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Comparison of Conventional and Custom Total Knee Arthroplasty Implants

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ABSTRACT

Total knee arthroplasty (TKA) is one of the most successful orthopedic procedures for the treatment of advanced knee osteoarthritis, providing predictable pain relief and functional improvement in a large proportion of patients. Conventional off-the-shelf (OTS) implants remain the standard comparator in studies of customized TKA and are supported by extensive clinical experience, registry-based survivorship data and long-term follow-up analyses. However, concerns regarding anatomical mismatch, variability in native knee alignment and persistent dissatisfaction in a subset of patients have contributed to the development of customized individually made (CIM) implants. The aim of this review was to compare conventional and customized TKA implants with regard to implant design, alignment philosophy, functional outcomes, survivorship and economic considerations. Current evidence suggests that CIM implants may improve anatomical conformity, implant fit and restoration of patient-specific knee geometry. Systematic reviews and meta-analyses have not consistently demonstrated superior clinical outcomes of CIM implants compared with modern OTS systems. Conventional implants continue to show excellent long-term survivorship and remain supported by extensive registry data. Furthermore, many studies evaluating CIM implants are limited by short follow-up duration, methodological heterogeneity and differences in implant design, alignment strategy and comparator groups. In conclusion, CIM implants represent a promising personalized approach in total knee arthroplasty, particularly in terms of anatomical fit and patient-specific reconstruction. Nevertheless, current evidence does not conclusively prove universal superiority over contemporary OTS implants in standard PROMs, revision rates or long-term survivorship, and further long-term comparative studies are required.

Keywords: *total knee arthroplasty, customized implant, patient-specific implant, off-the-shelf implant, kinematic alignment, mechanical alignment*

Abstract

Total knee arthroplasty (TKA) is one of the most successful orthopedic procedures for the treatment of advanced knee osteoarthritis, providing predictable pain relief and functional improvement in a large proportion of patients. Conventional off-the-shelf (OTS) implants remain the standard comparator in studies of customized TKA and are supported by extensive clinical experience, registry-based survivorship data and long-term follow-up analyses. However, concerns regarding anatomical mismatch, variability in native knee alignment and persistent dissatisfaction in a subset of patients have contributed to the development of customized individually made (CIM) implants.

The aim of this review was to compare conventional and customized TKA implants with regard to implant design, alignment philosophy, functional outcomes, survivorship and economic considerations. A narrative literature review was conducted using PubMed/MEDLINE, Google Scholar, PMC and selected orthopedic databases. Studies published between 2015 and 2025 addressing OTS and CIM implants, implant fit, alignment strategies, clinical outcomes, survivorship and economic aspects of primary TKA were included.

Current evidence suggests that CIM implants may improve anatomical conformity, implant fit and restoration of patient-specific knee geometry. Several studies also report improved joint perception, patient preference and selected functional outcomes after customized TKA. Some contemporary CIM systems are also increasingly incorporated into broader personalized arthroplasty concepts, including individualized or restricted kinematic alignment strategies. However, implant customization and alignment philosophy should be interpreted as related but distinct variables.

Systematic reviews and meta-analyses have not consistently demonstrated superior clinical outcomes of CIM implants compared with modern OTS systems. Conventional implants continue to show excellent long-term survivorship and remain supported by extensive registry data. Furthermore, many studies evaluating CIM implants are limited by short follow-up duration, methodological heterogeneity and differences in implant design, alignment strategy and comparator groups.

In conclusion, CIM implants represent a promising personalized approach in total knee arthroplasty, particularly in terms of anatomical fit and patient-specific reconstruction. Nevertheless, current evidence does not conclusively prove universal superiority over contemporary OTS implants in standard PROMs, revision rates or long-term survivorship, and further long-term comparative studies are required.

Keywords: total knee arthroplasty, customized implant, patient-specific implant, off-the-shelf implant, kinematic alignment, mechanical alignment.

Introduction

Total knee arthroplasty (TKA) remains one of the most effective surgical procedures for the treatment of advanced knee joint degeneration, providing predictable pain relief and functional improvement. Conventional TKA systems, based on off-the-shelf implants, have been widely

used for decades and are supported by extensive clinical experience and registry-based survivorship data. Many contemporary and established implant systems demonstrate low cumulative revision rates at 10–20 years, although outcomes vary according to patient age, implant design, fixation method and duration of follow-up [1,2]. Conventional implants are generally used as commercially available OTS systems, in contrast to patient-specific implants manufactured from preoperative imaging data. In comparative studies, OTS implants are commonly treated as the standard reference approach for evaluating customized implant systems [3,4].

