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Identification of the Landmark Registration Safe Zones During Total Knee Arthroplasty Using an Imageless Navigation System

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ABSTRACT

Incorrect registration during computer assisted total knee arthroplasty (CA-TKA) leads to malposition of implants. Our aim was to evaluate the tolerable error in anatomic landmark registration. We incorrectly registered the femoral epicondyles, femoral and tibial centers, as well as the malleoli and documented the change in angulation or rotation. We found that the distal femoral epicondyles were the most difficult anatomic landmarks to register. The other bony landmarks were more forgiving. Identification of the distal femoral epicondyles has a high inter-observer and intra-observer variability. Our observation that there is less than 2 mm of safe zone in the anterior or posterior direction during registration of the medial and lateral epicondyles may explain the inability of CA-TKA to improve upon the outcomes of conventional TKA.

Computer assisted total knee arthroplasty (CA-TKA) may reduce component positioning outliers (i.e., those patients whose alignment results are outside the acceptable range). Studies comparing CA-TKA to conventional jig-assisted TKA found femoral and tibial component alignment in the axial, sagittal and coronal planes as well as component matching significantly improved with use of CA-TKA [1–8]. The long-term clinical outcomes of CA-TKA have yet to be established in prospective clinical trials [9–12].

There are several types of CA-TKA navigation systems. One version of this technology is an imageless and wireless format, which consists of a computer workstation or cart, an infrared camera, and pin arrays (i.e., 'transmitters' or 'reflectors') that are implanted into the femur and tibia for the duration of the procedure [13]. Imageless CA-TKA does not use preoperative radiographs or intra operative fluoroscopy. Instead, it relies on the positioning of the pin arrays and the surgeon's registration of anatomic landmarks which are wirelessly transmitted to the computer for analysis and determination of the spatial orientation of the femur and tibia from which the bone cuts can be accurately calculated.

There are a number of potential sources of error in imageless CA-TKA. These lead to a discrepancy between what the computer calculates as the correct position for the implant and the actual position of the implant. Like all computer based applications, the output generated is highly dependent on the data that is input. Errors in final implant position when using imageless CA-TKA, may be caused by

a) software
b) hard ware calibration
c) pin array placement
d) registration of anatomic landmarks
e) pin array movement after registration
f) incorrect bone cuts (e.g., sclerosis), or
g) incorrect final placement of implants (e.g., cementation).

The software and hardware accuracy is outside of the control of the surgeon and is dependent on the particular manufacturer. Provided the array pins are inserted correctly and do not move during surgery, anatomic landmark registration is perhaps the most critical step in CA-TKA as it is subject to surgeon error and is critical to determine the future bone cuts. Inter-observer variability in landmark registration leads to errors in implant placement during CA-TKA [14–17]. Registration of anatomic landmarks may be inconsistent due to variations in anatomy and the surgeon's ability to correctly identify it. The level of accuracy required to safely register an anatomic landmark

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has yet to be determined. The aim of this study was to identify the zone around each anatomic landmark within which, if the surgeon registered a point, it would give rise to less than or equal to 1° of change to the bone cut.

Methods

A large left foam cortical shell femur and tibia (Sawbones, Pacific Research Laboratories, Vashon, WA) with lengths of 470 mm and 410 mm respectively were used along with a pelvic model. In each bone, two 5 mm stainless steel array pins were inserted 10 and 13 cm from the articular surface. Infrared transmitters were attached to the array pins, and the transmitters were activated and linked to the infrared camera and computer cart (Stryker Navigation System, Stryker Orthopaedics, Kalamazoo, MI). In addition, a hip resurfacing cup and femoral head (Corin, Cormet, Cirencester, UK) were applied to the acetabulum and femoral head to allow for smooth kinematic registration of the hip center.

The study was performed in two steps. In the first step, the default anatomic landmarks on the femora and tibiae were defined, marked, and registered per the navigation workflow. The medial femoral epicondyle was the most medial bony projection of the distal femur. The lateral femoral epicondyle was the most lateral bony projection of the distal femur. The center of the femoral articular surface was the projected site of the femoral medullary canal if it were to be opened for a standard jig-assisted TKA. The medial malleolus was the most medial bony projection of the distal tibia. The lateral malleolus was the most lateral bony projection of the distal fibula. The center of the tibial articular surface was the projected site of the tibial medullary canal if it were to be opened for a standard jig-assisted TKA (i.e., the center of the tibial spines just anterior to the anterior cruciate ligament insertion on the tibial plateau).

Using the navigation system, the proximal tibial cutting block was pinned into a position that would allow a proximal tibial cut of 0° of varus/valgus angulation and 0° of posterior tibial slope. Similarly, the distal femoral cutting block was pinned into a position that would allow a distal femoral cut at 0° varus/valgus angulation, 0° flexion/extension and 3° external rotation with respect to the posterior femoral condyles. These were the ‘default’ positions of the cutting blocks and none of the pins or the cutting blocks were moved for the remainder of the experiment.

