Patient-reported outcomes following single- and multiple-radius total knee replacement. A randomised, controlled trial

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Whilst single-radius designs of total knee replacement (TKR) have theoretical benefits, the clinical advantage conferred by such designs is unknown. The aim of this randomised, controlled study was to compare the short-term clinical outcomes of the two design rationales. 105 knees were randomised to receive either single radius (Scorpio, Strkyer, Newbury, UK; SR group) or multiple radius (AGC, Biomet, Bridgend, UK; MR group) TKR. Patient reported outcomes (Oxford Knee Score, OKS and Knee Society Score, KSS) were collected at six weeks, six months, and one year following surgery.

No knees were revised. There was no difference in primary outcomes: OKS was 39.5 (95%CI 36.9-42.1) in the SR group and 38.1 (95%CI 36.0-40.3) in the MR group (p=0.40). KSS was 168.4, (95%CI 159.8-177.0), in the SR group; 159.5, (95%CI 150.5-168.5) in the MR group (p=0.16). There was a small but statistically significant difference in the degree of change of the objective subscale of the KSS, favouring the SR design (p=0.04), but this is of uncertain clinical relevance. The reported benefits of single-radius designs do not provide demonstrable functional advantages in the short-term.

Keywords: total knee replacement; single-radius; multiple-radius, patient-reported outcome measures

Introduction

Total knee replacement (TKR) is a common and successful procedure. Several designs of TKR exist with excellent long-term data supporting their use [1]. However, implant manufacturers continue to innovate and over 60 designs of TKR are available on the market in the UK alone. The failure of new designs to provide substantial improvements in outcome following TKR has led some authors to question the need for further refinements in arthroplasty design [2].

Most TKR implants on the market today are modifications of the total condylar design first used in the 1970s [3]. In most designs, the femoral component is designed to replicate normal distal femoral anatomy, with variation in the radius of curvature of the femur in the sagittal plane, in an effort to replicate normal knee kinematics. An alternative approach is to use a single radius of curvature in an effort to maintain isometry of the collateral ligaments throughout the arc of flexion, preserving knee stability and minimising polyethylene wear. It is not clear whether knee replacements with different design rationales will lead to differences in patient-reported outcome [4].

The aim of this study was to compare patient-reported outcomes following single-radius (SR) or multiple-radius (MR) designs of TKR.

Patients and Methods

Following ethical approval, a randomised controlled study was designed with the aim of comparing clinical outcomes of patients receiving a single-radius TKR (Scorpio, Stryker, Newbury, UK), with those receiving a multiple-radius TKR (AGC, Zimmer Biomet, Bridgend, UK).

The primary outcome measure was knee function at one year, as measured using the Oxford Knee Score (OKS) and the Knee Society Score (KSS) [5,6]. The OKS is a validated, patient-completed questionnaire designed to assess outcome following TKR. The OKS consists of questions in 12 domains, each scored from 0 (the worst score) to 4 (the best), giving an overall score between 0 and 48 points [7]. The KSS consists of an ‘objective’ (physician-completed) subset assessing alignment, stability and range of movement, and a ‘functional’ (patient-completed) subset assessing pain and function, abbreviated to KSS(Obj) and KSS(Fcn) respectively. Each score is graded from 0 (the worst score) to 100 (the best); therefore the overall score can be graded from 0-200. As secondary outcome measures, interval scores (at six weeks and six months) and one year OKS and KSS analysed as change scores (the degree of change from pre-operative to one year scores) were analysed.

A power calculation was performed, on the basis of a previous study of TKR outcomes. In order to detect a difference of 10% in the primary outcome measure (OKS), with a power of 80% and a significance level of 0.05, 50 patients were required in each group.

Recruitment was completed by the senior author (PG) in the outpatient clinic. Consecutive patients being listed for total knee replacement were enrolled after they had given their informed consent. All patients undergoing a routine primary total knee replacement were eligible for the study. Exclusion criteria were a history of previous knee surgery (knee replacement, patellectomy or osteotomy); a history of trauma; and patients who were out of area and unable to complete follow-up.

