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Patient Satisfaction, Functional Outcomes, and Implant Survivorship in Patients Undergoing Customized Cruciate-Retaining TKA

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Abstract

Background: Customized total knee arthroplasty (C-TKA) systems are becoming increasingly popular in patients with end-stage knee arthritis. Manufactured with use of patient data derived from computed tomography or magnetic resonance imaging, these systems aim to restore the individual bone anatomy of the patient by providing customized fit and geometries. This retrospective study investigated implant survivorship, patient satisfaction, and functional outcomes following C-TKA with a cruciate-retaining prosthesis.

Methods: We retrospectively reviewed data from 540 knees in 433 patients who underwent C-TKA performed by a single surgeon at a single institution. Patient demographics, surgical variables, complications, and reoperations were evaluated. Follow-up evaluations were performed via a single telephone call to assess patient satisfaction, functional outcomes according to the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS-JR) questionnaire, and implant survivorship following C-TKA. Descriptive statistics were analyzed.

Results: At the time of C-TKA, the mean age was 71.8 years and the mean body mass index was 29.1 kg/m^2. The mean follow-up was 2.8 years. Patient satisfaction was high, with 89% of C-TKA patients being either satisfied or very satisfied. The mean KOOS-JR was 82. There were 8 revisions (1.5%) at an average of 0.7 years after the index C-TKA; hence, there was an implant survivorship of 98.5%.

Conclusions: To our knowledge, this was the largest retrospective study to date to report on patient satisfaction, functional outcomes, and implant survivorship following C-TKA. We observed a high satisfaction rate, satisfactory functional outcomes, and high implant survivorship at midterm follow-up.

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

Total knee arthroplasty (TKA) has been proven to be a successful procedure, with >600,000 procedures performed each year in the U.S. alone—a number that is projected to further increase[1,2]. However, studies have reported a 15% to 20% rate of patient dissatisfaction following TKA[3-6]. Since Themistocles Gluck implanted the first primitive hinge joints made of ivory in

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the 1880s[7], multiple generations of TKA technology have been observed, and technological advances have continually driven innovation.

With the introduction of patient-specific bone-cutting jigs and implants, a new approach for further improvement of the surgical procedure has become available. Data on the unique bone anatomy of the patient, as derived from either computed tomography (CT) or magnetic resonance imaging (MRI) of the knee, is utilized during the design process for these custom implants. Previous studies have shown that, compared with off-the-shelf implant designs, these customized TKA (C-TKA) prostheses offer patients a closer approximation of their normal knee kinematics and a superior fit of implant components with less over- or underhang, while also maintaining rotational alignment[8-11]. However, it remains to be proven whether these technical improvements will lead to higher overall patient satisfaction.

The goal of the present study was to retrospectively analyze surgical variables, complications, and reoperations from medical records and to determine implant survivorship, patient satisfaction, and functional outcomes at mid-term follow-up for patients who underwent C-TKA with a second-generation cruciate-retaining prosthesis.

Materials and Methods

After obtaining institutional review board approval, we identified all patients who had undergone C-TKA with the iTotal G2 (Conformis), which is a second-generation cruciate-retaining prosthesis, performed by a single surgeon. All procedures were performed between July 1, 2011, and January 31, 2018. There were no notable changes to the protocol for the TKA procedure during this time period. All cases utilized a minimally invasive medial parapatellar surgical approach and a multimodal postsurgical pain management regimen. Implant orientation in the coronal plane was performed following the mechanical alignment approach for all patients. The design process for C-TKA includes adaptation of the implant to the anatomy of the patient with use of CT scans of the knee. Differences in tibiofemoral bone geometry that influence the orientation of the joint line and sex-related differences in size and shape of the joint are incorporated into the C-TKA design according to the preoperative CT scans. Therefore, there were no differences in the predisposition for the use of the C-TKA design between male and female recipients.