Persistent dissatisfaction remains clinically relevant, as a subset of patients continue to report pain, instability, effusion or limited knee function after TKA despite the overall success of the procedure [4].

Despite these advantages, conventional implants are not manufactured to replicate each individual patient's anatomy. Multiple studies have demonstrated that variability in femoral and tibial morphology may lead to implant–bone mismatch, including mediolateral overhang, undercoverage and altered joint geometry when standard implants are used [3,5,6]. Such mismatch may require compromises in component sizing, bone coverage, rotation and soft-tissue balancing, potentially affecting postoperative biomechanics and patient-perceived function [3,5,6]. This limitation has been further emphasized by studies demonstrating significant inter-individual variability in tibial and femoral geometry, suggesting that mismatch is often difficult to avoid when using standard implant systems [5,6].

In addition, conventional TKA has traditionally relied on a mechanical alignment strategy, which aims to restore a neutral hip–knee–ankle axis. However, neutral mechanical alignment does not necessarily reflect the native alignment of all patients. Coronal limb alignment and joint-line orientation show substantial inter-individual variability, which may contribute to differences in postoperative biomechanics and clinical outcomes [7,8].

To address these limitations, customized individually made TKA implants have been developed as a patient-specific alternative. These systems are designed using preoperative imaging and digital planning to reproduce individual anatomy more accurately and improve bone–implant conformity [4,9]. Some contemporary customized systems may also be combined with personalized alignment strategies, but implant customization and alignment philosophy should

be considered distinct variables, since many comparative CIM studies have used conventional mechanical alignment [4,7–9].

Clinical evidence comparing customized and conventional implants remains heterogeneous. While some studies have demonstrated improved functional performance, better two-year outcomes or higher patient preference with customized implants, particularly in bilateral comparisons within the same patient [10–12], other analyses have reported no significant difference in patient satisfaction or early clinical outcomes between implant types [13–15].

Therefore, the aim of this study is to compare conventional and customized TKA implants, focusing on implant design, surgical technique, clinical outcomes and current evidence regarding their effectiveness and clinical applicability.

Materials and Methods

This study was conducted as a narrative literature review focused on the comparison between conventional off-the-shelf total knee arthroplasty implants and customized individually made implants in primary total knee arthroplasty.

A structured literature search was performed using PubMed/MEDLINE, Google Scholar, PMC and selected orthopedic journal databases. The PubMed/MEDLINE search used combinations of free-text terms and Medical Subject Headings (MeSH), whereas Google Scholar, PMC and orthopedic journal databases were searched using free-text keyword combinations. Search terms included: “total knee arthroplasty,” “total knee replacement,” “customized implant,” “custom implant,” “customized individually made implant,” “patient-specific implant,” “off-the-shelf implant,” “conventional implant,” “mechanical alignment,” “kinematic alignment,” “restricted kinematic alignment,” “implant survivorship,” “functional outcomes,” “patient-reported outcomes,” and “cost-effectiveness.”

The review primarily included studies published between 2015 and 2025 to ensure the relevance of contemporary implant designs, alignment strategies and surgical techniques. Eligible studies included systematic reviews, meta-analyses, randomized controlled trials, comparative cohort studies, registry-based analyses and economic evaluations related to primary TKA. Broader reviews of knee arthroplasty were included only when they contained relevant information on total knee arthroplasty or directly addressed the comparison between patient-specific and off-the-shelf knee implants.

The inclusion criteria were:

- studies comparing CIM and OTS implants in primary TKA,
- studies evaluating implant fit, alignment strategies, functional outcomes, PROMs, survivorship or economic aspects,
- peer-reviewed English-language publications.

The exclusion criteria included:

- unicompartmental knee arthroplasty studies without relevant TKA data,
- revision TKA,
- studies focused exclusively on robotic systems,
- conference abstracts and case reports without original clinical data.

A total of 21 key publications were selected for qualitative analysis. Due to heterogeneity among methodologies, implant systems, alignment strategies and reported outcomes, a formal quantitative meta-analysis was not performed.

Because this was a narrative review, no formal risk-of-bias assessment or quantitative evidence synthesis was performed. Therefore, the conclusions should be interpreted as a qualitative synthesis of selected contemporary evidence rather than as a systematic review.

Conventional TKA Implants

Design and Philosophy

Conventional total knee arthroplasty implants are generally based on an off-the-shelf concept, meaning that the surgeon selects the best-fitting commercially available component from a predefined range of sizes and morphologies rather than using a component manufactured specifically for an individual patient [3–6]. This design philosophy provides practical advantages in terms of familiarity, reproducibility and established clinical use, but it also requires the selected implant to approximate rather than fully reproduce individual knee morphology [3–6].

