Radiographic Results of an Accelerometer-based, Handheld Surgical Navigation System for the Tibial Resection in Total Knee Arthroplasty

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abstract

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In total knee arthroplasty (TKA), intramedullary and extramedullary tibial alignment guides are not proven to be highly accurate in obtaining alignment perpendicular to the mechanical axis in the coronal plane. The objective of this study was to determine the accuracy of an accelerometer-based, handheld surgical navigation system in obtaining a postoperative tibial component alignment within 2° of the intraoperative goal in both the coronal and sagittal planes. A total of 151 TKAs were performed by 2 surgeons using a handheld surgical navigation system to perform the tibial resection. Postoperatively, standing anteroposterior hip-to-ankle radiographs and lateral knee-to-ankle radiographs were performed to determine the varus/valgus alignment and the posterior slope of the tibial components relative to the mechanical axis in both the coronal and sagittal planes. Findings showed that 95.3% of the tibial components were placed within 2° of the intraoperative goal in the coronal plane and 96.1% of the components were placed within 2° of the intraoperative goal in the sagittal plane. Overall, mean postoperative lower-extremity alignment was −0.3°±2.1°, with 97% of patients having an alignment within 3° of a neutral mechanical axis. The handheld surgical navigation system improves the accuracy of the tibial resection and subsequent tibial component alignment in TKA. It is able to combine the accuracy of computer-assisted surgery systems with the ease of use and familiarity of conventional, extramedullary alignment systems, and the ability to adjust both the coronal and sagittal alignments intraoperatively may prove clinically useful in TKA.

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Drs Nam, Cross, Deshmane, and Jerabek have no relevant financial relationships to disclose. Dr Kang is a consultant for, receives research support from, and has stock options in OrthAlign, Inc. Dr Mayman has stock options in OrthAlign, Inc.

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Figure: The KneeAlign system features a 2×4×2 inch display console that attaches to the front of an extramedullary tibial jig and provides real-time feedback of both the posterior slope and varus-valgus alignment of the tibial cutting block. (Image provided by OrthAlign Inc, Aliso Viejo, California.)
Although total knee arthroplasty (TKA) is a proven and tremendously successful treatment for degenerative joint disease, accurate component positioning remains a concern. Component malalignment has been associated with earlier implant failure. Mulhall et al\(^6\) performed a multicenter, prospective observational study to determine the mechanisms of failure in TKA and noted that 16% of revisions could be attributed directly to implant malalignment and failure mechanisms, such as instability, wear, and component loosening, can be hastened by implant malpositioning. Berend et al\(^2\) reported that tibial varus alignment >3° increased the odds of implant failure by approximately 17 times, emphasizing the importance of accurate tibial component positioning to the longevity of TKA.

Computer-assisted surgery improves the precision and accuracy of implant positioning in TKA compared with conventional intramedullary and extramedullary alignment guides.\(^3,6\) Pang et al\(^7\) reported that computer-assisted surgery was able to achieve a postoperative mechanical axis of <3° of varus-valgus in 94% of patients, whereas conventional alignment guides achieved the same accuracy in only 74% of patients. However, despite reported improvements in component positioning and postoperative alignment with the use of computer-assisted surgery systems, <3% of TKAs are performed using computer-assisted surgery in the United States. Increased operative time, increased cost, and the associated learning curve are all limitations that have prevented the widespread use of computer-assisted surgery.

Therefore, the majority of surgeons use either conventional intramedullary or extramedullary alignment guides for performing the tibial resection in TKA, but neither method is accurate in obtaining tibial component alignment perpendicular to the mechanical axis in the coronal plane. In a prospective randomized control trial of 135 TKAs, Reed et al\(^8\) demonstrated only 65% accuracy with the use of extramedullary guides versus 85% with the use of intramedullary guides in obtaining tibial component alignment of 90°±2° to the mechanical axis in the coronal plane.

