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# Second Generation Patient Specific Total Knees Demonstrate a Higher Manipulation Rate Compared with "Off-the-shelf" Implants

Paul R. Haeder, M.D.<sup>1</sup>, Alexander C.M. Chong, MSAE, MSME,<sup>1,2</sup>, Tarun Bhargava, M.D.<sup>1,3</sup> <sup>1</sup>University of Kansas School of Medicine-Wichita, Department of Orthopaedics, Wichita, KS <sup>2</sup>Via Christi Health Department of Graduate Medical Education-Orthopaedics Surgery, Wichita, KS <sup>3</sup>Mid-America Orthopedics, Wichita, KS

## ABSTRACT

**Introduction**. Patient specific total knee arthroplasty (TKA) theoretically provides a more accurate fit to the native knee but may have difficulty achieving full range of motion (ROM) post-operatively. Post-operative ROM data were compared between patients who underwent cemented patient-specific cruciate-retaining (PSCR) and standard cemented posterior-stabilized (SPS) TKAs.

**Methods.** PSCR and SPS TKAs that were performed from January 2014 to September 2015 by the same surgeon using the same post-operative protocols at two selected facilities were reviewed. Twoand six-week post-operative ROM data were obtained and the number of patients with knee flexion less than 110° was recorded.

**Results.** Twenty-one patients in the PSCR group and 57 patients in the SPS group were included. The percentage of patients with knee flexion less than 110° was similar in both groups preoperatively (10% vs 14%, p = 0.60) and two-week post-operatively (57% vs 68%, p = 0.35). However, at six-week post-operatively there was significant difference (29% vs 7%, p = 0.01).

**Conclusions.** These results provide evidence to alert orthopaedic surgeons when using these patient specific implants versus conventional TKA methods. Patients whose TKA was performed using patient specific cutting guides struggled to obtain 110° of knee flexion. Close monitoring, aggressive physical therapy, and early manipulation are recommended when using patient specific cutting guides and custom total knee implants. Further evaluation in a larger group of patients is warranted. *KS J Med* 2016;9(4):88-92.

## INTRODUCTION

Total knee arthroplasty (TKA) is a successful surgical intervention for addressing pain and improving patient function. It is one of the most common orthopaedic procedures performed and whose demand continues to increase.<sup>1-4</sup> With the increasing demand comes a focus on ways to achieve a superior outcome. Poor alignment is a well-known risk factor for implant failure<sup>5-23</sup> which has led to improvements in surgical technique, instrumentation, and implant design.<sup>24,25</sup> One innovation is the use of patient-specific or custom cutting-blocks and custom implants, which theoretically provide a more accurate fit to the contour of the native knee,<sup>20,26-30</sup> thus allowing for a superior functional outcome and more efficient use of intraoperative resources.

Patient specific total knee replacements have been designed using computer technology utilizing preoperative magnetic resonance imaging (MRI) or computed topography (CT) to construct a three-dimensional representation of the knee. These data are used to create single-use patient-specific cutting-blocks for both the femur and tibia, which results in more accurate bone cuts for acceptable mechanical alignment and soft tissue balancing without the intra-operative reliance on fixed anatomical landmarks that often are distorted secondary to chronic arthritic changes (i.e., osteophytes). Additionally, these systems allow either predetermination of implant sizes or customized implants for each patient for both the femur and tibia prior to the operation.

Several studies compared these patient-specific instrumentations with standard instrumentation in terms of cost-effectiveness, coronal alignment, and operation time.<sup>4,22,23,31-50</sup> To our knowledge, however, the outcomes of these implants have not been as well studied.<sup>4,37,39</sup> We, therefore, retrospectively reviewed consecutive patients undergoing cemented patient-specific cruciate-retaining (PSCR) TKA and compared those patients to those who received a standard cemented posterior-stabilized (SPS) TKA, focusing on rates of postoperative knee manipulation under anesthesia (MUA). At the time of the study, a posterior stabilized custom knee replacement was not available on the market.

