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Does Implant Design Influence the Accuracy of Patient Specific Instrumentation in Total Knee Arthroplasty?

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ABSTRACT

PSI software adjusts preoperative planning to accommodate differences in implant design. Such adjustments may influence the accuracy of intraoperative jig placement, bone resection, or component placement. Our purpose was to determine whether implant design influences PSI accuracy. 96 and 123 PSI TKA were performed by a single surgeon using two different implant systems and identical PSI software. Femoral coronal alignment outliers were greater for Implant 1 (23.9% Implant 1 vs. 13.4% Implant 2; $P = 0.050$). Tibial coronal alignment outliers were greater for Implant 2 (10.9% Implant 1 vs. 22.7% Implant 2; $P = 0.025$). There was no difference in overall mechanical axes. Differences in implant design can influence bone resection and component alignment. PSI software rationale must align with surgeons' intraoperative goals.

Patient specific instrumentation (PSI) is a technique for performing total knee arthroplasty (TKA) that utilizes preoperative magnetic resonance imaging (MRI) or computed tomography (CT) to generate a preoperative plan aimed at achieving surgeon-specified preferences. Rapid prototyping technology is used to generate customized guides for intraoperative cutting block placement with the goal of executing the preoperative plan. The evidence surrounding PSI in the literature has shown mixed results. Compared to conventional instrumentation, PSI has been shown in some studies to improve alignment [1–3], reduce length of surgery [4,5], and demonstrate cost effectiveness [6]. However, other studies have shown PSI to be comparable to conventional instrumentation with regard to improving alignment [4,5,7–14], reducing length of surgery [8], and demonstrating cost effectiveness [4]. The variable results within the literature regarding PSI accuracy may be attributable to the use of different PSI systems or implant systems among published studies.

During the preoperative planning phase, PSI software fits a given implant onto a modeled knee. PSI software adjusts its preoperative planning to accommodate specific features of implant design. Due to the particularity of these planned adjustments, it is possible that the accuracy of a given PSI system with regard to intraoperative jig placement, bone resection, or component placement may vary when applied to different implant designs. Thus, the effect of implant design on PSI accuracy needs to be established in order to understand whether the accuracy of a given PSI system is consistent across implant systems. The purpose of this study was to determine whether implant design influences PSI accuracy by comparing the accuracy with which a single PSI system achieved planned intraoperative and radiographic goals in two different implant systems differing in femoral posterior condyle thickness, femoral sizing increments, and tibial tray design. We hypothesized that the accuracy of jig placement, bone resection, and component placement would differ when applying the same PSI planning software to two different implant systems.

Materials and Methods

In this retrospective comparative study approved by the institutional review board, we evaluated a single experienced surgeon's (SDS) initial 96 consecutive PSI TKA with Implant 1: Persona CR implant system (Zimmer, Warsaw, IN, USA) and initial 123 consecutive PSI TKA with Implant 2: NexGen CR Flex implant system (Zimmer). All patients during this period underwent PSI TKA unless unable to undergo preoperative MR scanning. All patients undergoing PSI TKA received the most current implant system available unless they had a nickel allergy, in which case the NexGen implant system was used. All TKA were performed with Zimmer Patient Specific Instruments, which utilizes an MR-based pin guide system. The Zimmer PSI, Persona, and NexGen systems are all FDA approved medical devices. Preoperative long-standing radiographs were obtained to evaluate overall preoperative mechanical axis.

There were no demographic or preoperative radiographic differences between the implant groups (Table 1).

Implant 1 includes a number of specific design changes compared to Implant 2 (Fig. 1), most notably femoral posterior condyle thickness, femoral component sizing increments, and tibial tray design. Femoral

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This study was performed at Northwestern Feinberg School of Medicine and approved by the Northwestern University Institute Review Board.

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Table 1
Demographic and Radiographic Data of Implant Groups.

Demographic	Implant 1 (95% CI)	Implant 2 (95% CI)	*P* Value
Preoperative Mechanical Axis[a] (°)	5.7 (4.3–7.0)	4.2 (2.7–5.7)	0.150
Age (Years)	66.5 (64.8–68.1)	67.3 (65.6–69.1)	0.479
Body Mass Index (kg/m^2)	31.0 (29.6–32.4)	30.8 (29.4–32.3)	0.878
Gender (% Female)	67.4	64.4	0.662
Preoperative Diagnosis (% Osteoarthritis)	98.9	100	0.264

[a] Positive values indicate varus in the coronal plane; CI = confidence interval.

component posterior condyle thickness is 9 mm in Implant 1 compared to 11 mm in Implant 2. PSI software adjusts targeted posterior femoral resection accordingly. Femoral component sizes are in increments of 2 mm posteriorly in Implant 1 compared to 4 mm posteriorly in Implant 2. Tibial component design is anatomic for Implant 1 and symmetric for Implant 2. We determined in a separate study that in order to maximize tibial surface coverage, the symmetric tray must be frequently internally rotated while the anatomic tray can be maintained in neutral rotation. PSI software similarly attempts to maximize tibial surface coverage in both systems and therefore uses different rotational axes between the two implants. The Implant 1 tibial component is rotated according to the line joining the medial third of the tibial tuberosity and the middle of the PCL, while the Implant 2 tibial component is rotated according to the line running through the midspine point that is perpendicular to the line connecting the geometric centers of the medial and lateral tibia plateau. This rotational difference plans the Implant 2 component to be internally rotated relative to the Implant 1 in the PSI software (Fig. 2).

