Cadaveric Analysis of an Accelerometer Based, Hand-held Navigation System for Distal Femoral Cutting Block Alignment in Total Knee Arthroplasty

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PURPOSE:
Concerns regarding implant malalignment in TKA still remain, as it has been shown to decrease component survivorship and increase the rate of revision surgery. The most commonly used method for distal femoral cutting block alignment is via an intramedullary (IM) guide, in which a cutting block is fixed to the distal femur at a specific angle relative to the IM rod. Most surgeons set the distal femoral resection angle to the same degree of valgus for all TKAs with a preoperative varus alignment (e.g. 6°), and to a different degree for all TKAs with a preoperative valgus alignment (e.g. 3°); the goal being to obtain a distal femoral resection perpendicular to the femoral mechanical axis. However, this method assumes no variation in the femoral mechanical-anatomical angle between patients, and relies on the assumption that the difference between the femoral mechanical and anatomic axes is approximately 6°. Unfortunately, numerous studies have demonstrated this to be inaccurate, and thus using a fixed resection angle for performing the distal femoral resection commonly fails to achieve a neutral resection. Although numerous studies have demonstrated statistically significant improvements in both overall mechanical alignment and femoral component positioning with CAS techniques, concerns over increased operative times, capital costs, and the associated learning curve have limited its widespread acceptance.

The KneeAlign2™ device (OrthAlign Inc., Aliso Viejo, CA) is an accelerometer based, hand-held surgical navigation system for performing the distal femoral resection in TKA (Figure 1). It does not require the use of a large-console for registration and alignment feedback as with most CAS systems. In addition, it relies on accelerometer-based navigation, versus CT-guided, image based, or imageless navigation technologies. The aim of this cadaveric study was to validate the accuracy of the KneeAlign2™ system in navigating distal femoral cutting block alignment in TKA. Our hypothesis is that the KneeAlign2™ system will align the distal femoral cutting block with the same accuracy as a predicate device, the Orthosoft Sesamoid CAS Navigation System (Zimmer Inc., Warsaw, IN).

Figure 1: Image of the KneeAlign2™ system (OrthAlign Inc., Aliso Viejo, CA)

MATERIALS & METHODS:
The KneeAlign 2™ system consists of a KneeAlign™ display console (2 x 4 x 2 inches in size), reference sensor, and femoral jig. The femoral jig is secured to the distal femoral condyles, at the approximate midpoint of the most distal point of the sulcus of the trochlea. The KneeAlign™ display console and reference sensor are attached to the jig, and the display console registers the cutting block’s initial position. Next, the hip center of rotation is registered by maneuvering the femur in a circular motion. The cutting block is set to the desired varus/valgus and flexion/extension angles, as the display console provides real-time feedback of its orientation relative to the hip center of rotation. Once in the desired alignment, the cutting block is secured to the anterior femur with two headless pins, after which the distal femoral resection is performed.
Five fresh-frozen cadaveric specimens (hip-to-toe lower extremities; 3 right, 2 left) were included in this study. Prior to each specimen, a specific target for the varus/valgus and flexion alignment of the distal femoral cutting block, relative to the mechanical axis of the femur was assigned (Table 1). The KneeAlign 2™ device was used to set the femoral cutting block to the target alignment for each specimen.

<table>
<thead>
<tr>
<th>SPECIMEN NUMBER</th>
<th>VARUS/VALGUS TARGET</th>
<th>FLEXION TARGET</th>
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<tbody>
<tr>
<td>1</td>
<td>0°</td>
<td>0°</td>
</tr>
<tr>
<td>2</td>
<td>-2°</td>
<td>2°</td>
</tr>
<tr>
<td>3</td>
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<tr>
<td>5</td>
<td>0°</td>
<td>5°</td>
</tr>
</tbody>
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Table 1: Target alignments for each cadaveric specimen. Negative value = valgus.

The Orthosoft CAS Navigation system is an imageless navigation system for TKA that requires an optical camera, computer display screen, femoral and tibial reference sensors, and registration pointer. For each specimen, the Orthosoft reference sensors were attached, and the hip center of rotation was registered. The Orthosoft CAS paddle and reference sensor were used to record the varus/valgus and flexion/extension alignment of the cutting block previously set by the KneeAlign 2™, by placing the Orthosoft paddle in the distal femoral cutting slot. The alignment of the cutting block, as determined by the Orthosoft CAS system was recorded.

For each cadaveric specimen, with the cutting block in place, the KneeAlign 2™ device was re-applied to again register the hip center of rotation and measure the cutting block’s alignment. Next, the Orthosoft system was re-calibrated to again determine the cutting block’s alignment. These steps were performed a minimum of five times for each specimen, and the mean absolute difference and standard deviation (± s.d.) between the preoperative target alignment, and the alignment reported by the Orthosoft CAS system was calculated, along with 95% confidence intervals for deviation from the target alignment.

RESULTS:
A total of 29 trials were performed. For varus/valgus alignment of the distal femoral cutting block, as navigated by the KneeAlign 2™ device and measured using the Orthosoft CAS system, the mean absolute difference between the preoperative target and the cutting block’s alignment was 0.83° + 0.60°. The 95% confidence interval of the mean absolute difference was 0.61° and 1.04°. For flexion/extension alignment, the mean absolute difference between the preoperative target and the cutting block’s alignment was 0.83° ± 0.83°. The 95% confidence interval of the mean absolute difference was between 0.53° and 1.13°.

DISCUSSION:
The aim of this study was to validate the performance and accuracy of the KneeAlign 2™ system in navigating alignment of the distal femoral cutting block in TKA. Our study protocol demonstrated that the KneeAlign 2™ can align and set the distal femoral cutting block with a high degree of accuracy, as measured using the Orthosoft CAS Navigation system. Based on this cadaveric study, the KneeAlign 2™ can accurately determine the hip center of rotation and femoral mechanical axis, and thus the authors feel that portable, accelerometer based navigation can reliably be used in total knee arthroplasty.

SIGNIFICANCE:
The accuracy of accelerometer based navigation for distal femoral alignment in total knee arthroplasty (TKA) has not been studied. Portable accelerometer-based navigation systems could improve postoperative mechanical alignment, and possibly replace large console, imageless navigation systems as the primary mode of computer-assisted surgery (CAS) in TKA.

REFERENCES: