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Original Research

Early Results of a Patient-Specific Total Knee Arthroplasty Implant Cast From a 3D-Printed Mold

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ABSTRACT

Background: The second generation of a custom total knee arthroplasty (TKA) implant cast from a 3D-printed mold was introduced into the market in 2012. The purpose of this retrospective study was to investigate short- to mid-term survivorship and complication rates of this novel implant.
Methods: This study is a retrospective analysis of 314 TKA procedures (264 patients) performed by a single surgeon using a customized TKA from September 2012 to November 2015. Patient demographics, rate of implant revision, rate of reoperation for any reason, and rate of postoperative complications were recorded.
Results: At the time of index surgery, the mean patient age was 64.7 years, and the mean follow-up duration was 3 years. At the final follow-up, implant survivorship free from revision was 98.1%, and survivorship free from reoperation for any reason was 92.4%.
Conclusions: Our analysis revealed favorable short- to mid-term survivorship for a customized TKA implant. While the short- to mid-term outcomes for this implant are promising, future studies are required to assess long-term outcomes and durability.

Introduction

Total knee arthroplasty (TKA) is a successful procedure that generally provides patients with pain relief and functional improvement [1,2]. Predictions suggest the number of primary TKA procedures performed annually could grow to 1 million procedures or more in the US alone by the year 2030 [3]. While TKA is largely successful, approximately 20% of patients may be dissatisfied after TKA, and overall complications are not insignificant [4,5]. Although optimal outcomes following TKA rely on many factors, implant design is one factor that may lead to differential results [6–8].

Novel implant designs have the potential to play a role in optimizing TKA outcomes [9–12]. Over time, implants with closer to "normal" anatomic features and kinematic properties have been designed in an attempt to more closely replicate natural knee function and to consequently improve postoperative patient satisfaction [13–17]. One recent novel implant design is a TKA implant cast from a patient-specific 3D-printed mold based on preoperative computed tomography (CT) scans. Preoperatively, a CT scan of the patient's knee is performed, and using a proprietary computer algorithm, a customized TKA implant is designed to match the prearthritic femoral and tibial contours (Conformis, iTotal, Billerica, MA) [1]. The design is then 3D-printed as a mold, and the final implant is cast utilizing the custom mold. Previous studies have demonstrated that custom TKA can provide improved radiographic outcomes with fewer outliers from coronal neutral leg alignment, better rotational alignment and tibial component fit, and more natural knee kinematics than conventional, off-the-shelf (OTS), TKA designs [18–22]. Long-term outcome data regarding this implant are not yet available, as clinical use has only recently reached a decade. The first-generation implant was cleared by the

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Food and Drug Administration (FDA) and launched into limited surgeon release in 2011. Based on surgeon feedback following this initial release, the second generation of this novel implant was produced (Conformis, iTotal G2, Billerica, MA) and has been commercially available since 2012. Changes present in the second-generation implant include an updated design to address a greater range of anatomies, a simplified surgical technique and patient-specific instrumentation (PSI), and additional surgical planning information.

While long-term follow-up is essential in order to assess the durability of any implant, short- to mid-term follow-up evaluations are necessary to monitor implant performance before long-term results are available. The purpose of this study was to determine survivorship and postoperative complication rates of the iTotal G2 implant design at short- to mid-term follow-up.

Material and methods

The study was approved by our institutional review board (IRB). We retrospectively reviewed all consecutive patients who underwent TKA by a single surgeon using a second-generation custom TKA cast from a 3D-printed mold (iTotal G2, ConforMIS Inc., Burlington, MA) between September 2012 and November 2015. Initially, this custom implant was limited (as a result of FDA approval) to deformities of no more than 10° of varus and no more than 15° of valgus. During the study period, these limitations were closely followed. Eligible patients were allowed to choose between the custom implant or an OTS implant. A total of 424 consecutive TKA procedures were identified. Among these procedures, minimum 2-year follow-up was available for 293 procedures (69%, 243 patients). In addition, 21 procedures (21 patients) with less than 2-year follow-up were included because a revision, reoperation, or complication occurred prior to 2-year follow-up. As a result, our final study cohort included 314 procedures (264 patients). Patient demographics, implant revision rate, rate of reoperation for any reason, and postoperative complication rate were recorded.

