Improving accuracy in total knee arthroplasty: A cadaveric comparison of a new surgical navigation tool, Intellijoint KNEE, with computed tomography imaging

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Abstract

Total knee arthroplasty (TKA) is a generally successful procedure that alleviates knee pain and restores range of motion. Accurate positioning of femoral and tibial components is important to ensure joint stability and proper alignment. Malalignment of components may contribute to complications such as component loosening and increased wear that limits implant longevity and patient satisfaction. Computer navigation systems have been shown to increase the accuracy of component alignment in TKA. The current study investigated the accuracy of a novel, imageless, optical surgical navigation tool to assist with femoral and tibial cuts performed during TKA. Five board-certified orthopedic surgeons participated in a laboratory cadaver investigation, performing femoral and tibial bone cuts. Varus/valgus and slope measurements from the device were compared with angular measurements calculated from computed tomography (CT) images. Measurements with the navigation tool were highly correlated with those achieved with CT scan, with an absolute mean difference between the two methods in varus/valgus of 0.83° (SD 0.46°, $r = 0.76$) and in slope of 1.91° (SD 1.16°, $r = 0.85$) for the femoral cut and an absolute mean difference in varus/valgus of 1.08° (SD 0.64°, $r = 0.85$) and in slope of 2.78° (SD 1.40°, $r = 0.60$) for the tibial cut. Intraoperative monitoring with the imageless navigation tool may aid surgeons in accurately performing and monitoring femoral and tibial cuts in TKA and thus, accurately align components.

Keywords
Orthopaedics, rehabilitation, surgery, computer-assisted navigation, revision, total knee arthroplasty

Date: October 10, 2019

Introduction

Total knee arthroplasty (TKA) is a common and effective procedure to alleviate knee pain (e.g., from degenerative osteoarthritis) and/or correct deformed, unstable knees. TKA procedures are increasing, with a more active, aging population creating a demand [1, 2]. A recent analysis suggests the number of primary TKAs is predicted to rise 85% over the next 10 years to an estimated 1.26 million procedures per year [3].

While successful the majority of the time, with a 25-year survivorship rate of 80% [4], 5-9% of total TKAs performed are revision surgeries [1, 5]. Complications include component loosening, instability, dislocation, infection, and/or fracture [6].

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A larger proportion of patients, approximately 20-25%, may experience minor complications including knee pain or reduced movement [7-10]. It is important for implant and joint stability to equalize the flexion/extension gap and ensure proper soft tissue balancing, restoring range of motion and improving quality of life [11]. Improper soft tissue balancing can create instability and lead to increased wear on implants. A major goal of TKA is to restore alignment to within ±3°of the mechanical axis [12]. Malalignment of the femoral and tibial components may contribute to component loosening [12], increased wear, and reduced range of motion, which ultimately affects patient satisfaction and implant longevity [13]. One study reported that when varus/valgus alignment exceeded 3°, aseptic loosening occurred 24% of the time [12], while a second study reported a 17.2 times increased implant failure when tibia alignment was greater than 3° varus [13].

Navigation systems, both computer-assisted and, more recently, accelerometer-based navigation (ABN), have been developed in order to improve accuracy and precision of component placement in TKA. Image-based navigation utilizes pre-operative imaging (e.g., MRI and/or CT) to register the articular surface and alignment, while imageless navigation relies on intra-operative registration of the articular surface, femur, and tibia [14]. U.K. and U.S. data suggest that, annually, 3-5% of TKAs performed use navigation [15], with use in Australia reaching 33.2% [5].

Despite limited adoption, there is ample evidence to support that surgical navigation and ABN systems improve the alignment of femoral and tibial components in TKA [16-21]. Meta-analyses showed that not only was TKA performed with computer navigation more likely than conventional surgery to achieve optimal alignment (within 3°) [22], but patients undergoing navigated surgery had a 25% reduced risk of malalignment over 3° compared to conventional surgery [23].

Disadvantages of these technologies that may hinder their adoption include a high initial capital investment and the cost per case [24-26]. Use of image-based and imageless navigation increased surgery duration, on average, by 23% [23] and often comes with additional surgeon and staff training; however, there is imageless navigation that does not significantly increase surgery duration [27].

