The Journal of Arthroplasty 30 (2015) 1906–1910

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Accuracy of A Handheld Accelerometer-Based Navigation System for Femoral and Tibial Resection in Total Knee Arthroplasty

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ARTICLE INFO

Article history:
Received 18 September 2013
Accepted 15 May 2015

Keywords:
total knee arthroplasty
navigation
computer-assisted surgery
alignment
replacement

ABSTRACT

Restoration of mechanical axis in total knee arthroplasty (TKA) is correlated with improved implant survivorship. We assessed the accuracy and required surgical time using a hand-held accelerometer-based navigation system for TKA. Data collected on 53 patients included assembly, resection, and tourniquet times. Implant alignment and mechanical axis were measured on radiographs. Femoral alignment was 0.29° ± 2.2° varus. Tibial alignment was 0.09° ± 1.4° valgus. Postoperative mechanical axis was 0.2° ± 2.1° varus. Malalignment rates for the femur, tibia, and axis were 13%, 3.8%, and 17%, respectively. Average time for pinning and navigating was 3.6 minutes for the femur and 2.6 minutes for the tibia; mean tourniquet time was 62 minutes. This navigation system accurately re-established mechanical axis without increasing surgical time.

One of the primary technical goals of total knee arthroplasty (TKA) is to restore the mechanical axis of the lower extremity. Despite Parratte's work, variance beyond ±3° has been established as the surrogate for 'inadequate alignment', even though no firm limit has been defined clinically [1]. Failure to achieve acceptable femoral and tibial component alignment and consequent limb alignment, particularly in the coronal plane (varus/valgus), has been shown to compromise the long-term survival of TKA [2,3]. Specifically, malalignment of greater than 3° leads to off-axis loading, polyethylene wear, implant loosening, and increases the rate of revision by up to 24% [4–6].

Conventional mechanical alignment guides are currently the most commonly used method for performing the distal femoral and proximal tibial resection. However, significant errors in mechanical axis alignment of greater than 3° have been reported, ranging from 22% to 35% of TKAs [7,8]. The development of computer-assisted navigation systems (CAS) as an alternative to conventional instrumentation was meant to improve the accuracy of component positioning. Studies demonstrate that CAS has reduced the frequency of component malalignment to between 3% and 19% [9]. However, the use of CAS is associated with increased costs and longer procedure times. As a result the use of CAS has been estimated to be no more than 3% of TKA procedures. More recently, patient specific instrumentation (PSI) was developed in an attempt to increase surgical efficiency and to improve accuracy. Limited studies have demonstrated mixed results with a rate of alignment outliers from 9% to 20% [10,11]. The increased cost and requirement of preoperative cross-sectional imaging (MRI or CT) and fabrication of cutting guides have limited the adoption of this technology. New devices or techniques that can improve surgical accuracy compared to conventional mechanical instrumentation without disruptions in surgical efficiency or significantly increased costs may be of benefit. Handheld accelerometer-based navigation systems have been developed in an attempt to improve accuracy without compromising surgical efficiency or logistics. The purpose of this study was to evaluate the accuracy of a handheld navigation device used for distal femoral and proximal tibial bone resections in TKA. In this pilot study, our aim was to determine the (1) surgical time and (2) accuracy of alignment. We hypothesized that this device, in comparison to data in the literature, would require minimal additional surgical time and would be more accurate than conventional mechanical instruments.

Methods and Materials

This was an institutional review board-approved prospective, single-arm study of patients undergoing an elective primary TKA using a handheld navigation system for distal femoral and tibial resection and positioning. Exclusion criteria included ipsilateral deformity/below knee amputation, previous TKA or osteotomy, and hip pathology limiting range of motion. Fifty-six consecutive TKA utilizing the handheld navigation system were performed by 1 of 2 senior surgeons at one institution from October 2012 to July 2013. Three patients were excluded because of inadequate postoperative radiographs. The remaining 53 patients comprised the study population. The average age was 65

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to http://dx.doi.org/10.1016/j.arth.2015.05.055.

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http://dx.doi.org/10.1016/j.arth.2015.05.055
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years (range, 40–82 years), 58% were female, and the average BMI was 30.

The KneeAlign navigation system (OrthAlign, Aliso Viejo, CA) is 510(K) FDA-cleared palm-sized navigation unit intended for use in TKA to assist the surgeon with coronal (varus/valgus) and sagittal (posterior slope) component positioning. The navigation system is a handheld, accelerometer-based surgical navigation system consisting of a display console and reference sensor mounted on a jig. Details of the device and navigation have been previously described [12,13]. The tibial device has two primary components that are articulated relative to one another on an extramedullary style tibial jig (Fig. 1). The fixed component is pinned to the bone, while the mobile component guides the cutting block. During the procedure, the unit is attached to the mobile component of the tibial jig, with the reference sensor attached to the fixed component of the tibial jig in order for the system to compensate for movement of the leg. The femoral jig also has two primary components that articulate with each other (Fig. 2). The fixed component is stabilized to the distal femur, while the mobile component guides the cutting block with the reference sensor. The femoral jig is seated on the distal femoral condyle, centered with reference to the deepest point of the intercondylar notch and fixed to the distal femur with three 3.2 mm threaded pins. The initial cutting block position is registered, followed by the hip center of rotation through a series of motions. The coronal and sagittal planes can then be adjusted at the surgeon's discretion. The resection depth is not navigated but set by sliding the cutting block a measured distance relative to the femoral condyle as in conventional instrumentation systems.