Although some studies report intramedullary guides to be more accurate, other studies report the contrary; furthermore, intramedullary guides potentially increase the risk of pulmonary events in TKA.\(^9,10\) Therefore, the accuracy and precision of tibial component positioning in TKA must be improved, preferably without violating the intramedullary canal. Although most surgeons would agree that the sagittal alignment of the tibial component is also crucial to knee stability and component wear, the accuracy of conventional intramedullary and extramedullary guides to obtain a specific posterior slope relative to the mechanical axis in the sagittal plane has rarely been assessed.

The KneeAlign device (OrthAlign Inc, Aliso Viejo, California) is a Food and Drug Administration-approved, accelerometer-based, handheld surgical navigation system for performing tibial resection in TKA. It was designed to combine the accuracy of computer-assisted surgery with the familiarity of conventional extramedullary alignment systems, without the use of a large console for registration and alignment feedback, as is required with most computer-assisted surgery systems.

The purpose of this study was to determine the accuracy of the KneeAlign system in obtaining a postoperative tibial component alignment within 2° of the intraoperative goal in the coronal plane and a posterior slope within 2° of the intraoperative goal in the sagittal plane. We hypothesized that tibial component alignment would be more accurate and precise using the KneeAlign system compared with previously published studies using conventional intramedullary and extramedullary tibial alignment guides.

**Patient Population**

From February 2010 to the present, 123 patients (44 men and 79 women) were enrolled in this prospective study from 2 institutions. The study was approved by the Institutional Review Board. All patients underwent TKA by 2 surgeons. Twenty-one patients underwent bilateral TKAs, for a total of 151 knees (75 right and 76 left knees). Inclusion criteria for this study were patients with a history of osteoarthritis, rheumatoid arthritis, or posttraumatic arthritis who received a posterior-stabilized TKA. Patients were excluded if they had a proximal tibial defect requiring a metal or allograft augment or if they received a unicompartmental or patellofemoral arthroplasty. Mean patient age was 62.6±11 years, and mean body mass index was 31.1±6.2 kg/m\(^2\).

Preoperatively, standing anteroposterior or hip-to-ankle radiographs were obtained for each patient, from which the lower-extremity mechanical and tibiofemoral anatomic axes were measured. Positive values represented a varus alignment, and negative values represented a valgus alignment. Standing lateral radiographs with the knee in approximately 45° of flexion were obtained to determine the native posterior slope of the tibia relative to the anatomic axis, with a positive value representing a posterior slope of the proximal tibia.

All patients received a posterior-stabilized TKA using the KneeAlign system to perform the tibial resection. One hundred six TKAs were performed by one of the senior authors (D.J.M.) using the PiGalileo Navigation system (Smith & Nephew, Memphis, Tennessee) to make the femoral cuts, with implantation of a Genesis II prosthesis (Smith & Nephew). Forty-five TKAs were performed by the other senior author (M.N.K.) using a conventional intramedullary guide to complete the femoral resection, with implantation of a Gender Solutions Flex

**Materials and Methods**

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prosthesis (Zimmer, Warsaw, Indiana) in 39 knees, LPS-Flex prosthesis (Zimmer) in 5 knees, and a constrained condylar prosthesis (Zimmer) in 1 knee.

Surgical Technique

The KneeAlign system is a handheld, accelerometer-based surgical navigation system (Figure 1) consisting of a KneeAlign display console that is 2 × 4 × 2 inches in size (Figure 2), reference sensor, and KneeAlign tibial jig. The KneeAlign display console and reference sensor each contain triaxial accelerometers and communicate wirelessly with each other.

The KneeAlign tibial jig has 2 primary components that are articulated relative to each other. The fixed component is pinned to the tibia, and the mobile component guides the tibial cutting block. During the procedure, the KneeAlign display console is attached to the mobile component to guide the angle of the cutting block, and the reference sensor is attached to the fixed component to compensate for movement of the tibia.