However, the reliance on standard sizing does not fully account for individual anatomical variability. Morphological studies have demonstrated significant variation in femoral and tibial dimensions, which may result in implant mismatch, including mediolateral overhang and undercoverage [5,6]. Such mismatch may require compromises in component sizing, bone coverage, rotation and soft-tissue balancing, with potential consequences for postoperative biomechanics.

Surgical Technique

Conventional TKA has traditionally been performed using a mechanical alignment strategy, which aims to restore a neutral hip–knee–ankle axis by performing distal femoral and proximal tibial bone resections perpendicular to their respective mechanical axes [7,8].

The rationale behind this approach is to restore a neutral load-bearing axis and achieve more symmetrical load distribution across the prosthetic joint, thereby reducing asymmetric polyethylene wear, implant loosening and instability [7,8]. However, increasing evidence suggests that neutral mechanical alignment does not reproduce native knee alignment in many patients, as coronal limb alignment and joint-line orientation show substantial inter-individual variability [7,8].

Advantages

Conventional TKA implants are supported by extensive clinical evidence demonstrating reliable long-term outcomes. Registry-based studies and long-term follow-up analyses commonly report durable implant survivorship, although outcomes vary by patient population, implant system, fixation method and duration of follow-up [1,2]. Furthermore, analyses of modern implant designs suggest that improvements in implant geometry have not necessarily resulted in significantly lower revision rates, indicating that conventional systems already provide a high level of durability [1].

In addition, conventional OTS implants remain the standard reference approach in comparative studies of CIM TKA and are widely represented in routine clinical datasets [16,17]. Cost comparisons with CIM implants have been addressed separately in economic and healthcare utilization analyses [16,17].

Limitations

Despite their success, conventional implants present several important limitations. Anatomical mismatch remains a key concern, as standard implants may not accurately replicate patient-specific joint geometry, potentially affecting bone coverage, soft-tissue balance and knee kinematics [3,5,6].

Furthermore, systematic pursuit of neutral mechanical alignment may fail to reproduce native limb and joint-line orientation in many patients. This is clinically relevant because native knee alignment is variable, and restoring every knee to a neutral mechanical axis may alter individual joint geometry and soft-tissue relationships [7,8]. These factors may contribute to suboptimal functional outcomes and persistent dissatisfaction in a subset of patients.

Custom TKA Implants

Design and Manufacturing

Custom TKA implants are designed to reproduce patient-specific anatomy using preoperative imaging, typically CT-based three-dimensional modeling. This process aims to improve implant fit, reduce mismatch and enable more precise patient-specific component positioning compared with conventional OTS systems [4,9].

In contrast to conventional implants, customized systems allow adaptation of component geometry and planned implant positioning to the individual patient. This may improve bone–implant conformity and potentially contribute to more physiological joint mechanics, although improved anatomical fit does not automatically guarantee superior clinical outcomes [4,9,14,15].

Surgical Workflow

The custom TKA workflow depends on preoperative imaging, digital planning and manufacturing of patient-specific implants and/or guides. Digital modeling is used to plan implant geometry and component positioning before surgery, with the aim of reproducing the planned reconstruction as accurately as possible [4,9].

Some newer CIM systems may be combined with individualized alignment concepts, including restricted kinematic alignment strategies, which aim to better reproduce aspects of native joint

alignment. However, this should be distinguished from implant customization itself, because customized implant geometry and alignment philosophy are related but not identical aspects of personalized arthroplasty [4,7–9].

Advantages

The main theoretical advantage of customized implants is improved anatomical fit. By tailoring implant geometry to the individual patient, custom systems aim to reduce bone–implant mismatch and restore more physiological joint geometry [3–6,9].

Clinical studies have reported promising results. Comparative studies have found improved functional test performance, higher joint-awareness scores, greater patient preference or better selected two-year PROMs in some CIM cohorts [10–12]. Non-comparative cohort studies have also reported favorable short-term PROMs, high satisfaction in selected cohorts and favorable short- to mid-term survivorship after CIM TKA, although such data do not by themselves prove superiority over OTS implants [18,19].

Limitations

Despite these advantages, current evidence does not consistently demonstrate superiority of customized implants over conventional systems. Some studies report no significant difference in patient-reported satisfaction or early clinical outcomes between implant types, particularly in short-term follow-up [13–15].

Müller et al. also reported considerably higher early revision rates in the custom TKA group, although this finding should be interpreted cautiously due to heterogeneity and limitations of the available evidence [15].

