Radiographic Analysis of a Hand-Held Surgical Navigation System for Tibial Resection in Total Knee Arthroplasty

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Abstract: Tibial intramedullary or extramedullary alignment guides have not been shown to be highly accurate in performing the tibial resection in total knee arthroplasty (TKA). Since May 2010, a total of 42 knees underwent a TKA using a hand-held, accelerometer-based surgical navigation system for performing the tibial resection (KneeAlign; OrthAlign Inc, Aliso Viejo, Calif). Postoperative standing anteroposterior hip-to-ankle and lateral knee-to-ankle radiographs demonstrated that 97.6% of the tibial components were placed within 90° ± 2° to the mechanical axis in the coronal plane, and 96.2% of the components were placed within 3° ± 2° to the mechanical axis in the sagittal plane. The KneeAlign greatly improves the accuracy of tibial component alignment in TKA. Keywords: knee, arthroplasty, navigation, tibial alignment, computer-assisted surgery.

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Total knee arthroplasty (TKA) has been tremendously successful in relieving pain and restoring function related to degenerative joint disease; however, TKA implants do fail. Implant survival is dependent on precise component placement. Concern still exists regarding the accuracy and precision of the tibial resection. Tibial component malalignment has been associated with increased implant failure. Berend et al [1] reviewed 3152 TKAs performed for osteoarthritis and noted that 1.3% of the tibial components were revised at an average of 4.2 years. The most common reason for tibial component revision was medial bone collapse, which was associated with varus tibial component alignment more than 3°, a body mass index greater than 33.7, and overall postoperative varus alignment [1]. In addition, tibial varus alignment of greater than 3° increased the odds of implant failure by roughly 17 times.

Although intramedullary (IM) alignment guides have become the most common method for performing the femoral resection in TKA, controversy remains regarding the accuracy and clinical safety of using tibial IM vs extramedullary (EM) alignment guides for the tibial resection. Numerous studies have demonstrated contradictory results regarding the accuracy of tibial IM vs EM alignment guides in obtaining a 90° resection relative to the mechanical axis [1-13]. Ultimately, neither tibial alignment method has proven to be highly accurate, as Dennis et al [2] demonstrated only 72% accuracy with the use of IM guides vs 88% with EM guides, in obtaining a tibial component alignment 90° ± 2° to the mechanical axis. In addition, the use of tibial IM guides may theoretically increase the incidence of fat emboli syndrome and pulmonary complications after TKA [2].

The KneeAlign device (OrthAlign Inc, Aliso Viejo, Calif) is a Food and Drug Administration–approved,
palm-sized, hand-held surgical navigation system for tibial alignment, which works similarly to conventional EM alignment systems but does not require the use of a large console for registration and alignment feedback as is required in most CAS systems. The purpose of this study is to determine the accuracy of obtaining a postoperative tibial component alignment 90° ± 2° to the mechanical axis in the coronal plane and a posterior slope of 3° ± 2° to the mechanical axis in the sagittal plane with the use of the KneeAlign system. Our hypothesis is that tibial component alignment when using the KneeAlign system will both be more accurate and precise when compared to previously published studies using conventional tibial IM and EM alignment guides. To our knowledge, this is the first report of a hand-held, surgical navigation system used for performing the tibial resection in TKA.

**Materials and Methods**

From May 2010 to the present, 32 consecutive patients (10 men and 22 women) were prospectively enrolled in this study as part of an institutional review board-approved arthroplasty registry at a single institution. All patients received a TKA from the same surgeon, with 10 patients receiving bilateral TKAs, for a total of 42 knees (21, right and 21, left). Patients were included in this study if they had a history of osteoarthritis, rheumatoid arthritis, or posttraumatic arthritis; received a posterior-stabilized TKA; and received a preoperative standing anteroposterior (AP) hip-to-ankle radiograph. Patients were excluded if they had a proximal tibial defect requiring a metal or allograft augment or those receiving a unicondylar arthroplasty. Included patients had a mean age of 61.3 ± 10.6 years, and a mean body mass index of 30.7 ± 6.1 kg/m². Thirty patients had a preoperative diagnosis of osteoarthritis, 1 patient had a prior TKA and underwent revision to a constrained condylar knee for instability, and 1 patient underwent conversion of a medial unicondylar knee arthroplasty to a TKA due to progression of lateral compartment osteoarthritis.