On the morning of surgery, patients were randomised to receive either the single-radius (SR group) or multiple-radius (MR group) knee replacement design. The randomization sequence was created using a computer-generated randomisation table, with the results being inserted into a series of sealed envelopes. At the time of induction of anaesthesia, the next envelope in the sequence was opened and the prosthesis selected accordingly. All functional assessments were performed by a single member of the physiotherapy team who was blinded to the prosthesis the patient had received. The patients were also blinded to the prostheses they had received.

Functional scores were measured pre-operatively, at six weeks, six months, and one year following implantation. This interval was selected as it is the point at which scores peak following TKR, before reaching a plateau and ultimately declining as the patient ages [8,9].

Outcomes were compared using an independent-samples T-test. All analyses were performed using Stata v.12 for Windows (Stata Corp, College Station, TX).

Results

105 patients were recruited to the study, 54 in the MR group and 51 in the SR group. Overall 48/105 were male (45%) and the mean age was 72.4 years. There were no significant differences in age, gender, or pre-operative knee scores between the two groups (Table 1).

Two patients (one in each group) died of unrelated causes prior to completion of the study. Two further patients (one in each group) failed to attend their final follow-up appointment. Therefore, 101 patients, 52 in the MR group and 49 in the SR group, entered the final analysis.

There were no revisions. Two patients required manipulation under anaesthesia for stiffness, 6 weeks following surgery (one in each group).

All functional scores increased significantly in both groups (Table 1). The OKS increased from a mean of 20.8 (95% Confidence Intervals 19.2-22.4) pre-operatively to 38.8 (95% CI 37.1-40.5) at one year ($p<0.0001$). The overall KSS increased from 101.1 (95% CI 95.5-106.6) to 163.8 (95% CI 157.6-170.0) over the same time period ($p<0.0001$). Subdivided into objective and functional subscales, the objective subscale increased from 51.6 (95% CI 48.2-55.0) to 75.2 (95% CI 71.0-79.4, $p<0.0001$) and the functional subscale increased from 49.5 (95% CI 45.9-53.0) to 88.5 (95% CI 85.6-91.5, $p<0.0001$).

The OKS was similar in both groups at each follow-up interval. At one year, the mean OKS was 39.5 (95% CI 36.9-42.1) in the SR group compared to 38.1 (95% CI 36.0-40.3) in the MR group ($p=0.40$, Figure 1). Similarly, whilst the overall KSS showed a trend towards superior function in the SR group, this did not reach statistical significance (mean KSS 168.4, 95% CI 159.8-177.0, in the SR group; 159.5, 95% CI 150.5-168.5, in the MR group, $p=0.16$, Figure 2). Findings were similar whether outcomes were expressed as absolute scores or as the degree of change from pre-operative to one year scores (change in OKS was 18.0 (95% CI 15.1-21.0) in the SR group compared to 18.0 (95% CI 15.4-20.5) in the MR group, $p=0.97$; change in KSS was 66.6 (95% CI 55.0-78.2) in the SR group compared to 59.1 (95% CI 49.1-69.1) in the MR group, $p=0.32$).

The objective subset of the KSS was similar in the two groups at each follow-up interval. At one year, the mean KSS(Obj) was 78.6 (95% CI 73.2-83.9) in the SR group compared to 72.0 (95% CI 65.6-78.4) in the MR group, $p=0.12$ (Figure 3). The functional subset of the KSS again showed no significant difference. At one year, the mean KSS(Fcn) was 89.3 (95% CI 85.4-93.9) in the SR group compared to 87.5 (95% CI 83.3-91.6) in the MR group, $p=0.47$, Figure 4). A significant difference was determined if the KSS(Obj) was expressed as a change score rather than an absolute score: change in KSS(Obj) was 28.6 (95% CI 22.1-35.0) in the SR group compared to 18.9 (95% CI 12.4-25.5), p=0.04. No significant difference was determined in KSS(Fcn) if expressed as a change score: change in KSS(Fcn) was 37.3 (95% CI 31.4-44.5) in the SR group compared to 40.1 (95% CI 34.0-46.2), p=0.62.

