Tailored to Fit: A Review of the Role of Custom Implants in Total Knee Arthroplasty

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Total knee arthroplasty (TKA) can be performed using either conventional off-the-shelf (OTS) implants or customized individually made (CIM) implants. This study aims to review existing literature and compare clinical outcomes between patients receiving CIM and OTS implants, specifically in terms of satisfaction, radiographic/alignment outcomes, revision rates, and costs. A review of literature was conducted using Medline, Cochrane, and Embase to identify articles comparing CIM and OTS implants in TKA patients. Data and outcomes were described qualitatively. Overall, based on the current evidence, custom implants have been shown to yield comparable to improved patient-reported and clinical outcomes, anatomic match, and excellent registry survival outcomes as compared with conventional OTS implants for the general population undergoing TKA. (Journal of Surgical Orthopaedic Advances 34(3):114-118, 2025)

Key words: total knee arthroplasty, custom implants, off-the-shelf implants

Total knee arthroplasty (TKA) can be performed using either conventional off-the-shelf (OTS) implants or customized individually made (CIM) implants. To date, the vast majority of TKAs performed have used OTS implants.[1] Nevertheless, there continues to be an appreciable amount of patients who are dissatisfied following TKA.[2] Although the exact cause of persistent dissatisfaction is unclear, it is possible that implant design plays a role.[3,4] Some clinical and biomechanical studies have suggested distal femur morphology differs with sex and ethnicity, arguing in favor for CIM implants.[3,5,6] The debate on whether CIM implants deliver superior outcomes compared with OTS implants is ongoing, with various studies providing mixed results.

This review aims to provide arthroplasty surgeons with an overview on the use of CIM versus OTS implants for TKA. This article compares clinical outcomes and satisfaction, radiographic/alignment outcomes, revision rates, and costs to determine if CIM implants offer any significant advantages over OTS implants.

Clinical Outcomes and Satisfaction

The comparative effectiveness of custom versus OTS TKA implants has been extensively evaluated in recent literature. Müller et al.,[7] through a systematic review and meta-analysis encompassing nine case-control studies and additional cohort data, demonstrated no significant advantage of custom TKA over OTS implants in early clinical outcomes, including Knee Society Score (KSS) and range of motion. Although custom implants exhibited higher early revision rates (odds ratio [OR], 0.4), the lack of statistical significance weakens the assertion of increased risk.[7] Similarly, Saeed et al.[8] conducted a more recent systematic review and meta-analysis including 23 studies with a total of 2,856 CIM and 1,877 OTS TKAs. Their findings corroborate Müller's results, indicating no significant differences in KSS or functional outcomes between custom and OTS implants.[7]

Some biomechanical studies have suggested that morphological differences in bone anatomy due to sex and ethnicity may argue in favor of gender-specific or CIM implants over OTS implants; however, clinical applications of these findings are limited.[5,6,9] Merchant et al.[10] conducted a systematic review of existing studies on gender-specific implants and concluded that despite proposed differences in Q angle, prominence of anterior medial and anterior lateral femoral condyles, and medial-lateral to anterior-posterior femoral condylar aspect ratio between male and female knees, current data do not suggest a difference in clinical outcomes between patients with gender-specific and OTS implants. Existing clinical data studying the possible role of ethnicity-specific morphologic differences in bone anatomy on TKA outcomes are not well studied.[11,12]

The National Joint Registry's 2023 Annual Report included 991 patients receiving CIM implants, as compared with 1.2 million patients receiving conventional OTS implants.[13] It was found that custom implants performed best at 10 years postoperatively. The registry showed that CIM implants had low rates of intraoperative adverse events without statistically significant deviation from expected rate of adverse events. Rates of revision for custom implants were also low and similar to that of OTS implants (12 revisions vs. 17.80 expected revisions). The registry report had insufficient data to make conclusions regarding patient-reported outcome measures (PROM) and satisfaction of CIM implants.

