Total Knee Arthroplasty With a Computer-navigated Saw

A Pilot Study

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Abstract

Background Computer-aided surgery aims to improve implant alignment in TKA but has only been adopted by a minority for routine use. A novel approach, navigated freehand bone cutting (NFC), is intended to achieve wider acceptance by eliminating the need for cumbersome, implant-specific mechanical jigs and avoiding the expense of navigation.

Questions/Purposes We determined cutting time, surface quality, implant fit, and implant alignment after NFC of synthetic femoral specimens and the feasibility and

alignment of a complete TKA performed with NFC technology in cadaveric specimens.

Methods Seven surgeons prepared six synthetic femoral specimens each, using our custom NFC system. Cutting times, quality of bone cuts, and implant fit and alignment were assessed quantitatively by CT surface scanning and computational measurements. Additionally, a single surgeon performed a complete TKA on two cadaveric specimens using the NFC system, with cutting time and implant alignment analyzed through plain radiographs and CT.

Results For the synthetic specimens, femoral coronal alignment was within $\pm 2^\circ$ of neutral in 94% of the specimens. Sagittal alignment was within 0° to 5° of flexion in all specimens. Rotation was within $\pm 1^\circ$ of the epicondylar axis in 97% of the specimens. The mean time to make cuts improved from 13 minutes for the first

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specimen to 9 minutes for the fourth specimen. TKA was performed in two cadaveric specimens without complications and implants were well aligned.

Conclusions TKA is feasible with NFC, which eliminates the need for implant-specific instruments. We observed a fast learning curve.

Clinical Relevance NFC has the potential to improve TKA alignment, reduce operative time, and reduce the number of instruments in surgery. Fewer instruments and less sterilization could reduce costs associated with TKA.

Introduction

TKA is a reliable and reproducible procedure for relieving pain and restoring function to the arthritic knee. Improvements in biomaterials and surgical instrumentation have played an important role in making the procedure durable and reproducible. While there have been many technologic advances, the basic requisites for the surgery have not changed and include attaining appropriate implant alignment and correct soft tissue balance [12, 16].

Navigation in TKA offers the orthopaedic surgeon an opportunity to improve accuracy and reduce the number of outliers [5, 6, 8, 11, 13]. The drawbacks to navigation include an increase in cost and operative time, without demonstrable improvements yet in implant longevity [3, 5]. The basic principles of navigation are to relate either radiographic or approximate (morphed) bone models to anatomic data through a registration process, graphically simulate and display implant alignment information, and guide the surgeon during the bony preparation and placement of implants. Modern navigation systems help to align cutting jigs that are similar to conventional cutting jigs. The technique is otherwise unchanged in that the cutting blocks are then used in a standard fashion to make the appropriate bony resections in preparation for the implant.

We have developed a technique for navigated freehand cutting (NFC) utilizing a navigated saw to complete bone cutting without the need for implant-specific jigs. In previous work, we found the freehand technique was faster than conventional jig-based cutting. There was an improvement in mean implant alignment (flexion/extension, varus/valgus, and rotation) and a reduction in the standard deviation (fewer outliers) [7]. The improved alignment was attributed to the fact that any errors in initial malpositioning of the conventional combination cutting block would similarly occur in all of the other cuts, producing systematic errors. Random errors can still occur due to any subsequent shift of the block. The NFC technique uncouples the cuts, allowing each cut to be performed independently, thereby removing the potential systematic

errors of a malpositioned cutting block. While we were previously able to demonstrate it was possible to prepare a synthetic femoral specimen for TKA with a navigated saw, we had not investigated the reproducibility of these results in the hands of other surgeons. We also sought to evaluate our ability to perform a complete TKA in cadaveric specimens using NFC.

We therefore (1) quantitatively analyzed the cutting time, surface quality, implant fit, and implant alignment after NFC of synthetic femoral specimens, (2) described a new smart saw by modifying our original navigated saw to not only provide feedback to the surgeons but also prevent them from making cuts that deviate from the preoperative plan, and (3) determined the feasibility and quality of a complete TKA performed with NFC technology in cadaveric specimens.

Materials and Methods

We recruited seven arthroplasty surgeons with no prior experience using NFC to participate in this study. Each surgeon prepared six custom synthetic femoral specimens for TKA (PFC® Sigma®; DePuy Orthopaedics Inc, Warsaw, IN, USA) using NFC. In a single day, each surgeon prepared five femurs after a single, undocumented practice run to become familiar with the instrumentation.