Because patellar resurfacing was part of the standard TKA procedure of the study surgeon and thus was performed in all cases included in the study, outcomes and implant survivorship should be interpreted accordingly. However, resurfacing the patella is not required for C-TKA and should be done at the discretion of the surgeon.

Two separate analyses were performed, 1 for implant survivorship and 1 for follow-up data. The rate of implant survivorship was calculated using the total number of patients enrolled, excluding those who had died. Follow-up analysis included the mean follow-up duration, functional outcomes, and satisfaction rates; patients who had died, had undergone revision, could not be contacted, or did not consent to participation were excluded from this analysis (Fig. 1).

Patient demographics, surgical variables, complications, and reoperations were assessed with use of electronic medical records. Patients were contacted via telephone for a single postoperative follow-up evaluation in order to assess patient satisfaction, functional outcomes, and implant survivorship. Component revision for any reason was utilized as the implant survival end point. Patients who could not be reached by telephone were contacted via email and asked to complete an attached follow-up questionnaire. If contact could not be established after 3 attempts, the patient was classified as non-contactable. Implant survivorship analysis was performed with use of 2 methods. First, a chart abstraction was conducted for all patients enrolled in order to identify whether a revision procedure had been recorded in the electronic medical record. If evidence of revision was found, presence of a revision was confirmed with the patient during the telephone follow-up. In non-contactable patients, medical chart data were utilized as the only source to determine whether a revision occurred.

To assess patient satisfaction, patients responded to the question "Are you satisfied with your knee replacement?" with 1 of 5 choices: very satisfied, satisfied, neutral, dissatisfied, or very dissatisfied. Additionally, patients were asked if the knee replacement felt "natural," with answer choices including always, sometimes, and never. To evaluate patient-reported functional outcomes, a validated, 7-item short form of the Knee injury and Osteoarthritis Outcome Score (KOOS), specifically for joint replacement (KOOS-JR), was also administered. This questionnaire assesses symptoms, pain, and functional limitations[12]. The interval score for the KOOS-JR ranges from 0 to 100, with 0 representing total knee disability and 100 representing perfect knee health.

Fisher exact tests and Student t tests were performed to determine nonrandom associations between the analyzed variables.

Source of Funding

Conformis, Inc. provided research support to cover the cost of patient follow-up and institutional review board fees.

Results

A total of 540 knees in 433 patients were included, with a mean age (± standard deviation) of 71.8 ± 9.2 years and body mass index of 29.1 ± 4.4 kg/m^2 at the time of the C-TKA (Table I). There were 269 female patients (62.1%). Six patients (7 knees; 1.4%) had died and were therefore excluded from both the implant survivorship and follow-up analysis. Two of the deceased patients died shortly after undergoing C-TKA. One patient had a cardiopulmonary arrest, presumably caused by a

