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Primary Knee

A Randomized Controlled Trial Comparing a Medial Stabilized Total Knee Prosthesis to a Cruciate Retaining and Posterior Stabilized Design: A Report of the Clinical and Functional Outcomes Following Total Knee Replacement

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ABSTRACT

Background: The purpose of this randomized controlled trial was to compare the performance of 3 total knee joint replacement (TKJR) designs 6 months after the surgery.
Methods: Patients were recruited between March 2015 and March 2018. Patients with osteoarthritis consented for TKJR were randomly allocated to a medial stabilized (MS), cruciate retaining (CR), or posterior stabilized (PS) design. Primary outcome measures were self-reported improvement in pain and function 6 months after TKJR, using the Oxford Knee Score. Secondary outcome measures were the Western Ontario and McMaster Universities Osteoarthritis Index, Veterans RAND 12-item Health Survey, Knee Society Score 2011, Timed Up and Go test, and Six-Minute Walk Test. Twelve-month outcomes were also measured.
Results: Ninety participants enrolled, 83 were randomized: PS (n = 26), CR (n = 28), and MS (n = 29) designs. One case withdrew before surgery: planned use of non-study implant; 7 did not complete all outcome measures. No 6-month between-group difference was observed for the primary outcome. A 6-month difference was observed in Knee Society Score 2011 Satisfaction: MS favored over CR and PS. Clinically meaningful 12-month differences in Western Ontario and McMaster Universities Osteoarthritis Index Pain, Function, and Global Subscales were observed: MS favored over CR. Twelve-month differences occurred in Veterans RAND 12-item Health Survey mental well-being, favoring MS and PS over CR.
Conclusion: MS prosthesis can be expected to yield similar clinical and functional outcomes to PS and CR designs 6 months after TKJR, and patients were more satisfied with their outcome. Compared with CR, patients with MS prosthesis also reported superior pain, function, and quality-of-life outcomes at 12 months.
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Total knee joint replacement (TKJR) enjoys excellent longevity, approximating 92% at 16 years [1]. The reliability and predictability of TKJR for treating end-stage osteoarthritis (OA) and the rising demand for this procedure makes it one of the most high-volume surgical procedures that is predicted to continue to increase [1,2].

Efforts to drive incremental improvement in function and survival now include a number of design features [3]. These include single radius [4], multiradii [5], fixed bearing [6], mobile bearing [7], posterior stabilized (PS) [8], cruciate retaining (CR) [9], and cruciate sacrificing [10]. The Australian Orthopedic Association National Joint Replacement Registry (AOANJRR) has reported over 119 femoral and tibial prosthesis combinations used in primary TKJR [1,2].

In a recent systematic review [11], an MS TKJR was compared with other prosthesis designs in terms of outcomes, utilizing patient-reported outcome measures (PROMs). However, due to the limited number of studies with appropriate statistical analysis, the authors were unable to reach a conclusion on the clinical performance of an MS construct.

Therefore, this study aimed to determine the effect the type of prosthesis design had on patient-reported pain and function, with the secondary aim of determining whether an MS design resulted in improved functional outcomes following knee replacement when compared to either a fixed-bearing CR or PS design. Our null hypothesis proposed that improvement in pain and function at 6 months after total knee replacement surgery would not be influenced by variations in the design of fixed-bearing TKJR prosthesis.

Methods

Trial Design

The trial was a single-center, CONSORT-compliant [12], assessor-blinded, 3-group, parallel randomized controlled trial (RCT) conducted between March 2015 and March 2018. The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613001278729) and the trial protocol has been published [13]. The trial was approved by the St Vincent's Hospital Human Research Ethics Committee (HREC-D 143/13) and participants gave written informed consent before taking part.

Setting and Recruitment

Participants were recruited from an orthopedic outpatient clinic at St Vincent's Hospital in Melbourne (SVHM), Australia, between March 2015 and October 2016. Patients were approached by the study coordinator during their attendance at the orthopedic outpatient clinic following surgeon assessment for TKJR and assessed for eligibility and willingness to participate. Written informed consent was obtained from all participants. Eligibility criteria included individuals 50-85 years of age with a clinical and radiographic diagnosis of knee osteoarthritis assessed by one of the 4 arthroplasty consultants and placed on the waiting list for TKJR. Exclusion criteria were revision surgery or surgery for neoplastic disease, inability to provide informed consent due to mental incompetence, active drug or alcohol use disorder; limited English language proficiency, severe angular deformity of the lower limb which in the opinion of the treating surgeon would be potentially deleterious to postoperative outcome if the patient was randomized, body mass index (BMI) >36 kg/m^2, unable to ambulate independently preoperatively, and existing TKJR in the contralateral knee.

Randomization and Blinding

Participants were randomly assigned 1:1:1 using computer-generated randomization, prepared in advance by an investigator not involved in participant recruitment and stored in a password protected file. When a subject fulfilled all study criteria and was enrolled, allocation took place. Patient assignment was performed by a research assistant who had no direct contact with the subjects either before or after assignment. The study coordinator involved in the assessment of patients had no role in the assignment process and was blinded to randomization throughout the entire study. Participants also remained blinded to prosthesis construct throughout the study. The 4 surgeons performing TKJR were informed of participant assignment 48 hours prior to surgery and had no role in patient follow-up. The blinded study coordinator was responsible for collection of outcome measures and a blinded statistician oversaw the final data analysis.

Interventions

All participants underwent surgery and postoperative care as per SVHM's routine TKJR program, which has been standardized through the use of clinical pathway protocols [14]. All 3 TKJR designs were sourced from a single manufacturer (Medacta International SA, Castel San Pietro, Switzerland)—the prosthesis of choice was the Medacta GMK Knee System. The GMK Sphere was used as the MS prosthesis in this study with both the CR and PS prostheses serving as comparators. Each of the 4 orthopedic surgeons performing TKJR on study participants had prior experience with the 3 different prosthesis designs used in this trial.