A stopwatch was used to record total time, actual cutting time, and time for refinements in seconds. The time did not include the fixation and registration of the reference frames. The timer was therefore started when surgeons were actually ready to begin cutting and stopped when they believed the bone was ready for cementing the implant.

The quality of bone cutting was assessed in terms of surface smoothness, accuracy of alignment of each individual planar surface relative to its corresponding planned surface, overall implant fit, and overall implant alignment (Fig. 1). Every cut specimen had some level of these types of errors relative to the operative plan, which was performed beforehand. We selected anatomic implant placement (5° of valgus, neutral alignment in the sagittal plane, and rotation parallel to the epicondylar axis). Sizing and placement of the femoral component were optimized to maximize bone coverage but avoid posterior overhang and anterior notching. The method used to uncouple and measure the errors separately has been detailed previously [1]. For surface quality, the specimens were digitized using high-resolution CT and the surface roughness indexes (R_a and R_{tm}) for each cut were computed [1]. Rotational and translational deviation indexes (P_R and P_T) were derived from CT data for the accuracy of each planar cut relative to the preoperative plan. On completion of bone preparation, the NFC system was used to track and record the positions

of a navigated implant trial relative to the bone. The implant trial was positioned on the distal femur and displaced toward the extremes of flexion, extension, internal rotation, external rotation, varus, valgus, sagittal offset, and axial offset (Fig. 2). At each of these positions, the user triggered the computer to record 20 sets of three-dimensional position and orientation coordinates from the navigation system for both the implant trial and the bone. The process was repeated five times at each position to obtain the average of 100 sets of readings at each position. Implant fit was determined with parametric indexes (F) representing those extremes [1]. Parametric alignment indexes for rotational and translational deviations (L_R and L_T) were computed from the data set used to determine implant fit [1]. These indexes represented the implant positions closest to the desired plan that the cuts permitted.

Next, one of the authors (CWH) performed two full TKAs (Optitrack™ PS; Exactech Inc, Gainesville, FL, USA) on two cadaveric extremities. The femurs were prepared with the same technique used for the synthetic specimens with the addition of a box preparation for a posterior-stabilized knee performed with a navigated reciprocating saw. The tibia was prepared with the navigated sagittal saw for the proximal cut, while a navigated drill and keel punch were used to prepare the metaphyseal bone. Implants were cemented with Simplex® P bone cement (Stryker Orthopaedics, Mahwah, NJ, USA). Implant alignment and rotation were analyzed with plain radiography (including long-leg films) and CT [2, 4, 6].

We built a smart saw (Fig. 3) by integrating a commercial oscillating saw (Stryker Sag 2000), a programmable microcontroller (ARM® Core; ARM Ltd, Cambridge, UK), infrared reflective optical trackers

Fig. 1 A schematic diagram depicting the different aspects of quality and the types of errors in bone cutting for TKR.

Fig. 2A–C Graphics illustrating the method for assessing implant fit and alignment with a navigated trial: extremes of (A) flexion/extension, (B) internal/external rotation, and (C) varus/valgus.

Fig. 3A–C (A) The prototype smart saw electronics and housing configuration and (B) device implementation are shown. (C) The main graphical aids resembles a flight simulator interface, showing

errors of the saw blade (alignment roll and pitch in degrees, position distance in millimeters) relative to the target planar surface being cut.

(Polaris®; Northern Digital Inc, Waterloo, Ontario, Canada), and a 4- × 6-cm touch screen. Bidirectional wireless communication was established between the saw and our custom navigation system that provided dynamic blade speed control. The main graphical aids resembled a flight simulator interface, showing errors of the saw blade (alignment roll and pitch in degrees, and position distance in millimeters) relative to the target planar surface being cut. The blade speed control reduced the blade speed within a selectable envelope of instrument alignment/location error, beyond which the blade was gradually slowed down and eventually stopped as the other threshold of deviation was reached.

Most of the data processing was performed using custom-written computer programs using the C++ programming language that processed the raw (DICOM format) CT data and included some elementary descriptive statistics, such as mean and SD calculations, and determinations of the quality indexes.

