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Improved Radiographic Outcomes With Patient-Specific Total Knee Arthroplasty

Conrad B. Ivie, MD [a], Patrick J. Probst [b], Amrit K. Bal [c], James T. Stannard [d], Brett D. Crist, MD [a], B. Sonny Bal, MD, JD, MBA [a]

[a] *University of Missouri Department of Orthopaedic Surgery, Columbia, Missouri*
[b] *University of Missouri School of Medicine, Columbia, Missouri*
[c] *Asheville School, Asheville, North Carolina*
[d] *Comparative Orthopaedic Laboratory, University of Missouri, Columbia*

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ABSTRACT

Patient-specific guides can improve limb alignment and implant positioning in total knee arthroplasty, although not all studies have supported this benefit. We compared the radiographs of 100 consecutively-performed patient-specific total knees to a similar group that was implanted with conventional instruments instead. The patient-specific group showed more accurate reproduction of the theoretically ideal mechanical axis, with fewer outliers, but implant positioning was comparable between groups. Our odds ratio comparison showed that the patient-specific group was 1.8 times more likely to be within the desired $+3°$ from the neutral mechanical axis when compared to the standard control group. Our data suggest that reliable reproduction of the limb mechanical axis may accrue from patient-specific guides in total knee arthroplasty when compared to standard, intramedullary instrumentation.

It is well known that during total knee arthroplasty (TKA), component alignment, particularly in the coronal plane, is correlated with long-term survivorship, with greater than three degrees of varus or valgus misalignment contributing to early failure rates [1–8]. Patient-specific cutting guides (PSI) – designed from computed tomography (CT)- or magnetic resonance imaging (MRI)-derived data and intended for single use during TKA – can simplify surgery and increase the accuracy of bone cuts and implant position. Studies have shown that PSI guides used during primary TKA improve the accuracy of frontal plane alignment with fewer outliers [9,10]. In contrast, other data have shown only a marginal improvement in extremity alignment in PSI-TKA, when compared to similar arthroplasties performed with conventional, non-PSI instruments [11,12].

The purpose of this investigation was to compare frontal plane limb alignment and femoral and tibial component positioning between TKAs done with PSI guides versus those done with standard instrumentation. The null hypothesis was that limb alignment and component positioning measurements would not differ significantly between PSI-TKA versus conventional TKA.

Materials and Methods

With Institutional Review Board approval, we reviewed the radiographs of 100 unilateral posterior-cruciate sparing TKAs, performed consecutively, using patient-specific cutting guides for the femur and tibia and custom-made femoral and tibial components (iTotal G2 system, Conformis, Boston MA). Preoperative CT scanning of the hip, knee and ankle was performed six weeks before surgery, according to a standard scanning protocol designed to calculate the mechanical axis of the leg and to determine sizing of the knee joint. Proprietary software was used by the manufacturer to create virtual 3D models of the tibia and femur and the program was used to determine the optimal size and shape of the prosthetic tibial and femoral components. Patient-specific disposable cutting guides were made of polyamide and shipped to the operating room with the custom implants in one sterile package.

The control group consisted of 100, consecutively-performed unilateral TKAs using a posterior-cruciate sacrificing implant (NK II knee, Zimmer, Warsaw, IN). These TKAs were done immediately before the surgeon switched to the iTotal G2 system that uses PSI. In this control group, the distal femur and proximal tibia cuts were made using conventional intramedullary and extramedullary instrumentation, respectively. Implants were sized during surgery using standard, multiple-use sizing jigs, supplied in several standard instrument trays. Guides were pinned to the bone surfaces and captured cuts were made through slots. Once implant sizing was determined by the surgeon, the components were opened from off-the-shelf inventory.

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Reprint requests: B. Sonny Bal, MD, JD, MBA, University of Missouri Department of Orthopaedic Surgery, 1100 Virginia Ave., DC953.00, Columbia, MO 65212.

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All operations were done by one surgeon and all components were cemented. Identical rehabilitation protocols were used for all patients. Three-peg, all polyethylene patella components were used in all TKAs. The patella component was implanted using a free-hand cut and conventional sizing methods in all knees.

