Clinical and Patient-reported Outcomes of Primary TKA With a Single-radius Design

STEVEN F. HARWIN, MD; KIMONA ISSA, MD; KRISTIN GIVEN, MS; KIRBY D. HITT, MD; KENNETH A. GREENE, MD; ROBERT PIVEC, MD; MARK KESTER, PHD; MICHAEL A. MONT, MD

Abstract

Full article available online at Healio.com/Orthopedics. Search: 20130624-17

Total knee arthroplasty (TKA) is a cost-effective procedure used to treat degenerative knee disease with excellent long-term outcomes. However, TKA has not always resulted in excellent functional and patient satisfaction outcomes, partly due to the use of prostheses that did not reproduce natural knee kinematics. Due to a paucity of reports on single-radius designs, the authors evaluated the clinical and patient-reported outcomes of primary TKA in patients who had received a single-radius prosthesis.

A total of 287 TKAs from 7 centers were prospectively evaluated. Mean follow-up was 5 years, with each patient undergoing year re-evaluation. Kaplan-Meier implant survivorship was 99.7% at a final follow-up of 7 years. The total reoperation rate was 1.4%. Clinical outcomes demonstrated significant improvements in Knee Society, Short Form 36, and activity scores at a mean follow-up of 5 years. The authors believe that various features of this prosthesis may have contributed to these excellent outcomes. Further longer-term studies are necessary to better evaluate these outcomes.

The authors are from the Adult Reconstruction and Total Joint Replacement Service (SFH), Beth Israel Medical Center, New York, New York; the Rubin Institute for Advanced Orthopedics (KI, RP, MAM), Center for Joint Preservation and Replacement, Sinai Hospital of Baltimore, Baltimore, Maryland; Stryker Orthopedics, Inc (KG, MK), Mahwah, New Jersey; Scott and White Memorial Hospital (KDH), Temple, Texas; and the Cleveland Clinic Main Campus (KAG), Cleveland, Ohio.

Dr Harwin receives royalties from, is on speakers bureau for, and has stock or stock options at Stryker and receives royalties from SLACK Incorporated. Ms Given is a paid employee at Stryker and has stock or stock options at Stryker. Dr Hitt receives royalties from, is on speakers bureau for, is a paid consultant for, and receives research support and other financial or material support from Stryker. Dr Greene receives royalties from, is on speakers bureau for, and is a paid consultant for Stryker. Dr Mont receives royalties from Stryker; is a consultant for Janssen, Sage Products, Inc, Salient Surgical, Stryker, OCSI, and TissueGenie; receives institutional support from Stryker; and is on the Speakers Bureau for Sage Products, Inc. Drs Issa, Pivec, and Kester have no relevant financial relationships to disclose.

The Triathlon Writing Group acknowledges the following investigators who contributed data for this study: Joseph Davies, MD; Jeffrey Nassif, MD; Knute Buehler, MD; Anthony Hedley, MD; Brian Covino, MD; Kenneth Krackow, MD; Matthew Phillips, MD.

Correspondence should be addressed to: Michael A. Mont, MD, Rubin Institute for Advanced Orthopedics, Center for Joint Preservation and Replacement, Sinai Hospital of Baltimore, 2401 W Belvedere Ave, Baltimore, MD 21215 (mmont@lifebridgehealth.org). doi: 10.3928/01477447-20130624-17
Although primary total knee arthroplasty (TKA) can offer high implant survivorship at long-term follow-up,1,2 this has not always correlated with equally excellent patient satisfaction rates or functional outcomes.3-11 Several studies, as well as registry data, have suggested that it is not uncommon for approximately 1 in 5 patients to be dissatisfied with the outcomes of their TKA procedure.3-11 Some authors have attributed the less-than-optimal patient satisfaction and functional outcomes to the abnormal kinematics of some of the modern prosthetic designs compared with natural knees.12-20 Thus, manufacturers have tried to address this by attempting to recreate the natural knee kinematics with new designs and implantation strategies.21-23

Anterior and posterior cruciate ligaments maintain the normal knee biomechanics; however, most knee implants are designed to function without the anterior cruciate ligament. Retention or sacrifice of the posterior cruciate ligament has been debated.24-27 Nevertheless, the use of a cruciate-retaining implant may promote more natural knee kinematics and maintain the femoral rollback during knee flexion,29 resulting in higher postoperative functional outcomes.