#### PATIENTS AND METHODS

Institutional review board approval was obtained for the study. A retrospective chart review was performed looking at consecutive PSCR TKAs from January 2014 through September 2015 utilizing the ConforMIS I-Total G2 TKA system (Confor-MIS, Inc, Bedford, MA; PSCR group). Patients who underwent SPS TKA during that same time period by the same surgeon were selected, based on the inclusion criteria, to serve as a control group, and the number of patients for this group was selected 3.5 times more than the PSCR group to reduce the percentage of outliers and, therefore, obtain better statistical analysis. In this SPS group, the implant was either Stelkast (Proven Gen-Flex, McMurray, PA) or Zimmer Gender Solutions NexGen (Zimmer, Inc., Warsaw, IN), ATTUNE (DePuy Synthes, Warsaw, IN), or Donjoy Motivation PS (Vista, CA). These two groups (PSCR and SPS groups) were operated on at two surgical centers.

<u>Subject Selection</u>. Inclusion criteria were PSCR TKAs and SPS TKAs performed from January 2014 through September 2015 by the lead surgeon at the two selected facilities. Patients selected were those with the principal diagnosis of osteoarthritis who underwent primary TKA. Patients with a history of trauma and/or a history of surgery on the operative knee also were included as long as there was no form of retained hardware. Since the production of the patient specific cutting guides was dependent on the quality of the preoperative CT, it was determined that the presence of hardware may interfere with the

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generation of accurate guides. SPS TKA patients were selected based on similar age, side, deformity, diagnosis, and preoperative range of motion with patients who underwent PSCR TKAs.

Exclusion criteria included all patients who underwent PSCR or SPS TKAs outside of January 2014 through September 2015 and not by the lead surgeon at the two selected facilities. Patients were excluded from the study if they underwent the pre-operative planning but the patient specific cutting guides were not utilized during the procedure.

Patient-Specific TKA Surgical Technique. Pre-operative planning was performed as described by the manufacturer's protocol. Prior to surgery, each patient had CT images of the operative lower extremity from hip to ankle performed. The CT imaging data were provided to the manufacturer who was responsible for the custom fabrication of the femoral and tibial patient specific cutting guides and custom total knee implants. Scheduling of the operation was made once the patient specific cutting guides and implants were provided by the manufacturer. This pre-operative planning usually required at least seven weeks from the time of the initial visit.

The surgery was performed through a traditional medial parapatellar approach under tourniquet control. For the PSCR TKA, the posterior cruciate ligament (PCL) was left intact, whereas for the SPS TKA the PCL was resected. Once bony exposures were achieved, and prior to any revision or resection of bone, the patient specific cutting guides were placed as manufacturer guidelines directed. The guides were pinned after appropriate placement. These initial steps were performed in similar fashion for both the femur and the tibia. In each of the operations, the femur was addressed first. After standard cuts were made, the trial femoral implant was placed and the surgeon evaluated femoral component size, femoral anterior-posterior translation, femoral component rotation, and femoral proximal-distal translation.

A similar procedure was performed on the tibia including placement of patient specific cutting guide and standard cuts. Following completion of the initial bone cuts, the tibial trial component was placed. Component placement was evaluated for appropriate tibial component size, tibial slope, tibial rotation, and tibial proximal-distal translation.

Manipulation under Anesthesia (MUA) Technique. Subjects who had knee flexion less than 110° by six-week post-operative were selected for MUA. A previous study indicated that patients with knee flexion less than 110° were not able to kneel,<sup>51</sup> and kneeling is one of the important functions of the knee joint required for many activities of daily living and in certain occupations.<sup>52,53</sup> Therefore, this study defined knee flexion less than 110° as the criterion for MUA. The procedure was performed with the patient taken to the operating room where general anesthesia was induced. After adequate muscle relaxation was achieved, the ipsilateral hip was flexed to 90°. To minimize the risk of iatrogenic fracture, the surgeons' hands were placed on the distal femur and proximal tibia close to the knee joint line. Steady progressive loading was applied to the tibia to flex the knee until audible and palpable break of adhesions were felt. The final range of motion (ROM) then was recorded. Patients underwent aggressive physical therapy in the post-operative period.

