How Precise Is Computer-navigated Gap Assessment in TKA?

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Published online: 18 July 2014

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Abstract

Background Methods to improve gap balancing in total knee arthroplasty (TKA) include the development of calibrated distractors and various devices to determine the distances of the gaps. However, few studies have validated the accuracy or precision of computer navigation to determine these measurements, especially gaps created after bone cuts have been made; doing so would be important, because optimal surgical technique relies on appropriate gap spacing.

Questions/purposes We investigated the ability of a new image-free computer navigation surface registration protocol to measure gap distances in TKA.

One of the authors certifies that he (JBS), has received or may receive payments or benefits, in the future, an amount greater than USD 500,000 and less than USD 1,000,000 from Blu Ortho, LaTronche, France.

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Methods Eight embalmed cadaveric specimens of the lower extremity were used. A surface registration software protocol defined the most distal and posterior surface points of the femoral condyles and the navigation system measured the distance of the most distal femoral condyle point to the surface of the tibia after tibial resection. The tibial resection was perpendicular to the mechanical axis and was cut with a 7° posterior slope. The navigation system measured gaps spaced by modular spacing blocks at 5° intervals from full extension to 120° of flexion. Repeatability assessed repeated measures by one surgeon. Reproducibility was assessed by performing the same measurements after complete reregistration of the computer protocol to the cadaver bones.

Results The gaps measured by the computer were statistically the same as those assessed with the use of blocks with a maximum measurement error of 1 mm. Reregistration did introduce error into the measurement. The gaps changed with position of knee flexion, and there was gradual and significant stretching of the gaps with repeated measurements.

Conclusions Preliminary testing shows that computer navigation can reproduce static measurements reliably and with equal accuracy as spacer blocks. We have not demonstrated that this could be applied in a dynamic setting.

Clinical Relevance This computer navigation system has sufficient precision to warrant investigation in the clinical setting for measuring gaps created during the surgical procedure.

Introduction

A major challenge for surgeons performing standard TKA has been the ability to balance the ligaments to optimize kinematics and ultimate clinical performance. Insall et al. [4]

and Ranawat et al. [9] pioneered early concepts of ligament balancing with the goal of equalizing medial and lateral soft tissue tension and creating a rectangular space in both extension and flexion. Originally, simple spacer blocks were used to assess the final gaps created after bone cuts had been made. Over the years, a variety of devices have evolved to allow for more precise creation of equal gaps. Typically, these devices allow the surgeon to create a defined distraction force on the medial and lateral aspects of the joint with calipers to measure the resulting space [5–7, 13].

Computer navigation has been used to measure the lower extremity alignment and to assess the gaps created by typical conventional instruments used for TKA. However, few studies cite the measurement error and none have validated the accuracy or precision of gap measurements, especially those created after bone cuts have been made [10, 14, 15]. Such validation seems important, because these systems have been used by surgeons to evaluate final prosthetic gaps in the clinical setting for many years.

The goal of this study therefore was to assess a new gap measurement scheme of a contemporary computer navigation system. The software protocol uses a technique of surface morphing in which the surgeon registers a surface such as a femoral condyle by painting the surface with the tip of a probe that is actively tracked by the navigation camera. The computer then makes this condylar surface virtual allowing for precise measurements to other points such as another bone surface. We used one embalmed lower extremity cadaver to simulate the intraoperative setting for which gap spacing measurements are made. We wanted to know how precisely one surgeon could measure gaps with the computer compared with spacing created by a modular spacing block of known dimension. Second, we wanted to know if the surgeon could obtain the same result if the computer navigation protocol was completely re-registered to the cadaveric bones. Multiple registrations are known to be a source of error for computer navigation systems.