Furthermore, some implant designs have incorporated a single-radius instead of a multiple-radius design for the femoral component to improve the mechanical function by providing a longer extensor moment arm, a more distal and posterior axis, and a maintained isometry during the whole range of motion.17,19,29 Thus, single-radius designs may offer advantages such as a decrease in the required muscular force for knee extension, better ligament stability, and a decrease in patellar load.17,18,20 This may contribute to higher functional outcomes, enhanced rehabilitation, shorter return to work time, and reduced anterior knee pain.30-34 Potentially resulting in higher patient satisfaction rates. Nevertheless, further studies are necessary to better evaluate the clinical outcomes of these theoretical advantages.

Due to a paucity of reports on single-radius designs, the authors evaluated the clinical and patient-reported outcomes of primary TKA in patients who received a single-radius prosthesis. Specifically, the authors assessed aseptic implant survivorship, reoperation rate, clinical outcomes measures by the Knee Society objective and function scores, patient activity, patient satisfaction measured by the Short Form 36 (SF-36) questionnaire, and radiographic outcomes.

**Materials and Methods**

A database of all patients who had undergone a primary TKA between 2005 and 2008 at 7 institutions as part of a multicenter study was prospectively evaluated. Appropriate review board approval for the study was obtained from each institution. Eleven patients (11 knees) were lost to follow-up and 29 patients (29 knees) withdrew from the study. The remaining patients included 287 TKAs in 108 men and 173 women with mean age of 66 years (range, 39-80 years) and mean body mass index of 30 kg/m² (range, 18-40 kg/m²). All remaining patients were evaluated clinically and radiographically at a mean follow-up of 5 years (range, 2-7 years). The underlying causes for a primary TKA were end-stage osteoarthritis (n=278; 97%), posttraumatic arthritis (n=6; 2%) or osteonecrosis (n=3; 1%). Any patient with a neurosensory or neuromuscular deficiency that would interfere with the performance or evaluation of the arthroplasty was excluded from the study. A portion of data from these patients at an earlier follow-up period has been previously reported.15,36

An additional 167 patients were originally enrolled in the multicenter study for which the presented data were collected; however, the minimum patient enrollment was not reached at 4 investigational sites. Thus, these sites were excluded from study participation prior to reaching the minimum required follow-up, and these cases are not included in the current study group. However, implant survivorship was separately analyzed.

A standard medial parapatellar approach was performed in 169 (59%) TKAs, a midvastus approach in 98 (34%) TKAs, and a lateral parapatellar approach in 20 (7%) TKAs. All patients received a cemented single-radius cruciate-retaining TKA (Triathlon; Stryker Orthopedics, Mahwah, New Jersey), with the use of standard universal cutting blocks.

All patients returned for follow-up clinical visits postoperatively at approximately 6 weeks, 6 months, and annually thereafter. Clinical outcomes were assessed by evaluating the Knee Society objective and function scores. All patient records were reviewed for any reoperations due to neural deficit, instability, stiffness, infection, osteolysis, or implant loosening.37 Patient activity was evaluated by comparing the pre- and postoperative lower-extremity activity scale (maximum of 18 points). Patient-reported outcomes included patient satisfaction that was evaluated by comparing pre- and postoperative SF-36 general health survey physical and mental components.38 Anteroposterior and lateral radiographs of the knees were obtained for all patients and reviewed at each postoperative visit for fixation, component failure or malalignment, and progressive radiolucencies around the implant.

All data were prospectively recorded and stored within a Structured Query Language server. Aseptic implant survivorship was defined as revision of femoral or tibial or prosthetic components for any aseptic cause. Statistical data analysis was performed using SAS version 9.1.3 statistical software (SAS Institute Inc, Cary, North Carolina) to evaluate pre- and postoperative the Knee Society objective and function scores, activity score, and SF-36 physical and mental component scores. A P value of less than .05 was considered statistically significant.

**Results**

Kaplan-Meier analysis demonstrated an aseptic implant survivorship of 99.7%...
(286 of 287) at final follow-up (Figure 1). However, no tibial or femoral component loosening was observed; thus, their survivorship was 100%. In this group, 1 aseptic failure occurred that was a revision of the tibial insert due to instability and loosening approximately 43 months after the index TKA. This patient underwent a successful revision procedure and achieved a Knee Society objective and function scores of greater than 82 points at 16-month postrevision follow-up.

