The use of 3D-CT Planning and Patient Specific Instrumentation in Total Hip Arthroplasty: Pre-, Intra- and Post-Operative Evaluation

Moralidou Maria

This thesis is submitted in accordance with the requirements for the degree of Doctor of Philosophy (PhD)

University College London

Faculty of Medical Science
Division of Surgery and Interventional Science

October 2022
Declaration

I, Maria Moralidou, 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.

Signature

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Date

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Στον αδερφό μου, Γεώργιο Μωραλίδη
Abstract

Optimal implant placement in Primary Total Hip Arthroplasty (THA) aims to restore physiological hip function. Three-Dimensional Computed-Tomography (3D-CT) and Patient-Specific Instrumentation (PSI) can guide implant positioning in THA. Despite growing evidence of preferable results compared to conventional templating, these tools remain underused in clinical practice. This thesis aimed to assess the role of 3D-CT planning and PSI in terms of femoral stem implantation through pre- and post-operative 3D-CT image analysis in primary THA.

3D-CT planning accurately predicted the femoral stem size (96% within one size) and femoral offsets in uncemented THA. Predicting Prosthetic Femoral Version (PFV) proved to be the unmet need given the limited surgical control of uncemented femoral stems to avoid an insufficient or retroverted PFV associated with THA instability. An insufficient PFV (<5°) was reported in 20% of the femoral stems.

The malleable nature of cement in cemented fixation offers increased control and can avoid delivering an insufficient PFV. All cases in a cemented THA group were antverted more than 5°. However, both uncemented and cemented THA reported high PFV variability, indicating the need to develop PSI to guide PFV.

First, the accuracy of a PSI osteotomy guide was evaluated by aligning pre- and post-operative 3D-CT reconstructed osteotomy levels to quantify their relative discrepancy, proving that planned neck osteotomy was delivered within the clinically accepted 5mm in 96% of cases.

Finally, a pilot study was conducted to evaluate whether a PSI guide, engineered to indicate the angle at which the stem was positioned intra-operatively, can achieve the target range of PFV. Post-operative CT measurements suggested its efficacy in achieving a lower variability of PFV, when compared to the non-guided THA.
These findings will inform that planning software cannot predict PFV in uncemented THA and highlight the potential of PSI in delivering the intended PFV in cemented THA.
Impact Statement

Over 700,000 primary THAs have been performed in the United Kingdom (UK) between 2012 and 2020, according to the National Joint Registry (NJR) of the UK [1]. Projections based on the current data indicate a significant increase [2], while the high cost associated with this surgical procedure and hospitalisation necessitates the need for improvement of current approaches [3].

Recently, 3D pre-operative planning and 3D-printed PSI, have been developed to guide the implant selection and positioning. Despite growing evidence that 3D-CT planning is more accurate than traditional templating, it has not been extensively adopted [4].

The findings of this research emphasise the usefulness of 3D-CT planning in predicting the femoral component size and FO in primary uncemented THA. This information could aid the widespread adoption of 3D-CT planning in the orthopaedic field since it has the potential to reduce the implant inventory and facilitate a safer surgery through the minimisation of untoward events due to incorrect implant size and position. Given that the implant is the costliest component of a THA [5], it may also result in a more economical clinical practice.

Clearly explaining, the caveats of this procedure will make issues broadly known. The results highlight the risk of delivering an insufficient PFV using conventional uncemented femoral stems. This understanding could equip surgeons with the knowledge that available commercial software cannot deliver the optimal PFV and may result in much more apprised endeavours that could solve this issue.

The findings suggest that cemented fixation offers greater control of PFV than uncemented fixation. Considering that an adequate PFV is crucial for a biomechanically stable hip joint [6], [7], surgeons may consider using a collarless, double-tapered,
polished, cemented femoral stem to deliver a more clinically accepted PFV for their patients.

The incorporation of 3D-printed PSI guides to facilitate optimal femoral component positioning was considered necessary. In this regard, the clinical validation of an osteotomy PSI guide could reassure orthopaedic surgeons about the usefulness of this tool in delivering the planned osteotomy and aid its widespread use. This would substantially benefit patients, given that femoral neck osteotomy can affect the leg length and femoral stem position after surgery [8]–[10].

The concept of PSI was adopted to guide PFV in primary cemented THA. Lower variability of PFV was reported when the guide was used compared to the non-guided THA group. This information could result in the adoption of PSI to accurately position the femoral stem, especially when compared to the highly accurate but remarkably expensive robotic-assisted surgery [11]. As a result, the management of THA patients could benefit from a potentially improved clinical outcome due to optimal implant orientation.

Overall, this work will make known the inadequacy of commercially available planning platforms to predict the optimal PFV and the economic potential of PSI in filling this gap.
Acknowledgements

A little over three years ago I left Greece and moved to London to visit Royal National Orthopaedic Hospital (RNOH). After studying engineering for many years, I strongly wanted to apply my knowledge in the clinical field. Pursuing a clinical PhD was an idea I was exploring for quite long, before actually doing it.

I would, therefore, like to express my special thanks to my primary supervisor, Professor Alister Hart, for giving me the opportunity to make my dream a reality. Your enthusiasm for novelties in the orthopaedic field is a flourishing example of how a young researcher should constructively position oneself to achieve great things.

I am also grateful to the members of my thesis committee, Dr Anna Di Laura and Dr. Harry Hothi. Dr. Di Laura, thank you for your valuable feedback and commitment, especially during the tough period of the Corona lockdown. I did my PhD in the middle of the pandemic, which made access to the hospital and the patients’ data difficult. You were there, to ease my accessibility and assist me in formulating my next research steps. Dr. Hothi, I really appreciated your positive attitude and your valuable guidance. Your professionalism guided me to be punctual with my academic deadlines, delivery of my monthly reports and gathering of essential milestones.

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I would also like to thank Dr. Martin Belzunce. Martin, your guidance and expertise in algorithmic image processing has been instrumental to the completion of my PhD.
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<td>AA</td>
<td>Anatomical Axis</td>
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<tr>
<td>ABD</td>
<td>Abduction</td>
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<td>AI</td>
<td>Artificial Intelligence</td>
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<td>APP</td>
<td>Anterior Pelvic Plane</td>
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<td>Anterior edge of the Pubic Tubercles</td>
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<tr>
<td>CoCr</td>
<td>Cobalt Chromium</td>
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<td>CoR</td>
<td>Centre of Rotation</td>
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<tr>
<td>CV</td>
<td>Combined Version</td>
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<td>DDH</td>
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<td>DICOM</td>
<td>Digital Imaging and Communications in Medicine</td>
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<td>FNA</td>
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<tr>
<td>NA</td>
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<td>NFV</td>
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<td>Range of Motion</td>
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Introduction
Chapter 1 Introduction

1.1 Motivation

Being able to walk normally is important. It allows us to explore the world around us; to be physically and mentally healthy. In the presence of trauma or disease, our skeletal system has been recorded to provide a dynamic and highly responsive activation. Quite often though, restoration of hip mobility and pain relief require human intervention.

Fast forward to today, and primary Total Hip Arthroplasty (THA) is among the commonest and safest operations carried out worldwide, aiming to restore the physiological function of the hip joint [12]. Recent literature stated that 19-35% of patients waiting for a THA are in a health state “worse than death”, and undergoing THA helps improve the hip joint function and the overall quality of life [13], [14].

Although a majority of patients report satisfactory post-operative clinical outcome [15], there is an ongoing demand for primary and revision THAs [16]. Worldwide, projections on current data estimate an 134-208% increase for primary and 31-137% for revision THAs [17]–[19]. The ageing population, the extension of these surgeries to the younger generation (50% increase in patients <65 years old) [16] and the prevalence of obesity are considered factors driving these increases [17].

Cost-wise, THA is an economically favourable surgery with £1372 per Quality Adjusted Life Years (QALY); way below the amount of £20000 that NHS decisions makers can pay per QALY [3]. However, the steady increase of primary and revision surgeries is estimated to constitute a significant financial burden to the hospital systems of up to $5.32 billion by 2030 [19]. At the same time, NHS is under financial challenges, with local authorities facing cuts that vary 0.3 to 42% per capita total service expenditure [20].
According to the 19th report of NJR, the most common indications for revision THA are aseptic loosening (42%), dislocation (14.8%), pain (14.8%), infection (14.6%) and lysis (13.6%) [1]. Elsewhere, mechanical failure is one of the main reasons for revision surgery (36.5%), followed by metallosis (21.4%) and dislocation (14.6%) [21]. Adverse clinical events are not the only bothersome aspect of primary THA. Even patients with radiographically stable hip implants often report an inability to perform daily tasks [15]. In addition, patients’ expectations have changed over the years; performing daily tasks is no longer sufficient and an active participation in yoga and sports is often expected [22], [23].

In light of the above-mentioned competing demands, one of the most important goals is to achieve long-term implant survival and avoid adverse clinical effects, such as dislocation, through optimal component implantation [24]. Human anatomy is highly variable however; the positioning of conventional femoral stem designs often impedes the successful reconstruction of native hip biomechanics [15], [24]–[26]. The placement of the femoral stem, in particular, varies considerably; its vertical position exceeds the clinically accepted threshold in 14-42% of THA patients [25], while 9-21% of patients have reported a Leg Length Discrepancy (LLD) of more than 1cm [27], [28]. Furthermore, existing literature has reported a high variability of the version of an uncemented femoral stem, ranging between -23° and 72° [9], [29]–[31].

Femoral stems featuring modular necks have been proposed to effectively restore hip biomechanics. However, these components have been proved to perform poorly in a number of material and design combinations [32], [33]. In addition, patient-specific implants have been developed to reconstruct native hip biomechanics with high precision [26]. However, the cost of customised implants is significantly higher (30% more) when compared to standard off-the-shelf implants [34]. As a result, the general population has limited access to this advanced technology [26], [34].
Recently, Three-Dimensional Computed-Tomography (3D-CT) pre-operative planning has been emerging as a more targeted and potentially cost-effective approach to guide the femoral component selection and positioning [4]. 3D-CT may also work as an enabler to produce 3D-printed bespoke surgical tools, known as Patient-Specific Instrumentation (PSI), assisting the surgeon in positioning the prosthetic components with greater accuracy [35].

Despite early evidence supporting the superiority of 3D-CT over conventional practice in primary THA, it has not been widely adopted in clinical practice [4]. The increased radiation exposure associated with CT, the lack of standardisation of imaging protocols and the complexity and learning curve of commercially-available planning platforms may have restricted the adoption of 3D-CT planning in clinical practice.

This research focuses on assessing and improving the CT-based patient-specific planning of THA, using conventional femoral stems. This may result in a widespread adoption of 3D-CT planning in clinical practice and potentially reduce the incidence of complications associated with incorrect implant position and orientation. The driving force behind this body of work has been to incorporate the advantageous patient-specific approach, in a cost-effective manner. Instead of manufacturing custom hip implants, 3D-CT planning and 3D-printed PSI were proposed to improve the positioning of conventional femoral stems in primary THA.

This information would improve the clinical function of hip arthroplasty through a more accurate planning of femoral stems pre-operatively. Accurate pre-operative planning would result in a more accurate, safer, time- and cost-effective surgery, potentially reducing the negative clinical effects of incorrect femoral component sizing and malposition.
1.2 Aim

The overarching aim of this thesis was to assess the accuracy of 3D-CT planning and 3D-printed PSI in terms of femoral stem component implantation in patients undergoing primary THA due to OA through pre- and post-operative 3D-CT computational image analysis.

1.3 Objectives

To achieve this aim, the objectives were:

- To review the evidence about the prevalence of 3D-CT planning and PSI in primary THA.
- To evaluate the current 3D-CT planning of a straight tapered femoral stem in primary uncemented THA in terms of femoral component size, position and orientation.
- To better understand the impact of the fixation technique on the Prosthetic Femoral Version (PFV) in primary THA.
- To evaluate the accuracy of a PSI femoral neck osteotomy guide, using 3D-CT image analysis.
- To introduce a PSI PFV guide and evaluate whether its intra-operative use can result in a more acceptable range of PFV in primary cemented THA.
1.4 Thesis Outline

This thesis consists of 7 chapters. Initially the concept of hip arthroplasty is introduced, including current methods of treatment and diagnosis. In this context, medical imaging plays a crucial role in planning a primary THA, while advances in Artificial Intelligence (AI) and 3D-Printing assisted the development of 3D-CT planning and PSI. A literature review follows, to assess the evidence about the prevalence of 3D-CT planning and PSI in primary THA.

In chapter 3, 3D-CT image analysis techniques are applied to evaluate the accuracy of a commercially available surgical planning software in predicting the size and position of a straight-tapered femoral stem in primary uncemented THA. Furthermore, this chapter aims to understand if the native version of the proximal femur (NFV) is a useful guide for planning and delivering PFV in primary uncemented THA.

Chapter 3 is followed by a subchapter that aims to understand how an uncemented straight tapered femoral stem fits within the internal femoral canal.

Chapter 4 investigates the effect of the fixation method on PFV.

In Chapter 5, 3D-CT image analysis techniques are applied to assess the accuracy of a PSI femoral neck osteotomy guide.

Chapter 6 introduces a novel PSI guide designed to deliver a PFV of 20° and aims to better understand whether its intra-operative use results in a PFV closer to the surgical target in primary cemented THA.

Finally, Chapter 7 outlines the key findings of this research and expresses them in terms of clinical relevance, including possible future work.
Appendices A and B include information relevant to the 4th, 5th and 6th research chapters of this thesis. Appendix C includes a list of publications and conference contributions that came as a result of this research.

1.4 Ethical Approval

The research chapters included in this thesis were conducted conforming the ethical principles of research. Patient details were anonymised and institutional approval was obtained (SE16.020).
Literature Review
Chapter 2 Literature Review

2.1 The Hip Joint

2.1.1 Bony Anatomy

Forming the connection between the axial skeleton and the lower limbs, the hip joint bears the weight of the human body and offers stability during daily or athletic activities [36]. It is a ball and socket articulation between the femoral head and the pelvic acetabulum, Figure 2-1 [36], [37].

![Figure 2–1: Anatomy of a normal hip joint](https://orthoaao.org)

The pelvic acetabulum has a cup shape formed by the innominate bone, with the ilium contributing around 40% of its structure, the ischium contributing 40%, and the pubis contributing the remaining 20% [38]. The anatomy of the pelvis varies depending on gender and ethnic characteristics [39]. For instance, females tend to exhibit wider pelvises and deeper acetabulum, often attributed to the need to give birth [39].

The acetabulum covers approximately 60-70% of the femoral head, which approximates the shape of a sphere and connects to the femur's shaft through the neck of the femur [40].
The angle between the femoral neck and femoral shaft is known as the Neck Shaft Angle (NSA). This angle exhibits considerable human variation, with an average value between 120 and 130°, while Coxa Varra refers to it being below 120° and Coxa Valga when this value exceeds 130°, Figure 2-2 [41].

Figure 2–2: From left to right examples of: Normal NSA, Coxa Varra, Coxa Valga [Reprinted from 41].

Besides NSA, the neck of the femur is anteriorly bowed and twisted, relevant to the knee joint, Figure 2-3A. The latter is known as femoral torsion [42], and it also demonstrates a high variability [43] with a range of between 15 and 20° to be considered normal [44]. NFV has been reported higher in the female population [45]. The NFV can be either anteverted or retroverted, with anteversion describing a femoral neck twisted anteriorly relevant to the knee joint, while retroversion refers to a posteriorly twisted neck. Usually, people with either excessive or retroverted NFV tend to have a compensatory toe-in or toe-out posture, respectively, Figure 2-3 [46].
Figure 2–3: A) Schematic representation of an anteverted NFV and respective toe-in posture; B) Schematic representation of a retroverted NFV and respective toe-out posture [Reprinted from 46]. * Denotes the angle

Regarding the femur’s long part, the Dorr classification is a common way to evaluate the bone quality of its intramedullary canal, expressed as the relationship between the diameter of the femoral canal at different levels considering the thickness of the cortical cortex [47]. According to this classification, Dorr type A characterises femurs with thick cortical bone, type B thinner cortical bone and type C describe substantially wide canals with significant loss of cortical bone, Figure 2-4 [47].
2.1.2 Cartilage and ligaments

The adjoining bony surfaces are covered with horseshoe-shaped articular cartilage to reduce friction between the two bony components during motion. The articular cartilage includes a membrane, that produces synovial fluid, justifying its synovial joint definition [41].

Various ligaments act as restricting structures contributing to the stability of the hip joint, Figure 2-5. These include the acetabular labrum that runs around the acetabular rim, the iliofemoral ligament, the pubofemoral ligament that lies inferiorly and posteriorly to the iliofemoral ligament, the ischiofemoral ligament posteriorly, the zona orbicularis, and finally the ligamentum teres or femoral ligament, which is located at the fovea capitis and has an additional function; it supplies blood to the femoral head of the hip joint [41], [48].
2.1.3 Hip biomechanics

The ball and socket configuration in collaboration with the 22 muscles supported by various neurovascular structures, allows movement around the three axes of the human body, Figure 2-6 [41].

Figure 2–5: Hip joint ligaments (Reprinted from teachmeanatomy.info).

Figure 2–6: Movements of the hip joint [Reprinted from 49].

The loads acting on the hip joint under static conditions are often described by a simplified free-body diagram, where R is the joint reaction force, M the abductor muscle force and K the weight of the human body. The joint reaction force causes a turning movement around the femoral head centre, while the combined abductor muscles resist this motion.
The abductor muscle force that act around the femoral head centre, create a moment arm b, known as the abductor lever arm, that significantly affects the magnitude of the forces, Figure 2-7 [40], [41].

Figure 2–7: Free-body diagram to estimate the force on the hip joint in single leg stance. K denotes the body weight, R the joint reaction force and M the combined abductor muscle force [Reprinted from 41].
2.2 Pathologies

Maintaining a healthy hip joint enables participation in daily tasks, leisure activities and an overall enhanced standard of living. The presence of disease or trauma can interfere with daily activities and deteriorate an otherwise independent way of living.

Osteoarthritis (OA) is one of the most common hip joint disorders, and the most prevalent form of joint arthritis seen in adults [50]–[53], often associated with socioeconomic consequences [54]. In hip OA, the articular cartilage within the hip joint degenerates, Figure 2-8. As a result, the mechanical stability of the hip joint deteriorates, leading to restrictions in mobility [50].

![Figure 2–8: Morphological differences between a normal and an arthritic hip joint (Reprinted from hopkinsmedicine.org).](image)

Abnormal hip joint morphology, such as increased anteversion of the femoral neck, has been associated with the development of hip OA [55]. Other risk factors include age, gender, obesity, genetics, physical activity and nutrition [56].

Reports on the prevalence of hip OA vary significantly in terms of ethnic and racial characteristics and depend on the applied diagnostic criteria [57]. For instance, the
The prevalence rate of OA in African American rural population was found to be 10% [57], compared with 3-6% in Caucasians [58] and nearly 1% in Asian ethnicities [59].

Another hip joint disease is Rheumatoid Arthritis (RA). The onset of RA usually affects multiple joints, with the hip joint being affected initially in 15% of all patients with RA and progressively in 28% a few years later [60]. Various risk factors have been associated with RA. Familial associations, female gender (3.6% in women compared to 1.7% in men) [61] and the exposure to smoking have been reported to be the strongest [62]. Worldwide, the prevalence rate of RA is estimated to be 0.24% [63].

Although bony deformities associated with OA characterise the older population [64], severe morphological abnormalities such as the Developmental Dysplasia of the Hip (DDH) commonly affect infants [65]. Radiographic abnormalities of the hip joint have been reported in 5% of newborns [65]. Interestingly, only 1.3 per 1000 cases report persistent abnormal hip morphology [66]. Risk factors of DDH include breech position, female sex and first gestation [65].

Hip fractures, including the acetabulum and the proximal femur, are not uncommon. More than 250,000 hip fractures occur in the United States each year [67]. These concern mostly the elderly, with the mortality rate at 1 year varying from 14% to 36% [67]. Factors associated with the risk of hip fracture include demographic characteristics, osteoporosis, medication, medical history and life-style [68].
2.3 Treatments

The most common symptom in hip joint pathologies is pain. Prescribed medication is often the first-line treatment to alleviate pain and discomfort [69]. Non-pharmacologic treatments include exercise, weight reduction and dietary changes [69], [70]. Physical therapy is an option to strengthen the muscles and enhance hip mobility [70]. Other strategies include transcutaneous electrical nerve stimulation and temperature extremes to relieve the pain [69]. Appropriate footwear with shock-absorbing abilities and assistive devices may also be advised in addition to the core treatment [69], [70].

When non-invasive treatments cannot sufficiently relieve symptoms, surgery is considered imperative [69]. One example of a minimally invasive operation is arthroscopy; a procedure where the surgeon can access the hip joint with specialised arthroscopic instrumentation to remove loose tissue and debris [71]. Hip resurfacing is another conservative option, particularly suitable for active young men, where the head of the femur is surgically modified to insert a metal femoral head [72]. Finally, THA is usually the surgical treatment when patients with previously mentioned hip joint pathologies experience persisting pain and functional limitation [69].
2.4 The Hip Arthroplasty

The main goal of primary THA is to relieve pain and eventually restore the normal hip function [15]. Over 3.1 million of primary THAs have been performed in Europe since the mid-twentieth century [73]. Growing levels of obesity, the prevalence of OA associated with an ageing population [19], [74] and the increase in sports-related injuries [75] are expected to cause a greater demand for future arthroplasty surgeries. Estimations based on current trends in the UK, indicate a significant increase in primary THA [2], with the cost per procedure being up to 7.000 £ [3]. Outside Europe, the United States (USA) report an expansion of primary THA (by 2030) [16], while the Australian healthcare system expects a rise of 208% (2013 to 2030), and an overall cost of over 5.32 billion Australian dollars [19]. (Figure 2-9)

![Infographics illustrating demand of THA.](image_url)

Figure 2–9: Infographics illustrating demand of THA.

2.4.1 Early recordings

Even though hip joint pathologies have been evident in ancient skeletons [12], [76], the earliest recordings of surgical intervention using prosthetic components go back a little
more than one century [77]. Initial attempts (during the 18th century) included surgical excision of the femoral head; a revolutionary method at the time, compared to the most common approach of amputation [78].

Anthony White of the Westminster Hospital, London, UK (1821), was the first to perform it on a 9-year-old patient suffering from tuberculosis [78], [79]. A few years later, John Rhea Barton from Lancaster, PA, USA (1826) performed the first intertrochanteric corrective osteotomy on an ankylosed hip, which resulted in a patient walking with a cane [80].

Later, surgeons started using human or animal tissues and wood blocks to fill the space between OA articulating hip surfaces [12], [78]. Leopold Ollier of the Hôtel-Dieu hospital, Lyon, France (1885) was the first to perform an interposition arthroplasty using adipose tissue in aseptic joints [80], [81]. Nevertheless, this approach was unsuccessful, considering the absence of fixation on the surrounding tissues [80].

The first recorded hip arthroplasty was performed by Professor Themistocles Gluck from Berlin, Germany (1891). Instead of femoral excision or natural tissues, he used an ivory-made prosthesis to replace the femoral head [82]. Ivory is a durable material that can be easily crafted, potentially explaining its use for the first designs of a hip prosthesis [83]. A breakthrough came during the early years of the 20th century when glass was firstly used by Marius Smith-Petersen from Boston, MA, USA (1925) to create a hollow prosthesis to fit over the femoral head and provide a smooth interface for motion [84]. Glass, however, although biocompatible, could not withstand the forces experienced in the hip joint [77].

For this reason, Marius Smith-Petersen, along with Philip Wiles from London, UK (1938), considered trialling stainless steel to create the first Metal-on-Metal (M-on-M) THA prosthesis fixated to the bone with screws, known as the Wiles hip replacement
From a design perspective, this approach included the replacement of both the acetabulum and the femoral head with metallic parts articulated together, Figure 2-10.

![Image of Wiles hip replacement](image1)

**Figure 2–10: The Wiles hip replacement [Reprinted from 85].**

Later, longer stems were designed to extend downwards from the femoral head potentially facilitating their insertion into the femoral canal and enabling a better anchor, such as the Thomson stem (1950) [78]. Further modifications included a modified Thomson stem featuring a fenestrated femoral stem to allow bone ingrowth, known as the Moore stem (1952); a design even used nowadays to treat fractures, Figure 2-11 [86].

![Image of Moore stem](image2)

**Figure 2–11: The Moore stem (Reprinted from Auxein.com).**
By the mid-twentieth century, M-on-M implants were the regular choice for hip surgeries [12]. Cobalt-chromium (CoCr) was the predominant material [87], while novel designs of long femoral stems with narrow femoral neck diameters emerged. One representative example of such an MoM prosthesis is the McKee-Farrar prosthesis, including a modified Thomson stem in Figure 2-12 (1953). Despite the reported good survival rate of 74% at 28 years [88], this method lost popularity due to the undesirable local effects of metallic particles [12], [87].

![Figure 2-12: The McKee-Farrar hip prosthesis (Reprinted from americanhistory.si.edu).](image)

It was Sir John Charnley (early 1960s) of the Manchester Royal Infirmary, Manchester, UK, that set the foundations for modern hip prostheses by introducing the idea of low friction arthroplasty of the hip, Figure 2-13. First, the incorporation of Polyethylene (PE), as a plastic material with low coefficient of friction in the acetabular cup implant, aimed to replicate the motion seen in the natural joint. Second, Charnley advocated the combination of a PE acetabular cup with a single metallic femoral component (femoral head and stem together), fixated to the bone with acrylic cement to achieve a rigid fixation.
and avoid undesirable twisting. The final modification was to combine a large acetabular cup with a small femoral head to optimise the friction between the bone-implant and implant-implant interfaces [12], [77], [89]–[91]. Long-term clinical studies, reporting 81% [92] and 77.5% [93] survivorship at 25-year follow-up, came to reassure Charnley’s idea and establish THA as the orthopaedic operation of the century [12].

Figure 2–13: Low friction arthroplasty: The Charnley hip prosthesis (Reprinted from [89], [90]).

However, the adoption of PE, although revolutionary for the time, was associated with osteolysis; the resorption of bone due to wear debris [77]. At the same time, M-on-M implants incorporated a potential risk of increased metal ion levels, associated with carcinogenic effects [77]. Ceramic implants were first introduced in 1977 by the French surgeon Boutin to overcome these concerns due to their hydrophilic and inert nature [77], [78], [94], [95]. However, these implants were expensive and associated with a high risk of fracture, leading many surgeons against their adoption [77].
The various complications of material, design and fixation configurations adopted throughout history led to ongoing research and development around the achievement of a long-lasting prosthesis that has contributed to the current state of modern THA.

2.4.2 The modern approach

Prosthetic Components

Modern THA consists of 4 components; 1. Acetabular Cup; 2. Acetabular liner; 3. Femoral Head/Ball; 4. Femoral stem, Figure 2-14. During the operation, the surgeon removes the femoral head and part of the femoral neck (femoral neck osteotomy) using an oscillating saw [96]. The acetabular cup is inserted within the reamed acetabulum, which hosts the liner. The intramedullary canal of the proximal femur is prepared to insert the femoral stem. The liner is then articulated with the artificial head and the femoral stem [97].

![Figure 2–14: Prosthesis in modern THA [Reprinted from 98].](image_url)

Fixation method & design configurations

Cemented

Charnley, not only introduced the notion of “low-friction” hip arthroplasty, but also popularised the implant fixation using bone cement [12]. Although the idea of
cementation goes back to 1970s’, the material composition of the cement mantle remains the same [12]. Contrastingly, bone preparation and implemented techniques have changed dramatically [12]. At first, cement was used without pressure resulting in poor penetration into the trabecular bone [12], [99]. Later, surgeons adopted the approach of cleaning and preparation of the endosteal space before pressurised insertion of the cement material [100].

The cemented design of the acetabular cup in Charnley’s “low-friction” hip arthroplasty has only changed subtly [12]. Interestingly, analysis of the Norwegian arthroplasty register, has revealed the superiority of the Charnley cemented cup over the current Hydroxyapatite (HA)-coated uncemented acetabular cups [101].

As far as the femoral stem is concerned, three major designs exist [12]; 1. A polished tapered femoral stem, known as force-closed design, Figure 2-15a; 2. A composite-beam or shape-closed design, Figure 2-15b; 3. A femoral stem design with an additional taper (triple-tapered) from lateral to medial to improve calcar loading, known as the C-stem, Figure 2-15c.

![Figure 2-15: a) A taper-slip cemented femoral stem design, such as the Exeter stem (Stryker Corp., Kalamazoo, Michigan, USA); b) A shape-closed femoral stem](image-url)
design, such as the Spectron hip system (Smith & Nephew, London, UK); c) A C-stem, such as the C-stem AMT (Depuy, Warsaw, Indiana, USA).

Long-term clinical studies have reported nearly excellent survivorship for each of the above mentioned cemented femoral stems [102]–[104]. This understanding led Spitzer et al. (2006) to characterise cemented fixation as the advised choice in patients undergoing THA [105].

Uncemented

Modern cemented hip arthroplasty has reported good clinical outcome. However, apparent osteolysis has accompanied the early implantation using cemented components [12], [106]. Consequently, the focus of researchers moved to the development of uncemented femoral and acetabular components [12].

The overarching goal was to achieve initial stability through direct contact of the bone and implant, known as osseointegration [12]. Titanium (Ti) was adopted, due to its desirable mechanical and biological properties [107]. Porous Ti coatings and rough surfaces were used to enhance bone ingrowth within the acetabular implant [12], Figure 2-16.
Primary fixation result from press-fit implantation of the acetabular cup, whilst the presence of screws enables further attachment [12]. However, survivorship of early implanted uncemented acetabular cups has been shown to be poor; predominant fibrous tissue formation instead of osseointegration was apparent at the bone-implant interface [12], [109]. Solutions include incorporating HA coatings to facilitate tissue regeneration [12], [110].

Concerning the femoral stem, the material initially used to develop uncemented designs made of cobalt-chromium alloys. However, due to the undesirable stress-shielding and thigh pain associated with differences in stiffness between native bone and implant, Ti and HA-coated designs were later widely adopted to eliminate these [111]. Incorporated porosity and roughness varied in shape and location, and this dictated where the stem is in contact with bone, resulting in various designs with distinct contact mechanisms [112]. This broad range of designs and the absence of a reported unified classification system make the overview and categorisation of all designs challenging [113]. So far, there is only one classification system on the femoral stem shape, suggested by Khanuja et al.
and further updated by Kheir et al. (2020) [114]. In this classification system, seven main designs of uncemented femoral stems exist: 1. Short; 2. Single-tapered or single-wedge; 3. Dual taper or double-wedge; 4. Gradually tapered; 5. Diaphyseal-engaging; 6. Modular; 7. Anatomic, Figure 2-17 [114].

Short stems were introduced to achieve primary fixation most proximally [114]. Their development was a result of the recent surgical preference for a metaphyseal fixation and the questioning of whether to keep the distal part of the femoral stem [113]. Short- and mid-term clinical studies so far, have reported controversial results; although good implant survivorship has been demonstrated [115]–[119], malalignment and fracture have been significantly apparent [120]. The authors have attributed the issue to the unorthodox rasping system associated with short femoral stems. In contrast with conventional femoral stems that include rasps systems that aim straight down to the femoral canal, short-stem rasping systems aim for initial contact at the lateral cortex. As the tip of the rasp is in contact with the lateral cortex, this may lead to a more valgus position of the femoral stem and, consequently, undesirable malalignment.

Single-tapered femoral stems, being flat in the anterior-posterior plane and wide medially laterally, enable excellent rotational stability and achieve the so-called three-point fixation [114]. Excellent implant survivorship, ranging from 90-98%, with revision as the endpoint at a maximum of 29 years, has been reported [121]–[123].
Figure 2–17: a) From left to right, the Birmingham Mid-Head Resection (BMHR, Smith & Nephew, London, UK), the Mayo stem (Zimmer Biomet, Warsaw, Indiana, USA), the Proxima stem (Depuy, Warsaw, Indiana, USA), the SMF hip system (Smith & Nephew, London, UK); b)
From left to right, the Taperloc stem (Zimmer Biomet, Warsaw, Indiana, USA), the Acolade hip system (Stryker Corp., Kalamazoo, Michigan, USA); c) From left to right, the Synergy stem (Smith & Nephew, London, UK); the Echo Bi-Metric stem (Zimmer Biomet, Warsaw, Indiana, USA), the Summit hip system (Depuy, Warsaw, Indiana, USA); d) From left to right, the Zweymüller stem (Zimmer Biomet, Warsaw, Indiana, USA), the CLS stem (Zimmer Biomet, Warsaw, Indiana, USA); e) From left to right, the Wagner SL Revision hip (Zimmer Biomet, Warsaw, Indiana, USA), the Echelon stem (Smith & Nephew, London, UK); f) From left to right, the S-ROM (Depuy, Warsaw, Indiana, USA), the Arcos modular femoral revision system (Zimmer Biomet, Warsaw, Indiana, USA); g) Anatomic stem [Reprinted from 124].
The strength of these studies was the long-term follow-up, accounting for the increased incidence of loosening in the third- or fourth-decade post-implantation [121]. Limitations included the retrospective nature of the sample selection. However, despite the excellent long-term implant survivorship [121]–[123], early migration and poor initial fixation were also apparent in short-term follow-ups [125].