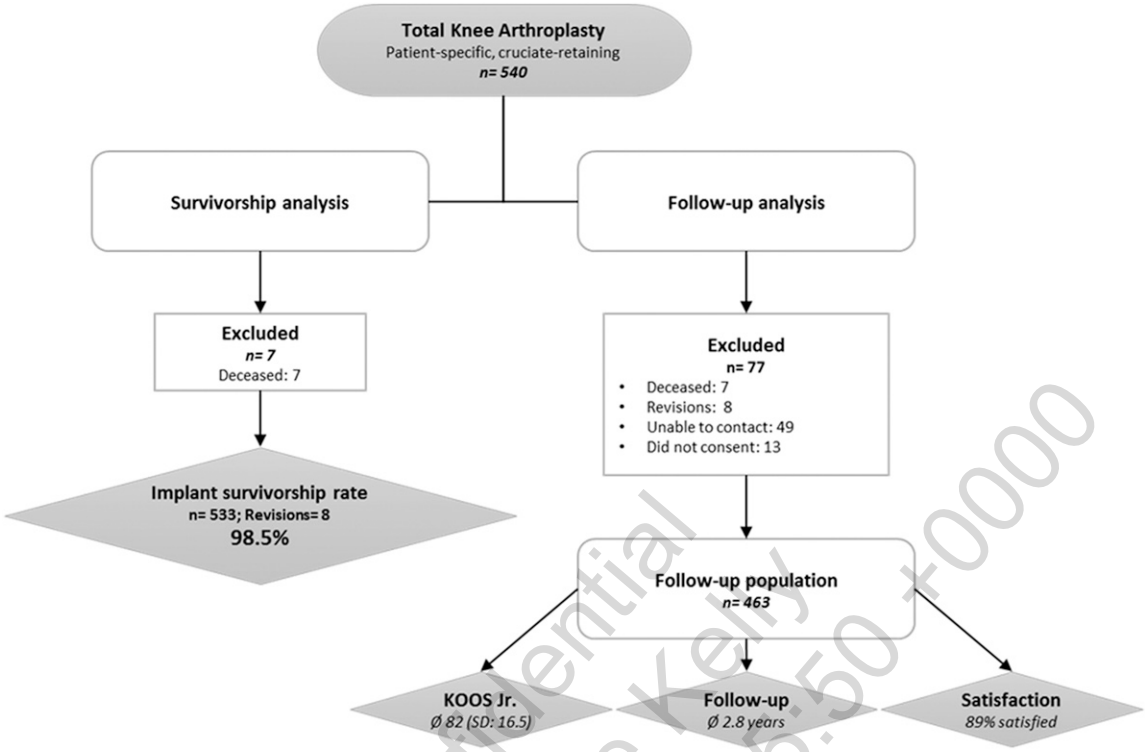

Fig. 1

Flowchart showing patient inclusions and exclusions as well as the results of the survivorship and follow-up analyses. φ = mean, and SD = standard deviation.

pulmonary embolus, and died during the postoperative hospital stay. The second patient was readmitted to the hospital for acute altered mental status following a fall at 2 weeks postoperatively and died during that hospitalization for unknown acute reasons. Death notice for the remaining 4 patients was received during the telephone calls, with no further investigation conducted. Eight patients (8 knees; 1.5%) underwent revision TKA at a mean of 0.7 years (range, 0.2 to 1.7 years) postoperatively, thus leading to an implant survivorship of 98.5% at the time of the latest follow-up (Fig. 1). Reasons for revision were infection (4 knees), arthrofibrosis (1 knee), "stiffness" as reported over the telephone (1 knee), nickel allergy (1 knee), and unknown (1 knee).

Of the patients enrolled, 372 (463 knees; 85.7%) were able to be contacted, consented for participation, and were therefore included in the follow-up analysis. The average follow-up, as defined as the time between preoperative hospital admission and the follow-up phone interview, was 2.8 years (range, 0.1 to 7.0 years). Thirty-seven knees (6.9%) had a follow-up of ≥5 years. Nine knees (1.7%) underwent manipulation under anesthesia for arthrofibrosis, of which 2 had arthrofibrosis persisting to the end of the study period, with no revisions performed for this indication. There were 12 complications related to the C-TKA procedure, of which 2 were unresolved at the time of postoperative hospital discharge; these included 1 patient with postoperative lumbar pain who was referred for pain management and spinal assessment and 1 patient with a postoperative foot drop secondary to peroneal nerve neurapraxia. There was also 1 adverse event possibly related to the customized device, with the patient experiencing postoperative hematoma and wound blistering. This patient underwent revision TKA following further signs of a nickel allergy.

TABLE I Patient Data

Implant survival analysis*	427 (533)
Follow-up analysis*	372 (463)
Follow-up† *(yr)*	2.8 (0.1-7.0)
Female sex‡	269 (62.1%)
Age§ *(yr)*	71.8 ± 9.2
Body mass index§ *(kg/m²)*	29.1 ± 4.4

*Values are given as the number of patients with the number of knees in parentheses. †Values are given as the mean with the range in parentheses. ‡Values are given as the number of patients with the percentage of the total patients in parentheses. §Values are given as the mean ± the standard deviation.