Discussion

This randomised, controlled study has failed to detect any clinically relevant difference in clinical outcome between TKR performed using a single-radius prosthesis and TKR using a multiple-radius prosthesis. Whilst statistical significance is achieved in one of the secondary outcome measures (the objective subscale of the KSS when expressed as a change score rather than an absolute score), this is of questionable clinical relevance and is likely to represent Type I error as a result of multiple testing [10].

Excellent results have been reported for both of the prostheses involved in this study [11-14]. The AGC has a polyradial femoral component, which was designed to match the normal femoral anatomy on the basis of anatomical studies prior to the design of the implant (Figure 5). By recreating the normal femoral anatomy, multiple-radius designs aim to re-create normal kinematics. By contrast, the Scorpio TKR has a single radius of curvature (Figure 6). This was primarily designed to avoid instability: by maintaining isometry of the collateral ligaments throughout the range of flexion, in theory, the knee should be stable at every increment of that range [15]. Single-radius designs also have the potential to improve quadriceps function compared to multiple-radius designs, probably due to a decrease in patellar flexion angle [16]. In practice, the differences in the geometry between the two designs are relatively small (Figure 7)

Whether these theoretical benefits translate into a measureable functional benefit for patients remains uncertain. Jo *et al* randomised 100 patients to receive either single- or multiple-radius TKR, finding increased knee stability at 30° of flexion in the single-radius group;

however, this did not correspond to any difference in functional outcome at two years [15]. Likewise, Larsen *et al* compared 16 single radius knees to 16 multiple radius knees and 16 healthy controls, finding that the single-radius knees had kinematics more similar to that seen in the controls, although the two designs again did not differ in functional outcome at one year [17]. Molt *et al* compared a single radius design to its predecessor, which was multiple-radius, in 60 patients [18]; they found no significant differences in migration (as measured using radiostereometric analysis) or functional outcome at one year. A single, retrospective cohort study compared two unmatched groups of patients receiving the same implants as studied in Molt's RCT, finding superior KSS results in the single-radius design, although it has to be noted that these results were not adjusted for differences between the two groups being studied [19].

This study was a double-blind, randomised controlled trial. All operations were performed by a single surgeon, and validated outcome measures were used. Limitations of this study include the short follow-up interval, although one year has been demonstrated in other studies to be predictive of outcome into the medium term [20,21]. Whilst the groups were small, the study was adequately powered to detect a clinically significant difference in the primary outcome studied. More subtle differences between the outcome of the two prostheses could have been detected by using outcome measures more suitable for high-performance arthroplasty patients [22,23], or by examining other outcomes such as gait or kinematic performance [17,24]. An ideal study design would have used implants which are identical aside from the geometry of the femoral component, however, to our knowledge there is no implant on the market which has single- and multiple-radius options within the same overall design. The two implants that we chose to use were comparable in design rationale and long-term evidence-base, however, they differed in a number of factors. Most important amongst these is the tibiofemoral articulation, which has a higher degree of conformity in the Scorpio than in the AGC.

Taken together with the existing literature, this study does not provide any evidence of superiority for either single- or multiple-radius designs in TKR. The presence of a longer-term benefit to one or the other cannot be excluded but further long-term studies are needed to elucidate this.