At the four-week follow-up visit, standard knee radiographs were obtained for each patient, including a full-length weight-bearing extremity view capturing the hip and ankle joints on the same image. The mechanical axis was determined according to previously-published methods [13]. All radiographic measurements were done by two independent reviewers who were trained for this study by an experienced musculoskeletal radiologist. Each measurement was taken in triplicate by each reviewer to minimize intraobserver error. The mean value of individual measurements gave the final calculation for each variable measured in this study. Deviations of more than 3° from a neutral mechanical axis were regarded as outliers and the corresponding fractions were calculated.

Varus/valgus position of the femoral and tibial components was determined by measuring the frontal femoral component (FFC) angle and frontal tibial component (FTC) angle relative to the mechanical axis on the long-leg radiographs (Fig. 1A and B). Values in excess of 90° indicated valgus positioning of the femoral and tibial component and values less than 90° indicated varus positioning. Fractions of outliers with >3° varus/valgus were calculated.

Femoral component flexion was measured as the lateral femoral component angle (LFC) and tibial component posterior slope was measured as the lateral tibial component (LTC) angle, on standard lateral radiographs according to techniques described previously (Fig. 2) [13]. Fractions of outliers of more than 3° were calculated.

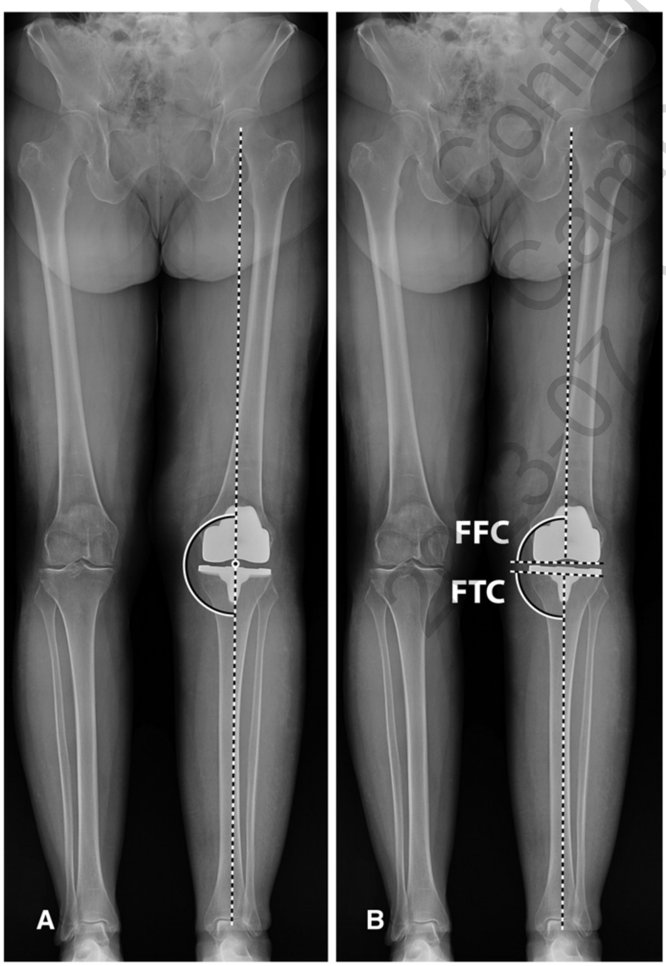

Fig. 1. (A) Standing radiograph showing measurement of mechanical axis of the limb; (B) varus/valgus position of the femoral and tibial components was determined by measuring the femoral component (FFC) angle and frontal tibial component (FTC) angle relative to the mechanical axis on the long-leg radiographs.

Means $\pm$ SD and 95% confidence intervals (CI) were determined for each measurement. *t*-tests were performed to determine significant differences between groups. Odds ratios were calculated based on number of cases with the desired $\pm 3°$ of deviation from neutral (0°) for mechanical axis for each group. All statistical calculations were done by an independent statistician without knowledge of treatment groups.

Results

Table 1 summarizes our results; showing mean values and statistical comparisons between study groups, for limb mechanical axis, femoral and tibial component varus/valgus alignment, femoral component flexion angle, and posterior slope of the tibial component.

PSI-TKA mechanical axis alignment was significantly different ($P = 0.0016$) than control-TKA mechanical axis. For both groups, while the 95% confidence interval completely contained the desired $\pm 3°$ of deviation from the neutral axis, the PSI-TKA radiographs were 1.8 times more likely to be within the desired $\pm 3°$ of deviation than non-PSI TKA radiographs.

