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Research Article

Patient Outcomes Following Single-Radius Versus Multi-Radius Total Knee Replacement: A Cohort Study Evaluation

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Abstract

Aim: Around 20% of patients are dissatisfied following total knee replacement (TKR). This cohort study compares the clinical outcome between Single-Radius (SR) and Multi-Radius (MR) TKR.

Methods: A single surgeon, prospective concurrent cohort study was undertaken as part of a procurement service evaluation. All consecutive patients in unit A received the SR TKR, and in unit B the MR TKR. 82 TKRs (45 SR and 37 MR) were performed in 80 patients using an otherwise identical treatment regime. All patients underwent regular clinical evaluation using the Oxford Knee Score (OKS).

Results: Overall, 88.6% of patients (38/42 in SR group, and 32/37 in MR group) experienced improvement in OKS score. Each group had comparable demographics for age, sex, BMI, ASA grade and baseline OKS ($p>0.05$). There were two significant complications in the SR group (one pseudoaneurysm, one pulmonary embolism) and two unrelated deaths occurred in the SR group. The MR group suffered no complications. No patients required revision surgery. Excluding deaths, data were available for all patients at 2 years follow-up. The median OKS score in SR knees improved from 14 (pre-operative) to 34 (2 years), and from 17 to 35 in MR knees ($p=0.662$). Internal comparison in 11 patients with the alternative implant in the contralateral knee showed no significant differences in OKS.

Conclusions: This unique single surgeon prospective comparative mid-term evaluation demonstrated improvement in OKS score in 88.6% of patients undergoing TKR. With 100% 2-year follow-up, no significant difference in outcome (OKS) was demonstrated between SR and MR implants.

Keywords: Total knee replacement, Single-Radius, Multi-Radius, Oxford Knee Score.

Introduction

Approximately 20% of patients remain dissatisfied following a total knee replacement (TKR) [1,2] and this proportion has not changed over the last two decades [3,4]. Furthermore, the current generation of patients undergoing TKR are heavier, younger, more active and have higher functional demands [5] than their previous counterparts. These demographic changes, coupled with higher expectations, appear to be one of the major driving forces in the quest for improved implant design (of which there are over 60 available in the UK [6]), aiming to combine both excellent function and survivorship.

One such development is the single radius (SR) TKR prosthesis with numerous purported theoretical advantages which may include improved survivorship [7,8] function [9,10] patient outcomes [11,12] and constraint options [7,13,14] when compared to the long-established multi-radius (MR) prosthesis.

Traditional TKRs have been based on early cadaveric studies in which the sagittal profile of the distal femur suggested a variable flexion-extension axis, which was located in the posterior femoral condyles, perpendicular to the sagittal plane. This has been the basis of the MR design that features a "J" curve [15]. Studies by Hollister and associates [16] and subsequently Churchill et al. [3] identified that the optimal flexion-extension axis and the transepicondylar axis were closely approximated and passed through the centres of the posterior femoral condyles, coinciding with the origin of the collaterals [17-21]. This has led to the development of the SR concept, with some convincing theoretical data of collateral ligament isometry and a consistent moment arm through the range of motion [3]. Although several studies have convincingly shown improved intra-operative stability for the SR versus MR prosthesis [10], apart from this there is little or no convincing data to reflect improved clinical benefits to patient outcomes.

In order to investigate the clinical outcomes for the two prostheses, and, importantly eliminate the inevitable differences in studies undertaken from multiple centres, with variable protocols, different surgeons, physiotherapists etc. we have prospectively collected data for a series of patients undergoing TKR split equally for SR versus MR prosthesis, all operated on by one clinical team (and specifically one senior surgeon undertaking / supervising all procedures) with identical pre- and post-operative protocols. Each patient was reviewed at identical times and each completed the validated and nationally recognised Oxford Knee clinical outcome score [22] for a minimum of 2 years. No patients were lost to follow up barring two patients due to unrelated deaths.

Materials & Methods

This evaluation was underpinned by cohort study methodology. All patients were reviewed preoperatively by the senior author (PML) and diagnosed as requiring TKR for degenerative osteoarthritis. Ethical approval was confirmed from the Research and Development department (CT/1061/19-20). Surgery was undertaken by the senior author (PML) or under his direct supervision in one of two hospital sites. The senior surgeon was experienced in both prosthetic systems and therefore required no additional training for either prosthesis (i.e. no 'learning curve').