Regarding patient satisfaction and PROMs, many studies reported superior results for patients receiving CIM implants. Buschner et al. conducted a single-center single-blinded study of 48 patients and found that patients with custom implants had significantly faster times in all functional tests and superior PROMs, as compared with the OTS patients.[14] Similarly, Schroeder et al. showed CIM patients, compared with OTS patients, had significantly higher Knee injury and Osteoarthritis Outcome Score, Joint Replacement (KOOS JR), and Forgotten Joint Score (FJS).[15] Schippers et al. reported that 93% of patients were satisfied or very satisfied with their CIM implant.[16] Steinert et al. conducted two cohort studies looking at outcomes and PROMs in CIM patients and found

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1548-825X/19/3403-0114$22.00/0
DOI: 10.3113/JSOA.2025.0114

improvement in functional outcomes and PROMs; however, these studies had no comparison with OTS implants, and thus, definitive conclusions on superiority of one type of implant cannot be made.[17,18] Also, some studies found no significant difference in PROMs and patient satisfaction between CIM and OTS implants[19,20] (Table 1).

Recent systematic reviews and meta-analyses indicate that custom TKA implants offer similar clinical outcomes compared with OTS implants. Several studies demonstrated high rates of patient satisfaction with CIM implants and superior postoperative functional scores and PROMs; however, other studies indicated no significant difference in these outcome measures. Overall, CIM implants yielded superior or similar outcomes as OTS implants, with few studies showing significant data that CIM implants produce inferior outcomes.

Radiographic Outcomes

Radiographic outcomes of TKA may include evaluation of alignment, joint space, implant fit, and complications. Demange et al. conducted a prospective cohort study showing improved radiographic outcomes in patients with CIM implants, compared with OTS implants with a decreased mean tibial implant lateral coverage mismatch (1.1 vs. 3.3 mm, $p < 0.01$).[21] Beel et al. conducted a case-series study demonstrating that patients with CIM implants, compared with OTS implants, had lower and less variable postoperative patellar tilt (95% confidence interval [CI] of 0.0° to 3.8° vs. 0.1° to 8.3°; $p < 0.001$).[22]

Two systematic reviews reporting radiographic outcomes were identified: Ner et al.[23] and Saeed et al.[8] Both studies found varying results on advantages of CIM implants with most studies concluding no significant difference in radiographic outcomes between CIM and OTS implants. Ner et al. conducted a systematic review of seven studies with a total of 1,510 patients comparing outcome measures of CIM and OTS implants.[23] Their review found that two of seven studies reported a statistically significant improvement of radiographic alignment, with Ivie et al. reporting CIM implants reduce alignment outliers greater than ±3° in the coronal plane mechanical axis, and Meheux et al. reporting that newer-generation CIM implants approached desirable knee alignment to a greater degree than older-generation CIM ($p = 0.004$) and OTS implants ($p < 0.001$).[24,25] The five other studies reported no significant difference in radiographic outcomes. In the systematic review by Saeed et al., they found that only one of five studies demonstrated a statistically significant difference in postoperative hip-knee-ankle (HKA) angle between patients receiving CIM and OTS implants.[8] The one study showing statistical significance, Ivie et al., found that custom implants were 1.8 times more likely to have HKA in the target zone, compared with OTS implants ($p = 0.0016$).[24] All other studies reporting HKA found no statistically significant difference.[8,26] There were varying data on the role of implant type on tibiofemoral angle and posterior tibial slope. Regarding implant fit, the personalized nature of CIM implants was thought to allow for higher accuracy in fit, with decreased or no overhang and underhang.[27,28] However, one study, Kumar et al.,[29] observed that CIM implants compared with OTS implants led to higher component malposition rates with greater rates of tibiofemoral instability (13.8 vs. 1.1%, $p < 0.01$), femoral notching (12.8 vs. 3.3, $p = 0.03$), and patellofemoral malalignment (20.2 vs. 7.7%, $p = 0.02$).[29] CIM implants have been shown to carry potential benefit with implant fit, but existing data of radiographic outcomes show generally no difference between use of CIM and OTS implants.

Revision Rates

Saeed et al. found that the custom group showed higher, albeit not statistically significant, rates of revision surgeries (5.9% vs. 3.7%; OR, 1.23 [95% CI, 0.69 – 2.18]) and complications (5% vs. 4.5%; OR, 1.45 [95% CI, 0.53 – 3.96]).[8] The meta-analysis further highlighted a statistically significant reduction in hospital length of stay for the custom group by 0.51 days (95% CI, −0.82 to −0.20), suggesting marginal efficiency gains without corresponding clinical benefits.