Patients received a spinal anesthesia with sedation and femoral nerve block prior to surgery. All procedures were performed in a bloodless field under tourniquet control. A standard midline skin incision was used, and the joint was exposed via a medial parapatellar approach. This was followed by excision of Hoffa's fat pad. The proximal tibial cut was performed using an extramedullary cutting guide, while the distal femoral cut was made using an intramedullary cutting guide. Femoral implant sizing was established using the femoral sizing jig before anterior, posterior, and chamfer cuts were completed using the relevant cutting guides. The tibial surface was prepared using the standard template and keel instruments. Posterior femoral osteophytes were routinely removed prior to trialling of the components and subsequently tested for stability through the full range of motion. All patellae were resurfaced using a 3-peg all-polyethylene patella component. The definitive components were cemented with SMARTSET GHV Bone Cement, (DePuy Synthes International, Zuchwil, Switzerland). The wound was then lavaged prior to layered closure with an intra-articular drain in situ for the first 24 hours postoperatively.

As part of routine post-surgical follow-up, all patients attended the same outpatient clinic at 6 weeks, 6 months, and 12 months post-TKJR for clinical review.

Follow-Up Assessments

Participants completed baseline outcome measures and functional assessments within 4 weeks of surgery, and at 6 months and 12 months post-TKJR (Supplementary Table 1). Questionnaires were given to participants during attendance at a preadmission assessment clinic for completion at which time functional assessments were also undertaken. Postsurgery questionnaires and functional assessments were administered again at the 6-month and 12-month review appointments, or if the participant was unable to attend, the blinded study coordinator made alternative arrangements to meet at a suitable time.

Primary Outcome

The primary outcome was self-reported pain and physical function at 6 months measured using the Oxford Knee Score (OKS)

[15]. The OKS is a condition-specific, 12-item self-administered questionnaire that examines 12 activities of daily living, with each item scored from 0 (extreme pain or functional difficulty) to 4 (no pain or functional difficulty). The worst to best score in OKS is 0 to 48. The OKS has proven to be valid, consistent, reliable, and responsive to changes [15,16].

Secondary Outcomes

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a multidimensional, self-administered outcome measure [17,18] that consists of 24 items covering 3 subscales: knee pain (range 0-20), stiffness (range 0-8), and physical function (0-68). It is validated, reliable, sensitive to change, and proven to be a responsive instrument for TKJR [19–21]. Subscales are transformed to a score ranging from 0 to 100, with a higher score indicating greater pain and worse physical function. Global physical and psychological health status was assessed using the Veterans RAND 12-item Health Survey (VR-12) [22], with a higher score indicating better quality of life.

The Knee Society Score 2011 (KSS) contains both patient-reported and surgeon-reported components [23]. The latest version continues to provide reliability, validity, and is widely accepted and adopted in the orthopedic community [23,24]. The scoring system is both clinician- and patient-derived and consists of a knee subscale completed by the surgeon, and satisfaction, functional activities, and expectation subscales which are completed by the patient, with higher scores indicating better outcomes [24].

The six-minute walk test (6MWT) and Timed up and Go (TUG) test were used to assess clinical function [25,26]. The 6MWT was developed by Butland et al [27] and is used to measure change in mobility following an intervention. In the 6MWT, a walking track of predetermined length is demarcated, and the patient is given 6 minutes to complete as many laps as they are capable of completing. The TUG [28] is a modified version of the Get-Up and Go test [29], which provides an objective measure of functional capacity, balance, and gait speed. In the TUG, the patient is observed and timed while they rise from an armchair, walk 3 metres, turn, walk back, and sit back down again. Both tests have been validated for the assessment of TKJR patients. The minimal detectable change indicating a clinically meaningful improvement from baseline is 26 m at 6 months post-TKJR for the 6MWT [30] and 2.27 seconds on the TUG [31]. Specifically, this means a patient must walk at least 26 metres further on their 6MWT at 6-month follow-up, compared to their preoperative 6MWT, to be deemed as having achieved a clinically meaningful benefit from TKJR. For the TUG, the patient must complete the test at least 2.27 seconds faster at 6-month follow-up, compared to their preoperative TUG, to be deemed as having achieved a clinically meaningful benefit from TKJR.

Patients were tracked for intraoperative adverse events at each follow-up by a blinded assessor. All adverse events were recorded onto the trial case report form and then entered onto a dedicated database for future analysis. Episodes of return to the operating theater subsequent to the index procedure were categorized and documented. Any adverse event, subsequent surgical intervention, or readmission was recorded as outlined above and followed until the event was resolved.

Statistical Analysis

Prosthesis performance was evaluated by comparing change in the primary outcome measure between groups. We aimed to detect the minimum clinically important difference in the OKS between groups, which was set at 5 (standard deviation 6.0) points based on prior work by Clement et al [32]. The sample size calculation was based on an analysis of covariance adjusting for baseline scores, estimating between-patient standard deviations of 6.0 points, baseline to 6-month follow-up correlations of 0.6, an alpha value = 0.05, and 2-sided test and power = 90%. To demonstrate a difference in OKS of at least 5.0 points, a total of 75 participants were required. We aimed to recruit 90 participants to allow for a 20% drop-out rate.

Analyses were conducted on an intention-to-treat basis by a blinded researcher using Stata, version 14.0 (StataCorp, College Station, TX) utilizing data from all randomized participants, excluding missing time points (Figure 1). All participants were analyzed according to group allocation. For continuous outcomes the mean difference (95% CI) in 6-month and 12-month outcome scores were estimated using an analysis of covariance, adjusting for baseline scores. Statistical significance was set at $P = .05$ for all analyses. We established a priori that adjustment for confounding variables would be performed if we identified imbalances in baseline patient characteristics hypothesized to influence the main outcomes, therefore models were adjusted for age, BMI, and comorbidity score (Table 1). There were no planned subgroup analyses.

Results

Between March 2015 and October 2016, 90 individuals awaiting TKJR were enrolled, of whom 7 were not randomized (Figure 1) because they either withdrew prior to treatment allocation (n = 5) or were medically unfit for surgery (n = 2). Of the 83 randomized participants, 1 was subsequently withdrawn by the treating surgeon based on a presurgery clinical decision to utilize an alternative implant. Of the 82 who proceeded to surgery, 2 in each group (n = 6) declined to complete most outcome measures and 1 patient did not complete any follow-up due to death at 6 months unrelated to the surgery (Figure 1). Randomization was balanced across surgeons ($P = .907$). The characteristics of each group were similar at baseline except for a higher BMI and a higher proportion of people with multiple comorbidities in the MS group and older age on average in the CR group (Table 1). The absolute scores for each outcome measure are available in Supplementary Table 2. The trial ended with completion of 12-month follow-up.

