

Research Article

Customized Individually-Made and Conventional Total Knee Implants are associated with Similar Improvements in Patient-Reported Outcomes

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Background

Customized individually-made (CIM) implants aim to reproduce knee kinematics by restoring patient-specific anatomy. There is sparse data comparing outcomes of CIM implants with conventional implants. The purpose of this study was to compare short-term outcomes of total knee arthroplasty (TKA) performed with CIM versus off-the-shelf (OTS) implants.

Methods

We retrospectively compared clinical outcomes of 123 CIM TKAs with 282 concurrent, matched OTS TKAs performed at a single academic medical center by two high-volume arthroplasty surgeons. All CIM TKA were included. Perioperative outcomes evaluated included hospital length-of-stay (LOS), discharge disposition, and patient-reported outcome measures (PROMs) at baseline, 3 months, and 1 year. Student's t-tests were used for continuous variables, and chi-squared tests were used for categorical variables.

Results

Baseline demographics were statistically similar between groups. CIM Baseline WOMAC Pain and Physical Function scores were statistically, but not clinically, better. There were no differences in LOS (CIM 2.19d vs. OTS 2.35d; $p=0.30$) or proportion discharged home (78.7% vs. 83.5%, $p=0.26$). There were no differences in WOMAC subscores or the KSS Functional Score at 3-month and 1-year follow-up. The CIM cohort had a statistically significant, but not clinically significant, higher KSS-Function score at 1-year (79.4 vs. 72.6, $p=0.02$), but the change from preoperative baseline was not significant between groups.

Conclusions

Compared to traditional TKA implants, CIM implants offered similar improvements and patient-reported outcome scores through the first postoperative year. Longer-term outcomes as well as cost-effectiveness of CIM implants should be studied.

INTRODUCTION

Primary total knee arthroplasty (TKA) is the standard of care for advanced degeneration of the knee joint that has failed appropriate nonoperative management. The National Institutes of Health estimates that greater than 4.7 million Americans are living with a knee implant after undergoing TKA (Kremers et al. 2015). Compared to international peers, the United States has the highest incidence rate of TKA procedures performed per capita which, under a conservative model, is projected to increase a further 143% by 2050 (Inacio et al. 2017). However, approximately 20% of TKA recipients are dissatisfied with either their improvement in knee function or relief of pain post-operatively (Gunaratne et al. 2017).

The high volume of TKAs performed in association with the notable rate of dissatisfaction has led to significant investment in new technologies to improve the procedure and its outcomes. Traditionally, implant manufacturers have tended towards maintaining a library of "off-the-shelf" (OTS) symmetrical implants at standard sizes that prioritize a functional approach toward balancing flexion

and extension gaps at the knee joint. Ideal placement of the OTS implant along with any necessary soft tissue releases results in a balanced flexion and extension gap (Daines and Dennis 2014). Custom individually made (CIM) implants are designed to provide an anatomic approach to knee arthroplasty and came to market in the United States in 2011. The implant is custom built for each patient based on a computed tomography (CT) scan completed prior to the surgery and provides customized cutting jigs, tibial and femoral implants, and polyethylene liners tailored to replicate the patient's asymmetric femoral condylar surfaces prior to degeneration. Theorized benefits of customization of these components include minimization of bone resection, restoration of the anatomic knee joint line, and minimization of flexion gap laxity leading to optimized mechanical reconstruction, knee strength, and joint kinematics (Daines and Dennis 2014).

Studies on the use of CIM implants in knee arthroplasty are beginning to emerge, but currently no consensus has been reached regarding the clinical benefits of these implants. Several studies have demonstrated improved alignment along the mechanical axis of the limb both intraop-



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eratively and in radiographs postoperatively when a CIM implant is used compared to an OTS implant (Ivie et al. 2014; Kang et al. 2017; Schroeder and Martin 2018). Furthermore, in a study using mobile fluoroscopy to evaluate kinematics, patients with CIM implants had greater weight-bearing flexion range of motion and greater axial rotation with maintenance of femoral internal rotation at full extension as would be observed in normal knee (Zeller et al. 2017). Surgical outcomes described thus far demonstrate significant reductions in estimated blood loss and hospital length of stay when using the CIM implant (Schwarzkopf et al. 2015; Culler, Martin, and Swearingen 2017). Significantly fewer blood transfusions and fewer adverse events overall have also been observed when using CIM implants (Schwarzkopf et al. 2015). Infection rates and incidence rates of thromboembolism were not significantly different between the implant types and fewer patients receiving CIM implants were discharged to a rehabilitation facility following hospitalization for their TKA (Culler, Martin, and Swearingen 2017). Patient-reported functional measures following TKA with customized implants has thus far been inconclusive. Multiple studies have shown little to no difference in outcomes of CIM vs. OTS (Kizaki et al. 2019; Kosse et al. 2017; Kotela and Kotela 2014).

