OPEN Research Article

The Effect of the Design of Polyethylene Inserts in Total Knee Arthroplasty on Patient Reported Outcomes

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ABSTRACT

Introduction: Several types of polyethylene liners have been developed to address the specific needs of patients' anatomy within total knee arthroplasty (TKA). In modern TKA, the posterior-stabilized (PS) and the cruciate-retaining (CR) designs are the most common, with the medial congruent (MC) design becoming more popular. The MC total knee arthroplasty has a posterior dwell point allowing for more flexion. The purpose of this study was to determine differences in patient-reported outcomes (PROMs) or postoperative outcomes between these three TKAs.

Methods: Patients who underwent a primary, elective, unilateral TKA between June 2021 and July 2023 were identified. Demographics and perioperative and postoperative outcomes were extracted from the medical record. PROMs from 624 patients were obtained through a digital engagement platform. A P value ≤ 0.05 was considered statistically significant.

Results: Patients were subdivided into three groups; 111 PS-TKA, 278 CR-TKA, and 235 MC-TKAs. Most implants were Zimmer (71.5%) and were cemented (92.9%). Patients in the CR group were predominantly male ($P = 0.003$) and had a lower body mass index ($P < 0.001$). No differences were seen in Knee Injury and Osteoarthritis Outcome Score for Joint Replacement scores at any time point (preoperative: $P = 0.073$; 12 weeks: $P = 0.144$; 6 months: $P = 0.666$; 1 year: $P = 0.622$). A similar percentage of patients met the minimal clinically important difference ($P = 0.480$), and Forgotten Joint Scores were equivalent ($P = 0.930$). Patient physical therapy parameters (Timed Up and Go test [$P = 0.779$] and ambulation distance [$P = 0.103$]), inpatient pain levels (at rest: $P = 0.101$, with activity: $P = 0.052$), or morphine milligram equivalents dosed ($P = 0.608$) were comparable. No differences were seen in 30-day complications.

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Conclusion: This study fails to demonstrate a difference in PROMs, functional parameters, or complications between the PS-TKAs, CR-TKAs, and MC-TKAs. All three constructs perform similarly in the immediate postoperative period. Because equivalent outcomes occur with each polyethylene, implant choice should be left to physician preference.

Total knee arthroplasty (TKA) is the benchmark treatment for patients diagnosed with severe knee osteoarthritis.[1,2] TKAs have become increasingly prevalent because of a larger aging population and a greater emphasis on quality of life without pain.[2,3] Approximately 15% to 20% of TKA patients are unsatisfied with the outcome,[4-6] and several types of total knee polyethylene insert designs have been developed to address the specific needs of patients and surgeons alike, with a goal of improving outcomes.[7] Posterior-stabilized (PS) and cruciate-retaining (CR) implant designs are still the most commonly used in modern TKA surgery.[8] A variety of other nonconstrained design variations are in use, including ultracongruent, medial pivot, condylar stabilizing, and medial congruent (MC).[1]

The posterior-stabilized TKA (PS-TKA) design contains a tibial post as part of the polyethylene insert and a femoral cam that engages with the post to allow femoral roll back during flexion.[9] The CR-TKA uses the native posterior cruciate ligament (PCL) to prevent anterior movement of the femur during flexion instead of the tibial post in PS-TKA. PS-TKAs have been historically classified as easier to achieve balance because of release of the PCL in settings of contracture or major deformity.[10]

Multiple studies and meta-analyses have been conducted comparing PS-TKAs and CR-TKAs. In 2016, Jiang et al[11] published a meta-analysis documenting 14 randomized controlled trials, which had been performed to compare these two knee types. No significant differences were seen in patient-related outcomes, alignment, and complication rates; however, a difference was seen in range of motion, with the PS-TKA showing markedly more motion and flexion.[11] Both the Mayo Clinic registry and the American Joint Replacement Registry have demonstrated increased survivorship in CR-TKA compared with PS-TKA.[12,13]

The MC polyethylene design was first developed in 2015.[14] This design is meant to replicate the motion of the healthy knee as it moves through the gait cycle, with limited medial translation of the medial femoral condyle relative to the tibia as flexion occurs.[14,15] This is accomplished through a dished insert design with a deep medial dish. MC-TKAs also have a posterior dwell point, which theoretically allow for more flexion (up to 155°) of the joint prosthesis.[14,15] This design is separate from a true "ball in socket" medial pivot–style knee arthroplasty commonly used in kinematically aligned TKA.[9]

Few studies have looked at MC-TKAs compared with PS-TKAs and CR-TKAs, and none of these studies has looked at a comparison of large patient cohorts.[4,5,16] Recent studies have shown statistically significant differences in range of motion and trends toward better patient-reported outcomes (PROMs) in the MC-TKA group[4,16] compared with PS-TKA and CR-TKA groups. These studies were relatively small and also reported that the MC-TKA showed improved early pain and patient satisfaction, when compared with PS-TKAs and CR-TKAs.[5] Finally, these studies could be affected by bias because at least one author in each study was a paid consultant for the company that produces the MC insert.

The purpose of this study was to determine whether there was a difference in PROMs (Knee Injury and Osteoarthritis Outcome Score for Joint Replacement [KOOS-JR]) out to 1 year between CR-TKAs, PS-TKAs, and MC-TKAs performed at our institution. Secondary aims were to evaluate differences in physical therapy parameters (ambulation distance and Timed Up and Go [TUG] test, pain, morphine milligram equivalents [MMEs] dosed) and 30-day complications between the groups.

Methods

A total of 624 primary elective TKA patients who underwent the procedure between June 1, 2021, and July 31, 2023, at a high-volume urban orthopaedic hospital were included in this retrospective study. Institutional review board approval was obtained (IRB #: E-HHC-2021-0349). Patients who were between 18 and 89 years were included. Demographics, perioperative, and postoperative clinical outcomes were extracted from the patient's medical record. These included postoperative acute care unit (PACU) time, length of stay, inpatient pain levels, inpatient morphine milligram equivalents (MMEs) dosed, and 30-day readmission/emergency department visit. Physical therapy outcomes, including range of motion, ambulation distance, and Timed Up and Go

(TUG) test, were collected while inpatient. All patients were electronically sent the KOOS-JR survey preoperatively and at 12 weeks, 6 months, and 1 year after surgery. Patients were included in this study only if they completed both a preoperative KOOS-JR and a 1-year KOOS-JR PROM form.

Exclusion criteria included patients who underwent a revision, conversion, or unicompartmental knee arthroplasty. If a patient underwent the arthroplasty because of cancer or fracture, they were also excluded, as were patients who were taking long-acting opiates for controlling chronic pain.

PS constructs included the Smith & Nephew Legion (Smith & Nephew, Andover, MA), the Stryker Triathlon (Stryker Corp, Kalamazoo, MI), and the Zimmer Persona (Zimmer Biomet, Warsaw, IN). CR constructs included the Stryker Triathlon, the Smith & Nephew Legion, and the Zimmer Persona. All MC knees were of Zimmer Persona brand. No rotating platform designs were used. Surgery using navigation was performed on approximately 5% of all knees spread evenly across each implant type. Implant choice was left to surgeon preference. Each operation was performed by a fellowship-trained arthroplasty surgeon, through a standard medial parapatellar approach. Data from seven experienced orthopaedic surgeons were included. For the purpose of this study, the minimal clinically important difference (MCID) for KOOS-JR scores was set at 15, as per Lyman et al and Hung et al.[17,18] The Forgotten Joint Score (FJS-12)[19] was also used to evaluate these patients, and the threshold for "forgetting" the joint was set at 33.3 per Singh et al.[20]

Patient demographics and single outcome measures, for example, readmissions or the presence of an inpatient complication, were compared using chi-square tests of proportion. KOOS-JR scores and continuous variables such as pain or length of stay were compared using one-way analysis of variance (ANOVA) or Kruskal-Wallis tests depending on the underlying distribution of the variable. STATA version 17 (StataCorp) or Microsoft Excel 2016 (Microsoft) was used to complete the analyses. Results were considered to be statistically significant if $P < 0.05$.

Results

Patient demographics were similar between groups, as given in Table 1. The CR-TKA group had statistically significantly more men ($P = 0.003$) and a lower average body mass index ($P < 0.001$) than the other groups. Implant characteristics are provided in Table 2.

No difference was seen in KOOS-JR scores between any of the groups, at any time point, as presented in Table 3. Preoperatively, there was no difference seen in KOOS-JR scores by implant brand ($P = 0.1662$, F-statistic = 1.528), so all brands were pooled for subsequent analysis. Preoperatively, the average KOOS-JR score was 53.13 ± 11.6 in the PS group, 55.51 ± 12.2 in the CR group, and 53.22 ± 12.6 in the MC group ($P = 0.073$, F-statistic = 2.629). At 12 weeks, the P value between the groups was 0.143 (F-statistic = 1.948). This persisted at 6 months ($P = 0.666$, F-statistic = 0.406). At one year, all groups showed very similar KOOS-JR scores (PS-TKA: 76.11 ± 14.0, CR-TKA: 75.76 ± 13.6, MC-TKA: 76.89 ± 13.2, $P = 0.622$, F-statistic = 0.475) and all brands had equivalent KOOS-JR scores as well ($P = 0.333$, F-statistic = 1.149). In addition, the percentage of patients meeting MCID at 1 year was similar for all groups (PS-TKA: 67.6%, CR-TKA: 63.3%, MC-TKA: 68.1%, $P = 0.480$, chi-squared statistic = 1.466) as were the number of patients who "forgot" their joint as measured by the FJS-12 (PS-TKA: 73.9%, CR-TKA: 73.4%, MC-TKA: 74.9%, $P = 0.926$, chi-squared statistic = 0.153). Raw FJS-12 scores were equivalent among groups (PS-TKA: 53.69 ± 26.6, CR-TKA: 52.94 ± 27.1, MC-TKA: 54.03 ± 26.8, $P = 0.930$, F-statistic = 0.072).

Physical therapy parameters, such as ambulation distance and Timed Up and Go (TUG) tests, were not different between groups, as given in Table 4. All patients had similar ambulation distances of approximately 150 feet ($P = 0.102$, F-statistic = 2.282) and TUG scores of approximately 22 seconds ($P = 0.779$, F-statistic = 0.250).

Pain scores were also not different among groups, although slightly more pain, both at rest and with activity, was seen in the MC-TKA group. This is not statistically significant (pain at rest: $P = 0.101$, F-statistic = 2.300, pain with activity: $P = 0.051$, F-statistic = 2.979). MMEs were also not different among groups (PS-TKA: 68.73 ± 45.7, CR-TKA: 62.67 ± 57.3, MC-TKA: 69.71 ± 39.7, $P = 0.607$, F-statistic = 0.499). Pain levels and MMEs are provided in Table 5.

Of the patients who returned to the emergency department or who were readmitted, the predominant reason was pain or exacerbation of a preexisting condition. One patient in the PS-TKA group was readmitted because of cellulitis, which was related to the surgery. In the CR-TKA group, one patient was readmitted because of pulmonary embolism and one patient was readmitted because of respiratory failure. In the MC-TKA group, one patient was readmitted because of wound dehiscence and another was readmitted for pulmonary embolism.

Table 1. Patient Demographics Subdivided by Total Knee Arthroplasty Type

Factor or Variables	Posterior Stabilized (n = 111)	Cruciate Retaining (n = 278)	Medial Congruent (n = 235)	*P*
Female sex	73% (81)	**55% (154)**	63% (152)	**0.003**
Age (yrs)	68.8 ± 7.3	70.0 ± 7.6	68.3 ± 8.7	0.104
Race				0.055
American Indian/Alaska Native	0% (0)	0.4% (1)	0% (0)	
Asian	0.9% (1)	0.4% (1)	0.4% (1)	
Black or African American	4.5% (5)	2.5% (7)	1.3% (3)	
Native Hawaiian/Pacific Islander	0% (0)	0% (0)	0% (0)	
Multiracial/other	0% (0)	5.0% (14)	2.6% (6)	
White or Caucasian	93.7% (104)	91.4% (254)	95.3% (224)	
Unknown/patient refused	0.9% (0)	0.4% (1)	0.4% (1)	
Ethnicity				0.352
Hispanic or Latino	0% (0)	2.9% (8)	1.7% (4)	
Not Hispanic or Latino	98.2% (109)	96.0% (267)	97.9% (230)	
Unknown/patient refused	1.8% (2)	1.1% (3)	0.4% (1)	
Body mass index (BMI) (kg/m^2)	33.1 ± 6.0	**31.6 ± 5.4**	34.3 ± 6.7	**<0.001**
Charlson Comorbidity Index (CCI)	3.4 ± 1.7	3.4 ± 1.6	3.4 ± 1.9	0.990
Laterality (left)	48% (53)	49% (135)	47% (110)	0.925
Length of stay (d)	1.98 ± 0.23	2.07 ± 0.54	2.04 ± 0.24	0.158
Surgical time (mins)	86.2 ± 12.5	84.0 ± 12.1	83.2 ± 18.4	0.351
PACU time (mins)	92.8 ± 39.5	88.7 ± 31.9	88.3 ± 27.8	0.425
Return to ED within 30 days	3.6% (4)	4.0% (11)	3.4% (8)	0.945
Readmission within 30 days	2.7% (3)	1.4% (4)	2.5% (6)	0.598

ED = emergency department; PACU = postoperative acute care unit
Patient demographics table showing patient characteristics.
Values in bold indicate statistical significance.

Discussion

Similar to previous studies, our study failed to demonstrate a difference in PROMs between PS-TKAs and CR-TKAs.[11,21-23] In addition, no difference was seen between MC-TKAs and PS-TKAs or CR-TKAs in our study regarding PROMs, functional parameters, or pain after surgery. This study is, to our knowledge, the largest cohort of MC-TKAs compared with standard articulations to date. The same percentage of patients in all groups met MCID per the KOOS-JR score and met the clinically important improvement threshold for the

Table 2. Implant Characteristics by Polyethylene

Factor or Variables	Posterior Stabilized (n = 111)	Cruciate Retaining (n = 278)	Medial Congruent (n = 235)
Noncemented	0.9% (1)	10.0% (28)	6.4% (15)
Implant brand			
Smith and Nephew	47.7% (53)	34.2% (95)	0.0% (0)
Stryker	6.3% (7)	8.2% (23)	0.0% (0)
Zimmer	46.0% (51)	57.6% (160)	100% (235)

Implant characteristics, subdivided by implant brand. The overarching brand is Zimmer Biomet with 71.5% of all implants. 92.9% of all implants were cemented.

Table 3. Knee Injury and Osteoarthritis Outcome Scores Subdivided by Total Knee Arthroplasty Type

KOOS	Preoperative	12 Weeks	6 Months	12 Months
Posterior stabilized	53.13 ± 11.6	68.57 ± 10.4	73.51 ± 13.5	76.11 ± 14.0
Cruciate retaining	55.51 ± 12.2	67.19 ± 11.0	72.68 ± 11.6	75.76 ± 13.6
Medial congruent	53.22 ± 12.6	69.09 ± 11.2	73.60 ± 12.2	76.89 ± 13.2

KOOS = Knee Injury and Osteoarthritis Outcome Score
No difference at any time point between groups (preoperative $P = 0.073$, F-statistic = 2.629; 12 weeks $P = 0.144$, F-statistic = 1.948; 6 months $P = 0.666$, F-statistic = 0.406; 1 year $P = 0.622$, F-statistic = 0.475)

FJS-12 score. Frye et al found that patients with an MC-TKA had a higher FJS-12 score at 1 year compared with PS-TKA and CR-TKA groups, but we did not find this to be the case,[5] nor did we find differences related to implant brand.