MR images were uploaded to Materialise (Leuven, Belgium) software, which generated a preoperative plan according to surgeon preferences. Surgeon preferences were as follows: overall mechanical axis 0°, femoral coronal alignment 90° relative to femoral mechanical axis, tibial coronal alignment 90° relative to the tibial mechanical axis, femoral flexion 3° relative to femoral sagittal mechanical axis, and tibial posterior slope 4–7° relative to tibial sagittal mechanical axis. Following plan approval, femoral and tibial guides customized to patient anatomy were manufactured for intraoperative use.

Intraoperatively, PSI guides were fitted onto the femur and tibia to establish cutting block placement and subsequent bony resection. The depth of resections from the medial and lateral distal femur, posterior femur, and proximal tibia were measured at designated anatomic points with calipers to the nearest 0.5 mm by a surgical assistant blinded to planned resection depth. Discrepancy between initial resection and PSI-planned resection was calculated, accounting for a saw blade thickness of 1.3 mm. A recut was performed if measured resection fell short of planned resection by more than 2 mm. This technique of measuring resection depth has been validated by Bae et al, who confirmed that caliper-measured thickness of resected condyles after cartilage removal corresponds well with radiographic-measured thickness (average difference of 0.3°) [15]. Our method differed only in that we measured resected bone as well as cartilage to compare with PSI-planned resection, since the MR-based PSI software included cartilage resection in its planning of resection. The surgeon determined appropriate component sizes based on his intraoperative assessment. Component sizes were recorded and compared to PSI predicted sizes to determine sizing accuracy. The surgeon's intraoperative goal for tibial rotation differed from that of the PSI planning software. While the PSI software attempted to maximize coverage and accordingly adjust rotation, the surgeon's priority was to minimize component rotation mismatch in an effort to avoid excess postoperative pain [16] and suboptimal tracking. The PSI planning software did not have the option to align the tibial component with the femoral component. In accordance with his intraoperative rotational goal, the surgeon set tibial rotation by floating the tibial tray to align with the femoral component. In both systems, this was most accurately achieved when the tibial component was aligned with the line joining the medial third of the tibial tubercle and the PCL attachment. Thus, the Implant 2 tibial component had to be frequently externally rotated relative to the PSI planned rotation. Intraoperative accuracy was assessed according to discrepancy between actual and PSI-planned resection and component sizing

Long-standing and lateral radiographs were obtained 4-weeks and 6-months postoperatively to determine postoperative alignment. Overall mechanical axis was measured on both 4-weeks and 6-months postoperative radiographs. Femoral and tibial coronal alignment was measured on 4-weeks postoperative long-standing radiographs. Femoral and tibial sagittal alignment was measured on 4-weeks postoperative lateral radiographs.

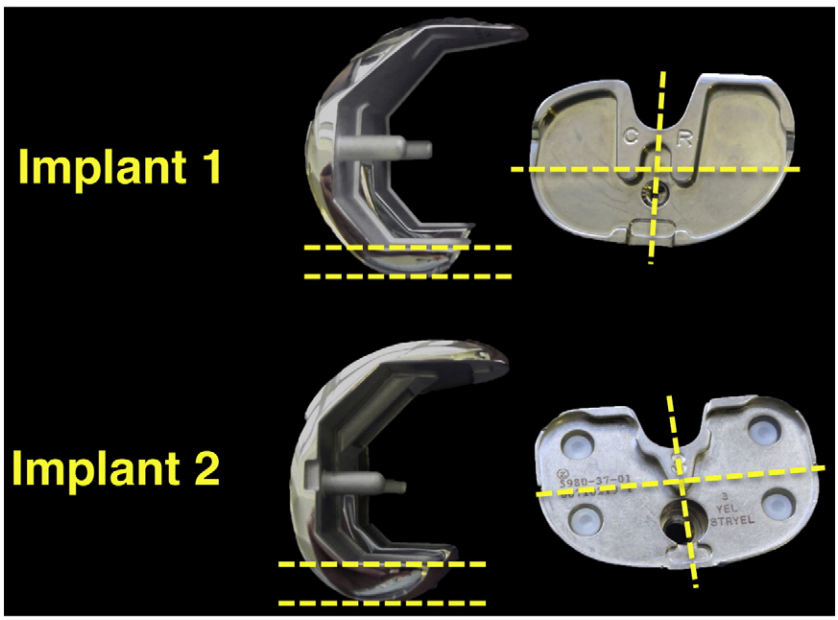

Fig. 1. Implant 1 and Implant 2 differ in femoral posterior condyle thickness (9 mm vs. 11 mm), femoral component sizing increments (2 mm vs. 4 mm), and tibial tray design (anatomic vs. symmetric).