Outcomes

At 6 months, there were no significant between-group differences in the OKS, on either the pain or function subscales (Table 2). Patients who received an MS knee reported higher KSS satisfaction at 6 months compared to the PS (7.2, 95% CI 0.9-12.3) and CR (6.0, 95% CI 0.3-11.6) constructs ($P = .030$). For secondary outcomes at 12 months, there was a clinically significant between-group difference in WOMAC subscales favoring an MS compared to a CR design: pain (−13.7, 95% CI −24.5 to −2.9, $P = .047$), function (−15.9, 95% CI −26.5 to −5.4, $P = .012$), and global (−15.2, 95% CI −25.3 to −5.2, $P = .013$) points. Between-group differences were also noted for the VR-12 Mental Component Score again favoring an MS compared to a CR construct (8.1, 95% CI 2.0-14.2), and the CR was also inferior to the PS construct (Mental Component Score −12.3, 95% CI −18.5 to −6.1, $P < .001$). No other between-group differences in secondary outcomes were observed at 12 months (Table 2). A post hoc assessment was performed to assess for any floor or ceiling effect in our primary outcome as well as any outcome measure that reported a significant finding. Based on a 15% threshold, no effect was observed (Supplementary Table 3). Length of stay was comparable between groups: PS 5.4 (3.0), CR 4.4 (1.3), MS 4.5 (1.5) days

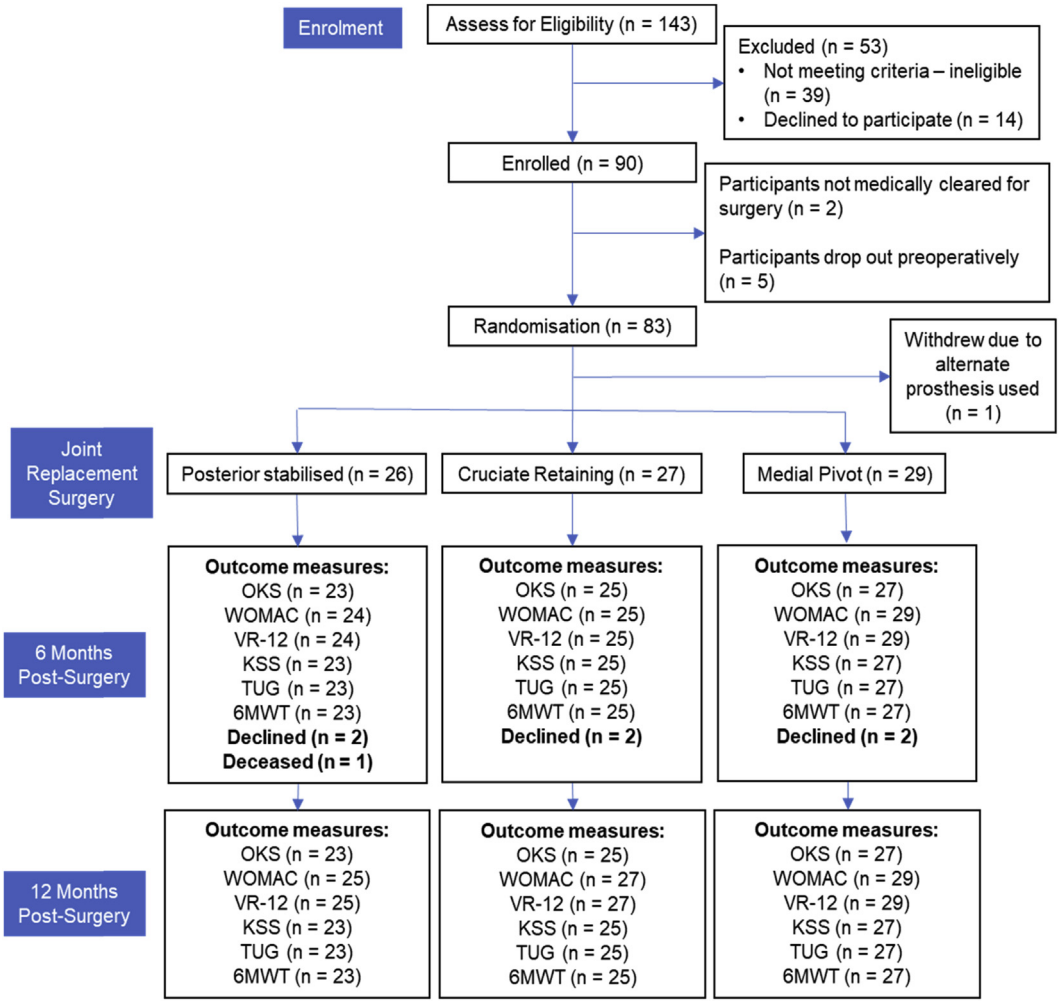

Fig. 1. CONSORT flow diagram depicting participant flow throughout the duration of the clinical trial, from eligibility assessment through enrollment, intervention, and data collection to completion of follow-up. OKS, Oxford Knee Score; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; VR12, Veterans RAND 12 Item Health Survey; KSS, Knee Society Score; TUG, Timed Up and Go Test; 6MWT, Six-Minute Walk Test.

($P = .187$). No differences in adverse events, readmissions, or reoperations were observed throughout the study period (Table 3).

Discussion

This is the first RCT to assess relative outcome measures of the MS prosthesis in comparison to CR and PS constructs, sourced from a single manufacturer. In this study, the MS prosthesis yielded similar clinical and functional outcomes when compared to both PS and CR prosthesis designs at 6 months post-TKJR; however, patient-reported satisfaction was higher at 6 months for the MS prosthesis. All groups reported clinically meaningful improvements across a range of functional measures and PROMs at 6 and 12 months irrespective of prosthesis design. At 12 months, patients who received a TKJR using an MS construct reported superior pain, function, and quality of life outcomes on a number of self-reported measures and these differences were clinically relevant [32–34].