Double-tapered, compared to the single-wedged stems, taper also in the medio-lateral plane to achieve bone contact both in the medial-lateral and anterior-posterior planes, reporting excellent implant survival rates so far (96-100% at 15-20 years) [126], [127]. This particular type of femoral stem design, has been designed to be thicker in the anterior-posterior plane to fill the whole space of the femoral metaphyseal region, justifying their “metaphyseal-filling” name [113].

Gradually-tapered stems, as the name indicates, taper in several planes to achieve a smooth and gradual, instead of an abrupt, taper within the femoral canal. The presence of proximal ribs aims to enhance the stability against rotation [114]. Long-term implant survival rates with aseptic revision as the end point ranged between 98% to 100% at 15-20 years [128], [129].

Diaphyseal-engaging femoral stems are preferable when proximal bone loss is apparent and proximal fixation is challenging, so fixation across the femoral diaphysis is preferable [114]. Although, excellent long-term implant survival rates have been reported with aseptic loosening as the end point, this particular type of stem is associated with stress-shielding and thigh pain due to its fixation across the distal femur [113].

The modular femoral stems, allow for intra-operative adjustment, to achieve an optimal component position and orientation [114]. This can be achieved since the modular systems, have been designed to allow intra-operative assembly of separate components
of various configurations to fit a patient’s anatomy. Typically, modular femoral stem designs are preferred for complex cases [114]. Disadvantages include undesirable clinical effects, like corrosion and local tissue reaction [32], [33], [130]. This incidence of corrosion does not concern the implant-bone interfaces across the intramedullary canal but the modular interfaces. The reciprocating motion between the different assemblies and the space at the junction, when enough, enables the aqueous solution to enter, leading to fretting corrosion [32].

Finally, anatomic designs were developed to resemble the anterior bow of the proximal femur [114] and achieve optimal fit-and-fill in the metaphyseal region [131]. There are limited studies on anatomic femoral stem designs, reporting mixed clinical outcomes so far [114]. While initial long-term prospective studies have reported a high complication rate concerning loosening and osteolysis, and an incidence of severe thigh pain at a maximum of 11 years [132], [133], later studies have reported that revision and complications rates did not differ between anatomic and non-anatomic systems. The latter compared short-type anatomic and non-anatomic femoral stems, potentially explaining the difference between the reported outcomes of these studies [134].
Uncemented versus Cemented hip arthroplasty

The main difference between uncemented and cemented fixation, is that in cemented fixation, the cement functions as an interlocking fit between the trabecular bone and the implant, whilst uncemented fixation relies on the tight press-fit of the femoral stem into the femoral canal, Figure 2-18 [135].

![Illustration of the A) cemented and B) uncemented fixations](image)

**Figure 2–18: Illustration of the A) cemented and B) uncemented fixations**

[Reprinted from 136].

Although there has been an increasing trend toward uncemented hip arthroplasty, cemented fixation has demonstrated the highest survivorship, with aseptic loosening as the endpoint [137]. However, a detailed analysis of data revealed a lower revision rate in younger patients (<65 years) with uncemented fixation [137]. Although existing literature does not specify the cause, the lower revision rate in uncemented THA may be due to the “cement disease” in cemented THA coupled with the demands of this age group [137].

According to the Dutch Arthroplasty Register, cemented and hybrid THAs (cemented femoral stem) [1] have reported 40% lower revision rates for other reasons when compared to uncemented THAs [138]. In terms of periprosthetic fracture, uncemented fixation has been associated with a higher risk of revision when compared to the cemented fixation [139]. As far as the dislocation is concerned, a lower rate was reported in the
cemented THA when compared to the uncemented THA [140]. However, most of these studies do not specify protheses brands to conclude the contribution of different cemented femoral stems designs to the outcomes.

Additionally, these reported percentages rely on specific reasons resulting in revision after primary THA, the incidence of which is dependent upon distinct national registry data reflecting different tendencies among various populations. The most often reported reason for revision is mechanical failure. The revision rate due to dislocation and fracture has been reported 14.6% and 10.4%, respectively [21]. NJR reports as the most common indications for revision THA aseptic loosening (42%), dislocation (14.8%), pain (14.8%), infection (14.6%) and lysis (13.6%) [1]. In the USA, dislocation is the primary cause of revision (22%) [141], where in Sweden aseptic loosening reaches up to 70% as the primary cause for revision [142].

**Surgical Approach**

The modern approach to hip arthroplasty includes various surgical procedures, depending on the location of the initial incision surgeons make to access the hip joint. Most commonly, the procedure is performed via a posterior, anterior, or lateral approach [143]. It has been reported that surgeons should be careful with complications associated with certain surgical approaches, such as periprosthetic fractures through the anterior approach or dislocation through the posterior approach [144]. However, existing literature does not report any difference in the risk of complications, such as dislocation or periprosthetic fracture [144]–[146], or in the quality of life [147]. In addition, no studies have reported any association with the type of the implants. Each surgical approach is associated with distinct characteristics, and surgeons are encouraged to choose whichever suits their experience and with which they are most familiar [145].
2.5 Diagnosis – Imaging modalities

Advanced progress in medical physics [148] allowed surgeons and radiologists to visually assess hip joint pathologies [149]. Various imaging modalities are available for thorough examination of the hip joint [149], [150], guidance for surgical preparation [151] and post-operative evaluation of the prosthetic hip joint [152].

Conventional radiograph constitutes the first imaging modality ever used [150] and, for many, remains the gold standard in the diagnosis of hip problems because it is considered a simple methodology and the cheapest among various imaging modalities [153], [154]. A plain Anteroposterior (AP) radiograph is the standard procedure to detect hip joint pathologies, such as OA, Figure 2-19 [149], [152]. A radiographic procedure includes ionising radiation (X-ray beam) passing through the human body and an X-ray detector to eventually project the shadows of the internal bony structures on a Two-Dimensional (2D) film [154]. Existing literature has reported it has a high spatial resolution to detect slight alterations in the joint space width [155].

Figure 2–19: Plain AP radiograph showing end stage of OA of the right hip (Reprinted from complexhipsurgery.com).
However, proper focus distance and position of the x-ray beam are essential to count for magnification issues [149]. Improper radiographic imaging, results in altered joint morphology [149], which could potentially misguide the preparation for hip surgery. Although plain radiography can detect most hip pathologies, it encounters limitations in visualising problems like bone injuries and soft tissue damage [150].

Conventional radiographs are flat images and their 2D nature may not allow a detailed examination of the hip joint anatomy. For instance, a conventional X-ray only enables an approximation of the internal femoral morphology, making it inadequate in the selection of the “best-fit” implant [156]. Although conventional radiography suffice in visualising the hip joint structure, it does not allow an accurate estimation of the bone mineral density [157].

Important anatomical and prosthetic variables, such as the acetabular and femoral anteversion, cannot be defined on plain radiographs [149], [158]. Multiple views of the acetabular walls are necessary to define the acetabular anteversion [149]. Similarly, the measurement of femoral version needs the definition of the Posterior Condylar Axis (PCA), which is not included in conventional radiographs [149].

When a more comprehensive assessment is necessary, CT is commonly equipped [150]. CT has an excellent spatial resolution of 0.5-0.6mm in the Z-axis, and 0.5mm in the other two axes [159]. Using a higher amount of radiation and an X-ray tube that moves across the human body, it enables the production of multiple images of the targeted organ [154]. The superiority of CT scans lies in the more realistic representation of the human anatomy due to the 3D nature of the procedure and the absence of magnification issues [154], [160]. CT enables segmentation of bony anatomies with accuracies under 0.5mm, allowing a 3D rendering of surface models for further processing [161]. Existing
scientific evidence have reported that important anatomical measurements taken on CT are more accurate than conventional radiographs [156], [162].

The detailed anatomical representation that CT offers is obstructed by the presence of metallic components, known as the metal artefact [152]. Physical effects causing metal artefacts include photon starvation and beam hardening [163]. In photon starvation, the way metals absorb energy is amplified compared to the surrounding soft tissue, due to its high atomic number [163]. This phenomenon results in dark shadows around the implant due to the high attenuation of metallic structures [164]. As a result, data is projected with a high statistical error, and dark streaks typically appear across the direction of highest attenuation, known as streaking artifacts (Figure 2-20a) [165]–[167].

Beam hardening stems from the polychromatic x-ray beam that conventional CT scanners use [163]. Beam hardening can result in either streaking or shading/cupping artifacts [168]. In the case of shading/cupping artifacts, beam hardening occurs more towards the centre of a uniform cylindrical object than through the edges due to the higher thickness it has to penetrate [169]. The result is that grey values vary from high to low towards the interior of the scanned sample, not reliably reflecting the “true” grey values of a homogenous material [168].

Not only do these biased grey values make visualisation and analysis of bony morphology troublesome, but they can also lead to an inaccurate segmentation [164]. The reason is that the segmentation step typically uses thresholding of grey-level values to cut out bone or metal [170], and the final reconstruction may reflect bias in these values due to artefacts. In this regard, post-operative evaluation of hip prosthesis has not performed well [152].
Fortunately, valuable technical advancements, such as the Metal Artefact Reduction (MAR) algorithms and the dual-energy CT procedures, have improved the quality of post-operative CT scans, Figure 2-20b [150].

![Figure 2–20: a) Metal artifact obstructs the accurate visualisation of the femoral implant in an axial CT scan, b) Implementation of the MAR algorithm enables a clearer representation of the hip prosthesis.](image)

The concept behind MAR algorithms is that projected data with high bias are first distinguished and then processed to estimate the corresponding corrected values [163]. Various types of MAR algorithms exist, but the most common is the sinogram inpainting method, using forward projection [171]. The process of forward projection aims to artificially calculate the original CT scans’ raw data [172]. This is often done by creating a sinogram, which is a simple 2D visualisation of these projections [172].

The algorithmic process of MAR can be summarised in four steps: 1. The original CT scan is processed using intensity thresholding (Hounsfield Unit threshold) methods to distinguish what looks like metal; 2. The original CT scan and the segmented metal pixels are algorithmically forward-projected to generate two separate sinograms. Non-zero inputs in the metal sinogram forms the metal trace. The metal trace defines the pixels of the original CT scan sinogram that needs to be replaced; These pixels are replaced with
interpolated or averaged data based on the neighbouring pixels; 4. The final processed sinogram is back-projected to form the correct CT scan; 5. The process is iteratively performed to achieve convergence, Figure 2-21 [163], [171]. Another option to eliminate metal artefacts is Dual-energy CT scanners that enable the formation of Virtual Monochromatic Spectral (VMS) [173]; images depicting how the scanned material would appear if the X-ray source included photons of a single energy [163]. This information results in improved image quality when beam hardening is apparent [173].

Figure 2–21: Illustration of the steps included in a projection-based MAR algorithm [Reprinted from 163].

CT-based imaging modalities are also associated with the concern of increased radiation dose. Recent scientific endeavours, have been focussing on the development of scanning protocols to further reduce the radiation dose without compromising imaging accuracy [174]–[178]. However, quantifying the benefit of CT scanning protocols at the expense of radiation dose is challenging. A conventional long-leg radiograph is associated with an effective radiation dose of 0.7mSv [179]. In contrast, a CT scan of the pelvis is associated with an effective radiation dose of 10mSv [180], which involves a 0.05% probability for carcinogenic effects [181]. At the same time, reconstructing anatomical variables like the
centre of the hip is of high importance to ensure a satisfactory functional outcome for THA patients [182], and CT has been reported as more accurate than conventional radiographs in measuring these [156], [162].

Another imaging modality that has been recently emerging, is Single Photon Emission Computed-Tomography combined with CT (SPECT/CT) [152], [183]. A SPECT is a nuclear imaging method that captures the distribution of a radioactive tracer, injected into the bloodstream and transferred to the tissue of interest, using specialised cameras. This enables the illustration of metabolic information that other imaging modalities do not allow [184]. The concept behind SPECT/CT is to combine this functional information provided by the SPECT with the high-resolution structural information given by the CT to enable a more detailed regional assessment of causes of pain or structures that may have appeared subtle or non-specific in other imaging modalities, Figure 2-22 [183].

Figure 2–22: Illustration of combined SPECT/CT images of referred hip joint pain. The fusion of SPECT with CT enables the identification of causes of pain or structures that may have appeared insufficiently in CT scans alone (left images), such as a) impingement between the femur and acetabulum; b) a femoral benign one
lesion; c) stress fracture across the diaphyseal femoral canal due to the chronic use of bisphosphonates; d) necrosis of the femoral head [Reprinted from 183].

Magnetic Resonance Imaging, known as MRI, is a nonionising imaging modality that is commonly equipped to analytically detect pseudotumors associated with M-on-M implants, Figure 2-23 [150]. In addition, MRI is often employed to analytically assess soft tissues and muscles, while is considered the gold standard in assessing the articular cartilage [149], [152].

![MRI scan of the right hip prosthesis illustrating a Pseudotumor](Reprinted from complexhipsurgery.com).

Figure 2–23: MRI scan of the right hip prosthesis illustrating a Pseudotumor

(Reprinted from complexhipsurgery.com).

MRI makes use of powerful magnets that force protons in the human body to align with their magnetic field [185]. When radio waves stimulate the protons of targeted organs, MRI sensors can detect these stimulations and convert them in a 3D image of the internal body structures [154]. MRI is susceptible to metal artefacts [152]. As in CT scans, Metal Artefact Reduction Sequence (MARS)-MRI algorithms and advanced algorithmic procedures are employed to eliminate artefacts [152]. Another limitation of MRI is that bone segmentation is challenging. While in CT the contrast between bone and tissue is excellent, the low proton density of bony anatomies results in insufficient signals using
conventional MRI sequences [186]. In addition, the spatial resolution of most MRI sequences has been reported inferior to CT, varying between 1 and 2mm. However, this is considered adequate for most clinical applications [159].

Finally, ultrasound may not serve an important role in the first line of visual examination of the hip joint, but is preferred to identify peri-prosthetic fluids and soft tissue damage in patients with OA [149], [150].

The above-mentioned modalities constitute part of the preparation for a THA. X-rays may suffice in detecting most hip joint pathologies at a low radiation dose and cost [150], contributing to their wide adoption in hospitals despite the limitations of 2D visualisation [4]. CT and MRI, on the other hand, offer a more detailed representation. CT offers better delineation of the cortical and cancellous bones [187] and allows a 3D reconstruction of bony anatomy [161] at the expense of radiation dose [174]. MRI is preferable when soft tissue evaluation is needed because bone is depicted as a non-distinguishable entity [186]. These, however, are associated with artefacts requiring advanced algorithms [166]. Finally, hybrid imaging constitutes a valuable method to analyse the metabolic function of the hip joint in association with its geometry [184].
2.6 Planning a hip arthroplasty

The modern approach to THA relies on the use of advanced imaging techniques for both diagnosis and treatment [4]. Surgeons have been encouraged to equip the previously mentioned imaging modalities to decide on the surgical equipment and prosthetic components [188], [189]. Pre-operative planning is an important step for elective THA [4], [190], [191]. Its technical goals include:

- Selection of the optimal acetabular cup and femoral components size in advance [160], [189], [190], [192]–[197].
- Optimising implant position, orientation and fit [160], [188], [190], [192], [195]–[197].
- Reconstruction of native Femoral Offsets (FO), correction of Leg Length Discrepancies (LLD) and restoration of Centre of Rotation (CoR) [153], [160], [188], [190], [192]–[195], [198].
- Definition of femoral neck osteotomy level [199].
- Preparation for intra-operative complications [188], [193], [196]–[198], [200].
- Shortening of operative time [195], [197].
- Minimising the implant inventory and the cost associated with it [192].

Achieving these can eventually lead to (1) a more accurate surgical procedure [153] with (2) reduced implants’ inventory [192] resulting in a more (3) cost- and time-effective surgery [4], [192].
2.6.1 Early evolution – Acetate templating

Initially, acetate templating on analogue films has been the traditional way of planning a primary THA [201]. Transparent templates including drawings of various acetabular cup sizes, are placed on plain AP radiographs, Figure 2-24 [190]. The size that best fits the acetabulum is selected and appropriately placed over the radiograph [190].

![Conventional analogue templating of acetabular cup](image)

**Figure 2–24: Conventional analogue templating of acetabular cup [Reprinted from 190].**

Appropriate radiographic landmarking, such as a horizontal reference line through the pelvic teardrops guides the orientation of the acetabular cup, Figure 2-25 [191], [200]. The goal is to achieve 40° of Inclination (INC); the angle between the horizontal reference line and the line across the cup rim [191]. The corresponding acetabular CoR is consequently marked to facilitate the selection of the femoral head [200]. However, delivering an INC of 40° while trying to reconstruct the CoR may have been challenging using conventional X-rays; the CoR is a 3D entity, potentially requiring multiple views of the acetabular walls to be defined.
Selection of the femoral stem aims to achieve a sufficient fixation within the femoral canal (Figure 2-26) [200]. Adjustment of the position of the femoral template follows, to achieve leg length equalising and restoration of the native FO [200]. Finally, the analogue film allows the marking of the desired femoral neck osteotomy and its distance from the Lesser Trochanter (LT), Figure 2-26 [191].

The percentage of the acetabular cup and femoral stem components implanted with a size that matched the one decided upon during pre-operative planning ranged between 20–90% and 40%–92%, respectively (Table 2-1). The fixation method, the different designs of the implants used, the surgeon’s experience, and the indication for surgery may have contributed to this broad range of prediction rates.

Studies concerning the restoration of dimensional characteristics such as CoR, LLD, and FO were limited (n=2) [191], [202]. Eggli et al. (1998) have reported a mean difference (achieved-planned CoR) of -2.5 ± 1.1 mm Craniocaudally (CC) and -4.4 ± 2.1 mm Mediolaterally (ML) [191]. Della Valle et al. (2005) have reported that 91% of the femoral stems had a distance within 5mm relative to the planned CoR [202]. Leg length equalisation within 3mm was reported in 89% of the cases [202].
Figure 2–26: Analogue templating of femoral stem [Reprinted from 190].

Table 2-1: Accuracy of acetate templating in predicting component size.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Indication for surgery</th>
<th>N</th>
<th>Uncem./Cement.</th>
<th>Match (%)</th>
<th>Cup</th>
<th>Stem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knight (1992) [188]</td>
<td>OA/RA/AVN</td>
<td>110</td>
<td>Uncem./Cement.</td>
<td>62</td>
<td>42/78</td>
<td></td>
</tr>
<tr>
<td>Carter (1995) [189]</td>
<td>AVN</td>
<td>74</td>
<td>Uncem.</td>
<td>NA</td>
<td>47</td>
<td></td>
</tr>
<tr>
<td>Eggli (1998) [191]</td>
<td>OA</td>
<td>100</td>
<td>Uncem.</td>
<td>90</td>
<td>92</td>
<td></td>
</tr>
<tr>
<td>Valle (2008) [202]</td>
<td>OA</td>
<td>64</td>
<td>Cement.</td>
<td>51</td>
<td>69</td>
<td></td>
</tr>
<tr>
<td>Iorio (2009) [193]</td>
<td>NA</td>
<td>250</td>
<td>NA</td>
<td>78**</td>
<td>77**</td>
<td></td>
</tr>
<tr>
<td>Gamble (2010) [198]</td>
<td>OA</td>
<td>40</td>
<td>Uncem.</td>
<td>20</td>
<td>40</td>
<td></td>
</tr>
</tbody>
</table>

OA, osteoarthritis; RA, Rheumatoid Arthritis; AVN, Avascular Necrosis; NA, not available/not applicable; Uncem., Uncemented; Cement., Cemented *Match (%): Percentage of prosthetic components implanted with a size that matched the one decided upon pre-operative planning.
** These percentages correspond to prediction rates within 1 size.
2.6.2 Progression to the digitalised era - Digital Templating

The progression from analogue to digital templating resulted in the development of software programs, specialised in the process of medical imaging data (X-rays) in the format of Picture Archiving Communication System (PACS), Figure 2-27 [201].

![Digital Templating Image](image)

**Figure 2–27: Pre-Operative digital templating using TraumaCAD software. The imaging data (X-rays) are imported in the format of PACS [Reprinted from 203].**

Digital templating offers a library of templates including a broad range of implant types and sizes [201], [204]. The operator can virtually place the prosthetic components over the digital radiographs and adjust their position and orientation to fit the patient’s hip anatomy, Figure 2-28 [190], [203].

The planning criteria remain the same as in the acetate templating [190]. The difference lies in the digital environment, which enables the semi-automatic measuring of essential pre-operative variables, such as the acetabular inclination, the femoral neck osteotomy level, FO and LLD, Figure 2-28 [204].
Figure 2–28: The templates of the chosen prosthesis is overlaid over the digital radiographs to fit the patient’s anatomy [Reprinted from 204].

Table 2-2 includes studies documenting the prediction rate of the acetabular cup and femoral stem sizes using a virtual overlay of the implant on digital conventional AP or lateral X-rays. These reported that 19-84% of the acetabular cups and 19-83% of the femoral stems, implanted with a size that matched the one decided upon pre-operative planning. Studies comparing the accuracy of acetate and digital templating in terms of components size have reported controversial results, Table 2-3 [190], [193], [198], [202].

In detail, Kosashvili et al. (2009) have reported no significant difference in the performance of the two technologies [190], Iorio et al. (2009) have concluded that digital planning is acceptably safe but not more accurate than analogue templating [193], Della Valle et. al. (2008) have found more predictable results using analogue templating [202], while Gamble et. al. (2010) have highlighted that digital templating is more beneficial than analogue templating [198]. In this context, it is unclear if shifting to the digitalised templating significantly improved the prediction rate of component sizing. As far as the clinical outcome is concerned, there were no studies documenting whether digitised or analogue templating have resulted in a more improved clinical outcome after a THA.
Table 2-2: Accuracy of digital templating in predicting component size.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Indication for surgery</th>
<th>N</th>
<th>Uncem. /Cement.</th>
<th>Match (%) *</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Cup</td>
<td>Stem</td>
<td></td>
</tr>
<tr>
<td>Kosashvili (2009) [190]</td>
<td>OA</td>
<td>18</td>
<td>Uncem.</td>
<td>19-84</td>
</tr>
<tr>
<td>Valle (2008) [202]</td>
<td>OA</td>
<td>64</td>
<td>Cement.</td>
<td>25</td>
</tr>
<tr>
<td>Wedemeyer (2007) [204]</td>
<td>AVN/OA</td>
<td>40</td>
<td>Uncem.</td>
<td>40</td>
</tr>
<tr>
<td>Iorio (2007) [193]</td>
<td>NA</td>
<td>50</td>
<td>NA</td>
<td>60**</td>
</tr>
<tr>
<td>Steinberg (2010) [203]</td>
<td>OA</td>
<td>73</td>
<td>Uncem.</td>
<td>51</td>
</tr>
<tr>
<td>Gamble (2010) [198]</td>
<td>OA</td>
<td>40</td>
<td>Uncem.</td>
<td>38</td>
</tr>
<tr>
<td>Holzer (2019) [206]</td>
<td>OA</td>
<td>632</td>
<td>Uncem.</td>
<td>37</td>
</tr>
</tbody>
</table>

NA, not available/ not applicable; OA, Osteoarthritis; AVN, avascular necrosis; Uncem., Uncemented; Cement., Cemented

* Match (%): Percentage of prosthetic components implanted with a size that matched the one decided upon pre-operative planning. **These percentages correspond to prediction rates within 1 size.

Table 2-3: Comparison between acetate and digital templating in predicting the component size.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Acetate</th>
<th>Digital</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cup</td>
<td>Stem</td>
<td>Cup</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.37-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td>Iorio (2009) [193]</td>
<td>78*</td>
<td>77*</td>
<td>60*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.09</td>
</tr>
<tr>
<td>Gamble (2010) [198]</td>
<td>20</td>
<td>40</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.084</td>
</tr>
</tbody>
</table>

*These percentages correspond to prediction rates within 1 size.

* Numbers represent percentage of prosthetic components implanted with a size that match the one decided upon pre-operative planning.
2.6.3 A step forward – 3D pre-operative planning

The 2D nature of digital radiographs do not offer reliable illustration of the patient’s anatomy, resulting in the incorrect measurement of essential dimensional characteristics [160]. CT-scanning produces a sequence of cross-sectional images - slices - depicting the targeted anatomy in a more detailed way [153], [154]. Innovation in informatics may have made feasible the transformation of 2D-CT slices to 3D models representing the patient-specific bony anatomy. This offered surgeons and engineers more references to plan a surgery, leading in the development of various commercially available 3D pre-operative planning software [151].
2.7 3D Pre-operative Planning

2.7.1 The workflow

Figure 2-29 illustrates the workflow behind the concept of 3D pre-operative planning.

![Workflow Diagram]

**Figure 2–29: Typical procedure of 3D pre-operative planning.**

The steps included in the workflow of 3D pre-operative planning are:

1. **Medical Imaging**: The process typically begins with medical imaging such as CT, MRI or Low Dose Bi-planar Radiographs, including cross-sectional images of the patient’s anatomy.

2. **Image segmentation and 3D-CT reconstruction**: Imaging data (Digital Imaging and Communications in Medicine-DICOM) of patients are subsequently imported in planning software [207], where 3D reconstruction of the patient’s anatomy take place [4]. The result is a 3D digital representation of the patient’s anatomy. This step includes segmentation of the patient’s bony anatomy from the surrounding tissues through intensity thresholding tools either automatically or based on a user-defined HU range [161]. Limited studies have documented which programs
they use for the segmentation/3D-CT reconstruction step of their 3D pre-operative planning software [208].

3. **Landmarks selection**: The user selects specific bony landmarks, necessary to define pre-operative planning variables [4], [197], [208], [209]. Once landmarks acquisition is finished, the software automatically compute the relevant axes, planes and planning metrics [4], [197], [208], [209].

4. **Implant selection**: The operator selects from available implant databases and virtually position the 3D models of the implants within the patient’s anatomy [4], [207]. At this step, the operator defines the implant size, position and orientation that mostly fits the patient’s anatomy according to the surgeon’s preferences [4], [207].

5. **PSI**: 3D-reconstructed bony models may also work as an enabler to produce 3D printed models of patients’ anatomy or PSI [35], [208]. Customised instrumentation and replica plastic models of the bones and implants are being developed for intra-operative use. Surgeons can visualize the planned surgery juxtaposed with the patient’s anatomy with the goal of optimising implant placement [35]. 3D printing and PSI may therefore be valuable steps to further assist the surgery, though not always implemented.

### 2.7.2 The digital environment

3D pre-operative planning is executed through specialised programs that help surgeon positioning and orientating the implants in a 3D representation of the patients’ anatomy, Figure 2-30 [207].
Figure 2–30: Illustration of Hip 3D (mediCAD, HecTec GmbH) planning software combing orthogonal views of the human body together with the 3D representation of the bones and the implant.

Source. Image Courtesy of mediCAD, HecTec GmbH, Altdorf, Germany.

Table 2–4 includes current commercially available 3D planning software. So far, no studies have compared these programs to identify any benefits or limitations with each. However, differences in specific characteristics exist. For instance, there is planning software using bi-planar X-rays (hipEOS) [210]. Other programs incorporate robots (MAKO planning, Stryker) [211] or PSI (MyHip, Corin OPS) [208], [212]. Additionally, some planning platforms require specific CT scanning protocols to ensure good spatial accuracy [208].

Most platforms predominantly equip CT as the imaging modality to visualise the patient’s anatomy, Table 2-4. CT, however, is a 3D image modality, and the one-century evolution of the implant design may have lied in the early use of acetate templating, which included 2D transparent templates of designs and sizes. Advances in technology may have made
possible the visual 3D representation of implant designs that current software platforms incorporate. Implant databases, which vary amongst software, include 3D models of acetabular and femoral components [207]; there are software, which are either tightly cooperating with one implant manufacturer[208], [209] or others incorporating a larger library of implants [197], [213].

**Table 2-4: Commercially available 3D Pre-operative planning software.**

<table>
<thead>
<tr>
<th>Software</th>
<th>Manufacturer</th>
<th>Modality</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIP-PLAN</td>
<td>Symbios</td>
<td>CT</td>
</tr>
<tr>
<td>hipEOS</td>
<td>EOS Imaging</td>
<td>LDB Radiography</td>
</tr>
<tr>
<td>ZedHip</td>
<td>LEXI Co., Ltd</td>
<td>CT</td>
</tr>
<tr>
<td>HipOp-Plan</td>
<td>Rizzoli Orthopaedic Institute</td>
<td>CT</td>
</tr>
<tr>
<td>MyHip</td>
<td>Medacta International</td>
<td>CT</td>
</tr>
<tr>
<td>MAKO Planning</td>
<td>Stryker</td>
<td>CT</td>
</tr>
<tr>
<td>Kyocera 3D-Template</td>
<td>Kyocera Medical</td>
<td>CT</td>
</tr>
<tr>
<td>modiCAS Plan</td>
<td>modiCAS</td>
<td>CT</td>
</tr>
<tr>
<td>MediCAD Hip 3D</td>
<td>MediCAD HecTec</td>
<td>CT</td>
</tr>
<tr>
<td>Mimics</td>
<td>Materialise</td>
<td>CT</td>
</tr>
<tr>
<td>Corin OPS</td>
<td>Corin Group</td>
<td>Radiograph &amp; CT</td>
</tr>
</tbody>
</table>

CT, computed tomography; LDB low-dose bi-planar.

The user can visualize the spatial relation between the implant and the host bone in three different windows, which represent the three different planes of the human body, Figure 2-31 [196], [207]. Combining three 2D view planes with a view representing the three-dimensional anatomy of the patient, has been proven the most accurate way of depicting 3D pre-operative planning in a software [214].
Figure 2–31: Illustration of ZedHip (LEXI Co., Ltd) planning software combining orthogonal views of the human body together with the 3D representation of the bones and the implant.

Source. Image courtesy of LEXI Co., Ltd, Tokyo, Japan.

2.7.3 Segmentation and surface reconstruction steps

Commercially available planning platforms use segmentation and surface reconstruction tools to generate a 3D representation of the patient’s anatomy. The mesh resolution of the reconstruction step has not been specified in previous studies documenting the use of 3D-CT planning software. However, the segmentation and surface reconstruction steps are two basic concepts of image analysis, potentially contributing to variability in terms of outcome.

Review of different studies assessing the segmentation step, revealed an accuracy of between 0.2 to 0.5mm for the manual segmentation and between 0.04 to 0.6mm for the segmentation based on global thresholding [161]. Regarding the 3D-CT reconstruction step, existing scientific evidence has reported a mean deviation error between 0.3 and 0.55mm compared to ground truth bony digitization [215], [216]. In addition, intra-
laboratory analysis of seven research groups, including various experts, revealed a mean deviation error of less than 0.8mm in generating the femur’s model based on 3D-CT data [217].

Elsewhere, 3D-printed bony models based on 3D-CT reconstruction as compared with cadavers’ models have had an overall reconstruction reproducibility of 0.3mm [218], and the mean error of generating 3D surface models of the proximal femur has been reported half the voxel size of the CT scan [219]. Concerning other imaging modalities, such as MRI, previous studies have documented a mean error of approximately 1mm and 0.56mm compared to 3D scans and ground truth, respectively [216], [220]. Finally, translating dry bone measurements to surface rendered models has reported high repeatability and reproducibility (Intraclass Coefficient>0.972; 95% reliability) and a mean difference of less than 1mm [221].

2.7.4 Planning steps and criteria

Anatomical Landmarks

Once 3D reconstruction of the patient’s anatomy is completed, the next step is to define appropriate anatomical landmarks [4]. Most commonly anatomical landmarks on the acetabular side include the acetabular CoR, the Anterior edge of the Pubic Tubercles (APT) and the Anterior Superior Iliac Spines (ASIS), Figure 2-32 and Table 2-5 [4], [222].

Femoral anatomical landmarks usually include the intramedullary canal centre, the medial and lateral posterior condyles, the medial and lateral epicondyles, the centre of the femoral head, the femoral neck centre, and the LT, Figure 2-32 and Table 2-5 [4], [153], [213], [223].
Table 2-5: Landmarks and calculated parameters during 3D planning

<table>
<thead>
<tr>
<th>Bone Region</th>
<th>Landmarks</th>
<th>Relevant Axes</th>
<th>Relevant Planes</th>
<th>Calculated Parameters</th>
<th>Surgeon's Input</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvis-Acetabulum</td>
<td>Pubic Tubercles</td>
<td></td>
<td>Anterior Pelvic Plane (APP)</td>
<td>Acetabular Inclination</td>
<td>Implant Type &amp; Implant Size</td>
</tr>
<tr>
<td></td>
<td>Anterior Superior Iliac Spines (ASIS)</td>
<td></td>
<td></td>
<td>Cup Inclination</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acetabular Anteversion</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cup Anteversion</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acetabular CoR</td>
<td></td>
</tr>
<tr>
<td>Femur</td>
<td>Femoral Head Centre</td>
<td>Mechanical Axis</td>
<td>Anteversion Plane</td>
<td>Native Femoral Version &amp; Prosthetic Femoral Version NSA/CCD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Femoral Neck Centre/Base</td>
<td>Femoral Neck Axis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medial Posterior Condyle</td>
<td>Posterior Condylar Axis (PCA)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lateral Posterior Condyle</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medial Epicondyle</td>
<td>Transepicondylar Axis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lateral Epicondyle</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intramedullary Canal Centre</td>
<td>Anatomical Axis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lesser Trochanter</td>
<td></td>
<td></td>
<td>Neck Cut Plane</td>
<td></td>
</tr>
</tbody>
</table>
Acquisition of anatomical landmarks is a process where the operator picks identifiable points using surface-rendering models corresponding to anatomical references. This step is laborious and can induce subjectivity between the measurements of the same or different users, potentially impacting the measuring accuracy during pre-operative surgical planning [224]. However, landmarks definition using CT-based femoral models have reported high accuracy and excellent intra- and inter-observer variability. In detail, the mean variability in defining the femoral head centre and the posterior condyles has been reported less than 1mm. Also, the mean angular deviation in computing the mechanical axis of the femur and the PCA have been reported, 0.05-0.08° and 0.48-0.99°, respectively [225].