Intellijoint KNEE (Intellijoint Surgical Inc., Kitchener, Ontario, Canada) is a novel, imageless, optical surgical navigation tool that provides real-time intra-operative measurements of the position of the cutting guides on the femur and tibia during TKA. This allows for proper alignment of instrumentation and proper positioning of components. The navigation tool requires little set-up, does not impede the surgeon's line-of-sight, and is compatible with all implants. To assess the initial accuracy of this surgical navigation tool in measuring varus/valgus and slope angles of femur and tibia cuts during TKA, a laboratory investigation using human cadavers was conducted with board-certified orthopedic surgeons. The device measurements were compared with angular measurements calculated from computed tomography (CT) images.

Materials and Methods

Five cadavers (10 knees) were used in this study. Five board-certified orthopedic surgeons participated, with each performing total knee arthroplasty (TKA) procedures consisting of two proximal tibia and two distal femur cuts on the same cadaver (left and right knee).

Intellijoint KNEE

The Intellijoint KNEE imageless optical navigation tool (Intellijoint Surgical, Inc., Kitchener, Ontario, Canada) uses infrared optical technology and integrated microelectronics to monitor the real-time position of the femur and tibia cutting guides during TKA. This pinless, miniature, surgeon-controlled tool provides real-time intra-operative measurements displayed on a computer workstation located outside the sterile field. The system consists of an optical bone tracker attached to either the femur or tibia with a bone screw, an optical probe tracker used for registration and monitoring cutting guide position, and an infrared camera mounted within the sterile field. The camera is placed where it can detect the position and orientation of the trackers within its field of view and communicates with the computer workstation, where positional measurements are displayed to the surgeon using application software.

The varus/valgus angle and the flexion/extension (anterior/posterior slope) angle of the femur and tibia cuts are measured relative to the mechanical axis.

Procedure

Torso to toe tip specimens were positioned supine on the operating table and secured with peg boards. Exposure of the knee was conducted by surgeons using their preferred technique followed by selection of the femur or tibia to proceed with first. The optical bone tracker was attached to the articular surface of the selected bone using a bone screw. Regardless of which cut was undertaken first, the registration procedure for each bone is unchanged. Femoral registration was performed by registering the hip center of rotation and using the tip of the optical probe tracker to define the femur center, AP axis (Whiteside's line), and the lateral and medial condyle. Tibial registration was performed by using the optical probe tracker to register the AP axis and define the tibia center, the medial and lateral malleolus, and the medial and lateral plateau. Additionally, insertion of the flat base of the optical probe tracker into the cutting guide allowed surgeons to position and adjust the cutting guide into the desired position whereupon the guide was secured to the bone. Bone cuts were made with 1.35 mm sawblades. When possible, a second measurement was obtained following resection by placing the base of the optical probe onto the cut surface to verify the position of the cut.

Imaging and image analysis

Cadaveric specimens were analyzed using CT imaging. Long leg CT scans from the acetabular roof to the talar dome were obtained pre- and post-operatively with a GE LightSpeed VCT CT system, using a 0.625 mm slice thickness (GE Healthcare, Chicago, Illinois). Scans were segmented in 3D Slicer (v.4.10.1) to create 3D models of the femur and tibia. The mechanical and rotational axes were registered using anatomical landmarks. Angles of the bone cuts on the post-operative CT scan were based on the plane of best fit in relation to the registered mechanical and rotational axes. All calculations were performed using MATLAB® software (MathWorks, Inc., Natick, Massachusetts).

<u>Femoral registration landmarks</u>

The medial-lateral axis was defined as the cross-product of the superior-inferior and anterior-posterior axes. The superior-inferior axis was defined as the line from the center of the femoral head to the femoral knee center. Femoral knee center was defined as the most anterior point in the middle of the femoral notch, aligning the hip center with the roof of the femoral notch. The anterior-posterior axis was defined by the projection of Whiteside's line onto the axial plane.