Given the widespread interest in CIM implants, further research is necessary to reach a consensus on short term surgical and functional outcomes in comparison to standard OTS implants. The goal of this study is to utilize a matched patient comparison of patients receiving primary TKA with either a patient-specific CIM implant or a standard OTS implant in order to evaluate patient-reported outcomes.

METHODOLOGY

In this retrospective cohort study, an institutional database was used to identify 123 primary TKA utilizing one model of custom-individually made implant (ConforMIS Inc.; Billerica, MA) between October 2016 and March 2020, performed by one of two fellowship-trained arthroplasty surgeons at a single academic medical center. All consecutive CIM TKA were included during this period with no exclu-

Table 1. Study Implant Composition

	Number (%)
ConforMIS Cohort	123
Cruciate Retaining	86 (69.9%)
Posterior Stabilized	37 (30.1%)
OTS Cohort	282
Smith and Nephew Journey II CR	11 (3.9%)
Smith and Nephew Journey II PS	45 (15.9%)
Zimmer-Biomet Persona CR	160 (56.7%)
Zimmer-Biomet Persona PS	66 (23.4%)

sion criteria. 86 were cruciate retaining (CR) and 37 were posterior-stabilized (PS) TKA. A 2.3:1 matched cohort of 282 traditional OTS implants utilized in primary TKAs performed in the same time interval by the same two surgeons was created for statistical comparison (226 (160 CR, 66 PS) Persona, Zimmer-Biomet, Warsaw, IN; 56 (11 CR, 45 PS) Journey 2, Smith & Nephew, Andover, MA) (Table 1). The surgeons used the two implants interchangeably and based on preference rather than patient factors. Approval from an Institutional Review Board was obtained prior to any data collection or data analysis being performed (Protocol IRB-AAAS4179).

Demographic data including sex, body mass index (BMI), age, and American Society of Anesthesiologists (ASA) class scores were collected from patient charts. Length of stay (LOS) and discharge disposition was attained from patient discharge paperwork in the electronic health record. Patient-reported outcome measures (PROs), composed of WOMAC scores and KSS Functional Scores, were obtained from an institutional database. Collection of scores for this database is completed via online survey delivered by email or paper survey delivered by mail at the patient's preference. Surveys utilized in this study were distributed to patients pre-operatively and at 3-month and 1-year postoperative follow-up.

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STATISTICAL ANALYSIS

Categorical variables were analyzed using Fisher's Exact Tests and Pearson's Chi-Square tests as appropriate, while continuous variables were analyzed using Student's T-test. All statistical analysis was completed using Excel (V16.0; Microsoft Inc.; Redmond WA). In addition to the raw WOMAC and KSS Functional scores, the change from patient baseline was calculated at both 3 months and 1 year and is included in the results.

A PRIORI POWER ANALYSIS

An *a priori* power analysis was completed for the KSS functional score endpoint and the WOMAC sum score endpoint to estimate necessary sample sizes prior to data collection. For the KSS Functional score, to detect the minimal clinically important difference (MCID) of 10 with an alpha of 0.05 and 80% power, at least 65 patients would be required in each of the two cohorts (Lizaur-Utrilla et al. 2019). For the WOMAC sum score, to detect the MCID at 12 months follow-up of 22.1 on a 96 point scale with an alpha of 0.05 and 80% power, at least 30 patients would be required in each of the two cohorts (Greco et al. 2009).

RESULTS

Comparing 123 CIM TKA with a matched cohort of 282 primary OTS TKA, no significant differences were found in baseline demographics, including age, BMI, gender, or ASA score distribution (Table 2). There was no difference in LOS (2.19 vs. 2.35; $p=.30$) or proportion of patients discharged home (78.7% vs. 83.5%, $p=.26$) for custom implants compared to traditional implants. 4 (3.3%) CIM and 7 (2.5%) OTS implants required reoperation following index surgery ($p=.66$). In the CIM cohort, indications for reoperation included incision and drainage due to superficial infection (1), revision due to infection (1), and revision due to periprosthetic fracture around the tibial component (2). In the OTS cohort, indications for reoperation included revision due to instability (3) and revision due to infection (4). 5 (4.1%) CIM and 5 (1.8%) OTS implants required manipulation under anesthesia following index surgery ($p=.17$).