Intraoperative data collection included navigation time (time between the device being handed to the surgeon and the cutting block being fixed to the bone) and tourniquet time. The target femoral coronal resection angle was 0° mechanical varus/valgus alignment. The target tibial coronal resection angle was 0° varus/valgus alignment. The target tibial slope was 3° posterior slope. The overall desired mechanical axis of the limb was 0° varus/valgus in all patients. Full length (51") anteroposterior hip to ankle and mediolateral radiographs were obtained on all patients at the first postoperative visit and reviewed utilizing a standardized protocol. Radiographic measurements for femoral component, tibial component, and mechanical alignment were performed by an independent outside musculoskeletal radiologist and by an orthopedic surgeon. By convention, all varus alignment measurements were assigned a negative value; valgus alignment measurements were assigned a positive value. Slope measurements were negative for anterior slope and positive for posterior slope. Interobserver reliability between the independent radiologist and the orthopedic surgeon was assessed by calculating Pearson correlation coefficients and interobserver correlation coefficients for all radiologic measurements. Means (including 95% confidence intervals) and frequencies were computed to summarize navigation time, tourniquet time, and radiographic results.

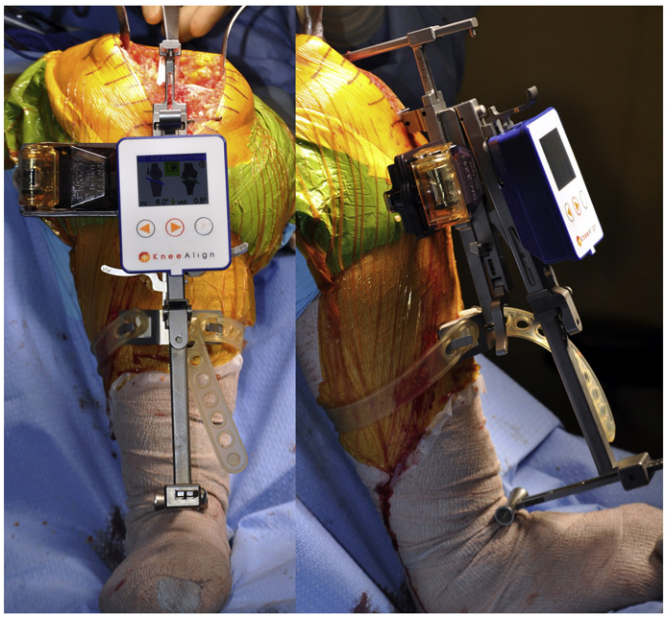

Fig. 1. KneeAlign navigation system tibial jig and assembly consisting of the fixed component pinned to the bone and the mobile component that guides the cutting block.

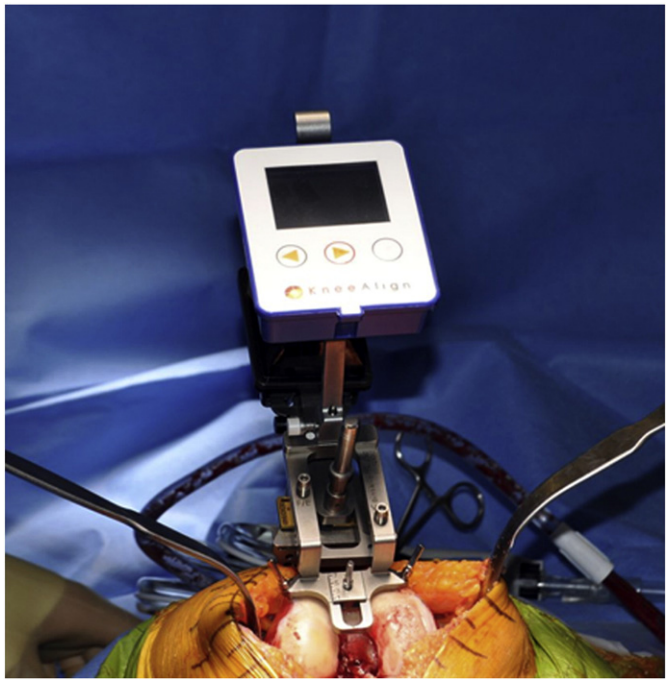

Fig. 2. KneeAlign navigation system femoral jig and assembly consisting of the fixed component stabilized to the distal femur and the mobile component, which guides the cutting block with the reference sensor.

Results

The average time for navigating and pinning the femoral cutting block was 3.6 minutes (95% confidence interval, 3.2–4.0). The average time for navigating and pinning the tibial cutting block was 2.6 minutes (95% confidence interval, 2.3–3.9). The average tourniquet time was 62 minutes (95% confidence interval, 58–67).

All correlation coefficients were above 85%, indicating a strong reliability between the independent radiologist and orthopedic surgeon for all radiographic measurements. Therefore, the measurements of both readers were averaged and used to calculate the means and frequency of outliers. The mean femoral coronal alignment was 0.8° ± 2.2° varus (range, 6.5° varus–3.8° valgus); 13% of the femoral components were placed in greater than 3° of coronal malalignment (Fig. 3). The mean tibial coronal alignment was 0.09° ± 1.4° varus (range, 3.5° varus–3.5° valgus); 3.8% of tibial components were placed in greater than 3° of coronal malalignment. The mean tibial slope was 3.3° ± 1.8° (range, 2.5°–7.0° flexion); 5.7% of tibial components were placed in greater than ± 3° of targeted tibial posterior slope (Fig. 4).The mean mechanical axis was 0.2° ± 2.1° valgus (range, 5.3° varus–5.3° valgus); 17% of knees had greater than 3° of coronal malalignment (Fig. 5).

Discussion

The purpose of this pilot study was to evaluate a novel, handheld accelerometer-based navigation device, KneeAlign, for use in TKA. We sought to determine if this device would lead to accurate femoral and