Repair of Chronic Incomplete Proximal Hamstring Avulsion Injuries $^a$ (N = 41)

<table>
<thead>
<tr>
<th>Angle</th>
<th>Preoperative</th>
<th>3 mo</th>
<th>Improvement, %, MD (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°</td>
<td>40.4 ± 8.8</td>
<td>84.9 ± 10.9</td>
<td>44.5 ± 9.8 (41.5 to 47.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>15°</td>
<td>44.2 ± 11.1</td>
<td>89.6 ± 7.6</td>
<td>45.3 ± 11.9 (41.6 to 49.1)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>45°</td>
<td>66.4 ± 9.0</td>
<td>94.1 ± 5.1</td>
<td>27.7 ± 8.1 (25.1 to 30.2)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>90°</td>
<td>86.2 ± 6.2</td>
<td>97.1 ± 3.5</td>
<td>10.9 ± 6.1 (9.0 to 12.8)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Preoperative 1 y

<table>
<thead>
<tr>
<th>Angle</th>
<th>Preoperative</th>
<th>1 y</th>
<th>Improvement, %, MD (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°</td>
<td>40.4 ± 8.8</td>
<td>93.2 ± 5.5</td>
<td>53.1 ± 6.3 (50.2 to 56.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>15°</td>
<td>44.2 ± 11.1</td>
<td>97.5 ± 4.6</td>
<td>53.3 ± 9.1 (50.4 to 56.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>45°</td>
<td>66.4 ± 9.0</td>
<td>98.6 ± 3.4</td>
<td>32.2 ± 7.4 (29.8 to 34.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>90°</td>
<td>86.2 ± 6.2</td>
<td>98.1 ± 3.8</td>
<td>11.9 ± 5.3 (9.0 to 14.8)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

3 mo 1 y

<table>
<thead>
<tr>
<th>Angle</th>
<th>3 mo</th>
<th>1 y</th>
<th>Improvement, %, MD (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°</td>
<td>84.9 ± 10.9</td>
<td>93.2 ± 5.5</td>
<td>8.3 ± 11.2 (4.8 to 11.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>15°</td>
<td>89.6 ± 7.6</td>
<td>97.5 ± 4.6</td>
<td>8.0 ± 8.1 (5.4 to 10.5)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>45°</td>
<td>94.1 ± 5.1</td>
<td>98.6 ± 3.4</td>
<td>4.6 ± 5.7 (2.8 to 6.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>90°</td>
<td>97.1 ± 3.5</td>
<td>98.1 ± 3.8</td>
<td>1.0 ± 4.4 (–0.4 to 2.3)</td>
<td>.18</td>
</tr>
</tbody>
</table>

$^a$MD, mean difference.
TABLE 4
PSLR in Study Patients Undergoing Surgical Repair of Chronic Incomplete Proximal Hamstring Avulsion Injuries* (N = 41)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Preoperative</th>
<th>3 mo</th>
<th>Improvement in PSLR, MD (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSLR, deg</td>
<td>45.4 ± 11.9</td>
<td>71.2 ± 13.5</td>
<td>25.9 ± 10.0 (22.7 to 29.0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PSLR deficit, degb</td>
<td>38.5 ± 9.6</td>
<td>12.7 ± 10.5</td>
<td>−25.9 ± 10.0 (−22.7 to −29.0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Preoperative</td>
<td></td>
<td>1 y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSLR, deg</td>
<td>45.4 ± 11.9</td>
<td>77.8 ± 7.9</td>
<td>32.2 ± 9.8 (29.7 to 34.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PSLR deficit, degb</td>
<td>38.5 ± 9.6</td>
<td>6.1 ± 6.7</td>
<td>−32.2 ± 9.8 (−29.7 to −34.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>3 mo</td>
<td></td>
<td>1 y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSLR, deg</td>
<td>71.2 ± 13.5</td>
<td>77.8 ± 7.9</td>
<td>6.6 ± 11.3 (3.1 to 10.1)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PSLR deficit, degb</td>
<td>12.7 ± 10.5</td>
<td>6.1 ± 6.7</td>
<td>−6.6 ± 11.3 (−3.1 to −10.1)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*MD, mean difference; PSLR, passive straight leg raise.
bCompared with contralateral limb.

Recurrence at short-term follow-up. Operative intervention was associated with high patient satisfaction and improved isometric hamstring muscle strength, range of motion, and functional outcome scores as compared with preoperative values. High patient satisfaction and improved functional outcomes were sustained at 2 years after surgery.

All study patients were able to return to preinjury level of sporting function at a mean 22.3 ± 6.9 weeks after surgery. These findings are consistent with those of Lempainen et al,16 who performed operative repair of 47 partial proximal hamstring avulsion injuries with bone suture anchors and found that 41 patients (87.2%) were able to return to sporting activity at a mean 5 months after surgery. The authors reported that 41 patients (87.2%) reported their outcomes as good or excellent, which is consistent with the findings of the current study at 1-year follow-up. Similarly, Wood et al28 described the outcomes of operative intervention in 71 proximal hamstring injuries, which included 7 proximal partial avulsion injuries treated with bone anchors. All patients made a full return to sporting activity with high patient satisfaction at 6-month follow-up. Barnett et al24 performed operative repair on 34 patients with chronic partial hamstring avulsion injuries and found that only 60% of patients were able to return to their preinjury level of function and 26% labeled their surgical outcomes as moderate. The mean time from initial injury to operative intervention was 510 days (2.5 times the mean time from injury to surgical intervention in our study), and patients did not have standardized postoperative rehabilitation, which may have contributed to the less favorable outcomes as compared with those observed in the current study.

Delays in operative treatment may lead to muscle weakness and fibrosis of scar tissue to the sciatic nerve and then to neurological complications, such as foot drop or paresis of the lower limb.9,18,22,24 In the current study, 3 patients had paresthesia in the distribution of the sciatic nerve, which resolved after operative intervention. In these patients, the proximal avulsed portion of the retracted hamstring was scarred and adhered to the adjacent sciatic nerve. The scar tissue was dissected and the sciatic nerve freed to minimize any tension. Bowman et al25 reported outcomes in 17 patients undergoing surgical repair of partial proximal hamstring injuries refractory to 6 months of nonoperative treatment and found that 5 of these patients developed postoperative paresthesia. Sarimo et al24 reviewed the outcomes of surgical treatment in 41 patients with acute or chronic complete proximal hamstring avulsion injuries and found that chronic cases were associated with the torn muscle having a macroscopically abnormal appearance with a hardened fibrotic texture. The authors reported that time from injury to operative intervention was 2.4 months in patients reporting good and excellent results but 11.7 months in patients with poor or moderate outcomes (P < .001).

Operative repair of chronic proximal incomplete hamstring avulsion injuries enabled improvements in isometric...
TABLE 5
LEFS and MARS in Study Patients Undergoing Surgical Repair of Chronic Incomplete Proximal Hamstring Avulsion Injuries (N = 41)\(^a\)

<table>
<thead>
<tr>
<th>Outcome: Time</th>
<th>Improvement in Scores, MD (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEFS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>48.4 ± 5.2</td>
<td></td>
</tr>
<tr>
<td>3 mo</td>
<td>70.9 ± 5.1</td>
<td>22.4 ± 6.5 (20.4-24.4)</td>
</tr>
<tr>
<td>1 y</td>
<td>75.2 ± 2.7</td>
<td>4.3 ± 3.8 (3.1-5.5)</td>
</tr>
<tr>
<td>2 y</td>
<td>77.0 ± 3.0</td>
<td>1.9 ± 3.0 (0.9-2.8)</td>
</tr>
<tr>
<td>MARS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>2.7 ± 1.0</td>
<td></td>
</tr>
<tr>
<td>3 mo</td>
<td>5.6 ± 2.8</td>
<td>3.1 ± 2.1 (2.2-4.0)</td>
</tr>
<tr>
<td>1 y</td>
<td>9.4 ± 1.5</td>
<td>3.8 ± 3.3 (2.8-4.9)</td>
</tr>
<tr>
<td>2 y</td>
<td>12.4 ± 2.4</td>
<td>3.0 ± 2.5 (2.2-3.8)</td>
</tr>
</tbody>
</table>

\(^a\)LEFS, lower extremity function scale; MARS, Marx Activity Rating Scale; MD, mean difference.

hamstring muscle strength through the arc of flexion. Maximum hamstring strength deficit was seen in the range of 0° to 45° of flexion with the least strength deficit at 90° of flexion. These findings are consistent with those of Young et al,\(^30\) who assessed hamstring muscle strength in 41 of 47 patients using a subjective measure of clinical weakness of hamstrings. The authors found that proximal hamstring insulsts resulted in maximum hamstring strength deficit in the first 45° of knee flexion. Improvements in isometric muscle hamstring strength observed in our study are consistent with those reported by Barnett et al.\(^3\) In their study, surgical repair of partial hamstring avulsion injuries resulted in improvements in hamstring muscle strength from 53.6% preoperatively to 84.1% postoperatively as compared with the contralateral side. Aldridge et al\(^1\) reported outcomes in 23 consecutive patients with chronic partial hamstring avulsion injuries who were undergoing surgical repair via reattachment with bone anchors. The authors found that mean isometric strength improved from 64% to 88% of the contralateral side at 6-month follow-up.

Operative intervention for chronic incomplete proximal hamstring avulsion injuries in our study was associated with improvements in functional outcomes. Although pre-injury scores were not available for comparison, 12 patients (29.2%) from this study had an LEFS score of 80 (out of 80), and 24 patients (58.5%) had a score >75 at 3 months after surgery. Statistically significant incremental improvements in LEFS and MARS scores were observed over 2 years after surgery, which suggests progressive improvements in confidence with sporting activity and daily functional activities over this period. In this study, observed improvements in objective functional outcome scores after surgical repair are consistent with existing literature on surgical repair of acute and chronic hamstring injuries.\(^7,25,26\) Sonnery-Cottet et al\(^26\) found that surgical repair of proximal or distal hamstring injuries in 10 professional athletes was associated with return to preinjury level of sporting activity at 3.4 months (range, 2-5 months). Cohen et al\(^7\) followed 52 patients undergoing suture anchor repair of proximal hamstring avulsion injuries and found a mean LEFS score of 75 (range, 50-80) at a follow-up of 33 months (range, 12-76 months).

The main clinical significance of this study is that it provides important prognostic information on muscle strength, range of motion, functional progress, and time to return to preinjury level of function after operative repair of chronic incomplete proximal hamstring avulsion injuries. The findings will facilitate postoperative rehabilitation and planning for return to sporting activity. This study supports existing literature showing that chronic proximal hamstring avulsion injuries may lead to fibrosis of the avulsed tendon and tethering to the adjacent sciatic nerve. These fibrotic adhesions may require intraoperative division to release the sciatic nerve and improve any distal neurological compromise. Operative intervention also enabled all study patients to return to preinjury level of sporting function. Although it remains unclear how the time to return to sporting function compares with a standardized nonoperative rehabilitation program, there was no clinical recurrence of the primary symptoms at short-term follow-up. This information should be included in any discussion between medical professionals and patients when deciding between nonoperative and operative intervention.

There are several limitations of this study that need to be considered when interpreting the findings. There was no control group of patients undergoing nonoperative management; therefore, it is difficult to ascertain the effect of...
surgical repair as compared with nonoperative treatment with the standardized rehabilitation program. Patient recruitment with prospective randomization to operative treatment or further nonoperative treatment is challenging in highly active patients who have already failed a minimum 6 months of nonoperative management. Furthermore, although all patients received a minimum 6 months of nonoperative treatment, the overall time from injury to surgical intervention was not correlated with study outcomes. Stratification of patients based on duration of nonoperative management may help to provide more detailed information about optimal time for surgical repair and prognostic outcomes. Repeat imaging with MRI was not used to assess healing at the operative site; therefore, asymptomatic recurrent injuries may not have been detected. Finally, study outcomes were not correlated with preoperative clinical findings or radiological grade of injury, and follow-up was limited to 2 years after surgery.

CONCLUSION
Operative repair of chronic incomplete proximal hamstring avulsion injuries enabled return to preoperative level of sporting function with no episodes of clinical recurrence at short-term follow-up. Surgical intervention was associated with high patient satisfaction and improved isometric hamstring muscle strength, range of motion, and functional outcome scores as compared with preoperative values. High patient satisfaction and improved functional outcomes were maintained at 2 years after surgery.

REFERENCES
Unicompartmental knee arthroplasty (UKA) is associated with improved functional outcomes but reduced implant survivorship compared to total knee arthroplasty (TKA).

Surgeon-controlled errors in component positioning are the most common reason for implant failure in UKA, and low UKA case-volume is associated with poor implant survivorship and earlier time to revision surgery.

Robotic UKA is associated with improved accuracy of achieving the planned femoral and tibial component positioning compared to conventional manual UKA.

Robotic UKA has a learning curve of six operative cases for achieving operative times and surgical team comfort levels comparable to conventional manual UKA, but there is no learning curve effect for accuracy of implant positioning or limb alignment.

Robotic UKA is associated with reduced postoperative pain, decreased opiate analgesia requirements, faster inpatient rehabilitation, and earlier time to hospital discharge compared to conventional manual UKA.

Limitations of robotic UKA include high installation costs, additional radiation exposure with image-based systems, and paucity of studies showing any long-term differences in functional outcomes or implant survivorship compared to conventional manual UKA.

Further clinical studies are required to establish how statistical differences in accuracy of implant positioning between conventional manual UKA and robotic UKA translate to long-term differences in functional outcomes, implant survivorship, complications, and cost-effectiveness.

Keywords: functional outcomes; implant positioning; limb alignment; robotics; unicompartmental knee arthroplasty

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Introduction

Unicompartmental knee arthroplasty (UKA) is an effective surgical procedure for end-stage single-compartment knee osteoarthritis.\(^1\) It is currently performed in over 10,000 patients per year in the United Kingdom.\(^2\) The first recorded UKA was performed by Campbell et al in 1940, although since then the procedure has undergone several modifications. Changes have been made to the surgical approach, operative indications, implant design, implant material, bearing surface, and surgical instrumentation in order to improve the outcomes and the efficiency of the procedure.\(^3-8\) Advantages of UKA over total knee arthroplasty (TKA) include reduced operative time, decreased intraoperative blood loss, reduced periarticular soft tissue trauma, improved preservation of native bone stock, better restoration of native kinematics, increased patient satisfaction, and improved functional outcomes.\(^4-9\) Furthermore, UKA is associated with reduced length of hospital stay, faster return to sporting and work activities, and better quality of life scores, which lead to improved cost-effectiveness and better resource use compared to TKA.\(^6-8,10,11\) Despite these advantages, UKA is often less favoured due to its association with reduced implant survivorship and increased revision rates when compared
to TKA. Existing registry data has also shown that surgical errors in implant positioning and suboptimal limb alignment are the most common reasons for implant failure and early revision surgery in UKA. To help overcome this, there has been a recent surge in robotic UKA. This procedure uses computer technology to preoperatively plan optimal bone resection and implant positioning, and employs an intraoperative robotic device to execute this plan with a high level of accuracy. This review article provides an overview of the limitations of conventional manual UKA, discusses the operative stages of robotic UKA, explores the different types of robotic UKA systems in practice, and details how robotic UKA impacts accuracy of implant positioning, functional outcomes, implant survivorship, and cost-effectiveness compared to conventional manual UKA. The limitations of robotic UKA are discussed and gaps in the existing medical literature are highlighted to aid future research.

Limitations of conventional jig-based UKA

Preoperative radiographic two-dimensional (2D) templating and intraoperative alignment guides are used in conventional manual UKA to help plan and perform error-free bone resection and implant positioning. However, this technique is associated with limited accuracy and poor reproducibility of achieving the planned component positioning, owing to inter-patient variations in anatomical landmarks for referencing, subjective assessments of optimal jig positioning, and lack of objective intraoperative data on limb alignment. Suboptimal pin placement into the tibial cortex, re-drilling guide pins, iatrogenic bone and soft tissue injury from the hand-held sawblade, and suboptimal mediolateral tibial component positioning may lead to stress fractures and/or bone collapse, requiring complex revision surgery. The manual technique for UKA also relies on several subjective intraoperative assessments of kinematics including the arc of flexion, limb alignment, and periarticular soft tissue tension, to guide bone resection and fine-tune implant positioning. Due to these reasons, conventional manual UKA is heavily dependent on the skill and expertise of the operating surgeon. Liddle et al reviewed outcomes of 37,131 UKAs from the National Joint Registry for England and Wales, and found surgical case-volume strongly influenced implant survivorship following UKA. For surgeons performing fewer than ten UKAs per year, the mean eight-year rate of UKA survival was 87.9% (95% confidence interval [CI] = 86.9% to 88.8%) compared with 92.4% (95% CI = 90.9% to 93.6%) for those who performed 30 UKAs or more per year.

Surgical technique

Robotic UKA uses computerized systems at several distinct stages for accurate execution of the patient-specific surgical plan. Preoperative plain radiographs or computerized tomography (CT) scans of the knee joint are used to create a virtual three-dimensional reconstruction of the patient’s native knee anatomy. The patient-specific reconstruction is then used by the surgeon to plan an implant position and size that best achieves the desired bone coverage, component position, and limb alignment. Computer software is used to calculate optimal femoral and tibial bone resection windows for an accurate execution of this surgical plan. Intraoperative bone registration and verification of bony landmarks are used to confirm the patient’s osseous knee anatomy prior to bone resection. In CT-based robotic knee systems, the patient-specific model of the knee joint is mapped intraoperatively to confirm bone geometry. In CT-free robotic application systems, registration is performed by mapping the patient’s osseous anatomy onto a generic virtual model of the knee joint, and planning of implant positioning and bone resection is performed intraoperatively. The surgeon then uses the robotic device to undertake the planned femoral and tibial bone resections within the confines of the preoperative surgical plan. Optical motion-capture technology is used to assess intraoperative flexion and extension gaps, joint stability, range of movements, and limb alignment. This allows the surgeon to make live, on-table modifications to the implant position and bone resections, and permits fine-tuning of soft tissue releases to achieve the desired bone coverage, component positioning, knee kinematics, and limb alignment.

Types of robotic UKA systems

Robotic UKA systems are classified as either fully active or semi-active depending on the degree of control that the robotic device provides the operating surgeon. Fully active robotic systems are able to carry out the planned femoral and tibial bone resections autonomously. This process is overseen and guided by the surgeon, who may activate an emergency deactivation if necessary. The Acrobat System (Acrobat Co. Ltd., London, UK) is an example of a hands-on robotic device that delivers more accurate implant positioning and limb alignment compared to conventional manual UKA. Semi-active robotic systems provide live intraoperative feedback to limit deviation from the preoperative surgical plan; however, the surgeon retains overall control over bone resection and implant positioning. The Navio Surgical System (Smith & Nephew, Andover, Texas, USA) is an example of an imageless, semi-active robotic system. With this system, the surgeon initially maps out the patient’s osseous anatomy onto a generic virtual three-dimensional (3D) model of the knee joint, which is then used to plan optimal bone resection and component positioning. A hand-held robotic platform helps to execute this plan with a high level of accuracy. The Mako Robotic Arm
Interactive Orthopaedic system (Stryker Ltd, Kalamazoo, MI, USA) is an example of an image-guided semi-active robotic system. It differs from the Navio System by using a preoperative CT scan to create a virtual patient-specific computer-aided design model, which the surgeon then uses to plan optimal bone resection and implant positioning. A robotic arm with audio, tactile, and visual feedback assists the surgeon to execute the plan within the confines of the haptic boundaries for femoral and tibial bone resections. Optical motion-capture tracking is used to assess knee kinematics through the arc of flexion and helps guide fine-tuning of bone resections and implant positioning.  

**Accuracy of implant positioning**

Robotic technology uses the combination of preoperative virtual 3D reconstructions and an intraoperative robotic device that helps to actively control the motor function of the operating surgeon, to help reduce surgeon-induced errors in component positioning and limb alignment. Cobb et al conducted a prospective randomized study of 27 patients with medial compartment knee osteoarthritis undergoing conventional manual UKA versus robotic UKA. The authors reported that all patients undergoing robotic UKA had tibiofemoral alignment in the coronal plane within 2° of the planned position, compared with only 40% in those undergoing conventional manual UKA. Bell et al performed a prospective randomized controlled study assessing accuracy of implant positioning using postoperative CT scans in 62 robotic UKAs versus 58 conventional UKAs, and found robotic UKA reduced root mean square errors in achieving planned femoral and tibial implant positioning. Herry et al retrospectively reviewed plain radiographs in 40 conventional manual UKAs versus 40 robotic UKAs, and found robotic UKA improved accuracy in restoration of the native joint line compared to conventional manual UKA. Iñiguez et al assessed the accuracy of implant positioning in 27 cadaveric specimens undergoing conventional manual UKA versus robotic UKA. The authors reported that robotic UKA was associated with improved accuracy of femoral and tibial component positioning, and more accurate prediction of the femoral component size than conventional manual UKA. Precision bone cuts and improved accuracy of implant positioning with robotic technology may help to facilitate reliable cementless fixation of components in future UKA designs, and also increase long-term implant survivorship compared to conventional manual UKA.  

**Learning curve of robotic UKA**

Studies have shown well-established learning curves for UKA, with the introduction of new component designs, minimally invasive surgery, computer-navigation, and patient-specific implants. The learning curve for robotic UKA is important for understanding the impact of this procedure on the surgical workflow, scheduling of operative cases and theatre lists, and establishing any additional risks or complications during the acquisition of surgical proficiency. Kayani et al conducted a prospective cohort study on 60 patients undergoing conventional manual UKA followed by 60 patients receiving robotic UKA and used cumulative summation (CUSUM) analyses to assess incremental changes in study outcomes until surgical proficiency was achieved. Robotic UKA had a learning curve of six operative cases for achieving operative time and surgical team comfort levels comparable to conventional jig-based UKA, but there was no learning curve effect for achieving the planned femoral and tibial implant positioning. There was no additional risk of complications compared to conventional jig-based UKA during the learning phase. These findings are important as they suggest that low case-volume UKA surgeons may be able to achieve high levels of accuracy in implant positioning, which has previously been a limitation of conventional manual UKA. Liddle et al reviewed outcomes of 41,986 UKAs from the National Joint Registry for England and Wales and found that optimal outcomes (as assessed using revision rates) were achieved when UKA comprised 40% to 60% of the surgeon’s practice. Acceptable outcomes were achieved when at least 20% of practice encompassed UKA, while surgeons with the lowest usage (less than 5%) had the highest revision rates. However, achieving the optimal UKA case-volume is challenging owing to limitations in the number of patients with single-compartment knee disease and strict inclusion criteria for conventional manual UKA. Robotic technology provides an avenue for low-volume UKA surgeons to achieve high levels of accuracy in implant positioning, which may help to reduce the burden of revision surgery following UKA.  

**Bone preservation**

More conservative bone resection is associated with reduced bone oedema, decreased postoperative pain, and faster rehabilitation following UKA. Preservation of the native bone stock is also important for aiding future revision surgery. In robotic UKA, bone resection is confined to the boundaries of the preoperative surgical plan, which helps to limit iatrogenic bone injury and better control the depth of bone resection compared to conventional manual UKA. Ponzo et al conducted a retrospective review of 8,421 robotic-arm-assisted UKAs versus
27,989 conventional manual UKAs from a range of manufacturers. They found that 15.5% of conventional cases were associated with more aggressive tibial resection with tibial inserts greater than 9 mm used, compared with only 6.4% of robotic-assisted cases (p < 0.001). Despite this, caution should be taken in interpreting these findings as the size of the bone resections were not recorded, and the depths of the resections were estimated using the component sizes implanted.

**Soft tissue balancing**

Achieving correct soft tissue tensioning and ligamentous balancing are important technical objectives for optimizing stability and long-term functional outcomes in UKA. In conventional manual UKA, assessment of the periarticular soft tissue tension and limb alignment are performed manually, which is dependent on subjective assessments performed by the operating surgeon. Robotic UKA uses optical motion-capture technology to provide real-time medial and lateral gap measurements while applying valgus and varus strain to appropriately tension the ligaments through the arc of flexion. Robotic systems allow intraoperative assessments of the soft tissue balance in degrees and/or millimetres whilst reducing the deformity through the arc of knee flexion with different joint positions. This live, patient-specific, intraoperative kinematic data may be used to predict limb alignment and periarticular soft tissue tension after removal of osteophytes and prior to performing any bone resections. Bone resection, implant positioning, and implant sizing are then fine-tuned to achieve the desired ligamentous tension and limb alignment through the arc of flexion. In UKA or high tibial osteotomy, this technology offers an avenue for executing the planned alignment with improved accuracy and reduces the risks of overcorrection or overtightening of the native compartments. More recently, optical motion-capture technology during robotic TKA has been used as an investigative tool to assess the effects of specific ligamentous releases on flexion–extension gaps, mediolateral soft tissue laxity, limb alignment, and fixed flexion deformity in patients undergoing TKA. Shalhoub et al recently reviewed gap measurements in 120 patients undergoing robotic TKA combined with an intraoperative tensioning device, and found mediolateral gap balance within 2 mm across the flexion range was achieved in over 90% of patients.

**Functional outcomes**

Robotic UKA is known to limit the action of the milling burr or sawblade to the confines of the preoperative surgical plan for bone resection. Conceptually, this helps to reduce periarticular soft tissue injury and limit the associated localized inflammatory response compared to conventional manual knee arthroplasty. Kayani et al performed a prospective cohort study of 146 patients undergoing conventional manual UKA versus robotic UKA, and found robotic UKA was associated with reduced postoperative pain, decreased opiate analgesia consumption, reduced inpatient physiotherapy, and decreased mean time to hospital discharge (42.5 ± 5.9 hours vs. 71.1 ± 14.6 hours respectively, p < 0.001) compared to conventional manual UKA. Blyth et al conducted a prospective randomized controlled trial with 139 patients undergoing conventional UKA versus robotic UKA, and reported median pain scores from postoperative day one to week eight after surgery. The scores of the robotic UKA group were 55.4% lower than the conventional manual UKA group. This information is valuable as many arthroplasty centres are now moving towards day case UKA. Robotic technology offers an avenue for improved pain control, enhanced functional rehabilitation, reduced need for physiotherapy, and earlier time to hospital discharge, which may facilitate the more widespread uptake of UKA as a day case procedure.