Preoperatively, standing AP hip-to-ankle radiographs were obtained for each patient, from which the lower extremity mechanical and tibiofemoral anatomical axes were measured. For convention, positive values represented a varus alignment, whereas negative values represented a valgus alignment. Thirty-four knees had a preoperative varus deformity, whereas 8 knees had a preoperative valgus deformity. In addition, the native posterior slope was measured from standing lateral knee radiographs.

Each patient received a posterior cruciate ligament substituting TKA using the PiGalileo Navigation system (Smith and Nephew, Memphis, TN) to perform the femoral resection and the KneeAlign system to perform the tibial resection. The KneeAlign system is a hand-held, disposable, accelerometer-based surgical navigation unit, 2 × 4 × 2 in. It is attached to an EM tibial jig, similar to conventional EM alignment systems (Fig. 1). The entire system is provisionally secured to the tibia using a spring placed around the leg and is fixed to the proximal aspect of the tibia using 2-headed pins. Before fixing the system proximally, an aiming arm is used to align the top of the device with the anterior cruciate ligament footprint and the medial one third of the tibial tubercle. Distally, a footplate connected to the tibial jig is used to keep the EM jig a set distance off of the tibial surface. A gyrometer within the navigation unit is then able to calculate the posterior slope of the tibial jig. Subsequent anatomical landmarkings of both the lateral and medial malleoli are performed using the distal aspect of the EM jig to establish the tibia’s mechanical axis. Similarly, the gyrometer within the navigation unit is able to calculate the varus or valgus alignment of the tibial jig relative to the tibia’s established mechanical axis. Once anatomical registration has been performed, the tibial cutting block is placed at the proximal aspect of the device, and real-time feedback is provided by the navigation unit to the surgeon, who is then able to set the cutting block’s varus/valgus and posterior slope alignment before performing the tibial resection (Fig. 2).

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**Fig. 1.** Image of the KneeAlign system. The 2 × 4 × 2 in navigation console is attached to the front of an EM 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, Calif).
The KneeAlign system does not require the use of a large-console for registration and alignment feedback, which is required in most CAS systems. In addition, the KneeAlign system is compatible with any TKA system, as only the KneeAlign tibial jig and hand-held console are required to use the device, and no other equipment is vendor specific. Before performing the tibial resection, the orientation of the tibial cutting block (varus/valgus, posterior slope) was recorded based on the information provided by the KneeAlign system. As the purpose of this study was to assess the accuracy of the KneeAlign system, in each respective surgery, only 1 tibial resection was made, and recutting of the tibia or alterations in the cut surface were not performed.

At the 6-week postoperative clinic visit, standing AP hip-to-ankle radiographs were obtained, from which the lower extremity mechanical axis, tibiofemoral anatomical axis, and tibial component varus/valgus alignment were digitally measured (Picture Archiving and Communication System imaging system; Philips Medical Systems, Sectra Imtec AB, Sweden). Tibial component varus/valgus alignment was determined in the following manner. First, a line was drawn from the most medial point to the most lateral point of the tibial plateau underlying the tibial tray. Again, the midpoint of this line was marked. A line connecting the 2 previously found midpoints represented the tibial mechanical axis in the coronal plane. The most inferior aspects of the tibial tray, both medial and lateral to the mechanical axis, were then marked, and a line was drawn connecting these 2 points. The angle between the tibial mechanical axis and the tangential line under the tibial tray formed the mechanical varus/valgus alignment of the tibial component (Fig. 3). 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, 27 knees received standing lateral knee-to-ankle radiographs to measure the mechanical posterior slope of the tibial component. These lateral radiographs were performed with the knee in

![Fig. 2. Image showing the face of the KneeAlign navigation console, which provides the surgeon with real-time feedback as to the alignment of the tibial cutting block before performing the tibial resection (image provided by OrthAlign Inc, Aliso Viejo, Calif).](image)

![Fig. 3. Anteroposterior radiograph demonstrating measurement of the tibial component varus/valgus alignment. Points delineating the most medial aspects of the medial and lateral subchondral talus and tibial plateau (used to determine the mechanical axis) have been removed. This component was measured to be in 0.4° of valgus.](image)
approximately 45° of flexion, and the ankle was included to determine the true mechanical axis of the tibia in the sagittal plane. The mechanical axis in the sagittal plane was determined in the following manner. 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 then 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. Again, the midpoint of this line was marked. A line connecting the 2 previously found midpoints represented the tibial mechanical axis in the sagittal plane. The most inferior aspects of the tibial tray, both anterior and posterior to the mechanical axis, were then marked, and a line was drawn connecting these 2 points. The angle between the tibial mechanical axis and the tangential line under the tibial tray was measured as the posterior slope of the tibial component (Fig. 4). 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 separately measured by 2 observers independently, and the results were assessed for interrater reliability.