After the user indicates all the necessary anatomical landmarks, the software automatically defines various planes and axes, important to guide the position and orientation of the components, Table 2-5 [4], [222]. For instance, appropriate acetabular angles can be precisely measured using established coordinate systems, such as the...
Anterior Pelvic Plane (APP) [226]. In addition, the Native Femoral Version (NFV) – the rotation of the femoral neck relevant to the posterior femoral epicondyles - can be defined on the anteversion plane, relevant to the PCA and using the mechanical axis of the femur, Figure 2-32 [4], [42]. Finally, the midpoint of the LT is used to define the depth of the femoral stem and neck cut plane [153], [209]. (Table 2-5)

**Acetabular Cup**

Selection of the sup size is based on the AP diameter of the acetabulum and according to the surgeon’s input [222]. When positioning the cup, the goals should be to restore the acetabular CoR, prevent cup excess towards the anterior wall and achieve an INC angle of 40° and an Anteversion (AV) angle of 20°, Figure 2-33a [4], [227]. This follows the most-cited “safe zone” of acetabular cup positioning as defined by Lewinnek et al. (1978) to avoid dislocation in primary THA, highlighting that acetabular cups implanted outside the range of 40 ± 10° for cup inclination and 15 ± 10° for cup anteversion reported an increased dislocation rate [228].

**Femoral Stem**

The size of the femoral stem is determined when the bone-implant contact area in the proximal femur is maximised, using the three CT views and according to the surgeon’s input [197]. Statistical atlases of the bone-implant interface, based on already-made surgical plans, can be incorporated into 3D pre-operative planning to automatically define the distance between the stem and the femoral bone and therefore generate the surgical plan of the femoral stem [229].
Figure 2–33: Planning criteria of the a) acetabular cup angles, b) femoral stem alignment and c) PFV.

Stem positioning within the proximal femur is achieved through aligning the stem axis with the femoral anatomical axis (sagittal, coronal), Figure 2-33b [229]. To define the depth of the femoral stem within the femur, the user marks the distance between the LT and the intended osteotomy plane [39], [153]. Restoration of the native vertical FO and leg length relevant to the contralateral side constitute two additional criteria in guiding the vertical position of the femoral stem [230]. Concerning the horizontal position of the femoral components, the surgeon can decide the size of the femoral stem and femoral head to adjust the Horizontal Femoral Offset (HFO), aiming to restore the native horizontal FO [4], [230].

Prosthetic Femoral Version (PFV) – the angle between the stem neck axis and the PCA - is another measurement necessary to ensure optimal end position of the stem [6]. In contrast with the orientation of the acetabular cup, where the recommended optimal positioning has been well established by previous literature, little has been written on the recommended optimal positioning for the PFV [231]. Most planning software use NFV to plan PFV, Figure 2-33c [230], [232]. The rationale relies on the hypothesis that
uncemented femoral stems, designed for a tight press-fit fixation into the internal femoral canal, are predetermined by the canal’s geometry, implying that this configuration replicates the NFV [233].

During the planning phase, the operator first selects anatomical landmarks on the patient’s femur to measure NFV. These are usually the medial and lateral posterior knee condyles, the medial and lateral epicondyles, the femoral head centre, and the femoral neck centre/base or the most posterior point of the femur [4], [42], [234]. After landmark acquisition, the software automatically computes the necessary axes and planes to measure NFV [4], [42]. These are usually the femoral neck axis (the line between the femoral head and neck centre/base), the axis across the line connecting the medial and lateral posterior condyles, and the anteversion plane (the plane normal to the mechanical or the anatomical axis of the femur) [4], [42], [234]. The operator then selects the most appropriate femoral stem size and virtually positions the femoral stem within the 3D-CT-reconstructed model of the proximal femur to either replicate the NFV or plan a specific PFV using the axes and planes defined during the previous step.

It should be noted, however, that NFV in adults with normal hip anatomy has been reported to vary highly, ranging from -15° to 34° [43]. Therefore, following exclusively the NFV may result in high variability in the PFV, ranging from retroversion to excessive anteversion [235]. Existing scientific evidence have reported a significantly increased torsional moment, posterior head migration and later progressive posterior movement in femoral stems of low PFV, suggesting that stems should be placed over 20° of PFV [6], [236], [237]. Additionally, existing literature have highlighted the association between low PFV angles and dislocation in primary THA via a posterior approach [31], [238]. However, long-term clinical studies are needed to confirm this information and establish objective criteria for the optimal range for PFV.
Kinematic Simulation

Some software include an additional step of kinematic simulation for Range Of Motion (RoM) of the planned hip [208], [239] using motion databases [208] and collision detection algorithms [196], to identify the possibility of impingement during daily activities [208], [239], Figure 2-34.

Figure 2–34: Illustration of hipEOS (EOS, EOS Imaging) planning software, which incorporates RoM simulation to detect the possibility of impingement.

2.7.5 PSI

The 3D environment of surgical planning software allows for planning component position and orientation according to a standard framework. Engineers equip this information to design patient-specific guides, the so-called PSI [35]. Once the generic design of the PSI is determined is, then personalised for each patient in terms of size, position and fitting. Personalisation is usually a semi-automatic process constrained by designated planes and axes defined during surgical planning and specific anatomical landmarks (e.g., specific anchoring points on the bone) provided by the user. The final step includes subtraction of the patient’s bone surface, using Boolean Mesh subtraction, to achieve the personalised fitting of the guide, Figure 2-35 [208].

As far as the manufacturing is concerned, 3D-printing enables the manufacturing of any design feature with geometrical complexities and is, therefore, used to fabricate the physical models of PSI [240]–[242]. The 3D-printed customised guides are then sterilised for intra-operative use to facilitate optimal implant placement [4], [35].

![Figure 2-35: PSI adaptation pipeline using an example of a femoral guide prototype. The design of the PSI guide is automatically scaled using variables defined during surgical planning (e.g., specific points -g1,2- and planes-P- relevant to the desirable position). The patient’s bone surface is subsequently removed from the 3D model of the adapted PSI using a Boolean mesh subtraction [Reprinted from 208].](image-url)
So far, there are studies documenting on the use and accuracy of PSI in different surgical orthopaedic procedures, including knee [243], [244], ankle [245], spine [246] and hip surgeries [247]. However, the accuracy of PSI in hip arthroplasty has been underdocumented, and it remains unclear how much and when PSI is routinely used. Considering the scarcity of publications on the subject [212], [248] in comparison with the number of hip arthroplasties occurred within one year [1], the uptake of PSI in primary THA is assumingly low.

In this context, free-hand implantation may constitute the regular choice. Robotic-assisted surgery exists and has been proven superior to the conventional technique in acetabular cup positioning [249], [250]. However, although accurate, it adds operating time and a significantly higher cost [11], [250]. 3D-CT surgical planning is a potentially time- and cost-effective alternative, but previous studies have documented a high variability in prosthetic component position (both for the acetabular cup AV and PFV) [209], [223], [230], [234], [251]. In this regard, 3D-printed PSI has been developed to increase the accuracy of prosthetic component implantation, potentially positively impacting the clinical outcome after a THA.

The potential of PSI in improving THA accuracy of the implant position is counteracted by issues like radiation exposure and the extra cost compared to the conventional technique [35]. Sakai et al. (2017) have reported that the manufacturing cost of the PS guide per case is $400 [252], whereas Henckel et al. (2018) have stated that PS guides cost approximately $371 per case [35]. However, this cost is significantly lower compared to cost associated with the robotic-assisted THA [11]. Additionally, it is uncertain whether PSI can result in an improved patient clinical response, as it is a relatively new concept in primary THA, and long-term data are needed to answer this question.
Nevertheless, commercially available PSI guidance systems (Table 2-6) exist, that include four designs to guide the position of the acetabular cup and two designs to perform the femoral neck osteotomy [35]. Currently, there is no PSI guiding the PFV [35]. A possible explanation may be that acetabular cup orientation has greatly received research interest while PFV has been under-investigated [231]. Additionally, quantifying PFV requires CT scanning of the knee region, potentially making it a bothersome measurement for surgeons and technicians.

Table 2-6: Commercially available PSI guidance systems [35].

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>Acetabular Guide</th>
<th>Femoral Guide</th>
<th>Planning Software</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature Hip</td>
<td>Zimmer</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Biomet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MyHip</td>
<td>Medacta</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>International</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip Plan</td>
<td>Symbios</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>OPS</td>
<td>Corin Group</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Figure 2-36 depicts commercially-available PSI in guiding the acetabular cup position. Pins or lasers guide the component positioning [35]. The majority of acetabular guidance systems make use of pins [35]. The PSI guide is placed into the acetabulum, and pins are inserted through optimally designed grooves [35]. The guide is removed and the remained pins serve as a reference to position the acetabular cup, Figure 2-36a-b [35].
Figure 2–36: Commercially available acetabular guidance systems: a) Signature, Zimmer Biomet [Reprinted from 35], b) MyHip, Medacta International [Reprinted from 35], c) Corin – OPS (Reprinted from Synopsis.com).

3D-printed patient-specific bony models are available for intra-operative use [35]. These assist surgeons in visualising the patient’s anatomy and how the guide should fit before implanting it into the patient, Figure 2-37 [35], [253].

The femoral neck osteotomy guides operate similarly, Figure 2-38. The guide is placed on the femoral-neck junction to fit the contours of the bone [4], [248]. Pins insertion follows to secure its position [4], [248]. The surgeon consequently cuts the femoral head-neck junction using an oscillating saw [4], [248].
Figure 2–37: During the surgery a patient-specific acetabular model is used to visualise the fitting of the guide within the acetabulum before the actual implantation in to the patient (Reprinted from complexhipsurgery.com).

Figure 2–38: Commercially available femoral neck osteotomy guides: a) MyHip, Medacta International [35], b) Corin-OPS (Reprinted from Synopsis.com).
2.8 Accuracy of 3D pre-operative planning and PSI in primary THA

2.8.1 3D Pre-operative Planning

Accuracy in predicting the prosthetic components size

The importance of component sizing in primary THA has been reported in the literature. The correlation of cups’ size and dislocation risk is supported by the evidence [254]. Improper positioning of the cup also leads to edge-loading and wear complications [255]. As far as the femoral component is concerned, undersized stems can lead to stem subsidence, while overestimation is a cause of intra-operative fracture [232].

The overall accuracy of 3D surgical planning in components’ size prediction has been proven satisfactory, followed by good inter-observer variability [213], Table 2-7. Prediction rate of femoral stem and acetabular cup sizes are ranged between 34-100% and 41-100% respectively.

Compared to conventional digital templating, which included either acetate templating using transparent templates over X-ray films or a digital overlay of components drawings on 2D radiographs, 3D pre-operative planning has been proven more accurate in predicting the component size. In detail, the prediction of the exact size of the acetabular cup has been improved by 12-53% and of the femoral stem by 13-57% (Table 2-8). However, no studies have shown if this improvement in terms of component size prediction using 3D-CT pre-operative planning, contributed to a better patients’ functional outcome.
Table 2-7: Accuracy of 3D pre-operative planning in predicting component size.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Indication</th>
<th>N</th>
<th>Uncem. /Cement.</th>
<th>Match (%)</th>
<th>Software</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reference</strong></td>
<td><strong>Indication</strong></td>
<td><strong>N</strong></td>
<td><strong>Uncem. /Cement.</strong></td>
<td><strong>Match (%)</strong></td>
<td><strong>Software</strong></td>
</tr>
<tr>
<td>Viceconti (2003) [256]</td>
<td>DDH</td>
<td>29</td>
<td>Uncem.</td>
<td>66</td>
<td>52</td>
</tr>
<tr>
<td>Sariali (2009) [209]</td>
<td>OA</td>
<td>223</td>
<td>Uncem.</td>
<td>86</td>
<td>94</td>
</tr>
<tr>
<td>Sariali (2012) [153]</td>
<td>OA</td>
<td>30</td>
<td>Uncem.</td>
<td>96</td>
<td>100</td>
</tr>
<tr>
<td>Hassani (2014) [160]</td>
<td>NA</td>
<td>50</td>
<td>Uncem.</td>
<td>94</td>
<td>100</td>
</tr>
<tr>
<td>Zeng (2014) [257]</td>
<td>DDH</td>
<td>20</td>
<td>Uncem.</td>
<td>70</td>
<td>NA</td>
</tr>
<tr>
<td>Mainard (2017) [210]</td>
<td>OA</td>
<td>31</td>
<td>Uncem.</td>
<td>41</td>
<td>34</td>
</tr>
<tr>
<td>Wako (2018) [213]</td>
<td>OA, AVN</td>
<td>60</td>
<td>Uncem.</td>
<td>45</td>
<td>43</td>
</tr>
<tr>
<td>Ogawa (2018) [222]</td>
<td>DDH</td>
<td>141</td>
<td>Uncem.</td>
<td>94</td>
<td>86</td>
</tr>
<tr>
<td>Wu (2019) [251]</td>
<td>DDH</td>
<td>49</td>
<td>Uncem.</td>
<td>71</td>
<td>NA</td>
</tr>
<tr>
<td>Knafo (2019) [192]</td>
<td>OA</td>
<td>33</td>
<td>Uncem.</td>
<td>55</td>
<td>48</td>
</tr>
<tr>
<td>Schiffner (2019) [197]</td>
<td>OA</td>
<td>116</td>
<td>Uncem.</td>
<td>57</td>
<td>59</td>
</tr>
<tr>
<td>Savov (2020) [223]</td>
<td>Cadavers</td>
<td>8</td>
<td>Uncem.</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Huo (2021) [258]</td>
<td>*</td>
<td>59</td>
<td>Uncem.</td>
<td>71</td>
<td>76</td>
</tr>
<tr>
<td>Ferretti (2021) [212]</td>
<td>OA</td>
<td>36</td>
<td>Uncem.</td>
<td>100</td>
<td>97</td>
</tr>
</tbody>
</table>

OA, osteoarthritis; DDH, Developmental Dysplasia of the Hip; ON, Osteonecrosis; AS, Ankylosing Spondylitis; RA, Rheumatoid Arthritis; NA, not available/ not applicable; Uncem, Uncemented; Cement., Cemented

* Match (%): Percentage of prosthetic components implanted with a size that match the one decided upon pre-operative planning. **DDH/OA/ON/AS/RA
Table 2-8: Comparison between 3D pre-operative and conventional templating in predicting the component size.

<table>
<thead>
<tr>
<th>Reference</th>
<th>N</th>
<th>Conventional Planning</th>
<th>3D Planning</th>
<th>P value - Cup</th>
<th>P value - Stem</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Cup</td>
<td>Stem</td>
<td>Cup</td>
<td>Stem</td>
</tr>
<tr>
<td>Viceconti (2003) [256]</td>
<td>29</td>
<td>41</td>
<td>35</td>
<td>66</td>
<td>52</td>
</tr>
<tr>
<td>Sariali (2012) [153]</td>
<td>30</td>
<td>43</td>
<td>43</td>
<td>96</td>
<td>100</td>
</tr>
<tr>
<td>Schiffner (2018) [197]</td>
<td>116</td>
<td>45</td>
<td>46</td>
<td>57</td>
<td>59</td>
</tr>
<tr>
<td>Huo (2021) [258]</td>
<td>59</td>
<td>41</td>
<td>49</td>
<td>71</td>
<td>76</td>
</tr>
</tbody>
</table>

NA, not available/ not applicable

* Numbers represent percentage of prosthetic components implanted with a size that match the one decided upon pre-operative planning.

**Accuracy of 3D pre-operative planning in predicting the component position**

Besides the prediction of the component size, dimensional characteristics such as LLD, FO and CoR should be restored to minimise complications and achieve an overall good functional outcome [25], [153], [182], [188], [190], [192], [259]–[261]. Renkawitz et al. (2016) have reported that a FO reconstruction error beyond 5mm results in a lower gait walking speed and hip ROM [262]. Additionally, Cassidy et al. (2012) have highlighted that a FO reconstruction errors of less than -5mm, resulted in deteriorated Patient-Reported Outcome Measures (PROMs) [260]. Rösler et al. (2000) have highlighted that a cranialisation of the CoR results in decreased hip flexion and extension, while Sariali et. al. (2011) have shown that the CoR in a group of THA patients that presented dislocation was significantly migrated medially and posteriorly [182], [261].
The number of studies found on the subject was limited (n=8), Table 2-9. The absolute average difference of the numbers reported in Table 2-9, reflecting the discrepancy between the planned and achieved values of leg length, offset and CoR craniocaudally and mediolaterally, was 1mm, 1mm, 2mm and 2mm, respectively.

Sariali et al. (2012) compared the accuracy of 3D-CT planning and digital templating in restoring FO and leg length. Digital templating showed that the discrepancy between planned and achieved FO and leg length ranged between -13 to 9 mm and -9 to 13 mm, respectively. Contrastingly, using 3D pre-operative planning the respective discrepancies ranged between -4 to 6 mm and -8 to 4 mm, respectively (P<0.001) [153]. These findings have highlighted that 3D-CT planning is more accurate in restoring the planned FO and leg length in comparison with conventional 2D templating.
Table 2-9: Accuracy of 3D pre-operative planning in predicting dimensional characteristics associated with the component position.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Indication for surgery</th>
<th>N</th>
<th>Uncem./Cement.</th>
<th>LLD (mm)</th>
<th>FO (mm)</th>
<th>CoR (mm)</th>
<th>CC</th>
<th>ML</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sariali (2009) [209]</td>
<td>OA</td>
<td>223</td>
<td>Uncem.</td>
<td>-0.30</td>
<td>-0.80</td>
<td>-0.7</td>
<td>-1.20</td>
<td></td>
</tr>
<tr>
<td>Pasquier (2010) [162]</td>
<td>OA</td>
<td>61</td>
<td>Uncem.</td>
<td>1.7</td>
<td>1.9</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Sariali (2012) [153]</td>
<td>OA</td>
<td>30</td>
<td>Uncem.</td>
<td>1.80</td>
<td>-1.30</td>
<td>-1.70</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Hassani (2014) [160]</td>
<td>NA</td>
<td>50</td>
<td>Uncem.</td>
<td>0.30</td>
<td>-1.40</td>
<td>0.2</td>
<td>-1</td>
<td></td>
</tr>
<tr>
<td>Zeng (2014) [257]</td>
<td>DDH</td>
<td>20</td>
<td>Uncem.</td>
<td>NA</td>
<td>NA</td>
<td>4.5</td>
<td>3.3</td>
<td></td>
</tr>
<tr>
<td>Knafo (2019) [192]</td>
<td>OA</td>
<td>33</td>
<td>Uncem.</td>
<td>1.90</td>
<td>-0.30</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Belzunce (2020) [230]</td>
<td>OA</td>
<td>30</td>
<td>Uncem.</td>
<td>NA</td>
<td>2.2</td>
<td>0.2</td>
<td>2.3</td>
<td></td>
</tr>
<tr>
<td>Savov (2020) [223]</td>
<td>Cadavers</td>
<td>8</td>
<td>NA</td>
<td>NA</td>
<td>3.6-4.5</td>
<td>-3.7</td>
<td>-4.8</td>
<td></td>
</tr>
</tbody>
</table>

OA, osteoarthritis; NA, not available/not applicable; DDH, developmental dysplasia of the hip; Uncem, Uncemented; Cemented, Cemented; LLD, Leg Length Discrepancy; FO, Femoral Offset; CoR, Centre of Rotation; CC, craniocaudally; ML, mediolaterally

* Accuracy is expressed as mean differences between the achieved and planned values.
Accuracy of 3D Pre-operative Planning in predicting the component orientation

Malpositioning of the acetabular cup and femoral stem can result in various complications including dislocation [255], [263]–[265], impingement [266] and implant instability [6], [236]. Table 2-10 includes the studies evaluating the difference between the achieved and planned acetabular angles (AV, Abduction-ABD, INC) in primary THA using 3D pre-operative planning software. In detail, cup INC has been proven accurately reproducible. Contrastingly, cup AV has reported a substantial discrepancy (-6.9° to 15°) when compared to the surgical plan. As far the cup ABD is concerned, controversial results have been reported.

Table 2-10: Studies addressing planned and achieved acetabular angles in primary THA using pre-operative planning.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Disease</th>
<th>N</th>
<th>AV (Deg)</th>
<th>ABD (Deg)</th>
<th>INC (Deg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sariali (2009) [209]</td>
<td>OA</td>
<td>223</td>
<td>6.30</td>
<td>2</td>
<td>NA</td>
</tr>
<tr>
<td>Hassani (2014) [160]</td>
<td>NA</td>
<td>50</td>
<td>-6.90</td>
<td>NA</td>
<td>-0.5</td>
</tr>
<tr>
<td>Zeng (2014) [257]</td>
<td>DDH</td>
<td>20</td>
<td>NA</td>
<td>9.7</td>
<td>NA</td>
</tr>
<tr>
<td>Sariali (2016) [227]</td>
<td>OA, ON</td>
<td>28</td>
<td>-2.70</td>
<td>-2</td>
<td>NA</td>
</tr>
<tr>
<td>Savov (2020) [223]</td>
<td>Cadavers</td>
<td>8</td>
<td>15</td>
<td>NA</td>
<td>-0.10</td>
</tr>
<tr>
<td>Wu (2019) [251]</td>
<td>DDH</td>
<td>49</td>
<td>9.8</td>
<td>NA</td>
<td>0.03</td>
</tr>
</tbody>
</table>

OA, Osteoarthritis; NA, not available/ not applicable; DDH, Developmental Dysplasia of the Hip; ON, Osteonecrosis; AV, Anteversion; ABD, abduction; INC, Inclination

*AV, ABD, and INC angles are expressed as mean differences between achieved and planned values.
Using conventional templating, the differences between planned and achieved acetabular AV and INC were 7 and 9 degrees, respectively [191]. However, due to the lack of randomised controlled studies between 3D-CT planning (excluding PSI) and conventional templating, it remains unclear if 3D-CT planning is more accurate in restoring the planned acetabular orientation. This information can only be assumed because cup AV cannot be precisely measured using plain radiographs [149].

Femoral component orientation has been under-studied when compared to the acetabular cup orientation. Table 2-11 includes all the studies evaluating the accuracy of 3D surgical planning in delivering the planned PFV. These have reported the accuracy of 3D planning as the mean (± Standard Deviation-SD) difference between the achieved and planned PFV.

The variable accuracy of 3D planning in restoring the planned PFV, reported in Table 2-11, may be attributed to the different surgical techniques (anterior, posterior, lateral) or the designs of the femoral stems adopted [267]. Low variability of PFV has been reported in primary THA using modular femoral stem designs [209]. Uncemented femoral stems featuring modular necks allow modularity of the femoral stem neck in various configurations of PFV and potentially a more accurate intra-operative reconstruction of the planned PFV. Contrastingly, metaphyseal fit-fill and straight-tapered femoral stems have demonstrated high variability of PFV [230], [234]. Straight designs of femoral stems follow the morphology of the internal proximal femoral canal, leaving the surgeon with limited control over the final position [268]. No studies have addressed the role of 3D planning software in predicting the PFV using cemented femoral stems.
Table 2-11: Studies addressing planned and achieved PFV angles in primary THA using 3D pre-operative planning.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Disease</th>
<th>N</th>
<th>PFV (Deg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sariali (2009) [209]</td>
<td>OA</td>
<td>223</td>
<td>0.8</td>
</tr>
<tr>
<td>Hassani (2014) [160]</td>
<td>NA</td>
<td>50</td>
<td>-0.6 ± 3</td>
</tr>
<tr>
<td>Imai (2016) [234]</td>
<td>DDH</td>
<td>65</td>
<td>-3 ± 7</td>
</tr>
<tr>
<td>Belzunce (2020) [230]</td>
<td>OA</td>
<td>30</td>
<td>-1.5 ± 8</td>
</tr>
</tbody>
</table>

OA, Osteoarthritis; ON, Osteonecrosis; PFV, Prosthetic Femoral Version

* PFV angles are expressed as mean differences between achieved and planned values (Mean, ± Standard Deviation-SD).
2.8.2 PSI

Accuracy of PSI in acetabular cup orientation compared to conventional technique

Studies so far have proven the superiority of PSI-guided implantation of the acetabular cup, when compared to the free-hand technique, Table 2-12 [253], [269], [270]. The mean discrepancies between the achieved and planned cup INC and AV angles ranged between 1.4° to 3.9° and 0.2° to 5.2°, respectively (Table 2-11).

For acetabular components, the safe zone for orientation is 15 ± 10º of AV and 45º ± 15º of INC [228]. Using conventional instrumentation, the percentage of cases within the targeted range of cup AV and INC using manual implantation, was 57-76%, and 57%, respectively. Using PSI, the respective percentages increased to 79-100% for the cup AV, and 100% for the cup INC [269], [270].

Accuracy of PSI as an additional step of 3D-CT planning

High variability of cup AV has been reported in studies using solely 3D planning software (see Table 2-10). Using 3D-CT planning only, the mean discrepancy between achieved and planned cup AV ranged between 3.6° and 15° (see Table 2-10), while 50% of the cases were within the clinically accepted range of cup AV [223]. PSI constitutes an optional step during planning a primary THA and has been reported to result in a lower variability of cup AV, Table 2-13. Using PSI, the mean discrepancy between achieved and planned cup AV ranged between 0.2° and 5.2°, while 79-100% of the cases were within the clinically accepted range of cup AV [212], [247], [253], [269]–[271].

With regards to the acetabular cup INC, studies using exclusively 3D planning have reported 63-100% of the cases within the clinically accepted range of INC [160], [223], [251], whereas studies incorporating additional PSI tools have reported 92-100% [212],...
In this regard, no significant advantage has been observed in terms of cup INC when compared to cup AV, Table 2-13.

**Accuracy of PSI in femoral neck osteotomy.**

Of the two commercially available femoral neck osteotomy tools, only one has been clinically evaluated [212], [248]. In a total of 30 cases, 96% reported a discrepancy between the planned and achieved osteotomy level within 3 mm [248], while a mean deviation of 1.6mm from the surgical plan has been reported [212].

**Contribution of 3D pre-operative planning and PSI to a better clinical outcome**

Although the accuracy of 3D surgical planning in predicting the component size has been well documented, there were limited data on the contribution of this advanced technology to a long-term clinical outcome. These reported high survival rate, however, it’s not clear if the incorporation of the three-dimensional planning resulted in improved clinical results compared to standard practice [272], [273].
Table 2-12: Accuracy of PSI in achieving the target with regards to cup INC and AV angles.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Free-Hand</th>
<th>PSI</th>
<th>p value - INC</th>
<th>p value - AV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hananouchi (2010) [270]</td>
<td>NA</td>
<td>5.2**</td>
<td>NA</td>
<td>3.7**</td>
</tr>
<tr>
<td>Buller (2013) [269]</td>
<td>10.4</td>
<td>14.9</td>
<td>1.4</td>
<td>5.2</td>
</tr>
<tr>
<td>Small (2014) [253]</td>
<td>NA</td>
<td>6.9</td>
<td>NA</td>
<td>0.2</td>
</tr>
<tr>
<td>Shandiz (2014) [271]</td>
<td>NA</td>
<td>NA</td>
<td>2.5**</td>
<td>2.5**</td>
</tr>
<tr>
<td>Gardner (2016) [247]</td>
<td>NA</td>
<td>NA</td>
<td>3.9**</td>
<td>3.6**</td>
</tr>
<tr>
<td>Ferretti (2021) [212]</td>
<td>NA</td>
<td>NA</td>
<td>3.9**</td>
<td>4.4**</td>
</tr>
</tbody>
</table>

INC, Inclination; AV, Anteversion; NA, not available/not applicable

* AV and INC angles are expressed as differences between achieved and planned values.

** These values represent the absolute mean difference between the achieved and planned orientation angles.

Table 2-13: Comparison of 3D planning and PSI in achieving the targeted cup orientation.

<table>
<thead>
<tr>
<th>3D Planning</th>
<th>PSI</th>
</tr>
</thead>
<tbody>
<tr>
<td>INC</td>
<td>AV</td>
</tr>
<tr>
<td>-0.5 to 0.03°</td>
<td>-6.9 to 15°</td>
</tr>
</tbody>
</table>

INC, Inclination; AV, Anteversion
With regard to the PSI, no studies have assessed its contribution to a better clinical outcome. Long-term clinical results are imperative to convince the surgeon that a more accurate implant positioning can compensate for challenges like the technological complexity and associated costs.

Current State

The first article proposing a framework of planning based on three planes of human anatomy was in 2002 [207], after which a moderate rise was noted until 2011. Subsequently, evidence around the use of 3D planning was considerably higher, reaching 100 citations around 2017, Figure 2–39.

![Figure 2–39: Line graph showing the growing trend of the use of 3D planning.](image)

The first articles documenting the prevalence of PSI in primary THA were noted a few years later than the first publications concerning 3D planning. This is due to the fact that PSI is a subsequence of 3D planning and 3D printing [35]. A steady increase followed mostly after 2012, reaching 70 citations around 2018, Figure 2–40. The highest number of citations for both 3D planning and PSI were reported around the same time.
Figure 2–40: Line graph showing the growing trend of the use of PSI.

Barriers in changing practice

Although previous studies have documented the superiority of 3D-CT over conventional radiographs, most hospitals incorporate 2D planning platforms [4]. Incorporating 3D-CT planning as part of the clinical pipeline prior to a hip surgery would face significant barriers. First, CT-based orthopaedic planning software is associated with increased radiation exposure [174]. Although recent scientific endeavours managed to reduce the radiation exposure at no expense of imaging quality [174]–[178], conventional radiographs are associated with low radiation exposure [179] and thus would be preferable. Second, pre-operative planning software usually entails additional time and cost compared to simple and cost-effective conventional radiography [150]. Finally, 3D-CT planning is a relatively new technique, not widely adopted in clinical practice, and as such, medical personnel, such as radiologists, may lack experience in using this tool. Specialised training would be required often associated with complexity and cost for the institution, to overcome this barrier.
2.9 Summary

3D-CT pre-operative planning in THA is being recognised as a useful tool in planning the elective surgery, crucial to define the optimal component size, position and orientation. It offers a more detailed representation of the patient’s anatomy, which enables surgeons and engineers to perform surgical planning using more anatomical landmarks. It also enables the design and fabrication of PSI and physical models representing the patient-specific bony anatomy to increase the accuracy of implant positioning. This literature review identified the following gaps in the narrative of planning a hip arthroplasty using 3D image analysis techniques:

◊ Research has mainly included two commercially available planning software, HIP-PLAN and Zed Hip, followed by HipEOS.

◊ Studies documenting the accuracy of 3D-CT planning software in predicting dimensional characteristics associated with the component position are limited.

◊ Overall, the femoral component orientation has been under-investigated when compared to the acetabular cup component.

◊ There were no studies addressing the role of 3D planning in primary cemented THA.

◊ Of the two commercially available femoral neck osteotomy guides, only one has been clinically evaluated.

◊ There is no PSI tool to guide the PFV.

◊ It is uncertain whether 3D-CT planning and PSI enhance the post-operative clinical outcome to compensate for barriers like the increased radiation dose.

◊ Despite growing evidence that 3D-CT planning is more accurate than conventional templating, it has not been widely adopted.
Evaluating current 3D-CT planning of a straight-tapered femoral stem
Chapter 3 Evaluating current 3D-CT planning of a straight-tapered femoral stem

3.1 Introduction

3D-CT planning has recently emerged as a more targeted approach towards a primary THA. Proper selection of the component size and restoration of anatomical parameters constitute its technical goals [4]. So far, many studies have shown that it is accurate in terms of component size (see Table 2-7), while the planning accuracy in terms of femoral component position and orientation has been under documented, particularly the PFV (see Tables 2-9 and 2-11).

Component positioning aims the reconstruction of important anatomical parameters, like the FO [24], [162]. Based on the literature review, 3D-CT planning has been proven a useful tool to predict FO. However, the number of studies found on the subject was limited (n=6) (see Table 2-9). These mainly assessed one commercially available software using stems featuring modular necks [153], [160], [162], [209]. In this regard, the accuracy of many commercially available software in terms of femoral stem component position, particular the FO, remains understudied.