Existing studies have not demonstrated any differences in middle- to long-term functional outcomes in conventional manual UKA versus robotic UKA. In the aforementioned randomized control trial by Bell et al, robotic UKA was associated with improved American Knee Society Scores for three months following surgery, but there was no difference in functional outcomes between the conventional and robotic groups one year postoperatively. The authors targeted the 35 most active patients included in the study, and further evaluation of these particular patients revealed that robotic UKA improved Knee Society Scores (KSS), Oxford Knee Scores, and Forgotten Joint Scores compared with conventional manual UKA at two years follow-up. More recently, Canetti et al conducted a study to review the outcomes of 28 highly active patients undergoing lateral compartment UKA, and discovered that robotic UKA enabled markedly earlier mean return to sporting activity compared with conventional UKA (4.2 ± 1.8 months vs. 10.5 ± 6.7 months respectively, p < 0.01). These studies suggest that robotic UKA improves short-term functional outcomes in highly active patients, although overall functional outcomes are similar to those of conventional jig-based UKA. Zhang et al recently performed a meta-analysis using 11 studies with 498 patients undergoing robotic UKAs versus 589 patients receiving conventional manual UKAs. The study found that robotic-assisted UKA was associated with lower complication rates (relative risk (RR)): 0.62, 95% CI: 0.45–0.85; P = 0.0041) and improved knee excursion during weight acceptance (standardised mean difference (SMD)): 0.62, 95% CI: 0.25–1.00; P = 0.001). There were no significant differences in patient-reported outcome measures, range of motion, and revision rates between conventional manual UKA versus robotic UKA. Similarly, Wong et al
compared the outcomes of 118 conventional manual UKAs with 58 robotic UKAs, and reported no difference in KSS, Western Ontario and McMaster Universities Arthritis Index (WOMAC) or Short Form Health Survey of 12 items (SF-12) scores at a minimum of two-years post-surgery.\textsuperscript{43}

**Implant survivorship**
Suboptimal limb alignment with overcorrection may lead to increased load on the unsurfaced compartments and accelerate the time to revision surgery.\textsuperscript{15,18,19} Intraoperative optical motion-capture tracking enables the surgeon to accurately assess intraoperative limb alignment and precisely execute the optimal limb alignment. Conceptually, this may help to limit disease progression in the unsurfaced compartment and improve long-term implant survivorship. Pearle et al conducted a prospective, multi-centre review of 1,135 robotic UKAs and found that these patients had an implant survivorship of 98.8% at minimum of 22 months follow-up.\textsuperscript{44} This is superior to the implant survival rates of conventional manual UKA reported in the national joint registries of the United Kingdom (95.6%), Sweden (95.3%), Australia (95.1%), and New Zealand (96.1%).\textsuperscript{45–48} In a retrospective study by Batailler et al, 80 conventional UKAs were compared with 80 robotic UKAs, and revision rates in the robotic cohort were found to be 5% compared with 9% in the conventional group, although this difference was not statistically significant.\textsuperscript{49} Notably, 86% of the revisions in conventional manual UKA were due to component malposition or limb malalignment, whereas in the robotic group, there were no revisions due to incorrect component placing. Vakharia et al reviewed outcomes in 13,617 robotic UKAs versus 21,444 conventional manual UKAs, and found implant survivorship was 100% in the robotic group compared to 97.5% in the conventional group at one-year follow-up.\textsuperscript{50} Similarly, Cool et al reported reduced revision rates in robotic UKA (0.81% [2/246] vs. 5.28% [26/492]; $P = 0.002$) compared to conventional manual UKA at two-year follow-up.\textsuperscript{51} In 2019, the Australian Joint Registry reported cumulative revision rates for robotic UKA at 2.8%, compared to 4.6% for non-robotic UKA at a three-year follow-up.\textsuperscript{47} Robotic-assisted UKA was associated with reduced revisions for implant loosening, progression of disease, residual pain, and fracture, but increased revisions for infection compared to non-robotic UKA. The results of multi-centre studies and longer-term joint registry data on implant survivorship and revision rates comparing non-robotic UKA versus robotic UKA are awaited.

**Cost-effectiveness**
Moscchetti et al analysed the cost-effectiveness of conventional manual UKA versus robotic UKA using a Markov decision analysis model. The system was cost-effective when 2-year failure rates were under 1.2% in robotic UKA, and under 3.1% in conventional UKA.\textsuperscript{52} The authors reported robotic UKA to be a more cost-effective procedure only if the case-volume for this procedure exceeded 94 cases per year. Clement et al also performed an economic evaluation of robotic UKA in the United Kingdom by comparing quality-adjusted life years (QALY) in patients with medial compartment disease undergoing robotic UKA, conventional manual UKA, and TKA.\textsuperscript{53} The overall health gain per patient was 13.59 QALYs after robotic UKA, 11.80 QALYs after TKA, and 12.20 QALYs after conventional manual UKA. Robotic UKA was found to be a more cost-effective intervention, with a cost per QALY relative to TKA and conventional manual UKA of £1,395 and £1,170, respectively. The shorter length of stay associated with robotic UKA significantly influenced the observed differences in QALYs, with day case procedures markedly reducing costs in this group compared to conventional manual UKA and TKA groups. Higher-volume centres achieved lower costs per QALY, in comparison to lower-volume centres, indicating that the procedure becomes more cost-effective with increased volume of cases. Further high-quality trials are required to determine the cost-effectiveness of robotic UKA compared to conventional manual UKA to help clinicians and healthcare managers make more informed decisions about implementing robotic technology into routine UKA practice.

**Limitations**
Robotic UKA is associated with substantial costs for purchasing the robotic device, additional preoperative CT scanning, further training for surgical staff, and increased operative times during the initial learning phase.\textsuperscript{15,54} Many robotic devices are also only compatible with specific implants and therefore additional costs for purchasing supplementary equipment and implants must be considered in any future cost analysis. Proponents of robotic UKA propose that these costs may be partially offset by decreased length of hospital stay, reduced need for physiotherapy, fewer discharges to rehabilitation units or skilled nursing facilities, less opiate analgesia consumption and reduced readmission rates compared to conventional jig-based TKA.\textsuperscript{33,39} Additional limitations of robotic UKA include extra incisions for the insertion of the femoral and tibial registration pins to enable optical motion-capture tracking. This may expose the patient to an increased risk of wound problems or infection. Accompanying CT scans with image-guided procedures are known to expose the patient to increased quantities of radiation. Overall time spent on the robotic procedure is also increased, with further time and resources required for preoperative segmenting and templating.\textsuperscript{54}
Conclusion

Robotic UKA improves the accuracy of implant positioning, enhances postoperative functional rehabilitation, and may improve short-term functional outcomes in highly active individuals compared to conventional manual UKA. Robotic technology also provides live intraoperative data on knee kinematics through the arc of flexion that can be used to fine-tune implant positioning and optimize soft tissue tensioning. Robotic technology offers an avenue for low-volume UKA surgeons to achieve high levels of accuracy in implant positioning, which may help to improve implant survivorship and reduce the burden of revision disease. However, further studies are required to assess the effect of robotic UKA on long-term functional outcomes, implant survivorship, cost-effectiveness, and complications compared with conventional manual UKA.

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ICMJE CONFLICT OF INTEREST STATEMENT
FSH reports board membership of the Bone and Joint Journal and The Annals of the Royal College of Surgeons; consultancy for Smith & Nephew, Corin, MatOrtho and Stryker; payment for lectures including service on speakers’ bureaus for Smith & Nephew and Stryker; royalties paid by Smith & Nephew, MatOrtho, Corin and Stryker, all outside the submitted work.

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The direct superior approach versus posterior approach for total hip arthroplasty: study protocol for a prospective double-blinded randomised control trial

Babar Kayani*, Sujith Konan, Jenni Tahmassebi, Atif Ayuob and Fares S. Haddad

Abstract

Background: The direct superior approach (DSA) is a minimally invasive modification of the posterior approach (PA) that preserves the iliotibial band and short external rotators except for the piriformis or conjoint tendon during total hip arthroplasty (THA). The objective of this study is to compare patient satisfaction, functional outcomes, accuracy of implant positioning, component stability, gait, cost-effectiveness, and complications in the DSA versus PA for THA.

Methods and analysis: This prospective double-blinded randomised control trial will include 80 patients with symptomatic hip osteoarthritis undergoing primary THA. Following informed consent, patients will be randomised to THA using the PA (control group) or DSA (investigation group) at a ratio of 1:1 using an online random number generator. Blinded observers will review patients at regular intervals for 2 years after surgery to record predefined study outcomes relating to postoperative rehabilitation, clinical progress, functional outcomes, accuracy of implant positioning, gait analysis on force plate treadmill, implant migration with radiosteriometric analysis, cost-effectiveness, and complications. A superiority study design will be used to evaluate whether the DSA provides improved outcomes compared to the PA for THA. Evaluation of study outcomes in DSA and PA will be used to quantify and draw inferences on differences in the efficacy of treatment between the two groups. Intention-to-treat and per-protocol population analysis will be undertaken. The following statistical methods will be employed to analyse the data: descriptive statistics, independent t test, paired t test, analysis of variance, Fisher exact test, chi-square test, and graphical displays. Ethical approval was obtained from the London-Fulham Research Ethics Committee, UK. The study is sponsored by University College London, UK.

Discussion: This study compares a comprehensive and robust range of clinical, functional, and radiological outcomes in THA performed using the PA versus DSA. The findings of this study will provide an improved understanding of the differences in the PA versus DSA for THA with respect to patient satisfaction, functional outcomes, implant survivorship, gait, cost-effectiveness, and complications.

Trial registration: ClinicalTrials.gov, NCT04191993. Registered on 10 December 2019

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Background
Total hip arthroplasty (THA) is an effective procedure for relieving pain, restoring function, and improving the quality of life in patients with end-stage hip osteoarthritis [2–5, 7, 16, 20]. Analysis of joint registry data from the UK, Sweden, and New Zealand has shown that the posterior approach (PA) is the most commonly used approach for THA [16]. The main advantages of the PA for THA are that it preserves the abductor mechanism, reduces intraoperative blood loss, and decreases the risk of heterotrophic ossification compared to the anterolateral and direct lateral approaches [10, 14, 16]. However, the PA is associated with increased risk of sciatic nerve injury during dissection, bleeding from the inferior gluteal artery as it leaves the pelvis below the piriformis, and increased risk of dislocation compared to these other approaches [6, 8, 11, 25]. Evolution in minimally invasive surgery and recent innovations in surgical instrumentation have led to the development of the direct superior approach (DSA), which is a modification of the PA that preserves the iliotibial band and the short external rotators except for the piriformis or conjoint tendon [17, 19, 21]. Conceptually, improved preservation of this periaricular soft tissue envelope may help to reduce postoperative pain, improve functional recovery, and better restore native hip biomechanics [13, 18].

Existing studies on the DSA for THA are case-controlled trials or case series with limited data on validated functional outcomes or clinically significant radiological outcomes [17, 19, 21]. Nam et al. conducted a prospective non-randomised trial comparing THA performed using 196 PAs versus 42 DSAs at three separate treatment centres [17]. The authors reported there was no difference in moderate to severe pain over the greater trochanter, anterior thigh, and lateral thigh between the two approaches at a minimum 1-year follow-up. Patients undergoing the PA had improved University of California at Los Angeles hip (UCLA) scores compared to those undergoing the DSA at 1-year follow-up. However, this study included different operating surgeons within three healthcare institutions, and the PA was performed through a modified mini-incision in patients that were younger and more active than the DSA group. Roger and Hill retrospectively reviewed outcomes in a case series of 135 patients undergoing the DSA for THA and reported good postoperative functional outcomes as assessed using the Harris hip score at 1-year follow-up [21]. Mean acetabular cup abduction was 41° (range 21–49°), and mean acetabular cup anteversion was 21° (range 15–27°). Femoral implant positioning greater than 2° varus and valgus was observed in 4% and 2% of patients respectively. This study was a retrospective study with no control group and heterogeneity in postoperative follow-up times.

Penenberg et al. followed 250 patients undergoing the DSA for THA and found mean Harris hip scores improved from 47.71 preoperatively to 95.6 within 3 to 6 months postoperatively [19]. Femoral implant positioning was within 2° of the planned position in 97% of patients with mean acetabular cup abduction of 42° (range 30 to 55°) and acetabular cup anteversion of 31° (range 22 to 40°) in all study patients. This was a retrospective study with limited follow-up, no control group, patients and clinicians were not blinded, and statistical analysis for assessing the significance of study outcomes was not performed. Amanullah et al. assessed periaricular muscle injury in eight cadaveric specimens in which the direct anterior approach was performed on one side and the DSA for THA on the contralateral side [1]. The DSA was associated with reduced iatrogenic injury to the gluteus minimus muscle, gluteus minimus tendon, tensor fascia lata, and rectus femoris compared to the direct anterior approach. This study had a small sample size and iatrogenic soft tissue injury was graded in cadaveric specimens, and therefore, it remains unknown how the observed differences in muscle injury translate to clinical outcomes between the two treatment groups.

There remains a paucity of high-quality evidence comparing clinical, functional, and radiological outcomes in the PA versus DSA for THA. Further, it remains unknown how differences in muscle preservation in the DSA and PA translate to postoperative pain scores between the two treatment groups. It is possible to improve on existing studies by assessing a more comprehensive and robust range of outcome measures, prospectively randomising patients to their respective treatment groups, standardising the surgical techniques within each group, using the same implant designs and postoperative rehabilitation protocol in all study patients, and blinding patients and observers recording study outcomes. Radiosteriometric analysis (RSA) will also be used to assess implant micromotion, which correlates with component loosening and provides prognostic information on long-term implant survivorship [22–24]. The findings of this study will provide an improved understanding of the differences in the PA versus DSA for THA with respect to patient satisfaction, functional outcomes, accuracy of implant positioning, component survivorship, cost-effectiveness, and complications.

Methods/design

Objectives
The primary objective of this study is to compare postoperative pain scores on the visual analogue scale (VAS) in the PA versus DSA for THA. The study hypothesis is that the DSA will reduce periaricular soft tissue dissection that will translate to reduced postoperative pain scores on the VAS compared to the PA for THA.
The secondary objectives are to compare the following outcomes between the two treatment groups:

1. Surgical efficiency
2. Postoperative functional rehabilitation
3. Patient satisfaction
4. Functional outcomes
5. Quality of life
6. Muscle group strength
7. Range of motion
8. Accuracy of restoring planned hip biomechanics
9. Accuracy of achieving planned component positioning
10. Implant stability
11. Gait analysis
12. Resource use and cost-effectiveness
13. Complications

Trial design
This study is a prospective, single-centre, double-blinded, randomised control trial. The study will be undertaken in the Department of Trauma and Orthopaedics, University College Hospital, 235 Euston Road, Bloomsbury, London NW1 2BU, UK. The study will include 80 patients randomly allocated to either PA (control group) or DSA (investigation group) for THA. The study commenced patient recruitment in June 2018 and is expected to complete patient recruitment in December 2020. All patients will be followed up for 2 years after surgery, and therefore, the anticipated completion date for the study is December 2022. The study is sponsored by University College London, UK. The patient enrolment flowchart is presented in Fig. 1. The schedule of enrolment, interventions, and assessments for all study patients is shown in Fig. 2.

Eligibility criteria
The inclusion criteria for this study are as follows: the patient has symptomatic hip osteoarthritis requiring primary THA; the patient is fit for surgical intervention following review by a surgeon and anaesthetist; the patient aged between 18 and 80 years at the time of surgery; the patient is able to give informed consent and agrees to comply with the postoperative review programme; and the patient has sufficient mobility to attend follow-up clinics. The exclusion criteria for this study are as follows: patient is undergoing revision surgery or second-stage THA; patients in whom the planned hip biomechanics are in a different position to the contralateral hip (e.g. developmental dysplasia of the hip or protrusio acetabuli); patient is not suitable to have the planned study implants (e.g. requiring dual mobility component or cemented implants); patient is immobile or has another neurological condition affecting musculoskeletal function; patient is already enrolled on another concurrent clinical trial; patient is unable or unwilling to sign the informed consent form specific to this study; and patient is unable to attend the study follow-up programme. Importantly, patients that do not receive the planned study implants (e.g. intraoperative assessment showing poor bone quality or bone loss necessitating cemented implants for THA) will be excluded from the study.

Recruitment
Patients will be recruited from the orthopaedic outpatient clinic at University College Hospital, London, UK. All patients will be screened by the clinical team (orthopaedic consultant surgeon, clinical research fellow, and orthopaedic registrar) for study participation based on the predefined inclusion and exclusion criteria listed above. Patients that fulfil the eligibility criteria and express an interest to participate in the study will be provided with an ethics committee-approved patient information sheet. This provides details about the study treatment, follow-up, and contact details for further information. All members of the clinical team are familiar with the study and will address any preliminary questions about the study. Details of those patients expressing an interest to participate in the study will be recorded in the patient contact form and forwarded to the research physiotherapist. The research physiotherapist will phone the patient 4 weeks after this consultation to discuss any further questions and confirm if the patient would like to participate in the study.

Consent
Informed consent will be obtained by the chief investigator or principal investigator when the patient attends for preoperative assessment. This is 6 weeks after the outpatient consultation for agreement to THA and 2 weeks before surgery. It is important to the data collection scheme that patients are able to follow commands, read, and interpret questions via questionnaires. For those who cannot hear, read, or understand English, an interpreter will be provided. Identical preoperative imaging modalities for surgical planning will be used in both treatment groups.

Allocation
After informed consent has been obtained, the research physiotherapist will randomise the patient into one of the two treatment groups using an online random number generator (www.random.org). A number from 1 to 80 can be randomly generated and will allocate a patient to one of the two arms of the study: 1–40 inclusive for the control group and 41–80 inclusive for the investigation group. The research physiotherapist will perform...
the randomisation procedure and store the designated treatment group for each patient on a password-encrypted file on the hospital computer. The operating surgeon will have this information communicated to them on the morning of surgery.

**Preoperative imaging**
All patients will undergo preoperative imaging with plain pelvic and hip radiographs. In both treatment groups, pelvic radiographs will be exported onto Traumacad software (Traumacad, Petach-Tikva, Israel) to template
optimal implant positioning and sizes for achieving the planned bone coverage, component version and inclination, horizontal and vertical centres of rotation, acetabular and femoral offset, and leg-length correction. All preoperative templating will be undertaken by the operating surgeon 2 weeks prior to surgery. Preoperative pain scores on the VAS, analgesia requirements, and functional outcome scores (Fig. 2) will also be collected preoperatively as baseline values.

Surgical intervention
All operative procedures will be performed by one of two consultant orthopaedic surgeons that are fully trained and experienced with both the PA and DSA for...
THA. In both treatment groups, the patient will be placed in the lateral decubitus position and a curved incision performed behind the posterior edge of the greater trochanter extending distally towards the shaft of the femur. This initial incision will be 8–10 cm in length but can later be extended as required. The fascia lata will be incised along the length of the incision and the fibres of the gluteus maximus split along the line of the incision to expose the underlying pericapsular fat. Retractors will be used to retract the gluteus medius anteriorly and the soft tissue along the posterior border of the proximal femur inferiorly. The pericapsular fat will be removed with diathermy and the plane between the gluteus medius and gluteus minimus muscle developed. The hip joint will then be internally rotated to place the short external rotators on stretch. In the PA, diathermy will be used to detach the external rotators (including piriformis) close to their femoral insertion. In the DSA, caution will be taken to identify and protect the iliotibial band during dissection (Fig. 3) [12, 19, 21]. A retractor will be placed directly under the obturator internus to protect the inferior gemellus muscle below. The piriformis (or conjoint tendon) will be detached as close to their femoral insertions as possible but the remaining external rotators preserved. The capsulotomy will start at the distal, inferolateral aspect of the wound and extend proximally and posteromedially towards the superior acetabular margin. The capsule will be elevated subperiosteally to create superior and inferior capsular flaps. The retractors will then be repositioned inside the capsule and the hip dislocated posteriorly by flexion, adduction, and internal rotation.

The femoral osteotomy site will be marked using the templated measurements from the greater and lesser trochanters with the femoral neck cutting guide in place. An oscillating saw will be used to perform the osteotomy with Hohmann retractors protecting the surrounding soft tissues. The femoral osteotomy will be performed with the saw blade 45° to the femoral shaft and in the plane of the tibia. Sharp Hohmann retractors will be positioned over the anterior wall to lever the femur anteriorly and under the transverse acetabular ligament to expose the whole acetabulum for preparation. Soft tissues overhanging the acetabular circumference will be excised. Osteophytes will also be excised with an osteome and the medial wall visualised. Hemispherical reamers will be used to remove the residual acetabular cartilage and expose the underlying subchondral bone. In the PA, this will be undertaken using sequentially larger straight reamers until the medial wall is reached. In the DSA, medial acetabular wall reaming will initially be undertaken using a straight acetabular reamer and then sequentially larger angled reamers until the medial wall is reached [19, 21]. In both groups, an external alignment guide will be attached to the cutting-edge reamer handle and acetabular impactor to improve the accuracy of acetabular cup positioning. Acetabular cup positioning will be guided by the preoperative surgical plan and transverse acetabular ligament to match the patient’s native acetabular cup inclination and version within Lewinnek’s safe zones (inclination 30–50°, anteverision 5–25°) [15]. Any residual osteophytes will be removed at this stage using an osteotome and bone nibbler, and the trial prosthesis inserted to ensure satisfactory coverage and stability. Line-to-line technique for acetabular implantation will be used with implantation of the acetabular cup that is the same size as the last reamer used, and this will be augmented with two acetabular screws. The leg will then be placed into 40° flexion, 40° internal rotation, and 40° abduction to visualise the femoral osteotomy site. A femoral elevator will be inserted under the anterior femoral neck to elevate and expose the proximal

Fig. 3 intraoperative photo showing the preservation of the iliotibial band.
femur, and a box chisel used to remove bone from the posterolateral femoral neck. The femur will be prepared using a rasp and sequential broaching until maximum cortical contact in the mediolateral dimension is achieved. The femur will be prepared and implanted with 10–20° anteversion. Trial femoral heads will be applied to check hip joint stability, offset, soft tissue tension, and leg-length discrepancy prior to definitive selection of the femoral head. The final femoral stem will then be implanted, femoral head applied to the taper, and hip joint reduced. The capsule and external rotators will be repaired back to the femur and a layered closure of the fascia, subcutaneous tissue, and skin performed.

All study patients will receive the Accolade II femoral stem (Stryker Ltd, Mahwah, NJ, USA) and the trident acetabular shell (Stryker Ltd, Mahwah, NJ, USA). Patients in both treatment groups will undergo the same postoperative rehabilitation programme prior to discharge. All patients will receive postoperative patient-controlled analgesia (PCA) with the background intravenous morphine infusion rate set at 0.5 mg/h, bolus dose of 2 mg, and lockout period of 10 min. Additional oral paracetamol and ibuprofen may be administered by the nursing staff if requested by the patient. The PCA will be stopped 24 h after surgery and converted to an oral regimen of regular paracetamol, ibuprofen, and dihydrocodeine, with oral morphine available for breakthrough pain.

Outcomes
All study patients will undergo review by two blinded observers (one orthopaedic registrar and one clinical research fellow) at 2 weeks, 6 weeks, 6 months, 1 year, and 2 years following surgery. During these follow-up times, predefined clinical, functional, and radiological outcomes will be recorded by these observers using case report forms (CRFs). The following outcomes will be recorded in all study patients:

1. Operating time (minutes)
2. Time to hospital discharge (hours)
3. Pain scores on the VAS and analgesia requirements preoperatively, during the inpatient admission, and postoperatively at 6 weeks, 6 months, 1 year, and 2 years
4. Patient satisfaction as assessed using the Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS) preoperatively and postoperatively at 6 weeks, 6 months, 1 year, and 2 years following surgery [9]
5. Patient-reported outcome measures including Oxford hip score (OHS), Harris hip score (HSS), hip disability and osteoarthritis outcome score (HOOS), University College Hospital hip (UCH) score, and Western Ontario and McMaster Universities Arthritis Index (WOMAC) preoperatively and postoperatively at 6 weeks, 6 months, 1 year, and 2 years following surgery
6. Health-related quality of life as measured using European Quality of Life questionnaire with 5 dimensions for adults (EQ-5D) preoperatively and postoperatively at 6 weeks, 6 months, 1 year, and 2 years
7. Accuracy of achieving the planned implant positioning and hip biomechanics as assessed using plain pelvic and hip radiographs preoperatively and postoperatively prior to discharge
8. Mobilisation distance (metres) and use of mobility aids preoperatively and postoperatively at 6 weeks, 6 months, 1 year, and 2 years
9. Range of movement (degrees) in hip joint preoperatively and postoperatively at 6 weeks, 6 months, 1 year, and 2 years
10. Muscle group strength testing in hip joint preoperatively and postoperatively at 6 weeks, 6 months, 1 year, and 2 years as measured using a dynamometer
11. Gait analysis performed postoperatively at 6 weeks, 6 months, 1 year, and 2 years as assessed using force plate treadmill testing
12. Femoral and acetabular implant early migration as assessed using RSA performed postoperatively at 2 weeks, 6 weeks, 6 months, 1 year, and 2 years
13. Resource use and cost-effectiveness including comparisons between the two treatment groups relating to operating time, theatre efficiency, equipment and sterilisation costs, analgesia requirements, inpatient rehabilitation, time to discharge, outpatient follow-up, functional outcomes, quality of life, return to work, additional imaging costs, and complications with their respective treatments
14. Complications

Blinding
All patients and clinical staff recording postoperative study outcomes will remain blinded to the treatment group. Study patients will be identifiable with a unique study number. Only the research physiotherapist will have the key to identify individual patients and their respective treatment arm. Any documents related to the study will be archived directly at the study site by the research physiotherapist within a locked filing cabinet in a locked research office. This office has swipe card access with onsite security and 24-h CCTV surveillance. Patient data will be logged electronically using each patient’s unique identification number with computer software on an encrypted, password-protected research computer.
Sample size
Prior to commencement of the study, a sample size of 80 patients (40 patients in each treatment arm) was selected to achieve a power of 80% (1 – β) for assessing differences in pain scores on the visual analogue scale at 24 h after surgery between the two treatment groups, using an effect size of 0.67, alpha value of 0.05, and accounting for 10% sample size attrition rate during the 2-year follow-up period [17, 20]. A sample size attrition rate of 10% was selected based on previous randomised controlled studies performed in our treatment centre.

