The Journal of Arthroplasty xxx (2017) 1–5

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Prospective Randomized Comparison of Posterior-Stabilized Versus Condylar-Stabilized Total Knee Arthroplasty: Final Report of a Five-Year Study

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ARTICLE INFO

Article history:
Received 5 October 2017
Received in revised form
12 November 2017
Accepted 20 November 2017
Available online xxx

Level of Evidence:
I

Keywords:
total knee arthroplasty
cruciate-sacrificing
condylar-stabilized
posterior-stabilized
Triathlon CS
Triathlon PS

ABSTRACT

Background: This report presents the minimum 5-year results of a prospective, randomized, Level of Evidence I study that evaluated cruciate-sacrificing total knee arthroplasty using either a posterior-stabilized (PS) device or a condylar-stabilized (CS) device. We hypothesized that the clinical outcomes of both groups would be equivalent and that there would be differences in operative time and/or blood loss parameters.
Methods: One-hundred eleven patients undergoing total knee arthroplasty were randomized to receive either a post-cam style tibial insert (PS, n = 56) or a more congruent anterior-lipped tibial insert (CS, n = 55). All posterior cruciate ligaments were sacrificed.
Results: Comparison of the clinical scores and radiographic results between both groups were essentially equivalent with no statistically significant differences at the final 5-year evaluation, although the CS knee group had significantly fewer incidences of postoperative mechanical sensations ($P = .01$).
Conclusion: These results demonstrate that the CS knee provides excellent clinical, functional, and radiographic outcomes that are comparable to the results achieved with the PS knee, with a lower incidence of mechanical sensations, and support the use of a CS device as an alternative to the PS device.

There is continuing debate in the orthopedic community about the relative merits of a post and cam, posterior-stabilized (PS) device vs a cruciate-sacrificing condylar-stabilized (CS) device in total knee arthroplasty (TKA). There have been few prospective trials comparing outcomes with the Triathlon CS and the Triathlon PS tibial insert devices (Stryker, Mahwah, NJ) [1–6]. Only 2 of these studies [3,4] were randomized. These studies reported favorable functional results with both devices.

Previously, we reported the 2-year preliminary results [3] of this now-completed 5-year prospective randomized trial. The purpose of this study is to evaluate and compare the final clinical outcomes and radiographic results of patients undergoing posterior cruciate-sacrificing TKA receiving the CS lipped tibial insert with patients receiving the PS tibial insert. The primary hypothesis was that the clinical outcomes of both groups would be equivalent. The secondary hypothesis was that there would be differences in the operative time and/or blood loss parameters. In this previous report, there was a significantly shorter tourniquet time for the CS group than for the PS group ($P = .002$), a shorter operative time for the CS group ($P = .0001$), and a difference in blood loss and transfusion rates, but no difference in the clinical, radiographic, and patient-reported outcomes at minimum 2-year follow-up.

Materials and Methods

The Western Institutional Review Board granted approval for this study, registered with ClinicalTrials.gov (NCT01367925). All patients presenting to the author's site for elective primary TKA were eligible for study inclusion. Exclusion criteria were a history of inflammatory arthritis, morbid obesity (body mass index > 40 kg/m^2), prior total or unicompartmental reconstruction of the affected joint, high tibial osteotomy or femoral osteotomy, neuromuscular or neurosensory deficiency, systemic or metabolic disorder leading to progressive

Financial support for the research was provided by Stryker Orthopedics, Mahwah, NJ.

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to https://doi.org/10.1016/j.arth.2017.11.037.

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https://doi.org/10.1016/j.arth.2017.11.037
0883-5403/

bone deterioration, immunological compromise, knee fusion of the affected joint, an active or suspected infection in or about the knee joint, or age >80 years.

A power analysis was performed to determine the number of subjects required to detect a statistical difference ($P \leq .05$) of 10% in mean tourniquet times between 2 independent groups, given an average tourniquet time of 33 minutes and a standard deviation of 2 minutes, using a large effect size, a beta of 0.95, and an allocation ratio of 1; it was calculated that a total sample size of 84 would provide the desired power for this study, and we chose to exceed this enrollment number by a minimum of 25%.