Our finding of superior improvements in WOMAC pain and function at 12 months for the MS compared to the CR knee has not previously been reported. In a recent single surgeon series, patients who underwent an MS TKJR reported comparable WOMAC scores to a CR design, with notable study differences including the use of implants sourced from 2 different manufacturers and surgery performed using kinematic alignment principles. Of note, 12-month outcome scores were not adjusted for baseline scores or other patient characteristics despite a significant difference in the age of the 2 study cohorts [35]. Significant differences favoring an MS design were reported in this study for the Forgotten Joint Score and the Knee Injury and Osteoarthritis Outcome Score Quality of Life Subscale.

In direct contrast to our findings, an earlier trial by Kim et al [36] reported worse outcomes for both Knee Society and Hospital for Special Surgery Scores within the first year of an MS fixed-bearing prosthesis, compared to a mobile-bearing prosthesis, again from a different manufacturer. A striking difference with this study was that TKJRs were performed in a single sitting, with participants randomized to receive either implant, with the alternative implant used for the second side. Although this may be advantageous for eliminating differences in between-group baseline patient characteristics, it is difficult to reliably assess differences in functional outcomes when simultaneous TKJRs have been performed. This calls into question how the authors arrived at between-group differences in function scores, when assessments were based on distance walked, use of gait aid, and ability to climb stairs. Furthermore, the use of 2 entirely different constructs in the one person, presents an uncommon scenario in a real-world setting.

Controversy still remains regarding the retention or sacrifice of the posterior cruciate ligament. Proponents of the MS design [37] suggest that mimicking the natural kinematic pattern of the knee is

Table 1
Baseline Characteristics of Randomized Participants, by Group.

Measure[a]	PS (n = 26)	CR (n = 27)	MS (n = 29)	*P*-Value
Age (y)	65.7 (7.7)	69.9 (7.6)	66.0 (6.8)	.068
Female gender, n (%)	11 (42.3)	10 (37.0)	15 (51.7)	.532
Body mass index (kg/m^2)	30.7 (3.8)	30.3 (3.7)	32.5 (3.6)	.070
Randomization				
Surgeon A	6 (35.3)	5 (29.4)	6 (35.3)	
Surgeon B	12 (27.9)	16 (37.2)	15 (34.9)	
Surgeon C	4 (44.4)	2 (22.2)	3 (33.3)	
Surgeon D	1 (16.7)	2 (33.3)	3 (50.0)	.907
Charlson Comorbidity Index, n (%)				
0	11 (42.3)	15 (55.6)	13 (44.8)	
1	13 (50.0)	6 (22.2)	5 (17.2)	
≥2	2 (7.7)	6 (22.2)	11 (37.9)	.016
Kellgren-Lawrence Grade, n (%)				
2	3 (11.5)	1 (3.7)	0 (0.0)	
3	5 (19.2)	6 (22.2)	9 (31.0)	
4	18 (69.2)	20 (74.1)	20 (69.0)	.311
Preoperative alignment, n (%)				
Neutral	0 (0.0)	0 (0.0)	1 (3.4)	
Valgus	4 (15.4)	8 (29.6)	2 (6.9)	
Varus	22 (84.6)	19 (70.4)	26 (89.7)	.147
Degree of deformity, n (%)				
0-5	11 (42.3)	6 (22.2)	11 (37.9)	
6-10	6 (23.1)	14 (51.9)	12 (41.4)	
11-15	7 (26.9)	6 (22.2)	3 (10.3)	
>15	2 (7.7)	1 (3.7)	3 (10.3)	.272
OKS Pain	8.4 (3.2)	10.1 (5.8)	9.4 (4.5)	.425
OKS Function	7.8 (3.1)	8.8 (3.8)	8.4 (3.4)	.577
OKS Total	16.2 (6.0)	18.9 (9.1)	17.8 (7.5)	.443
WOMAC Pain	63.5 (15.4)	54.6 (19.6)	58.1 (19.2)	.190
WOMAC Function	57.0 (14.0)	56.9 (19.3)	56.5 (22.3)	.996
WOMAC Stiffness	62.0 (23.3)	62.0 (23.4)	58.6 (26.3)	.834
WOMAC Global	59.6 (14.4)	56.8 (18.9)	57.0 (20.2)	.822
VR12 Physical Component Score	28.3 (6.8)	29.0 (6.9)	27.8 (8.6)	.835
VR12 Mental Component Score	48.6 (13.0)	48.7 (13.1)	46.1 (12.0)	.683
KSS Patient Symptoms	4.8 (2.9)	6.4 (5.3)	7.1 (5.2)	.211
KSS Patient Satisfaction	10.6 (7.2)	12.5 (8.5)	12.3 (7.7)	.652
KSS Patient Expectations	13.7 (1.9)	13.2 (1.7)	14 (1.8)	.324
KSS Patient Total	29.1 (8.1)	32.2 (12.3)	33.5 (11.4)	.350
KSFS Walking	12.2 (6.8)	11.3 (6.7)	11.6 (6.6)	.902
KSFS Standard Activities	9 (4.8)	10.7 (6.3)	10.2 (5.2)	.539
KSFS Advanced Activities	4.2 (3.5)	4.7 (5.2)	3.9 (3.4)	.765
KSFS Discretionary Activities	3 (2.5)	3.3 (3.4)	3.59 (3.2)	.793
KSFS Total	29.4 (14.9)	30.1 (18.7)	29.3 (14.6)	.937
KSS Surgeon	47.3 (6.4)	42.6 (14.4)	44.0 (10.4)	.329
Timed Up and Go Test	12.1 (3.5)	13.7 (5.2)	12.9 (4.1)	.451
Six-Minute Walk Test	360.6 (112.2)	332.6 (122.0)	215.2 (83.1)	.325

PS, posterior stabilized; CR, cruciate retaining; MS, medial stabilized; OKS, Oxford Knee Score; WOMAC, Western Ontario and McMaster Universities Arthritis Index; VR12, Veterans RAND 12 Item Health Survey; KSS, Knee Society Score Patient; KSFS, Knee Society Function Score.
[a] Data are expressed as mean (standard deviation) unless otherwise stated.

more likely to result in normal kinematics and greater satisfaction after TKJR. Specifically, in the normal knee, the physiologically constrained movement of the medial femoral condyle causes it to pivot within the medial compartment of the knee while the less congruent lateral condyle slides in an arc across the lateral compartment of the knee [38]. In this regard, Dennis et al. [39] in a study of 33 different knee designs observed that regardless of prosthetic design, at least 50% of patients had an MS pattern during gait and deep knee bend, suggesting that knee motion tended toward normal kinematics (MS) despite the constraints of different designs. Nishio et al [40] in an intraoperative evaluation of knee kinematics using a computed tomography navigation system reported that patients with intraoperative MS patterns had better functional performance, including improved knee flexion angle, and patient satisfaction when compared with those of the non-MS group. Whether the superior results in our MS group are directly related to the restoration of normal kinematics remains speculative. However, an analysis comparing the 6-degree-of-freedom kinematic characteristics of the 3 designs within our study [41] (Gray et al, in review) has found that the kinematic profiles observed for MS resemble those of the healthy joint more closely than PS and CR.