The first step in using the KneeAlign is to pin the fixed component of the system to the tibia. The fixed component is a rod that has a removable proximal aiming arm that aligns it with the footprint of the anterior cruciate ligament (Figure 3). Two headless pins are used to secure the proximal aspect of the fixed component to the proximal tibia. Distally, the rod is secured to the tibia using a spring that wraps around the distal tibia. Aligning the fixed component rod with the tibial crest (as with conventional extramedullary alignment systems) is not required. The functions of the fixed component are to act as a reference for the proximal mechanical axis point and to account for tibial movement while aligning the tibial cutting block (which is attached to the mobile component).

The distal mechanical axis point is approximated by weighted interpolation between the apexes of the medial and lateral malleoli, which are landmarked using the mobile component of the KneeAlign tibial jig. The mobile component articulates proximally with the fixed component. After registration is complete, the system is able to establish the orientation of the mobile component and tibial cutting block by using the differential between the outputs of the accelerometers between the mobile and fixed components of the tibial jig.

The KneeAlign display console provides real-time feedback of the alignment of the cutting block relative to the mechanical axis in both the coronal and sagittal planes. Thus, the surgeon is able to assess the alignment of the cutting block prior to fixing its position on the proximal tibia. The cutting block is fixed to the proximal tibia using 2 pins, as with standard extramedullary alignment systems (Figure 4). The KneeAlign system does not require the use of a large console for registration and alignment feedback, and it is compatible with any TKA system, as it is solely used for performing the tibial resection.

Radiographic Measurements

At each patient’s first postoperative clinic visit, standing anteroposterior (AP) hip-to-ankle radiographs were obtained, and the lower-extremity mechanical axis and tibial component varus-valgus alignment were digitally measured (PACS imaging system; Philips Medical Systems,
Sectra Imtec AB, Linkoping, Sweden). The lower-extremity mechanical axis was defined as the angle formed between one line drawn from the center of the femoral head to the central and most distal point of the intercondylar notch of the femur, and a second line drawn between the center of the tibial plateau and the center of the tibial plafond.

Tibial component varus/valgus alignment was determined using a previously published and validated method. First, a line was drawn from the most medial point to the most lateral point of the subchondral surface of the talus, and the midpoint of this line was marked. Next, a second line was drawn from the most medial point to the most lateral point of the tibial plateau underlying the tibial tray, and the midpoint of this line was marked. A line connecting the 2 previously found midpoints represented the tibial mechanical axis in the coronal plane.

Then, a line tangential to the tibial baseplate was drawn by connecting the most inferior aspects of the tibial tray on the medial and lateral sides. The angle between the tibial mechanical axis and the tangential line under the tibial tray formed the mechanical varus/valgus alignment angle of the tibial component (Figure 5). For convention, the difference between the measured angle and 90° was recorded, with negative values representing valgus alignment (ie, −0.5° represents a tibial component in 0.5° of valgus relative to the mechanical axis).

In addition, standing, lateral, knee-toankle radiographs were obtained for 129 knees to measure the posterior slope of the tibial component relative to the mechanical axis of the tibia in the sagittal plane. These lateral radiographs were performed with the knee in approximately 45° of flexion, and the ankle was included to determine the mechanical axis of the tibia in the sagittal plane using a previously published technique. First, a line was drawn from the most anterior point to the most posterior point of the articulating surface of the tibial plafond; the midpoint of this line was marked.

Next, a second line was drawn from the most anterior point to the most posterior point of the tibial plateau underlying the tibial tray and the midpoint of this line was marked. A line connecting the 2 previously found midpoints represented the tibial mechanical axis in the sagittal plane. A line tangential to the undersurface of the tibial baseplate was drawn by connecting the most inferior points of the tibial tray, anterior and posterior to the mechanical axis. The angle between the tibial mechanical axis and the tangential line beneath the tibial tray was measured as the posterior slope of the tibial component (Figure 6). For convention, the difference between the measured angle and 90° was recorded as the posterior slope, with a negative value representing an anterior slope to the tibial component. All postoperative radiographic measurements, both on AP and lateral radiographs, were independently measured by 2 observers, and the results were assessed for inter-rater reliability.