<u>Tibial registration landmarks</u>

The medial-lateral axis was defined as the cross-product of the superior-inferior and anterior-posterior axes. The superior-inferior axis was defined as the line from the tibial knee center to the ankle center (determined as a weighted average (57:43) of the lateral and medial malleoli of the tibia). The anterior-posterior axis was defined by the line connecting the tibial knee center to the medial third of the tibial tuberosity.

Statistical analysis

The mean absolute difference in degrees between the navigation tool measurements and measurements calculated from CT scans was determined for varus/valgus and flexion/extension measurements for the femoral and tibial cuts and correlated using Pearson's correlations. Data are presented as mean (standard deviation (SD)). Navigation and CT measurements were also compared using the Bland-Altman technique which evaluates the level of agreement between the two clinical measurements.

Results

Cut angle measurements for five specimens, two females and three males (10 knees), were collected. The mean age was 78.8 ± 2.8 years of age and mean BMI was 25.92 ± 7.27 (Table 1).

Varus/valgus and flexion/extension measurements for the navigation tool and CT are summarized in Table 2. The mean absolute difference in varus/valgus angles between the navigation tool and CT for the femoral cut was 0.83°

(SD 0.46°, range: 0.27°-1.53°, Pearson's r = 0.76) and 1.08° (SD 0.64°, range: 0.12°-2.02°, Pearson's r = 0.85) for the tibial cut. The mean absolute difference in flexion/extension angles between the navigation tool and CT was 1.91° (SD 1.16°, range: 0.45°-3.56°, Pearson's r = 0.85) for the femoral cut and 2.78° (SD 1.40°, range: 1.46°-4.91°, Pearson's r = 0.60) for the tibial cut. A Bland-Altman analysis demonstrated that 100% (20/20, Figure 1) of paired varus/valgus measurements and 95% (19/20, Figure 2) of paired flexion/extension measurements were within the statistical limit for agreement.

Table 1 Demographic information for cadaver specimens

Specimen	Gender	Age	BMI
1	F	81	20.53
2	F	80	19.08
3	M	74	22.86
4	M	80	35.71
5	M	79	31.42
	Mean	78.8	25.92
	SD	2.8	7.27

Table 2 Comparison of varus/valgus and flexion/extension cut angle measurements calculated from CT images and the navigation system

CT: computed tomography
Nav: Intellijoint KNEE® imageless navigation system

Specimen	**Varus/Valgus (°)**		**Absolute Delta (°)**	**Flexion/Extension (°)**	**Absolute Delta (°)**	
Femur	**Nav**	**CT**		**Nav**	**CT**	
1R	0.28	0.7349	0.4549	2.1	0.0488	2.0512
1L	-0.11	0.9737	1.0837	4.6	3.5253	1.0747
2R	-0.64	-1.7659	1.1259	-1.15	-4.7091	3.5591
2L	1.26	1.7095	0.4495	4.37	2.2446	2.1254
3R	-1.23	0.3043	1.5343	5.49	4.9691	0.5209
3L	-0.42	0.4865	0.9065	2.29	-1.21	3.5
4R	-0.33	-1.74	1.41	3.71	2.57	1.14
4L	-0.17	-0.45	0.28	3.81	2.18	1.63
5R	3.0	2.73	0.27	0.58	0.13	0.45
5L	0.89	1.71	0.82	3.62	6.67	3.05
		Mean	**0.83**		**Mean**	**1.91**
		SD	**0.46**		**SD**	**1.16**
Tibia	**Nav**	**CT**		**Nav**	**CT**	
1R	-1.4	-2.1448	0.7448	2.1	-2.7946	4.8946
1L	1.7	0.4246	1.2754	1.3	2.961	1.661
2R	-0.67	-2.6895	2.0195	4.18	1.9191	2.2609
2L	0.58	0.6952	0.1152	1.72	0.2552	1.4648
3R	0.15	0.4344	0.2844	1.26	-0.6515	1.9115
3L	-1.66	-2.3097	0.6497	3.91	-1.001	4.9101
4R	0.6	1.99	1.39	3.94	2.25	1.69
4L	1.88	3.49	1.61	7.11	5.41	1.70
5R	-0.97	-1.9	0.93	3.78	0.68	3.1
5L	0.21	-1.57	1.78	6.4	2.19	4.21
		Mean	**1.08**		**Mean**	**2.78**
		SD	**0.64**		**SD**	**1.40**