Data Collection. A chart review was performed of the pre-operative assessment and included documentation of gender, age, height, weight, body mass index (BMI), side of the knee, and deformities in the knee. Pre-operative ROM also was obtained from the history and physical. All patients underwent the same post-operative protocol, including post-operative physical therapy. Post-operative ROM was obtained at two- and six-weeks after surgery. All post-operative measurements were taken by a physical therapist with the aid of a goniometer to ensure accurate measurements. If the patient underwent a subsequent MUA, it was recorded along with post-MUA ROM. Two- and six-week post-operative ROM data were reviewed and the number of patients with knee flexion less than 110° was recorded.

### **STATISTICAL ANALYSIS**

The chi-square test using SPSS software (Version 19.0; SPSS Inc, Chicago, IL) was used to determine if there were any observed differences between the PSCR and SPS TKAs with respect to knee flexion pre-operatively and at two- and six-week post-operatively. The level of significant difference was defined as p < 0.05.

### RESULTS

There were a total of 96 patients that met the inclusion criteria, 22 patients (28%) in the PSCR group and 74 patients (72%) in the SPS group. One of the 22 patients in the PSCR group was excluded due to a popliteal artery thrombosis that subsequently led to above knee amputation in the immediate post-operative period. Seventeen (23%) out of the 74 patients in the SPS group were excluded due to lack of follow-up information, resulting in a total of 57 patients for the SPS group.

Table 1 summarizes the demographic profile of the patients for this study. Of the 21 patients in the PSCR group, 14 were females (67%) and 7 were males (33%). In the 57 patients in the SPS group, 41 were females (72%) and 16 were males (28%). The mean age for PSCR and SPS groups were  $59 \pm 10$  years (range: 36 - 72 years) and  $65 \pm 10$  years (range: 47 - 89 years), respectively. The mean BMI for PSCR group was  $30.7 \pm 6.7$  kg/m2 (range: 21.6 - 46.8 kg/m2), and  $35.0 \pm 7.0$  kg/m2 (range: 23.0 - 51.6 kg/m2) for the SPS group.

The summary of patients with knee flexion less than  $110^{\circ}$  is shown in Table 2. The SPS group had a higher percentage of patients with knee flexion less than  $110^{\circ}$  pre-operatively (14%) compared to the PSCR group (10%). Statistically, there was no difference between these two groups (p = 0.60). At the two-week post-operative visit, this trend continued with 68% of 57 patients in the SPS group versus 12 (57%) of 21 patients in the PSCR group (p = 0.35). However, at the six-week post-operative period, this trend significantly changed with 4 (7%) out of 57 patients in the SPS group having less than 110° of knee flexion compared

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continued.

with 6 (29%) out of 21 patients in the PSCR group (p = 0.01). The SPS group went from 68% of patients with less than 110° of flexion to only 7% during the two- to six-week post-operative time course. In comparison, the PSCR group went from 57% to 29%.

		PSCR Group (N = 21)	SPS Group (N = 57)
Gender	Female	14 (67%)	41 (72%)
	Male	7 (33%)	16 (28%)
Age (years, mean <u>+</u> SD) (range)		59 <u>+</u> 10 (36 - 72)	65 <u>+</u> 10 (47 - 89)
BMI (kg/m², mean <u>+</u> SD) (range)		30.7 <u>+</u> 6.7 (21.6 - 46.8)	35.0 <u>+</u> 7.0 (23.0 - 51.6)
Height (inches, mean <u>+</u> SD) (range)		67 <u>+</u> 4 (61 - 75)	66 <u>+</u> 4 (56 - 74)
Weight (lbs., mean <u>+</u> SD) (range)		196 <u>+</u> 53 (126 - 319)	216 <u>+</u> 51 (133 - 337)
Side	Left	7 (33%)	26 (46%)
	Right	14 (67%)	31 (54%)