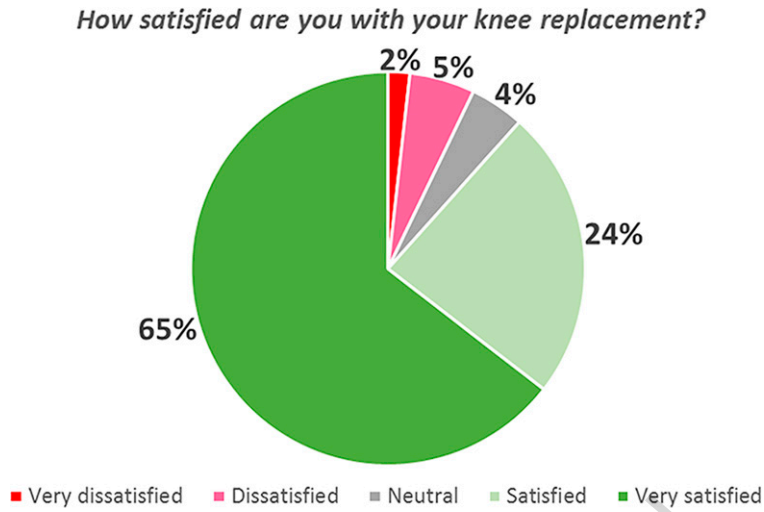

Fig. 2
Chart showing the distribution of patient responses to the question "How satisfied are you with your knee replacement?"

During the follow-up telephone evaluation, 65% of patients reporting being "very satisfied;" 24%, "satisfied;" 4%, "neutral;" 5%, "dissatisfied;" and 2%, "very dissatisfied" (Fig. 2). When asked if the knee felt "natural," 55% of patients reported that their knee "always" felt natural; 38%, "sometimes; " and 7%, "never" (Fig. 3). The average KOOS-JR score was 82 ± 16.5.

Discussion

To our knowledge, this is the largest retrospective cohort analysis to investigate patient satisfaction, functional outcomes, and implant survivorship in patients undergoing cruciate-retaining C-TKA. Previous research has analyzed various features of the customized implant design utilized in this study.

Arbab et al. reported that C-TKA achieved a closer restoration of the mechanical axis than conventional TKA[13]. Other studies have further investigated the ability to restore mechanical alignment in the coronal plane with use of the patient-specific instrumentation utilized in C-TKA. Previous studies have supported the findings of Arbab et al., showing a high accuracy and consistency and fewer outliers with use of patient-specific bone-cutting guides compared with standard, intramedullary instrumentation[14,15]. No data were collected in the present study regarding length of hospital stay because no comparative cohort was included; however, a previous study involving the same operative surgeon showed a shorter length of stay among patients undergoing C-TKA (mean, 2.97 days) compared with TKA utilizing an off-the-shelf prosthesis (mean, 3.20 days)[16]. Patients who underwent C-TKA in that study were also more likely to be discharged to home (rather than to an inpatient rehabilitation facility) compared with those who underwent TKA utilizing an off-the-shelf-prosthesis. Because of the lower cost of post-discharge postoperative care, C-TKA