Figures

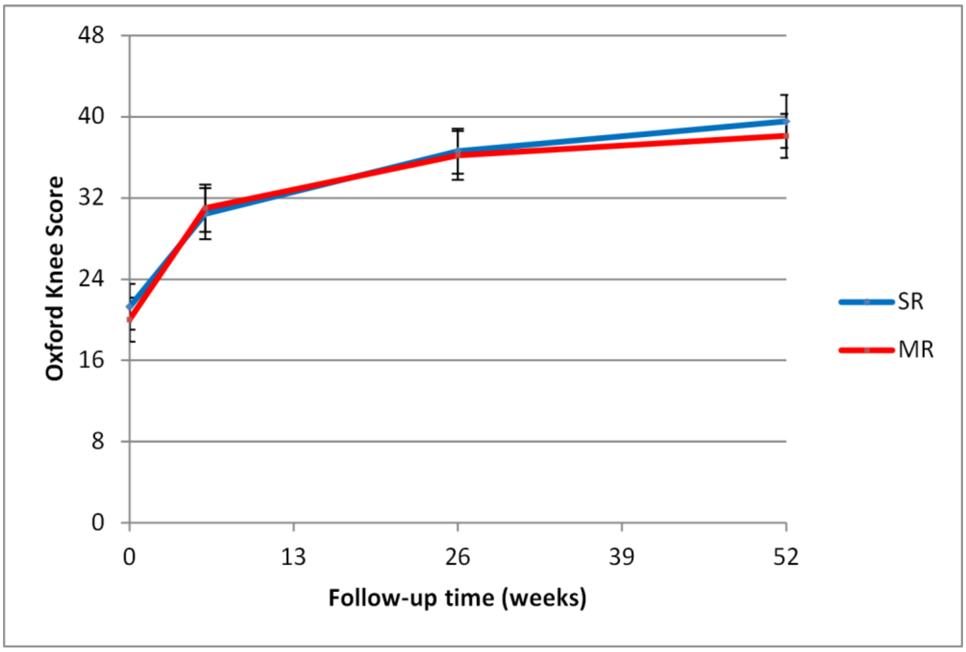

Figure 1: Oxford knee scores in single radius (SR) and multiple radius (MR) TKR preoperatively and at six weeks, six months and a year following surgery

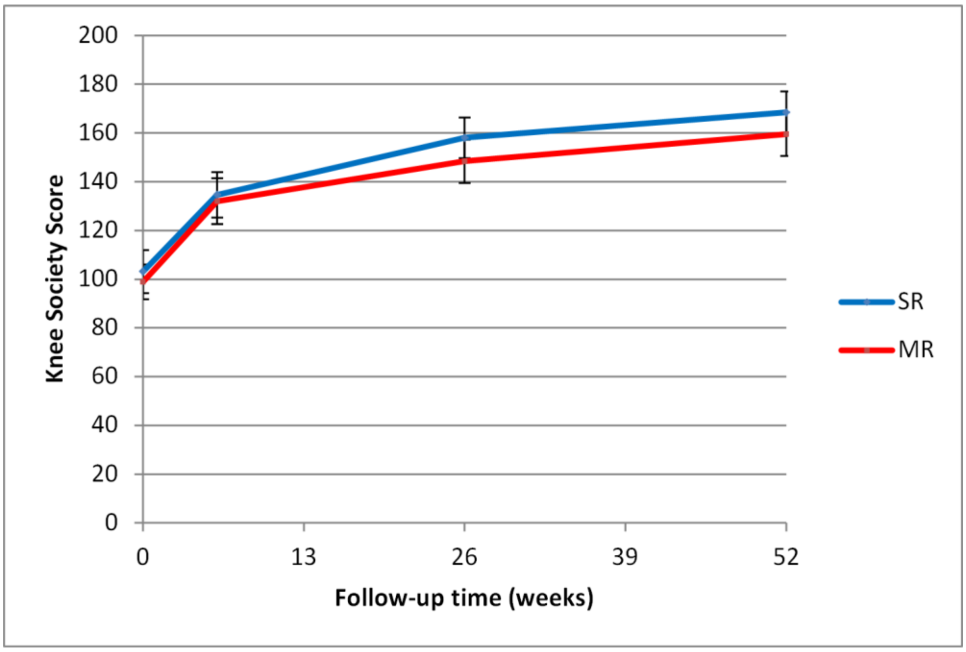

Figure 2: Overall Knee Society Scores preoperatively, at six weeks, six months and one year post-operatively in single radius (SR) and multiple radius (MR) groups.