In addition, no differences were seen in complications within the first 30 days after TKA. These three constructs perform in a very similar fashion in the immediate postoperative period and within the first year of implantation and provide patients with improved quality of life. Pain levels and MME use were not markedly different between groups.

The MC insert has been shown in vivo to alter tibiofemoral mechanics to drive kinematics toward a more "natural" state.[24] It is designed for use both with and without the PCL, with the dish preventing posterior tibial translation as a whole. A recent study demonstrated no major differences in outcomes when the MC-TKA was used with or without PCL resection.[25] Advantages of this construct include the ability to balance or resect the PCL, without cutting the "box" of a PS knee, which increases the risk of fracture.[26] An open CR-style femoral box also theoretically limits bone loss in the setting of revision vs. removal of a PS-style implant. Despite no differences found in PROMs or other recovery measures, the MC insert may, therefore, still represent an advantage over a PS insert for these reasons.

Our study has limitations. Patient data were collected prospectively but analyzed retrospectively. Patients were required to complete the KOOS-JR survey preoperatively and at 1 year to be included in the data set, which may have biased the data toward those with the means and time to complete the surveys on the electronic platform. Data from seven surgeons and multiple implant brands were pooled, with most being Zimmer, which was also a source of potential bias. This was also a single-center study, limiting the generalizability to surgeries performed in other settings. In addition, we were only able to assess short-term functional outcomes because the first patients with an MC-TKA were treated at our institution in mid-2021 and, therefore, we did not have PROMs beyond 1 year. An advantage of this research is that no authors have any relationship with any implant company, making this study unique in the context of the current MC-TKA literature. Additional study is needed to evaluate the intermediate-term rates of patient satisfaction and implant survivorship in the MC-TKA.

Conclusion

No differences were seen in outcomes, including the KOOS-JR and FJS-12 scores, between PS-TKA, CR-TKA, and MC-TKA groups across all brands assessed. Physical therapy parameters, postsurgical pain, postsurgical MMEs dosed, and complications requiring return to the emergency department or readmission were also the same between groups. The type of knee implant should be left up to physician and/or patient preference because similar outcomes occur regardless of the implant used. Additional research and innovation are needed to determine the ideal level of motion guidance, kinematic guidance, and constraint, which will help drive PROMs more positively after TKA.

Table 4. Physical Therapy Parameters Subdivided by Total Knee Arthroplasty Type

Physical Therapy Parameters	Ambulation Distance (ft)	Time to Up and Go Test (s)
Posterior stabilized	149.4 ± 111.8	21.99 ± 12.0
Cruciate retaining	155.2 ± 111.1	22.66 ± 11.2
Medial congruent	134.7 ± 102.4	22.08 ± 7.9

No difference between groups (ambulation distance $P = 0.103$, F-statistic = 2.282; TUG test $P = 0.779$, F-statistic = 0.250)

Table 5. **Inpatient Pain Levels and Morphine Milligram Equivalents Subdivided by Total Knee Arthroplasty Type**

Pain Levels and MMEs	Pain at Rest	Pain with Activity	Morphine Milligram Equivalents
Posterior stabilized	3.20 ± 2.2	4.01 ± 2.4	68.73 ± 45.7
Cruciate retaining	2.94 ± 2.0	3.96 ± 2.3	65.67 ± 57.3
Medial congruent	3.32 ± 2.0	4.44 ± 2.2	69.71 ± 39.7

MME = morphine milligram equivalent
No difference between groups. Trending toward more pain with activity in the MC group but did not reach significance (pain at rest $P = 0.101$, F-statistic = 2.300; pain with activity $P = 0.052$, F-statistic = 2.9788; MMEs $P = 0.608$, F-statistic = 0.487).

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