The difference between the intraoperative reading of the tibial varus/valgus alignment and posterior slope provided by the KneeAlign system was compared to the radiographic measurements obtained postoperatively for each respective case. In addition, the overall accuracy of obtaining a tibial component alignment of 90° ± 2° to the mechanical axis in the coronal plane and posterior slope of 3° ± 2° to the mechanical axis in the sagittal plane was calculated.

Statistical Methods

Interclass correlation coefficients for postoperative radiographic measurements were graded using previously described semiquantitative criteria: excellent for .9 < P < 1.0, good for .7 < P < .89, fair/moderate for .5 < P < .69, low for .25 < P < .49, and poor for .0 < P < .24 [18]. All data were collected and analyzed using Microsoft Excel software (Microsoft Corporation, Redmond, WA).

Results

Preoperatively, the mean lower extremity mechanical alignment for knees with varus malalignment was 7.4° ± 3.9° (mean ± SD), and the average mechanical alignment for knees with valgus malalignment was −8.3° ± 5.1°, as measured on full-length AP hip-to-ankle radiographs. Correspondingly, the average preoperative tibiofemoral anatomical alignment for varus knees was 2.0° ± 4.3°, and the preoperative anatomical alignment for valgus knees was −13.4° ± 5.7°, as measured on AP knee radiographs. Postoperatively, the average lower extremity mechanical alignment was −0.9° ± 3.1° in those with a preoperative varus deformity and −0.6° ± 1.1° in those with a preoperative valgus deformity.

Intraoperatively, the average reading provided by the KneeAlign system with regard to varus/valgus alignment before performing the tibial resection was 0.06° ± 0.2° or 0.06° of varus relative to the mechanical axis. The average postoperative radiographic alignment of the tibial component was −0.6° ± 0.9° or 0.6° of valgus. Of the 42 TKAs included in this study, only 1 tibial component was placed in greater than 2° of varus/valgus alignment relative to the mechanical axis, as it was measured to be in 2.6° of valgus. Therefore, 97.6% of the tibial components were placed 90° ± 2° to the mechanical axis, and 100% of the components were placed 90° ± 3° to the mechanical axis. The average tibial component alignment postoperatively in the knees with a preoperative varus deformity was −0.7° ± 0.9°, with 97.1% aligned 90° ± 2° to the mechanical axis, whereas the average tibial component alignment postoperatively in the knees with a preoperative valgus deformity was −0.4° ± 0.8°, with 100.0% within 90° ± 2° to the mechanical axis (Table 1).
Valgus alignment of the lower extremity mechanical axis was 0.64. The interclass correlation coefficient for measurement of the posterior slope relative to the alignment was good, with a value of 0.89, whereas of the postoperative tibial component varus/valgus alignment was recorded. 92.6% of the implants being positioned within 2° of the slope, the mean absolute difference was 1.0° ± 0.7°, with 95.2% of the implants being positioned within 2° of the intraoperative alignment recorded.

Preoperatively, the mean posterior slope relative to the tibial anatomical axis was 9.5° ± 3.6° for all knees included in the study. Postoperatively, using a lateral knee-to-ankle standing radiograph to obtain the mechanical axis, the mean posterior slope was 2.9° ± 1.4° for the 27 tibial components in which the mechanical posterior slope was measured. Only 1 tibial component was not positioned within the range of 3° ± 2°, and thus, 96.2% of the tibial components measured were within 3° ± 2° of posterior slope relative to the mechanical axis of the tibia. With regard to the accuracy between the intraoperative reading provided by the KneeAlign system and the postoperative tibial component coronal alignment, the mean absolute difference was 0.9° ± 0.6°, with 95.2% of the implants being positioned within 2° of the intraoperative alignment recorded.

The interclass correlation coefficient for measurement of the postoperative tibial component varus/valgus alignment was good, with a value of 0.89, whereas measurement of the posterior slope relative to the mechanical axis was fair/moderate, with a value of 0.64. The interclass correlation coefficient for measurement of the lower extremity mechanical axis was excellent, with a value of 0.96.