Ner et al.,[23] in their systematic review, reinforced the lack of substantial benefits of custom implants. Evaluating outcome scores, reoperation risks, and implant alignment, they found no significant improvements with custom TKA. In fact, custom implants were associated with poorer pain and function scores and higher reoperation rates, opposing the theoretical advantages of personalized alignment.[23]

Conversely, Beckmann et al.[30] provided a narrative perspective advocating for personalized medicine approaches in TKA. Although acknowledging the potential benefits of custom implants in respecting individual anatomical variations, their review did not present empirical evidence demonstrating superior outcomes. Instead, it emphasized the theoretical advantages and the need for further research to validate clinical benefits.[30]

In contrast to the predominantly negative findings, Demange et al.[21] presented a prospective clinical study focusing on patient-specific lateral unicompartmental knee arthroplasty. Their evaluation of 33 patients revealed superior tibial coverage and excellent short-term clinical outcomes compared with standard implants, with a higher survivorship rate (97% vs. 85%). However, the study is limited by its small sample size and short follow-up duration, which may not capture long-term outcomes and complications.[21]

Cost

With the rising number of TKAs performed each year and a predicted 3.48 million TKAs by 2030, cost is an increasingly important measure to consider.[31] O'Connor et al. analyzed TKA episode expenditures among Medicare fee-for-service members who received CIM implants with a propensity-matched cohort of patients who received OTS implants.[32] This study found that CIM implants provided significant savings as compared with OTS implants due to decreased average initial procedure cost and lower postoperative costs, which included 12-month emergency department, skilled-nursing facility, home health, inpatient, and outpatient visits. The average total episode spending for CIM implants was $18,585 versus $20,280 for OTS implants ($p < 0.0001$). The finding of decreased postoperative health care utilization is in contrast with other studies that have reported CIM implants lead to increased postoperative complication and revision rates.[23]

Culler et al.[9] found a similar trend of CIM patients requiring lower initial procedure and postoperative costs. CIM patients had significantly lower transfusion rates compared with OTS patients (2.4 vs. 11.6%, $p = 0.005$), lower adverse event rate at discharge (3.3 vs. 14.1%, $p = 0.003$), and lower 90-day postoperative adverse event rate (8.1 vs. 18.2%, $p = 0.023$). This study also identified fewer discharges to rehabilitation or acute care facilities for CIM patients (4.8 vs. 16.4%, $p = 0.003$). Despite lower rates of adverse events, total average real hospital cost and risk-adjusted per patient total cost were similar between CIM and OTS groups. Culler et al. concludes in favor of CIM implants, stating that these improved outcomes were attained without increasing health care costs.[9]