Furthermore, planning the version of the femoral stem (known as PFV) and achieving it is still in its infancy in primary THA. Most 3D-CT planning systems use the native version of the proximal femur, known as NFV, to plan PFV, following the recommended positioning to restore the native femur [230], [232], [233], [235], [274]. The rationale lies in the hypothesis that uncemented stem designs, designed for a tight press-fit into the corticocancellous interface, follow the internal femoral morphology, implying that this configuration replicates NFV [233].
Previous studies have focused on 3D-CT planning of femoral stems featuring modular necks or short fit-fill anatomical designs, reporting a high accuracy in terms of PFV [160], [209], [232]. However, studies using robotic tools or Two-Dimensional (2D) imaging techniques have documented an important difference between PFV and NFV in primary THA using conventional, straight, uncemented, femoral stem designs [233], [235], [268]. Among the various methods that have been incorporated to measure version angles, Three-Dimensional Computed Tomography (3D-CT)-based measurements have been highlighted as the equivalent to dry bone measurements [275]–[277].

In this context, this chapter aims to concurrently evaluate the accuracy of a commercially available 3D-CT planning software (MyHip Planner, Medacta International SA, Castel San Pietro, Switzerland) in primary uncemented THA using a straight-tapered femoral stem in terms of component size and FO. Additionally, this chapter aimed to assess the real-world useability of NFV as a guide for planning the achieved version of a straight-tapered femoral stem (PFV) in primary uncemented THA using 3D-CT analysis.

3.1.1 Motivation

Recent trends highlight a continuous increase in primary and revision THAs [16], [19], indicating the need to improve current tools and approaches. As previously mentioned, planning a THA using advanced imaging modalities, such as 3D-CT, offers a number of benefits for accomplishing more precise surgery. However, conventional radiography remains the gold standard, and only a fraction of surgeries has incorporated 3D-CT planning as part of their routine [4].

Robust clinical evaluation of commercially available 3D-CT planning platforms to identify possible benefits and limitations is essential. Proving the accuracy of 3D-CT planning would lower the reluctance of the orthopaedic field to adopt newly introduced
methods. On the contrary, highlighting potential caveats would aid orthopaedic companies in improving their products and focusing on the solutions to the issues.

3.1.2 Aim

To evaluate 1. the accuracy of commercially available 3D-CT planning software (MyHip Planner, Medacta International SA, Castel San Pietro, Switzerland) in predicting the final size and horizontal and vertical FO of a straight femoral stem, 2. the reliability of NFV as a planning guide of PFV of a straight stem in a series of 79 patients undergoing primary uncemented THA due to OA, using pre- and post-operative 3D-CT image analysis techniques.

3.1.3 Objectives

To achieve this aim, the objectives were:

- To compare the planned and achieved component sizes.
- To quantify the difference between the planned and achieved FO.
- To measure the NFV and PFV angles using 3D-CT image analysis.
- To understand if the version of the proximal femur (NFV) is useful for planning and delivering PFV by quantifying the difference between PFV and NFV.
- To evaluate the clinical outcome.
3.2 Materials and Methods

3.2.1 Study Design

Figure 3-1 illustrates the study design of this chapter.

Figure 3–1: Study Design.

This was a case series of 74 patients (82 hips) undergoing primary uncemented THA due to OA between February 2017 and May 2021. All patients had pre- and post-operative CT scans. Prior to the surgery, the patients underwent 3D-CT planning. The surgical plan for three of them was not available, resulting in 73 patients (79 hips) included in the analysis. The aim was to compare the surgical plan with the achieved outcome in terms of component size and femoral offsets and understand the relationship between the NFV and PFV. The clinical outcome was also evaluated. Table 3-1 includes characteristics of the study group.
The outcome measures were:

1. Planned and achieved femoral and acetabular component size.
2. Planned and achieved HFO and VFO.
3. NFV and PFV angles.

### Table 3-1: Study Group Characteristics.

<table>
<thead>
<tr>
<th>Study Group (n=79 Hips)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (Females) (%)</td>
<td>40 (51)</td>
</tr>
<tr>
<td>Age (Years) (Median, Range)</td>
<td>62 (32-86)</td>
</tr>
<tr>
<td>Treatment Side (Right) (%)</td>
<td>41 (52)</td>
</tr>
</tbody>
</table>

#### 3.2.2 Pre-operative CT scanning

Prior to the surgery, all patients underwent CT scanning of the hip and knee joint using a standard low-dose scanning protocol. Image acquisition consisted of two scans: 1. A scan of the pelvis and the proximal femur (10cm below the LT); 2. A scan of the distal femur including the femoral condyles [4].

#### 3.2.3 Processing of the pre-operative CT scans

The imaging data were anonymised before being saved in the DICOM format and imported into a DICOM reconstruction software (Simpleware ScanIP, Version 2021.03; Synopsis, Inc., Mountain View, USA). The CT data were then processed in Simpleware ScanIP using bilateral filtering and intensity thresholding tools to generate 3D models of the patients' anatomy, Figure 3-2.
Figure 3–2: The CT scans were saved in the DICOM format and imported into Simpleware. Bone segmentation is followed by using intensity thresholding tools to generate 3D models of the patient-specific anatomy. A constant threshold range (200–1500 Hounsfield Units-HU) was selected to generate the 3D-CT models of the patient’s anatomy for all cases.

3.2.4 External surgical planning

Additionally, the CT scans were sent to an external, commercially available, planning software (MyHip Planner, Medacta International SA, Castel San Pietro, Switzerland) to define the optimal size, position, and orientation for the prosthesis.

The role of the engineers at Medacta was to generate the surgical plan, including the size and position of the prosthetic components used. Their approach included a selection of
the most appropriate size from the available database of ten sizes to maximise the coverage of the intramedullary canal by the femoral stem based on a visual inspection of the three CT views per patient. For the femoral head, they chose the most appropriate size to achieve the desired FO. The plan was to restore the native horizontal and vertical FO and leg length with reference to the contralateral side. In addition, the surgeon aimed for a PFV of 20°. Regarding the acetabular component, the surgical plan aimed for an inclination of 40° and an anteversion of 20° in the radiographic definitions.

The planned sizes for the acetabular and femoral components were recorded, and the surgical plan (position of the selected prosthetic components within the patient’s anatomy) was saved in the Standard Tessellation Language (STL) format by Medacta. Import of these 3D models as STLS followed, overlaid on the respective CT scans in the DICOM reconstruction software (Simpleware ScanIP, Version 2021.03; Synopsis, Inc., Mountain View, USA).

3.2.5 Surgical approach, prosthetic components and PSI

All surgeries were performed through a posterior approach by one consultant orthopaedic surgeon, using a hemispheric press-fit HA coated cup (M pact System; Medacta International SA, Castel San Pietro, Switzerland) and an uncemented straight tapered stem (Quadra-H System; Medacta International SA, Castel San Pietro, Switzerland), with a straight rectangular shape, a trapezoidal cross-section, and a double tapered distal tip, Figure 3-3a-b. In the surgery, a PSI guide was used to cut the femoral head-neck junction (MyHip from Medacta, see Figure 3-3c).
3.2.6 Pre-operative CT analysis

Planned Horizontal and Vertical Femoral Offsets (HFO and VFO)

The Horizontal (HFO) and Vertical FO (VFO) describe the horizontal and vertical position of the femoral stem within the intramedullary canal [230]. The surgical plan (STL file), including the planned position of the femoral stem within the patient’s anatomy, was used to measure the planned HFO and VFO. For the measurements, only the 3D models of the implants were used (standard tessellated file of their generic design in the chosen size and planned position). The 3D-CT reconstructed model of the patient’s native anatomy, represented by the STL model and based on the MyHip Planner’s segmentation (MyHip Planner, Medacta International SA, Castel San Pietro, Switzerland), was imported into Simpleware (Simpleware ScanIP, Version 2021.03;
Synopsis, Inc., Mountain View, USA), but was not used. Instead, the 3D-CT reconstructed models generated by Simpleware were used.

The planned HFO was defined as the projection of the planned femoral head centre on the long axis of the planned femoral stem, Figure 3-4a [230]. Figure 3-4b illustrates that the planned VFO was calculated as the vertical distance between the planned femoral head centre and the most medial point of the LT [25]. This distance was measured along a line that was parallel to the long axis of the femoral stem.

![Figure 3–4: A schematic illustration of the planned HFO and HFO distances.](image)

The femoral head centre was obtained by computing the centre of a fitted sphere to the head of the implant [230]. The femur’s long axis, known as the Anatomical Axis (AA), is the line bisecting the medullary canal of the femur; it is clinically determined using a ruler between the ASIS and the knee joint. In the present thesis, the Anatomical Axis (AA) of the proximal femur was defined as the line connecting the PF with the
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Intercondylar Notch (IN); the centre of the Transepicondylar Axis (TA), which is the line connecting the most medial and lateral prominences of the epicondyles, Figure 3-5 [278].

**Figure 3–5:** The AA of the proximal femur; the line connecting the PF with the IN.

Since the goal of the femoral stem component positioning was to restore the native anatomy of the proximal femur and thus its AA, the long axis of the femoral stem was defined as the line between a clearly defined landmark at the top lateral area of the stem and the IN, Figure 3-6.
**Figure 3–6:** The long axis of the femoral stem was defined as the line connecting the IN with a landmark at the top lateral area of the femoral stem.

Preparation of the 3D-CT model representing the proximal femur

Analysis of useful pre-operative measurements relies on the selection of appropriate landmarks using the 3D model of the proximal femur. The femoral model generated by the CT segmentation includes various holes and cavities that make the procedure of landmark selection burdensome. Therefore, the 3D-CT models representing the proximal
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femur were processed by applying closing filtering in Simpleware, resulting in a solid representation of the patient’s anatomy.

Measurement of NFV

By definition, NFV is the angle between the Femoral Neck Axis (FNA) and the PCA projected on a plane (Anteversion-AV Plane) perpendicular to the Mechanical Axis (MA) of the proximal femur; the line connecting the centre of the femoral head with the IN, Figure 3-7 [42].

![Diagram of femur with axes and landmarks](image)

**Figure 3–7: Illustration of the coordinate system used to measure NFV.**

The FNA is assumed to pass through the most distal cross-section of the femoral neck (Point B) and the centre of the femoral head (Point A) [275]. To derive the centre of the femoral head, the femoral head was assumed to be spherical. The user painted the whole femoral head and a sphere was automatically best fitted (shape fitting module in Simpleware) to extract its centre [230]. To calculate point B, the centreline of the femur
was derived automatically (Centreline module in Simpleware) and all the cross-sections were calculated across the neck region. The coordinates of the centres of the cross-sectional areas were extracted and recorded. The centre of the most distal cross-section area is defined as the centre of the femoral neck (Point B) [275]. The PCA was defined as the line connecting the most prominent points of the posterior femoral condyles (CT-based slices selection), Figure 3-8 [268].

**Figure 3–8: Illustration of the method used to determine FNA and PCA.**

3.2.7 Post-operative CT scanning

All patients had post-operative CT scans of the hip and the knee region using the same scanning protocol adopted for the scans acquired before the surgery.
3.2.8 Processing of the post-operative CT scans

The post-operative CT scans were processed to generate the 3D models of the post-operative femoral morphology and prosthetic components (acetabular cup and femoral stem). The scans were corrected for metal artefacts. The Normalised Metal Artefact Reduction algorithm (NMAR) was implemented on the post-operative CT scans to eliminate the metal artefact and generate 3D models of the prosthetic components [171], [230].

3.2.9 Recording of the implants size and clinical evaluation

Post-operatively, the sizes of the implanted prosthesis were recorded and post-operative evaluation took place; the number of fractures and dislocations was recorded. Oxford Hip Score (OHS) of cases reporting complications was recorded.

3.2.10 Post-operative CT analysis

Achieved HFO and HFO

The achieved HFO was defined as the projection of the achieved femoral head centre on the long axis of the reconstructed femur. The achieved VFO was defined as the vertical distance between the achieved femoral head centre and the most medial point of the LT projected on a line parallel to the long axis of the reconstructed femur, Figure 3-9.
Measurement of PFV

The definition of NFV was adopted to define the PFV; this is the angle between the axis of the implant’s neck and the PCA projected on a plane perpendicular to the MA of the reconstructed femur (femoral implant) [42]. The neck axis was defined as the line connecting the post-operative CoR and a clearly identified landmark at the top lateral area of the femoral stem [230]. The MA axis was defined as the line connecting the post-operative CoR with the IN [42]. To compute the post-operative CoR a sphere was best fitted to the head of the femoral component, Figure 3-10 [230].
Figure 3–10: Illustration of the method used to determine PFV.
3.2.11 Repeatability and reproducibility analysis of the CT measurement method

The methodology adopted to measure pre- and post-operative FO, NFV, and PFV measurements included steps subjected to the user’s input. These were the following:

1. The estimation of the femoral stem head centre (included in HFO, VFO, and PFV measurements). During this step, the user paints the head of the femoral stem, and a sphere is best-fitted, using the automatic shape fitting module in Simpleware (Simpleware ScanIP, Version 2021.03; Synopsis, Inc., Mountain View, USA). This step is anticipated to induce moderate end-outcome variability, especially on post-operative CT scans, where the head of the femoral stem could not be split from the cup in the 3D-CT model. The operator then paints only the part of the implant’s head that is visibly available, and a sphere is extrapolated. The femoral head centre is then extracted as the centre of the best-fit sphere [230].

2. The estimation of the native femur’s head centre (included in NFV measurements). During this step the user paints the whole area of the femur’s head, and a sphere is best fitted using the fitting module of Simpleware (Simpleware ScanIP, Version 2021.03; Synopsis, Inc., Mountain View, USA).

3. The selection of the femoral stem top lateral landmark (included in the HFO, VFO and PFV measurements). This landmark is a clearly visible landmark, defined within the top lateral hole of the model representing the femoral stem.

4. The selection of the epicondyles and posterior knee condyles (included in the HFO, VFO and PFV measurements). During this step, the user chooses these landmarks based on the 3D model of the knee.

The repeatability and reproducibility of the above steps were evaluated by quantifying the intra- and inter-observer variability of the PFV measurements, respectively. For the
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intra-observer analysis, PFV was measured twice for 30 randomly chosen cases by the same user, more than two months apart. For the inter-observer analysis, PFV was measured for 20 randomly chosen cases based on landmarks chosen by a different user who was familiar with the software environment. The training included a brief visual description of where the implant and bony landmarks are typically located using an example model of the femoral morphology.

Measurements of PFV were also obtained using an independent commercially available software (ZedHip, LEXI Co, Ltd, Tokyo, Japan). Post-operative CT scans were imported into the software (ZedHip, LEXI Co, Ltd, Tokyo, Japan) and landmarks (posterior, medial and lateral condyles) were defined. The available implant database allowed to superimpose the CAD file of the femoral implant used intra-operatively to the position of the post-operative femoral implant shown on CT. Once the alignment was confirmed, the PFV was automatically measured by the software.

3.2.12 Statistical Analysis

SPSS software was used to perform the statistical analysis (version 28, SPSS, Chicago, USA). In order to establish whether the data analysed in this study was normally distributed, the Kolmogorov-Smirnov test \((n>50)\) was utilised [279]. The mean, median, Standard Deviation (SD), Interquartile Range (IQR), minimum \((\text{min})\), and maximum \((\text{max})\) values were estimated for the pre- and post-operative values that were normally distributed. The median and IQR values were estimated for the data that did not match the tendency expected for a normal distribution [280]. Spearman’s correlation was used to assess the relationship between the planned and achieved sizes of the femoral and acetabular components [281].

A linear regression model was fitted to the data to look for a linear relationship between the planned and achieved FO and between the NFV and PFV [282]. The coefficient of
determination ($R^2$) was used to indicate the level of correlation [283]. The NFV and PFV was compared for each case. A Bland-Altman (BA) plot was used to show the discrepancy and measure the upper and lower 95% Limits Of Agreement (LOA) between PFV and NFV [284]. Statistical outliers were also determined using the Tukey method, abiding by the following conditions [285], [286]:

\[
\text{Outliers} < Q1 - (1.5 \times IQR) \text{ or } Q3 + (1.5 \times IQR) \quad [1]
\]

Q1= 25th percentile
Q3= 75th percentile

For the reproducibility and reliability analysis, mean and SD of differences between the measurements of the same and different users were reported. Intraclass correlation coefficient (ICC) was obtained for both intra- and inter-observer reliability [287].
3.3 Results

3.3.1 Planned and Achieved Component Size

Ninety-four per cent (96%) of the femoral stems and of the acetabular components were within one size of the plan (Figure 3-11).

With regard to the femoral component, the achieved stem size corresponded to the planned size in 71% of the cases. A femoral stem that was one size smaller than the plan was implanted in 24% of the cases, while a femoral stem that was one size larger than the plan was implanted in 1% of the cases. Furthermore, a femoral stem that was more than one size different from the plan, was implanted in 4% of the cases (Figure 3-11a).

The implanted acetabular cup was the same as planned in 78% of the cases. An acetabular cup of one size larger than the plan was implanted in 13% of the cases, while a cup of one size smaller was implanted in 5% of the cases. Additionally, an acetabular cup of more than one size different from the plan was implanted in 4% of the cases (Figure 3-11b).

Planned femoral stem size was a median (IQR) of 3 (2 to 5); the implanted femoral stem size was a median (IQR) of 3 (2 to 5). There was a strong correlation between the planned and achieved femoral stem size (Spearman’s, r=0.96, P<0.001) (Figure 3-12a).

Planned acetabular component size was a median (IQR) of 50 mm (48 to 54 mm), while the achieved acetabular component size was a median (IQR) of 52 mm (48 to 54 mm). Strong correlation was reported between the planned and achieved acetabular component size (Spearman’s, r=0.95, P<0.001) (Figure 3-12b).
Figure 3–11: The distribution of a) the femoral component size agreement and b) the acetabular component size agreement.
Figure 3–12: a) Correlation between the planned and achieved values for the size of the femoral stem (Spearman’s, $r=0.96$, $p<0.001$); b) Correlation between the
planned and achieved values for the size of the acetabular cup (Spearman’s, r=0.95, p<0.001).

3.3.2 HFO and VFO Discrepancies

The data describing the planned and achieved HFO values approached the trend expected for a normal distribution (Kolmogorov-Smirnov, p1=0.08; p2=0.07). The mean (± SD) planned HFO was 39 (±5) mm (median=39 mm; IQR=35 to 44 mm; min=30 mm; max=52 mm). The mean (± SD) achieved HFO was 40 (±6) mm (median=39 mm; IQR=36 to 44 mm; min=29 mm; max=54 mm). (Figure 3-13a).

The data describing the HFO discrepancy matched the trend expected for a normal distribution (Kolmogorov-Smirnov, p=0.2). The mean (± SD) HFO discrepancy was 1 (±3) mm (median=1 mm; IQR=-1 to 3 mm; min=-6 mm; max=7 mm). A linear regression model was fitted to the data, revealing a strong positive correlation between the planned and achieved HFO ($R^2=0.8$; p<0.001) (Figure 3-14a).

The data describing the planned and achieved VFO measurements approached the trend expected for a normal distribution (Kolmogorov-Smirnov, p1=0.2; p2=0.2). The mean (± SD) planned VFO was 57 (±6) mm (median=56 mm; IQR=52 to 61 mm; min=43 mm; max=74 mm). There was one outlier outside the box and whisker plot of the data describing the planned VFO. This included a patient having a planned VFO of 74 mm. The mean (± SD) achieved VFO was 59 (±7) mm (median=59 mm; IQR=54 to 63 mm; min=43 mm; max=72 mm). (Figure 3-13b).

The data describing the VFO discrepancy did not match the tendency expected for a normal distribution (Kolmogorov-Smirnov, p=0.03). The median (IQR) VFO discrepancy was 2 mm (0 to 4 mm). A linear regression analysis showed a strong positive correlation between the planned and achieved VFO ($R^2=0.6$; p<0.001) (Figure 3-14b).
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Figure 3–13: a) Box and whisker plots comparing the planned and achieved HFO.; b) Box and whisker plots comparing the planned and achieved VFO. The mean, median, IQR and maximum and minimal values are reported.
Figure 3–14: a) A linear regression analysis plot illustrating the achieved HFO as a function of the planned HFO; b) A linear regression analysis plot illustrating the achieved VFO as a function of the planned VFO.
3.3.3 NFV and PFV

The data describing the NFV and PFV measurements matched the tendency expected for a normal distribution (Kolmogorov-Smirnov, p1=0.2; p2=0.2). The mean (± SD) NFV was 14° (± 9°) (median=15°; IQR= 7 to 20°; min=-13°; max=36°). There was one outlier outside the box and whisker plot of the data describing the NFV. This included a patient having a NFV of -13°. The mean (± SD) PFV was 13° (± 9°) (median=13°; IQR= 7 to 17°; min=-18°; max=33°). There were two outliers outside the box and whisker plot of the data illustrating the PFV angles. These included two patients having a PFV of -18° and 33°, respectively (Figure 3-15).

Figure 3–15: Box and whisker plots comparing the NFV and PFV.

With regard to the distribution of NFV in all patients, 20% of the patients had a NFV of between 0° and 5°, whilst 1% of the patients had retroversion of their native femur (<0°). A NFV of between 5° and 10° and between 10° and 15° was reported in 14% and 15% of the patients, respectively. Furthermore, 24% of the patients had a NFV of between 15°
and 20° and 15% had a NFV of between 20° and 25°. A NFV of between 25° and 35° was reported in 10% of the patients, Figure 3-16.

![Bar chart showing NFV and PFV distribution in 79 primary uncemented THAs.](image)

**Figure 3–16: NFV and PFV distribution in 79 primary uncemented THAs.**

The comparative histograms depicted in Figure 3-16 showed that PFV follows a similar variation to NFV. In detail, a PFV of between 0° and 5° was reported in 14% of the patients, while 6% of the patients had retroverted PFV (<0°). Sixteen per cent (16%) of the patients had a PFV of between 5° and 10° and 24% had a PFV of between 10° and 15°. A PFV of between 15° and 20° and between 20° and 25° was reported in 20% and 8% of the femoral stems respectively. Additionally, a PFV of between 25° and 35° was reported in 11% of the patients, Figure 3-16.

The data describing the version discrepancy (PFV-NFV) and the underlying residuals followed a normal distribution (Kolmogorov-Smirnov, p1=0.2; p2=0.2). The mean (± SD) version discrepancy was -1 (± 8) ° (median=-0.5°, IQR= -6 ° to 5 °; min= -23°; max= 14°). The discrepancy between PFV and NFV was low (<5°) in 42% of patients, moderate
Evaluating current 3D-CT planning of a straight-tapered femoral stem (5–10°) in 41%, high (10–15°) in 11% and very high (>15°) in 6%. Compared to NFV, PFV was increased by 0–5° in 23% of patients, by 5–10° in 19%, by 10–15° in 6%, and by 15° or more in 0%. In comparison with NFV, PFV was decreased by 0–5° in 19% of patients, by 5–10° in 22%, by 10–15° in 5%, and by 15° or more in 6%, Figure 3-17.

![Difference between PFV and NFV in Primary Uncemented THA](image)

Figure 3–17: Distribution of the discrepancy between PFV and NFV.

A linear regression model was fitted to the data, revealing a moderate positive correlation between the NFV and PFV ($R^2 = 0.4; p<0.001$), Figure 3-18. A BA analysis showed that the upper and lower LOA were at -17° and 15°, Figure 3-19.
Figure 3–18: Linear regression analysis plot illustrating PFV as a function of NFV.

Figure 3–19: BA plot displaying the LOA between the NFV and PFV.
3.3.4 Clinical outcome

No intra-operative complications such as fracture or implant loosening, indicating wrong implant planning, size or implantation, have been recorded, resulting in an overall functional clinical outcome. At the most recent follow-up, 45 months after surgery, none of the hips had been revised for any reason. Post-operative evaluation revealed adequate fixation with no loosening occurring at one year after the surgery.

There were two dislocations, which were reported at 5 weeks and 1 year post-operatively; these were successfully treated with one closed reduction. The NFV for the two dislocated cases was 18° and 8°, respectively. For both of these, the planned values of PFV and cup AV were 20°. Post-surgery, a PFV of 9° was reported in both cases, while the cup AV for these cases was 28° and 9°, respectively.

3.3.5 Repeatability and reproducibility analysis of the CT measurement method

The mean (± SD) difference between the two measurements of the first user was 0.01° (± 1°), while a BA analysis showed that the upper and lower LOA were at -2° and 2°, respectively (Figure 3-20a). The mean (± SD) difference between the two measurements of the two users was -0.4° (± 2°), whilst the 95% LOA were at -4° and 4°, respectively (Figure 3-20b). A strong correlation was found between the two measurements of the first user (R²= 0.99; p<0.001), and between the measurements of the two users (R²= 0.97; p<0.001), Figure 3-21. In both cases, the ICC was more than 0.99.

The mean (± SD) difference of PFV measured by the external software (ZedHip, LEXI Co, Ltd, Tokyo, Japan) and the methodology adopted in the present chapter, was -1 (± 2°). A BA analysis showed that the upper and lower LOA were at -5° and 3°, respectively (Figure 3-22).
Figure 3–20: a) A BA plot comparing two measurements taken by the same user; b) A BA plot comparing measurements taken by different users.
Figure 3–21: Comparison between the measurements involved in the intra- and inter-observer analyses.

Figure 3–22: BA of the comparison between measurements made using the methodology used in this study and ZedHip software.
3.4 Discussion

This was the first study to concurrently assess current 3D-CT planning of a straight-tapered femoral stem in a series of 79 primary uncemented THAs in terms of component size, position, and orientation. The surgical plan was compared with the achieved outcome in terms of component size and position (HFO and VFO). In addition, 3D-CT image analysis techniques were implemented to assess the real-world usability of NFV as a planning guide for PFV in primary uncemented THA.

The 3D-CT pre-operative planning software was proven accurate in predicting the size of the acetabular and femoral stem components as well as the achieved FO of the femoral stem. The unmet need of 3D-CT planning was found to be planning and delivering the indented PFV. Twenty per cent (20%) of the femoral stems reported a PFV less than 5º. These findings are clinically relevant, because delivering an insufficient or retroverted PFV has been associated with prosthesis instability, elevated torsional moments, impingement and dislocation in primary uncemented THA [6], [236], [265], [288].

3.4.1 Component size discrepancy

Correct implant sizing in THA is considered important to minimise complications [222]. It may also serve as the foundation to enable reconstruction of HFO, VFO, leg length, and CoR. Furthermore, it has the potential to scale down the intra-operative questioning regarding the size of hip components, which in its turn may reduce the component repository and operation time [4].

Conventional planning in primary hip arthroplasty included an overlay (digital or not) of drawing templates of the prosthetic components on 2D AP radiographs. Previous studies using conventional templating have documented implant size prediction rates between 33-90% for the acetabular cup and 40-92% for the femoral stem, including uncemented
and cemented prosthetic components (see Table 2-1). The respective percentages using solely uncemented femoral stems were 20-58% and 40-74%, respectively (see Table 2-1). Although no studies have documented whether the size mismatch using conventional templating was an issue in terms of the clinical outcome, existing literature have highlighted the superiority of 3D-CT planning over conventional templating [153], [256].

In the present study, 96% of the femoral stems and the acetabular cups were within one size of the surgical plan, while 71% of the femoral stems and 78% of the acetabular cups were predicted exactly. Previous studies addressing the accuracy of 3D-CT planning in OA patients undergoing primary uncemented THA using conventional prosthetic components have reported a size prediction rate of between 59% and 97% for the femoral stems and between 57 and 100% for the acetabular cups [153], [160], [197], [209].

In this study, eighteen percent (18%) of the acetabular cups implanted were one size larger than planned. A potential reason leading to size mismatch of the acetabular cup could lie in the reaming procedure of the acetabulum occurring before the cup implantation. During pre-operative planning, engineers cannot accurately predict the amount of bone removed during the surgery, and this step may result in greater reaming than needed, potentially resulting in an intra-operative choice of a larger acetabular cup. However, previous scientific evidence assessing the factors contributing to a mismatch between the planned and achieved acetabular cup sizes, have not reported any factors that could potentially contribute to an acetabular size mismatch [222].

Contrastingly, femoral stem size mismatch has been reported to be affected by the stem alignment within the intramedullary canal of the proximal femur [222]. In this study, 24% of the femoral stems were implanted with one size smaller than the surgical plan. During pre-operative surgical planning, engineers make use of the segmented internal femoral canal to decide upon the size of the femoral stem. The process includes a size selection
that maximises the contact between the femoral stem and the cortical bone based on the three views of CT scans. This step has a certain level of subjectivity induced by the operator, and it can result in a suboptimal selection of the planned femoral stem size, different from the one decided intra-operatively. It should be noted, however, that this constitutes an assumption, and it remains unclear whether it contributed to the 24% undersized femoral stems reported in this study.

Previous studies have reported stem subsidence and malignment as the clinical complications of an one size smaller femoral stem than the surgical plan [232]. An undersized femoral stem may be associated with an excessive space between implant and bone, potentially affecting the fixation interface. However, the cases where the femoral stem was implanted with one size smaller were not detected clinically or radiographically in this study. The post-operative evaluation revealed that this size difference did not affect the stability of the femoral stems. The most relevant possible adverse clinical outcomes are intra-operative fracture (suggesting that the implant is too big or has been impacted with too much force) and post-operative implant subsidence or malalignment (suggesting that the implant was too small) [289]. None of these adverse outcomes occurred, and specifically, the absence of loosening at one year confirms that the implants achieved adequate primary fixation to then go on to achieve secondary fixation.

3.4.2 FO discrepancy

3D-CT planning was accurate in predicting the achieved position of the femoral stem in terms of HFO and VFO. Using Cassidy's classification [260], 90% of the cases reported a normal HFO (-5 to 5 mm), 7.5% had an increased HFO and 2.5% had a decreased HFO [260], Figure 3-23.
Evaluating current 3D-CT planning of a straight-tapered femoral stem

Figure 3–23: Distribution of HFO discrepancy in a series of 79 patients.

The post-operative values of HFO reported in this study are similar to the results provided in previous studies. The mean (± SD) achieved HFO in the current study was 40 mm (± 6 mm). Massin et al. (2000) reported a mean (± SD) HFO of 41 mm (± 6 mm), and Noble et al. (2003) reported a mean (± SD) HFO of 43 mm (± 7 mm) [290], [291].

The achieved HFO was a mean of 1 mm (± 2.5 mm) greater than in the plan. Similar findings are reported in previous studies [153], [160], [209], [230]. Sariali et al. (2009) reported that the HFO was restored with a mean (± SD) of 0.8 mm (± 3 mm) [209], while Pasquier et al. (2010) reported a mean HFO discrepancy of 1.9 mm (± 4.7 mm) between the surgical plan and the achieved outcome [162]. Furthermore, Hassani et al. (2012) documented a mean (± SD) difference of 1.4 mm (± 3.1 mm) between the planned and achieved values of HFO [160].

The VFO discrepancy was slightly higher (median of 2 mm, IQR: -1 to 3 mm), and the data did not match the tendency expected for a normal distribution. This potentially
indicated a level of data asymmetry and inclusion of outliers, possibly contributing to an equality line that deviated from the regression line. However, the normality of the residuals was tested as one of the basic assumptions before implementing linear regression analysis, and according to the results a strong statistically significant correlation ($R^2 = 0.6; p<0.001$) was found between the surgically planned and achieved values. In this regard, 3D-CT planning was considered accurate in delivering the indented VFO.

These results are in accordance with those of previous studies using robotic tools. These have reported a mean discrepancy between the planned and achieved VFO of 2.7mm, with 75% of the cases within the clinically accepted threshold of 5mm [25]. In this study using 3D-CT planning, the median discrepancy was 2mm and 75% were within the clinically accepted limits.

Assessing the accuracy of 3D-CT planning in delivering the planned VFO is important; major deviation from the plan may contribute to post-operative LLD. Previous studies assessing the accuracy of 3D-CT planning software did not report the difference between the planned and achieved VFO. Instead, they focused on the restoration of LLD, reporting sufficient accuracy [153], [160].

In the present study, the VFO was planned to reconstruct the leg length with regard to the contralateral side. However, even an accurate restoration of the indented VFO does not directly imply an accurate reconstruction of LLD. VFO is defined as the distance between the CoR and the LT, while measurement of LLD usually includes the entire leg. There are several factors affecting the final leg length, which should be assessed in future research.
3.4.3 NFV: Is it a useable guide to plan the PFV of a straight-tapered femoral stem?

Anatomical twist of the proximal femur, known as NFV, is fundamental for a biomechanically stable hip joint; it defines the position of the GT relative to the knees and therefore the location of the muscles function [292]. Throughout human growth, NFV follows a downward trend, beginning with a value of 30° at birth and decreasing between 15° and 20° during adulthood [292]. NFV is considered to be normal within the same range [44]. However, NFV among adults with normal hip anatomy has been reported to have a large variability, ranging from -13° to 34° [43]. Existing literature has reported that this wide variation of NFV is apparent among adults of any age between 12 and 75 years old and does not vary significantly with age [292].

Most planning software use the patient’s NFV to plan PFV [230], [232], [233], [235]. However, the surgical target regarding PFV varies among surgeons’ philosophies [293], and it can be either planned to restore NFV [153], [230], or follow a specific target [209]. Although current literature has established the recommended positioning for the acetabular cup orientation, little has been has been written for the PFV in primary THA [231]. Given the wide variation of NFV and the fact that an abnormal value may even be a predisposing factor causing OA [43], [55], [294], following exclusively NFV may lead to a suboptimal PFV, potentially impacting the clinical outcome [235]. For this reason, the NFV was measured pre-operatively, but a constant PFV (20°) was used as surgical target.