Statistical analysis
The analysis of the per-protocol population will be considered the primary analysis. The differences between the PA and DSA groups will be analysed by calculating the difference from baseline, per patient, and a two-sided confidence interval for the difference between the changes from baseline values will be calculated. This confidence interval will cover the true difference in the percentage change from baseline with a probability of 95%. The following statistical methods will be employed to analyse the data: descriptive statistics, independent t test, paired t test, analysis of variance, Fisher exact test, chi-square test, and graphical displays. Assumptions of normality will be tested with the D’Agostino test. Assumptions of homogeneity of variance will be tested with Levene’s test. If the distributional assumptions are (severely) violated, non-parametric techniques, such as Mann-Whitney’s test will be employed. In the event that the DSA is converted to PA intraoperatively, analysis will be performed using the intention-to-treat population and the treatment actually received by the patients. Intraoperative conversion from DSA THA to PA THA will be documented and presented as part of the study. Statistical significance is set at a p value < 0.05 for all analyses and all statistical analysis will be performed using SPSS software version 26 (SPSS Inc., Chicago, IL, USA).

Adverse events
Adverse events are defined as any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved. A serious adverse event (SAE) is an adverse event that results in hospitalisation or prolongation of existing hospitalisation, persistent or significant disability or incapacity, life-threatening clinical sequelae, or death. All SAEs during the protocol treatment will be reported directly to the sponsor using the SAE web form. The chief investigator will also assess the SAE for severity, causality, seriousness, and expectedness using pre-existing criteria provided by the sponsor and inform the Data Safety Monitoring Board (DSMB) within 3 days of the initial observation of the event. The protocol treatment period is defined as the period from the day that the first study patient is recruited into the trial to the day that the final study patient has completed the 2-year follow-up. The chief investigator will also inform the London-Fulham Research Ethics Committee and local Health Research Authority within 3 days of the SAE taking place. Safety aspects of the study are closely monitored by the sponsor and DSMB using unblinded data for its judgment. In cases where the SAE arises due to a problem with the study implants, Stryker Limited will also be notified within 2 days of the event taking place. The chief investigator will record the following: onset date, complete description of the event, severity, duration, action taken, and outcome for each SAE. The chief investigator will also provide regular updates of all SAEs to the London-Fulham Research Ethics Committee, local Health Research Authority, DSMB, and sponsor.

Data management
Onsite monitoring visits shall occur throughout the course of the clinical study by the chief investigator. The chief investigator shall permit and assist the sponsor (should they chose to monitor the study) to carry out verification of all study forms against data in the source documents, which shall occur as per the departmental policy for undertaking such activities. University College Hospital recognises that there is an obligation to archive study-related documents at the end of the study. The study master file will be archived at University College London in accordance with the University College Hospital Standard Operating Procedure for Archiving of Investigator Site File (ISF) and Pharmacy Site File (PSF). It will be archived for a minimum of 5 years from the study end, and no longer than 30 years from the study end.

End of protocol treatment
Reasons for going off study protocol include:

- Completion of the last follow-up visit 2 years after surgery
- Patient non-compliance or withdrawal (the reason for discontinuation will be recorded in the case report form)
- Intercurrent death

All patients included in this study are free to withdraw from the study at any time without compromise to their future treatment. On withdrawal, patients will revert to the standard follow-up regimen for routine (non-study) THA at the study site. The end of the study form will be completed and the reason for withdrawal documented. This form will also be completed if the patient is lost to
follow-up or dies during the course of the study. Data to the point of discontinuation will be used for analysis.

**Monitoring**
The chief investigator will monitor the progress of the clinical study in the form of monthly research meetings for those involved in the trial. The chief investigator will be responsible for day-to-day monitoring and management of the study. The UCLH/UCL/Joint Research Office, on behalf of UCL as the sponsor, will monitor and conduct random audits on a selection of studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the Department of Health Research Governance Framework for Health & Social Care (April 2005) and in accordance with the sponsor’s monitoring and audit policies and procedures. As per the protocol, the principal investigator will email the sponsor twice yearly with the following: delegation log, adverse event log, deviation log, and any annual progress reports sent to the Ethics committee.

**Peer review**
The study protocol has undergone independent external peer reviewer. The suggestions and recommendations for improvement to the study design were implemented. The reviewers, sponsor, and London-Fulham Research Ethics Committee reviewed the revised protocol documents and confirmed that all queries and suggestions had been fully addressed.

**Discussion**
THA is an effective procedure for relieving pain, restoring function, and improving the quality of life in patients with end-stage hip osteoarthritis. The surgical approach in THA is important as it influences postoperative gait, hip stability, and muscle function [2–5, 7, 16, 20]. The DSA is a minimally invasive modification of the PA that preserves the iliotibial band and short external rotators except for the piriformis or conjoint tendon during THA [17, 19, 21]. This prospective double-blinded randomised control trial will include 80 patients with symptomatic hip osteoarthritis undergoing primary THA. Following informed consent, patients will be randomised to undergo THA using the PA (control group) or DSA (investigation group) at a ratio of 1:1 using an online random number generator. Blinded observers will review patients at regular intervals for 2 years after surgery to record predefined study outcomes relating to postoperative rehabilitation, clinical progress, functional outcomes, accuracy of achieving planned implant positioning and hip biomechanics, cost-effectiveness, and complications. Gait analysis will be undertaken using force plate treadmills and implant stability assessed using RSA [22–24]. The findings of this study will provide an improved understanding of differences in the PA versus DSA for THA with respect to patient satisfaction, functional outcomes, implant position, implant survivorship, gait, cost-effectiveness, and complications.

**Trial status**
Protocol: version 1.0; date 01 September 2017
Patient recruitment date: 1 June 2018
Estimated completion of recruitment date: 1 December 2020
Estimated completion of final follow-up: 1 December 2022

**Abbreviations**
CRI: Case report form; DSA: Direct superior approach; DSMB: Data Safety Monitoring Board; EQ-5D: European Quality of Life questionnaire with 5 dimensions for adults; HHS: Harris hip score; HOOS: Hip disability and osteoarthritis outcome score; ORs: Oxford hip score; PA: THA: Posterior approach; SAE: Serious adverse event; SF-12: Short form health survey of 12 items; WOMAC: Western Ontario and McMaster Universities Arthritis Index

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No funding was received for this study.

**Availability of data and materials**
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

**Ethics approval and consent to participate**
The study has been reviewed and approved for patient recruitment by the London-Fulham Research Ethics Committee, UK (reference: 18/LO/1972). Written informed consent will be obtained from participants during recruitment on site and prior to data collection. Consent to use the data collected for scientific reporting and publication will also be obtained at the same time as the consent to participate.

**Consent for publication**
The findings of this research will be published in peer-review journals. All study patients will provide informed consent for the publication of anonymised patient data and study findings. Authorship will reflect the amount of time spent designing the study, collating the data, analysing the results, and writing the manuscript.

**Competing interests**
FSH reports board membership of the Bone and Joint Journal and the Annals of the Royal College of Surgeons; consultancy for Smith & Nephew, Corin, MatOrtho and Stryker; payment for lectures including service on speakers’ bureaux for Smith & Nephew and Stryker; and royalties paid by Smith & Nephew, MatOrtho, Corin and Stryker, all outside the submitted work. SK reports consultancy, payment for lectures including service on speakers’ bureaux, payment for development of education presentations, and travel/...
accommodations/meeting expenses for Smith and Nephew and AO, all outside the submitted work. All other authors declare no competing interests.

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Musculotendinous Junction Injuries of the Proximal Biceps Femoris

A Prospective Study of 64 Patients Treated Surgically

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Background: Injuries to the hamstring complex most commonly involve the proximal musculotendinous junction of the long head of the biceps femoris (MTJ-BFlh). Nonoperative management of these injuries is associated with prolonged rehabilitation and high risk of recurrence. To our knowledge, the surgical management of acute MTJ-BFlh injuries has not been previously reported.

Hypothesis: Surgical repair of acute MTJ-BFlh injuries enables return to sporting activity with low risk of recurrence.

Study Design: Case series; Level of evidence, 4.

Methods: A total of 64 patients (42 male and 22 female) undergoing surgical repair of acute MTJ-BFlh injuries were included. Predefined outcomes were recorded at regular intervals after surgery. Mean follow-up time after surgery was 29.2 months (range, 24.0-37.1 months).

Results: All study patients returned to their preinjury levels of sporting activity. Mean ± SD time from surgical intervention to return to sporting activity was 13.4 ± 5.1 weeks. Three patients had reinjury at the operative site: 1 (1.6%) with MTJ-BFlh injury and 2 (3.2%) with myofascial tears. At 3 months after surgery, patients had improved mean passive straight-leg raise (72.0 ± 11.4° vs 24.1° ± 6.8°; P < .001); increased mean isometric hamstring muscle strength at 0° (84.5% ± 10.4% vs 25.9% ± 8.9%; P < .001), 15° (89.5% ± 7.3% vs 41.2% ± 9.7%; P < .001), and 45° (93.9% ± 5.1% vs 63.4% ± 7.6%; P < .001); higher mean Lower Extremity Functional Scale scores (71.5 ± 5.0 vs 29.8 ± 6.3; P < .001); and improved mean Marx activity rating scores (9.8 ± 2.2 vs 3.8 ± 1.9; P < .001), as compared with preoperative scores. High patient satisfaction and functional outcome scores were maintained at 1 and 2 years after surgery.

Conclusion: Surgical repair of acute MTJ-BFlh injuries enables return to preinjury level of sporting function with low risk of recurrence at short-term follow-up.

Keywords: biceps femoris; hamstrings; recurrence; surgical treatment

The hamstring muscles (semimembranosus, semitendinosus, and biceps femoris) are the most commonly injured muscle group in professional athletes and account for approximately one-third of all muscle injuries sustained during sprinting, soccer, and rugby.14,17,21 The proximal musculotendinous junction of the long head of the biceps femoris (MTJ-BFlh) is most frequently injured,15 as attributed to its long, narrow aponeurosis, which leads to poor dissipation of force from the muscle belly to the tendon at this interface.18,26,30 Nonoperative management of these injuries includes rest, nonsteroidal anti-inflammatory drugs, protected range of movement, and eccentric muscle exercises.9 Shockwave therapy or injections with corticosteroids or plasma-rich protein have also been used with varying degrees of success.9,30 Limitations of nonoperative treatment include large variations in time for convalescence and high risk of recurrence on return to sporting...
activity. Nonoperative treatment is also associated with residual muscle weakness, neurological complications secondary to tethering of the sciatic nerve, and poor return to preinjury level of function. In professional athletes, these injuries are often regarded as career threatening and may lead to premature retirement from sporting activity.

Operative treatment of proximal hamstring injuries is most commonly reserved for injuries that remain refractory to nonoperative treatment or are associated with large, displaced avulsion fractures. Surgical techniques to repair these injuries include reattachment of the avulsed tendon with anchors, debridement of residual tendon with fixation of the injured muscle belly to the adjacent hamstring muscles, endoscopic repair of the avulsed tendon, and iliotibial grafts to reattach chronic retracted tendons to the ischial tuberosity. Surgical repair for partial or complete avulsion injuries of the proximal hamstrings is associated with high patient satisfaction, rapid return to sporting activity, and low rates of complications at short-term follow-up. However, to our knowledge, there are no existing studies that assess the effect of surgical repair of MTJ-BFlh injuries on postoperative outcomes.

The rationale for undertaking operative intervention in these patients is the prolonged rehabilitation period and high risk of recurrence with nonoperative management of these injuries, as reported within the existing literature and based on the operating surgeon’s experience. Before study commencement, 54 of the 112 patients (21.4%) undergoing nonoperative management of MTJ-BFlh injuries had recurrence of the primary injury within 2-year follow-up. This prompted a change in practice from nonoperative to operative treatment for high-grade MTJ-BFlh injuries. The current study assesses a comprehensive and robust range of study outcomes in a series of patients with high-grade MTJ-BFlh injuries undergoing acute surgical repair and standardized postoperative rehabilitation. The findings of this study will provide an improved understanding of the effects of acute surgical repair of MTJ-BFlh injuries on return to preinjury level of sporting activity, injury recurrence, and functional performance at short-term follow-up.

The primary objective of this study was to assess the effect of operative repair of acute MTJ-BFlh injuries on injury recurrence. The study hypothesis was that operative repair of MTJ-BFlh injuries would lead to low risk of injury recurrence at short-term follow-up. Secondary objectives were to assess the effect of surgical intervention on return to sporting function, patient satisfaction, hamstring muscle strength, straight-leg raise, functional performance, and complications.

METHODS

Patient Selection

This prospective study included 64 patients undergoing surgical treatment for acute MTJ-BFlh injuries between March 2015 and September 2016 (Table 1).

### TABLE 1
Demographics and Baseline Data on Patients Undergoing Surgical Repair of Injuries to the Proximal Musculotendinous Junction of the Long Head of Biceps Femoris

<table>
<thead>
<tr>
<th>Characteristic: Category</th>
<th>Mean ± SD or No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>26.6 ± 3.9</td>
</tr>
<tr>
<td>Female</td>
<td>28.4 ± 3.4</td>
</tr>
<tr>
<td>Male</td>
<td>25.7 ± 3.8</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>22 (34.38)</td>
</tr>
<tr>
<td>Male</td>
<td>42 (65.62)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>26.1 ± 2.4</td>
</tr>
<tr>
<td>ASA score</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>64 (100)</td>
</tr>
<tr>
<td>II</td>
<td>0 (0)</td>
</tr>
<tr>
<td>III</td>
<td>0 (0)</td>
</tr>
<tr>
<td>IV</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Laterality of surgery</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>37 (57.8)</td>
</tr>
<tr>
<td>Left</td>
<td>27 (42.2)</td>
</tr>
<tr>
<td>BAMIC grade</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>0</td>
</tr>
<tr>
<td>II</td>
<td>0</td>
</tr>
<tr>
<td>III</td>
<td>36 (56.3)</td>
</tr>
<tr>
<td>IV</td>
<td>28 (43.7)</td>
</tr>
<tr>
<td>Time from</td>
<td></td>
</tr>
<tr>
<td>Injury to surgery, d</td>
<td>12.4 ± 6.2</td>
</tr>
<tr>
<td>Surgery to return to sporting activity, wk</td>
<td>13.4 ± 5.1</td>
</tr>
</tbody>
</table>

*N = 64. ASA, American Society of Anesthesiologists; BAMIC, British Athletics Muscle Injury Classification.

This study included 51 professional athletes (29 rugby players, 14 football players, 3 sprinters, 3 cricketers, and 2 weight lifters) and 13 amateur athletes (8 football players, 4 middle-distance runners, and 1 rugby player). All study patients underwent preoperative magnetic resonance imaging (MRI) scans to confirm diagnosis, assess for any concurrent injuries, and plan operative intervention (Figure 1). All MTJ-BFlh injuries were graded with the British Athletics Muscle Injury Classification (BAMIC) system (Table 2).

The inclusion criteria for study participation were as follows: acute hamstring injury within 4 weeks of presentation; preoperative MRI scan to confirm BAMIC grade IIIB, IIIC, or IV tear of the proximal MTJ-BFlh (Table 2); clinical loss of strength and/or flexibility of the hamstring muscle group; and operative intervention undertaken by the senior author (F.S.H.). Exclusion criteria included the following: MTJ-BFlh injuries sustained >4 weeks before surgical intervention (n = 6), recurrent MTJ-BFlh injury or previous hamstring surgery (n = 4), BAMIC grade I-IIIA MTJ-BFlh injuries (n = 9), nontraumatic tendinitis of the proximal biceps femoris (n = 3), and patient residence abroad (n = 3).

Informed consent was obtained from all study patients. Hospital ethical review board approval was obtained before commencement of the study.
Surgical Technique

All operative procedures were performed with the patient in the prone position under general anesthetic. The gluteal skin crease was marked and an 8- to 10-cm longitudinal incision performed distal to this (Figure 2). The underlying subcutaneous tissue and gluteal fascia were divided with electrocautery and the inferior border of the gluteus maximus muscle exposed. Care was taken to preserve the posterior cutaneous nerve of the thigh during dissection. The gluteus maximus was then retracted superiorly to expose the underlying fascia over the hamstring muscles. Caution was taken not to place the retractor deep on the ischium to minimize risk of injury to the inferior gluteal nerve. A longitudinal incision was performed in the hamstring fascia and any traumatic hematoma evacuated. The hamstring tendons were explored to confirm preoperative clinical and MRI findings and assess for any additional injuries within the operative field. The sciatic nerve was intact in all cases. The insertion of the biceps femoris was tracked down to the zone of injury at the MTJ-BFlh. The knee was flexed to 30°, and 2 No. 5 Ethibond (Ethicon) braided nonabsorbable sutures were used to close the defect without tension at the MTJ through the modified Kessler technique. The knee was then fully extended to ensure satisfactory tension in the biceps femoris throughout the arc of motion. The wound was copiously irrigated with normal saline. The overlying fascia, subcutaneous tissue, and skin were closed in layers with an absorbable suture, and a pressure dressing was applied to the wound.

Postoperative Rehabilitation

All patients received a standardized milestone-based rehabilitation program supervised by an experienced sports physical therapist. The rehabilitation program was divided into 4 distinct phases:

Phase 1: RICE (rest, ice, compression, and elevation), partial weightbearing with crutches, aspirin (75 mg, once daily), limited excessive combined hip flexion and knee extension, normalization of gait. A hinged knee brace was provided only if requested by the patient or physical therapist.

Phase 2: Pain-free range of motion, full weightbearing, concentric and eccentric training, core strengthening.

Phase 3: Muscle strengthening with resistance exercises, double- and single-leg squats, quadriceps extension.

Table 2: British Athletics Muscle Injury Classification

<table>
<thead>
<tr>
<th>Grade</th>
<th>Extent of Edema</th>
<th>Site</th>
<th>Architectural Disruption</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Nil</td>
<td>Nil</td>
<td>Nil (a)</td>
</tr>
<tr>
<td>I</td>
<td>&lt;10% CSA, &lt;5 cm</td>
<td>(a) Myofascial, (b) MTJ</td>
<td>(a) &lt;1-cm gap, (b) &lt;1-cm gap</td>
</tr>
<tr>
<td>II</td>
<td>10%-50% CSA, 5-15 cm</td>
<td>(a) Myofascial, (b) MTJ, (c) tendon &lt;50% CSA</td>
<td>(a) 1- to 5-cm gap, (b) 1- to 5-cm gap, (c) no gap or redundancy</td>
</tr>
<tr>
<td>III</td>
<td>&gt;50% CSA, &gt;15 cm</td>
<td>(a) Myofascial, (b) MTJ, (c) tendon &gt;50% CSA</td>
<td>(a) &gt;5-cm gap, (b) &gt;5-cm gap, (c) tendon redundancy</td>
</tr>
<tr>
<td>IV</td>
<td>Complete tear</td>
<td>Complete muscle tear, complete tendon tear with retraction</td>
<td></td>
</tr>
</tbody>
</table>

CSA, cross-sectional area; MTJ, musculotendinous junction.

Figure 1. (A) Coronal section T2-MRI slice shows BAMIC grade IV injury through the right proximal musculotendinous junction of the long head of the biceps. (B) Transverse section T2-MRI slice of BAMIC grade III-b injury through the proximal musculotendinous junction of the long head of the biceps with nearly 60% of cross section involved. BAMIC, British Athletics Muscle Injury Classification; MRI, magnetic resonance imaging.

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All operative procedures were performed with the patient in the prone position under general anesthetic. The gluteal skin crease was marked and an 8- to 10-cm longitudinal incision performed distal to this (Figure 2). The underlying subcutaneous tissue and gluteal fascia were divided with electrocautery and the inferior border of the gluteus maximus muscle exposed. Care was taken to preserve the posterior cutaneous nerve of the thigh during dissection. The gluteus maximus was then retracted superiorly to expose the underlying fascia over the hamstring muscles. Caution was taken not to place the retractor deep on the ischium to minimize risk of injury to the inferior gluteal nerve. A longitudinal incision was performed in the hamstring fascia and any traumatic hematoma evacuated. The hamstring tendons were explored to confirm preoperative clinical and MRI findings and assess for any additional injuries within the operative field. The sciatic nerve was intact in all cases. The insertion of the biceps femoris was tracked down to the zone of injury at the MTJ-BFlh. The knee was flexed to 30°, and 2 No. 5 Ethibond (Ethicon) braided nonabsorbable sutures were used to close the defect without tension at the MTJ through the modified Kessler technique. The knee was then fully extended to ensure satisfactory tension in the biceps femoris throughout the arc of motion. The wound was copiously irrigated with normal saline. The overlying fascia, subcutaneous tissue, and skin were closed in layers with an absorbable suture, and a pressure dressing was applied to the wound.

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Phase 1: RICE (rest, ice, compression, and elevation), partial weightbearing with crutches, aspirin (75 mg, once daily), limited excessive combined hip flexion and knee extension, normalization of gait. A hinged knee brace was provided only if requested by the patient or physical therapist.

Phase 2: Pain-free range of motion, full weightbearing, concentric and eccentric training, core strengthening.

Phase 3: Muscle strengthening with resistance exercises, double- and single-leg squats, quadriceps extension,
and hamstring curls. Aerobic conditioning with light jogging, cycling, and swimming. Sport-specific training. **Phase 4**: Return to full sporting activity when full pain-free range of motion was achieved, muscle strength was 90% of uninjured limb, and there were no concerns with sport-specific training.

**Outcome Measures**

All study patients were clinically reviewed by the operating surgeon at regular intervals until return to play. Study outcomes were recorded by a specialist nurse practitioner preoperatively and predefined intervals after surgery. All outcomes at 3 months and 1 year after surgery were collected during clinical consultation, and outcomes at 2-year follow-up were collated by telephone conversation, given the wide geographical location of study patients.

**Patient Satisfaction.** Patient satisfaction was recorded at 3 months, 1 year, and 2 years after surgery with the Musculoskeletal Outcomes Data Evaluation and Management System, which scores patient satisfaction on a scale of 1 to 5 (1, very unsatisfied; 2, unsatisfied; 3, neutral; 4, satisfied; 5, very satisfied).\

**Hamstring Strength.** Isometric hamstring strength was tested pre- and postoperatively at 3 months and 1 year. The patient was placed in the prone position with a hand-held dynamometer (Hoggan Scientific LLC) positioned over the ipsilateral calcaneus. Maximum resisted knee flexion force (newtons) was recorded at 0°, 15°, 45°, and 90°. This technique was repeated 3 times and the mean flexion force at each angle in the injured limb was calculated. All values were compared with the contralateral uninjured limb to calculate the percentage of normal hamstring muscle strength.

**Passive Straight-Leg Raise.** Maximum angle of passive straight-leg raise (PSLR) was tested pre- and postoperatively at 3 months and 1 year. In the supine position, the uninjured limb was passively elevated inducing flexion at the hip while maintaining extension at the knee joint to the point of failure secondary to pain or elastic limit of the limb. The maximum attainable PSLR (degrees) was measured with a standard goniometer and compared with the maximum PSLR in the contralateral injured limb. The deficit in PSLR between the limbs was recorded.

**Functional Progress and Return to Function.** All study patients completed the Lower Extremity Functional Scale (LEFS) and Marx activity rating score (MARS) preoperatively and at 3 months, 1 year, and 2 years after surgery. The LEFS is a validated and effective questionnaire for assessing specific lower limb function. It has an 80-point scale, with 20 questions and 4 points allocated to each question and with a minimum clinical difference of 9 points. The MARS measures patient activity level and knee function independent of age, sex, and type of sporting activity. Scores of 0 to 4 are assigned to 4 activities (running, changing direction, decelerating, and pivoting) with a total score of 16. Time from surgical intervention to full return to sporting activity was collected in all study patients.

All patients recruited into this study completed follow-up. Mean follow-up time was 29.2 months (range, 24.0-37.1 months) from date of surgery.

**Statistical Analysis**

Paired *t* tests were used to compare study outcomes found to be normally distributed, while the Mann-Whitney *U* test was used for continuous outcomes not normally distributed. Categorical outcomes were compared with the Fisher exact test. Statistical significance was set at a *P* value <.05 for all analyses, and all statistical analysis was performed with SPSS (v 24; IBM Corp).

**RESULTS**

**Return to Function and Recurrence**

All study patients returned to their preinjury level of sporting activity. Mean ± SD time from surgical intervention to return to sporting activity was 13.4 ± 5.1 weeks. At 1- and
2-year follow-up, all study patients were still participating at their preinjury levels of sporting activity.

Three patients (4.8%) developed sharp, localized pain over the operative site during postoperative rehabilitation. These were investigated with urgent MRI scans. Of these, 1 patient had complete rupture through the operated MTJ-BFlh site at 6 weeks after surgery. This patient underwent revision surgery through the previous incision, followed by debridement of residual scar tissue and re-repair of the MTJ-BFlh injury with the surgical technique described earlier. The patient went back into the rehabilitation program and returned to full sporting activity at 19 weeks after revision surgery without any further complications. The remaining 2 patients sustained myofascial tears at 1 and 4 months after primary surgery. Both patients were treated nonoperatively with a graded exercise rehabilitation program and made full return to sporting activity within 4 weeks of reinjury.

**Patient Satisfaction**

Surgical repair of MTJ-BFlh injuries was associated with high patient satisfaction at 1 and 2 years after surgery. At 1-year follow-up, 2 patients were unsatisfied with the outcomes of their surgery: 1 patient had rerupture requiring further surgical intervention, and 1 patient was frustrated at the pace of rehabilitation. At 2 years after surgery, all patients were either satisfied (18.8%) or very satisfied (81.2%) with the outcomes of their surgery.

