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Accelerometer-Based Navigation Is as Accurate as Optical Computer Navigation in Restoring the Joint Line and Mechanical Axis After Total Knee Arthroplasty

A Prospective Matched Study

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ABSTRACT

The Zimmer iASSIST system is a novel accelerometer-based navigation system for TKA. 76 patients (76 knees) were prospectively matched for age, BMI, gender, diagnosis, and pre-operative scores, and underwent TKA using the iASSIST (n=38) or optical CAS (n=38). There were no significant differences in clinical outcomes or satisfaction rates at six months post-operatively (P>0.05). Mechanical axis was 1.8±1.3° in the iASSIST cohort versus 2.1±1.6° in the CAS cohort (P=0.543). There were no significant differences in number of outliers for mechanical axis (P=1.000), coronal femoral-component angle (P=0.693), coronal tibial-component angle (P=0.204) or joint line deviation (P=1.000). The duration of surgery was significantly longer in the CAS group (P<0.001), while the added cost of accelerometer-based navigation was approximately $1000 per operation.

Total knee arthroplasty (TKA) is a successful treatment for advanced arthritis of the knee. Femoral and tibial component malalignment, however, remains a significant concern. There has been considerable debate over the acceptable range of mechanical alignment for successful TKA surgery. Recently, the importance of overall mechanical alignment in TKA and its impact on implant survivorship have been questioned, although most authors still favor placing the mechanical axis within 3° of a neutral mechanical axis to improve implant survivorship.

Currently, a number of technologies are available to help surgeons obtain the desired component position and mechanical alignment in TKA. These include extramedullary (EM) and intramedullary (IM) mechanical devices, large console computer-assisted navigation systems (CAS) and patient-specific instrumentation (PSI). The conventional method of using an EM tibial alignment guide and an IM femoral alignment guide to achieve proximal tibial and distal femoral resections perpendicular to their mechanical axes has a limited degree of accuracy for overall mechanical alignment and individual component placement [1]. CAS was developed as an alternative to conventional mechanical instrumentation to improve accuracy in component positioning. In a meta-analysis of 29 studies comparing CAS to conventional techniques, Mason et al demonstrated 90.4% in the CAS group with a femoral varus/valgus alignment within 2° perpendicular to the femoral mechanical axis (versus 65.9% in the conventional group), and 95.2% to achieve a tibial varus/valgus alignment within 2° perpendicular to the tibial mechanical axis (versus 79.7% in the conventional group) [2].

While improved survivorship has been linked to improved mechanical alignment, improved patient outcomes have been harder to demonstrate [3,4]. A meta-analysis by Bauwens et al in 2007 suggested that there were few benefits with CAS and that the advantages remained unclear [5]. Other concerns with CAS techniques such as the learning curve required, increased capital costs, longer operative times, extra pin sites and difficulties with sensitive optical instrumentations have limited its widespread acceptance [6].

Recently, navigation systems have been developed using accelerometer electronic components [7–10]. These devices attempt to combine the alignment accuracy of large console CAS systems with the ease of use of conventional alignment methods. The iASSIST does not require the use of a large computer console or navigation arrays for registration and alignment feedback, and relies on accelerometer-based navigation instead of computed tomography-guided, image-based, or imageless navigation technologies used in most CAS systems. A recent study of 14 patients undergoing TKA with the iASSIST reported good correlation

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between values measured on CT and validation measurements from the iASSIST [11].

Restoration of the joint line after accelerometer-based navigation has not been described to date. A joint line elevation of greater than 5° may result in patella baja, impingement of the patellar button component and anterior knee pain. Other potential problems affect the collateral ligament and quadriceps function, leading to mid-flexion/hyperextension instability and patient dissatisfaction [12,13].

The purpose of our study was to determine if the iASSIST accelerometer-based navigation system (1) improves the accuracy of overall lower extremity, femoral and tibial component alignment; and (2) provides accurate restoration of the joint line when compared to a large-console optical CAS system. The authors hypothesize that accelerometer-based navigation will be as accurate as optical CAS, while having a shorter duration of surgery.

Patients and Methods

Patient Selection

Between July 2013 and May 2014, 76 consecutive patients (76 knees) diagnosed with tricompartmental osteoarthritis of the knee underwent primary TKA using optical CAS or the iASSIST accelerometer-based navigation system by two senior surgeons at a single institution. Patients were included in this prospective study after approval from our institutional review board. The inclusion criterion was osteoarthritis of the knee requiring primary unilateral TKA after failure of conservative treatment. Patients with pre-operative varus or valgus deformity of more than 15°, rheumatoid arthritis, previous knee surgery, and infection and those who could not be treated with unconstrained TKA and a short stem tibial implant were excluded from the study.