In cemented femoral stem designs, the surgeon can adjust the PFV independently of the NFV using the malleable nature of the cement mantle, and therefore, there is no rationale to investigate the relationship between NFV and PFV [233], [288]. For conventional uncemented straight-tapered femoral stems, though, there is limited intra-operative control of the PFV, which is dictated by the internal morphology of the proximal femur.
In this context, it is questionable how the PFV compares to NFV and if NFV is a reliable guide for the 3D planning of PFV [233].

In the present study, the NFV of patients with OA ranged between -12° and 36°, and the PFV from -18° to 33°. The variability among the two measurements did not vary significantly (P=0.7). However, NFV was not a good predictor for PFV, and the LOA between the two variables were high at -17° and 15°. These findings are in accordance with existing literature. Previous studies, using different methodologies [29], [234], imaging techniques [233] and robotic surgical equipment [235], [268], have also documented a poor relationship between the NFV and PFV (Table 3-2). These reports indicate that whether or not the surgical procedure includes the guidance of the PFV, the surgeons have limited control of the orientation of an uncemented femoral stem. PFV has high variability, similar to the one of NFV in patients with OA, but NFV is not a good predictor for CT planning the PFV of an uncemented femoral stem.

Table 3-2: Previous studies comparing the NFV and PFV in primary uncemented THA.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Relationship of NFV and PFV</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present Study</td>
<td>r=0.6 (p&lt;.001)</td>
<td>3D-CT</td>
</tr>
<tr>
<td>Worlicek (2016) [268]</td>
<td>r=0.39 (p&lt;.003)</td>
<td>Navigation</td>
</tr>
<tr>
<td>Imai (2016) [234]</td>
<td>r=0.63 (p&lt;.01)</td>
<td>CT</td>
</tr>
<tr>
<td>Marcovigi (2019) [235]</td>
<td>r=0.5 (p&lt;.01)</td>
<td>Navigation</td>
</tr>
</tbody>
</table>

NFV, as currently measured, differs from the final anteversion of uncemented femoral stems, suggesting that there is a need to further study the anatomy of the proximal femur and improve 3D-CT planning. The version of the femoral stem is only partly dictated by the NFV, and the final position of the “best-fit” [235], [268], [295] stem (the PFV) is a
consequence of fitting a straight stem down the canal of a twisted and bowed proximal femur [295].

So far, limited studies have investigated different anatomical landmarks to guide PFV in primary uncemented THA. These measured femoral version across four levels of the intramedullary canal to indicate which mostly fits the PFV [29]. According to their findings, femoral canal version at the level of the LT mostly approximated PFV, with a mean difference of 0.1º (P=0.88), potentially suggesting this landmark for pre-operatively planning of PFV. However, these studies have used 2D imaging tools and only evaluated if the means of planned and achieved values varied significantly, not assessing the reliability of this particular landmark as a predictor of PFV and raising doubts about its use as a guide for CT planning [29].

In uncemented surgery, tight press-fit implantation of the femoral stem into the bone does not allow for any intra-operative surgical control of its version [231], [235], [238], [268], [295]. Femoral stem designs featuring modular necks or the variable thickness of the cement mantle in cemented fixation offer greater control of PFV [209], [231], [233], [266], [288], [295]. Furthermore, customised designs of femoral stems may better fit into the highly variable calcar region, resulting in a final position that better reconstructs the natural twist and bow of the patient’s femur [296]. Finally, given the limited surgeon control of an uncemented straight stem, the concept of the Combined Version (CV) – the sum of cup and stem version angles-was recently proposed to avoid dislocation in primary THA, recommending a value of the CV within 25-50º [288].

In this study, there were two dislocations. Of these, only one had a CV outside the optimal range, although both were planned within a CV of 40º. However, this low percentage of dislocations does not allow exporting of any conclusion about the influence of both the
stem and cup AV and of the CV on the incidence of dislocation. Future long-term studies with sufficient clinical data are required to determine this information.

3.4.4 Intra-operative translation of 3D planning metrics

In this study, the surgical plan was available to the surgeon preoperatively. This plan primarily reported the chosen type and size of the prosthetic components, the planned PFV, and the measurements characterising the level and angle of the osteotomy and leg length. Intra-operatively, the surgeon accessed the femoral canal using standardised surgical instrumentation and chose the femoral stem size by trialling sequentially increasing femoral rasps though having all the prosthetic component sizes available. In addition, although the planned PFV was 20°, the surgeon had limited control over changing the orientation of the femoral stem due to press-fit fixation to the internal femoral canal. Finally, the surgeon attempted to deliver the pre-operative measurements regarding the osteotomy, reflecting the planned VFO and leg length, through the PSI osteotomy guide.

In this context, the surgical plan constitutes a starting point for hip surgery regarding the prosthetic component size and version. However, intra-operatively, the surgeon incorporates his experience and surgical tools to open and prepare the femoral canal. This step may introduce a certain level of human variability, and future multi-centre studies would be necessary to define its effect on the reproducibility of the surgical plan in primary THA. Additionally, surgeons could intra-operatively measure the planning metrics through robots, navigation, or intra-operative measuring tools. In this study, these tools were not available, and the reproducibility of the surgical plan was defined post-surgery and through measurements on post-operative CT scans.
3.4.5 Limitations

To assess the accuracy of this 3D-CT surgical planning, pre- and post-operative CT scans were collected and processed to generate the 3D models of the patient’s anatomy and implants. 3D-CT image analysis techniques were then applied to measure the pre-operative and post-operative variables included in the analysis of the current study. The main limitation of this method relies on the measurement error of the post-operative analysis due to the manual selection of landmarks, the metal artefact and the scanning procedure. This was addressed by utilising an established methodology and by performing repeatability and reproducibility analysis tests. In addition, the results were compared with those of previous studies.

Overall, the processing chain of the implemented method included automated steps that aimed to eliminate the variability of the outcome measures. However, the adopted methodology included the selection of implant and bony landmarks to define axes and planes, necessary to compute certain variables. In this context, manual selection of even clearly identifiable anatomical landmarks to define subject-specific anatomical reference frameworks is subjective due to the variable human bony morphology. This step may result in slightly different coordinates of the chosen landmarks among the same and different users, affecting the end-outcome variability.

Nevertheless, according to the intra- and inter-observer analysis results, the method of measuring PFV proved reliable, as the ICC was more than 0.99 in both cases. Furthermore, PFV was measured using an external, commercially available, software, reporting good agreement with the results of this study. Regarding the FO and NFV measurements, an established methodology was utilised [230], [275], while the values of NFV and FO reported in this study are in accordance with the existing literature. Finally, previous studies have assessed the precision of the same landmarks acquisition, reporting
excellent results [225], and validated the measurement of NFV based on 3D-CT models against dry-bone measurements [276].

However, in this study the LOA in the inter-observer analysis were broader than the inter-observer analysis. A potential explanation may be that the training of the second operator included only one demonstration of where the typical landmarks lie in a representative 3D model of the femoral morphology. These findings indicate that the manual selection of specific landmarks may depend on the user’s experience and the time devoted to training, potentially improving with time.

Additionally, the CT scans have not been calibrated, and the patient’s position within the scanner may not be constant during the scanning procedure. However, PFV angles were measured using a standardised coordinate system that is not affected by the patient’s position within the scanner. Furthermore, the present study did not demand a thorough examination of the bone implant interface. The prosthetic components were CT-reconstructed to choose clearly identifiable landmarks. Therefore, even if the CT scans had not been calibrated, implementation of a constant Hounsfield Units (HU) threshold resulted in a sufficient 3D visualisation of the prosthetic components.

3D-CT analysis offers various advantages in comparison with conventional radiography. However, post-operative evaluation using CT scans requires a certain amount of radiation exposure [174], [178]. All patients in this study underwent post-operative CT scanning using a low-dose scanning protocol designed to minimise radiation exposure while preserving spatial accuracy [4].

Furthermore, the constraints of this study include the single femoral stem design adopted. Similar conclusions reflecting other implant designs cannot be exported. However, previous studies using different methods and implant designs reported similar results. Additionally, all surgeries were performed through a posterior approach. Different
Evaluating current 3D-CT planning of a straight-tapered femoral stem surgical approaches may influence the PFV. Furthermore, selecting the most appropriate implant size during pre-operative planning includes a certain level of subjectivity, potentially affecting the analysis of the implants size and FO. Previous studies have proved this step has excellent repeatability and reproducibility [213]. Finally, this single-surgeon series study does not reflect the influence and variability of the surgeon on the PFV. Nevertheless, the surgeon has very little control over the PFV of a straight-uncemented femoral stem, as stated in previous studies documenting the PFV reported from three different orthopaedic centres [235].

In addition, the planned size and position of the prosthetic components used in this study were determined by an external planning software within a 3D-CT reconstructed model of the patient’s femur (MyHip Planner, Medacta International SA, Castel San Pietro, Switzerland). This surgical plan was saved as an STL file and imported in Simpleware. However, the 3D-CT reconstructed models of the patient’s anatomy, as generated by the external planning, were not used for the measurements of this chapter, which may have induced subtle differences due to mesh reconstruction between the two software.

First, NFV and PFV measurements were based on the 3D-CT reconstructed models as generated by Simpleware. Regarding the FO measurements, all measurements were based on either the STL models of the femoral stem and the pre- and post-operative 3D-CT reconstructed models as generated by Simpleware. However, differences in the coordinates of the STL model of the femoral stem due to the export-import steps would affect the outcome measurements, even if this was generated in the coordinates from the same CT scans. The 3D model of the external surgical plan was loaded in Simpleware superimposed on the original CT scans, confirming visually that this follows precisely the contours of the patient’s bony anatomy for each case. This step ensured that the coordinates of the STL representing the planned position of the femoral stem are the same as the original CT scans.
Finally, proving the accuracy of this recently introduced technology is important. It signifies to what extent the surgical plan is reproduced during the surgery. This quantification can be further utilised as a benchmark to enable comparison with current and future technologies to improve surgical outcomes. However, it is not clear whether the presence of 3D computerised planning contributed to a better survival rate and a long-term clinical outcome. It is assumed based on the fact that correct implant sizing and positioning may positively affect the clinical outcome. Future research has yet to show the contribution of 3D planning to a better post-operative clinical outcome through long-term controlled studies showing that a more accurate reconstruction of anatomical variables, such as the FO or the PFV, using 3D-CT planning can result in improved PROMS or functional outcomes including gait analysis and hip ROM, when compared to patients where the FO or PFV reconstruction exceeds certain thresholds.
3.5 Conclusion

This study aimed to evaluate the accuracy of 3D-CT planning in terms of component size, position and orientation in primary uncemented THA using a straight-tapered femoral stem. Surgical planning was proven accurate in predicting the optimal component size and FO. Predicting the PFV was defined as the unmet need of 3D-CT planning.

The native version of the proximal femur (known as NFV) is not a reliable variable to predict the PFV of an uncemented straight-tapered femoral stem. The final position of the femoral stem is a compromise of implanting a straight femoral stem into the complex shape of the internal femoral canal.

Understanding how a straight femoral stem fits within the internal morphology of the proximal femur and its association with the PFV, may help improve current planning approaches towards a primary uncemented THA.
3.6 Key Findings

The key findings of this chapter are:

◊ 3D-CT planning can deliver 96% of the component sizes within one size of the surgical plan.

◊ 3D-CT planning can accurately predict achieved HFO and VFO, since regression analysis revealed a strong correlation between the planned and achieved values for both variables. These findings suggest that surgeons can use 3D-CT planning to achieve the HFO and VFO with a high level of accuracy to the plan.

◊ Planning and delivering the PFV was defined as the unmet need of 3D-CT planning. The NFV was not a reliable landmark for planning the PFV. The lower and upper 95% LOA were high at -17° and 15°, and the discrepancy was large enough to recommend against the use of NFV for planning the PFV of a straight un cemented femoral stem. These results indicate the need to improve current planning approaches and target philosophies regarding the PFV in primary, un cemented THA.
Evaluating current 3D-CT planning of a straight-tapered femoral stem
Understanding how an uncemented straight femoral stem fits within the internal femoral canal
Subchapter 3A: Understanding how an uncemented straight stem fits within the internal femoral canal

3A.1: Introduction

The PFV of an uncemented straight femoral stem was reported to significantly deviate from the NFV and the surgical target (20°), showing a range from -18° to 33° (see chapter 3). The final position of the femoral stem is a compromise of implanting a rectangular component within the highly irregular anatomical space of the proximal femur [295].

In this context, understanding how an uncemented straight femoral stem fits within the intramedullary femoral canal may provide the basis for predicting the final position and orientation of the femoral stem component. The final position and orientation of the implant within the femoral canal can be correlated to the areas of contact between the implant and the bone [297].

Currently, plain radiography remains the standard tool to assess post-operative implant position in spite of its significant drawbacks [298]. Advanced computational methods applied to CT overcome these limitations and can also offer bone density information [187], [289], [298].

This subchapter describes a method of deriving the areas of contact between the femoral stem and the internal femoral canal. Additionally, it constitutes an attempt to illustrate and understand how the bone-implant contact areas vary in femoral stems of different PFV.

3A.1.1 Motivation

From a surgical point of view, assessing the contact areas of an uncemented femoral stem at the corticocancellous interface is useful to inform the orthopaedic surgeon about the
achieved position of the femoral implant inside the proximal femur. This may improve current methods of preparing the femoral canal and reduce the possibility of malposition during a primary uncemented THA.

3A.1.2 Aim

To better understand the areas of 3D bone-implant contact of an uncemented straight tapered femoral stem in association with PFV.

3A.1.3 Objectives

To achieved this aim, the objectives were:

◊ To define a method of deriving the contact areas of the implant with the cortical bone using 3D-CT analysis.
◊ To build a heat map indicating the most prominent areas of contact between the implant and the bone.
◊ To illustrate the variability in contact areas between femoral implants of different PFV.
3A.2: Material and methods

3A.2.1 Study Design

A prospective study comprising the single surgeon series of Chapter 3 was designed. Two 3D models were computed, first, the pre-operative proximal 15 cm of the femoral surface and its corticocancellous interface, and secondly, the post-operative proximal 15 cm of the femoral surface and its implant. The two models were co-registered using their femoral surfaces, resulting in one 3D model containing the femoral surface, corticocancellous interface and the implant. Contact regions of the implant with the cortical bone were derived using computational methods and then registered to a reference implant to construct a heat map indicating prominent areas of contact. Distinct heat maps were computed, to measure and illustrate the variability in contact areas between femoral implants of different PFV.

3A.2.2 Pre-Operative CT Analysis

The surgical plan - 3D models of the femoral stems within the proximal femurs - was loaded in Simpleware ScanIP (Version 2021.03; Synopsis, Inc., Mountain View, USA). Additionally, pre-operative CT data were processed by intensity thresholding tools in Simpleware ScanIP (Version 2021.03; Synopsis, Inc., Mountain View, USA), to generate the 3D models of the corticocancellous bone of the proximal femur. A threshold of 600 HU was used to generate the cortical interface; it has been showed to accurately depict the corticocancellous interface of the proximal femur after surgical femoral preparation rasping, although dimensional inaccuracies may exist [187]. Finally, the resulting mask was manually adjusted to close open gaps, Figure 3A-1.
3A.2.3 Post-Operative CT Analysis

3D models of the post-operative implants and proximal femurs were generated, using intensity thresholding tools in Simpleware ScanIP (Version 2021.03; Synopsis, Inc., Mountain View, USA). For the 3D-CT models of the patient’s anatomy, a constant threshold range (200–1500 Hounsfield Units-HU) was used for all cases. For the implants, a threshold of >1700 HU was used.

The 3D-CT reconstructed models of the post-operative femoral stems included noise due to metal artefacts (red model in Figure 3A-2), negatively affecting the visualisation of the contact area between the stem and the cortical bone. For this reason, Computer-Aided Design (CAD) files of the respective femoral stems (blue model in Figure 3A-2) were
superimposed on the post-operative segmented femoral stems [289], [299], using an automatic rigid registration in Simpleware (Version 2021.03; Synopsis, Inc., Mountain View, USA), Figure 3A-2. A surface Boolean intersection between the two manifold meshes was then implemented to exclude the unshared areas of triangular facets and create a model representing a femoral stem without metal artefacts (yellow model in Figure 3A-2). This step was completed using the Mesh Boolean operation module in Simpleware (Version 2021.03; Synopsis, Inc., Mountain View, USA), where two meshes are given as inputs and a mesh representing the intersection area of the two is automatically computed.

Figure 3A-2: The CAD models of the femoral stems were registered with the segmented models of the prosthetic femoral components. A surface boolean
operation (intersection) was used to extract the area of the femoral stem that does not include metal artefacts.

3A.2.4 Pre- and Post-Operative CT Alignment

The corticocancellous interface of the proximal femur was not clearly visible on post-operative CT data, due to metal artefacts. To overcome this limitation, the pre- and post-operative CT data were registered using as a reference the surgical plan, Figure 3A-3. This was accomplished using the Simpleware automated registration module (Version 2021.03; Synopsis, Inc., Mountain View, USA).

Figure 3A–3: Registration of pre- and post-operative CT-reconstructed models was implemented using as a reference the surgical plan. This resulted in a 3D model
depicting the post-operative femoral implant within the intramedullary cavity of the pre-operative segmented femur.

3A.2.5 Contact Patterns and Heatmap

The contact regions of the femoral stem on the internal cortical bone are the regions where the femoral stem abuts the internal cortex. In other words, the contact regions are represented by the neighbouring pixels of the registered post-operative femoral stem and the pre-operative corticocancellous interface. To derive these neighbouring pixels, the corticocancellous interface was increased 1 pixel and Boolean operations (Intersection operation) was subsequently applied. The resulted intersecting regions represent the contact regions of the femoral stem and the cortical bone, Figure 3A-4. The mask including the contact regions was saved as MetaImage MetaHeader (.mhd) file for further process.

Figure 3A–4: (a) The segmented model of the pre-op femur (green mask), (b) is increased 1 pixel. (c) Boolean operations give the intersection regions (yellow mask)
between the femoral implant (red mask) and the cortical interface. These regions represent the contact regions of the femoral implant and the cortical bone.

This methodology was repeated to derive contact regions at the corticocancellous interface for each stem. There was a need, however, to develop a method to group the femoral stems based on their contact areas. It would be, therefore, convenient to utilise colour mapping to digitise and visually delineate the contact state by colour for groups of femoral stems in the same configuration.

For this reason, a number of Python software scripts were computed to first register all the femoral stems and their contact regions to a reference femoral stem and then to construct a colour-map indicating areas of most contact at the corticocancellous interface, Figure 3A-5. The registrations were performed using the image analysis toolkit SimpleITK in python [300]–[302]. The femoral stems were of a single design but of different sizes. A two-step registration was used, with affine registration as initial condition and B-spline registration as final step. An affine registration preserves lines and planes but enables scaling, while B-spline is a deformable registration which uses Bspline curves to map each voxel in the moving image to the corresponding voxel within the reference image [303], [304]. This ensured mapping femoral stems of different sizes and their contact points to a single size reference femoral stem.

The MetaImage files including the registered contact regions were loaded into Simpleware, added and then normalised to create one file, representing areas of most contact. The adding background module in Simpleware was used to add up and normalise the different backgrounds representing the distinct registered contact regions (Version 2021.03; Synopsis, Inc., Mountain View, USA). Consequently, the collective MetaImage file was loaded into Matlab (R2020b, MathWorks, USA), where the volume viewer application was used to illustrate areas of most contact using a custom colourmap. Areas
of contact are depicted in purple (most right figure in 3A-5), where the intensity of colour indicates where most femoral stems achieve contact with the cortical interface.

Figure 3A–5: The contact regions of distinct femoral implants (MetaImage format) were non-linearly registered to a reference femoral implant and then normalised, to create a colour map indicating areas of contact.

To investigate the variability of the contact regions between femoral stems of different PFV, the femoral stems were classified into three different groups based on the measured PFV: femoral stems with a PFV of less <10°, 10-25°, and more than >25°. The femoral stems and contact regions of each group were overlayed and registered, and contact colour-maps were constructed implementing the steps described above for each group of PFV.

The modified Gruen Zones classification system was adopted to illustrate and analyse the contact regions [299]. The proximal femur implant interface was split into 7 zones, with each zone subdivided into anterior and posterior segments.
3A.3 Results

Figure 3A-6 shows the contact areas between the femoral stem and the corticocancellous interface per group of PFV using the modified Gruen zone system. On the left, a representative 3D model of the femoral stem within the femur is given in the anteromedial view to identify the Gruen zones. On the right, three models of femoral stems with colour mapping reflecting the contact state represent the three groups of PFV (less <10°, 10-25°, and more than >25°). Colour intensity reflects contact state, varying from light blue, indicating no contact, to dark purple, indicating where most stems achieve contact with the cortical bone.

There were 37% of the femoral stems with a PFV of less than 10°, 52% with a PFV of 10-25°, and 11% with a PFV of more than 30°. Each group of PFV was characterised by contact at the anterolateral mid-portion (Gruen zone 2A) and the distal posteromedial (Gruen zone 5P) aspect of the bone-implant interface. Additionally, all groups of PFV demonstrated contact at the antero-medial aspect of the bone-implant interface (Gruen zone 6A). However, the group of >25° showed magnified contact at zone 6A. At the most proximal part of the bone-implant interface, femoral implants with a PFV of less than 25° were in contact both at the anterior and posterior zones (Gruen zones 7A and 7P), but the extent and location of the contact slightly varied among groups. Femoral implants with a PFV of more than 25° were more in contact at Gruen zone 7A when compared to Gruen zone 7P.
Figure 3A–6: Bone-Implant coloured maps in distinct groups of femoral stems of different PFV using the modified Gruen zones classification system.
3A.4 Discussion

In cementless femoral stems designs, primary fixation is obtained by tightly press-fitting the femoral component into the bone. Ideally, the femoral stem should be adequately fixated to the bone, characterised by bone-implant contact in the ML cortexes of femoral metaphysis [112], [298], and followed by rotational stability and proximal load transfer [299]. Achieving initial fixation is critical in minimising early complications like loosening and stress shielding, potentially resulting in revision THA [125], [298].

In primary uncemented THA, conventional radiography is often used to assess the contact between the femoral stem and the cortical bone [298]. The procedure includes recording bone remodelling and stem subsidence through bone hypertrophy, spot welds, and reactive lines on 2D X-rays using the conventional Gruen zones classification [299]. However, the 2D nature of radiographic analysis and the operator's subjectivity pose limitations [298]. Also, despite the fact that plain radiography allows visual assessment of bone quality, it does not offer a more accurate quantification of bone density [157]. CT analysis is regarded as a more accurate option to evaluate the corticocancellous interface of the proximal femur [187].

Existing literature has investigated the contact state of an uncemented femoral stem and the cortical bone using a commercially-available CT planning platform (ZedHip, LEXI Co, Ltd, Tokyo, Japan). This platform performs a density mapping to digitise the contact state of the implant based on HU values taken from pre- and post-operative aligned CT data [289], [297]–[299].

This subchapter aimed to generate the contact areas between the stem and corticocancellous interface using consecutive algorithmic steps and to visually identify if there is any link between the bone-implant contact regions and the PFV in primary
uncemented THA. Therefore, a computational method of mapping all the distinct contact regions of 79 femoral stems of different sizes to a single femoral component was proposed. This step was done to consider variations in implant size, representing the contact state on the surface area of a reference femoral stem. The reference femoral stem was a size 3 (the median size of the whole cohort). Choosing a reference femoral stem of a different size (e.g., a size of 5 instead of 3) would have resulted in similar contact areas, analogous to the femoral stem size, between the femoral and the corticocancellous interface.

3D-CT analysis allowed the visual assessment of the bone-implant contact areas of femoral stems of different PFV angles. This information equips the surgeon with the knowledge of where most femoral stems achieve contact within the femur. In this regard, surgeons could use this information to prepare the femoral canal accordingly, taking care of these areas during the rasping procedure, and then position the stem intraoperatively.

However, determining representative ways in which an uncemented femoral stem fits within the internal femoral canal was challenging. This was partly due to the fact that the sample size of each PFV group was different. In addition, femoral implants of different PFV were consistently in contact with the cortical bone at zones 2A and 5P, but the contact areas at the most proximal part of the bone-implant interface were variable (Zones 7A and 7P). Figure 3A-7 illustrates cross-sections of femoral implants of different PFV within the intramedullary canal and their corresponding contact areas. The extent and location at which the femoral stem abuts the internal proximal cortex are variable among femoral stems of different PFV. The explanation for this variability may lie in the complicated anatomy of the proximal femur compared to the area of the intramedullary cavity that hosts the distal part of the femoral implant.
Figure 3A–7: Cross-sections illustrating how the femoral stems of different PFVs are in contact with the cortical bone within the internal femoral canal. Red arrows indicate the level of cross-section. The green mask depicts the femoral stem, the red mask the contact area at this specific cross-section, and the white mask the proximal femur.

Although the methodology adopted in this subchapter resulted in an illustration of the contact areas between the implant and bone, it did not provide a quantitative analysis of the contact at the bone-implant interface. For this reason, it constituted a visually complementary subchapter of Chapter 3. Future studies are needed to quantify the contact regions and find potential associations with the achieved position of the femoral stem. In this context, quantifying the contact areas could include the calculated surface area of contact with respect to the total surface of the femoral stem and the Gruen zones. Researchers could then use this quantitative information to seek association with any parameters characterising the achieved position of the femoral stem or the clinical outcome.
The contact areas were defined as the intersecting pixels between the meshes of the femoral stem and the corticocancellous interface. In this regard, the resulting areas are primarily sensitive to the thresholding of the cortical interface and, secondarily, to a much lesser extent, to the thresholding of the femoral stem. Existing scientific evidence has reported that generating 3D surface models using CT scans has a mean error of half the voxel size of the CT scan [219].

The validity of the methodology adopted mainly depends on whether the segmented pre-operative cortical interface represents the post-operative corticocancellous interface after rasping. In light of this, the corticocancellous interface was segmented using a constant HU threshold [298]. This specific threshold has been reported to accurately depict the corticocancellous interface after rasping [187]. Furthermore, previous studies have used the same range to design patient-specific femoral stems [305], and to illustrate the bone-implant contact areas [299]. Finally, previous studies have reported similar areas of most contact between a different design of femoral stem and the cortical interface after a primary THA [299].

Additionally, the derivation of the contact areas lies on a 3D intersection of two manifold meshes, one representing the achieved position of the femoral stem and another depicting the femoral cortical interface after rasping. This method is independent of the patient’s position within the scanner, as it is not dependent on any measurements taken on the CT slices. However, the visual findings of this study do not consider any micromotion of the femoral stem within the femur, as they are not derived from weight-bearing CT scans to count for any over-time movement of the implant within the femur.

One further limitation of this study is the single femoral stem design adopted. Alternative shapes of femoral stems would have resulted in different contact areas. Furthermore, assessing post-operative implant position using CT is complex; not only because it
Evaluating current 3D-CT planning of a straight-tapered femoral stem requires post-operative CT image acquisition and analysis, therefore increasing radiation dose, but also due to the lack of standardisation of scanning protocols [178]. In this study, a standardised low-dose scanning protocol was utilised for all patients (see Paragraph 3.2.2).

As far as the repeatability of the methodology is concerned, this subchapter integrated a fully automated processing chain, including registration, computational methods, and algorithmic procedures, that aimed to eliminate the variability in the outcome measures. However, the co-registration of pre- and post-operative CT scans, although automatic, may have introduced some error due to the metal artefact of the post-operative CT. Previous studies assessing the repeatability and reproducibility of CT measurements, including pre- and post-operative CT registration, have reported an ICC>0.96 and a mean difference below half a millimetre between the same and among different users [230]. Elsewhere, the registration algorithm was evaluated with random simulated noise due to metal artefacts, confirming its successful outcome in terms of pre- and post-operative CT registration [306].
3A.5 Conclusion

3D-CT analysis is a useful tool to assess the initial fit-fill of the femoral implant after a primary THA; it offers better definition of the corticocancellous interface, which is not clearly visible using plain radiographs.

All groups of PFV showed contact in zones 2A and 5P. In addition, all groups of PFV were in contact with zone 6A, but the group of >25° demonstrated a magnified contact in that area. With regard to the proximal part of the bone-implant interface studied, the contact areas with a PFV of less than 25° were slightly different. The group of >25° was more in contact with the anterior aspect of the proximal femur when compared to the posterior aspect.

Even though groups of different PFV showed common areas of contact (zones 2A and 5P), the differences in contact in the most proximal part of the bone-implant interface and the unequal sample sizes of the different groups impeded the identification of any representative contact patterns.

There is a need to assess the initial fit-fill state of other designs using 3D-CT analysis and a larger sample size and further study the relationship between the contact patterns and the anatomy of the proximal femur.
3A.6 Key Findings

The key findings of this chapter are:

◊ Representative mechanisms of femoral stem fitting within the internal morphology of the proximal femur could not be identified. The extent and location at which the femoral stem abuts the internal proximal cortex are variable among femoral stems of different PFV.
Understanding the impact of the fixation technique on PFV
Chapter 4 Understanding the impact of the fixation technique on PFV

4.1 Introduction

3D-CT pre-operative planning is considered an essential step in the preparation of primary THA [4], [160], [190], [198], [200], [258]. However, planning and achieving the intended PFV in uncemented THA using a straight-tapered femoral stem is challenging (see chapter 3).

Commercially available surgical planning platforms typically use references characterising the external surface of the proximal femur (NFV) to plan the version of the femoral stem, known as PFV [209], [230], [232], [233]. In contrast, the final position of an uncemented stem is a consequence of press-fitting a specific stem design into the highly variable anatomy of the internal femoral canal [295]. As a result, PFV has been reported to be highly variable in primary uncemented THA, ranging from -23° of retroversion to 72° of anteversion [9], [30], [31].

Sufficient PFV is critical to ensure rotational stability, normal torsional moments, and an overall good long-term clinical outcome [6], [236], [237], [265]. An increased prevalence of dislocation has been reported to correlate with low PFV angles in primary THA via a posterior approach [238], [263], [265]. In addition, previous studies have highlighted that delivering a PFV of less than 10° is detrimental to the rotational stability of the reconstructed hip joint, while impingement is common in uncemented femoral stems with a PFV of less than 5° [6], [266].

The malleable nature of the cement mantle in the cemented fixation allows the surgeon to adjust the PFV independent of the anatomy of the intramedullary canal, and may be considered a targeted approach to deliver an adequate PFV [231], [233], [266], [288].
this context, this chapter aims to better understand the effect of the fixation technique on PFV.

4.1.1 Motivation

Existing literature has reported a lower incidence of revision and dislocation in the cemented THA [138], [140], [307]. Given this information and the fact that PFV is associated with possible untoward clinical events, it is important to know how the fixation method affects PFV.

The motivation behind this chapter was to understand if the cemented fixation can achieve a more clinically accepted PFV, potentially improving the clinical outcome of patients undergoing primary THA through the minimisation of complications associated with incorrect implant orientation.

4.1.2 Aim

To better understand the impact of the fixation method on PFV using 3D-CT image analysis.

4.1.3 Objectives

To achieve this aim, the objectives were:

- To measure and compare the PFV angles in uncemented and cemented primary THA using 3D-CT image analysis.
- To assess the clinical outcome including dislocation.
4.2 Materials and Methods

4.2.1 Study Design

Figure 4-1 illustrates the study design of this chapter.

Figure 4–1: Study design.

This was a prospective non-randomised controlled study including 106 hips of 95 patients that underwent primary THA due to OA between February 2017 and June 2021. Two groups of patients were consecutively studied: 1. A group of 73 patients (81 hips) undergoing primary uncemented THA; 2. A group of 24 patients (25 hips) undergoing primary cemented THA (Table 4-1). PFV angles were measured, using the post-operative CT data, in both groups and subsequently compared to understand the impact of the fixation method on PFV. In addition, the clinical outcome, including dislocation, was evaluated.
The outcome measures were:

1. NFV angles in the uncemented and cemented THA groups.
2. PFV angles in the uncemented and cemented THA groups.
3. Clinical outcome including dislocation rate.

Table 4-1: Study Group Characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Uncemented Group (n=81 Hips)</th>
<th>Cemented Group (n=25 Hips)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (Females) (%)</td>
<td>40 (49)</td>
<td>14 (56)</td>
<td>0.57</td>
</tr>
<tr>
<td>Age (Years) (Median, Range)</td>
<td>62 (32-86)</td>
<td>64 (42-89)</td>
<td>0.45</td>
</tr>
<tr>
<td>Treatment Side (Right) (%)</td>
<td>42 (52)</td>
<td>17 (68)</td>
<td>0.16</td>
</tr>
</tbody>
</table>

4.2.2 Pre-operative CT scanning

All patients had pre-operative low-dose CT scans according to the scanning protocol described in Chapter 3 (see Paragraph 3.2.2).