Complications were divided into surgical and nonsurgical complications. Surgical complications were complications that were treated with reoperation, including revision TKA. Revision TKA procedures included synovectomy with liner exchange and both tibial and femoral component revision (one and 2 stage). Reoperation procedures other than revision TKA included arthroscopic lysis of adhesions (LOA) with or without manipulation under anesthesia (MUA), open reduction internal fixation, and irrigation and debridement (I&D). Nonsurgical complications were assessed from patient charts and included wound-healing complications, deep vein thrombosis, arthrofibrosis, gout flare, venous ulcer, and nonfatal arrhythmia. These complications were noted for the entire duration of follow-up.

Surgical technique

A CT scan of the affected knee, according to proprietary protocol, is obtained at least 6 weeks prior to the operation. Using a proprietary computer algorithm, CT data are converted to a custom implant and disposable, PSI (high-grade plastic) that restore the neutral, mechanical axis. The PSI are created to tightly conform to anatomic landmarks, thereby improving precision of bony cuts. The implant kit includes all components needed to perform the operation (PSI, femoral and tibial components, and 3 medial and 3 lateral polyethylene components to adjust the balancing of the final construct).

All patients were positioned supine with the ability to flex the operative knee to 90°. A trivector approach was utilized, followed by appropriate medial and lateral soft-tissue releases to adequately expose the knee. The distal femoral resection was completed first. Femoral osteophytes were left in place, aiding appropriate placement of the patient-specific femoral jigs. Directed by jig placement, isolated remaining medial and lateral distal femoral cartilage was removed via coring, allowing subsequent jig placement securely to bone. Two pin holes were drilled into the distal femur for later placement of the anterior-posterior cutting block. The distal femur was then cut.

With the knee flexed to 90°, the proximal tibia was exposed, and isolated remaining cartilage removed with a curette, allowing jig placement securely to bone. Jig placement and alignment were verified with an alignment rod, and the proximal tibia cut was made with care to preserve the posterior cruciate ligament.

Femoral and tibial osteophytes were then removed, followed by an assessment of the extension and flexion gaps. Spacer blocks were placed within the extension and flexion spaces, respectively, and varus and valgus stresses were applied. Based on intraoperative assessment of the extension and flexion gaps, modifications to the distal femur and/or proximal tibia cut(s) were made utilizing the patient-specific jigs, or in the case of simultaneous loose extension and flexion gaps, thicker polyethylene inserts were utilized.

Anterior and posterior femoral resections, followed by chamfer resections, were then completed. A patient-specific jig was placed onto the distal femur over pins placed into previously drilled pin holes, with the ability to dial in 0° to 5° of external rotation. After ensuring anterior femoral notching would not occur, and that the profile of the patient-specific jig closely matched the profile of the posterior femoral condyles, bony cuts were made.

Tibial and femoral trials were then inserted and balancing verified. Final preparation of the proximal tibia was then completed with drill and keel punch after placing the trial tibia anatomically onto the proximal tibia. All patellae were then cut for resurfacing, and peg holes prepared. Bony beds were thoroughly irrigated, and final implants cemented in place. The wound was again irrigated and closed in a layered fashion. No posterior stabilized (PS) custom implants were used, and no custom implants were discarded during the study period. [2]

Statistical analysis

Microsoft Excel was used for data entry and management. All statistical analyses were performed in SPSS for Mac (Version 23.0, SPSS Inc, Chicago, IL). Kaplan-Meier survival curves were utilized in the TKA implant survivorship calculation using 2 separate endpoints (revision TKA and reoperation for any reason [with and without revisions excluded]) to calculate survivorship free from revision and reoperation rate, respectively. If a patient underwent at least one operation in addition to their index TKA and also underwent a revision, the reoperation was counted as a revision. Otherwise, all subsequent operations were counted as reoperations. Multiple patients underwent more than one additional operation ($n = 4$, 1.27%).