Additionally, customized implants require advanced imaging, digital planning and patient-specific manufacturing, which may increase logistical complexity and limit widespread implementation [4,9]. Existing studies are also heterogeneous with regard to implant design, alignment philosophy, follow-up duration and outcome measures, making direct comparison between CIM and OTS systems difficult [14,15].

Comparative Analysis: Custom vs Conventional TKA

Implant Fit and Alignment

The fundamental difference between customized and conventional TKA implants lies in their ability to reproduce patient-specific anatomy. Conventional off-the-shelf implants are based on standardized geometries and may not fully match individual bone morphology, potentially leading to implant overhang, undercoverage or altered joint geometry [3–6].

This limitation is further supported by studies demonstrating considerable inter-individual variability in tibial and femoral geometry, indicating that anatomical mismatch is often difficult to avoid with standard implant systems [5,6].

In contrast, customized individually made implants are designed using preoperative imaging and digital planning to improve patient-specific bone–implant conformity and reproduce planned component positioning more accurately [4,9].

An important issue in the comparison between customized and conventional implants is that implant fit and alignment should not be interpreted as identical outcomes. Customized implants are primarily intended to improve anatomical conformity by adapting the femoral and tibial components to the patient's individual morphology [4–6,9]. However, improved anatomical fit does not automatically guarantee superior clinical outcomes, because postoperative function also depends on soft-tissue balance, component rotation, ligament tension, rehabilitation, patient expectations and baseline joint deformity [7,8,13–15].

The role of alignment strategy is essential when interpreting outcomes of custom TKA. Evidence regarding kinematic alignment remains debated. Jamali et al. concluded that current review-level evidence is insufficient to determine a definitive advantage of kinematic alignment over mechanical alignment, whereas Gao et al. reported that restricted kinematic alignment may improve selected functional outcomes, particularly WOMAC and KSS, compared with mechanical alignment [20,21]. This is important because some CIM systems are not only different implant designs but may also be part of broader personalized arthroplasty concepts.

Functional Outcomes and PROMs

Clinical evidence comparing functional outcomes remains heterogeneous. In comparative studies, patients receiving customized implants have demonstrated improved performance in selected functional tests, including activities of daily living, as well as better locomotor function scores [10].

A particularly informative comparison is provided by bilateral within-patient studies, in which the same patient receives both implant types. In such analyses, customized TKA has been associated with significantly higher KOOS-JR and Forgotten Joint Score values. Most patients preferred the customized knee, and patients more frequently reported less pain, better perceived stability and a more normal joint feeling with the customized implant than with the off-the-shelf knee [11].

However, these findings are not universal. Other studies have demonstrated no significant differences in patient-reported satisfaction or early clinical outcomes between customized and conventional implants, particularly in short-term follow-up [13–15].

Recent systematic reviews and meta-analyses provide a more cautious interpretation of the clinical superiority of CIM implants. Saeed et al. concluded that current evidence does not demonstrate a clear clinical advantage of CIM over conventional OTS implants [14]. Similarly, Müller et al. reported no significant difference in early clinical outcomes between custom and OTS TKA, including commonly used clinical scores and range of motion, while also noting higher early revision rates in the custom TKA group [15].

Surgical and Economic Considerations

Customized implants introduce a different perioperative workflow compared with conventional systems. Preoperative imaging, digital planning and manufacturing processes increase logistical complexity but may allow for more individualized surgical execution and closer reproduction of preoperative planning [4,9].

Economic analyses have suggested that customized implants may not necessarily increase total healthcare costs and may even reduce overall expenditures in certain healthcare systems [16]. Culler et al. compared adverse event rates and hospital costs between CIM and OTS implants and found that CIM implants were not associated with higher hospital costs in their single-institution cohort [17]. However, these findings should be interpreted cautiously because available economic analyses are system-dependent and may be influenced by patient selection, reimbursement structure, institutional workflow and industry-related factors [16,17].

Complications, Revisions and Survivorship

Conventional TKA implants remain the benchmark for long-term survivorship, with extensive registry and long-term follow-up data demonstrating durable implant survival [1,2].

Customized implants have shown promising short-term patient-reported outcomes and favorable short- to mid-term survivorship in selected cohorts [18,19]. However, long-term data remain limited compared with conventional systems. Therefore, current evidence is insufficient to conclude that CIM implants provide superior long-term survivorship or lower revision rates than contemporary OTS implants [14,15].

Overall Interpretation

Overall, customized TKA implants offer clear theoretical and technical advantages in terms of anatomical personalization and implant fit, which may translate into improved functional performance, joint perception or patient preference in selected cohorts [4,9–11].