Materials and Methods

This study used eight embalmed whole lower extremity cadaver subjects obtained from a medical school anatomy department. The computer navigation system assessed was a contemporary image-free system that uses a digital camera system. Active LED trackers were used and line of site distance of the system was 6 feet (1.8 m) or less (Blue Ortho SAS, La Tronche, France). Trackers were mounted to base plates that also served as fixation points for navigated cutting jigs. Registration was performed for the imageless navigation protocol by a surgeon experienced with navigation. The registration protocol called for hip

Fig. 1 The modular spacer block of appropriate thickness spaces at a certain degree of flexion, and the computer measures against that gap.

center using the kinematic method, femoral knee center choosing the midpoint roof of the intercondylar femoral notch, the anatomic center of the proximal tibia, and the midpoint of the talar dome. The center of the proximal tibia is defined as the intersection point of the transtibial axis and the anterior posterior axis. The center of the talus is measured as 45% of the distance from the tip of the medial malleolus to the lateral malleolus. We used a surface registration technique as described by Stindel et al. [12] termed digital “bone morphing” [8]. Basically, the operator paints the surface by registering a cloud of points by passing an active tracker probe over that surface. The software program then realizes a geometric surface from which measurements can be made. The measurement error was described as 1 mm for that scheme. Bone morphing registration patches determined the anterior distal femoral cortex and the deepest points of the medial and lateral tibial plateaus. A customized software protocol allowed bone morphing of the lowest or most distal points of the entire medial and lateral femoral condyles from 0° to 120° of flexion. This system allowed measurement of the medial and lateral gap at each degree of flexion throughout the ROM.

Once registration was completed, the proximal tibial cut was made using the navigation protocol. This cut was guided by using a computer-guided cut block system (GPS; Exactech, Inc, Gainesville, FL, USA). The cut was made perpendicular to the mechanical axis of the lower extremity with a 7° posterior slope cut of the proximal tibia.

We assessed repeatability by comparing computer gap measurements with a set of modular spacer blocks that could be assembled to space the joint (DePuy Orthopaedics, Warsaw, IN, USA) (Fig. 1). Basically, a block spacer was inserted into the joint to adequately distract the joint.

The gap typically increased with flexion and thicker spacers were inserted. The specimen was measured eight times by the surgeon with a spacer block at 5° intervals from 0° to 120° of flexion recording the medial and lateral block thicknesses. At each point, the computer measured the gap created by the spacer block. Ideally, the computer measurement would be identical to the block thickness. Reproducibility of the computer scheme was assessed by completely reregistering the specimen by going back to the startup screen and performing the typical computer registration for the navigation protocol. We did not change the position of the active LED trackers applied to the base plates.

We had measured each block thickness with a Zeiss (Irvine, CA, USA) Calypso free-form measurement protocol that had an instrument measuring error of 12 µm. Our spacer blocks had a maximum measurement error of 200 µm from the stated thickness with no block exceeding this error.

Statistics

Descriptive statistics and SDs were determined for each flexion point for all tests using Minitab® Version 14 (Minitab Inc, State College, PA, USA). The generalized multivariate analysis of variance was used to compare multivariate (population) means of several data groups that included the dependent variables of the spacer block thickness and the computer navigation gap measure with independent variables of the degree of knee flexion and comparison of reregistration of the primary specimen. Power was calculated by using the analysis of variance test with projected ability to detect a 1-mm difference as our measurement threshold.

Results

The repeatability test measured the ability of the computer to assess the medial and lateral gaps in one specimen against known modular spacer blocks. We found no differences between the measurements obtained using computer navigation compared with the blocks ($p = \text{non-significant}$, $\beta = 0.9$). With changes in knee flexion, the gap was affected by knee position. The greatest residual errors were seen at the extremes of knee flexion. For comparison, descriptive statistics of navigation versus the blocks revealed a mean medial compartment measurement difference of 0.006 mm (SD, 0.32 mm) and a mean lateral compartment measure of 0.12 mm (SD, 0.41 mm). We projected a maximum measurement error of 1.0 mm capturing 100% of values to 90°.