Several limitations warrant mentioning. As a single center study, generalizability of our study findings may be limited. Given the small sample size and short-term follow-up we cannot comment on important longer term endpoints such as revision. In that regard the AOANJRR reports promising outcomes for the MS prosthesis, with no difference in failure rates compared to a minimally stabilized prosthesis, in the setting of a resurfaced patella [42].

Of note, our trial was powered to detect a difference in the OKS. We found no difference between prosthesis construct based on this outcome measure at either time point, nor did we find a difference in objective functional measures. Although the superior findings for the MS construct compared with CR prosthesis were consistent across a range of secondary outcome measures, we acknowledge the inclusion of multiple outcome measures that can increase the possibility of finding at least one test statistically significant due to chance. Careful planning and testing of appropriately selected, rigorous statistical models were employed to minimize the risk of

Table 2
Mean Change in Scores and Between-Group Differences for Continuous Outcome Measures, by Group.

Outcome Measure	Design	Change From Baseline to 6 mo, Mean (SD)	Between-Group Difference in Change From Baseline to 6 mo[a], Mean (95% CI)		*P*-Value	Construct	Change From Baseline to 12 mo	Between-Group Difference in Change From Baseline to 12 mo[a], Mean (95% CI)		*P*-Value
OKS Pain	PS	11.7 (5.6)	CR vs PS	−1.0 (−4.8 to 2.7)	.855	PS	11.9 (8.9)	CR vs PS	−1.7 (−7.1 to 3.7)	.811
	CR	10.6 (7.2)	MS vs PS	−0.4 (−4.2 to 3.4)		CR	9.4 (11.8)	MS vs PS	−1.1 (−6.4 to 4.3)	
	MS	10.3 (8.1)	MS vs CR	0.6 (−3.3 to 4.5)		MS	9.4 (9.6)	MS vs CR	0.7 (−4.9 to 6.2)	
OKS Function	PS	6.7 (3.1)	CR vs PS	−0.8 (−3.2 to 1.7)	.621	PS	5.9 (6.2)	CR vs PS	−1.6 (−5.1 to 1.9)	.621
	CR	6.0 (5.2)	MS vs PS	−1.2 (−3.7 to 1.3)		CR	4.3 (7.3)	MS vs PS	−0.4 (−3.9 to 3.0)	
	MS	5.1 (5.9)	MS vs CR	−0.4 (−3.0 to 2.1)		MS	5.0 (6.0)	MS vs CR	1.3 (−2.4 to 4.9)	
OKS Total	PS	18.3 (7.8)	CR vs PS	−1.8 (−7.8 to 4.2)	.804	PS	17.7 (14.5)	CR vs PS	−3.3 (−12.0 to 5.3)	.746
	CR	16.5 (11.9)	MS vs PS	−1.6 (−7.7 to 4.5)		CR	13.7 (18.8)	MS vs PS	−1.4 (−10.4 to 7.6)	
	MS	15.4 (13.5)	MS vs CR	0.2 (−6.1 to 6.5)		MS	14.3 (14.9)	MS vs CR	1.9 (−7.1 to 10.9)	
WOMAC Pain Score	PS	−32.7 (28.2)	CR vs PS	−0.6 (−12.8 to 11.5)	.214	PS	−42.6 (22.2)	CR vs PS	6.6 (−4.3 to 17.5)	**.047**
	CR	−31.8 (23.0)	MS vs PS	−10.1 (−22.5 to 2.3)		CR	−34.8 (22.9)	MS vs PS	−7.1 (−18.2 to 4.0)	
	MS	−36.9 (29.2)	MS vs CR	−9.5 (−22.3 to 3.4)		MS	−39.6 (23.4)	MS vs CR	**−13.7 (−24.5 to −2.9)**	
WOMAC Stiffness Score	PS	−25.5 (32.0)	CR vs PS	4.2 (−10.1 to 18.5)	.674	PS	−35.5 (28.8)	CR vs PS	6.1 (−6.3 to 18.5)	.068
	CR	−30.0 (32.1)	MS vs PS	−2.6 (−16.9 to 11.8)		CR	−32.6 (31.8)	MS vs PS	−8.7 (−21.2 to 3.9)	
	MS	−26.8 (29.4)	MS vs CR	−6.8 (−22.1 to 8.6)		MS	−37.9 (30.2)	MS vs CR	−14.8 (−27.3 to −2.3)	
WOMAC Function Score	PS	−27.0 (23.5)	CR vs PS	−1.1 (−11.8 to 9.6)	.522	PS	−33.8 (19.3)	CR vs PS	10.1 (−0.6 to 20.7)	**.012**
	CR	−34.1 (21.3)	MS vs PS	−6.0 (−16.8 to 4.9)		CR	−27.8 (25.0)	MS vs PS	−5.9 (−16.6 to 4.9)	
	MS	−34.2 (22.6)	MS vs CR	−4.8 (−16.1 to 6.4)		MS	−36.8 (26.2)	MS vs CR	**−15.9 (−26.5 to −5.4)**	
WOMAC Global Score	PS	−28.9 (23.9)	CR vs PS	−0.7 (−11.3 to 10.0)	.449	PS	−36.2 (17.8)	CR vs PS	8.9 (−1.1 to 19.0)	**.013**