Results

At the time of surgery, the mean patient age was 64.7 years. The mean follow-up duration was 3.0 years (range 0-90 months). Survivorship free from implant revision was 98.1% at the final follow-up. Survivorship free from reoperation for any reason was 92.4%. The Kaplan-Meier survival curve is displayed in Figure 1.

Implant revisions included 1 synovectomy with liner exchange for a diagnosis of arthrofibrosis (6 months), 1 synovectomy with liner exchange for a diagnosis of recurrent hemarthrosis (58 months), 1 both-component revision for a diagnosis of arthrofibrosis (13 months), 1 both-component revision for a diagnosis of

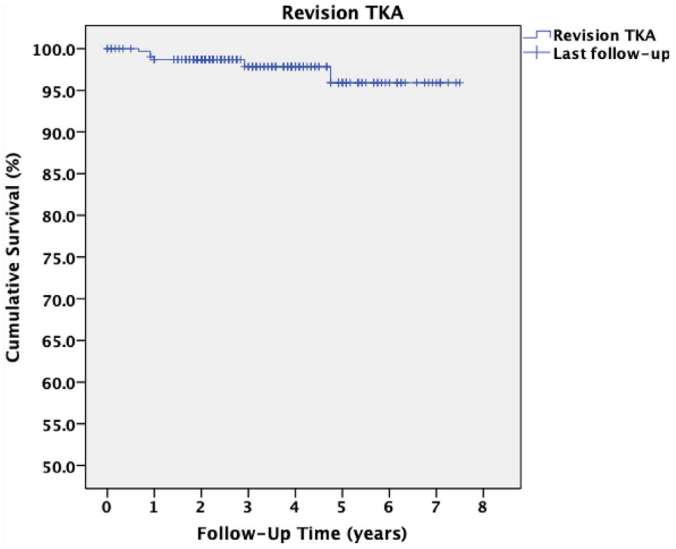

Figure 1. TKA survivorship curve—free from revision TKA.

instability (36 months), and 2 two-stage revisions for diagnoses of prosthetic joint infection (both at 11 months; n = 6, 1.9%). Reoperation for reasons other than revision included arthroscopic LOA with or without MUA for arthrofibrosis (n = 13, 4.1%), open reduction internal fixation, patellar tendon repair for patella fracture with patellar tendon disruption (n = 2, 0.64%), I&D for wound dehiscence (n = 1, 0.32%), I&D for an infected prepatellar bursa (n = 1, 0.32%), and I&D for hematoma evacuation (n = 1, 0.32%; Table 1).

Other nonsurgical complications included 15 wound-healing complications treated nonsurgically (local wound care with or without antibiotics; 4.78%), 3 deep vein thrombosis incidents within 90 days of surgery treated with anticoagulation (0.95%), 1 arthrofibrosis treated with MUA (0.32%), 1 gout flare treated with oral medication (0.32%), 1 slow-healing venous ulcer treated with local wound care (0.32%), and 1 nonfatal arrhythmia treated with permanent pacemaker (0.32%; Table 2).

Discussion

In our analysis of 314 customized TKAs performed by a single surgeon, survivorship free from revision at minimum 2-year follow-up was favorable at 98.1%. Survivorship from reoperation was also favorable over the same time period, at 92.4%. These short- to mid-term outcomes are promising and in accordance with survivorship data for both customized and OTS TKA in the literature. Schroeder et al. [23] performed a retrospective study of 540 customized TKAs (Conformis, iTotal G2), in which survivorship was found to be 98.5% at mean follow-up of 2.8 years. Mathijssen et al. [24] conducted a prospective study of 140 OTS PS and cruciate retaining (CR) TKA and found survivorship to be 99% at 2 years. Similarly, Gallego et al. [25] conducted a retrospective study of 91 OTS PS TKAs and found survivorship to be 96.7% at mean 5.9-year follow-up.

Table 1
Reoperations in the custom total knee arthroplasty (TKA) population.