The reproducibility test measured the effect of serial reregistration of the computer protocol on the cadaver subject. Reregistration did introduce error. The measurements obtained using the computer in comparison to the spacer blocks varied. The gaps changed with knee flexion through the ROM. However, we also did find that there were significant changes of the gaps with subtle increases on repetition of the tests. Descriptive statistics comparing the computer to the blocks revealed a medial compartment measure difference of 0.24 mm (SD, 0.54 mm) and a mean lateral compartment measure of 0.01 mm (SD, 0.42 mm). Again, the maximum error did not exceed 1.0 mm.

Discussion

Gap balancing is an important component of the typical TKA and can lead to early pain and implant failure if performed poorly. For surgeons, gap spacing often relies on the use of simple spacer blocks and final adjustments that can be made with prosthetic placement. Although computers have shown improvement of anatomical limb alignment, the ability to assess gap spacing has been limited to final gap assessment and the ability to measure the gaps at 0° and 90° of flexion. We wanted to study the ability of a new computer software scheme to enhance gap measurements by allowing the surgeon to accurately assess the gaps at each degree of flexion in the ROM. This system has not been validated and our first objective was to perform a basic metrology study of a clinical application.

Limitations of the present study include the lack of external validity, because only one surgeon experienced in both total joint arthroplasty and computer navigation methods performed all tests. This experience may not necessarily translate to other clinicians. However, we expect that the accuracy demonstrated in the spacer block experiment will reduce or eliminate the impact of individual surgeon technique variation. This can be explained by the fact that the block spacing comparison relies on the distance created by the spacer and not ligament tensing. Embalmed cadaver specimens are likely to have greater stiffness and the relaxation seen with serial testing may not exactly replicate in vivo or fresh cadaver specimens. The principal goal of the study was not to prove the consistency of serial tensing, but to make observations regarding the potential applications of our system and this observation should be regarded with the limitations of a post hoc conclusion.

The overall conclusion of our block studies was that the computer system was accurate and precise to at least 1 mm for measuring the gaps of the knee. Differences were seen with reregistration of the specimen. Stindel et al. [12] investigated the predicate technology for our current

system, which included the bone morphing surface registration. They found a maximum measurement error of 1 mm or 1°. With search of the literature, we do not find a validation study similar to ours performed on computer gap measuring systems. We presume that other navigation systems could show similar results to ours but manufacturers do not typically disclose the metrology details when their product is submitted for US FDA market approval. Siston et al. [10] made reference to a computer system used for a ligament balancing study, and they cited linear accuracy less than 2° or a measurement of 1.25 mm. A number of recent studies point to the potential errors during the registration process, but this is not unexpected with the known variability of landmark determination used in TKA (eg, transepicondylar axis, Whiteside's AP axis, etc) [2, 11, 15].

One problem with our study was the stretching of the gaps that occurred with serial testing. This progressive variability reflects a potential pitfall of cadaveric testing, where embalming can dramatically alter the dynamic properties of soft tissues surrounding the affected joint. Correlation with clinical practice, with special attention to differing levels of soft tissue tension throughout the arc of motion, should be explored. Bellemans et al. [1] identified in vivo stretching of the extension collateral ligaments intraoperatively over 30 minutes using a computer navigation assessment. Hamelynck [3] stated that there is long-term stretching of the collateral soft tissue stability in TKA, particularly in patients with rheumatoid arthritis who are not well balanced at the outset.

The conclusion of this study is that computer navigation systems offer the ability to digitally measure the soft tissue medial and lateral gaps with precision and versatility not allowed by most other mechanical systems. One important facet is the ability to measure the degree of flexion of the knee, whereas this is only estimated by typical mechanical systems.

Acknowledgments We thank Stephane Lavallee PhD, and Fabrice Bertrand MS, for technical support during this project and Chad Lamar BS, for laboratory support in performing testing.

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