#### Table 1. Patient demographics.

#### Table 2. Patients with knee flexion less than 110°.

	PSCR Group (N = 21)	SPS Group (N = 57)	p value
Pre-operative	2 (10%)	8 (14%)	0.60
2-week post-operative	12 (57%)	39 (68%)	0.35
6-week post-operative	6 (29%)	4 (7%)	0.01

All six patients in the PSCR group who had less than 110° of six-week post-operatively underwent flexion а MUA. Five significantly improved (average: 24 degrees, range: 10 40 degrees) their knee flexion to at least 115°. The other ultimately underwent a second MUA. Only one of the four patients in the SPS group with less than 110° of flexion six-week post-operatively underwent a MUA. The patient improved knee flexion from 95 to 110°. One patient had a post-operative stroke severely affecting the operative extremity in the immediate post-operative period. This patient ended up with 90° of flexion but did not have a MUA secondary to lack of motor function in the operative extremity. The other two patients presented with knee flexion of 105° at six-week post-operatively; both patients were counseled but elected not to undergo a MUA and improved ROM with further therapy. They had no functional limitations at that time.

#### DISCUSSION

Patients whoseTKAs were performed using cruciate retaining patient specific implants with custom cutting guides struggle to obtain knee flexion of 110°, which potentially could restrict patients from kneeling. Caution should be taken when using patient specific cutting guides and custom total knee implants. Patient specific or custom implants have the theoretical advantage of providing a more accurate fit to the contour of the native knee which is hoped will allow for a superior functional outcome, but they were not a substitute for careful preoperative planning, good clinical and intraoperative judgment, appropriate soft tissue balancing, and precise implantation technique.

Bali and colleagues<sup>33</sup> prospectively studied 32 TKAs performed in 29 patients with MRI-based custom cutting guides. Their results showed that 29 of the 32 knees had a mechanical axis restored to within 3° of neutral, and they concluded that this technology can be used safely in most cases of osteoarthritis of the knee. However, they did not study the functional outcome of these patients. In our study, the rate of knee flexion less than 110° in the PSCR group was significantly higher compared with the SPS group. There is no clear evidence for this lack of knee flexion in the PSCR group. It is suspected that the close fit of the implants may place the patient at risk for stiffness. There also could be errors in the data input or in the manufacturing of the cutting-blocks and implants which could lead to difficulty with ROM. Another possibility for the lack of post-operative knee flexion may be the over reliance on the custom design and lack of attention to proper soft tissue balancing. The patient specific cutting guides and implants produce accurate and precise limb alignment.<sup>22</sup> Static alignment is unfortunately only one variable that can affect TKA performance. One of the major disadvantages of using the custom guides and implants is that no other instrument can be used intra-operatively to judge proper bony cuts and soft tissues balancing.<sup>22</sup>

There are several limitations of this study. First, this was a retrospective chart review utilizing information that had to have been documented accurately in the medical record. Second, this study had a small sample size for the PSCR group, which prevents applying tests of significance due to a low power. The low number of procedures performed in the PSCR group was unavoidable because the treating surgeon stopped using the implant secondary to concerns over stiffness as the overall functional outcomes were found not to be satisfactory as the study progressed. This study compared cruciate retaining (CR) TKAs to the posterior stabilized (PS) TKAs. These designs are based on the retention or sacrifice of the posterior cruciate ligament. Several other cohort studies and randomized controlled trial studies have shown no difference in flexion or range of motion between the two designs.54-64 Given the available research models, we feel that the data are valid for the current investigation. One other weakness of the present study is the ROM measurements were taken by different therapists at different places. Nevertheless, this study contributes to the available literature on the functional outcomes of knee flexion for patient-specific total knee replacements. Further evaluation in a larger group of patients is required to resolve the question of functional results for the patient specific CR TKA.

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continued.

# CONCLUSION

The findings of this study provide additional evidence on the functional outcomes when using patient specific cutting guides/implants in TKA. Close monitoring, aggressive physical therapy, and early manipulation is recommended when using patient specific cutting guides and custom total knee implants.

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