The SR prosthesis (Triathlon, Stryker) was only used in one of two hospital sites, with all patients in unit A receiving the SR knee and those allocated to unit B received the MR prosthesis (PFC Sigma, DePuy). Allocation of patients was via the waiting list, based on residence and timing of listing for surgery and not influenced by the surgical team that cover both units, with identical pre and postoperative protocols. Oxford scoring was undertaken for each patient at regular and identical intervals post operatively, at 6 weeks, 4 months and then annually, for a minimum of two years. Patient demographics were collected and compared for all patients to ensure no significant difference in patient demographics for both units A and B.

All operations were performed by the senior surgeon (PML) or under his direct (surgically scrubbed) supervision. A thigh tourniquet was inflated after limb elevation and a routine anterior midline quadriceps splitting approach used. An intramedullary jig was used for the femoral cut and extramedullary jig for the tibial cut; all components were cemented. Cruciate retaining (CR) components were utilised routinely. A limited number of posterior stabilised (PS) TKRs were however undertaken selectively (8 PS knees in SR group, and 2 PS knees in MR) for any presenting valgus deformity (consistent with a routine release protocol) [23]. Each patella was cleared of osteophytes and denervated. Post operatively, standard and identical Early Rehabilitation after Surgery (ERAS) protocols were used for both groups. Chemical thromboprophylaxis and thromboembolic deterrent (TED) stockings were routinely administered to all cases.

Data were recorded in an SPSS (Version 20.0, IBM, Chicago, IL)

spreadsheet for statistical analysis. Continuous data were summarised as median (range) and non-parametric tests were used. Categorical data and continuous data were compared with the Chi^2 and Mann-Whitney U tests respectively. The significance value was set at 5% ($p < 0.05$).

An important subgroup analysis was also undertaken of a small group of bilateral TKR patients who had undergone both a SR and a MR TKR, at different times and under the care of senior surgeon (PML). The MR TKR will have been undertaken outside of the study period, either before or after, and thus allowed patients to act as their own control.

Results

During the evaluation period, a total of 82 TKRs were performed on 80 patients (males: 27, females: 53). Two patients underwent bilateral TKRs at staggered times. In total, 45 and 37 cases underwent SR and MR TKR respectively, 39 were left side and there were no simultaneous bilateral procedures.

Preoperatively the two groups of patients showed no statistical difference with regard to their demographics (Table 1). The tourniquet time was longer for the single radius group ($p<0.001$, see Table 1, Time SR 60 minutes, MR 51 minutes). Two patients receiving SR knees developed a significant complication. One patient, a pulmonary embolism (non-fatal) and one a popliteal artery pseudoaneurysm; possibly resulting from a saw blade injury or a traction injury, and this was successfully treated by stenting. There were two unrelated deaths (both in the SR group): one due to necrotic bowel (staged bilateral SR implants) and another to natural causes (old age). No complications were reported for the MR recipients. All surviving 79 TKRs (78 patients) were available for follow up at 2 years.

Improved scores were recorded in 88.6% of knees. The median OKS score in SR knees improved from 14 (pre-operative) to 34 (2 years), and from 17 to 35 in MR knees ($p=0.662$). Serial cohort OKS are presented in (Figure 1).

Subgroup analysis

Eleven patients were identified as having undergone the alternative type of procedure in their contralateral knee. During the study period, the largest interval between an individual's procedures was 4 years. The cases were of median age 67 years (range 56 - 82) and gender 5 male. There were no significant early or late differences in clinical outcome between implants used. At 6 weeks data was available for 10 cases and the median OKS improvement were 14 (-2-31) and 11.5 (0-27) for the SR and MR knees respectively ($p=0.944$). At 2 years data were available for 7 patients and the median OKS improvement were 14.5 (1-27) and 12.5 (-5-24) for SR and MR knees respectively ($p=0.727$).

