A Comparison of Clinical Outcomes and Implant Preference of Patients with Bilateral TKA

One Knee with a Patient-Specific and One Knee with an Off-the-Shelf Implant

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Abstract

Background: The purpose of this retrospective study was to compare clinical outcome results, perceived function, and overall preference among patients who had undergone staged bilateral total knee arthroplasty (TKA) with a cruciate-retaining, customized implant (customized TKA, or C-TKA) in 1 knee and an off-the-shelf (OTS) implant in the contralateral knee.

Methods: Forty-seven patients (94 knees) from a single study center who underwent C-TKA in 1 knee and had previously undergone TKA with an OTS implant in the contralateral knee were included in this study. As the primary outcome measures, the Knee injury and Osteoarthritis Outcome Score, Joint Replacement (KOOS, JR) and the Forgotten Joint Score (FJS) were self-administered by the study subjects at a single follow-up time point. Additionally, a follow-up questionnaire to compare patients' perceived joint stability, knee mobility, perceived feeling of the replaced joint, pain levels, and overall preference between their knees was administered.

Results: The average follow-up was 2.3 years (range, 0.7 to 3.8 years) for C-TKA and 6.7 years (range, 1.6 to 11.1 years) for the OTS TKA. Significantly higher KOOS, JR (82 versus 77; $p = 0.03$) and FJS (68 versus 58; $p = 0.04$) results were found with C-TKA. The evaluation of the follow-up questionnaire showed that more patients reported having "a little" or "a lot" less pain (49% versus 15%), better perceived mobility (45% versus 12%) and stability (36% versus 13%), and a more "normal" feeling of their knee (60% versus 10%) with the C-TKA implant compared with their OTS counterpart. When patients were asked to directly compare their knees, we found that 72.3% of the patients preferred the knee that received C-TKA over the contralateral OTS knee replacement, with 21.3% seeing no difference and 6.4% preferring the OTS knee replacement.

Conclusions: We believe that this is the first study to examine patient-reported outcomes of customized and OTS TKA implant designs in the same patient. We conclude that patients in this study cohort who underwent staged bilateral TKA with a C-TKA implant in 1 knee and an OTS prosthesis in the other knee reported better for their patient-specific knee replacement, with higher FJS and KOOS, JR values, and overall, preferred the C-TKA knee more often compared with the OTS knee replacement.

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJSREV/A802).

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

Over the past decades, total knee arthroplasty (TKA) has proven to be a successful and safe treatment of end-stage osteoarthritis, with high long-term rates of implant survivorship[1-6]. Since low revision rates and pain relief are now almost assured after modern TKA procedures, these older benchmarks of success have been replaced by high patient satisfaction and functional improvement as the primary goals for successful patient treatment.