	CR	−33.3 (20.8)	MS vs PS	−6.4 (−17.2 to 4.4)		CR	−28.8 (25.0)	MS vs PS	−6.3 (−16.5 to 3.9)	
	MS	−32.2 (21.7)	MS vs CR	−5.7 (−17.0 to 5.5)		MS	−37.9 (23.9)	MS vs CR	**−15.2 (−25.3 to −5.2)**	
VR12 Physical Component Summary	PS	9.8 (12.1)	CR vs PS	2.8 (−3.5 to 9.0)	.547	PS	13.7 (13.9)	CR vs PS	−7.0 (−13.0 to −0.9)	.081
	CR	12.8 (10.7)	MS vs PS	3.1 (−3.2 to 9.5)		CR	9.4 (10.9)	MS vs PS	−3.3 (−9.4 to 2.9)	
	MS	12.1 (9.5)	MS vs CR	0.4 (−6.2 to 6.9)		MS	12.9 (10.9)	MS vs CR	3.7 (−2.4 to 9.7)	
VR12 Mental Component Summary	PS	3.8 (13.4)	CR vs PS	−5.0 (−11.4 to 1.4)	.293	PS	10.1 (13.4)	CR vs PS	**−12.3 (−18.5 to −6.1)**	**<.001**
	CR	0.6 (13.0)	MS vs PS	−2.9 (−9.4 to 3.6)		CR	0.7 (15.3)	MS vs PS	−4.2 (−10.5 to 2.0)	
	MS	1.9 (15.1)	MS vs CR	2.1 (−4.6 to 8.8)		MS	7.0 (12.6)	MS vs CR	**8.1 (2.0-14.2)**	
KSS Patient Symptoms	PS	10.2 (6.7)	CR vs PS	1.3 (−2.4 to 5.0)	.352	PS	14.2 (5.5)	CR vs PS	−1.4 (−4.7 to 1.9)	.517
	CR	11.8 (7.3)	MS vs PS	2.8 (−1.0 to 6.7)		CR	12.0 (6.9)	MS vs PS	0.5 (−2.9 to 3.9)	
	MS	11.7 (6.1)	MS vs CR	1.5 (−2.4 to 5.4)		MS	11.7 (7.3)	MS vs CR	1.9 (−1.5 to 5.3)	
KSS Patient Satisfaction	PS	13.4 (14.8)	CR vs PS	1.2 (−6.5 to 5.8)	**.030**	PS	19.5 (11.0)	CR vs PS	−2.3 (−8.4 to 3.9)	.648
	CR	16.1 (9.5)	MS vs PS	**7.2 (−0.9 to 12.3)**		CR	16.8 (10.5)	MS vs PS	0.5 (−5.6 to 6.7)	
	MS	19.1 (10.0)	MS vs CR	**6.0 (0.3-11.6)**		MS	18.5 (11.5)	MS vs CR	2.8 (−3.6 to 9.2)	
KSS Patient Expectations	PS	−0.4 (2.9)	CR vs PS	−0.2 (−1.6 to 1.1)	.926	PS	−1.64 (4.2)	CR vs PS	0.6 (−1.3 to 2.5)	.796
	CR	−0.4 (2.4)	MS vs PS	0.0 (−1.4 to 1.4)		CR	−0.7 (2.9)	MS vs PS	0.1 (−1.7 to 2.0)	
	MS	−0.8 (2.3)	MS vs CR	0.2 (−1.2 to 1.7)		MS	−1.3 (2.5)	MS vs CR	−0.5 (−2.4 to 1.5)	
KSS Patient Total	PS	23.1 (20.8)	CR vs PS	2.3 (−6.8 to 11.4)	.097	PS	32.0 (17.1)	CR vs PS	−3.4 (−13.3 to 6.5)	.705
	CR	27.4 (15.3)	MS vs PS	10.0 (0.6-19.4)		CR	28.1 (16.8)	MS vs PS	0.6 (−9.5 to 10.7)	
	MS	30.0 (15.1)	MS vs CR	7.7 (−1.8 to 17.3)		MS	28.9 (17.6)	MS vs CR	4.0 (−6.4 to 14.3)	
KSFS Walking	PS	8.0 (8.8)	CR vs PS	−3.3 (−8.4 to 1.8)	.431	PS	9.3 (9.1)	CR vs PS	−1.0 (−5.7 to 3.7)	.754
	CR	6.2 (9.7)	MS vs PS	−1.6 (−6.7 to 3.6)		CR	9.4 (7.5)	MS vs PS	−1.8 (−6.5 to 3.0)	
	MS	6.5 (10.2)	MS vs CR	−1.7 (−3.6 to 7.0)		MS	8.0 (8.5)	MS vs CR	−0.8 (−5.7 to 4.1)	
KSFS Standard Activities	PS	10.7 (8.3)	CR vs PS	−0.8 (−4.8 to 3.2)	.376	PS	13.8 (7.2)	CR vs PS	−2.6 (−6.3 to 1.2)	.302
	CR	10.0 (7.4)	MS vs PS	2.1 (−2.0 to 6.1)		CR	10.9 (7.5)	MS vs PS	0.1 (−3.7 to 3.8)	
	MS	11.4 (6.5)	MS vs CR	2.9 (−1.3 to 7.0)		MS	13.1 (6.9)	MS vs CR	2.6 (1.3-6.5)	
KSFS Advanced Activities	PS	8.0 (5.2)	CR vs PS	−1.5 (−4.8 to 1.7)	.640	PS	10.5 (5.7)	CR vs PS	−2.2 (−6.4 to 2.1)	.587
	CR	7.0 (6.3)	MS vs PS	−0.5 (−3.8 to 2.8)		CR	8.4 (8.6)	MS vs PS	−0.6 (−4.9 to 3.6)	
	MS	6.9 (5.7)	MS vs CR	1.0 (−2.4 to 4.4)		MS	9.8 (6.6)	MS vs CR	1.5 (−2.9 to 6.0)	
KSFS Discretionary Activities	PS	4.1 (5.3)	CR vs PS	1.0 (−2.0 to 4.0)	.707	PS	7.6 (3.7)	CR vs PS	−1.6 (−4.2 to 1.0)	.462
	CR	5.1 (4.6)	MS vs PS	1.2 (−1.9 to 4.2)		CR	5.7 (6.2)	MS vs PS	−0.9 (−3.5 to 1.7)	
	MS	4.7 (5.7)	MS vs CR	0.2 (−3.0 to 3.4)		MS	5.6 (5.0)	MS vs CR	0.8 (−2.0 to 3.5)	
KSFS Total	PS	30.7 (20.6)	CR vs PS	−4.6 (−16.3 to 7.2)	.612	PS	41.2 (19.4)	CR vs PS	−7.6 (−20.1 to 4.9)	.481
	CR	28.2 (23.5)	MS vs PS	1.2 (−10.8 to 13.1)		CR	34.4 (25.7)	MS vs PS	−3.4 (−15.9 to 9.1)	
	MS	29.6 (20.7)	MS vs CR	5.8 (−6.6 to 18.1)		MS	36.5 (21.3)	MS vs CR	4.2 (−8.9 to 17.2)	