Fig. 1 Bland-Altman plot showing agreement between varus/valgus angular measurements for all cuts. The average difference between the two measurements is compared with the average of the two measurements. 100% (20/20) of paired measurements were within the statistical limits (±1.96 x SD, dashed lines) for acceptable agreement. Solid line denotes the mean difference between the two methods

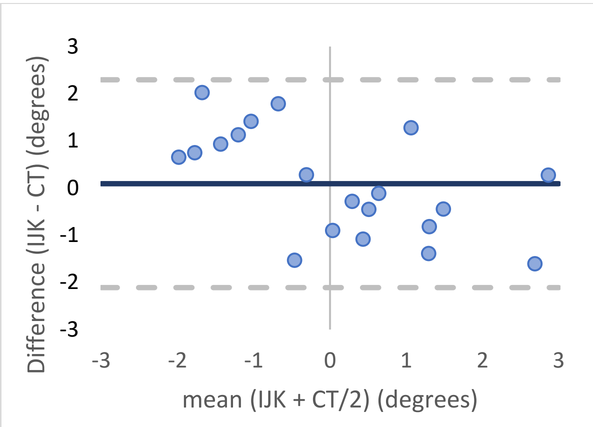
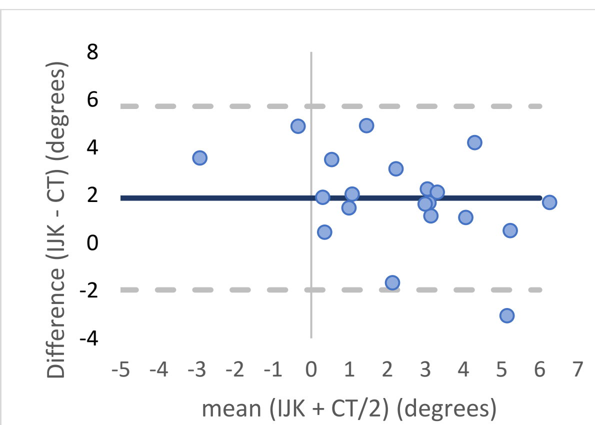


Fig. 2 Bland-Altman plot showing agreement between flexion/extension angular measurements for all cuts. The average difference between the two measurements is compared with the average of the two measurements. 95% (19/20) of paired measurements were within the statistical limits (±1.96 x SD, dashed lines) for acceptable agreement. Solid line denotes the mean difference between the two methods.



Discussion

Accurate alignment of components in TKA is critical to ensure a successful procedure and minimize future complications. Alignment to within ±3° of the mechanical axis is generally accepted as a goal of TKA [12]. Consequences of malalignment may include an asymmetric extension gap, contributing to increased wear, component loosening, limited range of motion, and potentially implant failure [6, 12, 13]. Post-operative varus greater than 3° significantly increased the risk of TKA failure [28]. Computer navigation systems have been developed to increase the accuracy and precision of component placement in TKA. The present study found that a novel, imageless, optical navigation tool was accurate in measuring femoral and tibial bone cuts as compared to CT images.

Factors that may adversely influence component alignment include variations in patient anatomy, and the intricacies of using alignment guides and cutting blocks. Performing accurate resection of the femur and tibia is a crucial step in successful TKA. Cutting errors have been investigated as a source of error that may contribute to accurate component placement [29-31]. Observed errors are generally higher for cuts in the sagittal plane; a cadaveric study reported maximum errors in the range of 1-2° for varus/valgus and 3-4° for flexion/extension [30]. A retrospective review of TKAs showed average absolute cutting errors of 0.8°-1.3° in the coronal plane and 1.3°-1.6° in the sagittal plane [31].

Extramedullary (EM) and intramedullary (IM) alignment guides are used to assist with accurate resection and component placement in TKA. Indeed, published studies report alignment of the mechanical axis within 3° varus/valgus in approximately 75% of patients [12, 16, 32]. However, even with alignment guides, there are challenges in achieving optimal alignment; for example, rotation of alignment rods has been shown to affect cutting planes [33]. Insertion of IM guides, even when performed with care, may still be associated with fat and marrow embolization [34], and obese patients present challenges in accurate placement of alignment guides [35, 36]. IM guides are invasive and require reaming of the femoral bone, while EM guides can be cumbersome. Both IM and EM guides rely on the surgeon's expertise in estimating angles to achieve optimal alignment.