In a previous study, Smith et al. investigated patient expectations before surgery in a representative population of Scottish patients and concluded that patients have very high, and sometimes unrealistic, expectations regarding their improvements after TKA[7]. Although cultural differences may exist, other studies have shown that 14% to 39% of patients report some level of dissatisfaction with their replaced knee due to lower-than-anticipated functional improvement, persistent postoperative knee pain, or an abnormal sensation with the replaced knee[8-11]. Technological advances have facilitated the development of robotic-assisted TKA, patient-specific instrumentation (PSI), and customized TKA (C-TKA) prostheses that aim to improve the surgical technique and address the discrepancy between high preoperative patient expectations and low postoperative patient-perceived outcomes. Although some studies have shown that the use of robotic-assisted TKA and PSI may improve the accuracy and consistency of implant alignment, the impact on patient-reported outcomes is a matter of controversy: Anderl et al. investigated early clinical outcome, radiographic limb alignment, and 3-dimensional (3D) component positioning among 108 patients with conventional instrumentation and 114 patients with PSI in primary mobile-bearing TKA[12]. The authors concluded that, although the use of PSI showed better accuracy in the restoration of mechanical alignment and 3D implant positioning, comparable clinical outcomes as assessed by the Knee Society Score (KSS), a visual analog scale (VAS) for pain, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, and the Oxford Knee Score were observed. Additionally, in a meta-analysis of 38 studies, Kizaki et al. concluded that the use of PSI does not improve patient-reported outcome measures compared with standard TKA[13]. Regarding robotic-assisted TKA, a recent meta-analysis by Zhang et al. of 16 studies examining clinical and patient-reported outcomes with robotic-assisted TKA showed that robotic-assisted TKA demonstrated improved accuracy of component positioning and patient-reported outcomes at short-term-follow-up. However, the results may lack clinical relevance, as studies on robotic-assisted TKA are few in number and mainly involve short-term-follow-up, and the acquisition of a robot is costly, which may hinder widespread use of this technology[14]. In general, a limitation of PSI in TKA and robotic-assisted TKA may be that, despite more accurate and consistent bone resection, both methods use standardized, off-the-shelf (OTS) implants. These implant designs are available in sizes and shapes that may not always adequately address patients' individual bone anatomy and, therefore, compromise natural joint geometry and kinematics[15,16]. Tailored to address patients' unique bone anatomy, C-TKA implants have been introduced to overcome limitations associated with contemporary knee replacement designs[17-19]. However, there is ongoing discussion on whether an anatomical design approach is better than the use of OTS TKA and thus leads to higher patient satisfaction and better patient-perceived clinical outcome. Reimann et al. compared patient-reported outcomes between those receiving C-TKA and TKA with OTS implants[17]. They found significantly higher values for the KSS and its function score and higher global patient satisfaction for patients with the C-TKA. However, demographic differences were noted between study cohorts, impeding conclusions drawn from direct comparison.

In general, studies comparing different population cohorts are subject to the risk of selection bias. Therefore, the primary purpose of this study was to compare patient-reported outcomes and patient perceptions of joint replacement at a single time point for patients who underwent staged bilateral TKA and received a customized, individually designed implant in 1 knee and an OTS implant in the contralateral knee.

We hypothesized that the patient-specific implant design of C-TKA would result in a more natural-feeling knee than with OTS TKA, which in turn would be reflected in improved patient-reported outcomes and patient preference for the customized implant design over the OTS implant.

Materials and Methods

Using medical records, we identified 51 patients who received a cruciate-retaining C-TKA implant (iTotal CR; Conformis, Inc.) in 1 knee between November 2014 and December 2017, and who previously had an OTS design implanted in the contralateral knee. Of the 51 patients, 3 could not be contacted and 1 had died. The remaining 47 patients (94 knees) provided informed consent for participation and were included in this study. All of the C-TKA procedures were performed by the same senior surgeon (D.D.) using the same surgical method; the postoperative rehabilitation protocol was the same for all of these knees. In the contralateral knee, an OTS TKA prosthesis had been previously implanted, with 64% of the OTS prostheses being implanted by the same surgeon who performed the C-TKA procedures.

Ethical approval was obtained from the institutional review board. In a single study visit, patients' knees were examined by a single assessor (D.D.), who was blinded to the type of implant in each knee. Data from this most recent follow-up visit are reported in this manuscript and compared. Range of motion for each knee was measured using a combination of goniometer recordings and visual inspection. Objective knee indicators, such as knee alignment measured on an anteroposterior standing radiograph and instability of the knee in the anteroposterior (at 90° of flexion) and mediolateral (in full extension) directions, were assessed as part of the follow-up. To evaluate patient-reported outcomes, the Knee injury and Osteoarthritis Outcome Score, Joint Replacement (KOOS, JR), the Forgotten Joint Score (FJS), and a follow-up questionnaire were self-administered by the participants for each knee. The KOOS, JR is a validated, 7-question patient-reported outcome measure (PROM) to assess pain, symptoms, and functional limitations. It has been shown to be an adequate and reliable clinical tool to examine the condition of the knee joint in patients undergoing TKA[18]. The FJS can be utilized to measure the patient's ability to forget the artificial joint in everyday life. With this questionnaire, the patient's ability to carry out daily activities are addressed to evaluate their satisfaction after TKA[19]. The additional questionnaire that was administered as part of the patient follow-up included questions to determine implant status, knee pain, patient preference between the 2 knees, and patient sensation with the knee replacement. Knee pain was assessed using a VAS from 0 to 9. To assess patient preference between the knee replacements, study participants were asked to compare both knees for perceived pain and their perception of mobility, sense of stability, and "normal" feeling, and to provide their general preference between the knees. On all questions, the study subjects had the options of the following answers: "right knee a lot," "right knee a little," "about the same," "left knee a little," or "left knee a lot."