Discussion

The key finding in this pragmatic study was that patient report-

Table 1 - Baseline Group Comparisons

Factor	Single Radius	Multi Radius	p-value
Number (%)	45 (54.9)	37 (45.1)	
Age, median years (range)	70 (45-84)	68 (52-85)	0.713*
Gender, n (%) Female Male	 29 (64.4) 16 (35.6)	 26 (70.3) 11 (29.7)	0.576†
BMI, Median (range)	34 (21-49)	33 (25-51)	0.327*
ASA grade, n (%) 1 2 3	 3 (6.7) 30 (66.7) 12 (26.7)	 5 (13.5) 23 (62.2) 7 (18.9)	0.469 †
Pre-op knee score, Median (range)	14 (2-36)	17 (6-38)	0.156*
Laterality, n (%) Left Right	 23 (51.1) 22 (48.9)	 16 (14.2) 21 (56.8)	0.478†
Tourniquet time, Median (range)	60 (41-84)	51 (43-83)	<0.001*

*Mann-Whitney U; †Chi^2 test

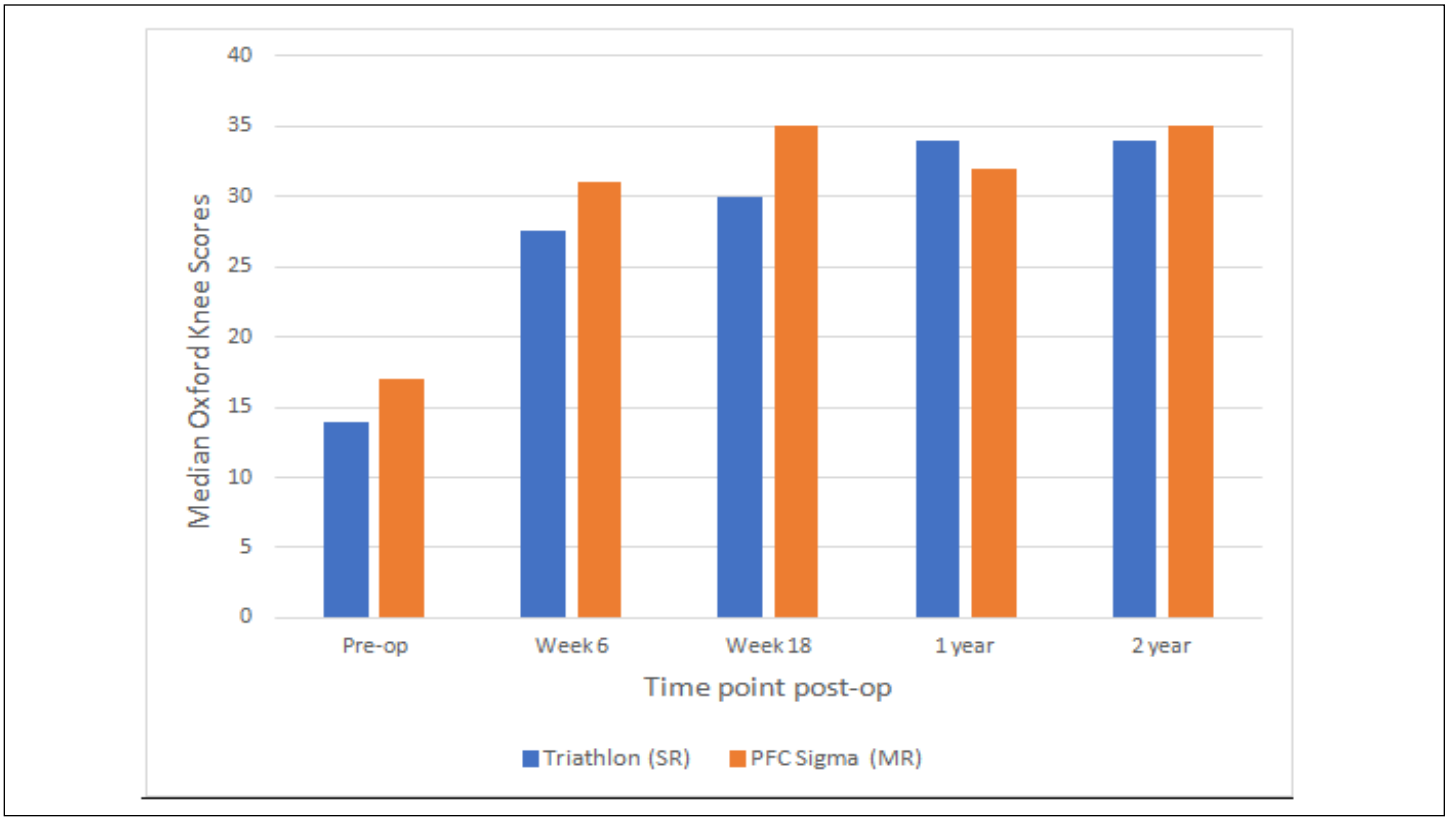

Figure 1 - OKS at Assessment Points

ed outcomes were comparable irrespective of the prosthesis type used. These results are broadly similar to the 94.3% improvement reported in the finalised PROMS data collected nationally in England between April 2017 and March 2018 utilising 44,072 completed questionnaires [24].