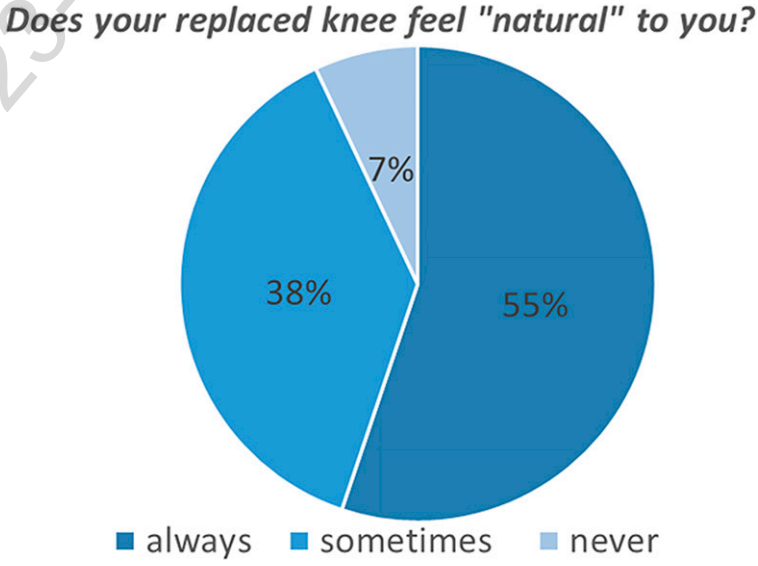

Fig. 3
Chart showing the distribution of patient responses to the question "Does your replaced knee feel 'natural' to you?"

patients in that study also had a lower episode-of-care cost compared with those who underwent TKA utilizing an off-the-shelf prosthesis. In another previous study, we compared C-TKA prostheses with 3 different off-the-shelf prostheses and found that by incorporating the individual anatomical features of the patient during the design process, the C-TKA prostheses provided better component fit and rotational alignment[9]. Zeller et al. utilized in vivo mobile fluoroscopy to analyze the short-term postoperative kinematics of 38 patients, of whom 24 underwent cruciate-retaining C-TKA and 14 underwent TKA utilizing an off-the-shelf prosthesis[10]. The authors concluded that the customized prosthesis showed movement patterns more consistent with normal knee kinematics compared with the off-the-shelf prosthesis. In 2 additional studies, Meier et al. suggested that the highly variable osseous anatomy of the knee represented a major challenge to surgeons attempting to maintain rotational alignment while achieving optimal component fit[8,17]. The authors suggested that a greater degree of implant customization could result in fewer soft-tissue releases and medial resections.

Whether the use of C-TKA translates to improved patient-reported outcomes and satisfaction rates was an incentive for the undertaking of the present study and must be further analyzed. Of the 533 knees included in the implant survivorship analysis, a total of 8 implant revisions (1.5%) had been performed at a mean follow-up of 2.8 years, for an implant survivorship of 98.5%. Kay et al. assessed the outcomes of 360 patients undergoing C-TKA and reported 3 total system revisions (99.2% survivorship)[18]. These rates of survivorship are comparable to those reported in the literature for various off-the-shelf prostheses, which range from 98% to 100% over similar follow-up durations[19-22]. Not all previous studies have reported positive outcomes following C-TKA. White and Ranawat reported a strikingly high rate of postoperative manipulation under anesthesia (6 of 21 patients; 28.6%) following C-TKA with use of the first-generation iteration of the prosthesis utilized in the present study[23]. Manipulation under anesthesia was performed if the patient had ≤90° of flexion or ≥10° of flexion contracture. One case of manipulation under anesthesia was reported to be unsuccessful, and the patient was scheduled for revision. These findings were not replicated in the present study, in which 9 knees (1.7%) underwent manipulation under anesthesia for arthrofibrosis. The rate observed in the present study is similar to those reported by Kay et al. (3.05%) and Kurtz et al. (3.8%) following C-TKA[18,24]. The study by White and Ranawat may have had a higher rate of manipulation under anesthesia as a result of utilizing a first-generation, rather than second-generation, C-TKA prosthesis, or because of a potential selection bias caused by the relatively small study cohort.