Medical history and patient demographic information as well as information on the surgical procedure and hospital stay were evaluated utilizing hospital records.

Statistical Analysis

We used a 2-tailed Fisher exact test and Student t test to determine significant differences. A p value of <0.05 was considered significant.

Source of Funding

Conformis, Inc., the manufacturer of the C-TKA implants used in this study, provided research support to cover the cost of patient follow-up and institutional review board fees.

Results

The average body mass index (BMI) was 33.7 kg/m^2 (range, 17.7 to 46.1 kg/m^2) at the time of surgery with C-TKA and 31.7 kg/m^2 (range, 22.1 to 44.8 kg/m^2) at the time of surgery with an OTS device ($p > 0.05$). Patient demographics and objective clinical parameters did not differ significantly when comparing C-TKA and OTS TKA (Table I).

The average time from surgery to the single follow-up study visit was significantly less for knees with the customized device (2.3 years; range, 0.7 to 3.8 years) than with the OTS implant (6.7 years; range, 1.6 to 11.1 years) ($p < 0.001$). The time between OTS TKA and C-TKA was, on average, 4.7 years (range, 0.3 to 8.4 years), and in all patients, the OTS knee replacement surgery was performed prior to the C-TKA procedure. In the C-TKA group, a flexion contracture of 1° to 5° was observed in 5 patients, and a flexion contracture of >5° to 10° was seen in 1 patient. In the OTS group, a flexion contracture of 1° to 5° was observed in 2 patients, while 1 patient had a flexion contracture of >10° to 15°.

The 2 knee groups did not differ in terms of the average postoperative length of stay: 2.5 days (range, 1 to 5 days) for C-TKA and 2.4 days (range, 0 to 5 days) for the knees with the OTS device ($p > 0.05$) (Table I). At the time of the single follow-up visit, the average range of motion was 118.1° (range, 90° to 140°) and 117.4° (range, 90° to 135°) for C-TKA and OTS, respectively. Outcome scores were found to be significantly higher for the C-TKA group with respect to both the FJS and KOOS, JR. With C-TKA, the average KOOS, JR score was 82.5 (range, 47.5 to 100; standard deviation [SD], 14.3) compared with 76.6 (range, 31.3 to 100; SD, 18) for OTS replacement ($p = 0.029$). The average total FJS was 67.9 (range, 2 to 100; SD, 26.4) for C-TKA and 58.3 (range, 0 to 100; SD, 29.2) for the contralateral knees with the OTS device at the time of the study visit ($p = 0.04$) (Fig. 1). When evaluating joint awareness during individual activities as assessed by the FJS, patients reported significantly less joint awareness following C-TKA when "walking

TABLE I Patient Demographics and Clinical Parameters at the Time of Receiving C-TKA and OTS Devices

	C-TKA			OTS		
	Average	Range	SD	Average	Range	SD
Time postop. *(yr)*	2.3	0.7-3.8	0.2	6.7	1.6-11.1	2.4
BMI *(kg/m^2)*	33.7	17.7-46.1	7.6	31.7	22.1-44.8	5.7
Length of stay *(day)*	2.5	1-5	0.9	2.4	0-5	0.9
Range of motion *(deg)*	118.1	90-140	10.0	117.4	90-135	10.1