KNEE SOCIETY SCORES

KSS Functional Scores are reported on a 0-100 scale with higher numbers representing better functional status. Compared to their preoperative state, both cohorts of patients reported improvement in KSS Functional Scores (Table 5) at 3-months and 1-year follow-up. Pre-operative KSS Functional Scores were similar in both cohorts (56.2 vs. 53.8, $p=0.16$). KSS Functional Scores failed to achieve statistical significance for CIM implants at 3-months (70.1 vs. 65.9, $p=0.06$), but was statistically better at 1-year (79.4 vs. 72.6, $p=0.02$). However, the average change from base-

line in KSS Functional Scores was similar at all time-points (3-months: +13.9 vs. +12.1, $p=0.14$; and 1-year: +23.2 vs. +18.8, $p=0.10$) (Table 4).

WOMAC SCORES

WOMAC Sum scores are reported on a scale 0-96, WOMAC Pain 0-20, WOMAC Stiffness 0-8, and WOMAC Physical Function 0-68, with lower scores indicating better status or function. Compared to their preoperative state, both cohorts of patients reported improvement in all WOMAC subscores (Tables 3 and 4) at both 3-month and 1-year follow-up. Pre-operative WOMAC Pain and Physical Function scores were significantly lower in the CIM cohort (10.4 vs. 11.3, $p=.03$ and 34.0 vs. 37.4, $p=.02$ respectively). No statistical differences were found in the WOMAC subscores improvement from baseline (Table 4).

DISCUSSION

Our study supports prior findings that patients undergoing primary TKA achieve reliable improvements in patient-reported outcomes at both 3 months and 1 year, and that patients who receive a customized implant do just as well as patients who receive standard off-the-shelf implants in the hands of high-volume arthroplasty fellowship-trained surgeons.

This study is the first to our knowledge to evaluate patient-reported functional outcomes of the ConforMIS custom TKA implant, and the largest study to date comparing CIM implants to standard OTS implants. Patients in the custom cohort had significant improvement from their baseline scores in all WOMAC subscores and the KSS Functional Score at both 3-month and 1-year follow-up, as did the patients in the OTS cohort. Both cohorts demonstrated clinically meaningful improvement in patient-reported pain, stiffness, and functional measures as recorded by the WOMAC and KSS Functional scales. When evaluated as a change from baseline, the custom and OTS cohorts achieved similar improvements, with no between-cohort comparisons achieving statistical significance. The only statistically significant difference was between the raw values of the KSS-Function scores at 1-year post-operatively, with the CIM cohort having a higher score (79.4 vs. 72.6, $p=.02$). However, this advantage does not meet the MCID of 10 points (Lizaur-Utrilla et al. 2019) and did not represent a significantly greater improvement from baseline from the traditional implant cohort.

Use of custom implants in TKA is a topic of interest given the hypothesized benefits these implants may provide toward anatomic reconstruction of the knee joint. However, prior data is inconclusive on patient-reported outcomes when using these implants, with one previously published study reporting significantly lower KSS scores in a custom implant cohort, though that study has an admittedly low sample size (21 patients) (White and Ranawat

Table 2. Demographic comparison

	Custom Implant Cohort	Traditional Implant Cohort	p - value
n =	123	282	
Age (yrs)	66.5 ± 7.2	67.2 ± 9.0	0.23
BMI	29.7 ± 6.0	29.2 ± 5.3	0.23
Female, n (%)	71 (57.7)	178 (63.1)	0.31
ASA Score			0.25
I	3 (2.4)	4 (1.4)	
II	102 (82.9)	215 (76.2)	
III	18 (14.6)	59 (20.9)	
IV	0 (0.0)	0 (0.0)	

ASA, American Society of Anesthesiologists; BMI, body mass index.

* Denotes significance at $p < 0.05$

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Table 3. Patient Length of Stay and Discharge Disposition

	Custom Implant Cohort	Traditional Implant Cohort	p - value
Length of Stay (days)	2.19	2.35	0.30
Percent Discharged Home	78.7%	83.5%	0.26

* Denotes significance at $p < 0.05$.

2016). To our knowledge, this is the largest study to date specifically looking at patient-reported outcomes following CIM TKA at 1-year follow-up.