To assess the accuracy of the KneeAlign system in obtaining a specific intraoperative goal for both varus/valgus alignment and posterior slope, the difference between the intraoperative reading of the cutting block’s alignment prior to performing the tibial resection was com-
All data were collected and analyzed using Microsoft Excel software (Microsoft Corp, Redmond, Washington).

RESULTS

Lower-Extremity Mechanical Alignment
Mean (± standard deviation) preoperative lower-extremity mechanical alignment was 7.6°±3.7° for knees with a varus alignment and 8°±4.9° for knees with a valgus alignment as measured on full-length, AP hip-to-ankle radiographs. Postoperatively, mean lower-extremity mechanical alignment was −0.3°±2.4° in knees with a preoperative varus deformity and −0.4°±1° in knees with a preoperative valgus deformity. Overall, mean postoperative lower-extremity alignment was −0.3°±2.1°, with 97% of patients having an alignment within 3° of a neutral mechanical axis.

Projected Versus Actual Tibial Component Alignment
Postoperatively, overall mean radiographic varus/valgus alignment of the tibial components was −0.6°±0.9°, or 0.6° of valgus. Intraoperatively, the average reading provided by the KneeAlign system for the varus/valgus alignment of the tibial cutting block, prior to performing tibial resection, was −0.04°±0.3°, or −0.04° of valgus. Mean absolute difference between the intraoperative reading provided by the KneeAlign system and the actual postoperative tibial component alignment measured on radiographs was 0.9°±0.8° for each TKA, with 95.3% of the implants positioned within 2° and 100% within 3° of the intraoperative reading (Table). Postoperatively, mean posterior slope of the tibial component was 3.0°±1.1° relative to the mechanical axis in the sagittal plane. Six components were positioned outside the range of 3°±2°, and thus 95.3% of the tibial components were within 3°±2° of posterior slope relative to the mechanical axis of the tibia.

Interobserver Correlation
The interclass correlation coefficient for measurement of the postoperative tibial component varus/valgus alignment was excellent (0.93), as was the interclass correlation coefficient for measurement of the lower-extremity mechanical axis (0.96). The interclass correlation coefficient for measurement of the posterior slope relative to the mechanical axis was good (0.82).

DISCUSSION

Total knee arthroplasty is one of the most successful operations in orthopedic surgery, with excellent clinical results for patients with degenerative joint disease. Concerns regarding component malpositioning remain, because implant survival has been shown to be dependent on precise component placement. In a review of 212 revision TKAs, Sharkey et al13 noted component malposition to be present in 11.8% of revisions. With regard to tibial component failure mechanisms, Berend et al2 found the most common reason for tib-
Table

Comparison of Intraoperative Readings of the KneeAlign System Before Tibial Resection With Postoperative Radiographic Measurements

<table>
<thead>
<tr>
<th>Alignment</th>
<th>Varus/Valgus</th>
<th>Posterior Slope</th>
</tr>
</thead>
<tbody>
<tr>
<td>KneeAlign intraoperative reading</td>
<td>$-0.04^\circ \pm 0.3^\circ$</td>
<td>$3.3^\circ \pm 0.7^\circ$</td>
</tr>
<tr>
<td>Mean absolute difference between intraoperative reading and postoperative measurement</td>
<td>$-0.9^\circ \pm 0.8^\circ$</td>
<td>$0.09^\circ \pm 0.7^\circ$</td>
</tr>
<tr>
<td>Percentage of tibial components within $2^\circ$ of intraoperative reading</td>
<td>95.3%</td>
<td>96.1%</td>
</tr>
</tbody>
</table>