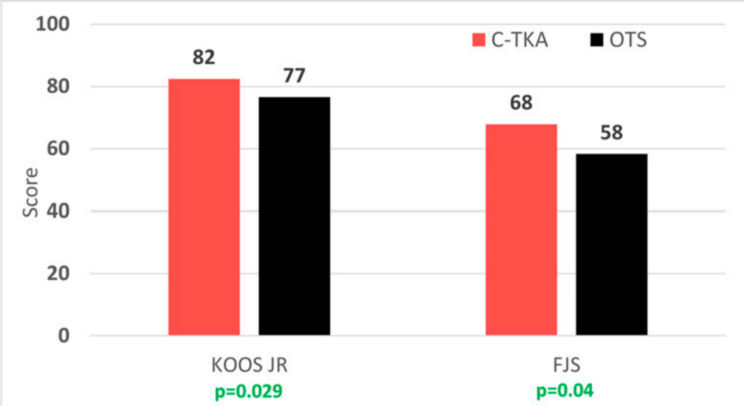

Fig. 1
KOOS, JR and Forgotten Joint Score (FJS) results. Significant differences between total knee arthroplasty (TKA) with an off-the-shelf (OTS) device and a customized implant (C-TKA) were observed for both scores evaluated.

for >15 minutes," "taking a bath/shower," "walking on uneven ground," and "doing housework/gardening" (Table II). The analysis of the VAS pain scores revealed low overall knee pain levels, averaging 1.1 for C-TKA and 1.9 for OTS, with no significant difference found ($p > 0.05$) (Fig. 2).

When assessing patients' perceived difference in pain between their knees, 49% of the patients reported "a lot" or "a little" less pain with the customized prosthesis, 15% of the patients reported "a lot" or "a little" less pain with the OTS implant, and 36% answered feeling no difference in pain between the knees. In terms of knee motion, 45% of the study cohort reported a difference in their perception of knee mobility between the knees in favor of C-TKA, 12% of the patients reported better knee mobility with OTS TKA, and 43% showed no preference. When the study participants were asked about their perception regarding stability of one knee compared with the other, 51% expressed no preference, 36% had "a lot" or "a little" more stable feeling with C-TKA, and 13% had "a lot" or "a little" more stable feeling with OTS TKA (Fig. 3). When comparing their knees with respect to a "normal feeling," 32% of the patients in this study reported having a feeling that was "a lot" more "normal" with C-TKA than with the OTS prosthesis, 28% preferred their custom-fit implant "a little" over the OTS design, 10% answered that their knee with the OTS replacement felt "a lot" or "a little" more "normal" than with C-TKA, and 30% of the patients were neutral (Fig. 4).

Overall, 72.3% of the study population preferred their C-TKA over the OTS implant, 6.4% liked their OTS replacement better, and 21.3% answered that they liked both knees equally (Fig. 5).

Discussion

New technological advances in the past decades have fueled the race for the

TABLE II Forgotten Joint Score Results

Are You Aware of Your Artificial Joint When…?	Average Score with C-TKA	Average Score with OTS TKA	P Value
1. In bed at night	0.83	1.17	0.09
2. Sitting in a chair >1 hr	0.96	1.4	0.05
3. Walking for >15 min	1.3	1.81	0.03*
4. Taking a bath/shower	0.64	1.09	0.04*
5. Traveling in a car	1.32	1.59	0.16
6. Climbing stairs	1.57	1.98	0.09
7. Walking on uneven ground	1.38	1.89	0.04*
8. Standing from low sitting position	1.53	1.83	0.16
9. Standing for a long period of time	1.61	1.89	0.16
10. Doing housework/gardening	1.47	2.02	0.03*
11. Taking a walk/hike	1.5	1.89	0.11
12. Doing your favorite sport	1.21	1.51	0.16
Total score†	67.88	58.31	0.04*

*Significant difference between the average score for OTS TKA and C-TKA. †Low scores in the individual categories reflect a low awareness of the artificial joint during the surveyed activity. As for the total score (range 0 to 100), high values indicate low joint awareness, i.e., a high degree of "forgetting" about the joint in everyday life.