38 patients (38 knees) who underwent TKA with the accelerometer-based navigation system were individually matched with control group of 38 patients (38 knees) who underwent CAS TKA. The matching of patients was undertaken prospectively using the pre-operative data in isolation. The two groups were matched for age, body mass index (BMI), gender, diagnosis (osteoarthritis), laterality (unilateral), pre-operative range of motion (ROM), Knee Society Score (KSS) and Oxford Knee Score (OKS), thus controlling for potential confounding factors. As it was not always possible to identify a control with the same pre-operative scores, the control with the closest score was identified.

Surgical Technique for the iASSIST Group

The iASSIST (Zimmer, Inc., Warsaw, IN) is an accelerometer-based navigation device that does not require a large console for registration and alignment feedback [11]. The surgical workflow follows the conventional method in which each bone is resected independently along the mechanical axis. The system makes use of disposable electronic pods that attach onto resection instruments. These pods contain accelerometer electronic components or gyroscopes that exchange information via a secure local wireless (Wi-Fi) network. For the tibial coordinate system registration, the angular relationship between the electronic pod of the digitizer and the bone reference is determined by the system through abduction, adduction, and neutral position (Fig. 1). The femoral coordinate system registration, like most optical navigation systems, requires the mechanical axis to be determined by anatomically locating the center of the distal femur and kinematically locating the femoral hip center using multiple stop-and-go movements by the surgeon. Once the necessary data is obtained during the procedure, alignment information is displayed to the surgeon on a user interface on the pods, directly within the operative field. The pods then guide the resection at the appropriate angles in the coronal and sagittal planes, after which, the accuracy of the alignment can be validated and any adjustments can be performed at this point.

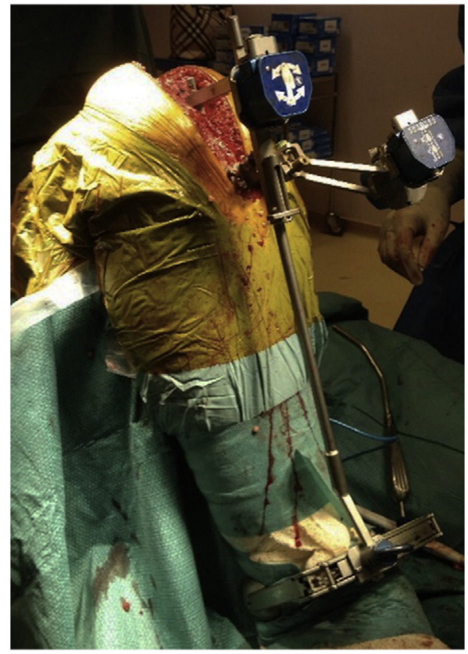

Fig. 1. Using the iASSIST accelerometer-based navigation system to guide the tibial resection.

Surgical Technique for the Computer Navigation Group

38 patients underwent optical CAS TKA with the BrainLab/DePuy Orthopaedics Inc. using Ci Mi TKR software version 1.0. Anatomical landmarks were registered through the use of dual 3-mm bicortical pins drilled into the femur and tibia at a distance from the surgical approach, and a pointer with passive infrared reflectors. The tibial and femur cuts were made using intra-operative navigation guidance. Soft tissue releases and ligament balancing were made to achieve rectangular flexion and extension gaps. The size and the position of the femoral and tibial components were adjusted (to within 1 mm of the joint line) in accordance to registration parameters to achieve equal gaps and desired posterior slope.

Radiological Evaluation

Post-operative weight-bearing films (anteroposterior, lateral, hip-to-ankle films) were performed in the specialist outpatient clinic at one-month follow-up. Coronal hip-to-ankle radiographs were taken with the patient standing and the knee in full extension on a 5-cm riser to visualize the ankle joint. Both lateral malleoli were placed 20 cm apart with the toes pointing forward. The patella was placed in the direction of the X-ray source as a rotation guide, with its anterior surface perpendicular to the X-ray source. We acknowledged the need to reproduce accurate and consistent X-rays for assessment. Radiographs were repeated if malrotation was detected. Malrotation was defined as: (1) asymmetry of the distal medial and lateral femoral condyles; or (2) unequal medial and lateral joint spaces in the ankle joint.

Evaluation of lower limb alignment was done using the Picture Archiving and Communication Systems (PACS). Two reviewers blinded to the surgical method performed the measurements on computer-based digital radiographic films on two separate occasions. Measurements were recorded to an accuracy of 0.1°. We used the modified Kawamura and Bourne AP method to measure joint line changes [14]. This involved drawing a line from the superior aspect of the fibular head perpendicular to the long axis of the tibia and measuring the perpendicular distance from this line to the inferior aspect of the femoral condyles or femoral component. Measurements were made to the medial and lateral femoral condyles as well as to the midpoint between