### Table 1. Comparison of the Preoperative and Postoperative Lower Extremity Mechanical Alignments, in Addition to the Tibial Component Positioning, for Both the Preoperative Varus and Valgus Knees

<table>
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<th>Preoperative Defor-</th>
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<th>Postoperative</th>
<th>Postoperative</th>
<th>Tibial Component,</th>
<th>Percent of Tibial Component, 90° ± 2° to</th>
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<td>Deformity</td>
<td>Mechanical Alignment</td>
<td>Mechanical Alignment</td>
<td>Mechanical Alignment</td>
<td>Mechanical Axis</td>
<td>Mechanical Alignment</td>
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<tr>
<td>Varus</td>
<td>7.4 ± 3.9°</td>
<td>−0.9° ± 3.1°</td>
<td>−0.7° ± 0.9°</td>
<td>97.1%</td>
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<tr>
<td>Valgus</td>
<td>−8.3 ± 5.1°</td>
<td>−0.6° ± 1.1°</td>
<td>−0.4° ± 0.8°</td>
<td>100.0%</td>
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Note that negative values correspond to a valgus alignment.

regard to the accuracy between the intraoperative reading provided by the KneeAlign system and the postoperative tibial component coronal alignment, the mean absolute difference was 0.9° ± 0.6°, with 95.2% of the implants being positioned within 2° of the intraoperative alignment recorded. Preoperatively, the mean posterior slope relative to the tibial anatomical axis was 9.5° ± 3.6° for all knees included in the study. Postoperatively, using a lateral knee-to-ankle standing radiograph to obtain the mechanical axis, the mean posterior slope was 2.9° ± 1.4° for the 27 tibial components in which the mechanical posterior slope was measured. Only 1 tibial component was not positioned within the range of 3° ± 2°, and thus, 96.2% of the tibial components measured were within 3° ± 2° of posterior slope relative to the mechanical axis of the tibia. With regard to the accuracy between the intraoperative reading provided by the KneeAlign system and the postoperative tibial component posterior slope, the mean absolute difference was 1.0° ± 0.7°, with 92.6% of the implants being positioned within 2° of the intraoperative alignment recorded.

The interclass correlation coefficient for measurement of the postoperative tibial component varus/valgus alignment was good, with a value of 0.89, whereas measurement of the posterior slope relative to the mechanical axis was fair/moderate, with a value of 0.64. The interclass correlation coefficient for measurement of the lower extremity mechanical axis was excellent, with a value of 0.96.

### Discussion

Although TKA has been shown to have a high long-term success rate, concerns still exist regarding component alignment and malposition, as they are believed to be risk factors for aseptic failure. Sharkey et al [19] performed a retrospective review of 212 revision surgeries performed after primary TKAs and noted component malalignment or malposition to be present in 11.8% of revisions, leading to both early (<2 years from the index procedure) and late (>2 years from the index procedure) failures. In addition, Berend et al, in a review of 3512 TKAs, noted that tibial varus malalignment of greater than 3° increased the odds of implant failure by roughly 17 times [1]. With an aging patient population and increasing prevalence of TKAs, the projected increase in the rate of revision surgery for TKA has been estimated to be 412% by the year 2030, and thus, methods of improving the accuracy of component positioning may prove crucial in helping to decrease this future revision burden [20].

Tibial component alignment in TKA is dictated by the orientation of the proximal tibial resection. Both IM and EM alignment guides have been used in the past with the goal of obtaining a tibial cut 90° to the mechanical axis in the coronal plane and 3° of posterior slope in the sagittal plane (for most posterior cruciate ligament-substituting implant systems). Although numerous studies have assessed the relative accuracy of tibial IM vs EM alignment guides in obtaining a tibial resection 90° to the mechanical axis in the coronal plane, little consensus exists regarding the superiority of one method over the other [2,3,5,8,14,21-24]. Brys et al [3] analyzed 52 primary TKAs performed using an IM tibial alignment system vs 62 TKAs performed using an EM tibial system and reported that 94% of the tibial components were within 90° ± 2° in the IM group vs 85% in the EM group, thus concluding that IM guides were superior. In contrast, Dennis et al [2] analyzed 60 TKAs performed using tibial IM alignment guides vs 60 TKAs performed using EM tibial alignment guides and found that, although there was no significant difference in the average postoperative alignment between both groups, only 72% of the tibial components in the IM group were aligned within 90° ± 2° vs 88% of the EM group, thus concluding that a wider range of error is encountered with the use of tibial IM guides. Interestingly, Simmons et al [8] assessed the accuracy of tibial IM alignment guides by comparing the radiographic results of 30 varus knees vs 30 valgus knees undergoing TKA. In this study, neutral alignment was achieved in 83% of the varus knees but only 37% of the valgus knees, with malalignment up to 5° being seen in patients with a preoperative valgus deformity. Therefore, a review of the literature demonstrates no clear superiority of either tibial IM or EM alignment guides with respect to mechanical alignment, whereas IM guides may also pose an increased risk of pulmonary events [25,26]. However, what does become evident is that there is clearly room for improvement, particularly in the presence of significant tibial deformities.