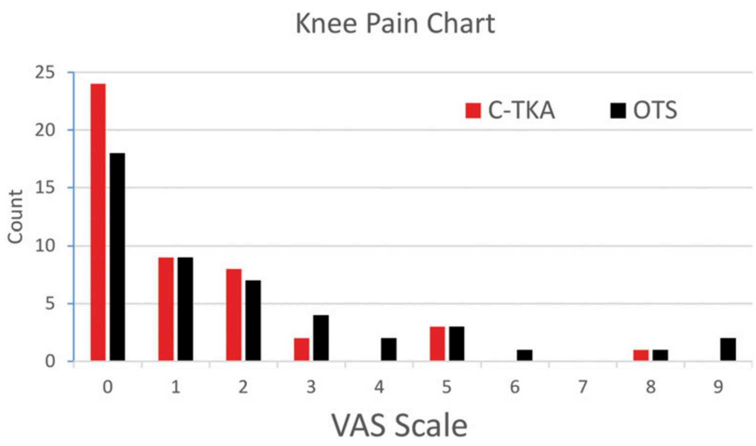

Fig. 2
Perceived knee pain for both implant designs was assessed using a visual analog scale (VAS).

"happiest patient" following TKA, challenging orthopaedic surgeons to stay up-to-date with their surgical procedures. Customized implants take advantage of preoperative computed tomography (CT) to closely replicate individual bone geometry in the implant design process. How this innovative technology translates to postoperative patient outcomes compared with standard OTS prosthesis designs is the subject of ongoing discussion. To our knowledge, this is the first study to compare patient-reported outcomes, perceived functionality, and overall preference between C-TKA and OTS TKA in the same patients.

The analysis of the KOOS, JR score (C-TKA: 82.5; OTS: 76.6) and FJS (C-TKA: 67.9; OTS: 58.3) collected for both implant types showed good results in both groups. However, when compared with their OTS implant, patients reported favorably on their customized counterpart, with a significantly higher outcome for both measures.

The ability to forget one's artificial knee joint in everyday activities can be considered the ultimate goal in TKA to ensure maximum patient satisfaction[19]. Previous studies have used the FJS as an outcome measure to compare different OTS TKA designs. Behrend et al. reported an average FJS of 50.0 among 86 patients who had undergone TKA[19]. Other authors have reported average FJS values of 70.0 and 77.1 in TKA populations[20,21]. Our results in the current study showed that the average FJS for knees implanted with an OTS prosthesis (58.3) was similar to that reported by Behrend et al. (50.0). In comparison, when patients in the current study were asked about their C-TKA knee (67.9), the average FJS was more similar to the