In the second step, each anatomic landmark on the tibia and femur was deliberately registered incorrectly, while keeping the remaining default landmarks correctly registered. For example, the medial malleolus would be registered incorrectly while the lateral malleolus and tibial center were left correctly registered. The incorrect registration of each anatomic landmark was done at 2 mm intervals up to a total 16 mm in four directions (anterior, posterior, superior, and inferior for the malleoli or epicondyles; anterior, posterior, medial, and lateral for the tibial and femoral center; Fig. 1).For each incorrectly registered point, the change in the varus/valgus angulation, flexion/extension, or rotation of the cutting block from the reference position was recorded. A change in angulation of 1º or more was out of the safe zone for a given anatomic landmark. All measurements were done in triplicate for each incorrectly registered anatomic landmark; the median of the three readings is reported. After each incorrectly registered anatomic landmark was investigated, all the anatomic landmarks were re-registered to ensure that none of the array pins moved and the reference position of the cutting block was unchanged.

Results

Incorrect registration of either the medial or lateral malleolus in the superior or inferior direction by up to 16 mm had no change in varus/valgus angulation from the default position of the proximal tibial cutting block (Table 1, Fig. 2A and B). Incorrect registration of either the medial or lateral malleolus in the anterior or posterior direction by 10 mm or more resulted in a 1° change in the posterior tibial slope from the default position of the proximal tibial cutting block (Table 1, Fig. 2A and B). Incorrect registration of the tibial center in the medial/lateral or superior/inferior direction by 6 mm or more resulted in a 1° change block in the varus/valgus or posterior tibial slope from the default position of the proximal tibial cutting block (Table 2, Fig. 2F).

Incorrect registration of either the medial or lateral epicondyles in the superior or inferior direction by up to 16 mm had no change in varus/valgus angulation from the default position of the distal femoral cutting block (Table 3, Fig. 2C and D). Incorrect registration of either the medial or lateral epicondyles in the anterior or posterior direction by 2 mm or more resulted in a 1° change in the internal/external rotation from the default position of the distal femoral cutting block (Table 3, Fig. 2C and D). Incorrect registration of the femoral center in the medial/lateral or superior/inferior direction by 6 mm or more resulted in a 1° change block in the varus/valgus or flexion/extension from the default position of the proximal tibial cutting block (Table 4, Fig. 2E).

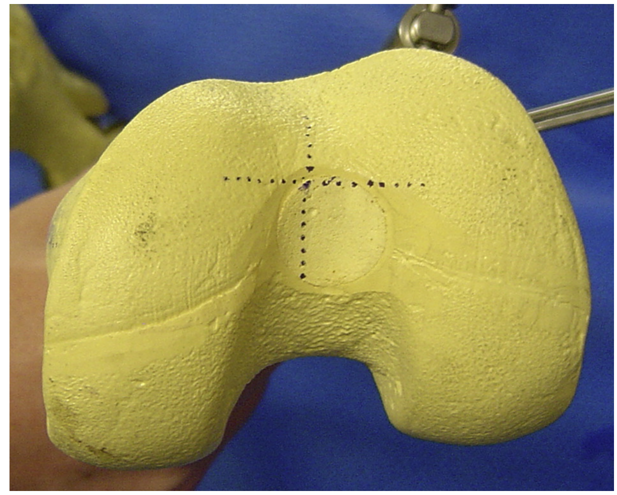

Fig. 1. The central point is the defined anatomic landmark (e.g., femoral center) and the other points are the points deliberately registered incorrectly in 2 mm intervals up to a total 16 mm in four directions (e.g., anterior, posterior, medial, and lateral) from the defined anatomic landmark.

Discussion

CA-TKA reduces component positioning outliers. CA-TKA improves femoral and tibial component alignment in the axial, sagittal, and coronal planes [1–8]. However, despite improved accuracy CA-TKA has yet to demonstrate clinical results superior to those of conventional TKA in prospective clinical trials [9–12]. Considerable inter-observer and intra-observer error in the identification of anatomic landmarks, especially the femoral epicondyles, affects the data input during registration and may negate the advantage of improved accuracy during CA-TKA. A study utilizing a virtual reality model evaluated the inter-observer variability in identifying the medial and lateral femoral epicondyles. The authors demonstrated an extremely wide range, from 0.2 mm to 25.9 mm, in the mean dispersion (i.e., distance identified to ideal anatomic site). Component rotational misalignment could be as high as 30° with this magnitude of inter-observer error [15]. A cadaveric study quantifying inter-observer error found that the mean dispersion in identifying the transepicondylar axis found a very large variation in the locations of the epicondyles registered by visual inspection when compared to the