When comparing the intraoperative varus/valgus alignment recorded from the KneeAlign display prior to the tibial resection to the alignment that was measured on postoperative radiographs, the KneeAlign was remarkably accurate, with 95.3% of the tibial components aligned within $2^\circ$ and 98.7% aligned within $3^\circ$ of the target alignment. These results more accurately represent the effectiveness and utility of the KneeAlign system as opposed to focusing on the 93.3% of tibial components placed within $2^\circ$ of perpendicular to the mechanical axis. There were several cases in which the planned alignment was not directly perpendicular to the mechanical axis. Similarly, 96.1% of the implants were aligned within $2^\circ$ and 100% within $3^\circ$ of the intraoperative goal for posterior slope indicated by the KneeAlign display console.

Thus, the KneeAlign system improves the accuracy of tibial component placement in both the coronal and sagittal planes compared with prior studies assessing the use of intramedullary and extramedullary alignment systems. In addition, it allows surgeons to accurately adjust the alignment of the tibial resection intraoperatively in both the coronal and sagittal planes, without using a large computer surgery console or violating the intramedullary canal.

Although the results of this study are encouraging, there are several limitations to this study. First, this study presents a series of patients who were treated by 2 surgeons and does not possess a control group of patients who were treated with either intramedullary or extramedullary alignment systems with which these results could be compared. Second, no data are presented with regard to the learning curve required to use the device. However, in a separate study, 4 surgeons used the KneeAlign system on 5 cadaveric specimens, and each surgeon was able to accurately use the device in $<5$ minutes by the final specimen. The device’s similarity to conventional extramedullary align-

Posterior slope

The AP location of tibiofemoral contact.\textsuperscript{24-27}

In one of the few studies assessing postoperative posterior slope alignment with the use of conventional alignment methods, Han et al\textsuperscript{18} used an intramedullary rod extending to the distal metaphysis of the tibia for alignment of the tibial cutting block. They found no incidence of anterior slope and $<3^\circ$ of variation in posterior slope in 31 TKAs measured on postoperative computed tomography (CT) scans.

Surgeons performing TKA preoperatively plan for precise and accurate bony resections, with the goal of achieving acceptable postoperative component position and mechanical alignment. Unfortunately, the execution of the surgical plan often is limited by the inaccuracy of contemporary extramedullary and intramedullary cutting guides. An instrument that could enhance a surgeon’s ability to achieve those goals could prove to be tremendously useful. The KneeAlign system is a handheld, accelerometer-based surgical navigation system for performing tibial resection in TKA that attempts to combine the accuracy of computer-assisted surgery systems with the convenience of conventional extramedullary alignment systems.

This article presents the experience of 2 surgeons who used the KneeAlign system in 151 TKAs, and the radiographic results achieved are encouraging.
ment systems contributes to its ease of use, which will limit the learning curve associated with the use of large console computer-assisted surgery systems.

In addition, although standing AP hip-to-ankle and lateral knee-to-ankle radiographs were used to measure tibial component alignment relative to the mechanical axis in both the coronal and sagittal planes, it could be argued that CT may more accurately determine tibial component position. However, CT has disadvantages, because it subjects patients to increased doses of radiation, it is costly, interpretation is subject to artifact around the implant, and it is not used for routine follow-up in the clinical setting. The radiographic analysis performed in the current study used acceptable axes that reproducibly depict the alignment of the tibial components in both the coronal and sagittal planes, as demonstrated by the good to excellent interobserver correlation coefficients seen in all of the radiographic measurements.

The KneeAlign system improves the accuracy of tibial resection and subsequent tibial component alignment in TKA. It is able to combine the accuracy of computer-assisted surgery systems with the ease of use and familiarity of conventional, extramedullary alignment systems, and the ability to adjust both the coronal and sagittal alignments intraoperatively may prove clinically useful in TKA.

REFERENCES