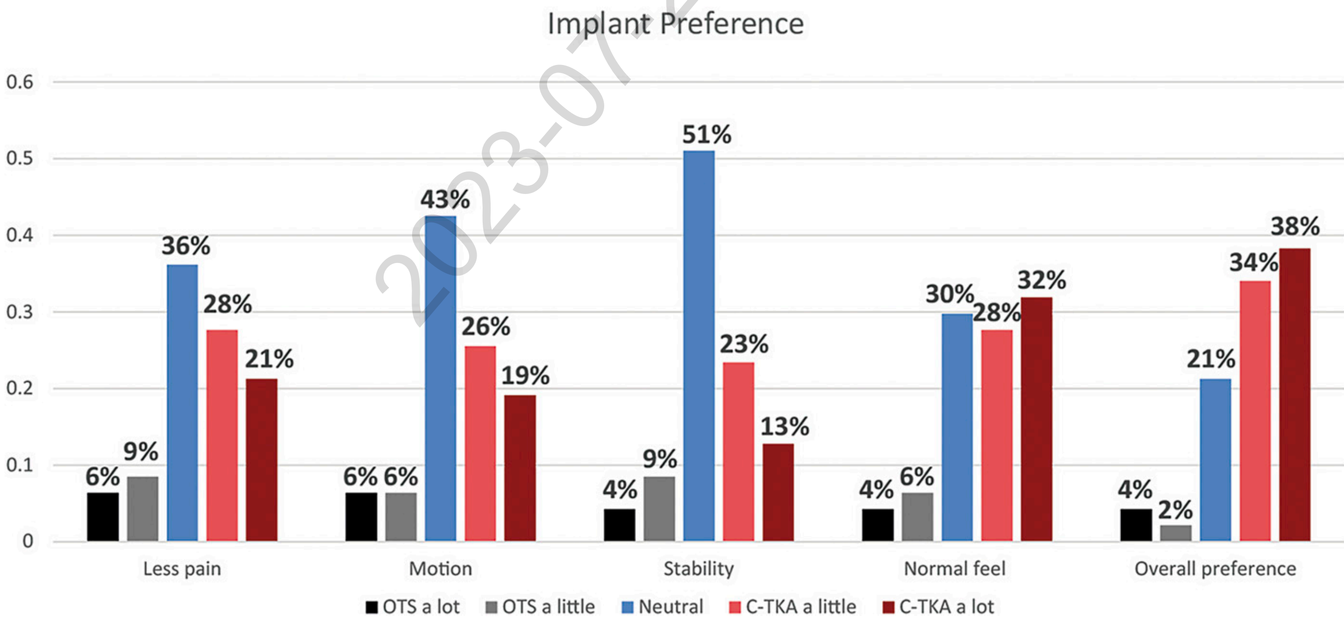

Fig. 3
Implant preference as assessed in different categories.

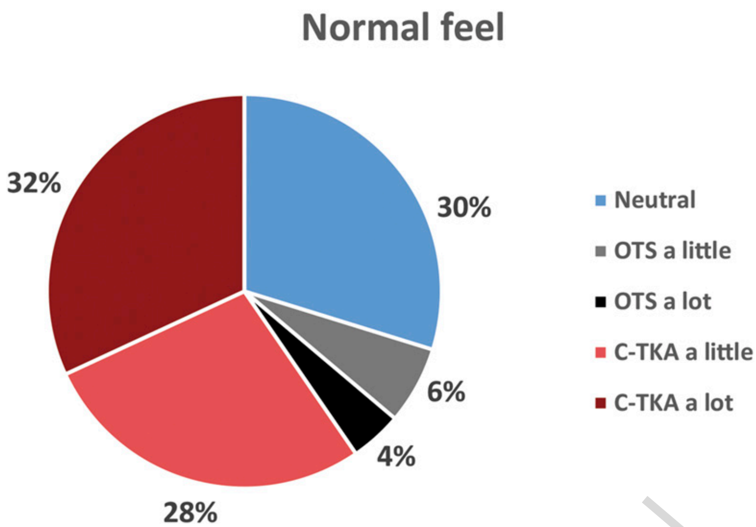

Fig. 4
Perceived feeling with OTS TKA and C-TKA.

result observed by Thienpont et al. (70.0)[20]. A possible explanation for the observed differences in these studies could be cultural and sociodemographic differences between the study populations as well as the differences in surgical technique or implant designs used in the study centers. Therefore, the comparison of FJS values for 2 artificial knee joints in the same patient may limit the bias of results caused by external factors and allow for better comparison of the reasons for superior scoring resulting from internal factors such as perceived sensation, functionality, and pain level.

In a study by Samy et al., the authors utilized the FJS to compare a medial-pivot type of TKA with a posterior-stabilized TKA[22]. The authors found a significant difference between the groups when patients were asked about their awareness of the joint when "standing from a low sitting position." This reflects on mid-flexion stability due to high load on the knee joint during such activities, as the authors concluded. Similar to their findings, FJS results in our study for questions about activities where mid-flexion stability is required were found to be better for the C-TKA compared with the OTS design. Moreover, the customized implant had significantly better scores for surveyed items that require a deep knee bend or cause increasing joint load (e.g., housework/gardening, walking >15 minutes, walking on uneven ground) (Table II). Zeller et al. analyzed tibiofemoral kinematics during weight-bearing deep knee bends and rising from a chair using mobile fluoroscopy for the same customized design investigated our study. They concluded that the C-TKA demonstrated kinematics more similar to normal knee kinematics than the compared OTS device[23]. The ability to regain closer-to-normal joint kinematics with the customized replacement by restoring distinctive anatomical features of the bone geometry may be crucial for patients' ability to perform complex movements without joint awareness.