Results

The mean ($\pm$ SD) time to prepare a distal femur with the NFC system was 10 ± 4 minutes (Table 1). The median time for preparing a distal femur was 9 minutes. A fast learning curve became evident when comparing the mean time required for each surgeon to complete each successive specimen (Fig. 4). The mean time required to cut the first specimen (13 ± 4 minutes) was higher ($p = 0.018$) than the time to complete the fourth specimen (9 ± 3 minutes), although the times to cut the fourth and fifth specimens were not different ($p = 0.167$). All specimens were between 2° of varus and 4° of valgus relative to our preoperative plan and 94% were within $\pm 2^\circ$ of it (Fig. 5). All specimens were sagittally aligned between 0° and 5° of flexion with no specimens in extension (Fig. 6). Ninety-seven percent of the specimens were rotationally aligned within $\pm 1^\circ$ of the epicondylar axis (Fig. 7).

The mean time (from skin incision to completion of cementation) to perform a TKA in the cadaveric specimens using NFC was 70 minutes and 3 seconds. Coronal alignment for the hip-knee-ankle angle was 0.3° varus for both specimens. Sagittal alignment of the femoral component was 92° for the first specimen and 87° for the second. Rotational alignment for the femoral component was 1.2° of external rotation for the first specimen and 0.5° external rotation for the second. The posterior slope of the tibial component was 2° for the first specimen and 2.9° for the second.

Neither hardware nor software failures had occurred during testing of the smart saw. The screen located on the saw was deemed an improvement relative to alternative computer screen configurations and locations. The oscillatory blade speed control responded to the established thresholds selected for errors. Although these parameters were selected for experimental purposes, a different envelope could be chosen depending on user preference. We believed it unnecessary to supply corrective guidance beyond 10° or 10-mm deviations as these were obvious to the naked eye. We also deemed it futile to try to respond to corrective guidance for deviations of less than 0.5° or 0.5 mm.

Discussion

TKA is a reliable and predictable treatment for patients suffering from debilitating knee arthrosis. Failure of TKA may occur because of several factors, some of which are attributed to component position and limb alignment [9, 15, 17]. Navigation was developed to address these problems by improving the accuracy of the component position and reducing the number of patients whose components are malpositioned. While navigation improves component position and limb alignment [3, 10, 18], we believe navigation has not been widely adopted due to its complexity, added

Table 1. Time and quality of bone cuts determined from previously described indexes [1]

Variable	Parameter	Mean	SD	Minimum	Maximum
Time of cutting	Cut only (minutes)	9	4	4	17
	Refinement (minutes)	2	2	0	9
	Total time (minutes)	10	4	5	20
Surface roughness	R _a (mm)	0.19	0.048	0.12	0.32
	R _{tm} (mm)	1.2	0.45	0.73	3.3
Accuracy of each planar cut	P _R (°)	1.6	0.64	0.45	3.1
	P _T (mm)	1.1	0.38	0.16	1.7
	FE (°)*	0.79	2.7	-10	12
	VV (°)*	-0.73	1.6	-5.5	4.9
	IE (°)*	-0.15	1.5	-4.4	5.4
	Offset (mm)*	0.25	1.3	-3.4	3.4
Implant fit errors	F (°)	1.0	1.7	0	8.0
	FE (°) [†]	1.6	2.8	0	14
	VV (°) [†]	0.41	0.69	0	2.6
	IE (°) [†]	0.40	0.63	0	2.7
	AP (mm) [†]	0.79	1.3	0	6.2
	Axial (mm) [†]	0.17	0.25	0	0.90
Implant location/alignment errors	L _R (°)	1.2	0.78	0	3.0
	L _T (mm)	1.4	0.63	0.058	3.0
	FE (°)	1.6	1.4	-0.50	4.7
	VV (°)	-0.55	1.1	-3.6	2.3
	IE (°)	-0.057	0.63	-1.3	2.0
	AP (mm)	-1.5	1.2	-4.0	0.80
	Axial (mm)	1.5	1.2	-0.80	4.2

* Surfaces weighted equally; [†] range of looseness; R_a = average roughness; R_{tm} = mean peak-to-valley height; P_R = rotational deviation index; P_T = translational deviation index; FE = flexion/extension; VV = varus/valgus; IE = internal/external rotation; F = fit index; L_R = rotational deviation index; L_T = translational deviation index.

