The Knee 21 (2014) 1225–1228

Contents lists available at ScienceDirect

The Knee

Accuracy of a hand-held surgical navigation system for tibial resection in total knee arthroplasty

William D. Bugbee [a,*], Arash Y. Kermanshahi [b], Michelle M. Munro [c], Julie C. McCauley [c], Steven N. Copp [a]

[a] Division of Orthopaedic Surgery, Scripps Clinic, La Jolla, CA, USA
[b] Kaiser Permanente, San Diego, CA, USA
[c] Shiley Center for Orthopaedic Research & Education at Scripps Clinic, La Jolla, CA, USA

ARTICLE INFO

Article history:
Received 9 February 2014
Received in revised form 15 July 2014
Accepted 17 September 2014

Keywords:
Total knee arthroplasty
Navigation
Tibial alignment
Computer-assisted surgery

ABSTRACT

Background: Accuracy of total knee arthroplasty (TKA) implant placement and overall limb are important goals of TKA technique.
Methods: The accuracy and ease of use of an accelerometer-based hand-held navigation system for tibial resection during TKA was examined in 90 patients. Preoperative goals for sagittal alignment, navigation system assembly time, resection time, and tourniquet time were evaluated. Coronal and sagittal alignment was measured postoperatively.
Results: The average coronal tibial component alignment was 0.43° valgus; 6.7% of patients had tibial coronal alignment outside of ±3° varus/valgus. The difference between the intraoperative goal and radiographically measured posterior tibial slope was 0.5°. The average time to completion of the tibial cut was 4.6 minutes.
Conclusion: The accelerometer-based hand-held navigation system was accurate for tibial coronal and sagittal alignment during TKA, with no additional surgical time compared with conventional instrumentation.

1. Introduction

Total knee arthroplasty (TKA) has been shown to be an important and successful treatment for advanced arthritis. Surgical techniques, materials, and implant design have evolved, leading to increasing success of this operation. Implant position as well as overall limb alignment have correlated with long-term durability of TKA [1,2]. Coronal (varus) malposition of the tibial component has also been shown to be an independent risk factor for wear and loosening [3]. Currently, a number of technologies are available for surgeons to use to obtain desired component position and mechanical alignment in TKA. These include extramedullary and intramedullary mechanical devices, large console computer navigation systems, and patient-specific cutting guides. The accuracy of extramedullary and intramedullary alignment guides has been extensively studied with the rate of alignment outliers greater than 3° averaging 30% [4–7]. Large console computer-assisted navigation systems (CAS) have been developed as an alternative to conventional mechanical instrumentation to aid with more accurate component positioning. Most studies have demonstrated a significant improvement in TKA alignment with CAS, with outliers averaging 8% [2,4,8]. However, longer procedure times, increased cost, and difficulties with sensitive optical instrumentations have prevented widespread use of CAS among the orthopedic community. Patient-specific instrumentation has also been introduced in an effort to provide improved accuracy and enhanced surgical efficiency. In a limited number of studies, patient-specific devices have shown to have intermediate accuracy between mechanical devices and CAS with outliers reported between 9% and 20% [9,10]. While controversy remains regarding the relationship of mechanical alignment and outcome in TKA, accuracy in surgical performance is unarguably an appropriate goal. Therefore, technologies that provide the potential benefits of improved accuracy such as CAS, yet do not adversely impact surgical efficiency, may be helpful in optimizing TKA. The primary purpose of this study was to assess the accuracy of coronal and sagittal resection angles utilizing a novel, accelerometer-based handheld navigation system during TKA.

2. Materials and methods

This was a prospective, single-arm study of patients undergoing TKA with an accelerometer-based hand-held navigation system for positioning of the tibial component. Exclusion criteria included age greater than 85 years, prior knee arthroplasty or osteotomy on ipsilateral side, major ankle deformity or absence of foot on ipsilateral side, and simultaneous bilateral arthroplasties. One hundred consecutive patients (100 knees) receiving a TKA between October 2010 and September 2011 met the inclusion criteria and provided consent to participate in the IRB-approved study. Five tibiae were re-cut freehand by one of two surgeons early in the utilization period and were therefore excluded from the study.

* Corresponding author at: Division of Orthopaedic Surgery, Scripps Clinic, 10666 North Torrey Pines Road, MS 116, La Jolla, CA 92037. Tel.: +858 554 7993.
E-mail address: bugbee.william@scrippshealth.org (W.D. Bugbee).

http://dx.doi.org/10.1016/j.knee.2014.09.006
0968-0160/

Five patients did not return for postoperative radiographs and were also excluded from the study. The remaining 90 patients (90 knees) comprised the study population. The average age was 67.6 years (ranging from 44 to 85 years) and 68% were female. The average height, weight, and BMI were 1.68 m, 84.14 kg and 29.7, respectively. All surgery was performed by either of two surgeons.