Additionally, we observed an association between reporting a normal-

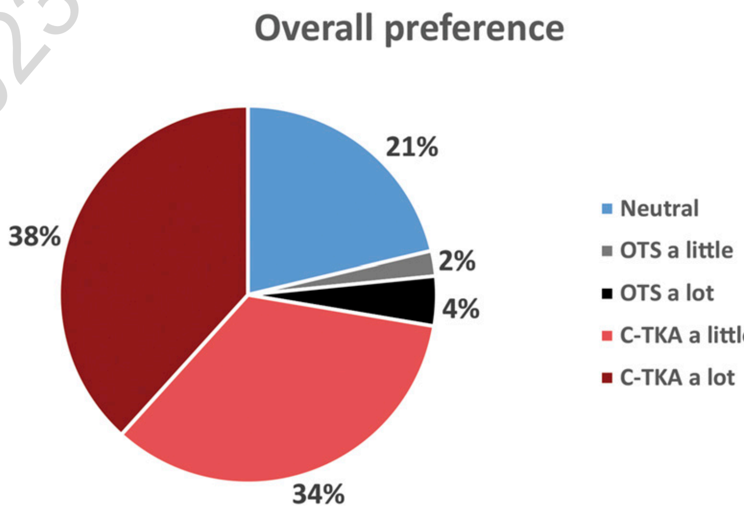

Fig. 5
Overall preference with OTS TKA and C-TKA.

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feeling knee with either replacement and patients' preference for that side; 73% (24) of the 33 patients who answered the question "does your knee feel normal to you" with the response "a little" or "a lot" gave the same answer when asked for their knee preference (e.g., a patient who answered "a lot" for the aforementioned question regarding the left knee also preferred the left knee "a lot"). Furthermore, knee pain severity was also found to be associated with implant preference. Pain VAS values of >3 were identified in 10 patients (13 knees). All of these patients preferred the knee in which they experienced less pain. We found that 49% of the study population noted "a little" or "a lot" less pain with C-TKA compared with 15% who described "a little" or "a lot" less pain with OTS TKA. Previous studies have described prevailing post-surgical knee pain as a major reason for patient dissatisfaction after total joint replacement, which is supported by the findings of this study[8,24,25]. Kim et al. aimed to identify causes and predictors of patients' dissatisfaction after TKA by evaluating patient satisfaction in 438 TKAs[8]. The authors concluded that residual pain after TKA was a leading factor of patient dissatisfaction. Similar findings were published by Halawi et al., who examined patient dissatisfaction in 276 TKAs and found postoperative persistent pain to be among the most common reasons for patient dissatisfaction, along with functional limitations, surgical complications, and reoperations[26].

Nicoll and Rowley found malrotation of the tibial component to be a major cause of functional deficit and pain after TKA[27]. Similarly, Mahoney and Kinsey described overhang of the femoral component to be a causative factor for pain after TKA[28]. Recent studies have compared implant fit and rotational alignment for several commonly used implant designs[29-31]. They concluded that surgeons are unable to achieve optimal results aiming for both (rotation and fit) because of the standardized shape of the implant components. Consequently, optimal implant fit would lead to malrotation of the component and optimal component rotation, to implant overhang if the component was not downsized. A study by Schroeder and Martin with the same C-TKA that was used in the present study showed significant improvement in achieving both features simultaneously[32].

Participants in the present study overall favored the C-TKA over the standard prostheses in all surveyed categories: pain, motion, stability, "normal" feel, and overall preference. On the basis of these findings, the combination of more precise implant fit and component rotation of C-TKA compared with OTS TKA may have been a contributing factor for lower pain levels and functional superiority, thus contributing to patients' preference for customized over OTS TKA.

Additionally, authors of previous research have stated that the use of C-TKA and PSI has the potential to provide more accurate implant alignment and better approximate normal knee kinematics than the use of standard OTS implants[23,33,34]. Improved implant fit without compromising rotational alignment and an implant design that reflects the patient's individual bone geometry and thus more closely approximates natural knee kinematics may have contributed to better results with C-TKA in the above categories.