The first patient was enrolled in July 2008 and the last patient was enrolled in September 2010. A consecutive series of 111 patients were randomized to either the CS or PS group using an online random number generator [7]. All other variables were held constant. Written informed consent was obtained from all participants and the study adhered strictly to inclusion/exclusion criteria, good clinical practices, and all regulatory mandates. Fifty-five patients received the CS lipped tibial insert and 56 received the PS tibial insert. The patients were blinded for the duration of the study to the model of implant that they received. Patients were assessed preoperatively and postoperatively at 6 weeks, 6 months, and annually for 5 years utilizing Knee Society pain/motion and function scores [8], lower extremity activity scale (LEAS) [9], the Short Form (36) health Survey (SF-36) [10] range of motion (ROM), alignment, and radiographic examination. An experienced, Certified Clinical Research Coordinator collected patient demographic data that were compared between groups (ie, mean patient age at surgery, gender, and body mass index), and intraoperative data consisting of estimated blood loss, hemovac drainage volume, and tourniquet and operative time, as well as hemoglobin preoperatively and on postoperative days 1-3. At the 1-year postoperative visit, a questionnaire was administered to each patient, asking if they felt any mechanical sensations such as clicking, clunking, and popping, and recorded the response as either “yes’ or “no.” All patient-reported outcomes measures including the patient-reported component of the Knee Society Score were administered by the Certified Clinical Research Coordinator in a blinded fashion. The physical examination section of the Knee Society Score was administered by the author/principal investigator in a uniform manner for all subjects at all visits, consistent with best practices for performing a clinical examination of the knee. All TKAs were performed by the author using the identical anatomic surgical technique [3], medial parapatellar arthrotomy, measured resection technique, intramedullary femoral and extramedullary tibial alignment, and posterior referencing without computer-assisted orthopedic surgery. In all cases, a tourniquet was inflated to 300 mm Hg prior to skin incision and deflated prior to closure once the final components were cemented. All posterior cruciate ligaments (PCLs) were sacrificed, all patellae were resurfaced, and all devices were cemented. The femur was positioned in neutral rotation with respect to the posterior condyles in a varus knee, and with respect to Whiteside’s line in a valgus knee, adjusting for cartilage and, when present, bone loss; posterior tibial slope was matched up to 10°, and proximal tibial varus, when present, was approximated. Ligament releases beyond the creation of a medial soft tissue sleeve during the initial exposure were rarely performed, and generally only in the face of a significant valgus deformity.

Statistical Analysis

Data were analyzed using a research database software package (Spokane Joint Replacement Center, Spokane, WA). Data were compared using chi-squared test and t-test with a significance level of .05.

Results

Enrollment screen fails included 1 patient who underwent hardware removal of a previous upper tibial osteotomy, 2 patients who had an alternate insert used (cruciate-retaining polyethylene), 1 patient who was taking antirejection drugs required by prior kidney and pancreas transplants, and 2 patients who had prior major surgeries (revision anterior cruciate ligament reconstruction, high tibial osteotomy); 1 patient withdrew because of moving away from the geographic region of the study site (See Fig. 1). Later, 2 participants had traumatic injuries requiring surgery and were also removed from the study, leaving 109 participants who were followed for the duration of the 5-year study. Fourteen participants were lost-to-follow-up during the study period and their data are included up to their last visit. Data from the 2 patients who were excluded due to trauma are included up to the time of their revision surgery.

Comparison of the demographic data of patients in both groups revealed no significant differences (Table 1). The clinical scores and results of radiographic evaluations are shown in Table 2. None of the comparisons was statistically significant between PS and CS groups. At 1 year postoperative, 12 PS group participants (21%) reported experiencing painless mechanical sensations (clicking, clunking, or popping sensations) as compared to 5 participants (9%) in the CS group, a statistically significant difference ($P = .01$).

There have been no adverse events or serious adverse events attributed solely to the implanted devices. There were no progressive radiolucencies. There were no infections requiring surgery. There have been 2 reoperations, 1 due to a patella fracture 6 months postoperatively and 1 due to traumatic loosening of the tibial baseplate after an automobile accident 1 year postoperatively. Excluding these 2 reoperations necessitated by traumatic events, implant survivorship at a minimum of 5 years was 100% for both groups.

Discussion

The purpose of this study is to compare the clinical outcomes and radiographic results of participants undergoing PCL-sacrificing TKA who received the Triathlon CS anterior-lipped tibial insert with participants who received the Triathlon PS tibial insert. The present report presents the results of this 5-year prospective randomized trial that included 111 participants. The primary hypothesis was that the clinical and radiographic outcomes would be comparable and the secondary hypothesis was that there would be differences in the operative times and/or blood loss parameters.

The data show that there are no statistically significant differences in the postoperative clinical outcomes between the 2 groups (Table 2) and these results are comparable with the 2-year results we reported previously [3]. The ROM, Knee Society scores, LEAS scale, SF-36, and radiographic outcomes are all statistically similar between both groups. This is consistent with the primary hypothesis that the CS anterior-lipped insert would provide clinical results that are comparable/equal to the results obtained with the PS insert. Other reports of cruciate-sacrificing knee arthroplasty utilizing “ultracongruent” [11,12] and cruciate-retaining devices [13] have demonstrated good clinical results including patient-reported outcomes measurements (PROMs) without utilizing a post/cam posterior-stabilizing implant. This suggests that the previously posited concern [14] of increased flexion instability with release of the PCL may not always be clinically relevant; indeed, a recent study [15] found that the flexion gap did not change with PCL release.

The author recognizes that these “ultracongruent” implants have a deeper dish with a higher anterior jump height compared to