**Hamstring Strength**

Surgical intervention was associated with improved hamstring muscle strength at 3 months after surgery as compared with preoperative strength (Table 3, Figure 3). At 1-year follow-up, all patients had restored hamstring muscle strength to >90% of the contralateral side.

**Passive Straight-Leg Raise**

Surgical intervention was associated with improved PSLR and decreased PSLR deficit at 3-month follow-up as compared with preoperative values (Table 4).

Of note, at 3-month follow-up, 5 patients had straight-leg raise of <30°: 2 with myofascial tears of the MTJ-BFlh, 1 with complete rerupture of the MTJ-BFlh, and 2 with chronic lumbar back pain. At 1-year follow-up, only 1 patient with chronic lumbar back pain was unable to achieve PSLR >30°. There were further improvements in straight-leg raise at 1 year after surgery as compared with 3-month follow-up (Figure 4).

**Functional Progress**

At 3 months after surgery, mean LEFS and MARS outcomes improved as compared with their preoperative values (Table 5).

Statistically significant improvements in LEFS and MARS were observed at 3 months, 1 year, and 2 years after surgery (Figure 5). At 1 year follow-up, 7 patients (10.9%) had an LEFS score of 80 (out of 80), and 33 patients (51.6%) had a score >75. At 2-year follow-up, 20 patients (31.3%) had an LEFS score of 80, and 37 (57.8%) had a score >75.

**Complications**

In addition to the aforementioned 3 patients with recurrence, 12 patients had postoperative hematomas distal to the wound incision, and 4 patients had neurapraxia over the distribution of the posterior cutaneous nerve of the thigh. These complications were managed nonoperatively and fully resolved within 8 weeks of surgery. No other complications were reported during the 2-year follow-up period.

**DISCUSSION**

This study found that surgical intervention in acute MTJ-BFlh injuries enabled return to preinjury level of function with low risk of recurrence, high patient satisfaction, increased hamstring muscle strength, and improved functional outcome scores at short-term follow-up. To our knowledge, this is the first study to report on the operative management of acute MTJ-BFlh injuries, and it provides

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**TABLE 3**

Changes in Hamstring Strength (vs Contralateral Limb) During Study Intervals

<table>
<thead>
<tr>
<th>Angle</th>
<th>Preoperative Strength</th>
<th>Postoperative 3-mo Strength</th>
<th>Improvement in Strength (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°</td>
<td>25.9 ± 8.9</td>
<td>84.5 ± 10.4</td>
<td>58.7 ± 10.4 (56.0-61.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>15°</td>
<td>41.2 ± 9.7</td>
<td>89.5 ± 7.3</td>
<td>48.3 ± 10.5 (45.7-50.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>45°</td>
<td>63.4 ± 7.6</td>
<td>93.9 ± 5.1</td>
<td>30.5 ± 7.5 (15.3-28.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>90°</td>
<td>86.3 ± 6.0</td>
<td>96.9 ± 3.8</td>
<td>10.6 ± 5.6 (9.2-12.0)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Postoperative 3-mo Strength</th>
<th>Postoperative 1-y Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°</td>
<td>84.5 ± 10.4</td>
</tr>
<tr>
<td>15°</td>
<td>89.5 ± 7.3</td>
</tr>
<tr>
<td>45°</td>
<td>93.9 ± 5.1</td>
</tr>
<tr>
<td>90°</td>
<td>96.9 ± 3.8</td>
</tr>
</tbody>
</table>

* N = 64. Statistics represent mean ± SD (percentages). Bold indicates P < .05.
important prognostic information on functional outcomes and return to sporting activity after the surgical repair of these injuries. Nonoperative treatment of biceps femoris injuries is associated with highly variable rehabilitation times and uncertainty in time to return to sporting activity.\(^1,2,13,27\) Askling et al\(^2\) reviewed outcomes in 18 elite sprinters with biceps femoris injuries treated nonoperatively and found that the median time to preinjury level of function was 16 weeks (range, 6-50 weeks). Comin et al\(^14\) reviewed outcomes in 62 elite Australian rules football players with acute hamstring injuries, which included 45 patients with biceps femoris injuries, and reported that the median recovery time was 10 weeks (interquartile range, 6-18 weeks) with central tendon involvement, as compared with 3 weeks (interquartile range, 1-3 weeks) without central tendon disruption. Malliaropoulos et al\(^28\) reviewed outcomes in 90 elite track and field athletes with hamstring abnormalities identified on ultrasonography, which included 68 patients with biceps femoris injuries. The authors found that return to full sporting function ranged between 2 and 6 weeks, depending on preoperative degree of range of motion deficit. In our study, mean time to return to sporting activity was 13.4 ± 5.1 weeks, which is longer than the range for the previously cited nonoperative management.\(^2,14,28\) However, direct comparisons of rehabilitation times in this study with those reporting on nonoperative management are not possible, owing to differences in the grade and location of biceps femoris injury, variations in rehabilitation protocols, and inconsistencies 

**TABLE 4**  
Changes in Time to PSLR During Study Intervals\(^a\)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Preoperative</th>
<th>Postoperative 3 mo</th>
<th>Change in PSLR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSLR</td>
<td>24.1 ± 6.8</td>
<td>72.0 ± 11.4</td>
<td>48.0 ± 10.9 (45.2 to 50.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PSLR deficit(^b)</td>
<td>59.5 ± 10.3</td>
<td>11.5 ± 9.8</td>
<td>-48.0 ± 10.9 (-45.2 to -50.7)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Postoperative 3 mo</th>
<th>Postoperative 1 y</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSLR</td>
<td>72.0 ± 11.4</td>
<td>77.8 ± 7.2</td>
</tr>
<tr>
<td>PSLR deficit(^b)</td>
<td>11.5 ± 9.8</td>
<td>5.0 ± 8.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Change in PSLR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSLR</td>
<td>5.8 ± 10.0 (3.3 to 8.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PSLR deficit(^b)</td>
<td>-5.8 ± 10.0 (-3.3 to -8.3)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

\(^a\)N = 64. Statistics represent mean ± SD (degrees). Bold indicates P < .05. PSLR, passive straight-leg raise.

\(^b\)Difference in PSLR angle vs contralateral side.

**Figure 3.** Box plot shows percentage hamstring muscle strength as compared with contralateral side at various angles of knee flexion in patients undergoing surgical repair of proximal musculotendinous injuries at the long head of the biceps femoris. Values are presented as median (line), interquartile range (box), 95% CI (error bars), and outliers (circles).
in the definition of return to sporting activity. Furthermore, different sporting activities place different physiological demands on the hamstring complex; therefore, the sporting profile of each study group may influence time to return to sporting activity. Overall, surgical repair of MTJ-BFlh injuries did increase time to return to sporting activity but markedly reduced recurrence rates as compared with nonoperative management.

Nonoperative treatment of proximal hamstring injuries is associated with high risk of rerupture at short-term follow-up.\textsuperscript{22,23,27,42} Gibbs et al\textsuperscript{19} reported that nonoperative management of biceps femoris injuries resulted in recurrence in 5 of 13 patients (38.5%) within 28 days of the initial injury. Pollock et al\textsuperscript{34} reviewed outcomes in 44 elite track and field athletes with 65 proximal hamstring injuries, which included 28 patients with injuries to the long head of the biceps femoris. Nonoperative management resulted in 13 reinjuries (20%) during rehabilitation or immediately after return to sporting activity. In our treatment center, before undertaking this study, 112 patients (21.4%) with BAMIC grade III and IV injuries were treated nonoperatively, and 34 (21.4%) of them had recurrence of the primary injury within 2-year follow-up. Direct comparison of the current study findings with this historical control group undergoing nonoperative management is not possible given the limited number of functional outcomes recorded in the control group. Nevertheless, transitioning from nonoperative to operative management of these high-grade injuries led to a markedly reduced recurrence rate of 4.8% in the current study. In our study, 1 patient (1.6%) required revision surgery for MTJ-BFlh reinjury, and 2 patients (3.2%) received nonoperative treatment for myofascial tears during postoperative rehabilitation. All 3 patients required further rehabilitation but were able to make a full return to sporting activity. These complications highlight the importance of close observation and early referral for appropriate imaging during postoperative rehabilitation and return to sporting activity.

The timing of surgical intervention in proximal hamstring injuries is paramount. Acute operative intervention (within 4 weeks of injury) in proximal hamstring avulsion injuries is associated with improved patient satisfaction, better pain control, increased muscle strength, and earlier return to sporting activity as compared with chronic operative repair (after 4 weeks of injury).\textsuperscript{7,41} Nonoperative treatment in avulsion injuries is associated with reduced patient satisfaction and reduced return to preinjury level of function as compared with acute and chronic repairs.\textsuperscript{7} Furthermore, nonoperative treatment and delays in surgical intervention are both associated with secondary problems, such as muscle weakness and fibrosis of scar tissue.

### Table 5

<table>
<thead>
<tr>
<th>Outcome: Time</th>
<th>Mean ± SD</th>
<th>Improvement in Scores (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LEFS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>29.8 ± 6.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 mo</td>
<td>71.5 ± 5.0</td>
<td>41.7 ± 7.1 (40.0-43.5)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>1 y</td>
<td>75.2 ± 2.3</td>
<td>3.7 ± 4.0 (2.7-4.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>2 y</td>
<td>77.2 ± 2.6</td>
<td>2.0 ± 2.6 (1.3-2.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>MARS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>3.8 ± 1.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 mo</td>
<td>9.8 ± 2.2</td>
<td>6.0 ± 2.4 (4.3-7.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>1 y</td>
<td>11.6 ± 2.4</td>
<td>1.8 ± 2.1 (1.2-2.4)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>2 y</td>
<td>13.1 ± 2.0</td>
<td>1.6 ± 2.2 (1.2-1.9)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*N = 64. Bold indicates P < .05. LEFS, lower extremity functional Scale; MARS, Marx Activity Rating Scale.

### Figures

**Figure 4.** Box plot shows passive straight-leg raise angle (degrees) in patients undergoing surgical repair of proximal musculotendinous injuries at the long head of the biceps femoris. Values are presented as median (line), interquartile range (box), 95% CI (error bars), and outliers (asterisk and circles).

**Figure 5.** Box plot shows Lower Extremity Functional Scale score in patients undergoing surgical repair of proximal musculotendinous injuries at the long head of the biceps femoris. Values are presented as median (line), interquartile range (box), 95% CI (error bars), and outliers (asterisks and circles).
to the sciatic nerve, leading to neurological complications such as foot drop or paresthesia of the lower limb.12,23,42 Bowman et al8 reported outcomes in 17 patients undergoing surgical repair of partial proximal hamstring injuries refractory to 6 months of nonoperative treatment and found that 5 of them developed postoperative paresthesia. Sarimo et al36 reviewed the outcomes of surgical treatment in 41 patients with acute or chronic complete proximal hamstring avulsion injuries and found that chronic cases were associated with the torn muscle having a macroscopically abnormal appearance with a hardened fibrotic texture. The authors also indicated that time from injury to operative intervention was associated with return to preinjury level of function.

The authors also found a mean LEFS score of 80 and MARS score of 16 at 3-month follow-up, which are similar to the values cited in this study. Cohen et al13 followed 52 patients undergoing suture anchor repair of proximal hamstring avulsion injuries and found a mean LEFS score of 75 (range, 50–80) at 33-month follow-up (range, 12-76 months). Bowman et al8 indicated that operative management of partial hamstring tears was associated with a mean MARS of 6.5 ± 5.3 at 32-month follow-up (range, 12-51 months). The patients had a mean age of 43 years (range, 19-64 years) and had failed 6 months of nonoperative treatment, which may have led to the reduced MARS as compared with those in this study.

Several limitations of this study need to be considered when interpreting the findings. First, there was no control group of patients undergoing nonoperative management; therefore, it is difficult to ascertain the benefit of surgical repair as compared with nonoperative treatment by using the standardized rehabilitation program alone. Based on our previous experience and the existing literature, nonoperative treatment of these injuries is associated with prolonged periods of rehabilitation and high risk of recurrence. All study patients were high-performance athletes who did not want randomization and potential allocation to nonoperative management. These patients preferred to make their own decisions about treatment; as such, prospectively randomizing these patients to a control group with nonoperative management was not possible. However, this is the largest study to date on the operative management of proximal musculotendinous injuries; all study patients were selected per their BAMIC injury grade; surgery was undertaken by a single surgeon using a standardized approach; and functional outcomes were recorded at regular intervals after a standardized rehabilitation program. Second, study outcomes were not correlated with preoperative clinical findings or radiological grade of injury. Third, additional imaging, such as ultrasound or MRI, was not used to assess MTJ-BFlh healing during follow-up.

CONCLUSION

Surgical intervention in acute MTJ-BFlh injuries enabled return to preinjury level of function with low risk of recurrence, high patient satisfaction, increased hamstring muscle strength, and improved functional outcome scores at short-term follow-up. Surgical repair of MTJ-BFlh injuries is associated with increased time to return to preinjury level of sporting activity but markedly reduced recurrence rates as compared with nonoperative management as reported in the existing literature.

REFERENCES


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Acute Surgical Repair of Complete, Nonavulsion Proximal Semimembranosus Injuries in Professional Athletes

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Investigation performed at University College London Hospital, London, UK

Background: Nonoperative management of proximal semimembranosus injuries is associated with prolonged periods of convalescence and high risk of recurrence. To our knowledge, the outcomes of acute surgical repair for complete, nonavulsion proximal semimembranosus injuries have not been previously reported.

Hypothesis: Acute surgical repair of complete, nonavulsion proximal semimembranosus injuries enables early return to sporting activity with low risk of recurrence.

Study Design: Case series: Level of evidence, 4.

Methods: This prospective single-surgeon study included 20 professional athletes undergoing acute primary surgical repair of complete, nonavulsion proximal semimembranosus injuries confirmed on preoperative magnetic resonance imaging. All study patients underwent a standardized postoperative rehabilitation program. Predefined outcomes were recorded at regular intervals after surgery. Mean follow-up time was 27.6 months (range, 24.0-34.6 months) from date of surgery.

Results: Of the 20 patients, 19 (95%) returned to their preinjury level of sporting activity. Mean ± SD time from surgical repair to full sporting activity was 11.9 ± 5.7 weeks. No patients had recurrence of the primary injury. At 3 months after surgery, patients had improved mean passive straight leg raise (71.5 ± 5.9° vs 31.1 ± 7.2°; P < .001); increased mean isometric hamstring muscle strength at 60° (83.8% ± 5.9% vs 48.4% ± 8.3%; P < .001), 15° (77.6% ± 6.0% vs 52.3% ± 14.7%; P < .001), and 45° (88.6% ± 5.4% vs 66.7% ± 13.1%; P < .001); higher mean lower extremity functional scores (64.8 ± 4.6 vs 34.4 ± 5.1; P < .001); and improved Marx activity rating scores (10.7 ± 1.6 vs 5.5 ± 2.0; P < .001) as compared with preoperative values. High patient satisfaction and functional outcome scores were maintained at 1 and 2 years after surgery.

Conclusion: Acute surgical repair of complete, nonavulsion proximal semimembranosus injuries is associated with high patient satisfaction, increased muscle strength, improved functional outcome scores, and high return to preinjury level of sporting activity with low risk of recurrence at short-term follow-up.

Keywords: semimembranosus; hamstrings; recurrence; surgical treatment

Hamstring injuries are among the common muscle injuries sustained by athletes.1,12,13,18 These injuries represent a spectrum of conditions ranging from acute traumatic rupture to chronic degenerative tears. Semimembranosus injuries account for 8% to 18% of all hamstring injuries, with the majority occurring within the proximal musculotendinous junction.4,16,18,26 These injuries are associated with an ominous prognosis, with prolonged time for rehabilitation, delays in return to preinjury level of sporting activity, and high risk of recurrence.4 Several anatomic and physiological factors increase the susceptibility of the semimembranosus to injury as compared with the other hamstring muscles. The semimembranosus is the largest of the hamstring muscles, traverses 2 major articular joints, and contains proximal and distal intramuscular tendons that extend for 60% to 70% of the muscle length.12,25 This leads to the generation of large forces through the semimembranosus muscle with poor dissipation of this
force from the muscle belly into its tendinous portions. The mechanism of injury is often a “slow-stretching exercise” of the hamstrings with simultaneous extremes of hip flexion and knee extension. Patients usually have pain over the ischial tuberosity, reduced range of motion, hamstring weakness, and inability to participate in sporting activity. 

Nonoperative management of proximal semimembranosus injuries includes rest, avoidance of exacerbating maneuvers, nonsteroidal anti-inflammatory medication, and physical therapy with progressive rehabilitation. However, nonoperative treatment of these injuries is associated with prolonged periods of rehabilitation, poor return to preinjury level of sporting activity, and high risk of recurrence. Acute surgical repair of proximal hamstring avulsion injuries and musculotendinous tears of the biceps femoris and semitendinosus are associated with high patient satisfaction, restoration of hamstring muscle strength, and improved functional outcomes. Delays in surgical repair of proximal hamstring avulsion injuries are associated with reduced patient satisfaction, residual hamstring muscle weakness, and neurological compromise owing to tethering of the retracted muscle to the sciatic nerve. To our knowledge, the outcomes of acute surgical repair for complete, nonavulsion proximal semimembranosus injuries have not been previously reported. The findings of this study will provide an improved understanding on the effect of acute surgical repair for complete, nonavulsion proximal semimembranosus injuries on functional rehabilitation, restoration of hamstring muscle strength, time to preinjury level of sporting activity, and complications at short-term follow-up.

The primary objective of this study was to assess the effect of acute surgical repair of complete, nonavulsion proximal semimembranosus injuries on time to return to preinjury level of sporting function. The secondary objectives were to assess the effect of acute surgical repair of these injuries on patient satisfaction, hamstring muscle strength, straight leg raise, functional performance, recurrence, and complications.

 METHODS

 Patient Selection

This prospective study included 20 professional athletes undergoing acute surgical repair for complete, nonavulsion proximal semimembranosus injuries. All operative procedures were performed by the senior author (F.S.H.) between September 2014 and September 2016. Patient data for all study patients are shown in Table 1. Preoperative magnetic resonance imaging (MRI) was undertaken in all study patients to confirm the diagnosis, grade the injury with the British Athletics Muscle Injury Classification (BAMIC) system (Table 2), and identify any concurrent injuries (Figure 1). Inclusion criteria included the following: injury sustained within 4 weeks of operative intervention; MRI to confirm complete, nonavulsion tear (BAMIC grade IV injury) in the proximal semimembranosus tendon/aponeurosis; and operative intervention undertaken by the senior author. Exclusion criteria included the following: avulsion injury of the semimembranosus (n = 5); recurrent semimembranosus injury after nonoperative treatment (n = 4) or previously failed surgical repair (n = 2); injury sustained >4 weeks before operative intervention (n = 2); BAMIC type I (n = 8), type II (n = 2), or type III (n = 1); and patient living abroad (n = 2). Informed consent was obtained from all study patients. Hospital review board approval was obtained before commencement of the study.

Patient and public involvement was not undertaken before the commencement of this study. No individual participant data or patient-identifiable information is used in this study. No funding was received for the study. There is no conflict of interest to declare for this study.

 Surgical Technique

All operative procedures were performed with the patient in the prone position under general anesthesia. The gluteal skin crease was marked, and a longitudinal incision measuring 8 to 10 cm was performed distal to this landmark (Figure 2A). The underlying subcutaneous tissue was divided with electrocautery until the inferior border of gluteus maximus was exposed. Care was taken to preserve the posterior cutaneous nerve of the thigh. The hamstring fascia was divided and any

<table>
<thead>
<tr>
<th>Characteristic: Category</th>
<th>Mean ± SD or No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>28.8 ± 4.8</td>
</tr>
<tr>
<td>Female</td>
<td>30.6 ± 5.4</td>
</tr>
<tr>
<td>Male</td>
<td>27.4 ± 3.8</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>9 (45)</td>
</tr>
<tr>
<td>Male</td>
<td>11 (55)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>25.3 ± 3.5</td>
</tr>
<tr>
<td>ASA score (I-IV)</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>20 (100)</td>
</tr>
<tr>
<td>II</td>
<td>0 (0)</td>
</tr>
<tr>
<td>III</td>
<td>0 (0)</td>
</tr>
<tr>
<td>IV</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Laterality</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>14 (70)</td>
</tr>
<tr>
<td>Left</td>
<td>6 (30)</td>
</tr>
<tr>
<td>Sporting activity</td>
<td></td>
</tr>
<tr>
<td>Rugby</td>
<td>7 (35)</td>
</tr>
<tr>
<td>Soccer</td>
<td>6 (30)</td>
</tr>
<tr>
<td>Dancing</td>
<td>3 (15)</td>
</tr>
<tr>
<td>Gymnastics</td>
<td>3 (15)</td>
</tr>
<tr>
<td>Ice skating</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Time from</td>
<td></td>
</tr>
<tr>
<td>Injury to surgery, d</td>
<td>20.9 ± 4.8</td>
</tr>
<tr>
<td>Surgery to return to sporting activity, wk</td>
<td>11.9 ± 5.7</td>
</tr>
</tbody>
</table>

ASA, American Society of Anesthesiologists.
underlying hematoma evacuated. The hamstring muscles were traced proximally to their insertion into the ischial tuberosity, and the zone of injury in the semimembranosus was identified. Intraoperative examination confirmed a complete, nonavulsion proximal semimembranosus tear with extension into the proximal semimembranosus tendon or aponeurosis (Figure 2B). The remaining hamstring muscles were inspected to identify any concurrent injuries, and care was taken to preserve the integrity of the adjacent sciatic nerve (Figure 2C). The knee was flexed to 30° and the semimembranosus tear repaired to restore tension with No. 5 Ethibond (Ethicon) braided nonabsorbable sutures (Figure 2D). The knee was fully extended to ensure satisfactory tension in the repair throughout the arc of motion. The overlying hamstring fascia was closed with absorbable sutures. The wound was copiously irrigated with normal saline, and absorbable sutures were used to perform a layered closure of the overlying fascia, subcutaneous tissue, and skin.

Postoperative Rehabilitation

All patients received a standardized milestone-based rehabilitation program supervised by an experienced sports physical therapist. The rehabilitation program was divided into 4 distinct phases:

**Phase 1:** Surgery to postoperative 4 weeks. RICE (rest, ice, compression, and elevation), mobilize partial weightbearing with crutches, aspirin (75 mg, once daily), limit excessive combined hip flexion and knee extension, normalization of gait. Hinged knee brace provided only if requested by patient or physical therapist.

**Phase 2:** Begin after meeting phase 1 criteria (usually begin at postoperative 4 weeks but can be done earlier as well). Regain pain-free range of motion, full weightbearing, concentric and eccentric training, core strengthening, and gait training. No impact, running, or dynamic stretching.

**Phase 3:** Begin after meeting phase 2 criteria (usually postoperative 7 weeks). Muscle strengthening with resistance exercises, double- and single-leg squats, quadriceps extension, and hamstring curls. Aerobic conditioning with light jogging, cycling, and swimming. Sport-specific training.

**Phase 4:** Begin after meeting phase 3 criteria (usually postoperative 9-10 weeks). Return to sporting activity with full pain-free range of motion, muscle strength 90% of uninjured limb, and no concerns with sport-specific training.

Outcome Measures

All study patients were reviewed by the operating surgeon in the outpatient clinic at regular intervals until return to

![Image](image_url)
Study outcomes were recorded by a specialist nurse practitioner preoperatively 1 week before surgery and at predefined intervals after surgery. All outcomes at 3 months and 1 year after surgery were collected during clinical consultation, and outcomes at 2-year follow-up were collated by telephone conversation given the wide geographical dispersion of study patients.

**Patient Satisfaction.** Patient satisfaction was recorded at 3 months, 1 year, and 2 years after surgery with the Musculoskeletal Outcomes Data Evaluation and Management System, which scores patient satisfaction on a scale of 1 to 5 (1, very unsatisfied; 2, unsatisfied; 3, neutral; 4, satisfied; and 5, very satisfied).

**Hamstring Muscle Strength.** Isometric hamstring muscle strength was tested pre- and postoperatively at 3 months and 1 year. The patient was placed in the prone position and a handheld dynamometer (Hoggan Scientific LLC) positioned over the ipsilateral calcaneus. Maximum resisted knee flexion force (newtons) was recorded at 0°, 15°, 45°, and 90°. This technique was repeated 3 times and mean flexion force at each of these angles in the injured limb calculated. All values were compared with the contralateral uninjured limb to calculate percentage of normal hamstring muscle strength.

**Passive Straight Leg Raise.** Maximum angle of passive straight leg raise (PSLR) was tested preoperatively and at postoperative 3 months and 1 year. With the patient in the supine position, the uninjured limb was passively elevated inducing hip flexion while maintaining extension at the knee joint to the point of failure secondary to pain or elastic limit of the limb. The maximum attainable PSLR was measured with a standard goniometer and compared with the maximum PSLR in the contralateral injured limb. The deficit in PSLR between the limbs was recorded.

**Functional Assessment Scores.** All study patients completed the Lower Extremity Functional Scale (LEFS) and Marx Activity Rating Scale (MARS) preoperatively and at 3 months, 1 year, and 2 years after surgery.5,18 The LEFS is a validated and effective questionnaire for assessing specific lower limb function. It has an 80-point scale with 20 questions and 4 points allocated to each question and with a minimum clinical difference of 9 points.5 The MARS measures patient activity level and knee function independent of age, sex, and type of sporting activity. Scores of 0 to 4 are assigned to 4 activities (running, changing direction, decelerating, and pivoting) with a total score of 16.18 Time from surgical intervention to full return to sporting activity was collected in all study patients. All complications with their respective treatments and outcomes within 2 years of the primary surgery were recorded.

All patients recruited into this study completed follow-up. Mean follow-up time was 27.6 months (range, 24.0-34.6 months) from date of surgery.