The overall reoperation rate, not including revision surgery, was 1.4%, with 4 patients undergoing additional procedures. One patient underwent a popliteal tendon release 12 months after the index procedure. This patient achieved Knee Society objective and function scores of 82 and 84 points, respectively, at 61-month follow-up. Two patients developed knee stiffness and reduced range of motion postoperatively, of which 1 was treated with open lysis of the adhesions at 4 months postoperatively and the other by arthroscopic excision of scar tissue at 12 months postoperatively. These 2 patients achieved Knee Society objective and function scores of 80 and 82 points at 61- and 58-month follow-up, respectively. Another patient underwent a reoperation for removal of an embedded staple in the tibia 14 months after the procedure. This patient achieved a Knee Society function score of 84 points at 59 months after reoperation; the lower objective score of 56 points was primarily due to peripheral neuropathy and increased pain.

Significant improvements were observed in mean Knee Society objective and function scores at final follow-up ($P=.0001$ and $.0001$, respectively). Knee Society objective and function scores improved from mean preoperative values of 39 (range, 7-95 points) and 53 (range, 0-100 points) points to mean postoperative values of 93 (range, 47-100 points; $P=.0001$) and 85 (range, 0-100 points; $P=.0001$) points, respectively (Figure 2).

Significant improvements were observed in mean patient activity scores at final follow-up ($P=.001$). Patient activity scores improved from a mean preoperative value of 9 points (range 4-17 points) to a mean postoperative value of 11.5 points (range, 6-18 points) ($P=.001$).

Significant improvements were observed in mean SF-36 physical and mental component scores at final follow-up. The SF-36 physical and mental component scores improved from mean preoperative values of 33 (range, 16-54 points) and 52 (range, 11-72 points) points to mean postoperative values of 46 (range, 12-63 points; $P=.0001$) and 56 (range, 20-69 points; $P=.004$) points, respectively.

On radiographic review of all patients, except for the patient who had undergone
a revision surgery, all prosthetic components appeared to be well positioned with no evidence of progressive radiolucentencies, loosening, subsidence, or stress shielding.

**DISCUSSION**

Due to the less-than-optimal functional outcomes and patient satisfaction rates after primary TKA, implant manufacturers have attempted to introduce new prostheses with single-radius designs that would provide a more natural knee kinematics as an alternative to multiple-radius prosthesis. These single-radius implants may improve mechanical function, enhance rehabilitation, and reduced anterior knee pain, thus potentially improving patient satisfaction rates. However, more studies are needed to better clinically evaluate these purported advantages. The purpose of this study was to evaluate the clinical and patient-reported outcomes of primary TKA in a cohort who had received single-radius cruciate-retaining knee implants. Excellent aseptic implant survivorship was found with a minimal reoperation rate, significant improvements in mean Knee Society objective and function scores, lower-extremity activity scores, and patient satisfaction as measured by SF-36 questionnaire at mid-term follow-up.

This study has several limitations. A case series of patients were evaluated who had received only 1 type of prosthesis, and no comparison was made of the cohorts of patients who received other types of prostheses. Other forms of functional outcomes, such as Western Ontario and McMaster Universities Osteoarthritis Index scores, were not evaluated. The UCLA activity score has been shown to better evaluate activity levels. Mean follow-up was short, and outcomes may change with longer follow-ups. All procedures were performed by experienced fellowship-trained surgeons (S.F.H., K.D.H., K.A.G.).

Four revisions were needed among the 167 patients enrolled at the 4 investigational centers requiring early termination and were not included in the current analysis. Isolated tibial insert revisions occurred in 3 patients at 2.5, 9, and 12 months after the index TKA, and both the tibial insert and femoral component were revised 1.3 months postoperatively in the fourth patient; an additional Kaplan-Meier aseptic implant survivorship analysis including the cases from the terminated investigational centers showed no significant difference in implant survivorship (98.9% vs 99.7%; P = .79) (Figure 3). Nevertheless, the authors believe that the outcomes are valuable to evaluate clinical and patient-reported outcomes of primary TKA using this type of prosthesis.