4.2.3 Processing of the pre-operative CT scans

The pre-operative CT scans were processed in Simpleware ScanIP (Version 2021.03; Synopsis, Inc., Mountain View, USA), to generate the 3D models of the patients’ anatomy according to the methodology described in Chapter 3 (see Paragraph 3.2.3 and Figure 3-2).

4.2.4 External surgical planning

All patients underwent 3D-CT pre-operative planning to define the appropriate acetabular and femoral component sizing and position (MyHip, Medacta International SA, Castel San Pietro, Switzerland). The surgical planning of the prosthetic components in both
uncemented and cemented THA groups was done according to the same criteria described in Chapter 3 (see Paragraph 3.2.4). Cup inclination and anteversion angles were planned at 40° and 20°, respectively. Intra-operatively, the plan was a PFV of 20°.

4.2.5 Surgical approach, prosthetic components and PSI

All surgeries were performed through a posterior approach by a single consultant orthopaedic surgeon. A straight tapered femoral stem was adopted in the uncemented THA group (Quadra-H; Medacta International SA, Castel San Pietro, Switzerland). In the cemented THA group, a collarless double-tapered femoral stem was used (X-Acta system; Medacta International SA, Castel San Pietro, Switzerland). In both THA groups, a hemispheric press-fit HA coated cup was used. In the surgery, a PSI guide was used to cut the femoral head-neck junction (MyHip from Medacta, see Figure 2-30a).

4.2.6 Pre-Operative CT analysis

NFV angles were measured based on the 3D-CT reconstructed models of the preoperative proximal femurs for both THA groups according to the methodology described in Chapter 3 (see Paragraph 3.2.6).

4.2.7 Post-Operative CT scanning

All patients underwent low-dose CT scanning of the hip and the knee joint according to the scanning protocol described in Chapter 3 (see paragraph 3.2.2).

4.2.8 Processing of the post-operative CT scans

3D models of the post-operative femurs and prosthetic components were generated, using Simpleware ScanIP software (Version 2021.03; Synopsis, Inc., Mountain View, USA). The CT scans were corrected for metal artefacts using the NMAR algorithm (see Paragraph 3.2.8) [171].
4.2.9 Post-Operative CT analysis

PFV was measured based on the 3D-CT reconstructed models as the angle between the stem neck axis and the PCA using the same coordinate system defined in Chapter 3 (see Paragraph 3.2.10), Figure 4-2.

**Figure 4–2: A schematic illustration of the methodology adopted to measure PFV in both THA groups.**

Figure 4-3 depicts the definition of the stem neck axis in both uncemented and cemented femoral stem designs; the line connecting the post-operative CoR and an identifiable landmark at the top lateral area of the femoral stems.
Figure 4–3: Definition of the stem neck axis in uncemented and cemented femoral stem designs.

The cemented femoral stem design includes the top landmark at a slightly different location. Figure 4-4 depicts an axial view of the cemented femoral stem design, showing that this point is located in the middle of the cemented stem neck, ensuring that the designated axis bisects the cemented design.

4.2.10 Statistical analysis

Statistical analysis software (SPSS, version 28, Chicago, USA) was used to compute the descriptive statistics of the outcome measures.

Normality of data was tested using the Shapiro-Wilk test in both THA groups [279]. Differences between the two THA groups with regards to the study group characteristics, were evaluated using the Mann-Whitney U test [308].

Considering that the data describing the NFV and PFV angles had different sample sizes, an assessment of any statistically significant difference between the two THA groups was done using the Welch’s test [309]. A BA plot was used to show the discrepancy and
measure the LOA between NFV and PFV in both THA groups. Statistical outliers were determined using the Tukey method [285], [286].

![Figure 4-4: a) The location of the top landmark at the middle of the stem neck in the cemented design (from Medacta.com), b) ensures that the defined neck axis bisects the neck of the cemented femoral stem. The right figure depicts a 3D representation of a surgical plan using a cemented femoral stem, oriented according to the coordinate system used in this chapter, for illustration purposes of the stem neck and PCA axes, using the landmarks chosen in this chapter.](image)
4.3 Results

4.3.1 NFV in uncemented and cemented THA groups

The data describing the NFV in the uncemented THA group were normally distributed (Shapiro-Wilk, p=0.3). The data describing the NFV in the cemented THA group did not match the tendency expected for a normal distribution (Shapiro-Wilk, p=0.04). In the uncemented THA group, the median (IQR) NFV was 14° (7° to 20°). The cemented THA group had a median (IQR) NFV of 14° (10° to 18°).

In the uncemented THA group, 20% of the patients had a NFV of between 0° and 5°, whilst 1% of the patients had retroversion of their native femur (<0°). A NFV of between 5° and 10° and between 10° and 15° was reported in 15% and 16% of the patients, respectively. Furthermore, 23% of the patients had a NFV of between 15° and 20° and 15% had a NFV of between 20° and 25°. A NFV of between 25° and 30° was reported in 10% of the patients, Figure 4-5.

With regard to the distribution of NFV in the cemented THA group, 12% of the patients had a NFV of between 0° and 5°, whilst 4% of the patients had retroversion of their native femur (<0°). A NFV of between 5° and 10° and between 10° and 15° was reported in 8% and 36% of the patients, respectively. Furthermore, 28% of the patients had a NFV of between 15° and 20° and 4% had a NFV of between 20° and 25°. A NFV of between 25° and 30° was reported in 8% of the patients, Figure 4-5.
Figure 4–5: NFV distribution in the uncemented and cemented THA groups.

Discrepancy between NFV and PFV of individual cases in both THA groups

Figure 4-6 depicts a BA plot showing the lower and upper LOA between the NFV and PFV in both THA groups. In the uncemented THA group, a BA analysis showed that the mean difference between NFV and PFV was low, but the upper and lower LOA were both high at -17° and 15°.

In the cemented THA group, the mean difference between NFV and PFV was greater (10°), and the LOA were narrower. In detail, the lower LOA was only at -2°, and the upper LOA was high at 23°.
Figure 4–6: BA plot of the comparison between NFV and PFV of individual cases in a) the Uncemented THA group and b) the Cemented THA group.
4.3.2 Comparison of PFV in uncemented and cemented THA groups

The data describing the PFV in uncemented and cemented THA matched the tendency expected for a normal distribution (Shapiro-Wilk, p1=0.2; p2=0.2). In the uncemented THA group, the mean (± SD) PFV was 13° (± 9°) (median=13°; IQR= 8 to 17°; min=-18°; max=33°). There were two outliers outside the box and whisker plot of the data describing the PFV in the uncemented THA group. These included two patients having a PFV of -18° and 34°, respectively. In the cemented THA group, the mean (± SD) PFV was 23° (± 8°) (median=24°; IQR= 18 to 28°; min=5°; max=34°). There was a statistically significant difference between the mean values of PFV in two THA groups (p<0.001), Figure 4-7.

![Box and whisker plots comparing the PFV angles in the uncemented and cemented THA groups (*p<0.001).](image_url)
4.3.3 Range of PFV in the uncemented and cemented THA groups

In the uncemented THA group, PFV measurements ranged from -18° retroversion to 33° anteversion. Five patients in the uncemented THA group had retroverted PFV. In the cemented THA group, PFV values ranged between 5° and 34°, Figure 4-8.

**Figure 4-8:** Range of PFV in the a) uncemented THA group and b) cemented THA group. Each horizontal bar represents the PFV [Deg] per case in both THA groups.

4.3.4 Distribution of PFV in the uncemented and cemented THA groups

**Uncemented THA group**

A PFV of less than 5° was reported in 20% of the femoral stems. Sixteen per cent (16%) of the femoral stems had a PFV between 5° and 10° and 25% had a PFV between 10° and 15°. A PFV of between 15° and 20° and between 20° and 25° was reported in 21% and
7% of the femoral stems. Finally, 11% of the femoral stems were anteverted of more than 25°, Figure 4-9.

Cemented THA group

In the cemented THA group, 8% of the femoral stems reported a PFV between 5° and 10° and between 10° and 15°. A PFV of between 15° and 20° and between 20° and 25° was reported in 16% and 20% of the femoral stems respectively. A PFV of more than 25° was reported in 48% of the femoral stems, Figure 4-9.

Figure 4–9: A histogram depicting the distribution of PFV in uncemented and cemented THA.

4.3.5 Clinical Outcome

The median follow-up time for the uncemented THA group was 45 months (15 to 66 months). The cemented THA group had a median follow up time of 21 months (14 to 30 months). There were no adverse intra-operative complications such as femoral fracture,
whilst evaluation at one-year post-operative revealed adequate fixation. In the uncemented THA group, two dislocations were reported: 1. One as a result of deep hip flexion 5 weeks post-operatively, 2. One while doing yoga 12 weeks post-operatively. Treatment included one closed reduction procedure with no surgeries recorded so far. The mean OHS was 48/48 for both cases at 12 months post-operatively. A PFV of 9° was reported in both cases. There were no dislocations reported in the cemented THA group.
4.4 Discussion

Suboptimal placement of the femoral stem with regards to its version, is associated with the biomechanical instability of the reconstructed hip joint [6], [7], [236], [237]. The surgical plan does not always deliver the optimal component orientation in uncemented hip surgery, and PFV demonstrates increased variability (see chapter 3) [9], [30], [31], [230]. Cemented fixation may offer greater control of the PFV through the variable thickness of the cement mantle.

The present study aimed to better understand the impact of the fixation method on PFV. Post-operative 3D-CT analysis was proposed to quantify and compare the PFV angles in two groups of patients undergoing uncemented and cemented THA. The PFV in the uncemented THA was found to be significantly lower in comparison with the cemented THA group (p<0.001).

However, what is clinically relevant is not the difference between the mean values of PFV in both THA groups but the distribution of outliers. In the uncemented THA group, 20% of the patients reported a PFV of less than 5°, whilst five patients had a retroverted PFV. This percentage dropped to 0% in the cemented THA group. There were not any retroverted femoral stems in the cemented THA group.

These findings are congruent with the increased control of the position of cemented femoral stem designs and highlight that by intra-operatively adjusting the PFV, using the variable thickness of the cement mantle, surgeons can avoid delivering a retroverted or insufficient PFV. These findings are clinically relevant considering the importance of an adequate PFV in primary THA [6], [265].

The virtual pre-operative planning process was performed according to the same criteria across the two THA groups and the surgical target was a PFV of 20°. The only difference
was the design of the femoral stem used and the cementation technique intra-operatively. In this regard, the difference in the outcome measurements between uncemented and cemented THA was due to the fixation technique using these particular femoral stem designs, and the surgeon’s visual judgement using the cement mantle (in uncemented THA, the surgeon has little control over the PFV that is press-fit to the internal femoral canal).

4.4.1 Comparison with existing literature

Table 4-2 and Figure 4-10 include all the studies assessing the PFV using CT scans or 3D-CT analysis. High variability of PFV has been reported, ranging from -23° to 72°. Most studies documented the PFV of an uncemented femoral stem, while only two studies assessed the PFV of a cemented femoral stem [6], [310]. These used CT scans to measure the PFV.

In this study, the PFV of an uncemented straight-tapered femoral stem ranged between -18° and 33°. Previous studies assessing the PFV of an uncemented straight press-fit femoral stem have reported a similar range between -23° and 39° [9], [30], [230].
Table 4-2: CT-measured PFV in previous studies

<table>
<thead>
<tr>
<th>Ref</th>
<th>N</th>
<th>CT/ 3DCT</th>
<th>Uncem./Cement.</th>
<th>Stem Design</th>
<th>PFV (Mean ± SD, Range) [Deg]</th>
<th>SA</th>
<th>CO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Komeno (2006) [263]</td>
<td>38</td>
<td>CT</td>
<td>NA</td>
<td>NA</td>
<td>24</td>
<td>P</td>
<td>*</td>
</tr>
<tr>
<td>Suh (2006) [311]</td>
<td>33</td>
<td>CT</td>
<td>Uncem.</td>
<td>Straight Non-Anatomic (Zimmer)</td>
<td>18 ± 6 (3 To 28)</td>
<td>P</td>
<td>NA</td>
</tr>
<tr>
<td>Wines (2006) [310]</td>
<td>111</td>
<td>CT</td>
<td>Uncem./Cement.</td>
<td>29 C. Ted /75 C. Less / 7 Other Design</td>
<td>17 ± 11 (-15 To 45)</td>
<td>80 P / 31L</td>
<td>0% Dis.</td>
</tr>
<tr>
<td>Reikeras (2011) [312]</td>
<td>91</td>
<td>CT</td>
<td>Uncem.</td>
<td>Straight Stem (Corail, Depuy)</td>
<td>23 ± 12 (-17 To 60)</td>
<td>40 L / 51P</td>
<td>0% Dis., 0% Rev.</td>
</tr>
<tr>
<td>Nakashima (2014) [313]</td>
<td>111</td>
<td>CT</td>
<td>Uncem.</td>
<td>Straight Metaphyseal Fit-Fill (Kyocera)</td>
<td>34 ± 11 (9 To 60)</td>
<td>P</td>
<td>0% Dis.</td>
</tr>
<tr>
<td>Hirata (2013) [314]</td>
<td>73</td>
<td>CT</td>
<td>Uncem.</td>
<td>Straight Metaphyseal Fit-Fill (Kyocera)</td>
<td>35 ± 11 (9 To 60)</td>
<td>P</td>
<td>0% Dis.</td>
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<tr>
<td>Fujishiro (2014) [31]</td>
<td>1411</td>
<td>CT</td>
<td>Uncem.</td>
<td>Straight Stem</td>
<td>40 ± 11 (0 To 72)</td>
<td>L</td>
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<tr>
<td>Hirata (2014) [29]</td>
<td>122</td>
<td>CT</td>
<td>Uncem.</td>
<td>Straight Metaphyseal Fit-Fill (Kyocera)</td>
<td>38 ± 11 (14 To 63)</td>
<td>P</td>
<td>0% Dis.</td>
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<tr>
<td>Study</td>
<td>Sample Size</td>
<td>Modality</td>
<td>Component Type</td>
<td>Ref. Value</td>
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<td>Dislocation</td>
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<tr>
<td>Fujishiro (2016)</td>
<td>1555</td>
<td>CT</td>
<td>NA</td>
<td>NA</td>
<td>40 ± 12</td>
<td>P</td>
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<tr>
<td>Okada (2020)</td>
<td>81</td>
<td>CT</td>
<td>Uncem.</td>
<td>Taper Wedge</td>
<td>27 ± 5 (17 To 39)</td>
<td>AL</td>
<td>0% Dis.</td>
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<tr>
<td>Jackson (2020)</td>
<td>29</td>
<td>CT</td>
<td>Uncem.</td>
<td>Straight Stem</td>
<td>22 ± 11</td>
<td>A</td>
<td>NA</td>
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<tr>
<td>Hochreiter (2021)</td>
<td>12</td>
<td>CT</td>
<td>Uncem.</td>
<td>6 Calcar-Guided /6 Straight</td>
<td>Calcar-Guided: 23 ± 5.5/Conv.:</td>
<td>AL</td>
<td>NA</td>
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<tr>
<td>Imai (2016)</td>
<td>65</td>
<td>CT</td>
<td>Uncem.</td>
<td>Straight Metaphyseal Fit-Fill (Kyocera)</td>
<td>32 ± 10 (12 To 58)</td>
<td>L</td>
<td>0% Dis.</td>
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<tr>
<td>Sariali (2009)</td>
<td>223</td>
<td>3DCT</td>
<td>Uncem.</td>
<td>SPS-Modular (Symbios)</td>
<td>27 ± 14</td>
<td>183 AL/40P</td>
<td>NA</td>
</tr>
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<td>Sendtner (2010)</td>
<td>60</td>
<td>3DCT</td>
<td>Uncem.</td>
<td>Straight Stem (Corail, Depuy)</td>
<td>6 ± 11 (-19 To 33)</td>
<td>A</td>
<td>NA</td>
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<tr>
<td>Kiernan (2013)</td>
<td>60</td>
<td>3DCT</td>
<td>Cement.</td>
<td>ScanHip System (Biomet)</td>
<td>20 (1 To 43)</td>
<td>P</td>
<td>***1% Rev.</td>
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<tr>
<td>Inoue (2015)</td>
<td>65</td>
<td>3DCT</td>
<td>Uncem.</td>
<td>Short Anatomical Stem (Zimmer)</td>
<td>19 ± 9 (-2 To 39)</td>
<td>P</td>
<td>NA</td>
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<td>Study Author and Year</td>
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<td>Park (2015) [275]</td>
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<td>Dimitriou (2015) [9]</td>
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<td>Weber (2016) [295]</td>
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<td>Hayashi (2017) [297]</td>
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<td>Nodzo (2018) [317]</td>
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<td>Belzunce (2020) [230]</td>
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<td>19 3DCT Uncem.</td>
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<td>19 3DCT Uncem.</td>
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<td>123 3DCT Uncem.</td>
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<td>44 3DCT Uncem.</td>
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<td>20 3DCT Uncem.</td>
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<td>30 3DCT Uncem.</td>
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<td>Tapered Wedge Stem (DJO Global)</td>
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<td>Straight Stem (Corail, Depuy)</td>
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<td>Tri-Lock BPS Stem (Depuy)</td>
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<td>Restoris Femoral Stem (Stryker)</td>
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<td>Straight-Tapered (Quadra-H, Medacta)</td>
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<td>19 ± 9 (0 To 34) P</td>
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<td>11 ± 13 (-23 To 33) P</td>
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<tr>
<td>8 ± 10 (-19 To 38) AL</td>
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<tr>
<td>31 ± 10 AL NA</td>
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<td>9 ± 6 P 0% Dis.</td>
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<tr>
<td>14 ± 10 (-5 To 39) P ****3% Dis.</td>
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</table>

Cement., Cemented; Uncem., Uncemented; SA, Surgical Approach; P, Posterior; L, Lateral; AL, Anterolateral; CO, Clinical Outcome; Dis., Dislocation; Rev., Revision; NA, not available/ not applicable

* This study retrospectively compared the PFV in; 1. A group of dislocated stems 2. A group of non-dislocated stems. The mean PFV in the posterior dislocated group was 15°, while the PFV in the control group was 24°.

** This study measured the PFV of 1555 primary THAs and documented the frequency of dislocation. The mean PFV of hips with dislocation was 35 ± 15°, while the mean PFV of hips without dislocation was 40 ± 12°. The difference was statistically significant.
*** In this study, 1% of the femoral stems were revised. However, among femoral stems with a PFV<10°, the revision rate reached 40%.

****The current study is an extension of this reference in terms of the sample size. In the current study, there were two dislocations in a series of 81 uncemented THAs. Therefore, the real dislocation rate is 2%, instead of 3%.
In the cemented THA group of this study, the PFV ranged from 5° to 34°. Previous studies assessing the PFV of a cemented femoral stem have reported a similar range (1° to 43°) [6]. However, the results of this study contrast with those of a prior study that evaluated the impact of fixation technique on PFV using MRI scans (13° versus 23° in this study) [267]. They declared 2.3% of retroverted cemented femoral stems. In the present study, there were no retroverted femoral stems in the cemented THA group. The difference may be explained by the different designs of the femoral stems used (Avenir, Zimmer Biomet Holdings Inc., Warsaw, Indiana, and Quadra-C, Medacta Group SA, Castel San Pietro, Switzerland).

4.4.2 Uncemented versus Cemented Fixation

Although the surgical target of PFV was the same among the two THA groups, there was a disparity between the surgical target and what occurred in the operating theatre in the
Understanding the impact of the fixation technique on PFV uncemented and cemented THA. In uncemented surgery, the femoral stem is press-fitted within the intramedullary canal and therefore its orientation may be significantly affected by the internal morphology of the proximal femur. In cemented femoral stems, the surgeon can intra-operatively adjust the version of the femoral stem to a desired position within the variable thickness of the cement mantle [233], [266], [288].

The BA plot (Figure 2-4) confirmed this, where the 95% LOA in the uncemented THA group were high at -17 and 15 degrees. In contrast, in the cemented THA group, the upper LOA was higher than the lower LOA, reflecting the greater surgeon’s control of putting the stem in a more anteverted state. Considering that there is a continuing debate around the most appropriate fixation technique in primary THA [318], the findings of this study suggest that PFV may constitute an additional criterion during the selection process.

However, PFV variability was comparable across the two THA groups. During the surgery, the surgeon visually assesses the PFV through knee flexion and vertical placement of the leg. This technique is subjected to the surgeon’s perspective and has proved to be imprecise [231], [314]. Surgical instruments in the form of robots or 3D-printed PSI guides are required to guide PFV during a primary cemented THA.

Additionally, long-term clinical studies are imperative to detect any significant association between the fixation technique, the PFV and clinical outcome. So far, a few studies have reported a higher dislocation rate in the uncemented primary THA when compared to the cemented THA [140]. According to the Dutch Arthroplasty Register, cemented and hybrid THAs (cemented femoral stem) have reported 40% lower revision rate for other reasons when compared to uncemented THAs [138]. Dobzyniak et al. (2006) demonstrated that switching from uncemented to cemented femoral stem designs reduced aseptic loosening from 38% to 24% [307]. Existing literature has reported that low PFV angles are associated with posterior head migration in primary THA, and early
posterior migration of the femoral stem component is predictive of aseptic loosening [6], [236]. In this respect, it is plausible that this increased prevalence of untoward events in uncemented THA may stem from the high variability of femoral stem orientation [288].

4.4.3 CV

Given the limited surgical control of an uncemented femoral stem, scientists have recently considered the notion of the CV to control implant placement, with existing literature to support that a CV within the optimal range (25° to 50°) can reduce the risk of dislocation in uncemented THA [288]. Despite the fact that PFV was the primary outcome measure for this chapter, radiographic cup anteversion was computed post-operatively to assess CV (see Appendix A.1). Figure A-2 shows that 69% of the femoral stems in the uncemented THA group and 56% of the femoral stems in the cemented THA group had a CV that was within the optimal range.

However, a CV within the optimal range does not guarantee an optimal version for the individual prosthetic components and is not considered a satisfying condition for the post-operative clinical outcome. For instance, a case with a PFV of -5° and a cup AV of 35° will result in a CV of 30°. Considering the association of an insufficient PFV with dislocation [238], [265] and the Lewinnek safe zone for the cup anteversion (5° to 25°) [228], a CV within the optimal range would potentially result in untoward clinical events due to misorientation of the femoral stem or the acetabular cup component. Instead, planning a CV of 40° (consisting of a PFV of 20° and a cup AV of 20°) would be preferable.

Existing scientific evidence has reported that focusing solely on the cup AV to define a universal safe optimum for hip motion is not sufficient [319], and even when the generally accepted optimal range of CV is achieved, dislocations are not infrequent [320]. In
response, a design- and patient-specific determination of the CV was recommended to achieve an impingement-free optimal target zone [319].

4.4.4 Planning the PFV

Given that a “less-than-optimal” PFV [230] constitutes a critical variable associated with the biomechanical stability of the hip joint [6], [236], emphasis should be made on planning the version of an uncemented straight-tapered press-fit femoral stem. So far, engineers and surgeons started using NFV as the target, considering that a primary THA aims the reconstruction of the physiological hip function [290]. This hypothesis is based on the fact that the femoral stem adapts more to the host anatomy and therefore reproduces to a significant extent the native version of the proximal femur [233]. However, previous literature has reported a high variability of NFV [43]. In addition, an abnormal morphology of the hip joint, including an increased NFV, has been associated with the development of OA [55].

Therefore, following exclusively proximal femoral anatomy could lead to excessive stem anteversion or retroversion, potentially impacting the clinical outcomes through replicating the pathology intra-operatively. In this context, NFV was measured pre-operatively, but the surgical target was a standard goal of 20°. Independently of the surgical plan, however, the surgeon cannot fully control the PFV of a straight uncemented femoral stem that is dictated by the internal proximal femoral morphology and the stem design, and the final PFV significantly varies from the NFV and the surgical target.

4.4.5 Limitations

3D-CT analysis techniques were used to measure PFV angles in two groups of patients:
1. A group of 81 uncemented THAs;
2. A group of 25 cemented THAs. CT analysis has
several limitations, including the metal artefact, landmark selection, CT measurement error, radiation exposure, and the scanning protocol [165], [174], [178], [230].

In light of this, post-operative CT scans were corrected for metal artefacts to ease the 3D-CT reconstruction and the landmark selection. In addition, the inter-observer and intra-observer analyses showed excellent results regarding the CT measurement method of PFV (see paragraph 3.3.5). Lastly, patients in both THA groups underwent CT scanning according to a standardised low-dose scanning protocol.

The primary objective of this chapter was to quantify and compare the PFV angles in uncemented and cemented THA. Cup orientation and CV angles were also computed as a secondary measurement using a Simpleware plug-in (Appendix A.1). The operator was asked to select clearly identified landmarks on the 3D models representing the pelvis and the acetabular cup. These points were the ASIS and pubic tubercles, defined on the APP plane. Other methods use the CT scans coordinate system, not fully reflecting the bony anatomical coordinate system [226]. Additionally, the APP plane is not always parallel to the patient’s sagittal plane [226]. In light of these, all the measurements relevant to the acetabular cup included in this thesis were based on the alignment of the CT scans coordinate system to the APP plane, representing a pelvis supine on the CT scan table [226]. This methodology has been reported both accurate and precise [321]. For this reason, a repeatability and reproducibility analysis of the plug-in measurements was not performed to account for any impact on the outcome measures.

The basic limitation of this study lies in the unequal sample sizes of both groups. This was a prospective, consecutive comparative study. The surgeon changed practice from uncemented to cemented to take advantage of the flexibility that the cement mantle offers and improve the range of PFV. A suitable statistical test was equipped to account for the
sample size differences, that is considered a robust statistical technique when comparing two groups with unequal variances [309].

Further limitations are acknowledged. The two groups had different follow-up periods. However, dislocation has been reported to occur within the first 12 months of the surgery [322]. In light of this, the author assumed that the follow-up time of the cemented THA group (21 months) is considered an adequate follow-up time to detect any clinically adverse effects. Furthermore, the results may depend on the design of the femoral stems used, not fully representing the effect of cemented femoral stems of a different shape on PFV.

This study was designed to compare two groups of patients according to the implants used and not according to the anatomy or the disease. In the present study, though, all patients had hip OA and presented similar hip pathology. It is true that more women are reported to display DDH and abnormal NFV [323]. There were not any gender differences between the two groups (49% of females in the uncemented THA group versus 56% in the cemented THA groups, p=0.57) that may have caused any differences in native femoral anatomy and achieved PFV angles between the two THA groups.

Additionally, special attention should be given to the placement of cemented femoral stems. Deviations in the PFV of the femoral broach and of the implanted cemented femoral stem would result in an asymmetrical cement column. Previous studies have stated that the thickness of the cement mantle affects cement strains [324], stem subsidence [325], micro-movement at the cement-bone interface [326], and the overall long-term radiographic outcome [327]. In addition, the presence of defects may act as an area of osteolysis [328]–[330]. However, there is still a debate around the optimal thickness of the cement column [331], [332], indicating the need for long-term studies to understand if an asymmetrical cement column negatively impacts the implant’s longevity.
Concerning the femoral canal preparation in both THA groups, this was prepared using a starter reamer and sequential femoral rasps up to the size that surgeon decides based on test by twisting. In the uncemented THA group, the stem was press-fitted and tested by twisting the implant within the femur to ensure no movement. In the cemented THA group, the surgeon inserted the cement mantle using retrograde cementation, implanted the stem and adjusted its position according to his intra-operative visual estimation of 20°, using the malleable nature of the cement mantle. However, previous studies have reported a significant correlation between the final broach version and PFV in primary uncemented THA [268]. In this regard, the broaching technique in the uncemented THA may affect the PFV of a straight femoral stem, potentially signifying this step in delivering the intended PFV.

Lastly, the assumption used was that the high variability of PFV in the uncemented THA group is due to the fact that an uncemented femoral stem adapts more to the previous internal morphology of the proximal femur. In the future, researchers should try to figure out the shape and size of the intramedullary canal and see if different canal sizes are related to the wrong position of the femoral stem or an abnormal PFV.
4.5 Conclusion

Using a cemented collarless femoral stem, the surgeon has greater control of PFV and can avoid delivering a retroverted or insufficient PFV in primary THA. In the uncemented THA group, 20% of the patients reported a PFV of less than 5°, whilst five patients had a retroverted PFV. In the cemented THA group, this clinically important threshold dropped to 0%. However, a similarly high level of PFV variability indicated the need to develop surgical tools that can intra-operatively guide the PFV of a cemented femoral component closer to the surgical target.
4.6 Key findings

The key findings of this chapter are:

◊ The cemented fixation using a highly polished, straight femoral stem helps avoid insufficient or retroverted PFV in primary THA. In the uncemented THA group, 20% of the patients reported a PFV of less than 5°, with five patients having a retroverted PFV. This percentage dropped to 0% in the cemented THA group.

◊ Despite eliminating outliers using the cemented fixation, both groups reported a wide range of PFV, indicating the need to develop surgical tools to guide the PFV in primary THA.
Accuracy of a PSI femoral osteotomy guide: A CT study
Understanding the impact of the fixation technique on PFV
Chapter 5 Accuracy of a PSI femoral osteotomy guide: A CT study

5.1 Introduction

Optimal implant placement during primary THA aims to restore normal hip function, but is not always achieved [15], [24], [25]. There is considerable variability in the vertical placement of the femoral stem within the femur [24], [25]. Sub-optimal vertical placement of the femoral stem is associated with poor hip biomechanics [182] and LLD [24]. Post-operative LLD is not only a bothersome complication [333], but also one of the main reasons for lawsuits after THA [334], [335].

Femoral neck osteotomy creates a critical anatomical landmark, for surgeons carrying out primary THA [160], to visually control the position of the femoral stem [153], [209] and to avoid LLD [8], [335]. Studies so far, have proved that the femoral neck osteotomy level also determines the eventual orientation of the femoral stem, including the varus/valgus alignment and the PFV [9], [10].

Surgeons usually perform the osteotomy using either eye-balling / free-hand osteotomy [8] or technology, such as a robotic arm [211] or 3D-printed PSI [35], [248]. Conventional free-hand femoral neck osteotomy is performed relying on the surgeons’ experience and their finger measurements. This process may induce end outcome variability, and it may be challenging for inexperienced surgeons to deliver the planned femoral neck cut plane. PSI has been developed to guide the delivery of the surgical plan.

However, PS femoral osteotomy guides are a relatively new concept in hip arthroplasty, and, currently, it is uncertain how often are intra-operatively used, as quantifiable data are not publicly available. So far, previous studies have mainly assessed the accuracy of PSI for knee osteotomy [243], [244], [336]–[348], while very few studies have quantified the accuracy of PSI for femoral osteotomy [248].
These studies mainly used conventional radiographs to assess the accuracy of the PSI guides. However, the 2D nature of digital radiographs does not offer reliable illustration of the patient’s anatomy, resulting in the incorrect measurement of essential dimensional characteristics [153], [160], [162]. CT-scanning produces a sequence of cross-sectional images - slices – depicting the targeted anatomy in a more detailed way.

This chapter aims to evaluate the accuracy of a commercially available PSI femoral osteotomy guide (MyHip from Medacta) using 3D-CT analysis in primary THA.

5.1.1 Motivation

Optimal vertical placement of the femoral stem during a primary THA is critical to avoid abnormal gait, implant instability, and an inferior clinical outcome [10], [182], [259], [260], [262], [349]. Femoral neck osteotomy is an essential step in primary THA [8] because it defines the entry point of the femoral stem within the femur, guiding component position and orientation [9], [10], and thus being critical in avoiding LLD [8], [335]. Surgeons usually perform femoral neck osteotomy relying on their experience and finger measurements. This method may be particularly challenging for inexperienced surgeons.

This PSI femoral osteotomy guide has been developed to guide the delivery of the virtual surgical plan, but its accuracy and repeatability have not yet been evaluated. Clinical evaluation of a commercially available PSI osteotomy guide is crucial to confirming its safety. Proving its accuracy would reassure surgeons that they can rely on 3D-printed PSI femoral guides to deliver the femoral neck osteotomy as planned. In contrast, emphasising its inaccuracy in executing the surgical plan would advise against a potentially unfavourable surgical instrument.
5.1.2 Aim

To assess the accuracy of a commercially available PSI femoral osteotomy guide using 3D-CT image analysis.

5.1.3 Objectives

To achieve this aim, the objectives were:

◊ To accurately define the achieved osteotomy plane using 3D-CT analysis.

◊ To quantify the vertical discrepancy between the achieved and planned femoral neck osteotomy levels.

◊ To quantify the angular discrepancy between the achieved and planned femoral neck osteotomy levels.

◊ To assess the clinical outcome.
5.2 Materials and Methods

5.2.1 Study Design

Figure 5-1 illustrates the study design of this chapter.

Figure 5–1: Study Design.

A case cohort study was designed, involving a total of 107 patients (118 hips) undergoing primary THA due to OA between February 2017 and December 2021. All patients
underwent pre- and post-operative CT scanning. Before the surgery, the implant manufacturer performed a pre-operative plan using proprietary software (MyHip Planner, Medacta International SA, Castel San Pietro, Switzerland) to define the optimal femoral neck osteotomy level. A PSI osteotomy guide was designed using the pre-operative CT scans and 3D-printed for each case. During surgery, the guide was used to perform the femoral neck osteotomy. The surgical plan was not available in 3 cases and the PSI guide was not used in 12 cases due to feasibility reasons (Non-guided THA group), resulting in 103 cases where the PSI guide was used (PSI-guided THA group). Post-operative CT scans of the patients were used to perform a 3D analysis of the achieved osteotomy level. The surgical plan was registered to the post-operative CT scans and planned versus achieved osteotomy levels were measured in terms of their vertical and angular discrepancies. The clinical outcome was also evaluated. Table 5-1 includes characteristics of the study groups.