Noble et al. concluded in their study that impairment of function reported by TKA patients cannot simply be attributed to effects of age or unrealistic expectations, but is also due to the shortcomings of current TKA procedures and biomechanical deficiencies of present implant designs[11]. On the basis of our results of high FJS values for C-TKA and the overall functional superiority perceived by patients compared with OTS TKA, we believe that the C-TKA investigated is able to overcome some of these limitations of current standard prothesis designs.

We are aware that this study has limitations that need to be addressed. First, we did not collect information on age at the time of surgery as part of the study design. However, on average, patients received their OTS TKA 4.7 years prior to C-TKA, indicating that patients were about 5 years younger at the time of the OTS implant placement. Second, the average post-surgical follow-up time of 6.7 years for OTS replacement was significantly longer than that for C-TKA (average, 2.3 years). The difference in patient age between the 2 procedures might have resulted in differences in comorbidities or bone quality between the 2 surgical dates, presenting confounding factors influencing postoperative patient outcome after TKA. As health conditions usually worsen with age, and all C-TKA procedures were performed as the later surgery, this would have had more distinct effects at the time of C-TKA. Additionally, previous studies that have reported on the influence of age on patient-reported outcomes concluded that the overall outcome is comparable across ages, with a trend for greater improvement in younger patients[35-37]. With respect to our study, one would assume better PROMs with the OTS implant, as patients were younger at the time of OTS surgery. However, this was not confirmed by the results, which showed significantly better FSJ and KOOS, JR results for the C-TKA knee. Although the assessor was blinded during the single follow-up examination, we could not blind the patient, as they were aware of which knee was replaced with a C-TKA and therefore may have reported favorably on this side. Thirty-six percent of the OTS TKA prostheses had been implanted in different centers in the U.S., and we had little information on the surgical and postoperative protocol as well as on the implants used. However, we believe that most of the OTS implants were posterior-stabilized (PS) TKAs, as most surgeons in the area around the study site are "PS surgeons" who perform TKA following mechanical alignment goals. Consequently, one might expect increased range of motion, a more predictable balancing of the knee, and thus better patient-perceived knee stability with the PS replacement compared with the customized cruciate-retaining TKA, as reported in literature[38-40]. However, the results of this study showed that, in comparison, patients reported favorably on the C-TKA when asked about perceived knee stability and showed similar range of motion with both TKAs. We found worse survey results for the OTS knees when the patients had undergone TKA in a different clinic. This might be because patients who were particularly unsatisfied with their first knee replacement changed their surgeon before undergoing TKA on the contralateral side. However, when comparing implant designs, patients, on average, reported favorably for C-TKA irrespective of the location for the first TKA. Although all patients from the study center who met the inclusion criteria for participation were asked to participate, and the positive response rate was high (92%), the sample size of the study population is relatively small. Lastly, because of the retrospective study design, no preoperative baseline scores, preoperative diagnoses, or complications during and after surgery for either knee were assessed in this study, and patients were surveyed at a single time point, which aggravates the interpretation of postsurgical results. The indication for surgery of either knee in the study center was degenerative joint disease and was multifactorial, based on the patient's history, diagnostic imaging, symptoms the patient was experiencing, and associated reduction in quality of life. By using patients as a self-control, we believe that severity of functional impairment and knee symptoms would have been very similar for both knees when the decision to undergo TKA was made. Additionally, it is important to note that patients enrolled in this study had to have well-functioning implants in both knees, as the purpose of the study was to compare outcomes with different types of implants in the same patient.

Comparative studies to determine differences in patient-reported outcomes between 2 patient cohorts with different TKA implant designs typically have limitations because of differences in confounding factors between study groups. In addition, randomized controlled trials comparing custom and OTS implants are difficult to conduct because patients are unlikely to give their informed consent to implant randomization for open-label products. To our knowledge, this is the first study that has investigated the influence of C-TKA on patient-reported outcomes, perceived functionality, and overall implant preference when compared with OTS TKA, where the patient serves as a self-control.

In conclusion, patients in this study with bilateral knee joint replacement showed an overall preference for C-TKA, with higher postoperative outcome scores at a single follow-up time point for customized compared with contralateral OTS implants. However, additional studies with larger patient cohorts are needed to validate the results of present study.

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