TABLE 1. Summary of studies

Reference	Study Type	No. of Patients	Outcomes	Results and Conclusions
Biomechanical and Kinematics Studies				
Piovan et al.[34]	Biomechanical via validated finite element model	N/A	Stress distribution, Von-Mises stresses, risk of fracture	Custom-made metaphyseal cones had more favorable stress distribution in femoral and tibial bones, as compared with conventional stem
Zeller et al.[35]	Kinematics study	38 (24 CIM, 14 OTS)	Weight-bearing range of motion, femorotibial translation, femorotibial axial rotation, condylar liftoff occurrence	CIM patients had statistically greater axial rotation compared with traditional posterior cruciate-retaining TKA patients (p = 0.05) Only CIM patients were able to carry out femoral internal rotation at full extension. CIM patients also experienced fewer incidences of paradoxical sliding and reverse rotation during flexion and extension
Clinical Studies				
Buschner et al.[14]*	Single-center, single-blinded study	48 (16 CIM, 32 OTS)	Functional testing (TUG, Walk, TUDS, BBS), VAS pain score, ALF score, PROMs	CIM group shows significantly faster times in all functional tests CIM group demonstrate higher PROM ratings
Schroeder et al.[15]*	Single-center, retrospective cohort study	47 (94 knees)	KOOS, JR; FJS	CIM group had significantly higher KOOS, JR (82 vs. 77, p = 0.03) and FJS (68 vs. 58, p = 0.04)
Schippers et al.[16]	Retrospective cohort study	(116 CIM)	Satisfaction, VAS, weight, OKS, FJS-knee	93% of patients were satisfied with the CIM implant
Demange et al.[21]*	Prospective cohort study	53 (33 CIM, 20 OTS)	Radiographic, KSS, survivorship at 24 months follow up	The mean tibial implant lateral coverage mismatch in the CIM group was decreased compared with the OTS group (1.1 vs. 3.3 mm, p < 0.01) CIM group demonstrated higher survivorship, compared with the OTS group (97% at 37 months vs. 85% at 32 months)
Wendelspiess et al.[19]	Prospective cohort study	243 (74 CIM, 169 OTS)	Clinical, PROM	CIM and OTS groups showed similar clinical outcomes and PROMs
Vogel et al.[20]	Prospective cohort study	170 (85 CIM, 85 OTS)	Patient satisfaction, PROMs (KOOS, FJS, HAAS, EQ-5D-3L, EQ-VAS, KSS, surgeon satisfaction)	Patient satisfaction was similar between CIM and OTS groups and was not correlated with implant type Patients in CIM group had a greater EQ-VAS and HAAS scores Other PROMs were similar between CIM and OTS groups
Pelkowski et al.[36]	Retrospective cohort study	43 (23 CIM, 20 OTS)	PROMIS, operative characteristics, range of motion (ROM) return, reoperations	CIM and OTS implants had similar postoperative ROM, rates of reoperations, and PROMs
Steinert et al.[17]	Retrospective cohort study	(60 CIM)	Postoperative infection, reoperations, radiographic analysis of implant fit, WOMAC, EuroQol-5D Score	(No comparison to OTS implants in this study) There was 1 septic revision, 1 reoperation to replace patella because of patella osteoarthritis, and 3 manipulations under anesthesia to increase range of motion. Implant fit radiographic analyses showed < 2 mm of overhang or subsidence. At 1-year postoperative follow up, WOMAC score improved from 154.8 to 83.5 and EuroQol-5D Score improved from 11.1 to 7.7
Steinert et al.[18]	Retrospective cohort study	(73 CIM)	Functional outcomes, PROMs	(No comparison to OTS implants in this study) Mean KSS knee (41 to 92) and function scores (53 to 86); SF-12 Physical (28 to 50) and Mental (50 to 53) scores; overall knee range of motion (106° to 122°); and WOMAC scores (49.1 to 11.4) improved significantly following CIM implant (p < 0.001) at 5 years follow up
Radiographic Studies				
Arnholdt et al.[28]	Radiographic case series study	(106 CIM)	Implant fit, positioning, correction of mechanical axis (HKA), restoration of joint line	HKA was corrected, on average, from 174.4° ± 4.6° preoperatively to 178.8° ± 2.2° postoperatively. There was an average coronal femoral-tibial angle of 4.4°. Mean preoperative tibial slope was 5.3° ± 2.2° and postoperative tibial slope was 4.7° ± 1.1°. There were 4 cases of underhang and 11 cases of overhang; no patients had femoral notching