The outcome measures were:

1. Relative vertical discrepancy of the osteotomy level.
2. Relative angular discrepancy of the osteotomy level.
3. Clinical outcome.
Table 5-1: Study Groups Characteristics.

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<th>Non-guided Group (N=11 Hips)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (Females) (%)</td>
<td>53 (51)</td>
<td>8 (73)</td>
</tr>
<tr>
<td>Age (Years) (Median, Range)</td>
<td>62 (39-89)</td>
<td>71 (32-80)</td>
</tr>
<tr>
<td>Treatment Side (Right) (%)</td>
<td>56 (54)</td>
<td>7 (64)</td>
</tr>
<tr>
<td>Follow-Up (Median, Range)</td>
<td>37 (8-66)</td>
<td>45 (15-60)</td>
</tr>
</tbody>
</table>

5.2.2 Pre-operative CT scanning

Before the surgery, all patients had low-dose CT scans of the hip and the knee joint according to standard protocol (see Paragraph 3.2.2).

5.2.3 External surgical planning

Pre-operative 3D-CT planning was performed (MyHip Planner, Medacta International SA, Castel San Pietro, Switzerland), following the planning criteria described in Chapter 3 (see Paragraph 3.2.4). Medacta performed the virtual femoral neck osteotomy as part of the external surgical planning. The goal was to restore leg length with reference to the contralateral side. The neck cut plane was defined by the MyHip planning software after anatomical landmark acquisition. The anatomical landmark used to calculate where to cut initially was the anterior tubercle, the middle region of the anterior prominence just below the femoral neck (Figure 5-2a). The relevant anatomical axis used to define the 3D neck cut angle was the long axis of the proximal femur. The osteotomy plane was then computed by the software as a 3D plane inclined by a solid angle of 45° to the long axis of the proximal femur (Figure 5-2a). The operator finally removed the femoral head-neck junction following this defined plane.
Figure 5–2: a) Illustration of the anatomical landmarks used to define the planned osteotomy level b) The design of the PSI femoral osteotomy guide.

5.2.4 Design and manufacturing of the PSI femoral osteotomy guide

A PSI femoral osteotomy guide was designed based on the pre-operative surgical plan of each patient, Figure 5-2b. This guide was designed as a cutting block to perfectly fit the contours of the femoral head neck junction. The design also includes two optimally designed grooves, hosting two threaded pins to secure its position and fitting once seated on the femoral head-neck junction.

Regarding its manufacturing, the guide was 3D-printed using an EOS Selective Laser Sintering (SLS) printer, utilising Polyamide (PA) 2200, a nylon 12 material. Sterilisation using an autoclave followed, and the guide was stored and shipped to the hospital, conforming to current standards.
5.2.5 Surgical approach and prosthetic components

One consultant orthopaedic surgeon performed all the surgeries through a posterior approach. Two designs of femoral stems were adopted: 1. An uncemented straight stem in 71 hips (Quadra-H System; Medacta International SA, Castel San Pietro, Switzerland); 2. A cemented femoral stem (X-acta System; Medacta International SA, Castel San Pietro, Switzerland) in 32 hips.

5.2.6 Intra-operative use of the PSI femoral osteotomy guide

During the surgery, the surgeon used the sterilised PSI cutting jig to perform the femoral neck osteotomy. The guide was positioned on the femoral head-neck junction and two pins secured its position. The surgeon then performed the osteotomy with the oscillating saw blade flush on the surface of the guide, Figure 5-3.

Figure 5–3: a) The PSI femoral osteotomy guide was designed to fit the patient-specific anatomy of each patient; b) Two pins secured its position and the surgeon cut the femoral neck using an oscillating saw; c) The femoral head-neck junction was removed with the guide attached (from comlexhipsurgery.com).

5.2.7 Definition of the planned osteotomy plane

The planned osteotomy level was defined as the distance between the planned osteotomy plane and the midpoint of the LT. To define the planned osteotomy plane, the surgical
plan -3D models of the femoral stems within the proximal femurs, including the planned osteotomy- was loaded in Simpleware in STL format (Version 2021.03; Synopsis, Inc., Mountain View, USA). A representative example of an STL representing the virtual surgical plan, is depicted in Figure 5-4. A 3D plane was then automatically best fit to the osteotomy area, using the surface fitting module in Simpleware (purple plane, Figure 5-4). During this step, the operator paints the region of interest, and a 3D plane is best fit based on the user input. As depicted in Figure 5-4, the osteotomy surface area is clearly visible in the STL model of the virtual surgical plan. Therefore, the operator painted the region of interest covering the surface of osteotomy area so that the automatically defined 3D plane best represented this region.

Figure 5–4: A plane was best fit to the osteotomy area of the surgical plan.

5.2.8 Post-operative CT scanning

Post-operatively, CT scans of the hip and the knee region were obtained using the same scanning protocol adopted for the scans acquired before the surgery.
5.2.9 Processing of the post-operative CT scans

The post-operative CTs were pre-processed with the NMAR algorithm prior to segmentation to attenuate artefacts, as described by Meyer et al. (2010) [171]. Then, the 3D models of the post-operative femurs and implants were generated using the bilateral filtering and intensity thresholding tools, Figure 5-5. The bilateral filtering is an automatic tool, available in Simpleware to eliminate CT noise (Version 2021.03; Synopsis, Inc., Mountain View, USA). The operator selects the type of filtering, and the software returns a filtered version of the original CT scan, optionally overlaid on the CT data. For the segmentation, the operator defines a specific HU range to segment the 3D models of the anatomy and implants. For the patient’s bony anatomy, a range of between 200 and 1500 HU was selected. For the implants, a threshold of >1700 HU was selected.

![Figure 5-5: The post-operative CT scans were pre-processed with the NMAR algorithm to generate an image segmentation mask that sufficiently preserves the femoral bone geometry.](image-url)
5.2.10 Definition of the achieved osteotomy plane

The achieved osteotomy plane was defined as the distance between the achieved osteotomy plane and the midpoint of the LT. To define the achieved osteotomy plane, a plane was best fit to the osteotomy area of the post-operative model representing the proximal femur, Figure 5-6a. During this step, the operator paints the region of interest, capturing the whole surface of the osteotomy. A plane was subsequently best fit to this surface area, using the surface fitting module in Simpleware (Version 2021.03; Synopsis, Inc., Mountain View, USA). The result is a 3D plane following the 3D slope of the osteotomy area that is visible both in the 3D view and in every slice of the three CT views. The metrics of this 3D plane, such as the vector normal to this plane, are automatically stored so the operator can retrieve these if needed. Since this plane was fit to a post-operative 3D model that potentially includes noise due to artefacts, the operator checked its validity using the sequence of the CT slices, Figure 5-6b. In addition, a second operator checked the fitted plane in 20 randomly selected cases.
Figure 5–6: a) A plane was best fit to the osteotomy area painted by the operator using the surface fitting module in Simpleware; b) The operator checked the validity of the fitted plane using the sequence of the CT slices.

5.2.11 Osteotomy discrepancy

Alignment of the surgical plan (red model) to the post-operative 3D-CT model (white model) was performed automatically in Simpleware (Version 2021.03; Synopsis, Inc., Mountain View, USA), Figure 5-7. The vertical osteotomy discrepancy was defined as the vertical difference between the achieved and planned osteotomy levels at the posterior femoral cortex across a line parallel to the long axis of the reconstructed proximal femur, Figure 5-8. In addition, the solid angle between the achieved osteotomy plane (fitted plane) and the long axis of the proximal femur was measured. The planned angle (45°) was subsequently subtracted from the achieved osteotomy angle, to quantify the angular osteotomy discrepancy.
Figure 5–7: Alignment of the surgical plan to the post-operative model, using the automatic registration method in Simpleware.

Figure 5–8: Schematic illustration of the vertical difference between the achieved and the planned osteotomy planes.
5.2.12 Statistical Analysis

Statistical analysis software (SPSS, version 28, Chicago, USA) was used to compute the descriptive statistics for the outcome measures.

In order to establish whether data analysed in this study was normally distributed, the Kolmogorov-Smirnov test (n>50) was utilised [279]. The median values of the data describing the planned and achieved osteotomy levels were compared using the non-parametric Sign Paired test [350].

A linear regression model was fit to the data to look for a linear relationship between the planned and achieved osteotomy levels [282]. The coefficient of determination (R^2) was used to indicate the level of correlation [283]. A BA plot was also used to show the discrepancy and measure the LOA between achieved and planned osteotomy levels [284].

The mean values of the data describing the osteotomy discrepancy in the PSI-guided and non-guided THA groups were compared using the Welch test [309].
5.3 Results

5.3.1 Description of the planned and achieved osteotomy levels in PSI-guided THA

The data describing the planned and achieved osteotomy levels were not normally distributed (Kolmogorov-Smirnov, p1<0.001; p2=0.01). The median (IQR) planned osteotomy level was 32 mm (28 to 35 mm). The median (IQR) achieved osteotomy level was 32 mm (29 to 36 mm). There was no statistically significant difference between the mean values of the planned and achieved osteotomy levels (p=0.8), suggesting that the average planned osteotomy level was delivered post-operatively (Figure 5-9).

![Box and whisker plots comparing the planned and achieved osteotomy levels in the PSI-guided THA group (p=0.8).](image)

Figure 5–9: Box and whisker plots comparing the planned and achieved osteotomy levels in the PSI-guided THA group (p=0.8).
5.3.2 Vertical Osteotomy Discrepancy in PSI-guided THA

The data describing the vertical osteotomy discrepancy and the underlying residuals approached the trend expected for a normal distribution (Kolmogorov-Smirnov, p1=0.2; p2=0.1). The mean (± SD) vertical osteotomy discrepancy was 0.5 (± 2) mm (median=0.3 mm; IQR= -1 to 2 mm; min=-5 mm; max=8 mm).

A BA plot of the discrepancy between the planned and achieved osteotomy level showed that the 95% limits of agreement (Mean ± 1.96 SD) were -4 mm and 5 mm, respectively, Figure 5-10. These results suggested, that most cases reported an osteotomy discrepancy within the clinically acceptable threshold of 5mm.

![BA plot of discrepancy and LOA between planned and achieved osteotomy levels.](image)

Figure 5–10: A BA plot displaying the discrepancy and LOA between the planned and achieved osteotomy levels.
5.3.3 Planned osteotomy as a predictor for the achieved osteotomy level in PSI-guided THA - Linear Regression analysis

A linear regression model was fitted to the data, revealing a strong positive correlation between the planned and achieved osteotomy levels ($R^2 = 0.9; p<0.001$), showing the reliability of the planned osteotomy plane as a predictor for the achieved osteotomy using this PSI guide (Figure 5-11).

![Linear Regression Analysis Plot](image)

**Figure 5–11:** A linear regression analysis plot illustrating achieved osteotomy level as a function of the planned osteotomy level.

5.3.4 Distribution of the osteotomy discrepancy in PSI-guided THA

For individual patients, 38% and 68% of the cases reported a vertical osteotomy discrepancy within 1 mm and 2 mm, respectively. An osteotomy discrepancy within 3mm was reported in 86% of the cases. Furthermore, 96% of the patients reported a vertical osteotomy discrepancy within 5mm. In 4% of the cases, the vertical osteotomy discrepancy was more than 5mm, Figure 5-12.
Figure 5–12: A histogram depicting the distribution of the vertical osteotomy discrepancy in a series of 103 THAs.

5.3.5 Angular osteotomy discrepancy in PSI-guided THA

The data describing the achieved osteotomy angle matched the tendency expected for a normal distribution (Kolmogorov-Smirnov, p=0.1). The mean (± SD) achieved osteotomy angle was 45° (± 3°) (median=45°; IQR= 44 to 48°; minimum=36°; maximum=54°), suggesting the accuracy of this PSI guide in delivering the achieved femoral osteotomy angle, Figure 5-13a-b and Figure 5-14.
Figure 5–13: a) A box and whisker plot displaying the achieved osteotomy angle in the PSI-guided THA group; b) A box and whisker plot displaying the angular osteotomy discrepancy in the PSI-guided THA group.

Figure 5–14: Range of achieved osteotomy angle in 103 PSI-guided THAs.

There were three outliers outside the box and whisker plots of the data describing the achieved osteotomy angle. These included three patients having an achieved osteotomy angle of 36°, 54° and 54°, respectively.
The data describing the angular osteotomy discrepancy were normally distributed (Kolmogorov-Smirnov, p=0.2). The mean (± SD) angular osteotomy discrepancy was 0.4° (± 3°) (median=0.2°; IQR= -1 to 3°; minimum=-9°; maximum=9°), Figure 5-13b. There were three outliers outside the box and whisker plots of the data describing the angular osteotomy discrepancy. These included three patients having an angular osteotomy discrepancy of -9°, 9° and 9°, respectively.

With regard to the distribution of the angular discrepancy, 62% of the cases reported a discrepancy within 3°. In 93% and 97% of the cases, the angular discrepancy was within 6° and 9°, respectively. Three pre-cent (3%) of the cases reported an angular discrepancy beyond 9°, confirming the efficacy of this guide in delivering the surgical plan with regards to the angle as well, Figure 5-15.

Figure 5–15: Distribution of the absolute angular osteotomy discrepancy in 103 PSI-guided THAs.
5.3.6 Vertical osteotomy discrepancy in the group of patients that did not receive the PSI guide

The data describing the vertical osteotomy discrepancy in the group of patients (n=11) that did not receive the PSI guide matched the tendency expected for a normal distribution (Shapiro-Wilk, p=0.9). In this group, the mean (± SD) vertical osteotomy discrepancy was 2 mm (± 7 mm) (median=3 mm; IQR= -4 to 7 mm; min=-9 mm; max=13 mm). With regard to the distribution of the vertical osteotomy discrepancy in this group, 9% of the cases reported a discrepancy within 1mm. An osteotomy discrepancy within 4mm was reported in 36% of the cases. In addition, 55% of the patients reported a vertical osteotomy discrepancy within 5mm. In 45% of the patients, the vertical osteotomy discrepancy was beyond 5mm, Figure 5-16.

![Figure 5–16: A histogram depicting the distribution of the vertical osteotomy discrepancy in 11 patients that did not receive the PSI cutting jig due to feasibility reasons.](image-url)
5.3.7 Comparison of vertical osteotomy discrepancy in the PSI-guided and non-guided THA groups

In the PSI-guided THA group the vertical osteotomy discrepancy ranged from -5mm to 8mm. In this THA group, the mean and median vertical osteotomy discrepancy was 0.5 mm and 0.3 mm, respectively. There were three outliers outside the whiskers of the box plot, illustrating the data of vertical osteotomy discrepancy in the PSI-guided THA group. These included three patients having a vertical osteotomy discrepancy of 8 mm, 8 mm and 6.5 mm, respectively, Figure 5-17.

In the non-guided THA group, the vertical osteotomy discrepancy ranged between -9 mm and 13 mm. In this THA group, the mean and median vertical osteotomy discrepancy was 2 mm and 3 mm, respectively. The mean values describing the vertical osteotomy discrepancy in both THA groups, did not vary with any statistically significant difference (p=0.4), Figure 5-17.

Figure 5–17: Box and whisker plots comparing the vertical osteotomy discrepancy in the non-guided and guided THA groups.
5.3.8 Distribution of outliers in the PSI-guided and non-guided THA groups

In the PSI-guided THA group, 4% of the cases reported a vertical osteotomy discrepancy of more than 5mm. In the non-guided THA group, an osteotomy discrepancy beyond 5mm was reported in 45% of the cases, Figure 5-18.

![Bar chart showing distribution of outliers in PSI-guided and non-guided THA groups.]

**Figure 5–18: Distribution of outliers in the PSI-guided and non-guided THA groups.**

5.3.9 Clinical Outcome

No untoward intra-operative events have been recorded, resulting in an overall satisfactory clinical outcome. There were no revisions at the latest follow-up, with a median of 37 months post-operative. This included both the THA group where the femoral osteotomy was PSI-guided, and the cases where this guide was not used. There were two dislocations, both reported in the THA group where the femoral osteotomy was PSI-guided, which were treated with one closed reduction procedure. No further surgery has been reported so far. The mean OHS was 48/48, at one-year post-operative.
5.4 Discussion

This was the first study to evaluate the accuracy of a PSI osteotomy guide in 103 primary THAs using 3D-CT analysis. The achieved osteotomy plane was defined on the post-operative CT scans and compared to the surgical plan. The relative vertical and angular discrepancies between the achieved and planned osteotomy planes were subsequently quantified.

The findings of this study suggested the efficacy of the PSI femoral osteotomy guide to deliver the osteotomy plane as planned. The discrepancy between the achieved and planned osteotomy levels was a median of 0.3 mm, and there was a very strong positive correlation between the two measurements ($R^2=0.9$, $p<0.01$). In addition, the mean ($\pm$ SD) angular osteotomy discrepancy was $0.4^\circ$ ($\pm 3^\circ$).

5.4.1 Comparison with existing literature

Table 5-2 includes previous studies addressing the accuracy of commercially available PSI cutting guides in different areas of human body. A great number of studies have assessed the accuracy of PSI for knee osteotomy [243], [244], [336]–[348], while very few studies have assessed the accuracy of a PSI femoral osteotomy guide [212], [248] (Table 1). Schneider et al. (2017) have quantified the distribution of osteotomy discrepancy in 30 cases using conventional radiography, reporting 3% of outliers [248], while Ferretti et al. (2021) have quantified a mean absolute osteotomy discrepancy of 1.6mm in 36 cases using CT analysis [212]. In the present study, using pre- and post-operative 3D-CT models of the osteotomy level that co-registered to quantify the osteotomy discrepancy in 103 THAs, 4% of outliers beyond the clinically accepted threshold were reported.
Table 5-2: Previous studies assessing PSI cutting guides in the ankle and knee arthroplasty.

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Body Area</th>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>Method of Assessment</th>
<th>Accuracy (Mean, Range) *</th>
<th>% Of outliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saito (2019)</td>
<td>Ankle</td>
<td>PROPHECY</td>
<td>Wright Medical Technology</td>
<td>Radiographs</td>
<td>Coronal: 1.6°; Sagittal: 1.9°**</td>
<td>(&gt;5°) 1%</td>
</tr>
<tr>
<td>[245]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spencer (2009)</td>
<td>Knee</td>
<td>OTIS Knee</td>
<td>OtisMed Inc.</td>
<td>Scanograms</td>
<td>1.2° (-6° to 4°)</td>
<td>(&gt;3°) 10%</td>
</tr>
<tr>
<td>[336]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ng (2012)</td>
<td>Knee</td>
<td>Signature -Vanguard</td>
<td>Biomet Inc.</td>
<td>Radiographs</td>
<td>2°</td>
<td>(&gt;3°) 9%</td>
</tr>
<tr>
<td>[337]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Nunley (2012) | Knee      | Signature -Vanguard & OTIS Knee | Biomet Inc. & OtisMed Corp. | CT scanograms | Sig: -0.7° (-7° to 5°), Ot: -2.8° (-8° to 5°) | (>3°) 18%-
<p>| [338]         |           |                 |                       |                      |                          | 44%          |
| Conteduca (2012)| Knee    | VISIONAIRE      | Smith &amp; Nephew        | Navigation           | 1.3 (0° to 5°)           | (&gt;3°) 17%    |
| [339]         |           |                 |                       |                      |                          |              |
| Noble (2012)  | Knee      | VISIONAIRE      | Smith &amp; Nephew        | Radiographs           | 1.7° (0° to 6°)          | NA           |
| [244]         |           |                 |                       |                      |                          |              |
| Bali (2012)   | Knee      | VISIONAIRE      | Smith &amp; Nephew        | Radiographs           | -0.1° (-4° to 5°)        | (&gt;3°) 9%     |
| [341]         |           |                 |                       |                      |                          |              |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Component</th>
<th>Guide/Tool</th>
<th>Procedure</th>
<th>Accuracy Range</th>
<th>Valgus (&gt;3°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daniilidis (2013) [243]</td>
<td>Knee</td>
<td>VISIONAIRE</td>
<td>Smith &amp; Nephew</td>
<td>Radiographs</td>
<td>-3° (-6° to 3°)</td>
</tr>
<tr>
<td>Chareancholvanich (2013) [340]</td>
<td>Knee</td>
<td>PSI</td>
<td>Zimmer</td>
<td>CT scanograms</td>
<td>0° (-3° to 4°)</td>
</tr>
<tr>
<td>Lustig (2013) [342]</td>
<td>Knee</td>
<td>VISIONAIRE</td>
<td>Smith &amp; Nephew</td>
<td>Navigation</td>
<td>-0.2°</td>
</tr>
<tr>
<td>Chotanaphuti (2013) [343]</td>
<td>Knee</td>
<td>Trumatch</td>
<td>Depuy</td>
<td>CT &amp; Radiographs</td>
<td>0.5° (-3.5° to 3.5°)</td>
</tr>
<tr>
<td>Chen (2014) [344]</td>
<td>Knee</td>
<td>PSI</td>
<td>Zimmer</td>
<td>Radiographs</td>
<td>NA</td>
</tr>
<tr>
<td>Pourgiezis (2016) [345]</td>
<td>Knee</td>
<td>VISIONAIRE</td>
<td>Smith &amp; Nephew</td>
<td>CT</td>
<td>1.2° (-12° to 8°)</td>
</tr>
<tr>
<td>Levengood (2018) [346]</td>
<td>Knee</td>
<td>Conformis</td>
<td>Conformis Inc.</td>
<td>Navigation</td>
<td>0.18° (0° to 2°)</td>
</tr>
<tr>
<td>Pauzenberger (2019) [347]</td>
<td>Knee</td>
<td>MyKnee</td>
<td>Medacta International S. A</td>
<td>Radiographs</td>
<td>1.7°</td>
</tr>
<tr>
<td>Turgeon (2019) [348]</td>
<td>Knee</td>
<td>VISIONAIRE</td>
<td>Smith &amp; Nephew</td>
<td>Radiographs</td>
<td>-1.6°</td>
</tr>
<tr>
<td>---------------------</td>
<td>------</td>
<td>------------</td>
<td>----------------</td>
<td>-------------</td>
<td>-------</td>
</tr>
<tr>
<td>Schneider (2018) [248]</td>
<td>Hip</td>
<td>OPS</td>
<td>Corin</td>
<td>Radiographs</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Accuracy in the knee arthroplasty studies, represents the deviation from the neutral mechanical limb alignment (0°).

** These values represent the absolute alignment deviation from the intended alignment.
This was the first study assessing the angular osteotomy discrepancy using 3D-CT analysis. Therefore, the limited number of studies do not allow for any comparison. However, an angular osteotomy discrepancy of 0.4° (± 3°) suggests the efficacy of the PSI guide in delivering the planned osteotomy angle.

5.4.2 Optimising femoral neck osteotomy

Primary THA aims to restore normal hip function and relieve the pain associated with OA. A satisfactory clinical outcome is commonly reported for the majority of patients. However, there are still minor, but not insignificant, percentages reporting post-operative pain and an inability to fully participate in daily human activities [15]. LLD is most commonly considered a reason behind post-surgical dissatisfaction [333]. Abnormal human gait, pain and instability may arise from major LLD [259], [333]. Successful restoration of LLD is burdensome to achieve and up to 18% of the patients report a LLD of more than 1.5 cm [335]. In addition, lesser LLD may still be perceived by patients (>5 mm) [262].

Femoral neck osteotomy is not only a critical factor to avoid LLD [8], but also defines the insertion point of the femoral component and may therefore affect its final position and orientation [9], [10]. In this context, eliminating outliers (>5 mm) is more vital than reporting the average values of the osteotomy discrepancy.

The findings of this study showed that the intra-operative use of a PSI osteotomy guide resulted in a much lower percentage of outliers (4%) in comparison with the non-guided THA group (45%). However, the author acknowledges that this study was a non-randomised uncontrolled study. Future research should evaluate if the intra-operative use of this PSI osteotomy guide increases the accuracy when compared to the free-hand osteotomy in terms of outliers.
So far, limited studies have reported the accuracy of the free-hand osteotomy. Yang et al. (2015) compared the osteotomy accuracy in two groups of patients: 1. A group that received an osteotomy guide; 2. A group that did not receive the guide. They reported a mean osteotomy discrepancy of 0.8 mm when the guide was used and 1.7 mm in the non-guided THA group ($p < 0.001$) [8]. Eggli et al. (1998) have reported a mean osteotomy discrepancy of 4.2 ± 2.8 mm when using conventional templating and no PS guides [191]. In the present study, the median (IQR) femoral neck osteotomy discrepancy with the use of a PS guide was 0.3 mm (−1 to 2 mm).

5.4.3 Limitations

Recently, 3D-CT analysis is considered a more accurate alternative to conventional X-rays [177]. However, the comprehensive anatomical representation is frequently obstructed by metal artefacts, which may hamper the definition of the osteotomy plane [165]. In response, the NMAR algorithm was utilised to differentiate between the bone and the implant. This considerably enhanced the outcome.

Overall, the processing chain of the adopted technique comprised automated stages with the intent of eliminating end measure variability. However, precise measurements of the outcome values depend on the registration of the pre- and post-operative CT scans. According to the findings of earlier CT studies, this step has been deemed credible [230].

In addition, a semi-automatic approach was used to define the achieved osteotomy as the best-fitting plane on the osteotomy area painted by the operator. Subsequently, the fitted plane was confirmed by utilising the 3D model and the sequence of CT scans, while a second operator verified its correctness in 20 randomly selected cases. Overall, the area to be painted was unambiguous, and the painting phase was deemed to have a negligible effect on the outcomes' variability.
In the current study, 4 cases (4%) reported a vertical osteotomy discrepancy beyond the clinically accepted threshold of 5mm. It is true that 3D-printed PSI guides are built based on the 3D models of the bone. In this context, the presence of soft tissue may prevent the PSI guide from fitting as planned. In addition, malposition of the oscillating saw and its width may contribute to a significant deviation of the osteotomy level from the surgical plan.

PSI is designed to fit the contours of the patient’s femoral neck in a specific configuration. However, for femurs with long necks especially, the external bony morphology may be similar across the femoral neck, and the guide may fit perfectly at more than one region. This can result in a fitting that slightly deviates from the designed, potentially contributing to a higher discrepancy from the planned osteotomy.

Although, in this study only 4% of outliers were present, design recommendations may be useful to further eliminate outliers. Future research should revolve around the design improvement of PSI neck osteotomy guides and interrogate the elimination of outliers in primary THA. Effective design alterations would be incorporated to act in restrictive way in terms of fitting, so that the design results in a specific fitting across the femoral head-neck junction. For instance, incorporating a protrusion so that the guide also encloses the femoral head, like in Figure 5-19, would potentially restrict the guide’s fitting across the femoral neck.

Additionally, the angular discrepancy between the planned and achieved osteotomy planes characterises how accurate the PSI guide is and may affect the vertical osteotomy discrepancy most medially. However, even in cases where the vertical discrepancy is moderately variable between the medial and proximal part due to angular inconsistencies, surgeons typically equip a particular area to assess the vertical position of the femoral stem. This region corresponds to where the saw blade is initially positioned (posterior
aspect of the proximal femur), making its selection the most suitable for evaluating the accuracy of the PSI guide.

Figure 5–19: A design alteration may be effective for eliminating outliers. The inclusion of a protrusion enclosing the femoral head (A), for instance, may result in a more exact fit of the PSI guide across the femoral head-neck junction (blue line-B), restricting a potential deviation of the fitting from the planned (transparent light grey position of the guide - C).

Lastly, only one PSI femoral osteotomy guide was evaluated in this study, and the results may not be relevant to other commercially available PSI designs. In addition, future randomised controlled trials with an estimated sample size are required to assess critically the contribution to better clinical function and survivorship.
5.5 Conclusion

Clinical evaluation of a commercially available PSI femoral neck osteotomy guide is important to assess whether the plan is achieved intra-operatively. The findings of this study propose that through the use of a 3D-printed PSI femoral neck osteotomy guide, the surgeon can deliver the femoral neck osteotomy as planned with the potential to reduce errors and limit outliers that may lead to asymmetry.
5.6 Key findings

The key findings of this chapter are:

◊ The commercially available PSI osteotomy guide, MyHip from Medacta, can adequately deliver the femoral neck osteotomy with high accuracy to the plan in primary THA.

◊ Four per cent (4%) of the cases reported a discrepancy beyond the clinically accepted threshold of 5mm.
Guiding PFV using a PSI guide
Chapter 6 Guiding PFV using a PSI guide

6.1 Introduction

Among the variables involved in surgical planning of a primary THA is PFV. Implantation of the femoral stem with either excessive or inadequate PFV is associated with post-operative complications [6], [7], [236]–[238], [263], [265], [296], [322].

In primary uncemented THA, the femoral stem adapts to the morphology of the proximal femur, leaving the surgeon with limited control of the PFV [231], [235], [238], [268], [295]. As a consequence, high variability of PFV has been reported in primary uncemented THA (see Table 4-2). In cemented THA, the variable nature of the cement mantle accommodates the intra-operative surgical adjustability of the PFV [231], [233], [266], [288]. However, this technique is subjected to the surgeon’s perspective and has proven to demonstrate poor precision [231], [314].

In the previous chapter, the PFV of a cemented femoral stem design reported a high variability, ranging from 5° to 34° (see Figure 4-8), whilst 20% of the femoral stems reported a PFV of more than 30° (see Figure 4-9). This information indicated the need to develop a surgical tool to guide PFV closer to the surgical target (20°) during primary cemented THA.

3D-printed PSI has recently been developed to guide the implantation of the femoral component in primary THA [35] and may act as an aiding tool in guiding the PFV closer to the surgical target. However, there is no commercially available PSI tool for guiding the PFV of a cemented femoral stem in primary THA.
This chapter introduces a novel PSI guide designed to deliver a PFV of 20° and aims to better understand whether its intra-operative use results in a more acceptable range of PFV in primary cemented THA.

6.1.1 Motivation

To deliver a PFV within the intended range. This would improve the clinical function of the hip arthroplasty and patients would potentially benefit from optimal post-operative hip biomechanics.

6.1.2 Aim

To assess if a novel PSI guide results in a lower variability of PFV in primary cemented THA.

6.1.3 Objectives

To achieve this aim, the objectives were:

- To measure and compare the PFV angles in two groups of patients; 1. A PSI-guided THA group; 2. A non-guided THA group.
- To evaluate the clinical outcome.
6.2 Materials and Methods

6.2.1 Study Design

Figure 6-1 illustrates the study design of this chapter.

Figure 6–1: Study Design.

This was a prospective non-randomised controlled study involving a total of 36 hips of 35 patients that underwent primary cemented THA due to OA between February 2020 and December 2021. Two groups of patients were consecutively studied: 1. A group of 24 patients (25 hips) that did not receive a PSI PFV guide; 2. A group of 11 patients (11 hips) that received a PSI PFV guide (Table 6-1). Before the surgery, a customised guide was designed and developed based on a patient-specific femoral coordinate system. During the surgery, it was used to assist the surgeon in achieving the surgical target with regard to the PFV in the PSI-guided THA group. PFV angles were subsequently measured using the post-operative CT data, in both groups and subsequently compared to...
understand if the intra-operative use of PSI guide delivered a more acceptable range of PFV. In addition, the clinical outcome was evaluated.

The outcome measures were:

1. PFV angles in the non-guided and PSI-guided THA groups.
2. Clinical outcome.

**Table 6-1: Study group characteristics.**

<table>
<thead>
<tr>
<th></th>
<th>Non-Guided Group (N=25 Hips)</th>
<th>PSI-Guided Group (N=11 Hips)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (Females) (%)</td>
<td>14 (56)</td>
<td>8 (73)</td>
<td>0.35</td>
</tr>
<tr>
<td>Age (Years) (Median, Range)</td>
<td>64 (42-89)</td>
<td>69 (42-83)</td>
<td>0.64</td>
</tr>
<tr>
<td>Treatment Side (Right) (%)</td>
<td>17 (68)</td>
<td>8 (73)</td>
<td>0.4</td>
</tr>
</tbody>
</table>

6.2.2 Pre-operative CT scanning

Before the surgery, CT scans of the hip and the knee region were obtained for each patient according to the protocol described in chapter 3 (see paragraph 3.2.2).

6.2.3 External surgical planning

All patients underwent pre-operative CT planning (MyHip Planner, Medacta International SA, Castel San Pietro, Switzerland), according to the planning criteria defined in Chapter 3 (see paragraph 3.2.4).

PFV was planned at 20° relative to the PCA (Figure 6-2a), as measured on a plane perpendicular to the axis connecting the midpoint of the PCA and the intertrochanteric crest (a bone eminence located at the posterior aspect of the proximal femur) (Figure 6-2b). This coordinate system was chosen by engineers at Medacta because it represents the position of the proximal femur on the operating table.
Figure 6–2: Illustration of a) the surgical target with regard to PFV angle and b) the coordinate system used to plan the PFV and design the PSI guide.