PSI-TKA femoral component varus–valgus alignment was significantly different ($P = 0.032$) than non-PSI TKA. While the 95% confidence interval completely captured the desired $\pm 3°$ of deviation from the neutral axis (90°) for both groups, PSI-TKA radiographs were 1.5 times more likely to be within the desired $\pm 3°$ of deviation from the neutral axis of the femoral component than non-PSI TKA radiographs.

Tibial component varus–valgus alignment did not differ significantly ($P = 0.56$) between PSI-TKA versus controls. The 95% confidence interval contained the desired $\pm 3°$ of deviation from the neutral axis (90°) for both groups. Statistically, radiographs of PSI-TKA were equally likely as non-PSI TKA to be within the desired $\pm 3°$ of deviation from the neutral axis. Observations for the posterior tibial

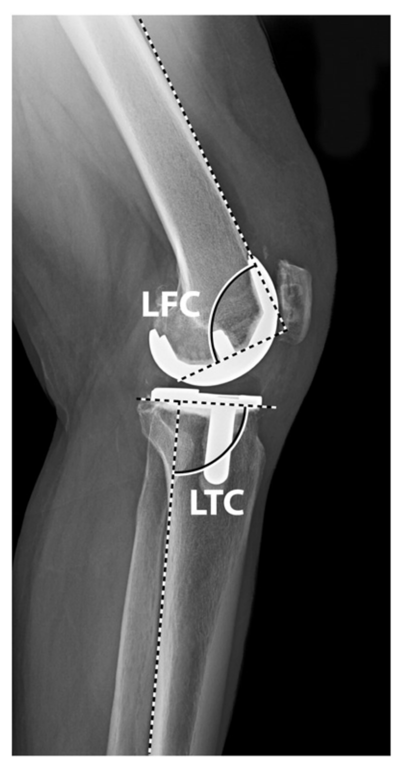

Fig. 2. Standard lateral radiograph shows the femoral component flexion, measured as the lateral femoral component angle (LFC) and tibial component posterior slope, measured as the lateral tibial component (LTC) angle.

Table 1
Summary of Radiographic Measures Comparing PSI-TKA to Non-PSI, Control TKA.

Outcome Measure	PSI-TKA Mean ± SD	Control-TKA Mean ± SD	*t*-Test *P* Value	PSI-TKA 95% CI	Control-TKA 95% CI	DR	PSI-TKA % ODR	Control-TKA % ODR
Mechanical Axis	−0.47 ± 3.15	1.68±3.65	$P = 0.0016$	−1.33 to 0.39	0.66–2.706	0 ± 3°	29.6	43.1
Femoral Varus–Valgus	87.37 ± 3.87	88.32±1.51	$P = 0.032$	86.31–88.43	87.89–88.75	90 ± 3°	29.6	19.6
Tibial Varus–Valgus	87.81 ±1.54	87.71±1.44	$P = 0.56$	87.39–88.23	87.31–88.11	90 ± 3°	24.1	29.4
Femoral Flexion Angle	85.90 ±2.84	86.10±2.22	$P = 0.92$	85.09–86.71	85.48–86.72	90 ± 3°	59.1	52.9
Tibial Posterior Slope	86.42 ±2.61	87.12±1.73	$P = 0.37$	85.67–87.17	86.63–87.61	85 ± 3°	57.1	58.8

CI = confidence interval.
DR= desired range.
%ODR = percentage of cases falling outside the desired range for clinical accuracy.

slope measurements were similar to those for the tibial component varus/valgus alignment.

Likewise, the femoral flexion angle did not differ significantly between PSI-TKA versus non-PSI TKA radiographs. For both groups, the 95% confidence interval was not completely within the ±3° of deviation from the neutral axis, i.e., radiographs of PSI-TKA were just as likely to be within the desired ±3° of deviation from the neutral axis as non-PSI TKA. All operations described in this report proceeded without complications and unanticipated conversion to standard total knee instrumentation with off-shelf implants was not required in any of the PSI-TKA patients.