Although there are numerous publications in the literature comparing MR to SR TKRs, including a recent meta-analysis [25], we report a UK based comparative study with identical pre- and post-operative protocols for a single surgeon/team undertaking all procedures. In our study, the comparison was confined to patient outcome as defined by the Oxford Knee Score (OKS), a validated and reproducible outcome measure of the patient's satisfaction [22]. Although a meta-analysis represents one of the most reliable means of clinical outcome evaluation, in this review [25] of 15 articles and over 2000 patients, there were significant variations inevitably from hospital to hospital, outcome measures and often the number of surgeons undertaking the procedures not defined. Furthermore, other quoted articles are often from differing countries e.g. Jo et al from South Korea [26], and although includes scientific data such as improved valgus and varus measurements made during operations, did not demonstrate any clinical improvement in either group.

One criticism of our study, particularly as many articles include it, is that we have not evaluated pre- and post-operative range of movement for these patients receiving TKR. We would argue strongly that the Oxford Knee score has been both developed and validated as a practical assessment as to patient outcome and satisfaction for TKR, minimizing bias by surgeons and the influence of patient comorbidities [27]. It is for this very reason this system has been adopted by the UK National Joint Registry and indeed to both the New Zealand and Swedish registries [24,27]. Lastly, in an article where 860 patients were assessed at 5 years and 273 at 10 years post operatively, regression analysis showed a significant correlation between the OKS and the range of movement ($R=0.38$) and $p<0.001$ [28]. These authors concluded the OKS is an independent predictor of range of movement for total knee replacement.

Although the number of patients included in our study is relatively small, and involve 2 hospitals, most importantly all patients were under the care of one surgeon, with identical pre- and

post-op rehabilitation protocols and with all operations undertaken by the senior surgeons or under his direct (scrubbed) supervision.

Admittedly, there was no formal patient randomisation to each unit, but the pre-operative co-morbidities and demographics were identical (Table 1). Outcomes were measured in our groups for a minimum of 2 years, without any loss to follow up bar the two patients who died of unrelated disease, which again is greater than most publications and twice that of Mustaq et al. [6]. These latter authors, with similar number of patients in each group but with only 12 months follow up, suggest a significant improvement in SR versus MR only on objective assessment and only 'determined if the KSS(Obj) was expressed as a change score rather than an absolute score'. Interestingly, this group reported OKS values of 39.5 and 38.1 at 1 year ($p>0.05$).

In all our patients (either SR or MR) follow up, including OKS, was for a minimum of 2 years. Is this period of follow up adequate to identify late failure or any deterioration in outcome score? This has been thoroughly investigated by Matharu at al. [29] who studied a large number of joint replacements (Including almost 20000 TKRs) over a prolonged period. They showed that after 1 year there was no further appreciable change in the Oxford score. This is similarly represented within our findings with no significant subsequent change between 1 and 2 years of follow up.

Within the literature can be found further scientific assessments of SR vs MR TKRs. These include one study using a navigation system, which assessed stability showed greater intra-operative stability at 30^0 of flexion with SR knees [26]. Also, several cadaveric studies have supported the biomechanical benefits of an SR TKR design over a MR TKR design [19,30]. Two studies have shown significant difference in isokinetic muscle testing and ability to rise from a chair [21,31]. Lastly, some studies have shown improved gait with SR knees [9,11] and significantly better stair climbing [11]. However, consistent with our study, none showed any differences in clinical outcome [9,21,26,31].