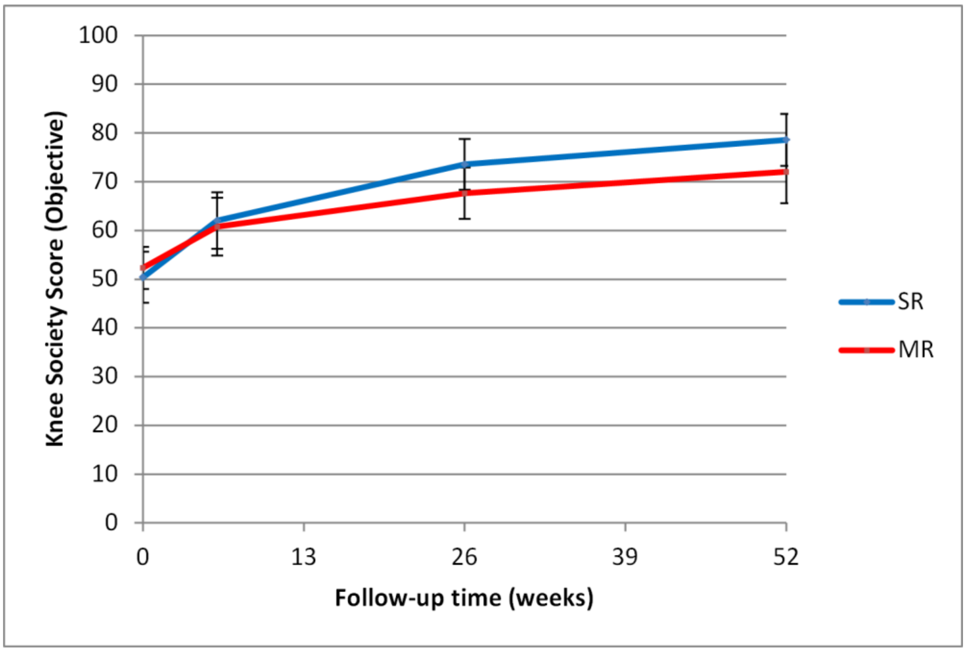

Figure 3: Knee Society Score (Functional component) pre-operatively, at six weeks, six months and one year following surgery in single radius (SR) and multiple radius (MR) groups.

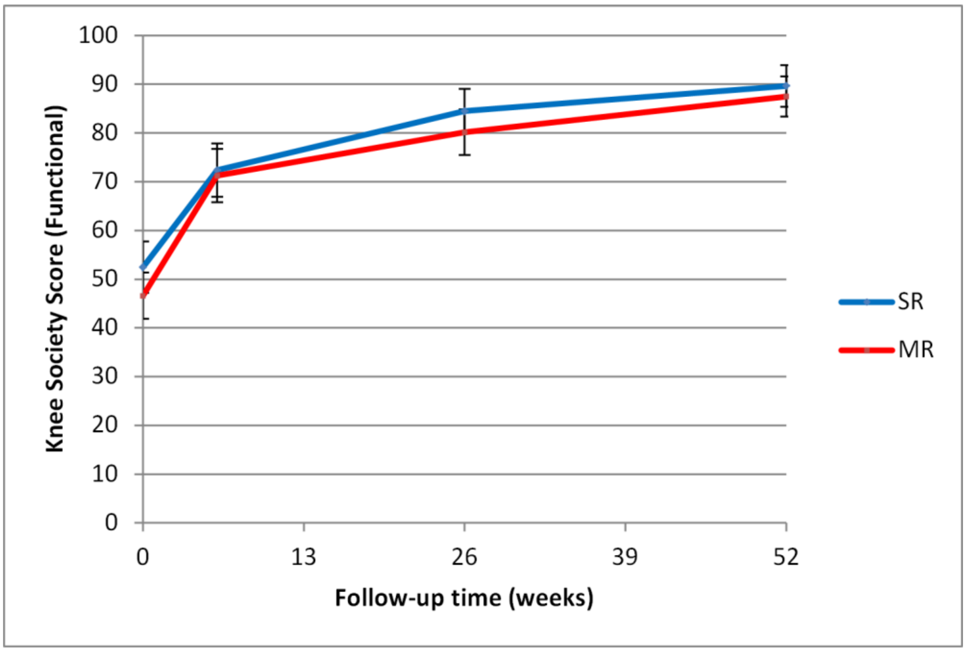

Figure 4: Knee Society Score (Objective component) pre-operatively, at six weeks, six months and one year following surgery in single radius (SR) and multiple radius (MR) groups.