Fig. 4 A graph shows times of bone cutting for all surgeons, broken down and averaged according to the order in which the bones were cut. Values are expressed as mean and SD. A clear and steep learning curve is evident.

cost, and increased time needed to perform the surgery and because the outcome and durability of the surgery even with better alignment have not been measurably improved [2, 3, 5, 6, 8, 10, 11, 18]. Additionally, previous work has questioned the validity of a broad traditional target of a neutral

Fig. 5 A graph shows the frequency and magnitude of errors in coronal alignment. The errors never exceeded 4° in either direction.

mechanical axis of $\pm 3^\circ$, finding knees outside this target were not less durable than knees within the targeted range of alignment [14]. As an alternative to standard navigation, we

Fig. 6 A graph shows the frequency and magnitude of errors in sagittal alignment. The error in more than 90% of the cases was less than 3°. The skew in the data showed all the surgeons were conservative and tried to avoid excessive cutting that might cause anterior notching.

Fig. 7 A graph shows the frequency and magnitude of errors in rotational alignment. The errors never exceeded 2° in either direction. ER = external rotation; IR = internal rotation.

have developed freehand navigation to address most of the shortcomings of standard navigation. This includes cost, as the technology would free the surgeon from the need of conventional mechanical instrumentation. Freehand navigation differs from standard navigation by navigating the saw rather than the jigs; therefore, with freehand navigation, the costly jigs are no longer necessary. We assessed cutting time, surface quality, implant fit, and implant alignment in synthetic femoral specimens using this NFC technique, developed a smart saw by modifying a navigated saw to provide feedback to the surgeons and prevent them from

making cuts that deviate from the preoperative plan, and verified the feasibility and quality of a complete TKA performed with NFC technology in cadaveric specimens.

The study has several limitations. First, the devices we used are prototypes and therefore we are uncertain of the extent of obstacles that may impede further development of this technology. These might include the ability to sterilize or sufficiently shield smart electronic instruments, the susceptibility of such technology to electromagnetic noise and interference, and of course the flexible integration of such novel technology with the brands of power instruments surgeons prefer and are accustomed to. Second, the NFC technology has been tested by a small number of surgeons whose length and type of experience were widely different, but all had some experience with who are familiar with arthroplasty. The data may differ if even less experienced surgeons had participated. We believe a navigated saw programmed to prevent erroneous cuts would mitigate this problem; however, we do not have conclusive data to support this hypothesis. Finally, the study is not a prospective randomized trial. However, as with many evolving technologies, we have developed prototypes over the course of several years based on scientific engineering design and trial and error. Randomized trials would logically follow to further assess the benefit of this technology.

Our surgeons showed a quick learning curve with NFC on the femoral components with synthetic bones. The mean time required by all surgeons to prepare the fourth specimen was nearly ½ of the time required to prepare the first specimen. Our previous work comparing NFC to conventional jigs demonstrated the NFC technique was indeed faster than using jigs [7]. We have also demonstrated the NFC system can reliably produce quality bone cuts. The accuracy and alignment of implants were manifested through comprehensive quantitative assessment. The coronal alignment included only one specimen (3%) outside the $\pm 3^\circ$ error range commonly cited as acceptable alignment [3, 10]. Assessment of sagittal alignment found all specimens were between 0° and 5° of flexion, with no specimens in extension and no femoral notching. These findings demonstrate the surgeon's conservative nature when cutting the anterior femur as the errors were clearly skewed to flexion (Fig. 6). Assessment of rotational alignment also found all but one specimen was within 1° of the epicondylar axis and all were within 2° .

We were able to perform a complete TKA using NFC on two cadaveric knees. The mechanical axis, sagittal alignment, and rotation of the femoral and tibial components were well within the accepted range of anatomic reconstruction in TKA [3, 10].

Our preliminary work supports the concept that, with the type of NFC technology presented here, bone can be accurately prepared and implants can be anatomically placed without the use of jigs in TKA. Our previous work suggested

these techniques could be performed in less time than standard techniques using jigs. It is possible that NFC, as with other navigation techniques, will increase the number of prostheses placed in acceptable alignment. The improvement in operating time and elimination of instruments give this innovative technology the added benefit of cost savings. We believe previous navigation systems do not have those advantages. Because of these advantages, including an easier procedure with less cost and shorter operating time, freehand navigation using guided saws, drills, bone cut assessment devices and implant trials has the potential to be embraced by arthroplasty surgeons. We are optimistic about the future of the novel NFC technology presented here.

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