The KneeAlign® navigation system (OrthAlign®, Aliso Viejo, CA) is a 510(K) cleared palm-sized navigation unit intended for use in TKA to assist the surgeon with coronal (varus/valgus) and sagittal (posterior slope) tibial component positioning. The navigation system is a hand-held accelerometer-based surgical navigation system consisting of a display console, a reference sensor, and a tibial jig (Fig. 1). The tibial jig has two primary components that are articulated relative to each another with the fixed component pinned to the bone and the mobile component guiding the cutting block. During the procedure, the unit is attached to the mobile component of the jig, with the reference sensor attached to the fixed component of the jig in order for the system to compensate for movement of the leg.

The tibial jig is pinned onto the tibial tubercle, and the mechanical axis of the tibia is established. The mechanical axis is defined by the line joining the footprint of the anterior cruciate ligament (the proximal mechanical axis point) and the center of the ankle joint (distal mechanical axis point). The device is connected to the adjustable component of the jig, and the reference sensor is connected to the fixed component. The medial and lateral malleoli are registered utilizing the mobile component of the handheld tibial jig. The distal mechanical axis point is defined by the center of the tibial plafond, which is approximated by weighted interpolation between the apices of the medial and lateral malleoli. During registration, the system uses the differential between the outputs of the accelerometers to establish the orientation of the mobile component of the jig relative to the tibia. Once registration is complete, the display console provides dynamic numerical measurements of the alignment of the cutting block relative to the mechanical axis in both the coronal and sagittal planes. The surgeon is able to select the desired resection angles prior to pinning the cutting block into place (Fig. 2).

Intraoperative data collected included preoperative goals for sagittal alignment, navigation system assembly time, resection time, and tourniquet time. Full-length anteroposterior hip to ankle and mediolateral digital radiographs were obtained postoperatively on all 90 patients using a standardized protocol. Radiographic measurements for tibial component coronal position (varus/valgus) and sagittal position (slope) were performed by an independent outside musculoskeletal radiologist (RadCore Labs, Torrance, CA) and an orthopedic surgeon. For convention, tibial components measured in varus were represented as a negative value; the tibial components measured in valgus as positive values. Tibial slope was designated negative for an 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 intraclass correlation coefficients for all radiological measurements. Means (including 99% confidence intervals) and frequencies were computed to summarize navigation assembly time, resection time, tourniquet time, and radiographic results.

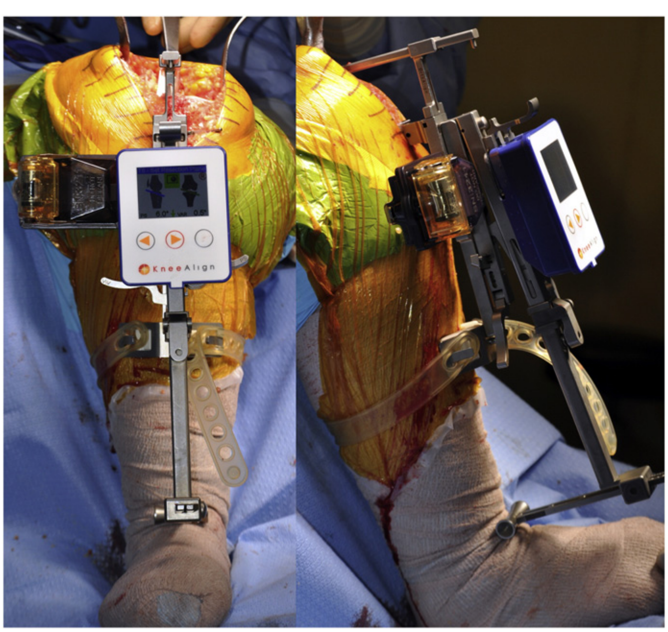

Fig. 1. The KneeAlign® navigation system consists of a display console, reference sensor, and tibial jig.

Fig. 2. The KneeAlign® navigation system display console.

3. Results

The average time to pinning the tibial cutting block was 3.4 minutes (99% confidence interval, 3.1 to 3.6). The average time to completion of tibial cut was 4.6 minutes (99% confidence interval, 4.3 to 5.0). The average tourniquet time was 62 minutes (99% confidence interval, 59 to 66).

Radiographic measurements between the independent radiologist and the orthopedic surgeon had strong reliability (all correlation coefficients were above 80%). Therefore, measurements from both readers were averaged and the average value was used to calculate means and frequency of outliers.

Target intraoperative tibial coronal alignment (varus/valgus) was 0°. Postoperatively, the average tibial component coronal alignment was 0.43° valgus ± 1.5 (ranging from 2.3 varus to 5.2 valgus). A total of 6.7% of patients had tibial coronal alignment outside of $\pm 3°$ varus/valgus (Fig. 3). Tibial component sagittal alignment measurements (posterior slope) were divided into 2 groups. In group 1, all surgeries were performed by 1 surgeon with an intraoperative posterior slope goal of 3°. In group 2, all surgeries were performed by another surgeon with an intraoperative posterior slope goal of 5°. In group 1, posterior slope was 2.8° ± 1.6. In group 2, posterior slope was 3.7° ± 1.8. The difference between intraoperative goal and radiographically measured posterior tibial slope in both groups was 0.5° ± 1.7. A total of 4.5% of patients had posterior slope outside $\pm 3°$ of the intraoperative goal.