6.2.4 Design and manufacturing of the PSI PFV guide

Design criteria and rationale

The design requirements for the PSI PFV guide were the following:

1. Patient-specific fitting

*Rationale*: Considering the high variability of femoral anatomy among patients [43], the guide should be designed according to each patient’s femoral anatomy to fit the bone contours and to deliver the surgical target.

2. Fitting of the guide on the osteotomy plane

*Rationale*: The osteotomy plane defines the entry point of the femoral stem in the intramedullary canal, potentially affecting the final position of the femoral stem [9]. Various anatomical landmarks could be appropriate to design and fit the guide to the patient’s femur. However, these approaches would exclude a significant step of hip arthroplasty:
the neck cut to insert the femoral stem. Given that the femoral neck cut in this series of patients was defined using a PSI guide, the accuracy of which was quantified (see Chapter 5), the anatomical landmark used for this PFV guide was the planned neck cut plane.

1. A targeted PFV at 20°

*Rationale:* The guide should indicate the targeted PFV intra-operatively to ensure accurate delivery of the surgical plan. For this reason, the design should incorporate a visual indication that surgeon can use intra-operatively to position the femoral stem according to the surgical target of PFV. This visual indication should be in congruency with the patient's coordinate system.

**Design and manufacturing**

Once the design requirements were defined, the author designed iterations of a concept demonstrator for this PSI block (see Appendix B), in collaboration with the surgeons to account for intra-operative factors that may affect the guide. Consequently, the unmet need defined in previous chapters regarding the PFV, the design requirements, and the final iteration of the concept demonstrator were discussed with Medacta engineers, where the PSI guide’s final design was defined, Figure 6-3.
Figure 6–3: Descriptive illustration of the PSI tool used to guide the PFV around the surgical target of 20°.

This guide is designed to fit and complement the patient’s native anatomy using bony and soft-tissue landmarks on the CT scan. It is placed at the osteotomy level, capturing the anterior and posterior superior cortexes of the planned neck cut plane. An additional protrusion on the guide helps the surgeon stabilising it on the femur, while manually adjusting the position of the femoral stem. Finally, the lateral spikes covering the length of the box chisel aim to increase stability. To guide orientation, 3D-printed slots are constructed in conformity with the femoral coordinate system utilised during planning (Figure 6-2). Intra-operative alignment of the femoral stem according to the marks indicates a PFV of 20° relative to PCA, Figure 6-3

The surgical planning was performed by Medacta (MyHip Planner, Medacta International SA, Castel San Pietro, Switzerland) as part of their established planning protocol for a primary THA. The workflow included adapting the guide’s generic design in size, position and fit to each patient’s anatomy. During the planning of each case, the generic design of the guide was virtually positioned on the planned femoral neck cut plane, and its exact AP position was determined so that the incorporated middle slot would indicate
the targeted PFV according to the patient-specific coordinate system. The 3D model of the chosen size of femoral stem was positioned accordingly. Additionally, the guide was automatically resized across the AP direction to enclose the posterior and anterior cortices of the planned femoral neck cut plane. Finally, the patient’s surface bone was removed from the guide using a Boolean Mesh subtraction. This step ensures a unique fitting of the PSI guide on the patient’s anatomy in the position defined during surgical planning.

Once the planning has been validated by the surgeon, the in-house 3D printing manufacturing process followed, using SLS as the printing method and polyamide (PA 2200) as the material, a type of nylon that is a specific moulding material developed by EOS (EOS, Munich, Germany). Nylon is considered an ideal material for the purpose of printing PSI guides. It is biocompatible and has a high melting point, making it practical for sterilisation [351]. At the same time, SLS is a powder bed fusion-based technique that allows a more precise construction of anatomical details (a highest trueness of $0.11 \pm 0.016$ mm has been reported) and without the need for supports compared to other 3D-printing techniques [352]. Finally, the PSI PFV guide was sterilised using an autoclave and stored in containers conforming to current standards.

6.2.5 Surgical approach, prosthetic components and PSI

A single consultant orthopaedic surgeon performed all the surgeries through a posterior approach. A collarless double-tapered femoral stem (X-Acta system; Medacta International SA, Castel San Pietro, Switzerland) and a hemispheric HA coated cup were used (M pact system; Medacta International SA, Castel San Pietro, Switzerland).

During the surgery, two PSI guides were used; 1. To define the osteotomy level and angle (see Figure 5.2.b), 2. To guide PFV at an angle of $20^\circ$ in the PSI-guided THA group.
6.2.6 Intra-operative adjustability of the femoral stem in the non-guided and PSI-guided THA groups

Intra-operatively, the surgeon filled the femoral canal with cement through retrograde cementation. He subsequently implanted the femoral stem within the intramedullary canal of the femur, using a stem impactor and a distal centraliser in place. In the non-guided THA group, the surgeon visually adjusted the femoral stem using the cement mantle to deliver a PFV of 20°. In the PSI-guided THA group, after the cement mantle and femoral stem are implanted into the patient’s intramedullary canal and before the cement hardens, the surgeon fit the sterilised 3D-printed guide on the osteotomy plane and secured it in this position using his hands. The PFV is achieved by alignment of the stem in the guide within the slot and secured as the cement mantle hardens.

6.2.7 Post-operative CT scanning

Post-operatively, patient-specific CT scans of the hip and the knee region were obtained using the same low-dose scanning protocol adopted for the scans acquired before the surgery (see paragraph 3.2.2).

6.2.8 Processing of the post-operative CT scans

The CT scans were corrected for metal artefacts and processed (see Paragraph 3.2.8) to generate the 3D models of femurs and implants for each patient, using Simpleware ScanIP software (Version 2021.03; Synopsis, Inc., Mountain View, USA).

6.2.9 Post-operative CT analysis

PFV was measured; the angle between the neck of the reconstructed femur and the PCA. Neck axis was defined as the line connecting the post-operative CoR and a clearly identified landmark at the top lateral area of the femoral stem [230].
The coordinate system used during planning was adopted for the post-operative measurements, to assess the accuracy (PFV – surgical target) of the PSI PFV guide (see Figure 6-2).

The PFV angles in the PSI-guided THA group were also measured using the coordinate system defined in chapter 3 (see Figure 3-10), to allow comparison between the PFV angles of the PSI-guided and the non-guided cemented THA groups.

6.2.10 Statistical Analysis

SPSS software was used to perform the statistical analysis (version 28, SPSS, Chicago, USA). The mean, median, SD, IQR, minimum, and maximum values were estimated for the PFV angles of both groups.

The Shapiro-Wilk test (sample size <50) [279] was used to evaluate if the data matched the tendency expected for a normal distribution and Mann-Whitney U test was implemented to evaluate differences between the two groups with regard to the study group characteristics [308].

The data describing the PFV angles were of different sample size and variance. Therefore, to assess if the mean values of PFV in both THA groups were statistically different, the Welch’s test was utilised [309].
6.3 Results

6.3.1 Discrepancy between the PFV and the surgical target (20°) in the PSI-guided THA group

The data describing the discrepancy between the PFV and the surgical target (20°) in the PSI-guided THA group were normally distributed (Shapiro-Wilk, p=0.8). The mean (± SD) version discrepancy in the PSI-guided THA group was 1° (± 5°) (median=2°; IQR= -2 to 4°; min=-7°; max=9°), Figure 6-4.

Figure 6–4: Planned vs achieved PFV angles in the PSI-guided THA group (n=11).

6.3.2 Comparison of PFV in the non-guided and PSI-guided THA groups

The data describing the PFV in the non-guided and PSI-guided THA groups were normally distributed (Shapiro-Wilk, p1=0.2, p2=0.8). In the non-guided THA group, the
mean (± SD) PFV was 23° (± 8°) (median=24°; IQR= 18 to 28°; min=5°; max=34°). The PSI-guided THA group had mean (± SD) PFV of 22° (± 5°) (median=22°; IQR= 18 to 24°; min=13°; max=29°). There was one outlier outside the whiskers of the box plot, illustrating the data of PFV in the PSI-guided THA group. This included 1 patient having a PFV of 13°. The mean values of PFV in two THA groups did not vary with any statistically significant difference (p=0.4), Figure 6-5.

Figure 6–5: Box and whisker plots comparing the PFV angles in the non-guided and PSI-guided THA groups (p=0.4).

6.3.3 Range of PFV in the non-guided and guided THA groups

In the non-guided THA group, PFV measurements ranged from 5° to 34°, while in the PSI guided THA group, PFV measurements ranged from 13° to 29°, Figure 6-6.
Figure 6–6: PFV in a) a group of 25 non-guided primary cemented THAs and b) a group of 11 PSI-guided primary cemented THAs. Each horizontal bar represents the PFV [Deg] per case in both THA groups.

6.3.3 Distribution of PFV in the non-guided and guided THA groups

Non-guided THA group

A PFV of less than 10° was reported in 8% of the femoral stems. Eight per-cent (8%) and 16% of the femoral stems reported a PFV of between 10° and 15° and between 15° and 20°. A PFV of 20° and 25° and between 25° and 30° was reported in 20% and 28% of the femoral stems. Twenty per-cent (20%) of the femoral stems reported a PFV of more than 30°, Figure 6-7.
Guiding PFV using a PSI guide

PSI-Guided THA group

Nine per cent (9%) and 18% of the femoral stems reported a PFV between 10° and 15° and between 15° and 20°, respectively. A PFV of between 20° and 25° and between 25° and 30° was reported in 55% and 18% of the femoral stems respectively, Figure 6-7.

Figure 6–7: A histogram depicting the distribution of PFV in the non-guided and PSI-guided THA groups.

6.3.4 Clinical outcome

The median follow-up time for the non-guided THA group was 21 months (14 to 30 months). The guided THA group had a median follow up time of 9 months (8 to 11 months). Satisfactory clinical outcome was recorded without any intra-operative complications, such as femoral fracture, based on the post-operative CT scans.
6.4 Discussion

This was the first study to evaluate the intra-operative use of a PSI guide designed to deliver a PFV 20° in primary cemented THA. PFV angles were measured in two groups of patients: 1. A group of patients (n=25) that did not receive the PSI PFV guide and one group (n=11) that received the PSI PFV guide. According to the results, the mean values of PFV did not vary with any significant difference (p=0.4). However, in the non-guided THA group, 28% of the femoral stems reported a PFV outside the intended range (surgical target ± 10°). In the PSI-guided THA group, this percentage was 0%.

6.4.1 Surgical target of PFV

In the present study, the surgeon aimed for a PFV of 20°. Following the patient’s NFV would result in a high variability of PFV, potentially affecting the outcome. Previous studies have reported that there is no consensus regarding the surgical target of the PFV in primary THA [293]. However, the femoral version is typically assumed to be normal within the range of 15° to 20° [44].

In this study, a posterior surgical approach was adopted. Komeno et al. (2006) reported that a low PFV is associated with dislocation in primary THA via a posterior approach. The mean PFV in the posterior dislocation group was 15°, while the mean PFV in the non-dislocated group was 24° [263]. Since a low PFV has been reported to link to dislocation in primary THA with a posterior approach, the surgical goal was set at the upper end of what was considered to be the normal range (15° to 20°) [44].

6.4.2 Optimal range of PFV

Adequate PFV is considered crucial for a biomechanically stable hip joint [6]. A PFV of less than 5° is associated with increased risk of impingement [266], while a PFV of less than 10° is deleterious for the rotational stability of a cemented femoral stem [6]. In this
study, 8% of the femoral stems in the non-guided THA group reported a PFV of less than 10°. In the PSI-guided group, this percentage was 0%.

The optimal range for the acetabular component orientation has been well documented. On the other hand, not much has been written about the best range for femoral component orientation. Dorr et al. (2009) has reported that the generally accepted range of PFV is between 10° and 20° [231], while Reikeras et al. (2011) has reported that the intended range of PFV is between 10° and 30° [312]. According to the findings of this study, 20% of the femoral stems in the non-guided THA group reported a PFV of more than 30°. This percentage dropped to 0% in the PSI-guided THA group.

Although the PFV was the main focus of this study, CV angles were also measured taking into consideration the importance of CV and cup AV angles in avoiding dislocation after primary THA (see Appendix A.2). Dorr et al. (2009) has suggested that the sum of the cup and the stem version should be within 25° and 50° to avoid complications [288]. Jolles et al. (2002) has reported that a CV of less than 40° or more than 60° is highly associated with dislocation after a primary THA [264].

In the non-guided THA group, 28% and 44% of the femoral stems reported a CV outside the optimal range as defined by Jolles [264] and Dorr [288], respectively. In the PSI-guided THA group, the respective percentages were 9% and 55% (see Appendix A.2). In the present study, the acetabular cup was placed prior to the femoral component. Given that a CV within the optimal range is considered crucial to avoid dislocation in primary THA, the surgeons may consider preparing the femur first [353] using surgical tools, like the proposed PSI guide, and then adjust the cup anteversion.
6.4.3 3D-CT Measurement of PFV angles

PFV angles were measured in both THA groups to check if the intra-operative use of PSI delivers a more acceptable range of PFV. PFV angles were measured based on the 3D models representing the proximal femurs and prosthetic components. This method has reported to be equivalent to the dry bone measurement method [275]–[277]. In addition, the measurements were standardised according to the coordinate system used to design the PSI guide pre-operatively. This represented the position of the patient’s femur on the operating table. As a result, post-operative measurements were independent of the scanner’s coordinate system or the patient’s position within the scanner. The PFV angles in the PSI-guided THA group were also measured using the coordinate system defined in chapter 3 for comparison, reporting excellent agreement, Figure 6-8.

Despite the undeniable advantages of the 3D-CT measurement method, CT is associate with drawbacks including a certain exposure to radiation exposure and metal artefacts [163], [176]. To address these, all patients underwent CT-scanning using the same low-dose protocol and post-op CT scans were corrected for metal artefacts.
Figure 6–8: BA of the comparison between measurements made using the coordinate system used in this study and coordinate system used in chapters 3 and 4.

6.4.4 Limitations

Figure 6-9 illustrates the 3D-printed femoral bony models of five patients and the respective PSI PFV guides that were used during the surgery. Visual intra-operative adjustment of the femoral component is necessary to align the femoral stem according to the incorporated slots.
Figure 6–9: 3D-Printed models of the proximal femurs and of the PSI guides, with incorporated slots indicating the target of the PFV.

In this regard, a femoral stem of one size more than the surgical plan may affect the intraoperative adjustability of the stem within the spikes of the PSI PFV guide. Analysis of any potential relationship between the size discrepancy of the femoral stem component and the PFV discrepancy (planned versus achieved PFV) showed that a different implanted size compared to the surgical plan did not induce a significant deviation of PFV from the surgical target (p=0.1). For instance, a case where a femoral stem of 3 sizes bigger was implanted, had a PFV that deviated 2° compared to the surgical target. In addition, a case where a femoral stem of one size smaller was implanted had a PFV that was 5° more retroverted in comparison with the surgical target, Figure 6-10.
Figure 6–10: A graph depicting the size discrepancy (achieved – planned) in the X axis and the PFV discrepancy (PFV – surgical target) on the Y axis to detect any impact of the size discrepancy on the PFV deviation from the surgical target.

In addition, the fitting of this PSI guide is dependent on the accuracy of the PSI femoral neck osteotomy guide. Potential error induced by the osteotomy guide may impact the fitting of the PFV guide. The findings of the 5th chapter suggested the efficacy of the PSI femoral neck osteotomy guide to deliver the osteotomy height and angle as planned. As far the PSI-guided THA group is concerned, the vertical osteotomy discrepancy was within 3mm in all cases. Analysis of any potential relationship between the accuracy of the PSI femoral osteotomy guide and the accuracy of the PSI PFV guide did not reveal any statistically significant association (p=0.6 for the vertical osteotomy discrepancy and p=0.4 for the angular osteotomy discrepancy), Figure 6-11.

Furthermore, this specific design of PSI would not work with an uncemented femoral stem design. In uncemented hip surgery, the femoral component tends to follow the twist
of the proximal femur and, therefore, the surgeon has limited control over the orientation of the femoral stem [231], [235], [238], [268], [295]. In this context, the surgical use of the specific PSI guide may restrict the surgical application of uncemented fixation, which is preferred when chronological and bone assessment criteria are considered [318].

Further limitations of this study include the small sample size of both groups to assess the accuracy of the PSI guide. Future research should include a prospective randomised controlled study using a large number of cases to assess the accuracy of the PFV guide, when compared to the standard technique. Additionally, PSI is considered to be a relatively recent concept in hip arthroplasty with no long-term studies on the subject, suggesting uncertainty about its contribution to a better survival rate and a sufficient long-term clinical outcome.
Figure 6–11: In cases where both the PSI osteotomy and the PFV guide were used, a) the vertical osteotomy discrepancy and b) the angular osteotomy discrepancy are plotted against the PFV deviation from the surgical target.
6.5 Conclusion

High variability of PFV has been reported in primary THA. Excessive or insufficient PFV is associated with the biomechanical instability of the reconstructed hip joint. PSI is sought to improve the accuracy of femoral stem positioning. This is the first study to evaluate the accuracy of a PSI guide designed to deliver a PFV of 20° in primary cemented THA. Lower variability of PFV values was reported when the PSI PFV guide was used compared to the non-guided THA group, highlighting the usefulness of the intra-operative tool in achieving the plan. Extensive clinical studies are necessary to convince surgeons around the accuracy of PSI and if its clinical application contributes to a sufficient long-term clinical outcome without post-operative complications.
6.6 Key findings

The key findings of this chapter are:

◊ Using a PSI guide, the PFV of a cemented femoral stem was within the intended range of PFV.
Conclusions & Future Work
Chapter 7 Conclusions & Future Work

The primary pre-operative expectation of a THA is the relief of pain and enhanced mobility, Figure 7-1 [354]. In these terms, THA is largely successful [15]. However, recent trends indicate a continuous increase in primary and revision THAs, emphasising the need to improve current tools and approaches [16]. Additionally, patients’ demands have changed over the years and often deviate from the standard expectations [12]. Patients following hip arthroplasty are now willing and expecting to join demanding activities like sports and yoga [22], [23].

![Pre-operative patients’ expectations following THA](354)

**Figure 7–1: Pre-operative patients’ expectations following THA [Reprinted from 354].**

With the continuous progress of implant materials and various surgical strategies at surgeon’s arsenal, the surgeon’s role is to sufficiently meet the competing demands, Figure 7-2 [23]. The primary goal is to achieve long-term implant survival through optimal component implantation.
Figure 7–2: The surgeon’s role in response to the contradicting demands of THA.

Restoration of native hip biomechanics is highly important to ensure implant longevity [24], [153]. However, due to the variable nature of human anatomy, traditional THA implants impede the successful restoration of natural hip biomechanics [15], [24], [25]. Alternative solutions are either highly expensive and therefore not approachable by the general population [26], [34], or have poor material and mechanical performance [32], [33].

The modern approach to THA involves a more targeted treatment relying on the use of 3D-CT pre-operative planning and 3D-printed PSI, to guide the implant selection and positioning [4].

Interestingly, the majority of hospital PAC systems utilise standard 2D X-rays, while 3D-CT planning and PSI have not been widely adopted [4]. CA strategies were used in less
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than 1% of the total number of primary THAs performed between 2012 and 2020 in the
UK [1].

Orthopaedic surgeons consider it difficult to adopt and implement technological
advancements into clinical practice [355]. Consideration of marketing criteria and of the
latest scientific evidence are often the leading lines of decision making to change practice,
highlight issues and raise awareness [355].

3D-CT planning software and the training of the medical personnel comes at an additional
monetary cost to hospitals, making their incorporation into the hospital PAC systems
challenging. Conventional radiographs can suffice in diagnosing hip arthritis at an
approximate cost of 33€ [150]. The direct cost of pre-operative CT per patient is estimated
to be not significantly higher at 53–116€ [356], which is well below the mean cost of a
primary (£7000) [3] or a revision THA surgery (£11897) [357]. At the same time, the
reported threshold below which the National Institute for Health and Clinical Excellence
is willing to pay for recommending a new treatment is £20000 to £30000 per QALY [3].

Studies have yet to prove that 3D-CT contributes to an improved clinical outcome to
justify this technological shift. So far, existing scientific evidence has supported that 3D-
CT planning is more accurate than conventional radiography in predicting the size of the
implant by up to 57%, in quantifying anatomical variables by 8%, and in restoring
parameters related to the implant position by twice as much [153], [162], [256].
Additionally, previous literature has highlighted that parameters such as the PFV, the FO
and the cup orientation angles are associated with adverse clinical events such as
do
dislocation in a primary THA [6], [260], [313].

In this context, this body of work aimed to assess and improve the role of 3D-CT pre-
operative planning and 3D-printed PSI in primary THA. Four research objectives have
been defined at the beginning of this thesis and met throughout the last four research chapters.

First, the accuracy of 3D-CT planning in predicting the implants size, FO and orientation was quantified. According to the results, surgical planning, using the commercially available Medacta MyHip system, can accurately predict the size of the femoral stem component. Correct implant size may lower the likelihood of unintended complications [222], which could benefit both surgeons and patients. More precise surgery may reduce surgical time and implant inventory [4], resulting in a more cost-effective clinical practice.

Concerning the position of the femoral component, the MyHip system can predict the FO of the femoral stem. These findings are clinically significant, considering that most surgeons use conventional X-rays to plan the position of the femoral stem and anatomical features like FO may be wrongly estimated up to 13.7 mm [209] due to patients’ malposition [162] using X-rays.

However, planning a THA based on a 3D-CT-based patient’s bony anatomy did not help predict the eventual version of an uncemented straight femoral stem (known as PFV). A PFV of less than 5° was found in 20% of the femoral stems.

The final version of an uncemented straight femoral stem is a result of inserting an object of a geometrical shape (the stem) into a highly irregular anatomical space (the proximal femur), leaving the surgeon with limited control of the PFV [295]. This was confirmed by a 3D-CT analysis of the bone-implant contact areas, which showed that these areas vary in the proximal part of the internal femoral canal, reflecting the wide range of the PFV.
This information implies that a certain fraction of hip arthroplasties using a straight-tapered femoral stem may demonstrate a tendency for a "less-than-optimal" PFV [230], potentially impacting the clinical outcome. Predicting the PFV of a straight-tapered femoral stem is therefore essential for distinguishing these cases.

Pre-operative analysis of the internal morphology of the proximal femur and the influence of the stem design may assist in better understanding of the final PFV. Additionally, equipping a large sample size of post-operative CT scans may help implement reverse engineering algorithms to eventually understand what kinds of “internal morphologies” result in an insufficient PFV.

Predicting the final PFV of a conventional femoral stem may be challenging, though, because of the radiation exposure problems with post-operative CT evaluation and the technological complexity of the required advanced algorithmic methods.

Intra-operative measurement of the final version of the broach, using either robotic or 3D-printed customised tools, may inform the surgeon about the version of the femoral stem and is considered useful to distinguish the cases that tend to exhibit greater discrepancy when compared to the NFV or the surgical target. After identifying the cases where the PFV is not sufficient (< 5°), the surgeon then, can consider the cemented fixation to deliver an adequate PFV.

Investigating whether cemented fixation can deliver a more acceptable PFV was the second research objective of the present thesis. The findings indicated that the intra-operative flexibility of the cement mantle shifted the PFV towards a more anteverted state, and all cases in the cemented THA group were anteverted of more than 5° (see Figure 7-3).
Given that an adequate PFV is crucial to avoid dislocation [238], [263] and ensure a biomechanically stable hip joint [6], [236], the above-mentioned findings are clinically relevant. However, 20% of the femoral stems in the cemented THA group were anteverted by more than 30°, resulting in a high variability of PFV. These results showed that the visual intra-operative adjustment of the cemented femoral stem helped prevent insufficient PFV but did not deliver the best range of PFV.

Figure 7–3: PFV in the a) uncemented THA group; b) non-guided cemented THA group; c) PSI-guided cemented THA group.

In light of this, my research team and I recognised the necessity to build a tool to enhance the accuracy of PFV in the group of cemented THAs. Given that femoral stem implantation follows femoral neck osteotomy, the PSI surgical instrument would depend on the osteotomy level's accuracy.
Conclusions & Future Work

In this single surgeon series, the femoral neck osteotomy was performed using a commercially available PSI guidance system (MyHip from Medacta). Although PSI osteotomy guides have been commercially available for several years, little has been published on this new technology. For the first time, the accuracy of this PSI osteotomy guide was tested in a clinical setting using 3D-CT analysis, which was the third research objective of the current thesis. The findings suggested that surgeons can use this tool to deliver the planned femoral neck osteotomy with high accuracy to the surgical plan. Additionally, a comparison with a small sample size of non-PSI-guided THAs highlighted that PSI-guided osteotomies reported fewer outliers than the conventional manual approach. In the non-guided THA, the osteotomy discrepancy was beyond the clinically accepted threshold in 45% of patients. In the PSI-guided THA, this percentage dropped to 4%.

The final objective of this thesis was to assess whether the surgical use of a new PSI PFV guide can deliver a more acceptable range of PFV in primary THA. The new guide was used in 11 cemented THAs. According to the results, all cases in this THA group reported a PFV between 10° and 30°, Figure 7-3. Certainly, the benchmark of this newly introduced technology is not merely accomplishing a statistically significant difference in terms of PFV but also contributing tangibly to an improved clinical outcome for patients.

Besides 3D-printed PSI, the modern approach to THA involves robotic-assisted or image-navigated technologies. However, these advanced modalities do not alleviate the concern of radiation dose, as they require pre-operative CT scans to perform virtual 3D reconstruction [358]. Advantages include increased accuracy compared to conventional THA [288], [358]. Regarding the sophistication of this technology, previous studies have reported no learning curve in implant placement. Nevertheless, a learning curve of 12-35 cases was apparent in other studies [359], and mechanical problems have led to the
conversion of robotic-assisted to manual THAs in 18% of patients [358]. Additionally, the robots are compatible with only specific implant brands [358].

Regarding the femoral side, which is the focus of this thesis, the main asset of these tools over 3D-CT is that their use enables the measurement of the orientation of the femoral stem intra-operatively to indicate the final PFV [235]. Inspite of this, robotic technologies cannot guide the PFV of an uncemented femoral stem, and the existing solutions of PS implants cost significantly higher than a conventional implant. For this reason, previous studies have suggested the notion of CV to avoid dislocation [288]. Recent scientific evidence, however, have highlighted that focusing solely on the CV to avoid dislocation is insufficient [320] and suggested a patient-specific dynamic hip planning considering the hip-spine relationship, stem design and PFV [319].

In this context, the findings of this thesis inform the modern concepts of implant placement by highlighting that surgeons can guide the PFV of a cemented femoral stem using 3D-printed PSI. From an economic point of view, the potential to minimise complications through correct implant orientation using PSI instead of the highly expensive robotic-assisted surgery benefits all the players involved in the chain. The cost of the Stryker Mako robot is estimated at up to $750,000, excluding the annual maintenance cost and the expenses of the disposable equipment per case [11]. Contrastingly, the cost of the PSI guide per case, including the CT planning, is estimated up to $1475 [360], with the possibility of bending the cost curve if the 3D-printing equipment is provided within the hospital.

Despite the fact that long-term clinical studies are needed to identify if the delivery of an optimal PFV contributes to a sufficient long-term clinical outcome, the improvement of the femoral component version in a relatively cost-effective manner may result in the widespread adoption of 3D-CT planning and PSI.
Appendix A

Cup Orientation & Combined Anteversion (CV) Measurements (See Chapters 3 & 4)
Appendix A Cup Orientation & CV Measurements (See Chapters 4 & 6)

The concept of the CV has been recently considered towards the surgical approach of a primary uncemented THA; the sum of the stem and cup version angles should be within a range of 25-50° [288]. Radiographic cup anteversion was post-operatively computed to measure and check CV [361]. This was defined as the angle between the axis across the cup rim and the coronal plane [361]. In addition, radiographic cup inclination was measured to check how many cases were within the safe zone as defined by Lewinnek in both THA groups [228].

The angles were semi-automatically measured using a Simpleware plug-in called CT measurement report (Simpleware ScanIP, Version 2021.03; Synopsis, Inc., Mountain View, USA). The coordinate system used for the measurements was the APP plane [226]. First, the operator was asked to select three anatomical landmarks based on the 3D reconstructed pelvic model. These include: the ASIS and the pubic symphysis. Once the APP plane was defined, the cup rim was utilised to locate 10 points to define the best fit cup plane. Automatic computation of the cup anteversion and inclination angles by the software followed.

A.1 Cup Orientation and CV in uncemented and cemented THA (see chapter 4)

Cup INC Measurements

The data describing the cup inclination in the uncemented THA were normally distributed (Shapiro-Wilk, p=0.5). The data describing the cup inclination in the cemented THA did not match the tendency expected for a normally distributed (Shapiro-Wilk, p=0.01). In
the uncemented THA group, the median (IQR) cup inclination was 39° (34° to 43°). The cemented THA group had a median (IQR) cup inclination of 39° (37° to 41°).

**Cup AV Measurements**

The data describing the cup AV in uncemented and cemented THA matched the tendency expected for a normal distribution (Shapiro-Wilk, p1=0.5; p2=0.5). In the uncemented THA group, the mean (± SD) cup anteversion was 23° (± 8°) (median=23°; IQR= 17° to 28°; min=5°; max=40°). In the cemented THA group, the mean (± SD) cup AV was 26° (± 7°) (median=25°; IQR= 20 to 30°; min=14°; max=41°). The mean values of cup AV angles in both THA groups did not vary with any statistical difference (p=0.09).

**Acetabular cup placement in target zone in uncemented and cemented THA**

Acetabular cup placement within the safe zone as defined by Lewinnek [228], was obtained for 49% of the femoral stems in the uncemented THA group and 52% of the femoral stems in the cemented THA group, Figure A-1.

**CV in uncemented and cemented THA groups**

The data describing the CV in the uncemented and cemented THA groups matched the tendency expected for a normally distributed (Shapiro-Wilk, p1=0.1; p2=0.9). CV of the uncemented THA group was a mean (± SD) of 35° (± 12°) (median=37°; IQR= 27 to 45°; min=7°; max=56°). CV of the cemented THA group was a mean (± SD) of 49° (± 11°) (median=49°; IQR= 42 to 56°; min=28°; max=73°).

A combined version within the optimal range (25° to 50°) [288], was obtained for 69% of the femoral stems in the uncemented THA group and 56% of the femoral stems in the cemented THA group, Figure A-2.
Figure A–1: A scatterplot depicting acetabular cup placement in the uncemented and cemented THA groups.
Figure A–2: CV in a) the uncemented THA group and b) the cemented THA group.
A.2 Cup Orientation and CV in the non-guided and PSI-guided THA (see chapter 6)

Cup AV Measurements

The data describing the cup anteversion in the non-guided THA matched the tendency expected for a normal distribution (Shapiro-Wilk, p=0.5). The data describing the cup anteversion in the PSI-guided THA group, were not normally distributed (Shapiro-Wilk, p=0.05). In the non-guided THA group, the median (IQR) cup anteversion was 25° (20° to 30°). The PSI-guided THA group had a median (IQR) cup anteversion of 25° (24° to 31°).

CV in the non-guided and PSI-guided THA groups

The data describing CV angles in the non-guided THA group matched the tendency expected for a normal distribution (Shapiro-Wilk test, p1=0.9). The data describing the CV angles in the PSI-guided THA group were not normally distributed (Shapiro-Wilk test, p1=0.05). CV of the non-guided THA group was a median (IQR) of 49° (42 to 56°). CV of the PSI-guided THA group was a median (IQR) of 49° (41 to 53°).

A CV within the optimal range (25° to 50°) [288], was obtained for 56% of the femoral stems in the non-guided THA group and 45% of the femoral stems in the PSI-guided THA group, Figure A-3.
Figure A–3: Bar charts displaying the CV angles in a) the non-guided THA group and b) the PSI-guided THA group. Bars lying within the green box depict the cases in which the CV is within the optimal range of 25–50°, as defined by Dorr [288].
Appendix B
Conceptual Designs
(See Chapter 6)
Appendix B Conceptual designs (see chapter 6)

Figure B–1: Conceptual designs of PSI guides.

Figure B-1 includes the design iterations of the concept demonstrator for the PSI block, designed in SolidWorks (Dassault Systèmes SOLIDWORKS Corp., Waltham, Massachusetts, USA) before discussing the idea of a PFV PSI guide with the engineers at Medacta.
Appendix C
Publications and Conference Contributions
Appendix C: Publications & Conference Contributions

C.1 Full list of publications (current and intended)


◊ **Moralidou M**, Di Laura A, Henckel J, Hothi H., Hart A. Cemented or uncemented fixation: which allows a more acceptable prosthetic femoral version in total hip arthroplasty? (Under review)


C.2 Conferences

C.2.1 Podium Presentations

◊ American Academy of Orthopaedic Surgeons (AAOS). (2022)

Understanding the Impact of Fixation Technique on the Stem Version in Primary Total Hip Arthroplasty (THA).

C.2.2 Poster Presentations

◊ European Federation of National Associations of Orthopaedics and Traumatology (EFORT). (2022)

Femoral Prosthetic Version in Primary Total Hip Arthroplasty (THA): Understanding the effect of the fixation method using 3D-CT analysis.
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