Numerous studies have demonstrated an improved accuracy and precision with the use of CAS techniques. In addition, supporters of computer-assisted TKA also point toward the advantage of immediate intraoperative feedback and a reduction in outliers in obese patients or...
patients with extra-articular deformities, for which conventional techniques may be inadequate [15]. Pang et al [16] compared the mechanical knee alignments in CAS vs conventional EM tibial and IM femoral alignment systems, with 35 TKAs in each group, and noted that 94% of the CAS and only 74% of the conventional TKAs obtained a postoperative mechanical axis of less than 3° of varus/valgus [14]. In addition, Mason et al [27] performed a meta-analysis of studies performed between 1990 and 2007 comparing the alignment outcomes of CAS vs conventional TKA and noted that mechanical axis malalignment of greater than 3° occurred in 9.0% of CAS procedures vs 31.8% of conventional TKAs, with CAS tibial slope also showing a statistically significant improvement vs conventional TKA. However, despite studies documenting improved alignment with CAS in TKA, concerns regarding increased operative time, increased cost, and the learning curve associated with conversion to CAS have limited its widespread acceptance.

The KneeAlign system is a hand-held, accelerometer-based surgical navigation system for performing the tibial resection in TKA, which is compatible with conventional EM alignment systems and does not require the use of large consoles for intraoperative feedback as with most CAS systems. This study presents the radiographic results of the first 42 TKAs performed using the KneeAlign system, and the results obtained are promising. The intraoperative measurement provided by the KneeAlign system proved to be accurate in predicting the postoperative tibial component alignment, as 95.2% of the implants in the coronal plane and 92.6% of the implants in the sagittal plane were within 2° of the intraoperative reading provided. As noted above, the average postoperative radiographic alignment of the tibial component was −0.6° ± 0.9° of valgus, with 97.6% of the tibial components being placed within 90° ± 2° to the mechanical axis and 100% of the components placed within 90° ± 3° to the mechanical axis. No significant difference was appreciated between knees with a preoperative varus deformity or a preoperative valgus deformity, as only 1 tibial component, overall, was placed outside 90° ± 2° to the mechanical axis. In addition, the posterior slope, as measured on lateral knee-to-ankle standing radiographs, was 2.9° ± 1.4° for the 27 tibial components in which these radiographs were available, with 96.2% of the components measured to be within 3° ± 2° of posterior slope relative to the mechanical axis. The importance of obtaining the appropriate posterior slope when performing a posterior cruciate–substituting TKA is crucial, as increasing the posterior slope can predispose the knee to flexion instability. However, the accuracy of obtaining a posterior slope of 3° has rarely been reported.

One concern with the implementation of any new technological device is the extra time the system adds to the overall procedure. Although the time required to use the KneeAlign system was not the primary focus of this study, it is worth noting that based on the surgeon’s experience, the time required to calibrate and position the KneeAlign is approximately 3 minutes. In addition, in a cadaveric pilot study using the KneeAlign system, 4 surgeons were asked to use the device on 5 separate specimens. By the fifth specimen, each surgeon was able to accurately position the device in less than 5 minutes. A second concern with the use of any new technological device is the possible associated financial costs required to use the system. Although the KneeAlign system does require an additional cost for its use when compared to conventional EM alignment systems, it does avoid the large capital expenditures required to both purchase and maintain a large console CAS system.

Based on this initial series of patients, the KneeAlign system improves the accuracy of tibial component placement when compared to studies assessing the use
of IM and EM alignment systems. In addition, the authors believe that the KneeAlign system will prove even more useful in patients possessing a significant tibial deformity, as superficial landmarks used in aligning an EM guide, such as the tibial crest, may be misleading (Fig. 5). However, although the results of this study are promising, it does possess several limitations. This study presents a series of patients who were treated by a single surgeon and does not possess a control group to which these patients are concurrently compared. In addition, no data are presented with regard to the learning curve required to use the device. However, anecdotally, because of its similarity with conventional EM guides, it is felt to be easy to use, in addition to minimally affecting the overall operative time. However, despite the aforementioned limitations, the present study is valuable, as it is the first study reporting the accuracy of a hand-held surgical navigation system for performing the tibial resection in TKA. Although further trials are necessary to formally assess the learning curve required to use the KneeAlign system and to compare the radiographic results to those who have had a TKA with conventional guides, it is felt that the use of this device will significantly improve tibial component alignment in TKA.

References