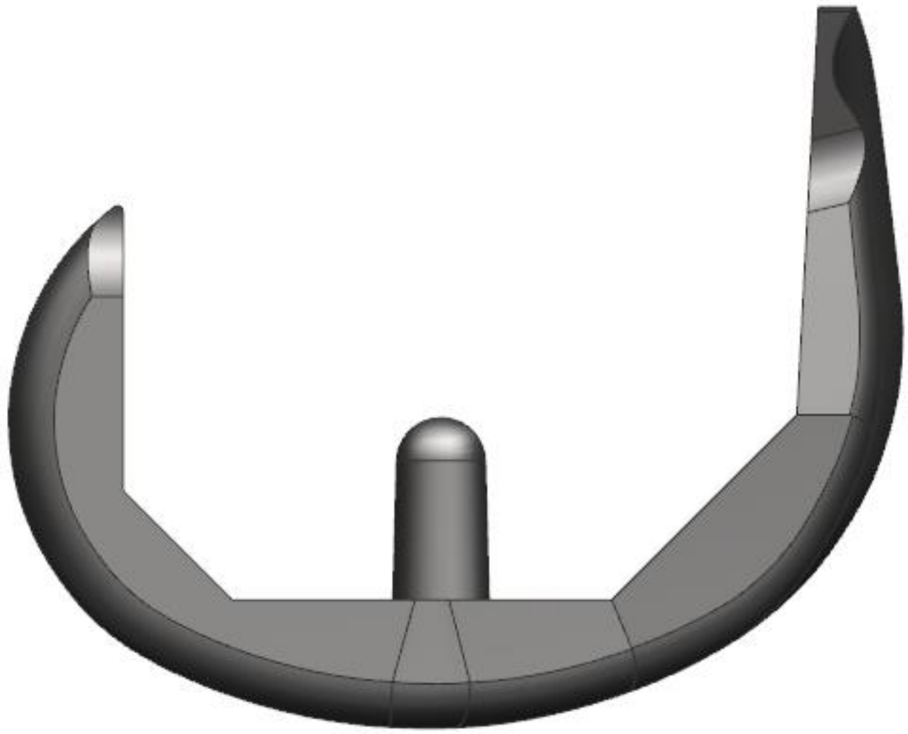

Figure 5: A CAD model of the femoral component of the AGC implant, demonstrating the multiple radii of curvature. Image courtesy of Zimmer Biomet.

Figure 6: A photograph of the Scorpio implant demonstrating the single radius femoral component. Image courtesy of Stryker.

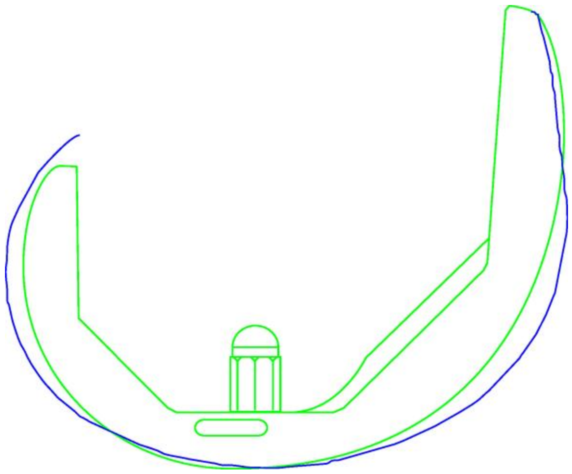

Figure 7: A composite image of the two implants demonstrating the difference in geometry between the femoral components. The Scorpio is in green, whilst the AGC is in blue.

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