The excellent results in the current study may be due in part to the single-radius design of the prosthesis. The Triathlon total knee system is a cruciate-retaining implant design that has a single-radius and a spherical rotary arc to potentially increase the rotation needed for deep knee flexion. In addition, a deeper anterior cutout in the tibial polyethylene insert also allows for decreased patellar tendon stresses and deep flexion arc range of motion. These specific designs were used in an attempt to reconstruct natural knee kinematics to maximize range of motion without losing stability. The increased stability of single-radius prosthesis at higher flexion degrees has been shown in an in vitro biomechanical study. Ezechiel et al compared single- and multiple-radius designs on 7 left human knees that were implanted using a navigation system. They reported that although under varus and valgus stress, the varus/valgus axis deviation was not significant from 0° to 60° between the 2 groups; at 90° flexion, varus/valgus deviation with the single-radius component was significantly (P < .05) smaller compared with the multiple-radius design.

The excellent results found in the current study are also in agreement with previous reports on the outcomes of primary TKA using single-radius prostheses. Cook et al analyzed 426 TKA procedures that received a single-radius (Triathlon) component with 133 TKA procedures that received a multi-radius curvature knee system (Duracon; Stryker Orthopaedics) at 3.9-year average follow-up. The single-radius design showed significant improvements over the multiple-radius design in pain (P = .021), stability (P = .002), flexion (P = .006),...
ability to completely straighten the knee (P = .025), stair climbing (P = .001), walking (P = .0001), use of assistive devices (P = .0005), postoperative knee score (P = .0005), and postoperative function (P < .0001). Analysis of the change in Knee Society knee (P = .002) and function (P = .002) scores pre- to postoperatively also favored the single-radius design.18

Harwin and Kester43 evaluated a consecutive series of 94 cemented single-radius posterior cruciate ligament–retaining TKAs (Scorpio; Stryker Orthopaedics). At a minimum 8-year follow-up, they reported no cases of instability or revisions, as well as an early return of range of motion and extensor mechanism function.43

Gómez-Barrena et al50 compared 30 TKAs that had received a cemented posterior stabilizer single-radius femoral design prosthesis (Scorpio) to 30 TKAs that had received a cemented posterior stabilized multi-radius design (NexGen system; Zimmer, Inc, Warsaw, Indiana). At a mean follow-up of 7 to 9 months (range, 7-14 months), they reported higher functional Knee Society scores (86.6 ± 1.89 vs 80.3 ± 1.90, respectively), fewer physiotherapy sessions (19.9 ± 4.65 vs 22.2 ± 3.34, respectively), less time with 2 crutches (3.5 ± 1.2 vs 5.2 ± 1.04 weeks, respectively), decreased flexion peak torque (40.3 ± 7.9 vs 48.7 ± 9.6, respectively), increased extension peak torque (77.2 ± 16.1 vs 69.1 ± 14.4, respectively), and lower flexor/extensor ratio (0.5 ± 0.08 vs 0.7 ± 0.1, respectively) for patients receiving the single-radius design.30

Harwin et al32 evaluated 1999 knees in 1672 patients with a mean age of 65 years (range, 38-95 years) who underwent a primary TKA using the Triathlon Knee System. At a mean follow-up of 21 months (range, 4-48 months), only 4 revisions were needed: 1 revision of a tibial base plate as a result of a posttraumatic tibial plateau fracture, 2 poly exchanges for late instability, and 1 patella revision for loosening following trauma. Mean Knee Society objective and function scores had improved to 96 points (range, 72-100 points) and 85 points (range, 66-100 points) postoperatively, respectively.32 These data support the use of single-radius implants and provide evidence of improved outcomes in terms of function, stability, and pain.

In the current study, a 99.7% aseptic survivorship implant survivorship was found, with minimal reoperation rates (1.4%), in the cohort of patients who had received a cemented, single-radius cruciate-retaining knee implant (Triathlon) at a mean follow-up of 5 years. In addition, excellent clinical outcomes and significant improvements in pain and function scores, activity scores, and patient satisfaction scores were observed. The authors believe that these excellent outcomes may have been attributed, in part, to the single-radius design prostheses. Further prospective multicenter studies at longer follow-ups are necessary to better evaluate these outcomes.

References


14. Johnson AJ, Harwin SF, Krakow KA, Mont MA. Alignment in total knee arthroplasty: where have we come from and where are we going? Surg Technol Int. 2011; X11:183-188.