An RCT from Edinburgh in 2015 with a 3-year follow up does warrant specific mention [12]. This was a well-conducted prospective randomised trial comparing their MR knee (Kinemax) with the SR Triathlon prosthesis [12]. Unfortunately, the Kinemax knee is no longer available [32] and is in fact the predecessor to the Triathlon prosthesis (having incorporated a number of implant changes including the single radius). This randomised study had surgery performed by 6 different consultants revealed little if any clinically significant difference between the 2 implants. Furthermore, it is worth noting Kinemax implants have not been used for more than three years on the NJR report of 2019, and have in fact been withdrawn from the market. This Stryker implant presumably represents a historic design requiring evolution and changes to the current Triathlon design. Importantly, within our study, the comparative implants used are two of the most frequently utilised prostheses in the UK (2019 NJR report, number of knee joints: PFC 384,076: Triathlon 113,137 implants. (Total (all): 1,194,059)) [32].

In our study a small group of patients underwent both SR and MR TKRs at different times provided the opportunity to allow patients to act as their own controls, also demonstrating patients were randomly allocated to hospitals A & B. Again, the senior author/team operated on all these patients and although not all data is available yet for up to 2 years, to date there have been no identified differences in clinical outcome, supporting the main finding of our study, namely no clinical difference between the two prostheses.

Lastly, although a formal cost analysis was not undertaken, during the study period, both implants were provided essentially at that same cost. With this equivalent cost and equivalent patient reported clinical outcomes, the decision therefore as to which type of prosthesis is utilised (MR or SR) should be at the discretion of the surgeon and/or orthopaedic unit, respecting alternative issues such as prosthesis rationalisation or the availability/need for revision adjuncts etc.

Strengths

This was a pragmatic investigation that captured the 'real life' patient demographic and natural variations of the population group undergoing arthroplasty operations. As the data is derived from a single Surgeon series, the treatment methods in the peri-operative period and rehabilitation protocol were identical for all patients irrespective of hospital site. Furthermore, there was a 100% follow up at 2 years excluding deaths for the main analysis group.

Although the internal self-controlled comparison included small numbers (n=11) with OKS data not available for all cases for two years, it contributed another level of robustness to the analysis and confirmed the patterns of the main study held true on an individual patient level.

Limitations

This was an observational study and is, therefore, vulnerable to confounding and bias. For example, there may be unmeasured variation in the populations attending or the services provided at the different hospitals. Such systematic variation, if present, may have resulted in bias. However, it can be argued that this work reflects the reality of clinical practice, and is in keeping with the pragmatic nature of the evaluation.

We have focussed on the OKS as the primary outcome, which is an example of a patient reported outcome measure (PROM), rather than biomechanical measurements used in other studies [4,18]. As this was a pragmatic real-life series, and given the current drive toward patient value-based healthcare [33], we (in keeping with the view of the NJR) decided that functional outcomes (as measured by the OKS) was the most appropriate measure.

As noted our caseload was low, and no power calculations were carried out. Therefore, we cannot exclude the possibility of a Type II statistical error, meaning that we may not have a large enough sample to demonstrate a true difference between the prosthesis types. Furthermore, as major complications are relatively uncommon, our sample is likely to be too small to compare the complication profile between the prosthesis types.

The tourniquet time was longer for the SR group (60 vs 51 minutes, $p<0.001$). However, this difference is very unlikely to influence the final outcomes as both groups were well below 120 minutes, which has been used as a definition of an excessive tourniquet time [34]. Furthermore, previous studies in TKR have demonstrated that tourniquet times only beyond 100 minutes were associated with increased complications [35]; the longest tourniquet time in any of our study group cases was only 84 minutes.

Recent past experience with total hip replacement metal on metal hips [36], and other implants [37], has created an air of scepticism and caution, thus we think it is appropriate to establish robust and demonstrable clinical advantages before adapting newer techniques or implants. These are early to mid-term results and it may well be that one of the groups may go on to outperform the other, although, there are no early indicators for such an outcome. Indeed, one previous study has suggested the median time at which no further appreciable change in OKS occurs following a TKR was 0.9 years [29] which strengthens our premise that its unlikely long-term results will be different from those presented here.

Conclusions

This study compares two groups of patients with comparable preoperative demographics requiring TKR. The same surgeon operated on each patient, with identical juniors and pre- and post-operative protocols. Each patient completed the nationally recognised clinical outcome Oxford scoring system collected by staff blinded to the prosthetic type for a minimum post-operative period of two years. There was no significant difference in either prosthesis at any interval with an overall improvement in outcome score in 88.6% of patients.

Conflict of interest statement

None of the authors have a conflict interest in the preparation of this manuscript.

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