**Statistical Analysis**

Paired t tests were used to compare demographic characteristics and study outcomes found to be normally distributed, while the Mann-Whitney U test was used for continuous outcomes found not to be normally distributed. Categorical outcomes were compared with the Fisher exact test. Statistical significance was set at a P value <.05 for all analyses, and all statistical analysis was performed with SPSS (v 24; IBM Corp).

**RESULTS**

**Return to Function and Recurrence**

Of the 20 patients recruited into this study, 19 (95%) returned to their preinjury levels of sporting activity. Mean ± SD time from surgical intervention to return to full sporting activity was 11.9 ± 5.7 weeks. No study patients had recurrence of the primary injury. Two gymnasts had delayed return to full sporting activity, requiring 21 and 28 weeks of postoperative rehabilitation owing to pain over the ischial tuberosity on deep hip flexion and...
knee extension. One soccer player retired from sporting activity before return to sporting activity. The patient was 35 years old and in the final year of his career. There was no objective functional compromise in performance at time of retirement, and he went onto play at a less competitive level of sporting activity.

**Patient Satisfaction**

Surgical repair of complete, nonavulsion proximal semimembranosus injuries was associated with high patient satisfaction at 1 and 2 years after surgery. Nineteen patients (95%) were either very satisfied or satisfied at these time intervals. The patient who retired from sporting activity was satisfied at 1 and 2 years after surgery, as he achieved acceptable functional performance despite not returning to full sporting activity. One gymnast with prolonged rehabilitation time for achieving full pain-free hip flexion remained neutral about the outcome of surgery at 1- and 2-year follow-up.

**Hamstring Strength**

Most pronounced hamstring strength deficit was observed preoperatively between 0° and 45° of knee flexion. Surgical intervention was associated with improved hamstring muscle strength at 3 months after surgery as compared with preoperative hamstring muscle strength. At 1-year follow-up, all patients had restored hamstring muscle strength to >90% of the contralateral side (Table 3, Figure 3).

**Passive Straight Leg Raise**

Surgical intervention was associated improved absolute PSLR of the operated limb and reduced PSLR deficit at 3-month follow-up as compared with preoperative values (Table 4). At 1-year follow-up, 2 gymnasts and 1 dancer had a PSLR deficit of 20°. Both patients required further rehabilitation, but this did not delay their time to return to preinjury level of sporting function.

**Functional Progress and Return to Function**

At 3 months after surgery, median LEFS and MARS scores improved as compared with their preoperative values. Progressive improvements were observed in LEFS and MARS at 1 and 2 years after surgery (Table 5). At 3-month follow-up, 3 patients (15%) had a LEFS score of 80 (of 80), and 4 (20%) had a score >75. At 2-year follow-up, 6 patients (30%) had a LEFS score of 80, and 9 (45%) had a score >75. MARS scores followed a similar trend to LEFS scores, with statistically significant improvement at each follow-up interval after surgery.

### TABLE 3

Changes in Hamstring Strength (vs Contralateral Limb) During Study Intervals in Patients Undergoing Acute Surgical Repair of Complete, Nonavulsion Proximal Semimembranosus Tears (N = 20)

<table>
<thead>
<tr>
<th>Angle</th>
<th>Preoperative</th>
<th>Postoperative 3 mo</th>
<th>Improvement in Strength (95% CI), %</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°</td>
<td>48.4 ± 8.3</td>
<td>83.8 ± 5.9</td>
<td>35.4 (30.7 to 40.1)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>15°</td>
<td>52.3 ± 14.7</td>
<td>77.6 ± 6.0</td>
<td>25.4 (18.4 to 32.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>45°</td>
<td>66.7 ± 13.1</td>
<td>88.6 ± 5.4</td>
<td>22.0 (15.3 to 28.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>90°</td>
<td>75.9 ± 12.8</td>
<td>92.3 ± 4.8</td>
<td>16.4 (10.1 to 22.5)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Angle</th>
<th>Postoperative 3 mo</th>
<th>Postoperative 1 y</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°</td>
<td>83.8 ± 5.9</td>
<td>92.3 ± 3.7</td>
</tr>
<tr>
<td>15°</td>
<td>77.6 ± 6.0</td>
<td>92.0 ± 5.0</td>
</tr>
<tr>
<td>45°</td>
<td>88.6 ± 5.4</td>
<td>92.3 ± 6.0</td>
</tr>
<tr>
<td>90°</td>
<td>92.3 ± 4.8</td>
<td>94.6 ± 6.3</td>
</tr>
</tbody>
</table>

aBold indicates P < .05.
DISCUSSION

This study found that acute surgical repair of complete, nonavulsion proximal semimembranosus injuries was associated with high patient satisfaction, increased muscle strength, improved functional outcome scores, and return to preinjury level of sporting activity with low risk of recurrence. To our knowledge, this is the first study to report on the acute surgical repair of complete, nonavulsion proximal semimembranosus injuries and provides important prognostic information on postoperative functional rehabilitation, return to sporting activity, and complications at short-term follow-up.

Acute surgical repair of complete, nonavulsion proximal semimembranosus injuries enabled 95% of patients in this study to return to their preinjury levels of sporting activity, which is more favorable than that reported with nonoperative management of proximal semimembranosus injuries. Askling et al reviewed outcomes in 30 patients from a range of sporting activities who were undergoing nonoperative treatment for proximal hamstring injuries, which included 25 patients with semimembranosus injuries confirmed on MRI. The authors reported that 16 patients returned to their preinjury levels of sporting activity at a median 31 weeks (range, 9-104 weeks) of nonoperative treatment but 14 patients retired from their sporting activities after a median 63 weeks (range, 26-104 weeks) of rehabilitation. The study also reported that 88% of patients had ongoing pain over the injury site after returning to sporting activity. Nonoperative treatment or delayed surgical repair of hamstring injuries may also lead to secondary problems, such as persistent pain, muscle weakness, and neurological complications, including foot drop or paresthesia of the lower limb attributed to fibrosis of scar tissue to the sciatic nerve. Early surgical exploration and repair may have helped to limit these complications in the current study population.

Improved return to preinjury level of sporting function observed with acute surgical repair in this study, as compared with nonoperative management in the existing literature, may be in part due to the limited sensitivity and specificity of MRI in grading these complex injuries. Preoperative MRI may overlook or undergrade the extent of injury to the partially retracted semimembranosus, leading to some patients with high-grade semimembranosus injuries receiving nonoperative management. In this study, preoperative MRI in 7 study patients showed no gross tendon disruption in the coronal or sagittal planes. However, an oblique semimembranosus tear extending into the membranous portion was visible with partial retraction of the injured segment and surrounding edema. Intraoperative examination confirmed complete semimembranosus tears with loss of muscle tension and limited functional

Complications

Four patients (20%) had postoperative hematomas that were diagnosed clinically. These were managed nonoperatively and resolved within 3 weeks after surgery without causing any delays to rehabilitation or return to sporting function. One patient had a superficial wound infection that was treated with oral antibiotics for 1 week. No other complications were observed within the follow-up period.

TABLE 4
Changes in PSLR During Study Intervals in Patients Undergoing Acute Surgical Repair of Complete, Nonavulsion Proximal Semimembranosus Tearsa (N = 20)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Preoperative</th>
<th>Postoperative 3 mo</th>
<th>Change in PSLR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSLR, deg</td>
<td>31.1 ± 7.2</td>
<td>71.5 ± 5.9</td>
<td>40.5 (36.3 to 44.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PSLR deficit, degb</td>
<td>65.5 ± 12.8</td>
<td>25.0 ± 11.4</td>
<td>–40.5 (–44.7 to –36.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Postoperative 3 mo</td>
<td>Postoperative 1 y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSLR, deg</td>
<td>71.5 ± 5.9</td>
<td>91.5 ± 9.3</td>
<td>20.0 (15.2 to 24.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>PSLR deficit, degb</td>
<td>25.0 ± 11.4</td>
<td>5.0 ± 8.3</td>
<td>–20.0 (–24.8 to –15.2)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Values are presented as mean ± SD. Bold indicates P < .05. PSLR, passive straight leg raise.
bMean ± SD of differences between the PSLRs of the injured side to the preoperative PSLRs of the healthy side.

TABLE 5
Changes in LEFS and MARS Scores During Study Intervals After Surgical Repair of Complete, Nonavulsion Proximal Semimembranosus Injuriesa (N = 20)

<table>
<thead>
<tr>
<th>Outcome: Time</th>
<th>Score, Mean (95% CI)</th>
<th>Improvement, Mean (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEFS Preoperative</td>
<td>34.4 ± 5.1</td>
<td>30.4 (28.2 to 32.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>3 mo</td>
<td>64.8 ± 4.6</td>
<td>9.7 (7.8 to 11.5)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>1 y</td>
<td>74.4 ± 3.0</td>
<td>3.5 (2.2 to 4.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>MARS Preoperative</td>
<td>5.5 ± 2.0</td>
<td>5.1 (4.3 to 5.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>3 mo</td>
<td>10.7 ± 1.6</td>
<td>1.6 (1.2 to 1.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>1 y</td>
<td>12.3 ± 1.8</td>
<td>1.0 (0.7 to 1.2)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Bold indicates P < .05. LEFS, Lower Extremity Functional Scale; MARS, Marx Activity Rating Scale. 
Nonoperative management of hamstring injuries is associated with recurrence of the primary injury in 12% to 31% of patients. The majority of these injuries occur within 2 months of returning to sporting activity and with a greater radiological extent than the primary injury. Injuries to the musculotendinous junction are associated with hematoma formation and residual scar tissue at the site of injury. Sherry and Best reviewed outcomes in 24 patients with acute hamstring strains managed nonoperatively with graded rehabilitation programs and found that the overall reinjury rate was 25% at 2 weeks and 35% at 1-year follow-up. In the current study, none of the study patients had recurrence of the primary injury, but these findings should be interpreted with caution given the small study population and heterogeneity in the type of sporting activities. Semimembranosus injuries are more common in stretching-type injuries; therefore, a higher proportion of gymnasts or dancers may have led to an increased recurrence rate than currently observed.

Nonoperative management of hamstring injuries is associated with highly variable periods of convalescence and time to return to preinjury level of sporting function. Askling et al reviewed outcomes of nonoperative management in 15 professional dancers, which included 13 semimembranosus injuries, and reported that the median time to return to full dance activity was 50 weeks (range, 30-76 weeks). Comin et al reported that nonoperative treatment in 62 patients with proximal hamstring injuries was associated with a median time of return to sporting activity of 21 weeks (interquartile range, 14-42 weeks). Eleven of these patients had semimembranosus injuries, and their median time of return to sporting activity was 32 weeks (interquartile range, 21-35 weeks). The wide variation in rehabilitation times reflects interstudy differences in physical therapy protocols and definitions of return to sporting function. Overall, the findings of this study show more favorable rehabilitation times as compared with existing studies on nonoperative management of proximal semimembranosus injuries, which is consistent with previous reports comparing operative versus nonoperative management of proximal hamstring avulsion injuries and incomplete tears of the biceps femoris and conjoint tendon.

Surgical repair of complete, nonavulsion proximal semimembranosus injuries was associated with high patient satisfaction and early restoration of hamstring muscle strength. All study patients were able to achieve hamstring muscle strength to within 90% of the uninjured limb within 3 months of injury, which is comparable with outcomes reported with surgical repair of acute hamstring avulsion injuries. Lempainen et al reviewed outcomes in 42 patients undergoing surgical repair of partial tears from the proximal hamstring origin and reported patient satisfaction as excellent in 33 cases, good in 9 cases, fair in 4 cases, and poor in 2 cases, at a follow-up of 36 months (range, 6-72 months). In total, 41 patients returned to their preinjury level of sporting activity at a mean 5 months (range, 1-12 months) after surgery. Study patients had previously failed between 2 weeks and 9 years of nonoperative treatment before surgical intervention, which may have led to less favorable time of return to sporting activity as compared with the current study. Klingele and Sallay reviewed outcomes in 11 professional athletes undergoing surgical repair of proximal avulsion injuries and found that 9 of these patients were satisfied with the outcome of their surgery. Seven of the 9 athletically active patients returned to their preinjury level of sporting activity at a mean 6 months after surgery (range, 3-10 months). Isokinetic hamstring muscle strength returned to a mean of 91% of the contralateral uninjured limb.

Surgical intervention was associated with improvements in LEFS and MARS scores at each time interval after surgery. There are no existing studies reporting on these functional outcome scores with nonoperative management of proximal semimembranosus injuries, but our findings are comparable with previous studies reporting on surgical repair of other hamstring injuries. Cohen and Bradley followed 52 patients undergoing suture anchor repair of proximal hamstring avulsion injuries and found a mean LEFS score of 75 (range, 50-80) at a follow-up of 33 months (range, 12-76 months). Bowman et al found that operative management of partial hamstring tears was associated with a mean MARS of 6.5 ± 5.3 reported at a follow-up of 32 months.

Figure 4. Diagrammatic representation of an oblique complete, nonavulsion injury through the aponeurosis of the semimembranosus. The tear is undisplaced; therefore, the injury severity may not be fully appreciated on magnetic resonance imaging with the British Athletics Muscle Injury Classification system.
(range, 12-51 months). A recent meta-analysis of 24 studies with 795 proximal hamstring avulsion injuries also found that surgical repairs resulted in significantly higher patient satisfaction (90.81% vs 52.94%), hamstring strength (85.01% vs 63.95%), and LEFS scores (72.77 vs 69.53) as compared with nonoperative management.

The main strengths of this study are that surgical repair was undertaken with a standardized technique by a single surgeon, all patients received a standardized postoperative rehabilitation program, and a comprehensive range of validated study outcomes were recorded at regular intervals after surgery. However, several limitations of this study need to be considered when interpreting the findings. First, there was no control group of patients undergoing nonoperative management; therefore, it is difficult to ascertain the effect of operative repair as compared with nonoperative treatment with the standardized rehabilitation program. A control group was not possible as these were high-performance athletes who did not want randomization and potential allocation to nonoperative management, which is associated with a prolonged period of rehabilitation and high risk of recurrence. Second, the sample size was relatively small because of the scarcity of semimembranosus injuries, which increases the risk of type II error. Third, follow-up was limited to 2 years after surgery. Fourth, additional imaging, such as ultrasound or MRI, was not used to assess semimembranosus healing during follow-up.

CONCLUSION

Acute surgical repair of complete, nonavulsion proximal semimembranosus injuries is associated with high patient satisfaction, increased hamstring muscle strength, improved functional outcome scores, and high return to preinjury level of sporting activity with low risk of recurrence at short-term follow-up. Early surgical intervention for complete, nonavulsion proximal semimembranosus injuries should be considered as a treatment option in patients with high functional demands to enhance rehabilitation and restore functional performance.

REFERENCES

Surgical Repair of Distal Musculotendinous T Junction Injuries of the Biceps Femoris

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Investigation performed at Trauma and Orthopaedic Department, University College Hospital, London, UK

Background: Nonoperative management of injuries to the distal musculotendinous T junction of the biceps femoris is associated with variable periods of rehabilitation and high risk of recurrence. To our knowledge, the efficacy of operative treatment in patients with these acute injuries has not been previously reported.

Hypothesis: Surgical repair of injuries to the distal musculotendinous T junction of the biceps femoris would enable return to preinjury level of sport with low risk of recurrence.

Study Design: Case series; Level of evidence, 4.

Methods: This prospective single-surgeon study included 34 professional athletes (mean age, 26.4 ± 3.1 years; 31 male [91.2%]; 3 female [8.8%]; body mass index, 25 ± 2.0 kg/m²) undergoing primary surgical repair of acute injuries to the distal musculotendinous T junction of the biceps femoris. All study patients underwent a standardized postoperative rehabilitation program. Predefined study outcomes relating to time for return to sporting activity, patient satisfaction, range of motion, hamstring muscle strength, passive range of motion, functional progress, and complications were recorded at regular intervals after surgery. Mean follow-up time was 28.4 months (range, 24.0-36.3 months) from date of surgery.

Results: All study patients returned to their preinjury level of sporting activity. Mean time from surgical repair to full sporting activity was 11.7 ± 3.6 weeks. No patients had recurrence of the primary injury. At 1-year follow-up, 18 patients (52.9%) were very satisfied and 16 patients (47.1%) were satisfied with the outcomes of their surgery. At 3 months after surgery, patients had improved mean passive straight leg raise (69.7° ± 11.7° vs 24.1° ± 7.4°; P < .001); increased mean isometric hamstring muscle strength at 0° (93.1% ± 5.4% vs 63.1% ± 7.7%; P < .001), 45° (76.8% ± 9.7% vs 24.8% ± 8.3%; P < .001), and 90° (86.4% ± 3.9% vs 85.6% ± 5.9%; P < .001); higher mean lower extremity functional scores (64.5 ± 4.5 vs 27.2 ± 5.4; P < .001); and improved mean Marx Activity Rating Scale scores (10.7 ± 2.7 vs 2.2 ± 2.1; P < .001) compared with preoperative values. High patient satisfaction and functional outcome scores were maintained at 1 and 2 years after surgery.

Conclusion: Surgical repair of acute injuries to the distal musculotendinous T junction of the biceps femoris is associated with high patient satisfaction, increased muscle strength, improved functional outcome scores, and high return to preinjury level of sporting activity with low risk of recurrence at short-term follow-up.

Keywords: biceps femoris; hamstrings; musculotendinous junction; recurrence; surgical treatment

The hamstring complex is among the most commonly injured muscle groups in several sporting activities, including soccer, rugby, athletics, and football.7,11,13 These injuries are associated with prolonged rehabilitation, poor return to preinjury level of sporting function, and recurrence rates of 12% to 63%,7,11,13,16,26 Previous hamstring injury is an independent risk factor for recurrent injury, and often this recurrence is of the same or worse severity than the primary injury.10,13,16 The biceps femoris is most frequently injured and accounts for 57% to 87% of all hamstring strains.9,11,13,20 This has been attributed to the complex anatomic relationship and dual innervation to the 2 heads of this muscle. The long head of the biceps femoris is a biarticular muscle and is innervated by the tibial nerve, whereas the short head is a uniarticular muscle.
and is innervated by the common peroneal nerve.\textsuperscript{10,28,29} Muscle contraction therefore leads to asynchronous activation and different force vectors through the long and short heads.\textsuperscript{10,28,29} The proximal and distal musculotendinous junctions of the biceps femoris are most susceptible to injury owing to their long, narrow aponeuroses that lead to poor dissipation of forces from the muscle belly to the tendons at these interfaces.\textsuperscript{28,29}

The distal musculotendinous T junction of the biceps femoris is formed through a complex coalition of the epimysial surfaces of the long and short heads of the biceps femoris as they traverse distally through the thigh (Figure 1).\textsuperscript{10,28,29} The anterolateral epimysium of the long head condenses to form one-half of the proximal horizontal limb of the T junction. This appears as an L- or C-shape on the axial magnetic resonance imaging (MRI) slice. As the fibers of the long head taper distally, the opposing posterolateral epimysium of the short head condenses to form the second horizontal limb of the T junction. Together, these epimysial condensations form the 2 horizontal limbs of the T junction visible on an axial MRI slice. Distally, the condensation of the posterolateral epimysium of the short head forms the vertical limb of the T junction. This appears as a complex crescent-shaped structure on axial and coronal MRI slices. Injuries to the distal musculotendinous T junction of the biceps femoris are often regarded as a unique clinical entity that is separate from the rest of the hamstring complex. Nonoperative management of these injuries is associated with variable periods of convalescence and high risk of recurrence.\textsuperscript{10,18}

The rationale for undertaking the current study was the high rate of injury recurrence with nonoperative management of these injuries observed in our own treatment center and reported within the existing literature.\textsuperscript{8,10,20} Before study commencement, 34 of 62 patients (54.8%) receiving nonoperative management of high-grade injuries to the distal musculotendinous T junction of the biceps femoris within our treatment center had recurrence of the primary injury within 2 years of follow-up. This prompted a change in our practice from nonoperative to operative treatment for these injuries. To our knowledge, the efficacy of operative treatment of acute injuries to the distal musculotendinous T junction of the biceps femoris has not been previously reported. The findings of this study will provide an improved understanding of the efficacy of surgical repair for these acute injuries in terms of return to preinjury level of sporting activity, injury recurrence, and functional performance at short-term follow-up.

The primary objective of this study was to assess the effect of surgical repair of acute injuries to the distal musculotendinous T junction of the biceps femoris on injury recurrence. The study hypothesis was that surgical repair of these acute injuries would enable return to preinjury level of sport with low risk of recurrence. The secondary objectives were to assess the effect of surgical repair of acute injuries to the distal musculotendinous T junction of the biceps femoris in terms of time to return to preinjury level of sporting function, patient satisfaction, hamstring muscle strength, straight leg raise, functional performance, and complications.

Figure 1. Schematic demonstrating the sequential axial anatomic features of the distal musculotendinous T junction of the biceps femoris. (Reprinted with permission from Entwisle T, Ling Y, Splatt A, Brukner P, Connell D. Distal musculotendinous T junction injuries of the biceps femoris: an MRI case review. Orthop J Sports Med. 2017;5(7):2325967117714998.)

METHODS

Patient Selection

This prospective study included 34 professional athletes undergoing surgical repair of acute injuries to the distal musculotendinous T junction of the biceps femoris. All operative procedures were performed by the senior author (F.S.H.) between March 2015 and July 2017. Baseline and demographic data for all study patients are shown in Table 1. It was not possible to include a control group undergoing nonoperative management. All study patients were high-performance athletes who did not want randomization and potential allocation to nonoperative management, which is associated with high risk of recurrence.

Preoperative MRI was undertaken in all study patients to confirm diagnosis, to grade injury severity through use of the British Athletics Muscle Injury Classification (BAMIC) system,\textsuperscript{22} and to identify any concurrent injuries (Figure 2). All operative procedures were performed by the
senior author. Inclusion criteria for study participation included the following: injury sustained within 4 weeks of operative intervention; MRI to confirm injury to the distal musculotendinous T junction of the biceps femoris classified as BAMIC grade IIIb (extension into the musculotendinous junction) or grade IIIc (extension into the intratendinous portion); clinical loss of strength and/or flexibility of the hamstring muscle group; and operative intervention undertaken by the senior author. Exclusion criteria included the following: recurrent distal biceps femoris injury after nonoperative treatment (n = 12); injury sustained more than 4 weeks before operative intervention (n = 6); BAMIC grade I (n = 4), grade II (n = 5), grade IIIa (n = 1), or grade IV (n = 2) injuries; and patient living abroad (n = 2). The study was prospectively reviewed by the hospital review board, who advised that further research ethics committee approval was not required. Written informed consent for participation was obtained from all study patients.

Surgical Technique

All operative procedures were performed with the patient in the prone position under general anesthesia (Figure 3). The distal musculotendinous junction of the biceps muscle was palpated along its length, and the detensioned portion was indicated with a marker pen. A curvilinear longitudinal incision was made extending approximately 8 to 10 cm proximally from this base. Electrocautery was used to divide the underlying subcutaneous tissue along the length of the skin incision. The fascia overlying the biceps femoris was identified and split longitudinally, friable scar tissue broken with finger dissection, and any underlying seroma evacuated. The retracted and defunctioned biceps femoris was traced distally to the zone of injury at the musculotendinous T junction, and any scar tissue at this site was excised via electrocautery. Two No. 5 Ethibond sutures were temporarily inserted into the distal portion of the biceps femoris and used to stretch the muscle to its preinjury length. The influence of the injuries in the distal musculotendinous portions of the long and short head of the biceps femoris created a large surface area at the zone of injury. This defect was repaired with 4 or 5 Kessler-type sutures using No. 5 Ethibond, which enabled the stress forces to be distributed evenly across the repair site. The knee was fully extended to ensure satisfactory tension in the repair throughout the arc of motion. The overlying hamstring fascia was closed and reinforced to the iliotibial band with absorbable sutures. The wound was copiously irrigated with normal saline, and absorbable sutures were used to perform a layered closure of the overlying fascia, subcutaneous tissue, and skin.

Postoperative Rehabilitation

All patients received a standardized milestone-based rehabilitation program supervised by an experienced sports physiotherapist. The rehabilitation program was divided into 4 distinct phases:

**Phase 1:** Rest, ice, compression, and elevation (RICE), mobilize partial weightbearing with crutches, aspirin 75 mg once daily, limit excessive combined hip flexion and knee extension, normalize gait.

**Phase 2:** Regain pain-free range of motion, full weight-bearing, concentric and eccentric training, core strengthening.

**Phase 3:** Aerobic conditioning with light jogging, cycling, and swimming. Muscle strengthening with resistance exercises, double- and single-leg squats, quadriceps extension, and hamstring curls. Sport-specific training.

**Phase 4:** Return to full sporting activity when full pain-free range of motion, muscle strength 90% of uninjured limb, and no concerns with sport-specific training.

Outcome Measures

All study patients were reviewed by the operating surgeon (F.S.H.) in the outpatient clinic at regular intervals until return to play. Study outcomes were recorded by a specialist nurse practitioner 1 week before surgery and at predefined intervals after surgery. All outcomes at 3 months and 1 year after surgery were collected during clinical evaluation.

**TABLE 1**

| Characteristics and Baseline Data for Study Patients (N = 34) Undergoing Surgical Repair of Acute Injuries to the Distal Musculotendinous T Junction of the Biceps Femoris$^a$ |
|---|---|
| **Age, y** | 26.4 ± 3.1 |
| All patients | 26.3 ± 3.1 |
| Female patients | 27.3 ± 4.0 |
| Male patients | |
| **Sex** | |
| Female | 3 (8.8) |
| Male | 31 (91.2) |
| **BMI, kg/m$^2$** | 25 ± 2.0 |
| All patients | 26.4 ± 3.1 |
| Male patients | 27.3 ± 4.0 |
| Female patients | 26.3 ± 3.1 |
| **ASA score** | |
| I | 34 (100) |
| II-IV | 0 (0) |
| **Laterality** | |
| Right | 15 (44.1) |
| Left | 19 (55.9) |
| **BAMIC grade** | |
| I | 0 |
| II | 0 |
| IIIa | 0 |
| IIIb | 21 (61.8) |
| IIIc | 13 (38.2) |
| IV | 0 |
| **Sporting activity** | |
| Rugby | 19 (55.9) |
| Soccer | 12 (35.3) |
| Athletics | 2 (5.9) |
| Gymnastics | 1 (2.9) |
| **Time from injury to surgery, d** | 16.3 ± 2.7 (range, 12-24) |

*$^a$Values are presented as n (%) or mean ± SD. ASA, American Society of Anesthesiologists; BAMIC, British Athletics Muscle Injury Classification$^2$; BMI, body mass index.
consultation, and outcomes at 2 years of follow-up were collected by telephone conversation due to the wide geographical location of study patients.