Navigation has been shown to further improve the accuracy of tibial and femoral component alignment in TKA, with increased accuracy as compared to traditional alignment guides [16, 17, 19]. Imageless navigation, while still relying on the surgeon's expertise and instrument control, provides real-time intraoperative monitoring of the cutting planes. This allows for intraoperative adjustments to cuts that would not otherwise be possible and potential avoidance of complications that would not become apparent until follow-up.

The current cadaver investigation sought to determine the accuracy of TKA femoral and tibial bone cuts performed with a novel imageless, optical navigation tool by comparing measurements with that of CT imaging. Orthopedic surgeons performed bone cuts on two knees each and varus/valgus and flexion/extension angular measurements from the navigation tool were recorded. The mean absolute difference between the device measurements and those calculated from CT images were within 3° and highly correlated. Thirty-nine out of 40 (97.5%) paired measurements (device-CT) were within the statistical limit for agreement. This is consistent with the acceptable range of ±3° from mechanical axis for aligning TKA components. Alignment within 3° may decrease complications including implant loosening, increased wear, and implant failure [12, 13, 28]. Additionally, the navigation tool limits trauma to the femoral bone as use of IM alignment guides are not required. The use of this novel navigation tool does not require permanent alteration of the operating room or pre-operative CT imaging, increasing the potential cost-effectiveness of this device compared to other navigation options.

Our data are consistent with previous accuracy studies of navigation systems [37-39]. Accuracy of a handheld imageless tool was determined by comparing planned implant and actual implant orientation in 25 cadavers. Both femoral and tibial cuts were performed within 3° of the planned implant orientations [37]. Anteroposterior and lateral knee radiographs were compared to CT scans of 10 cadavers (20 knees) to determine if surgeons performing tibial resections could meet a random varus/valgus and posterior slope target with an ABN device. Surgeons were able to resect the tibia to within 3° of the pre-operative target [38]. Lastly, a study of 70 patients demonstrated the accuracy of an imageless navigation system by comparing the pre- and post-operative navigation and CT measurements for femoral and tibial cuts. Navigation and CT measurements were highly correlated both pre- (r = 0.84) and post-operatively (r = 0.66) [39].

Limitations associated with this study include the use of cadaver specimens and the associated drawbacks. There is some concern that frozen tissue may not mimic normal patient movement [40]; however, in this study, the tissue was thawed sufficiently to allow natural movements duplicating that of live human tissue. This laboratory cadaver simulation was the first time the participating orthopaedic surgeons had experienced the imageless navigation tool, operating on the two knees of one cadaver. There is a learning curve associated with any new technology and this potentially influenced the accuracy of the surgeons. Proficiency using a navigation tool for total hip arthroplasty developed by the same manufacturer was shown to drastically improve within 3-5 patient cases [41], substantially less than the cases required for proficiency with other navigation systems. Experience in a clinical setting with the current knee arthroplasty device will likely yield similar improvements, as the technology is similar. Clinical studies are required to confirm the navigation tool's accuracy in an operating room setting and provide comparisons to conventional alignment guides.

Conclusion

Femoral and tibial cadaver bone cuts were performed with an imageless, optical navigation tool with varus/valgus and slope measurements within ±3° of the mechanical axis. Measurements with the navigation tool were similar to those achieved with CT scan, with an absolute mean difference in varus/valgus of 0.83° (SD 0.46°) and in slope of 1.91° (SD 1.16°) between the tool and CT for the femoral cut and an absolute mean difference in varus/valgus of 1.08° (SD 0.64°) and in slope of 2.78° (SD 1.40°) between the tool and CT for the tibial cut. Intra-operative monitoring with the imageless navigation tool may aid surgeons in accurately positioning components in TKA using a less cumbersome device than traditional guides and/or navigation.

Funding
The authors received no financial support for the research, authorship, and/or publication of this article.

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