As part of the follow-up telephone evaluation in the present study, patients were asked if their replaced knee felt "natural" to them. The ultimate goal of TKA should be to provide the patient with a "natural"-feeling knee and the ability to "forget" that the biological knee has been replaced. Noble et al. concluded that one of the strongest determinants for patient dissatisfaction was the perception of an abnormal-feeling knee[3], with 46% of dissatisfied patients reporting that their knee did not feel normal compared with only 20% of satisfied patients ($p < 0.0001$). Similarly in the present study, 40.6% of patients who reported being dissatisfied or very dissatisfied also reported that their knee felt abnormal all of the time, compared with only 2.2% of patients who reported being satisfied or very satisfied; this difference was significant ($p < 0.0001$). We concluded that patients who underwent a C-TKA procedure that resulted in an abnormal-feeling knee were more likely to be dissatisfied than patients who experienced a natural feeling some or all of the time.

In a recent systematic review that included 95,560 patients from 208 studies, Kahlenberg et al. reported a median rate of patient satisfaction of 88.9% at midterm follow-up[25]. The overall satisfaction rate in the present study was similarly high, with 89% of patients being either "satisfied" or "very satisfied" and only 7% of patients reporting that they never experience a natural-feeling operative knee. We believe that the use of patient joint characteristics in the design of the C-TKA prosthesis is a salient feature of this procedure that allows for greater restoration of normal knee kinematics, as described by Zeller et al.[10]. In addition, we believe that these prostheses influence patient perception of the operative knee and create a more natural feeling during movement, contributing to the high satisfaction rates observed in the present study.

The use of the KOOS-JR as the primary patient-reported outcome measure was mandated by the Comprehensive Care for Joint Replacement program instituted by the Centers for Medicare & Medicaid Services and the American Joint Replacement Registry. Due to the short length of the questionnaire, the KOOS-JR can easily be completed via a telephone interview and is therefore a useful tool to assess patient-reported outcomes in large cohorts. Unsurprisingly, the KOOS-JR scores of patients who reported being either "dissatisfied" or "very dissatisfied" with the C-TKA were significantly lower than those of patients who reported being "satisfied" or "very satisfied" (56.9 compared with 85.5, respectively; $p < 0.0001$). The mean KOOS-JR for the entire study population was 82 ± 16.5, which can be classified as satisfactory midterm results following TKA.

This study had limitations, and the results must be interpreted accordingly. First and foremost, a control arm utilizing off-the-shelf prostheses was not included for comparison. Confounding variables such as patient selection,

patient-surgeon relationship, and surgeon skill level may not be able to be accounted for when comparing satisfaction rates in the present study to those reported for off-the-shelf prostheses in previous studies. Future studies should focus on making these comparisons. Because of the retrospective study design, no baseline values were collected for patient-reported outcomes, which may weaken the interpretation of the postoperative results. However, because the most common indication for TKA is patient-perceived reduction in quality of life, we believe that baseline preoperative scores would have been consistently low for all patients. We acknowledge that patient satisfaction is clearly subjective, multifactorial, and influenced by other factors, such as patient preoperative expectations, socioeconomic status, and mental-health status. Furthermore, patients were contacted and consented for participation retrospectively, which could have biased the results toward more positive answers if the likelihood of participation was dependent on the level of satisfaction. Telephone reporting of satisfaction could possibly have distorted results if responses were influenced by the social pressure of a telephone conversation compared with a written questionnaire; however, our aim was to assess patient-reported outcome measures in a large cohort, and the use of telephone interviews allowed for the inclusion of more subjects and an increased response rate.

Conclusions

We retrospectively assessed patient satisfaction, patient-reported outcomes, and implant survivorship in a large cohort undergoing cruciate-retaining C-TKA. The response rate was high, with 85.7% of patients completing the postoperative telephone evaluation. A total of 8 knees (1.5%) underwent revision, leading to an implant survivorship of 98.5% at a mean follow-up of 2.8 years. The use of C-TKA showed promising midterm results, with an overall satisfaction rate of 89%, an average KOOS-JR score of 82, and a high proportion of patients reporting a natural-feeling knee. Further studies are needed to verify our results in a multicenter setting.

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