TABLE 1. Continued

Reference	Study Type	No. of Patients	Outcomes	Results and Conclusions
Beel et al.[22]*	Radiographic case series study	385	Postoperative patellar tilt	The CIM group, compared with the OTS group, had lower ($p < 0.001$) and less variable (95% CI of 0.0° to 3.8° vs. 0.1° to 8.3°) postoperative patellar tilt
Li et al.[5]*	Retrospective cohort study	NR (532 knees)	Radiographic	There was a statistically significant difference in width and symmetry of knees based off sex ($p < 0.001$)
Wunderlich et al.[26]	Radiographic case series study	562 (283 CIM, 279 OTS)	HKA, rate of outliers outside of ± 3° target zone	The CIM and OTS groups showed similar corrected postoperative HKA (179.0° ± 2.8° vs. 179.2° ± 3.1°, $p = 0.34$). The rate of outliers was equal in both groups (32.9%)
Cost Studies				
O'Connor et al.[32]*	Cost-analysis database study	4,434 (739 CIM; 3,695 OTS)	Reimbursement for initial procedure, preoperative CT scan, 12-month postoperative health care utilization expenditure	Total episode spending was significantly lower in CIM group compared with OTS group ($18,585 vs. $20,280; $p < 0.0001$)
Culler et al.[9]*	Retrospective cohort study	248 (126 CIM, 122 OTS)	Clinical, cost	In the CIM group compared with the OTS group, there were significantly lower transfusion rates (2.4 vs. 11.6%, $p = 0.005$), decreased adverse event rate at discharge (3.3 vs. 14.1%, $p = 0.003$) and 90 days after discharge (8.1 vs. 18.2%, $p = 0.023$), and fewer discharges to a rehabilitation or acute care facility (4.8 vs. 16.4%, $p = 0.003$) Total average real hospital cost and risk-adjusted per patient total cost were similar between CIM and OTS groups
Namin et al.[33]*	Simulation study	—	90-day readmission, 3-year revision, recovery period, time savings in operating rooms, associated cost within 3 years of primary knee replacement implants from 2018 to 2026	By 2026, if there is an adoption rate of 90% for CIM implants, rates of readmission and revisions can decrease by 62% and 39%, respectively. Predicted cost savings include 6% on procedure time and $38 billion of health care costs
Systematic Reviews				
Beckmann et al.[30]	Systematic review	NR (90 articles)	Qualitative commentary	—
Saeed et al.[8]*	Systematic review and meta-analysis	4,733 (285 CIM, 1,877 OTS) from 23 studies	Clinical, radiographic, alignment	Length of stay was significantly shorter in CIM group compared with OTS group (2.9 vs. 3.5 days) (−0.51 days [95% CI, −0.82 to −0.20]) Revision rate and KSS were similar between CIM and OTS groups
Müller et al.[7]	Systematic review and meta-analysis	1,927 (929 CIM, 998 OTS)	Early clinical	Between CIM and OTS groups, there were similar revision rates, KSS, and range of motion
Ner et al.[23]	Systematic review	1,510 (749 CIM, 761 OTS)	PROMs (KSS, FJS, KOOS), revision rate, postoperative alignment	Overall, CIM and OTS groups showed similar PROM scores and mean coronal plane limb alignment CIM implants, compared with OTS, were associated with more frequent reoperations

* Study showing statistically significant superiority for a given outcome measure for CIM implants, in comparison to OTS implants.
N/A, not applicable; CIM, customized individually made; OTS, off-the-shelf; TUG, Timed Up and Go Test; TUDS, Timed Up and Down Stairs Test; BBS, Berg Balance Scale; VAS, Visual Analogue Scale; ALF, Aggregated Locomotor Function; PROM, patient-reported outcome measures; KOOS, JR, Knee injury and Osteoarthritis Outcome Score, Joint Replacement; FJS, Forgotten Joint Score; OKS, Oxford Knee Score; HAAS, High-Activity Arthroplasty Score; KSS, Knee Society Score; EQ-VAS, EuroQol Visual Analogue Scale; PROMIS, Patient Reported Outcomes Measurement Information System; ROM, range of motion; WOMAC, Western Ontario and McMaster Universities Arthritis Index; SF-12, Short Form-12 Survey; HKA, hip-knee-ankle; CI, confidence interval; NR, not reported; CT, computed tomography

The study by Namin et al.[33] focuses on the adoption dynamics and cost-effectiveness of customized implants through a simulation model. Their findings suggest significant potential cost savings and reductions in revision surgeries and readmissions with high adoption rates of custom implants. The model predicted cost savings of $38 billion for the health care system. However, this model-based evidence does not directly address clinical efficacy and relies on assumptions that may not hold in real-world settings.[33]

Cost-analysis studies suggest that CIM implants may provide decreased intraoperative health care costs and decreased utilization of health care services in the postoperative period.

Conclusion

The synthesis of current literature reveals that custom TKA implants yield similar clinical, radiographic, functional, and patient-reported outcomes as compared with off-the-shelf implants, with some studies demonstrating superior outcomes in patients receiving CIM implants. Cost-effectiveness models and analyses have shown that widespread adoption of custom TKA implant use may provide economic benefit through predicted decrease in intraoperative costs and postoperative health care utilization. More studies must be undertaken to thoroughly understand and identify the role of custom implants in TKA.

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