KSS Surgeon	PS	40.1 (14.9)	CR vs PS	0.6 (−6.7 to 7.9)	.947	PS	45.9 (7.2)	CR vs PS	−0.5 (−5.2 to 4.2)	.059
	CR	46.4 (19.9)	MS vs PS	−0.6 (−8.0 to 6.7)		CR	50.8 (18.4)	MS vs PS	−5.2 (−9.8 to −0.6)	
	MS	42.6 (12.8)	MS vs CR	−1.2 (−8.8 to 6.3)		MS	44.7 (14.0)	MS vs CR	−4.7 (−9.6 to 0.1)	
Timed Up and Go Test	PS	−2.9 (3.1)	CR vs PS	−0.2 (−1.8 to 1.4)	.149	PS	−3.2 (3.3)	CR vs PS	−0.1 (−1.9 to 1.6)	.156
	CR	−4.2 (5.3)	MS vs PS	1.3 (−0.3 to 3.0)		CR	−3.8 (4.3)	MS vs PS	1.4 (−0.3 to 3.1)	
	MS	−2.1 (4.9)	MS vs CR	1.5 (−0.2 to 3.2)		MS	−2.2 (5.1)	MS vs CR	1.6 (−0.2 to 3.4)	
Six-Minute Walk Test	PS	70.9 (99.6)	CR vs PS	−10.3 (−63.1 to 43.1)	.322	PS	94.3 (96.1)	CR vs PS	−4.4 (−59.9 to 51.1)	.351
	CR	68.1 (118.3)	MS vs PS	−40.5 (−95.8 to 14.1)		CR	82.4 (114.0)	MS vs PS	−38.2 (−94.1 to 17.7)	
	MS	62.1 (110.8)	MS vs CR	−30.1 (−86.2 to 25.9)		MS	83.2 (111.3)	MS vs CR	−33.8 (−92.3 to 24.7)	

PS, posterior stabilized; CR, cruciate retaining; MS, medial stabilized; OKS, Oxford Knee Score; WOMAC, Western Ontario and McMaster Universities Arthritis Index (Normalized); VR12, Veterans RAND 12 Item Health Survey; KSS, Knee Society Score; KSFS, Knee Society Functional Score; SD, standard deviation; CI, confidence interval.
Bold indicates the statistical significance.
[a] Adjusted for age, body mass index, and comorbidity.

Table 3
Adverse Events and Complications, by Group.

Adverse Event	PS (n = 23)	CR (n = 25)	MS (n = 27)	*P*-Value
Total adverse events	7	4	6	.490
Pain[a]	1	0	1	
Hemarthrosis	1	0	0	
DVT	2	0	1	
PE	1	0	0	
AMI	0	0	1	
Clostridium difficile infection	1	0	0	
Knee stiffness[b]	1	1	2	
Hematoma	0	1	0	
Superficial wound infection	0	1	0	
Wound dehiscence	0	0	1	
Delirium	0	1	0	
Death[c]	1	0	0	
Readmission	3	2	6	.338
Return to operating theater	2	1	3	.633

PS, posterior stabilized; CR, cruciate retaining; MS, medial stabilized; DVT, deep vein thrombosis; PE, pulmonary embolism; AMI, acute myocardial infarction.
[a] Severe enough to delay discharge or prompt readmission.
[b] Requiring manipulation under anesthesia.
[c] Occurred at 6-mo postsurgery due to complications associated with bladder cancer (not included in count).

detecting statistically significant findings that resulted from chance alone. Between-group differences were also notably consistent across several domains and were clinically meaningful. Finally, despite a relatively low and balanced dropout rate, the PS group had one additional participant lost to follow-up (due to death) compared to the CR and MS groups and we acknowledge that minor differences in dropout rate may impact results in a trial with a small sample size.

Conclusion

Comparative longevity of different knee replacement prostheses validates the procedure of TKJR as a cost and clinically effective means of treating end-stage osteoarthritis. Despite well-performed surgeries, a significant proportion of patients remain dissatisfied. Subtleties in design features now seem more directed toward improving PROMs which reflect real-world success or failure by way of patient satisfaction. This study confirms that the MS design appears to provide similar clinical results to PS and CR implant systems. The MS design was associated with better patient-reported outcomes in this RCT and whether this also equates to longer term survival remains to be seen.

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Appendix

Supplementary Table 1
Trial Study Visits.

Assessment/Activity	Enrollment	−T1 (1-mo Pre-TKJR)	Randomization	T0 (Surgery)	T1 (6-mo Post-TKJR)	T2 (12-mo Post-TKJR)
Demographics	X					
Eligibility screen	X					
Informed consent	X					
PROMs[a]		X			X	X
Functional tests[b]		X			X	X
Randomization			X			
TKJR				X		

PROMs, patient-reported outcome measures; TKJR, total knee joint replacement; T, timepoint.
[a] PROMs: Oxford Knee Score, Western Ontario and McMaster Universities Osteoarthritis Index, and Knee Society Score.
[b] Functional tests: Six-Minute Walk Test and Timed Up and Go Test.

Supplementary Table 2
Absolute Values of Outcome Measures at 6 mo and 12 mo, by Group.