**Patient Satisfaction.** Patient satisfaction was recorded at 3 months, 1 year, and 2 years after surgery through use of the Musculoskeletal Outcomes Data Evaluation and Management System, which scores patient satisfaction on a scale of 1 to 5 (1, very unsatisfied; 2, unsatisfied; 3, neutral; 4, satisfied; and 5, very satisfied).

**Hamstring Strength.** Isometric hamstring muscle strength was tested preoperatively and postoperatively at 3 months and 1 year. The patient was placed in the prone position, and a handheld dynamometer (Hoggan Scientific LLC) was positioned over the ipsilateral calcaneus. Maximum resisted knee flexion force (in newtons) was recorded at 0°, 15°, 45°, and 90°. This technique was repeated 3 times, and mean flexion force at each of these angles in the injured limb was calculated. All values were compared with the contralateral uninjured limb to calculate percentage of normal hamstring muscle strength.

**Passive Straight Leg Raise (PSLR).** Maximum angle of PSLR was tested preoperatively and postoperatively at 3 months and 1 year. In the supine position, the uninjured limb was passively elevated inducing hip flexion while maintaining extension at the knee joint to the point of failure secondary to pain or elastic limit of the limb. The maximum attainable PSLR was measured by use of a standard goniometer and compared with the maximum PSLR in the contralateral injured limb. The deficit in PSLR between the 2 limbs was recorded.

**Functional Progress and Return to Function.** All study patients completed the Lower Extremity Functional Scale (LEFS) and Marx Activity Rating Scale (MARS) preoperatively and at 3 months, 1 year, and 2 years after surgery. The LEFS is a validated and effective questionnaire for assessing specific lower limb function. It has an 80-point scale with 20 questions and 4 points allocated to each question, and a minimum clinically important difference of 9 points. The MARS measures patient activity level and knee function independent of age, sex, and type of sporting activity.
Scores of 0 to 4 are assigned to 4 activities including running, changing direction, decelerating, and pivoting, with a total score of 16. Time from surgical intervention to full return to sporting activity was collected in all study patients. All complications with their respective treatments and outcomes within 2 years of the primary surgery were recorded.

All patients recruited into this study completed follow-up. Mean follow-up time was 28.4 months (range, 24.0-36.3 months) from date of surgery.

Statistical Analysis

Paired t tests were used to compare study outcomes found to be normally distributed, whereas the Mann-Whitney U test was used for continuous outcomes found not to be normally distributed. Categorical outcomes were compared using the Chi-squared test and Fisher exact test. Statistical significance was set at $P < .05$ for all analyses, and all statistical analyses were performed by use of SPSS software version 25 (SPSS Inc).

RESULTS

Return to Function and Recurrence

All study patients returned to their preinjury level of sporting activity. Mean time from surgical intervention to return to full sporting activity was 11.7 ± 3.6 weeks. At 1 and 2 years of follow-up, all study patients were still participating at their preinjury level of sporting activity. No study patients had recurrence of the primary injury. However, 2 study patients had proximal semimembranosus BAMIC grade II injuries in the contralateral limb within 1 year of follow-up. Both patients were rugby players who received nonoperative treatment of their contralateral limb injuries. Both players returned to full sporting activity within 8 weeks of the contralateral limb injury without any functional compromise or further complications.

Patient Satisfaction

Surgical repair of acute injuries to the distal musculotendinous T junction of the biceps femoris was associated with high levels of patient satisfaction at 1 and 2 years after surgery. At 1-year follow-up, 18 patients (52.9%) were very satisfied and 16 patients (47.1%) were satisfied with the outcomes of their surgery. At 2 years after surgery, 26 patients were very satisfied (76.5%) and 8 patients were satisfied (23.5%) with the outcomes of their surgery.

Hamstring Strength

Surgical intervention was associated with improved hamstring muscle strength at 3 months after surgery compared with preoperative hamstring muscle strength (Table 2). At 1-year follow-up, all patients had restored hamstring muscle strength to more than 90% of the hamstring muscle strength on the contralateral side.

Passive Straight Leg Raise

Surgical intervention was associated with improved absolute PSLR of the operated limb and reduced PSLR deficit at 3 months of follow-up compared with preoperative values (Table 3). Further improvements in the absolute PSLR and PSLR deficit were observed at 1-year follow-up compared with 3 months after surgery.

Functional Progress

At 3 months after surgery, median LEFS and MARS scores improved compared with their respective preoperative values (Table 4). Progressive improvements were observed in

<table>
<thead>
<tr>
<th>Angle</th>
<th>N</th>
<th>Preoperative</th>
<th>3 Months Postoperative</th>
<th>Improvement</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°</td>
<td>34</td>
<td>63.1 ± 7.7</td>
<td>93.1 ± 5.4</td>
<td>30.0 (27.2-32.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>15°</td>
<td>34</td>
<td>38.9 ± 9.5</td>
<td>88.2 ± 8.1</td>
<td>49.3 (45.3-53.3)</td>
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<tr>
<td>45°</td>
<td>34</td>
<td>24.8 ± 8.3</td>
<td>76.8 ± 9.7</td>
<td>52.0 (48.6-55.4)</td>
<td>&lt;.001</td>
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<tr>
<td>90°</td>
<td>34</td>
<td>85.6 ± 5.9</td>
<td>96.4 ± 3.9</td>
<td>10.8 (8.9-12.8)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Angle</th>
<th>N</th>
<th>3 Months Postoperative</th>
<th>1 Year Postoperative</th>
<th>Improvement</th>
<th>$P$ Value</th>
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<tbody>
<tr>
<td>0°</td>
<td>34</td>
<td>93.1 ± 5.4</td>
<td>98.4 ± 2.8</td>
<td>5.3 (3.2-7.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>15°</td>
<td>34</td>
<td>88.2 ± 8.1</td>
<td>95.9 ± 2.9</td>
<td>7.7 (4.9-10.5)</td>
<td>&lt;.001</td>
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<tr>
<td>45°</td>
<td>34</td>
<td>76.8 ± 9.7</td>
<td>89.9 ± 4.1</td>
<td>13.1 (10.0-16.1)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>90°</td>
<td>34</td>
<td>96.4 ± 3.9</td>
<td>101.1 ± 2.3</td>
<td>4.7 (3.1-6.3)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

aSummary statistics are presented as percentages, either mean ± SD or mean (95% CI). Boldface indicates statistical significance.
LEFS and MARS at 1 and 2 years after surgery. At 3 months follow-up, 4 patients (11.7%) had LEFS scores of 80 (of a maximum of 80), and 7 patients (20.1%) had LEFS scores higher than 75. At 2 years of follow-up, 11 patients (32.3%) had LEFS scores of 80, and 19 patients (55.9%) had LEFS scores higher than 75. MARS scores followed a similar trend to LEFS scores, with statistically significant improvement at each follow-up interval after surgery.

Complications

In addition to the 2 players sustaining hamstring injuries to the contralateral limb discussed above, 3 other patients had complications during the follow-up period. This included 2 patients with postoperative thigh hematomas confirmed on ultrasonography. These were managed nonoperatively and resolved within 3 weeks after surgery without causing any delays to rehabilitation or return to sport. We noted that 1 study patient developed paresthesia around the wound site that fully resolved within 48 hours of surgery. No other complications were observed within the 2-year follow-up period.

DISCUSSION

This study found that surgical repair of acute injuries to the distal musculotendinous T junction of the biceps femoris enabled return to preinjury level of function with low risk of recurrence, high patient satisfaction, increased hamstring muscle strength, and improved functional outcome scores at short-term follow-up. To our knowledge, this is the first study to report on the surgical repair of acute injuries to the distal musculotendinous T junction of the biceps femoris, and it provides important prognostic information on functional outcomes and return to sporting activity after the surgical repair of these injuries.

Nonoperative management of injuries to the distal musculotendinous T junction of the biceps femoris is associated with high risk of recurrence.10,20 Malliaropoulos et al20 reviewed outcomes in 165 elite track and field athletes with posterior thigh injuries, which included 90 patients

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N</th>
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<th>3 Months Postoperative</th>
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<th>P Value</th>
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<tr>
<td>PSLR, deg</td>
<td>34</td>
<td>24.1 ± 7.4</td>
<td>69.7 ± 11.7</td>
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<td>60.3 ± 10.3</td>
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<th>1 Year Postoperative</th>
<th>Change in PSLR</th>
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<td>PSLR, deg</td>
<td>34</td>
<td>69.7 ± 11.7</td>
<td>77.9 ± 8.1</td>
<td>8.2 (4.3 to 12.1)</td>
<td>&lt;.001</td>
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<tr>
<td>PSLR deficit, deg</td>
<td>34</td>
<td>14.7 ± 11.9</td>
<td>6.5 ± 6.9</td>
<td>-8.2 (-4.3 to -12.1)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

aSummary statistics are presented as mean ± SD or mean (95% CI). Boldface indicates statistical significance.

bDifference in PSLR angle compared with contralateral side.

TABLE 3
Passive Straight Leg Raise (PSLR) in Patients Undergoing Surgical Repair of Acute Injuries to the Distal Musculotendinous T Junction of the Biceps Femorisa

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Time</th>
<th>N</th>
<th>Mean ± SD</th>
<th>Improvement in Scores</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEFS score</td>
<td>Preoperative</td>
<td>34</td>
<td>27.2 ± 5.4</td>
<td>37.3 (34.9-39.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>3 mo</td>
<td>34</td>
<td>64.5 ± 4.5</td>
<td>10.5 (9.1-11.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>1 y</td>
<td>34</td>
<td>75.0 ± 2.3</td>
<td>1.4 (0.6-2.2)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>MARS score</td>
<td>Preoperative</td>
<td>34</td>
<td>2.2 ± 2.1</td>
<td>8.4 (7.8-9.0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>3 mo</td>
<td>34</td>
<td>10.7 ± 2.7</td>
<td>1.5 (0.8-2.2)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>1 y</td>
<td>34</td>
<td>12.3 ± 2.5</td>
<td>1.6 (0.9-2.1)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>2 y</td>
<td>34</td>
<td>13.2 ± 1.8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

aImprovements in scores are presented as mean (95% CI). Boldface indicates statistical significance.

LEFS and MARS at 1 and 2 years after surgery. At 3 months follow-up, 4 patients (11.7%) had LEFS scores of 80 (of a maximum of 80), and 7 patients (20.1%) had LEFS scores higher than 75. At 2 years of follow-up, 11 patients (32.3%) had LEFS scores of 80, and 19 patients (55.9%) had LEFS scores higher than 75. MARS scores followed a similar trend to LEFS scores, with statistically significant improvement at each follow-up interval after surgery.
Injuries to the distal musculotendinous T junction of the biceps femoris are associated with highly variable periods of convalescence and time for return to sporting activity.10,18 In the aforementioned study by Malliaropoulos et al,13 133 of the 165 patients (81%) with acute hamstring injuries returned to sporting activity within 2 weeks, with an active range of motion deficit of less than 20° compared with the contralateral side. However, the study included patients with normal ultrasound findings and pooled outcomes for all grades and locations of hamstring injuries, which may have led to more favorable times for return to sporting activity than observed in our study. Lempainen et al18 followed 18 patients undergoing surgical repair of distal hamstring injuries, which included 9 patients with injuries to the distal musculotendinous T junction of the biceps femoris. The study included patients with chronic hamstring injuries, and surgical repair was undertaken on average 8.5 months after injury. Patients reported their outcomes as excellent in 13 cases, good in 1 case, and fair in 3 cases at 12-month follow-up, and mean time to return to sporting function was 4 months (range, 2-6 months). Overall patient satisfaction rates and time for return to preinjury level of sporting activity were more favorable in our study. This may be attributable to our study population including only professional athletes and the shorter time intervals between injury and surgical intervention. Patient satisfaction improved further between 1 and 2 years after surgery, likely owing to athletes gaining more confidence and assurance in performing sport-specific tasks without complications during this time period.

In this study, we used clear inclusion criteria to select patients with BAMIC grade IIb and IIc injuries confirmed on preoperative MRI. However, there was poor correlation between preoperative MRI findings and intraoperative examination of the musculotendinous T junction injury severity. In 12 study patients (35.3%), intraoperative examination revealed a complete tear through the distal musculotendinous T junction of the biceps femoris. Postoperatively, we revisited the preoperative MRI scans of these patients and confirmed correct radiological grading of these injuries as BAMIC grade IIb and IIc injuries, with no radiological evidence of complete musculotendinous dissociation. Previous studies have also shown poor correlation between MRI findings and clinical progress with hamstring injuries and have highlighted the limited sensitivity and specificity of MRI in diagnosing and grading these complex injuries.5,23,24 In the current study, surgical intervention enabled intraoperative identification of complete distal musculotendinous T junction injuries that were not visible on preoperative MRI. Surgical repair enabled the length and tension of the injured segment to be restored, which would have not been possible with nonoperative management alone. The large surface area for the injury at the distal confluence of the 2 heads of the biceps femoris also enabled us to create a robust repair using several Kessler-type sutures. This construct enabled more uniform stress distribution across the repair site, which may have facilitated faster postoperative rehabilitation and reduced the risk of reinjury compared with...
nonoperative management of these injuries. Incremental improvements in passive range of motion and hamstring muscle strength were observed at each follow-up interval. These outcomes have not been previously reported in patients undergoing surgical repair of injuries to the distal musculotendinous T junction of the biceps femoris. However, these findings are consistent with several other studies showing marked improvements in range of motion and muscle strength after operative repair of complete proximal and distal hamstring avulsion injuries, proximal musculotendinous tears, and chronic hamstring injuries refractory to nonoperative treatment.1,4,7,17,19,25

In our study, 2 patients developed postoperative thigh hematomas. These resolved with nonoperative management without causing any delays in rehabilitation or return to sporting activity. Also, 1 patient had postoperative paresthesia, which resolved within 48 hours after surgery. These complications are similar to those described in the above study by Lempainen et al.18 who reported that 2 patients developed postoperative seromas that were treated with needle aspiration and 1 patient had hyperesthesia around the skin wound that resolved spontaneously. Delays in the operative management of proximal and distal complete hamstring injuries have been previously associated with tethering to the adjacent neurological structures and peripheral sensory disturbance and motor weakness.6,27,30 In our study, early surgical intervention helped to limit the formation of scar tissue or adhesions causing tethering to the adjacent nervous structures. None of the study patients required intraoperative neurolysis, and all patients made a full neurological recovery.

Surgical repair of injuries to the distal musculotendinous T junction of the biceps femoris was associated with improvements in LEFS and MARS at short-term follow-up. Most marked improvements in functional outcome scores were observed between preoperative values and 3 months after surgery. Thereafter, statistically significant increases in these functional outcomes scores were observed, but these incremental improvements were less than the reported minimum clinically important difference for these outcome scores.2,21 At 2 years of follow-up, 11 patients (32.3%) had LEFS scores of 80 (of a maximum of 80), and 19 patients (55.9%) had LEFS scores of greater than 75. Due to low ceiling effect of LEFS, we also used the MARS to assess more specialized sporting activities that were self-reported as functional outcomes. At 2 years after surgery, 12 patients (35.3%) had MARS scores of 16 (of a maximum of 16), and 19 patients (55.9%) had MARS scores of 12 or higher. Validated functional scores have not been previously reported with injuries to the distal musculotendinous T junction of the biceps femoris, and therefore the current findings can be compared only indirectly with studies on other hamstring injuries. Cohen and Bradley6 followed 52 patients undergoing suture anchor repair of proximal hamstring avulsion injuries and found a mean LEFS score of 75 (range, 50-80) at 33 months (range, 12-76 months) of follow-up. Bowman et al19 found that operative management of partial hamstring tears was associated with a MARS of 6.5 ± 5.3 reported at 32 months (range, 12-51 months) of follow-up.

The patients had a mean age of 43 years (range, 19-64 years) and had experienced failure of 6 months of nonoperative treatment, which may have led to the reduced MARS scores compared with those in the current study.

The strengths of the current study are that all study patients were prospectively recruited via strict inclusion criteria, preoperative MRI was used to confirm the location and grade of injury, surgery was performed by a single surgeon using a consistent operative technique, rehabilitation was undertaken with a standardized milestone-based program, and a comprehensive range of outcomes were recorded at regular follow-up intervals after surgery. However, several limitations of this study need to be considered when interpreting the findings. First, there was no control group of patients undergoing nonoperative management. On the basis of our own previous experiences and the existing literature, nonoperative treatment of these injuries is associated with high risk of recurrence.10,18 All study patients were high-performance athletes who did not want randomization and potential allocation to nonoperative management. These patients preferred to make their own decisions about treatment, and therefore prospectively randomizing these patients to a nonoperative control group was not possible. Second, all of the study patients were professional athletes, and so the generalizability of the study findings to the general population remains unknown. Third, additional imaging such as ultrasonography or MRI was not used to assess healing at the distal musculotendinous T junction of the biceps femoris or identify any subclinical recurrences during follow-up. Fourth, study outcomes were not correlated with preoperative sporting activity, level of competition, or radiological grade of injury. Further prognostic stratification using these criteria may be possible in future studies with larger study populations.

CONCLUSION

Surgical repair of acute injuries to the distal musculotendinous T junction of the biceps femoris enabled return to preinjury level of function with low risk of recurrence, high patient satisfaction, increased hamstring muscle strength, and improved functional outcome scores at short-term follow-up. Surgical repair of these injuries should be considered as a treatment option in patients with high functional demands to reduce recurrence rates compared with nonoperative management reported in the existing literature.

REFERENCES


Robotic-arm assisted medial unicompartmental knee arthroplasty versus jig-based unicompartmental knee arthroplasty with navigation control: study protocol for a prospective randomised controlled trial

Babar Kayani*, Sujith Konan, Jenni Tahmassebi, Atif Ayuob, Peter D. Moriarty and Fares S. Haddad

Abstract

Background: There remains a paucity of clinical studies assessing how any differences in accuracy of implant positioning between robotic-arm assisted unicompartmental knee arthroplasty (RO UKA) and conventional jig-based unicompartmental knee arthroplasty (CO UKA) translate to patient satisfaction, functional outcomes, and implant survivorship. The objectives of this study are to compare accuracy of implant positioning, limb alignment, patient satisfaction, functional outcomes, implant survivorship, cost-effectiveness, and complications in CO UKA versus RO UKA. Computer navigation will be used to assess intraoperative knee kinematics in all patients undergoing CO UKA.

Methods and analysis: This prospective randomised controlled trial will include 140 patients with symptomatic medial compartment knee arthritis undergoing primary UKA. Following informed consent, patients will be randomised to CO UKA (control group) or RO UKA (investigation group) at a ratio of 1:1 using an online random number generator. The primary objective of this study is to compare accuracy of implant positioning in CO UKA versus RO UKA. The secondary objectives are to compare the following outcomes between the two treatment groups: limb alignment, surgical efficiency, postoperative functional rehabilitation, functional outcomes, quality of life, range of motion, resource use, cost effectiveness, and complications. Observers will review patients at regular intervals for 2 years after surgery to record predefined study outcomes pertaining to these objectives. Ethical approval was obtained from the London-Bloomsbury Research Ethics Committee, UK. The study is sponsored by University College London, UK.

Discussion: This study compares a comprehensive and robust range of clinical, functional, and radiological outcomes in CO UKA versus RO UKA. The findings of this study will provide an improved understanding of the differences in CO UKA versus RO UKA with respect to accuracy of implant positioning, patient satisfaction, functional outcomes, implant survivorship, cost-effectiveness, and complications.

Trial registration: ClinicalTrials.gov NCT04095637. Registered on 19 September 2019.
Background
Unicompartmental knee arthroplasty (UKA) is an established and highly effective treatment for patients with end-stage arthritis affecting a single compartment of the knee joint [2]. The procedure accounts for between 8 and 10% of all knee arthroplasty procedures performed in the UK [1, 15]. There are several advantages of performing UKA over total knee arthroplasty (TKA), including reduced operating time, decreased intraoperative blood loss, reduced periarticular soft tissue trauma, improved preservation of bone stock, better restoration of native kinematics, increased patient satisfaction, and improved functional outcomes [7, 16, 20, 21, 34, 35]. However, UKA is associated with decreased implant survivorship and increased revision rates compared with TKA [9, 28]. Accuracy of component positioning and limb alignment are important prognostic variables that affect implant survival and time to revision surgery following UKA [5, 9, 38]. Consequently, techniques that improve the accuracy of implant positioning and limb alignment in UKA may help to improve long-term survivorship and reduce the burden of revision disease. Conventional jig-based UKA (CO UKA) is performed using manually positioned alignment guides and cutting blocks, limited intraoperative data on knee kinematics, and handheld milling devices or sawblades for bone resection. These techniques are highly dependent on the skill and expertise of the operating surgeons [32, 34]. Studies using data from three separate national joint registries have demonstrated a relationship between the surgical (or unit) case-load and revision rate following UKA [29–32]. Surgeon-controlled errors in implant positioning are the most common reason for implant failure, and low case-volume has been identified as a risk factor for early revision surgery following UKA [30, 32].

Evolution in surgical technology has led to the development of robotic-arm assisted UKA (RO UKA). This uses a preoperative computerised tomography (CT) scan to create a patient-specific virtual three-dimensional reconstruction of the knee joint. The surgeon uses this virtual model to plan optimal bone coverage, implant positioning, and limb alignment for each patient’s unique knee anatomy. An intraoperative robotic arm then helps to execute this plan with a high-level of accuracy, and stereotactic boundaries limit bone resection to the predefined femoral and tibial haptic windows [4, 26, 37]. Intraoperative optical motion capture technology provides real-time medial and lateral gap measurements whilst applying valgus/varus strains to appropriately tension the ligaments through the arc of flexion [10, 24, 26]. Intraoperative data on the ‘tightness’ and ‘looseness’ of the knee joint through the arc of flexion may be used to further adjust bone resection, implant sizes, and implant positions to achieve the desired knee kinematics. Aseptic loosening and progression of osteoarthritis in the remaining native knee compartments are common reasons for failure in UKA [8, 15, 16]. RO UKA enables accurate intraoperative assessment of limb alignment to avoid overcorrection, which may reduce disease progression in the remaining native compartments and help to improve overall implant survivorship. Improved accuracy of bone resection within the confines of the predefined stereotactic boundaries may also reduce periarticular soft tissue injury and enhance postoperative rehabilitation compared to CO UKA [25, 37]. Initial studies have shown that RO UKA is associated with improved accuracy of implant positioning, reduced outliers in limb alignment, faster postoperative rehabilitation, earlier time to hospital discharge, and improved implant survivorship compared to CO UKA [4, 6, 10, 26, 27, 36]. Despite these promising preliminary results with RO UKA, there remains a paucity of high-quality studies comparing a comprehensive and robust range of clinical, functional, and radiological outcomes to CO UKA. Cobb et al. conducted a prospective randomised study on 27 patients with medial compartment knee osteoarthritis undergoing CO UKA versus RO UKA [10]. The authors reported that all patients undergoing RO UKA had tibiofemoral alignment in the coronal plane within 2° of the planned position compared with only 40% in those undergoing CO UKA. Bell et al. performed a prospective randomised controlled study assessing accuracy of implant positioning using postoperative CT scans in 62 RO UKAs versus 58 CO UKAs and found that RO UKA reduced root mean square errors in achieving planned femoral and tibial implant positioning [4]. Blyth et al. followed these patients and found RO UKA was associated with reduced median pain scores by 55.4% compared with CO UKA from postoperative day 1 to week 8 after surgery [6]. RO UKA was associated with improved American Knee Society Score for 3 months following surgery, but there was no difference in functional outcomes observed between CO UKA and RO UKA at 1 year after surgery. Subgroup analysis of the 35 most active patients revealed robotic UKA improved Knee Society Scores, Oxford Knee Scores, and Forgotten Joint Scores compared with CO UKA at 2 years’ follow-up. Herry et al. reviewed plain radiographs in 40 CO UKAs versus 40 RO UKAs and found improved restitution of the native joint line with robotic-guided surgery [18]. Kayani et al. conducted a prospective cohort study on 146 patients showing RO UKA was associated with reduced postoperative pain, decreased opiate analgesia consumption, reduced need for inpatient physiotherapy sessions, and decreased mean time to hospital discharge compared with CO UKA [27]. The main limitations of the aforementioned studies were that outcomes were recorded by non-blinded observers, surgery
was undertaken by multiple surgeons with varying experience in UKA, and only limited clinical or functional outcomes were presented at short-term follow-up.

The delayed uptake of RO UKA has been attributed to the substantive installation and maintenance costs of this technology and limited data showing any clinical or functional benefit to an already well-established and successful CO UKA [4, 6, 8, 15, 26, 34, 35]. Pearle et al. conducted a prospective, multicentre review of 1135 RO UKAs and found implant survivorship was 98.8% at a minimum of 22 months’ follow-up, which is superior to the survival rates of CO UKA reported in the national joint registries of the UK (95.6%), Sweden (95.3%), Australia (95.1%), and New Zealand (96.1%) [36]. Batailler et al. compared outcomes in 80 CO UKAs versus 80 RO UKAs and found revision rates in RO UKA were 5% compared with 9% in CO UKA, although this difference was not statistically significant [3]. Moschetti et al. used a Markov decision analysis tool to compare cost-effectiveness of CO UKA versus RO UKA [33]. Using a 2-year failure rate of 1.2% for RO UKA and 3.1% for CO UKA, the authors reported that RO UKA was a cost-effective procedure only if RO UKA case-volume exceeded 94 cases per year. The main limitations of this study were that it did not include the additional costs associated with purchasing the robotic device, buying new implants compatible with the robotic computer software, additional training for the surgical team, increased operative times during the learning phase, and patient resource use. There remains a paucity of data on how RO UKA impacts functional outcomes, quality-adjusted-life years (QALYs), implant survivorship, and cumulative revision rates compared to CO UKA.