Although we did not study costs, the expenses associated with CIM are relevant to this present discussion. CIM implants require additional resources including the pre-operative imaging and associated radiation, manufacturing disposable instruments, and non-scalable implant manufacturing. Using a budget impact model derived from the Medicare Standard Analytical Files database, O'Connor et al. determined that 12-month postoperative spending in TKA patients was significantly lower in those receiving the ConforMIS implant compared to an OTS implant, even with consideration of the higher preoperative planning and manufacturing costs. Their analysis determined that customized implants offered a \$1695 savings attributed to lower average index procedure costs and lower postoperative spending for inpatient services and skilled-nursing facility costs. Demographic and comorbid variables were similar between the two cohorts thus indicating that even if

quality is equivalent to OTS implants, CIM implants may offer a significant cost savings warranting further adoption (O'Connor and Blau 2019).

As with any study, limitations regarding this dataset exist. Although this is the largest study reporting on CIM functional outcomes, the overall sample size presented here remains low and would benefit from a larger, multi-center, randomized clinical trial. Second, the preoperative WOMAC Pain and Physical Function subscores were statistically better (but not clinically significant) in the custom implant cohort, suggesting some degree of selection bias for CIM TKA. This may be explained by the authors' possible selection bias for slightly higher-functioning patients to receive this implant system and should be considered when referencing these results. Conversely, the general trend of better pre-operative scores in the CIM cohort can limit the room for improvement in comparison to the OTS cohort.

Table 4. WOMAC Scores

			Custom Implant Cohort	Traditional Implant Cohort	p - value
WOMAC Sum	Raw Scores	Pre-op	49.1 ± 17.9	53.1 ± 18.5	0.06
		3-month	25.9 ± 18.8	27.4 ± 18.0	0.54
		1-Year	17.1 ± 15.9	19.6 ± 21.5	0.40
	Change from Preoperative Baseline	3-month	-22.8 ± 20.5	-25.0 ± 21.6	0.40
		1-Year	-33.5 ± 23.4	-34.0 ± 21.8	0.89
	WOMAC Pain	Raw Scores	Pre-op	10.4 ± 4.1	11.3 ± 4.3
3-month			4.2 ± 3.9	5.0 ± 3.8	0.07
1-Year			2.8 ± 3.6	3.1 ± 3.8	0.30
Change from Preoperative Baseline		3-month	-6.2 ± 4.9	-6.3 ± 4.9	0.45
		1-Year	-7.6 ± 5.7	-8.2 ± 4.4	0.22
WOMAC Stiffness		Raw Scores	Pre-op	4.6 ± 1.9	4.4 ± 1.9
	3-month		3.4 ± 1.6	3.1 ± 1.7	0.10
	1-Year		2.4 ± 1.5	2.5 ± 2.0	0.39
	Change from Preoperative Baseline	3-month	-1.2 ± 2.7	-1.3 ± 2.5	0.24
		1-Year	-2.2 ± 2.8	-1.9 ± 2.6	0.09
	WOMAC Physical Function	Raw Scores	Pre-op	34.0 ± 13.4	37.4 ± 13.9
3-month			18.3 ± 14.4	19.3 ± 13.5	0.29
1-Year			12.1 ± 12.1	14.0 ± 16.4	0.19
Change from Preoperative Baseline		3-month	-15.7 ± 15.2	-18.1 ± 16.0	0.16
		1-Year	-21.9 ± 17.2	-23.4 ± 17.0	0.42

* Denotes significance at p < 0.05.

Table 5. KSS Scores and KSS Score Change from Pre-op Baseline

			Custom Implant Cohort	Traditional Implant Cohort	p-value
KSS Score	Raw Scores	Pre-op	56.2 ± 19.7	53.8 ± 21.2	0.16
		3-month	70.1 ± 20.3	65.9 ± 21.2	0.06
		1-Year	79.4 ± 20.6	72.6 ± 22.1	0.02*
	Change from Preoperative Baseline	3-month	+13.9 ± 20.7	+12.1 ± 20.6	0.14
		1-Year	+23.2 ± 19.6	+18.8 ± 23.8	0.10

* Denotes significance at p < 0.05.

CONCLUSIONS

In summary, our results demonstrate custom individually made implants provide similar improvements to traditional implants in patient-reported pain, stiffness, and functional measures at 3-month and 1-year post-operative follow-up. This is the largest study to date to address this question and the first to evaluate the ConforMIS implant. It corroborates the currently available literature in demonstrating similar improvement in PROs in patients undergoing CIM

TKA vs. OTS in experienced surgeon's hands. Further study is necessary to determine patient satisfaction and cost-effectiveness of CIM designs given the similar functional performance to traditional OTS implants.

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