Measure[a]	PS (n = 26)			CR (n = 27)			MS (n = 29)		
	Presurgery	6 mo	12 mo	Presurgery	6 mo	12 mo	Presurgery	6 mo	12 mo
OKS Pain	8.4 (3.2)	20.1 (6.4)	20.3 (8.4)	10.1 (5.8)	20.6 (6.0)	19.7 (8.7)	9.4 (4.5)	19.9 (5.8)	19.0 (8.3)
OKS Function	7.8 (3.1)	14.4 (3.7)	13.5 (5.4)	8.8 (3.8)	14.8 (4.3)	13.3 (5.9)	8.4 (3.4)	13.6 (3.9)	13.4 (5.1)
OKS Total	16.2 (6.0)	34.5 (9.8)	33.8 (13.4)	18.9 (9.1)	35.4 (10.2)	33.0 (14.4)	17.8 (7.5)	33.4 (9.3)	32.4 (13.2)
WOMAC Pain	63.5 (15.4)	29.6 (22.2)	22.8 (18.8)	54.6 (19.6)	23.4 (21.7)	24.1 (22.5)	58.1 (19.2)	20.2 (14.2)	16.7 (15.9)
WOMAC Function	57.0 (14.0)	29.4 (20.0)	22.7 (19.2)	56.9 (19.3)	23.2 (18.2)	29.4 (22.1)	56.5 (22.3)	22.3 (15.2)	19.7 (15.3)
WOMAC Stiffness	62.0 (23.3)	34.4 (26.9)	26.0 (22.2)	62.0 (23.4)	32.5 (23.1)	29.6 (20.3)	58.6 (26.3)	31.0 (19.4)	20.7 (19.3)
WOMAC Global	59.6 (14.4)	29.9 (20.3)	23.0 (18.1)	56.8 (18.9)	24.0 (18.3)	28.3 (21.1)	57.0 (20.2)	22.6 (14.3)	19.2 (14.8)
VR12 Physical Component Score	28.3 (6.8)	38.0 (10.4)	42.3 (10.5)	29.0 (6.9)	41.9 (10.5)	38.8 (10.7)	27.8 (8.6)	40.1 (8.7)	40.8 (10.3)
VR12 Mental Component Score	48.6 (13.0)	51.8 (10.3)	58.1 (7.7)	48.7 (13.1)	49.5 (12.0)	49.1 (14.1)	46.1 (12.0)	48.7 (12.4)	53.1 (10.5)
KSS Patient Symptoms	4.8 (2.9)	15.0 (7.4)	19.0 (5.5)	6.4 (5.3)	18.2 (6.3)	18.6 (5.8)	7.1 (5.2)	18.8 (4.3)	18.8 (4.6)
KSS Patient Satisfaction	10.6 (7.2)	24.0 (11.6)	30.1 (9.9)	12.5 (8.5)	28.6 (9.5)	29.8 (9.5)	12.3 (7.7)	31.4 (6.3)	30.8 (9.2)
KSS Patient Expectations	13.7 (1.9)	13.2 (1.8)	12.0 (3.5)	13.2 (1.7)	12.8 (2.7)	12.5 (2.5)	14 (1.8)	13.2 (2.6)	12.7 (2.8)
KSS Patient Total	29.1 (8.1)	52.2 (18.2)	61.0 (16.5)	32.2 (12.3)	59.6 (16.1)	60.8 (15.9)	33.5 (11.4)	63.4 (11.0)	62.4 (14.3)
KSFS Walking	12.2 (6.8)	20.2 (7.2)	22.4 (7.5)	11.3 (6.7)	17.5 (10.4)	20.9 (7.8)	11.6 (6.6)	18.1 (7.2)	19.6 (7.0)
KSFS Standard Activities	9 (4.8)	19.7 (7.4)	22.9 (6.1)	10.7 (6.3)	20.7 (6.7)	21.5 (7.0)	10.2 (5.2)	21.7 (5.6)	23.3 (4.6)
KSFS Advanced Activities	4.2 (3.5)	12.2 (5.2)	14.8 (6.2)	4.7 (5.2)	11.7 (6.5)	13.2 (7.1)	3.9 (3.4)	10.8 (5.2)	13.7 (6.6)
KSFS Discretionary Activities	3 (2.5)	7.1 (4.8)	10.7 (3.2)	3.3 (3.4)	8.4 (4.1)	9.1 (5.0)	3.59 (3.2)	8.3 (5.2)	9.2 (3.9)
KSFS Total	29.4 (14.9)	59.1 (20.2)	70.4 (19.4)	30.1 (18.7)	58.3 (23.2)	64.7 (23.4)	29.3 (14.6)	58.9 (15.9)	65.7 (17.3)
KSS Surgeon	47.3 (6.4)	87.4 (12.8)	93.2 (5.9)	42.6 (14.4)	89.1 (13.0)	93.1 (8.2)	44.0 (10.4)	86.6 (10.1)	88.8 (11.0)
Timed Up and Go Test	12.1 (3.5)	9.2 (2.0)	9.1 (1.9)	13.7 (5.2)	9.5 (2.3)	9.4 (2.3)	12.9 (4.1)	10.8 (3.2)	10.7 (3.5)
Six-Minute Walk Test	360.6 (112.2)	431.5 (85.5)	450.5 (90.8)	332.6 (122.0)	400.7 (90.1)	425.7 (95.7)	215.2 (83.1)	377.7 (100.3)	398.4 (96.1)

PS, posterior stabilized; CR, cruciate retaining; MS, medial stabilized; OKS, Oxford Knee Score; WOMAC, Western Ontario and McMaster Universities Arthritis Index; KSS, Knee Society Score; KSFS, Knee Society Function Score; VR12, Veterans RAND 12 Item Health Survey.
[a] Presented as mean (standard deviation).

Supplementary Table 3
Assessment of Floor and Ceiling Effect.

Outcome Measure[a]	% With Worst Possible Score (Floor Effect)	% With Best Possible Score (Ceiling Effect)
OKS Pain -T^1	1.3%	0%
OKS Function -T^1	0%	0%
OKS Total -T^1	0%	0%
OKS Pain T^1	0%	6.7%
OKS Function T^1	0%	4%
OKS Total T^1	0%	2.7%
OKS Pain T^2	0%	12.0%
OKS Function T^2	0%	12.0%
OKS Total T^2	0%	8.0%
KSS Patient Satisfaction T^1	0%	9.3%
WOMAC Pain T^2	0%	12.3%
WOMAC Function T^2	0%	4.9%
WOMAC Global T^2	0%	1.3%
VR12 Mental Component Score T^2	0%	0%

OKS, Oxford Knee Score; WOMAC, Western Ontario and McMaster Universities Arthritis Index; KSS, Knee Society Score; VR12, Veterans RAND 12 Item Health Survey; T, timepoint.

[a] -T^1 (1-month pre-TKJR); T^1 (6-months post-TKJR); T^2 (12-months post-TKJR)