In the proposed study, we aim to improve on existing trials by assessing a more comprehensive and robust range of functional and radiological outcomes, prospectively randomising patients to their treatment groups, using standardised surgical techniques in each treatment group, and collecting data at regular follow-up intervals after surgery. This study aims to build on the previous trials by Bell et al. and Blyth et al. by using three-dimensional preoperative templating in both treatment groups, inserting navigation pins to assess knee kinematics and limb alignment in CO UKA, assessing a more comprehensive range of functional outcome scores, blinding patients and observers recording clinical outcomes, and recording study outcomes for a robust analysis of cost-effectiveness and resource use between the two treatment groups [4, 6, 14]. The findings of this study will enable an improved understanding of differences in CO UKA versus RO UKA with respect to patient satisfaction, functional outcomes, implant survivorship, cost-effectiveness, and complications.

**Methods/design**

**Objectives**

The primary objective of this study is to compare accuracy of implant positioning in CO UKA versus RO UKA. Accuracy of implant positioning will be assessed by measuring differences in the planned implant position on preoperative CT scan versus the achieved implant position on postoperative CT scan. The null hypothesis is that there is no difference in accuracy of implant positioning between CO UKA versus RO UKA.

The secondary objectives are to compare the following outcomes between the two treatment groups:

1. Limb alignment
2. Surgical efficiency
3. Postoperative functional rehabilitation
4. Functional outcomes
5. Quality of life
6. Range of motion
7. Mobilisation distance
8. Resource use and cost effectiveness
9. Complications

**Trial design**

This study is a prospective, single-centre, randomised controlled trial. The study will be undertaken in the Department of Trauma and Orthopaedics, University College Hospital, 235 Euston Road, Bloomsbury, London NW1 2BU, UK. The study will include 140 patients randomly allocated to either CO UKA (control group) or RO UKA (investigation group). The Oxford UKA was selected as the comparator as this was the most commonly used implant for UKA by all three operating surgeons at the study hospital and the most commonly used implant for UKA within the UK [1]. The study commenced patient recruitment in November 2017 and is expected to complete patient recruitment in April 2021. All patients will be followed up for 2 years after surgery, and therefore, the anticipated completion date for the study is April 2023. The study is sponsored by University College London, UK. The patient enrolment flowchart is presented in Fig. 1. The schedule of enrolment, interventions, and assessments for all study patients is shown in Fig. 2.

**Eligibility criteria**

The inclusion criteria for this study are as follows: patient has sufficient mobility to attend surgery, and therefore, the anticipated completion date for the study is April 2023. The study is sponsored by University College London, UK. The patient enrolment flowchart is presented in Fig. 1. The schedule of enrolment, interventions, and assessments for all study patients is shown in Fig. 2.
follow-up clinics. The exclusion criteria for this study are as follows: patient undergoing revision surgery following previously failed correctional osteotomy or ipsilateral UKA; patient not suitable for UKA (e.g., multi-compartment knee disease or ruptured anterior cruciate ligament); patient is immobile or has another neurological condition affecting musculoskeletal function; patient already enrolled on another concurrent clinical trial; patient unable or unwilling to sign the informed consent form specific to this study; and patient unable to attend the study follow-up programme.
Recruitment
Patients will be recruited from the orthopaedic outpatient clinic at University College Hospital, London, UK. All patients will be screened by the clinical team (orthopaedic consultant surgeon, clinical research fellow, and orthopaedic registrar) for study participation based on the predefined inclusion and exclusion criteria listed above. Patients that fulfil the eligibility criteria and express an interest to participate in the study will be provided with an ethics committee-approved patient information sheet. This provides details about the study treatment, follow-up and contact details for further information. All members of the clinical team are familiar with the study and will address any preliminary questions about the study. Details of those patients expressing an interest to participate in the study will be recorded in the patient contact form and forwarded to the research physiotherapist. The research physiotherapist will phone the patient 4 weeks after this consultation to discuss any further questions and confirm if the patient would like to participate in the study.

Consent
Informed consent will be obtained by the chief investigator or principal investigator when the patient attends for the preoperative planning CT scan. This is 6 weeks after the outpatient consultation for agreement to UKA and 2 weeks before surgery. It is important to the data collection scheme that patients are able to follow commands and read and interpret questions via questionnaires. For those who cannot hear, read, or understand English, an interpreter will be provided. Identical preoperative imaging modalities for surgical planning will be used in both treatment groups.

Allocation
After informed consent has been obtained, the research physiotherapist will randomise the patient into one of the two treatment groups using an online random number generator (www.random.org). A number from 1 to 140 can be randomly generated and will allocate each patient to one of the two arms of the study: 1–70 inclusive for the control group, 71–140 inclusive for the...
invasion group. The research physiotherapist will perform the randomisation procedure and store the designated treatment group for each patient on a password-encrypted file on the hospital computer. The operating surgeon will have this information communicated to him on the morning of surgery.

Preoperative imaging
All study patients will undergo preoperative long-leg alignment radiographs, anteroposterior and lateral knee radiographs, and CT scans of the knee joint. In both treatment groups, plain radiographs will be exported onto Traumacad software (Traumacad, Petach-Tikva, Israel) to template implant positioning and sizes for achieving the planned bone coverage, component position, and limb alignment. In CO UKA, fixed target values for component implantation will be obtained from the manufacturer’s manual, and the preoperative CT scans will be used to fine-tune bone resection and implant positioning. In RO UKA, preoperative CT scans will be exported onto a computer software programme (Mako system software, Stryker Limited, Kalamazoo, MI) to create a patient-specific, three-dimensional, computer-aided design model of the patient’s knee anatomy. This will be used to create a preoperative surgical plan for implant positioning. Intraoperative assessments of soft tissue tension, gap measurements, and limb alignment will be used to fine-tune bone resection and guide definitive component implantation. All preoperative templating will be undertaken by the senior supervising surgeon 2 weeks before surgery. Preoperative CT scans are not routinely used for preoperative surgical planning in CO UKA. However, both treatment groups in this study will have preoperative CT scans for three-dimensional surgical planning. This will help to limit any confounding effects from differences in preoperative planning techniques between the two treatment groups impacting the study outcomes.

Surgical intervention
All surgical procedures will be performed under the direct supervision of a single surgeon using the minimally invasive medial parapatellar approach for medial UKA. A tourniquet will be applied, but not inflated unless there are intraoperative concerns with haemostasis. All patients will receive 1 g of tranexamic acid at induction. Patients in both treatment groups will receive 40 ml of 0.25% bupivacaine into the joint capsule prior to wound closure.

CO UKA will be performed using standard instrumentation, with extramedullary referencing to guide tibial bone resection and intramedullary referencing for femoral bone resection. Fixed target values will be used for all patients using the manufacturer’s recommendations and manual instrumentation. Tibial bone resection will be performed using a tibial saw guide positioned with its shaft parallel to the long axis of the tibia. A reciprocating saw with a narrow blade will be used to perform the vertical tibial cut medial to the origin of the ACL. An oscillating saw blade will be used to perform the horizontal tibial cut perpendicular to the mechanical axis of the tibia whilst matching the patient’s native posterior tibial slope. Extra-incisional bicortical femoral and tibial registration pins will be inserted prior to the medial parapatellar approach. Computer navigation will be used to assess knee kinematics and limb alignment before and after component implantation. Trials implants will be inserted and assessments of limb alignment, flexion-extension gaps, mediolateral laxity, and range of motion performed prior to definitive implant selection. The Oxford Phase-3 mobile-bearing cemented UKA (Zimmer Biomet, Bridgend, UK) will be implanted in all patients undergoing CO UKA.

RO UKA will be undertaken using extra-incisional bicortical femoral and tibial registration pins with fixed infra-red arrays mounted onto these to enable intraoperative optical motion capture technology to assess knee kinematics and alignment. Bone registration will be performed by mapping radiological landmarks displayed on the computer screen to register and verify osseous anatomy and bone geometry. Joint balancing will be used to capture femoral and tibial poses with corrective valgus and varus forces to assess knee kinematics through the arc of motion, and fine-tune implant positioning based on laxity of the soft tissue envelope. Bone resection will be performed within the stereotactic boundaries of the haptic bone windows using a high-speed, water-cooled burr with tactile, visual, and audio feedback. Optical motion capture technology will be used to assess limb alignment, flexion-extension gaps, mediolateral laxity, and range of motion with trial implants prior to definitive selection and cement implantation of final components. The RESTORIS MCK (Mako Surgical Corporation, Kalamazoo, Michigan) fixed-bearing UKA system will be implanted using the RIO robotic interactive arm orthopaedic system (Mako Surgical Corporation, Stryker, Kalamazoo, USA) in all patients undergoing RO UKA.

Outcomes
All study patients will undergo review by two blinded observers (one orthopaedic registrar and one clinical research fellow) at 6 weeks, 6 months, 1 year, and 2 years following surgery. During these follow-up times, predefined clinical outcomes will be recorded by these observers using case report forms (CRFs). In addition,
three independent observers (clinical research fellows) will collect radiological outcomes. It is not possible to blind observers recording radiological outcomes as different implant designs will be used within each treatment group. However, the three observers will independently calculate the accuracy of femoral and tibial implant positioning in each patient, and interobserver agreement for all radiological outcomes will be investigated using interclass correlation coefficients.

The following outcomes will be recorded in all study patients:

1. Accuracy of achieving the planned implant positioning as assessed using CT scans performed postoperatively at 6 weeks.
2. Operating time (minutes)
3. Time to hospital discharge (hours)
4. Analgesia requirements during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year, and 2 years
5. Patient-reported outcome measures including Oxford knee score (OKS) and short form (SF-12), Western Ontario and McMaster Universities Arthritis Index (WOMAC), Knee injury and Osteoarthritis Outcome Score (KOOS), and University College Hospital (UCH) functional score during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year, and 2 years.
6. Health-related quality of life as measured using European Quality of Life questionnaire with 5 dimensions for adults (EQ-5D) preoperatively and postoperatively at 6 weeks, 6 months, 1 year, and 2 years
7. Mobilisation distance (metres) and use of mobility aids during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year, and 2 years
8. Range of movement (degrees) in the knee joint during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year, and 2 years
9. Resource use and cost-effectiveness including comparisons between the two treatment groups relating to: Operating time, theatre efficiency, equipment and sterilisation costs, analgesia requirements, inpatient rehabilitation, time to discharge, outpatient follow-up, additional imaging costs, and need for further surgery.
10. Complications

All patients will undergo preoperative and postoperative CT scans of the knee joint using a standardised protocol within a dedicated research scanner in the study hospital. The CT scans will be uploaded in DICOM (Digital Imaging and Communication in Medicine) format and then loaded onto Mimics software (Materialise) to calculate the accuracy of implant positioning. Accuracy of implant positioning will be assessed by comparing differences in the target values in the preoperative plan to the achieved values in the postoperative scan. These outcomes will be used to calculate root mean square errors values for accuracy of femoral and tibial component positioning within the coronal, sagittal, and axial planes as described by Bell et al. [4]. The posterior condylar offset ratio (PCOR) and posterior tibial slope will be assessed using the methods described by Gaudiani et al. and Johal et al. respectively [13, 23].

The WOMAC, OKS, SF-12, EQ-5D, and KOOS are validated tools for the clinical assessment of patients after knee arthroplasty [11, 12, 17, 22, 39]. In addition, the observers will calculate the UCH knee score to assess overall, pain, function, and mobility [19]. This will help to overcome any potential ceiling effect with the OKS and WOMAC and facilitate further subgroup analysis in patients with high functional demands [19]. Each of these clinician- and patient-reported scores will be collected preoperatively at the time of consenting to the study and also postoperatively at 6 weeks, 6 months, 1 year, and 2 years after surgery.

Blinding
All patients and clinical staff clinical outcomes will remain blinded to the treatment group. It is not possible to blind observers recording radiological outcomes as different implant designs will be used within each treatment group. Both conventional manual instrumentation and robotic-arm-assisted surgery are only compatible with implants from their respective manufacturers, and so identical implant designs could not be used in both treatment groups. Study patients will be identifiable with a unique study number. Only the research physiotherapist will have the key to identify individual patients and their respective treatment arm. Any documents related to the study will be archived directly at the study site by the research physiotherapist within a locked filing cabinet in a locked research office. This office has swipe card access with onsite security and 24-h CCTV surveillance. Patient data will be logged electronically using each patient’s unique identification number with computer software on an encrypted, password-protected research computer.

Sample size
Using the study by Bell et al. assessing differences in accuracy of component positioning between conventional and robotic UKA, the mean difference in femoral sagittal component positioning was set at 2° and standard deviation assumed at 4° [4]. Using a two-tailed, two-sample t test with a power of 80% (1–β), significance level of 5%, and an effect size of 0.5, this study required 128 patients to detect this minimum difference between the two
follow-up. The chief investigator will also inform the day that the final study patient has completed 2 years treatment period is defined as the period from the day of the initial observation of the event. The protocol the Data Safety Monitoring Board (DSMB) within 3 days pre-existing criteria provided by the sponsor and inform severity, causality, seriousness, and expectedness using form. The chief investigator will also assess the SAE for reported directly to the sponsor using the SAE web disability or incapacity, life-threatening clinical sequelae, adverse event that results in hospitalisation or prolongation procedure involved. A serious adverse event (SAE) is an occurrence in a patient or study participant, which does not necessarily have a causal relationship with the adverse event (SAE) is an adverse event that results in hospitalisation or prolongation of existing hospitalisation, persistent or significant disability or incapacity, life-threatening clinical sequelae, or death. All SAEs during the protocol treatment will be reported directly to the sponsor using the SAE web form. The chief investigator will also assess the SAE for severity, causality, seriousness, and expectedness using pre-existing criteria provided by the sponsor and inform the Data Safety Monitoring Board (DSMB) within 3 days of the initial observation of the event. The protocol treatment period is defined as the period from the day that the first study patient is recruited into the trial to the day that the final study patient has completed 2 years follow-up. The chief investigator will also inform the London-Bloomsbury Research Ethics Committee and local Health Research Authority within 3 days of the SAE taking place. Safety aspects of the study are closely monitored by the sponsor and DSMB using unblinded data for its judgement. In cases where the SAE arises due to a problem with the robotic device, Stryker Limited will also be notified within 2 days of the event taking place. The chief investigator will record the following: onset date, complete description of the event, severity, duration, action taken, and outcome for each SAE. The chief investigator will also provide regular updates of all SAEs to the London-Bloomsbury Research Ethics Committee, Local Health Research Authority, DSMB, and sponsor.

Statistical analysis
The analysis of the per-protocol population will be considered the primary analysis. The differences between the CO UKA and RO UKA groups will be analysed by calculating the difference from baseline, per patient, and a two-sided confidence interval for the difference between the changes from baseline values will be calculated. This confidence interval will cover the true difference in the percentage change from baseline with a probability of 95%. The following statistical methods will be employed to analyse the data: descriptive statistics, independent t test, paired t test, analysis of variance, Fisher’s exact test, chi-square test, and graphical displays. Assumptions of normality will be tested with the D’Agostino test. Assumptions of homogeneity of variance will be tested with Levene’s test. If the distributional assumptions are (severely) violated, non-parametric techniques, such as Mann-Whitney’s test, will be employed. In the event that RO UKA is converted to CO UKA intraoperatively, analysis will be performed using the intention-to-treat population and the treatment actually received by the patients. Intraoperative conversion from RO UKA to CO UKA will be documented and presented as part of the study. The Bonferroni correction will be used to determine the level of significance due to multiple comparisons of secondary outcomes. Statistical significance is set at a p value < 0.05 for all analyses, and all statistical analysis will be performed using SPSS software version 26 (SPSS Inc., Chicago, IL, USA).

Adverse events
Adverse events are defined as any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved. A serious adverse event (SAE) is an adverse event that results in hospitalisation or prolongation of existing hospitalisation, persistent or significant disability or incapacity, life-threatening clinical sequelae, or death. All SAEs during the protocol treatment will be reported directly to the sponsor using the SAE web form. The chief investigator will also assess the SAE for severity, causality, seriousness, and expectedness using pre-existing criteria provided by the sponsor and inform the Data Safety Monitoring Board (DSMB) within 3 days of the initial observation of the event. The protocol treatment period is defined as the period from the day that the first study patient is recruited into the trial to the day that the final study patient has completed 2 years follow-up. The chief investigator will also inform the

Data management
On-site monitoring visits shall occur throughout the course of the clinical study by the chief investigator. The chief investigator shall permit and assist the sponsor (should they choose to monitor the study) to carry out verification of all study forms against data in the source documents, which shall occur as per the departmental policy for undertaking such activities. University College Hospital recognises that there is an obligation to archive study-related documents at the end of the study. The study master file will be archived at University College London in accordance with the University College Hospital Standard Operating Procedure for Archiving of Investigator Site File (ISF) and Pharmacy Site File (PSF). It will be archived for a minimum of 5 years from the study end and no longer than 30 years from the study end.

End of protocol treatment
Reasons for going off study protocol include:

- Completion of last follow-up visit 2 years after surgery
- Patient non-compliance or withdrawal (the reason for discontinuation will be recorded in the case report form)
- Intercurrent death

All patients included into this study are free to withdraw from the study at any time without compromise to their future treatment. On withdrawal, patients will revert to the standard follow-up regimen for routine (non-study) UKA at the study site. The end of study form will be completed and the reason for withdrawal documented. This form will also be completed if the patient is lost to follow-up or dies during the course of the study. Data to the point of discontinuation will be used for analysis.
Monitoring
The chief investigator will monitor the progress of the clinical study in the form of monthly research meetings for those involved in the trial. The chief investigator will be responsible for day to day monitoring and management of the study. The UCLH/UCL/ Joint Research Office, on behalf of UCL as Sponsor, will monitor and conduct random audits on a selection of studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the Department of Health Research Governance Framework for Health & Social Care (April, 2005) and in accordance with the sponsor’s monitoring and audit policies and procedures. As per the protocol, the principal investigator will email the sponsor twice yearly with the following: delegation log, adverse event log, deviation log, and any annual progress reports sent to the Ethics committee.

Peer review
The study protocol has undergone independent external peer review. The suggestions and recommendations for improvement to the study design were implemented. The reviewers, sponsor, and London-Bloomsbury Research Ethics Committee reviewed the revised protocol documents and confirmed that all queries and suggestions had been fully addressed.

Discussion
Accuracy of component positioning and limb alignment are important prognostic variables that affect implant survival and time to revision surgery following UKA [5, 9, 38]. CO UKA is performed using manually positioned alignment guides, limited intraoperative data on knee kinematics, and handheld milling devices or sawblades for bone resection. However, these manual techniques are highly dependent on the skill and expertise of the operating surgeon. Surgeon-induced errors in implant positioning are the leading cause of premature implant failure and early revision surgery following UKA [29–32]. RO UKA uses a preoperative CT scan to create a virtual three-dimensional reconstruction of the patient’s osseous anatomy. The surgeon uses this virtual model to plan optimal bone coverage, implant positioning, and limb alignment. An intraoperative robotic arm then helps to execute this plan with a high-level of accuracy and reproducibility, and stereotactic boundaries limit bone resection to the predefined femoral and tibial haptic windows [4, 10, 26]. This prospective randomised controlled trial will include 140 patients with symptomatic medial compartment knee arthritis undergoing primary UKA. Following informed consent, patients will be randomised to CO UKA (control group) or RO UKA (investigation group) at a ratio of 1:1 using an online random number generator. Observers will review patients at regular intervals for 2 years after surgery to record predefined study outcomes pertaining to accuracy of implant positioning, limb alignment, postoperative rehabilitation, clinical progress, functional outcomes, cost-effectiveness, and complications. The following statistical methods will be employed to analyse the data: descriptive statistics, independent t test, paired t test, analysis of variance, Fisher’s exact test, chi-square test, and graphical displays. The findings of this study will provide an improved understanding of the differences in CO UKA versus RO UKA with respect to accuracy of implant positioning, limb alignment, patient satisfaction, functional outcomes, implant survivorship, cost-effectiveness, and complications.

Trial status
Protocol: version 1.0; date 18 April 2017.
Patient recruitment date: 1 November 2017.
Estimated completion of recruitment date: 1 April 2021.
Estimated completion of final follow-up: 1 April 2023.

Abbreviations
CO UKA: Conventional jig-based unicompartmental knee arthroplasty; CT: Computerised tomography; DSMB: Data Safety Monitoring Board; EQ-5D: European Quality of Life questionnaire with 5 dimensions for adults; KOOS: Knee injury and osteoarthritis outcome score; OKS: Oxford knee Score; RO UKA: Robotic-arm assisted unicompartmental knee arthroplasty; SAE: Serious adverse event; SF-12: Short-form health survey of 12 items; UCH: University College Hospital knee functional score; WOMAC: Western Ontario and McMaster Universities Arthritis Index

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Nil

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The study is sponsored by University College London, 235 Euston Road, Bloomsbury, London, NW1 2BU, UK (Reference: 220437).

Authors’ contributions
BK, JT: performed background research, identified gaps in medical literature, created study objectives, trial design, created CRFs, attended Research Ethics Committee meeting, helped write study protocol, and prepared National Institute for Health Research (NIHR) Clinical Research Network (CRN) Industry Costing Template. SK, PM, and FSH: helped write study protocol. The authors read and approved the final manuscript.

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Funding was obtained from Stryker Limited. There are no terms or conditions to the funding that will impact the study design, data collection, analysis, interpretation of data, and writing the manuscript.

Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate
The study has been reviewed and approved for patient recruitment by the London-Bloomsbury Research Ethics Committee, UK (Reference: 17/LO/0955). Written informed consent will be obtained from participants during recruitment on site and prior to data collection. Consent to use the data collected for scientific reporting and publication will also be obtained at the same time as the consent to participate.
Consent for publication
The findings of this research will be published in peer-review journals. All study patients will provide informed consent for publication of anonymised patient data and study findings. Authorship will reflect the amount of time spent designing the study, collating the data, analysing the results, and writing the manuscript.

Competing interests
FSH reports board membership of the Bone and Joint Journal and the Annals of the Royal College of Surgeons; consultancy for Smith & Nephew, Corin, MatOrtho and Stryker; payment for lectures including service on speakers’ bureaus for Smith & Nephew and Stryker; and royalties paid by Smith & Nephew, MatOrtho, Corin and Stryker, all outside the submitted work.
SK reports consultancy, payment for lectures including service on speakers’ bureaus, payment for development of education presentations, and travel/accommodations/meeting expenses for Smith and Nephew and AO, all outside the submitted work.
All other authors declare no competing interests.

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Computerised tomography-based planning with conventional total hip arthroplasty versus robotic-arm assisted total hip arthroplasty: study protocol for a prospective randomised controlled trial

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Abstract

Background: Robotic-arm assisted surgery aims to reduce manual errors and improve the accuracy of implant positioning during total hip arthroplasty. The objective of this study is to compare the accuracy of implant positioning, restoration of hip biomechanics, patient satisfaction, functional outcomes, implant survivorship, cost-effectiveness, and complications in conventional manual total hip arthroplasty (CO THA) versus robotic-arm assisted total hip arthroplasty (RO THA). Preoperative pelvic computerised tomography (CT) scans will be used to create patient-specific, virtual, three-dimensional reconstructions for surgical planning in both treatment groups.

Methods and analysis: This prospective randomised controlled trial will include 60 patients with symptomatic hip osteoarthritis undergoing primary THA. Following informed consent, patients will be randomised to CO THA (control group) or RO THA (investigation group) at a ratio of 1:1 using an online random number generator. Observers will review patients at regular intervals for 2 years after surgery to record predefined study outcomes relating to the accuracy of implant positioning, hip biomechanics, postoperative rehabilitation, clinical progress, functional outcomes, cost-effectiveness, and complications. Primary and secondary objectives will be used to quantify and draw inferences on differences in the efficacy of treatment between the two groups. Intention-to-treat and per-protocol population analysis will be undertaken. Intention to treat relates to the allocated treatment (CO THA or RO THA), and per-protocol refers to the actual treatment received by the patient. The following statistical methods will be employed to analyse the data: descriptive statistics, independent t test, paired t test, analysis of variance, Fisher exact test, chi-square test, and graphical displays. Ethical approval was obtained from the London-Bromley Research Ethics Committee, UK. The study is sponsored by University College London, UK.

Discussion: This study compares a comprehensive and robust range of clinical, functional, and radiological outcomes in CT-planned CO THA versus CT-planned RO THA. The findings of this study will enable an improved understanding of the differences in CO THA versus RO THA with respect to patient satisfaction, functional outcomes, implant survivorship, cost-effectiveness, and complications.

Trial registration: ClinicalTrials.gov NCT04095845. Registered on 19 September 2019

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Background

Total hip arthroplasty (THA) is a highly successful surgical treatment for symptomatic hip osteoarthritis, which is performed in over 70,000 patients per year in the UK [1]. The procedure has well-established middle- to long-term clinical outcomes, and implant survivorship is greater than 90% at a minimum of 10 years’ follow-up [24]. Achieving accurate implant positioning and restoring native hip biomechanics are important technical objectives in THA. Studies have shown accuracy and reproducibility of achieving these surgeon-controlled factors during THA influences postoperative acetabular bone stock, abductor function, joint stability, soft tissue injury, impingement, bearing surface wear, and long-term implant survival [3, 5, 6, 12, 15, 18, 23]. Conventional manual THA (CO THA) uses radiographic templating, surgical alignment guides, and intraoperative landmarks such as the transverse acetabular ligament to help guide acetabular reaming and implant positioning. However, it is reported that only 38–47% of acetabular components are within the desired range of anteversion and inclination with CO THA, and low surgeon volume is a risk factor for inaccurate implant positioning [2, 3, 8, 10]. Suboptimal implant positioning outside of the acceptable safe ranges may lead to increased hip instability, poor restoration of native hip biomechanics, and premature component failure requiring more complex revision surgery [3, 10, 11, 15, 16].