Reoperations	Total (%)
Revision TKA	6 (1.9)
Arthroscopic LOA ± MUA	13 (4.14)
I&D for wound dehiscence	1 (0.31)
I&D for infected prepatellar bursa	1 (0.31)
I&D for hematoma evacuation	1 (0.31)
ORIF patella fracture with patellar tendon repair	2 (0.64)

I&D, irrigation and debridement; LOA, lysis of adhesions; MUA, manipulation under anesthesia; ORIF, open reduction and internal fixation.

Table 2
Nonsurgical complications in the custom total knee arthroplasty (TKA) population.

Nonsurgical complications	Total (%)
Wound healing	15 (4.78)
Arthrofibrosis	1 (0.32)
Venous ulcer	1 (0.32)
Deep vein thrombosis	3 (0.96)
Gout	1 (0.32)
Nonfatal arrhythmia	1 (0.32)

Long-term survivorship of modern-day, OTS TKA is excellent and typically falls in the 90% range. Meftah et al. [26] conducted a prospective study of 138 OTS rotating-platform, PS TKA and found survivorship to be 97.5% at 10 years. Similarly, Choi et al. [27] conducted a retrospective study of 113 OTS PS or CR hybrid TKA and reported survivorship to be 93.8% at 12 years.

Patient-specific customized TKA is a relatively novel concept, seeking to restore the anatomic joint surface and joint line, improve implant fit, and approach near-normal knee kinematics. In comparison to custom TKA, utilization of OTS implants can result in increased bony resection, improper implant fit, and altered kinematics. Kurtz et al. [28] studied bone preservation in 100 custom TKAs vs 37 PS and 32 CR TKAs by intraoperative measurement and using the computer-aided design (CAD) software. Analysis revealed significantly less bone resected in all measured zones in the custom TKA [28]. Schroeder and Martin [21] studied intraoperative implant fit and rotational alignment measured by CT in custom vs 3 different OTS implants in 44 knees. Analysis revealed significant implant overhang of ≥3 mm in 18% of the OTS implants, with no overhang in the custom implants. In addition, in reference to the tibial rotational axis, 45% of OTS implants were rotationally deviated >5°, and 4% > 10°, with no deviation observed in the custom implants [21]. Implant overhang can be clinically meaningful, as femoral implant overhang ≥3 mm has been associated with a near 2-fold increase in pain [29]. In addition, both cadaveric and human studies have shown improved kinematics in custom TKA vs OTS TKA, likely a result of the fit and alignment of the custom TKA anatomic approach [5,20,22].

Multiple benefits of custom TKA have been reported, including enhanced patient satisfaction, bone preservation, improved implant fit and knee kinematics, decreased operating room time and estimated blood loss, reduced inventory burden, and improved cost-effectiveness [2,30,31]. Notably, Namin et al. [32] created a simulation model to study the outcomes of widespread adoption of custom TKA from 2018 to 2026. Analysis revealed that a custom TKA adoption rate of 90% by 2026 would reduce readmissions by 62%, revisions by 39%, and cumulative healthcare costs by $38 billion [32]. Culler et al. [31], in their retrospective analysis of 248 consecutive TKA patients (128 custom TKA, 122 OTS TKA), found that custom TKA resulted in a risk-adjusted, per-patient total cost-savings of $913.87, which included the preoperative CT scan. Furthermore, the custom TKA group had a significantly lower rate of blood transfusion and of adverse events at the time of discharge and at 90 days after discharge, as well as a smaller percentage of discharges to rehabilitation facilities [31]. In addition, O'Connor and Blau [33], in their analysis of TKA episode expenditures among Medicare fee-for-service (FFS) beneficiaries, found average total episode spending to be significantly lower ($1695 difference) in the