Discussion

In this study, patient-specific cutting guides showed a significant improvement in extremity mechanical alignment and femoral component frontal plane position during primary TKA. Other variables related to femoral and tibial component positioning did not vary between PSI-TKA and conventional TKA. Previous studies have shown that the principal benefit of PSI cutting guides in TKA relates to improved frontal plane alignment, generally considered to be within 3° varus/valgus of the mechanical axis [1–3]. The three-degree leeway is arbitrary and derived from acceptable radiographic measurement error. Logically, any deviation from the theoretical neutral limb alignment can be reasonably expected to reduce the longevity of TKA in proportion to the amount of malalignment [14]. Therefore, limb alignment is of particular importance when performing TKA.

Conventional TKA instruments rely on the alignment of the intramedullary femoral canal, the tibial canal, and/or external landmarks to guide limb alignment during TKA. These methods are susceptible to error from variations in canal geometry, and bowing of the femur and/or tibia. Teter et al found that 8.5% of femoral cuts made with intramedullary instrumentation during TKA were suboptimal and suggested caution in bowed femora and in capacious femoral canals [15]. Elloy et al tested the accuracy of intramedullary alignment in 100 TKAs – using full-length weight-bearing x-rays – and found a maximum error in valgus alignment of 6.68° and 4.62° in varus [16].

PSI instrumentation should, at least in theory, improve the accuracy of limb alignment by guiding the critical bone cuts toward the theoretically ideal position for each patient. When compared to conventional cutting guides, PSI guides may be better able to overcome errors arising from extramedullary deformities, large bone canals, patient obesity, and other anatomic variations. Several orthopaedic vendors have adopted disposable PSI cutting blocks to facilitate bone cuts during TKA. This technology offers improved accuracy, less blood loss, and avoidance of intramedullary instrumentation, albeit at an increased cost [17].

Some authors have reported that PSI-TKA technology offers benefits beyond improved limb alignment and implant positioning. Single-use instruments and cutting blocks are associated with decreased bacterial contamination in the operating room and may lead to fewer infections [18]. While implants costs are similar between PSI-TKA versus non-PSI TKA [19] and while improvements in limb alignment with PSI-TKA may be marginal over conventional TKA [11], authors agree that PSI cutting jigs simplify surgery and shorten overall operative times. As such, PSI cutting guides may have a significant economic advantage for the health care system [11,19]. Using activity-based cost accounting, Tibesku et al found that PSI cutting blocks led to significant efficiencies in operating room utilization that contributed to increased revenues for the hospital [20]. Another advantage is a decreased need for inventory and shelf space for instruments since only the patient-specific block is sent.

Despite the claimed advantages, the reported accuracy of reproducing limb alignment of TKA with PSI guides has been mixed. Dossett et al found that kinematic alignment obtained with PSI guides led to improved knee flexion and better clinical outcomes, when compared to mechanical alignment with conventional instruments [21]. In contrast, Nunley et al found little advantage to using PSI guides in restoring limb axis during TKA over conventional instrumentation, although there were slight improvements in OR time management with PSI technology [22].

Our study showed significantly improved accuracy in the mechanical axis and femoral component frontal plane alignment using PSI-guided TKA. All operations were performed by an experienced arthroplasty surgeon and none of the PSI-guided TKAs in this investigation required additional surgeon intervention or a change from the preoperative surgical plan. This is in contrast to other investigations that have shown frequent surgeon-directed changes during PSI-TKA, most of them directed at changing the templated implant sizes, or fine-tuning the recommended alignment of the limb and components [23].

Computer-assisted TKA is a comparable technology aimed at improving limb and component alignment, and while some studies have shown improved radiographic outcomes from such, the precise clinical benefits have yet to be demonstrated. Both computer-assisted TKA, and patient-specific guides reflect advancements designed to improve the outcomes of TKA by reducing surgeon error, and by facilitating precise and accurate component positioning in TKA [24,25].

The limitations of this study include the retrospective design, different implant models used in the study groups, and the overall lack of randomization. An ideal control group would have consisted of the same TKA design implanted with conventional instruments. Even so, our data suggest that patient-specific guides may be helpful in assuring accurate limb alignment during TKA. This is a significant advantage since precise extremity alignment is considered a valid short-term proxy for the long-term durability and function of TKA. Other potential benefits associated with the use of PSI-guides relate to a potentially lower risk of periprosthetic infection, operating room efficiency, improved health economics and less blood loss. If future studies can validate these advantages, then PSI-guided TKA may reflect the modern standard of surgical care in knee arthroplasties.

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