Evolution in surgical technology has led to the development of robotic-arm assisted THA (RO THA), which aims to facilitate preoperative surgical planning, reduce intraoperative errors in bone resection, and improve the accuracy of implant positioning compared to CO THA. Preoperative computerised tomography (CT) scans of the pelvis and proximal femur are used to create virtual three-dimensional reconstructions of the patient’s anatomy. The surgeon uses this patient-specific computer-aided design (CAD) model to map optimal implant positioning to achieve the desired bone coverage, component positioning, hip biomechanics, and correction of any limb-length discrepancy. An intraoperative robotic device with audio, visual, and tactile feedback helps to execute the planned bone resection and implant positioning plan with a high level of accuracy. Existing reports comparing CO THA versus RO THA have shown conflicting outcomes [6, 14, 15, 20, 22]. Initial studies found RO THA was associated with improved functional outcomes as assessed using the Harris ship score, increased accuracy of acetabular implant positioning, better preservation of acetabular bone stock, improved restoration of native femoral offset, and reduced postoperative leg-length inequality compared to CO THA [6, 7, 9, 14, 15, 20]. However, further studies have shown no difference in CO THA versus RO THA with respect to functional outcomes, implant survivorship, and complications at short-term follow-up [4, 17, 19, 21]. Delays in the widespread implementation of RO THA have been attributed to the limited data showing any functional benefit with this procedure compared to an already established and highly cost-effective CO THA [7, 13].

Illgen et al. reviewed outcomes in 200 consecutive CO THAs followed by 100 consecutive RO THAs and found RO THA was associated with an additional 71% improvement in the accuracy of acetabular implant positioning compared with manual THA in the first year of use [9]. Acetabular implant positioning within Lewinnek’s safe zones (inclination, 30–50°; anteversion, 5–25°) was achieved in 30% of the first 100 consecutive CO THAs, 45% of the last 100 consecutive CO THAs, and 77% in the first 100 consecutive RO THAs (p < 0.001) [9]. Domb et al. conducted a retrospective radiological review of 50 patients undergoing CO THA versus 50 patients receiving RO THA [6]. All operative procedures were performed through the posterior approach. The study showed that all 50/50 (100%) RO THAs had acetabular cup positioning within Lewinnek’s safe zone compared to only 40/50 (80%) in the CO THA group (p = 0.001). Furthermore, 46/50 (92%) RO THAs had acetabular cup positioning within Callanan’s modified safe zone (inclination, 30–45°; anteversion, 5–25°) compared to only 31/50 (62%) in the CO THA group (p = 0.001). The odds ratio for an implanted acetabular cup out of Lewinnek’s safe zones was zero and Callanan et al. was 0.142 (95% CI 0.044–0.457). Nawabi et al. conducted a study on 12 cadaveric specimens that received CO THA on one side and RO THA on the contralateral side [20]. All procedures were performed using the posterior approach. The root-mean-square error for manual implantation was five times greater for acetabular cup inclination and 3.4 times greater for acetabular cup anteversion compared to robotic-arm assistance (p < 0.01). Tsai et al. conducted a retrospective study in which 12 patients undergoing RO THAs and 14 patients undergoing CO THAs had postoperative CT scans to assess implant positioning [25]. This study found that there was increased combined anteversion of 19.1 ± 11.7° in the RO THA group compared to 23.5 ± 23.6° in the CO THA group (p < 0.001). Cup inclination decreased by 16.5 ± 6.0° in the robotic THA group compared to 10.2 ± 6.8° in the CO THA group (p < 0.001).

The main limitations of existing studies comparing CO THA versus RO THA are that they are based on cadaveric specimens or retrospective clinical trials with limited data on functional outcomes, radiological results, or complications [6, 7, 9, 14, 15, 20]. Within each treatment group, different preoperative imaging modalities were used for surgical planning, operative procedures were performed with varying implant designs, and
postoperative rehabilitation was not standardised. Observers recording outcomes were not blinded to the treatment group, and follow-up of outcomes and complications within each treatment group was limited to the early postoperative period [6, 7, 9, 14, 15, 20]. There is a need for high-quality evidence comparing CO THA versus RO THA. It is possible to improve on these previous studies by using the same preoperative planning technique in both treatment groups, prospectively randomising study patients to the treatment groups, and collecting data on a more comprehensive and robust range of clinical, functional, and radiological outcomes. All operative procedures will be undertaken using the standard posterior approach, sitting and standing spino-pelvic radiographs will be used to assess patient-specific functional pelvic kinematics, and identical implant designs will be used in both treatment groups, which will help to blind observers recording radiological outcomes. The findings of this study will enable an improved understanding of differences in CO THA versus RO THA with respect to patient satisfaction, functional outcomes, implant survivorship, cost-effectiveness, and complications.

**Methods/design**

**Objectives**

The primary objective of this study is to compare the accuracy of achieving the planned centre of hip rotation in CO THA versus RO THA. This will be assessed within each treatment group by measuring the difference in the achieved centre of rotation on postoperative CT scanogram compared to the planned centre of rotation on preoperative pelvic CT scan. The study hypothesis is that RO THA will improve the accuracy of achieving the planned centre of rotation compared to CO THA.

The secondary objectives are to compare the following outcomes between the two treatment groups:

1. Accuracy of achieving planned component positioning
2. Accuracy of restoring planned hip biomechanics
3. Spinopelvic functional kinematics
4. Surgical efficiency
5. Postoperative functional rehabilitation
6. Functional outcomes
7. Quality of life
8. Range of motion
9. Resource use and cost-effectiveness
10. Complications

Specific study outcomes related to the primary and secondary objectives are discussed in the “Outcomes” section below.

**Trial design**

This study is a prospective, single-centre, randomised controlled trial. The study will be undertaken in the Department of Trauma and Orthopaedics, University College Hospital, 235 Euston Road, Bloomsbury, London NW1 2BU, UK. The study will include 60 patients randomly allocated to either CO THA (control group) or RO THA (investigation group). The study commenced patient recruitment in December 2018 and is expected to complete patient recruitment in December 2020. All patients will be followed up for 2 years after surgery, and therefore, the anticipated completion date for the study is December 2022. The study is sponsored by University College London, UK. The patient enrolment flow chart is presented in Fig. 1. The schedule of enrolment, interventions, and assessments for all study patients is shown in Fig. 2.

**Eligibility criteria**

The inclusion criteria for this study are as follows: patient has symptomatic hip osteoarthritis requiring primary THA, patient fit for surgical intervention following review by surgeon and anaesthetist, patient aged between 18 and 80 years at time of surgery, patient able to give informed consent and agrees to comply with the postoperative review programme, and patient has sufficient mobility to attend follow-up clinics. The exclusion criteria for this study are as follows: patient undergoing revision surgery or second-stage THA, patients in whom the planned hip biomechanics are in a different position to the contralateral hip (e.g. developmental dysplasia of the hip or protrusio acetabuli), patient not suitable to have the planned study implants (e.g. requiring dual mobility component or cemented implants), patient had previous contralateral THA, patient is immobile or has another neurological condition affecting musculoskeletal function, patient already enrolled on another concurrent clinical trial, patient unable or unwilling to sign the informed consent form specific to this study, and patient unable to attend the study follow-up programme.

**Recruitment**

Patients will be recruited from the orthopaedic outpatient clinic at University College Hospital, London, UK. All patients will be screened by the clinical team (orthopaedic consultant surgeon, clinical research fellow, and orthopaedic registrar) for study participation based on the predefined inclusion and exclusion criteria listed above. Patients that fulfil the eligibility criteria and agree to participate in the study will be provided with an ethics committee-approved patient information sheet. This provides details about the study treatment, follow-up, and contact details for further information. All members of the clinical team are familiar
with the study and will address any preliminary questions about the study. Details of those patients expressing an interest to participate in the study will be recorded in the patient contact form and forwarded to the research physiotherapist. The research physiotherapist will phone the patient 4 weeks after this consultation to discuss any further questions and confirm if the patient would like to participate in the study.

**Consent**
Informed consent will be obtained by the chief investigator or principal investigator when the patient attends for the preoperative planning CT scan. This is 6 weeks after the outpatient consultation for agreement to THA and 2 weeks before surgery. It is important to the data collection scheme that patients are able to follow commands, read, and interpret questions via questionnaires. For those who cannot hear, read, or understand English, an interpreter will be provided. The consent form describes the benefits and complications associated with THA and details additional risks associated with participation in this study, including additional radiation exposure (equivalent to two plain radiographs) compared to routine (non-research) patients undergoing THA. The consent form also explains that patients are free to withdraw from the study at any timepoint without their medical or legal rights being affected, their medical notes will be reviewed by the research team, and their general practitioners will be informed of their participation in the study.

**Allocation**
After informed consent has been obtained, the research physiotherapist will randomise the patient into one of the two treatment groups using an online random number generator (www.random.org). A number from 1 to
60 can be randomly generated and will allocate a patient to one of the two arms of the study: 1–30 inclusive for the control group, 31–60 inclusive for the investigation group. The research physiotherapist will perform the randomisation procedure and store the designated treatment group for each patient on a password-encrypted file on the hospital computer. The operating surgeon will have this information communicated to him on the morning of surgery.

**Preoperative imaging**

All patients will undergo preoperative imaging with sitting and standing spinopelvic radiographs, pelvic and hip radiographs, and CT scan of the pelvis and proximal femur. Preoperative templating will be undertaken by the operating surgeon. In both treatment groups, pelvic radiographs will be exported onto Traumacad software (Traumacad, Petach-Tikva, Israel) to template implant positioning and sizes for achieving the planned bone coverage, horizontal and vertical centres of rotation, acetabular and femoral offset, and leg-length correction. In all patients, the pelvic CT scan will be uploaded onto a computer software programme (Mako Surgical, Kalamazoo, MI, USA) to create a patient-specific CAD model of the patient’s osseous anatomy. The operating surgeon will use this virtual three-dimensional reconstruction to plan the operative procedure to restore the patient’s native hip biomechanics as guided by the contralateral side. In both treatment groups, the surgical objectives will be to restore the native horizontal and vertical centres of rotation, reproduce the native combined offset, restore natural femoral and acetabular version and inclination within Lewinnek’s and Callanan’s safe zones, and fully correct any pre-existing leg-length discrepancy. The computer robotic software will be used to calculate the required acetabular bone reaming, femoral osteotomy site, implant size, and implant positioning for achieving these surgical objectives.

**Surgical intervention**

In patients undergoing CO THA, the femoral osteotomy site will be marked using the patient-specific CAD using
measurements from the greater and lesser trochanters with the femoral neck cutting guide in place. An oscillating saw will be used to perform the osteotomy with Hohmann retractors protecting the surrounding soft tissues. The femoral osteotomy will be performed with the saw blade 45° to the femoral shaft and in the plane of the tibia. An entry point will be created in the proximal femur using a box chisel, with sequential reaming until contact with the cortical bone is felt, and then progressively larger rasps inserted into the proximal femur while maintaining the planned femoral version. Rasps will be used until the point where stability can be achieved with the definitive components. Sharp Hohmann retractors will be positioned over the anterior wall to lever the femur anteriorly and under the transverse acetabular ligament to expose the whole acetabulum for preparation. Soft tissues overhanging the acetabular circumference will be excised. Osteophytes will also be excised with an osteotome and the medial wall visualised. Sharp, hemispherical reamers will be used to remove the residual acetabular cartilage and expose the underlying subchondral bone. Reamers will be sequentially increased in size until the planned depth is reached. An external alignment guide will be attached to the cutting-edge reamer handle and acetabular impactor to improve the accuracy of acetabular cup positioning. The transverse acetabular ligament will be used as a fixed internal anatomical landmark for accurate positioning of the acetabular component within the safe zones of Lewinnek et al. and Callanan et al. to optimise stability and reduce the risk of dislocation. Any residual osteophytes will be removed at this stage using an osteotome and bone nibbler, and the trial prosthesis inserted to ensure satisfactory coverage and stability. Line-to-line technique for acetabular implantation will be used with implantation of the acetabular cup that is the same size as the last reamer used, and this will be augmented with two acetabular screws. The final femoral stem will then be implanted, femoral head applied to the taper, and hip reduced. The adjustment to a shorter or longer head can be performed at this stage.

In patients undergoing RO THA, three threaded registration pins will be inserted into the iliac crest for the attachment of the fixed pelvic array. One large screw will be inserted into the junction of the intertrochanteric ridge and lesser trochanter for the attachment of the femoral array, and a femoral checkpoint will be inserted just anterior to the greater trochanter. Femoral registration will be undertaken by registering and verifying the position of patient-specific anatomical landmarks displayed on the screen. Intraoperative measurements in the coronal plane as described by Murray will be displayed throughout the procedure. The femoral osteotomy will be marked using the probe and the osteotomy performed using an oscillating saw blade with Hohmann retractors protecting the surrounding soft tissues. The femur will be prepared with a box chisel, sequential reamers inserted, and progressively larger rasps inserted using the planned femoral version. The final rasp will be left in position and the femoral version recorded. The pelvic checkpoint will then be positioned outside the acetabular cavity in the bone just superior to the acetabular rim. Acetabular registration will be undertaken by registering and verifying the position of osseous landmarks displayed on the screen. The acetabular position and orientation may be fine-tuned based on intraoperative data on femoral version and inclination. The RIO robotic arm interactive orthopaedic system (Mako Surgical Corporation, Kalamazoo, USA) will be used to guide acetabular bone reaming within the confines of the haptic tunnel and implant the acetabular component into its final position and orientation as defined in the surgical plan. The final stem will then be implanted, trial head positioned onto the taper, and hip reduced. The femoral array will be inserted into the femoral screw, and the leg-length and offset change shown on the screen. The adjustment to a shorter or longer head can be performed at this stage.

All surgical procedures will be performed under the direct supervision of a single surgeon using the standard posterior approach. Trial implants will be used to assess hip stability, offset, soft tissue tension, and leg-length discrepancy prior to implantation of the permanent acetabular and femoral components in both treatment groups. Patients in both treatment groups will receive the standard or high-offset Accolade II femoral stem (Stryker Ltd., Mahwah, NJ, USA) and the trident acetabular shell (Stryker Ltd., Mahwah, NJ, USA). Patients in both treatment groups will undergo standardised inpatient and outpatient rehabilitation programmes. This will include six outpatient physiotherapy sessions at two-weekly time intervals. Patients will receive physiotherapy-supervised closed and open chain exercises to transition through four phases of rehabilitation with predefined milestones relating to the following: core strength and stability, lower limb proprioception, muscle strengthening, hip and knee range of motion, mobility with and without walking aids; ascending and descending stairs; and functional activities to return to pre-disease level of activity. Any deviations from the standardised proforma will be recorded and presented with the study findings.

Outcomes
All study patients will undergo review by two observers (one orthopaedic registrar and one clinical research fellow) at 6 weeks, 6 months, 1 year, and 2 years following surgery. During these follow-up times, predefined
Clinical, functional, and radiological outcomes will be recorded by these observers using case report forms (CRFs). The following outcomes will be recorded in all study patients:

1. Accuracy of achieving the planned implant positioning and hip biomechanics (horizontal centre of rotation, vertical centre of rotation, acetabular offset, femoral offset, and leg-length discrepancy) as assessed using CT scanograms performed postoperatively at 6 weeks
2. Operating time (minutes)
3. Time to hospital discharge (hours)
4. Analgesia requirements during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year, and 2 years
5. Patient-reported outcome measures including Oxford hip score (OHS), Harris hip score (HSS), Hip disability and osteoarthritis outcome score (HOOS), University College Hospital hip (UCH) score, Western Ontario and Mcmaster Universities Osteoarthritis Index (WOMAC), and University of California at Los Angeles hip (UCLA) score preoperatively and postoperatively at 6 weeks, 6 months, 1 year, and 2 years following surgery
6. Health-related quality of life as measured using European Quality of Life questionnaire with 5 dimensions for adults (EQ-5D) preoperatively and postoperatively at 6 weeks, 6 months, 1 year, and 2 years
7. Mobilisation distance (metres) and use of mobility aids during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year, and 2 years
8. Range of movement (degrees) in the hip joint in the supine position as assessed with a goniometer during inpatient admission and postoperatively at 6 weeks, 6 months, 1 year, and 2 years
9. Resource use and cost-effectiveness including comparisons between the two treatment groups relating to operating time, theatre efficiency, equipment and sterilisation costs, analgesia requirements, inpatient rehabilitation, time to discharge, outpatient follow-up, additional imaging costs, and need for further surgery
10. Complications

**Blinding**

It is not possible to blind study patients as RO THA is associated with an additional incision over the iliac crest for insertion of the acetabular registration pins. However, all observers recording radiological outcomes will remain blinded to the treatment group. Study patients will be identifiable with a unique study number. Only the research physiotherapist will have the key to identify individual patients and their respective treatment arm. Any documents related to the study will be archived directly at the study site by the research physiotherapist within a locked filing cabinet in a locked research office. This office has swipe card access with on-site security and 24-h CCTV surveillance. Patient data will be logged electronically using each patient’s unique identification number with computer software on an encrypted, password-protected research computer.

**Sample size**

Prior to commencement of this study, a pilot study was performed to assess the accuracy of restoring the centre of rotation using CO THA versus RO THA [15]. Using data from this study, the mean centre of rotation was set at 3.7 mm for CO THA and 2.9 mm for RO THA, with standard deviation of 1.0 mm. Using a two-tailed, two sample t test with a power of 80% (1–β), significance level of 5%, and an effect size of 0.8, this study required 52 patients (26 in each treatment arm) to detect the minimum difference between the two treatment groups. To account for 10% attrition in the sample size during follow-up, the total sample size was set at 60 patients.

**Statistical analysis**

The analysis of the per-protocol population will be considered the primary analysis. The differences between the CO THA and RO THA groups will be analysed by calculating the difference from baseline, per patient, and a two-sided confidence interval for the difference between the changes from baseline values will be calculated. This confidence interval will cover the true difference in the percentage change from baseline with a probability of 95%. The following statistical methods will be employed to analyse the data: descriptive statistics, independent t test, paired t test, analysis of variance, Fisher exact test, chi-square test, and graphical displays. Assumptions of normality will be tested with the D’Agostino test. Assumptions of homogeneity of variance will be tested with Levene’s test. If the distributional assumptions are (severely) violated, non-parametric techniques, such as Mann-Whitney’s test will be employed. In the event that RO THA is converted to CO THA intraoperatively, analysis will be performed using the intention-to-treat population and the treatment actually received by the patients. Intraoperative conversion from RO THA to CO THA will be documented and presented and published as part of the study. All statistical analysis will be undertaken by a blinded observer. Statistical significance is set at a p value < 0.05 for all analyses, and all statistical analysis will be performed using SPSS software version 25 (SPSS Inc., Chicago, IL, USA).
Reasons for going off study protocol include:

- End of protocol treatment
- Study end, and no longer than 30 years from the study end, and
- Investigator Site File (ISF) and Pharmacy Site File (PSF).

Hospital Standard Operating Procedure for Archiving of study-related documents at the end of the study. The Hospital recognises that there is an obligation to archive documents, which shall occur as per the departmental policy for undertaking such activities. University College London in accordance with the University College London-Bromley Research Ethics Committee, local Health Research Authority, DSMB, and sponsor.

Adverse events

Adverse events are defined as any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved. A serious adverse event (SAE) is an adverse event that results in hospitalisation or prolongation of existing hospitalisation, persistent or significant disability or incapacity, life-threatening clinical sequelae, or death. All SAEs during the protocol treatment will be reported directly to the sponsor using the SAE web form. The chief investigator will also assess the SAE for severity, causality, seriousness, and expectedness using pre-existing criteria provided by the sponsor and inform the Data Safety Monitoring Board (DSMB) within 3 days of the initial observation of the event. The protocol treatment period is defined as the period from the day that the first study patient is recruited into the trial to the day that the final study patient has completed the 2-year follow-up. The chief investigator will also inform the London-Bromley Research Ethics Committee and local Health Research Authority within 3 days of the SAE taking place. Safety aspects of the study are closely monitored by the sponsor and DSMB using unblinded data for its judgement. In cases where the SAE arises due to a problem with the robotic device, Stryker Limited will also be notified within 2 days of the event taking place. The chief investigator will record the following: onset date, complete description of the event, severity, duration, action taken, and outcome for each SAE. The chief investigator will also provide regular updates of all SAEs to the London-Bromley Research Ethics Committee, local Health Research Authority, DSMB, and sponsor.

Data management

On-site monitoring visits shall occur throughout the course of the clinical study by the chief investigator. The chief investigator shall permit and assist the sponsor (should they chose to monitor the study) to carry out verification of all study forms against data in the source documents, which shall occur as per the departmental policy for undertaking such activities. University College Hospital recognises that there is an obligation to archive study-related documents at the end of the study. The study master file will be archived at the University College London in accordance with the University College Hospital Standard Operating Procedure for Archiving of Investigator Site File (ISF) and Pharmacy Site File (PSF).

End of protocol treatment

Reasons for going off study protocol include:

- Completion of last follow-up visit 2 years after surgery
- Patient non-compliance or withdrawal (the reason for discontinuation will be recorded in the case report form)
- Intercurrent death

All patients included into this study are free to withdraw from the study at any time without compromise to their future treatment. On withdrawal, patients will revert to the standard follow-up regimen for routine (non-study) THA at the study site. The end of study form will be completed and the reason for withdrawal documented. This form will also be completed if the patient is lost to follow-up or dies during the course of the study. Data to the point of discontinuation will be used for analysis.

Monitoring

The chief investigator will monitor the progress of the clinical study in the form of monthly research meetings for those involved in the trial. The chief investigator will be responsible for day-to-day monitoring and management of the study. The UCLH/UCL/Joint Research Office, on behalf of UCL as sponsor, will monitor and conduct random audits on a selection of studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the Department of Health Research Governance Framework for Health & Social Care (April 2005) and in accordance with the sponsor’s monitoring and audit policies and procedures. As per the protocol, the principal investigator will email the sponsor twice yearly with the following: delegation log, adverse event log, deviation log, and any annual progress reports sent to the Research Ethics Committee. Any adverse events will also be included in any publications or presentations relating to the trial.

Peer review

The study protocol has undergone independent external peer reviewer. The suggestions and recommendations for improvement to the study design were implemented. The reviewers and sponsor re-examined the revised protocol documents and confirmed that all queries and suggestions had been fully addressed.

Discussion

Accurate restoration of hip biomechanics and implant positioning in THA are important surgeon-controlled variables that affect clinical outcomes and implant survivorship [3, 5, 6, 12, 15, 18, 23]. CO THA is performed using preoperative radiographic templates and intraoperative anatomical landmarks to manually guide implant positioning. However, this hand-held conventional
technique is associated with 38–47% of patients receiving acetabular components outside of the planned safe ranges [2, 3, 8, 10]. The development of RO THA has enabled surgeons to use preoperative CT scans to create patient-specific surgical plans for achieving optimal implant positioning and hip biomechanics, and an intraoperative robotic-arm to execute this plan with a high level of accuracy [6, 14, 15, 20, 25]. This prospective randomised controlled trial compares a comprehensive and robust range of clinical, functional, and radiological outcomes between CO THA versus RO THA. All operative procedures will be undertaken using a standard posterior approach, sitting and standing spinopelvic radiographs will be used to assess patient-specific functional pelvic kinematics, and identical implant designs will be used in both treatment groups. The findings of this study will enable an improved understanding of differences in CO THA versus RO THA with respect to patient satisfaction, functional outcomes, implant survivorship, cost-effectiveness, and complications.

**Trial status**

Protocol: version 3.0; date 26 October 2018

Patient recruitment date: 1 December 2018

Estimated completion of the recruitment date: 1 December 2020

Estimated completion of the final follow-up: 1 December 2022

**Registration**

Registry name: ClinicalTrials.gov; reference: NCT04095845.

Date registered: 19 September 2019.


**Abbreviations**

CO THA: Conventional manual total hip arthroplasty; DSMB: Data Safety Monitoring Board; EQ-SD: European Quality of Life questionnaire with 5 dimensions for adults; HH5: Harris hip score; HOOS: Hip disability and osteoarthritis outcome score; OHS: Oxford hip score; RO THA: Robotic-arm assisted total hip arthroplasty; SAE: Serious adverse event; SF-12: Short form health survey of 12 items; UCLA: University of California at Los Angeles hip score; WOMAC: Western Ontario and McMaster Universities Arthritis Index

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**Authors’ contributions**

BK and JT performed background research, identified gaps in medical literature, created study objectives and trial design, created CRFs, attended Research Ethics Committee meeting, helped write the study protocol, and prepared the National Institute for Health Research (NIHR) Clinical Research Network (CRN) Industry Costing Template. SK and FSH helped write the study protocol. The authors read and approved the final manuscript.

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**Availability of data and materials**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

**Ethics approval and consent to participate**

The study has been reviewed and approved for patient recruitment by the London-Bromley Research Ethics Committee, UK (Reference: 18/LO/0862). Written informed consent will be obtained from participants during recruitment on site and prior to data collection. Consent to use the data collected for scientific reporting and publication will also be obtained at the same time as the consent to participate.

**Consent for publication**

The findings of this research will be published in peer-reviewed journals. All study patients will provide informed consent for the publication of anonymised patient data and study findings. Authorship will reflect the amount of time spent designing the study, collating the data, analysing the results, and writing the manuscript. No professional writers will be used. All study patients will receive a lay summary of the pertinent findings from the study.

**Competing interests**

FSH reports board membership of the Bone and Joint Journal and the Annals of the Royal College of Surgeons; consultancy for Smith & Nephew, Corin, MatOrtho and Stryker; payment for lectures including service on speakers’ bureaus for Smith & Nephew and Stryker; and royalties paid by Smith & Nephew, MatOrtho, Corin and Stryker, all outside the submitted work. SK reports consultancy, payment for lectures including service on speakers’ bureaus, and payment for development of education presentations and travel/accommodations/meeting expenses for Smith & Nephew and AO, all outside the submitted work. All other authors declare no competing interests.

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**References**


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