custom TKA group than that in the OTS group. While there are many reported benefits of custom TKA, there are certainly potential negatives as well, including the need to obtain a CT or magnetic resonance imaging for implant production, as well as time required for production, the risk of discarding an implant, and reportedly high results of postoperative manipulation following custom TKA in some studies. In our cohort, arthrofibrosis was the most-common major complication found following TKA, requiring reoperation for LOA with or without MUA in 4.7% of procedures. Increased rate of MUA in custom TKA has been shown, and also refuted, in the literature [34,35]. White and Ranawat [34] prospectively evaluated MUA rates and clinical outcomes in 21 custom TKAs matched with 42 OTS PS and 11 OTS CR TKAs. Analysis revealed significantly limited range of motion in the custom TKA group in comparison to the OTS groups. In addition, MUA rate in the custom TKA group was 28.6% (6 of 21), while there were no manipulations performed in the OTS groups [34]. Kay et al. [35], in their prospective review of 360 custom TKAs, found their MUA rate to be 3.05% (11 of 360), consistent with MUA rates for all designs in the literature. Our reported MUA rate is certainly not as high, or as low as rates reported in the literature.

As the number of TKA procedures continues to increase annually in the setting of our current healthcare landscape focused on cost-reduction and value-based care delivery, custom TKA has an opportunity to offer cost-effective results with high survivorship. Our single surgeon study shows favorable short- to mid-term survivorship of the iTotal G2 (Conformis) customized, anatomic 3D-printed custom TKA. While short- to mid-term follow-up is imperative to monitor implant performance before long-term results are available, we stress that long-term follow-up is necessary to fully assess implant durability and value-based outcomes.

Limitations

Our study has several limitations. Our sample size was rather small (314 TKA procedures), which could negatively affect internal and external validity. In addition, we did not include a control group, making comparison to other implants possible only through the available literature. Selection bias may have also been present, as eligible patients during the study period were allowed to choose between the custom implant and an OTS implant. Our study also looked at procedures performed by a single surgeon, which could also negatively affect external validity. In addition, we present only short- to mid-term results, with the knowledge that longer follow-up is essential to properly evaluate implant durability and value-based outcomes. However, we are assessing a novel implant, and future analysis of this same large cohort will provide data in regard to long-term survivorship. We do acknowledge that our follow-up was less than optimal, and dissatisfied patients may have sought treatment elsewhere. Lastly, patient-reported outcome measures, which provide clinically important postoperative information, were not assessed, as they were not available in a large-enough percentage of the cohort to provide meaningful conclusions.

Conclusions

Our analysis of a novel custom TKA cast from a 3D-printed mold revealed excellent survivorship free from revision of 98.1% at average 3-year follow-up, which corroborates survivorship data in the literature for both customized TKA and OTS TKA. However, studies including long-term follow-up are required to further investigate the performance and durability of this implant.

Conflicts of interest

AFC received royalties from Stryker; is a paid consultant for Adaptive Phage Therapeutics, Avanos, BICMD, Convatec, Ethicon, GLG, Guidepoint, Heraeus, IrriMax, Pfizer, Stryker, and TrialSpark; has stock or stock options in Hyalex, Irrimax, Joint Purification Systems, Sonoran, and IlluminOss; receives financial or material support from SLACK Incorporated and UpToDate; is in the editorial/governing board of *Journal of Arthroplasty*, *Clinical Orthopaedics and Related Research*, *Journal of Bone and Joint Infection*, *Journal of Bone and Joint Surgery*, and *Arthroplasty Today*; and is a member of AAOS, AJRR, and AAHKS. JKL received royalties from OnPoint Knee; is a paid consultant for Aesculap and Conformis; receives financial or material support from SLACK Incorporated; and is a member of AAHKS. All other authors declared no conflicts to disclose.

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CRediT authorship contribution statement

Adam E. Roy: Writing – review & editing, Writing – original draft, Investigation, Formal analysis. **Alexandre Barbieri Mestriner:** Writing – review & editing, Formal analysis, Data curation. **Brielle Antonelli:** Writing – review & editing, Data curation. **Jakob Ackermann:** Writing – review & editing, Formal analysis. **Antonia F. Chen:** Writing – review & editing, Supervision, Formal analysis, Conceptualization. **Jeffrey K. Lange:** Writing – review & editing, Validation, Supervision, Methodology, Investigation, Formal analysis, Conceptualization.

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