However, the current body of clinical evidence remains heterogeneous, as some studies demonstrate comparable satisfaction or early clinical outcomes between customized and conventional implants [13–15]. Consequently, customized implants should currently be regarded as a promising personalized technology rather than a universally superior replacement for conventional TKA systems.

Discussion

The central question of this review is whether customized individually made total knee arthroplasty implants are truly superior to conventional off-the-shelf systems. Based on the available literature, the most balanced answer is that CIM implants demonstrate clear theoretical and technical advantages, but their universal clinical superiority over OTS implants has not yet been conclusively proven.

The strongest argument in favor of CIM implants concerns anatomical fit. Conventional OTS implants are manufactured in predefined sizes and shapes, which cannot fully reflect the wide variability of femoral and tibial morphology between patients [3–6]. CIM implants directly address this limitation by using preoperative imaging and digital planning to improve patient-specific implant fit and reproduce planned implant positioning [4,9].

Studies comparing CIM and OTS implants have reported better functional performance, higher Forgotten Joint Scores, greater patient preference and a more natural knee feeling in some cohorts [10–12]. However, Saeed et al. concluded that CIM implants do not currently demonstrate a clear clinical advantage over conventional OTS implants [14]. Müller et al.

similarly found no significant difference in early clinical outcomes between custom and OTS implants and reported higher early revision rates in the custom TKA group, although this finding should be interpreted cautiously [15].

Several explanations may account for this discrepancy. First, modern OTS implants already provide reliable long-term outcomes in many registry and follow-up studies, leaving limited room for measurable improvement in short-term comparative studies [1,2]. Second, standard PROMs may be insufficiently sensitive to detect subtle differences in joint awareness or natural joint feeling. Third, many CIM studies have relatively short follow-up periods, whereas differences in wear, loosening or revision risk may require many years to become visible. Fourth, study designs differ substantially with regard to implant type, alignment philosophy, patient selection and comparator groups.

Alignment strategy is another key issue. Conventional TKA has traditionally relied on mechanical alignment [7,8]. However, kinematic and restricted kinematic alignment approaches aim to reproduce native joint orientation more closely. Evidence regarding KA remains debated, with Jamali et al. concluding that current review-level evidence is insufficient to determine a definitive advantage over MA [20]. In contrast, Gao et al. reported that rKA may improve selected functional outcomes, particularly WOMAC and KSS, compared with MA [21]. This complicates interpretation of CIM studies, because improved outcomes may result not only from customized implant geometry but also from personalized alignment, patient selection or surgical planning.

Cost-effectiveness also remains unresolved. CIM implants require additional imaging, planning and manufacturing, which may increase upfront logistical complexity. However, economic analyses suggest that total episode-of-care costs may be comparable or lower in selected healthcare systems [16]. Culler et al. also reported that CIM implants were not necessarily associated with higher hospital costs compared with OTS implants [17]. These findings should be interpreted cautiously because they may depend on reimbursement model, healthcare system, institutional workflow and patient selection.

This review has several limitations. Because it was designed as a narrative review, the literature search and study selection were not performed according to a formal systematic review protocol. No formal risk-of-bias assessment or quantitative meta-analysis was conducted. In addition, the included studies were heterogeneous with regard to implant design, alignment

strategy, surgical workflow, follow-up duration, patient population and reported outcome measures. Therefore, the conclusions should be interpreted as a qualitative synthesis of selected contemporary evidence rather than as definitive evidence of superiority or equivalence.

Future research should focus on well-designed prospective comparative studies with longer follow-up, clear separation of implant design from alignment philosophy and standardized reporting of functional, radiological, economic and survivorship outcomes. Particular attention should be given to determining whether improved anatomical fit translates into clinically meaningful benefits, lower revision rates or better long-term patient satisfaction.

Conclusions

Customized individually made total knee arthroplasty implants represent a promising personalized approach that may improve anatomical conformity, implant fit and reproduction of planned component positioning compared with conventional off-the-shelf systems. These theoretical and technical advantages may translate into improved joint perception, patient preference or selected functional outcomes in some patient cohorts.

However, current evidence does not conclusively demonstrate universal clinical superiority of CIM implants over contemporary OTS implants. Systematic reviews and meta-analyses have reported heterogeneous findings, with no consistent advantage in standard PROMs, early clinical outcomes or survivorship. Conventional OTS implants remain supported by extensive clinical experience, registry-based survivorship data and reliable long-term outcomes.

At present, CIM implants should therefore be considered a valuable and evolving option within personalized knee arthroplasty rather than a definitive replacement for conventional implant systems. Further high-quality, long-term comparative studies are required to determine which patient groups may benefit most from customized implant design and whether these potential benefits justify the additional imaging, planning and manufacturing requirements.

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