Reliability of Image-Free Navigation to Monitor 3D Long Leg Alignment

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Introduction: Proper long leg alignment following opening-wedge high tibial osteotomy (HTO) is critical to ensure a good surgical outcome (Hernigou, Sprenger). An intraoperative means of monitoring 3D long leg alignment would be useful in addressing anterior-posterior knee instabilities and in directing the weight bearing line away from chondral lesions in a controlled fashion. Image-free navigation systems provide such monitoring of intraoperative alignment in three dimensions, though uncertainty in the reliability of such systems persists (Hankemeier, Jenny, Yau).

Our work had two objectives: (1) Determine the reliability of a skin-contact registration process for 3D navigated alignment through an intra/interobserver analysis. (2) Determine the reliability of the navigation system in monitoring changes in lower limb alignment during HTO in three dimensions as compared to a novel CT 3D reconstruction method. We hypothesized that surgical navigation has excellent intra/interobserver reliability and correlation with CT in all three planes.

Materials and Methods: Eight fresh-frozen pelvis to toe-tip cadavers (7 male, 1 female), were obtained resulting in a total of thirteen limbs with sufficient bone quality for plating. The average age was 68 yrs (range 35-92). During all data acquisition, feet were held in foam molds, such that legs were positioned at approximately 15° hip flexion, 0° rotation, and full knee extension. The VectorVision 1.0 (BrainLAB, Munich/Germany) image-free navigation system with skin contact registration was used. For the intra/interobserver analysis, six observers with varying surgical and navigation experience (three skilled, three unskilled) registered and recorded initial varus-valgus alignment on a subset of six cadaver legs on three occasions spaced at intervals at least 36 hours apart.

The opening-wedge HTOs were performed by two surgeons (observers 1 and 2) with extensive surgical and navigation experience according to the manufacturer's specifications. The navigation system guided the positioning of the osteotomy plane, which was then distracted and fixated using a 12.5 mm tapered Puddu plate (Arthrex, USA). Pre- and post-operative alignment and relative motion of the proximal tibial fragment were monitored and recorded via varus-valgus angle, change in posterior slope, and change in tibial torsion.

Limbs were CT scanned before and after HTO using a GE MEDICAL SYSTEMS/LightSpeed VCT with scan spacing of 2.5 mm at three fields: hip, knee, and ankle. The CT data was then converted into 3D computer models using Mimics 10.11 (Materialize, Leuven/Belgium) from which varus-valgus angle, posterior slope, and tibial torsion were measured. Intraclass correlation coefficients (ICCs) were calculated for the intra/interobserver analysis and between navigation and CT data for preoperative, postoperative and delta values for varus-valgus. For posterior slope and tibial torsion, pre- to postoperative delta was used for ICC calculations because absolute measurements were not reported by the navigation system.

Results: The ICCs for intra/interobserver analyses are summarized in Table 1. These data indicate good intraobserver reliability for skilled observers only. Reliability between all users and even skilled users is below the accepted cutoff value, suggesting only fair interobserver reliability.

Table 1: Varus-Valgus Angle Intra*/Interobserver Reliability

Observer	Experience Level	ICC	P-value
Observer 1*	Extensive	0.756	0.001
Observer 2*	Extensive	0.922	<0.001
Observer 3*	Extensive	0.918	<0.001
Observer 4*	Moderate	0.504	0.022
Observer 5*	Minimal	0.526	0.017
Observer 6*	Minimal	-0.064	0.558
All (1-6)	-	0.395	0.002
Skilled (1,2,3)	-	0.644	0.004

The ICCs for navigation-CT comparison during HTO are summarized in Table 2. Correlation between navigation and CT measurements of varus-valgus angle is good, both pre- and postoperatively, and is even higher for pre-to-postoperative delta in varus-valgus angle. Correlation for change in tibial slope was only fair, while correlation for change in tibial torsion was poor.

Table 2: Navigation and 3D CT Correlation

Quantity	ICC	P-value
Varus-Valgus (pre-op)	0.784	<0.001
Varus-Valgus (post-op)	0.846	<0.001
Varus-Valgus (delta)	0.873	<0.001
Tibial Slope (delta)	0.709	0.002
Tibial Torsion (delta)	-0.196	0.750

Table 3 summarizes the maximum and mean differences in the measurements of each quantity for all trials, and then separately for trials where deformity was less than 12 degrees. Notably, the maximum difference between the delta in varus-valgus measurements is smaller with smaller deformities, suggesting that the navigation system may be more accurate under this constraint. The maximum differences for change in tibial slope and tibial torsion are also large even for small deformities.

Table 3: Differences in Navigation and 3D CT Measurements

	All Trials		Small Deformities	
Quantity	Max Diff	Mean Diff	Max Diff	Mean Diff
Varus-Valgus (pre-op)	3.6°	1.7°	3.6°	1.5°
Varus-Valgus (post-op)	5.6°	2.4°	2.2°	1.5°
Varus-Valgus (delta)	4.5°	1.8°	2.6°	1.4°
Tibial Slope (delta)	8.8°	3.9°	7.3°	4.3°
Tibial Torsion (delta)	16.5°	7.6°	16.5°	9.3°

Discussion: While interobserver reliability was only fair during registration, reliability between varus-valgus angle measurements made by navigation and CT was good, particularly in measuring pre- to postoperative delta in smaller deformities. These results suggest that the navigation system may be a poor tool for measuring absolute coronal alignment, but may be sufficiently accurate for tracking intraoperative changes in varus-valgus angle. Acknowledging this limitation, the navigation system may have clinical utility when used in conjunction with an accurate measure of preoperative alignment.

The low ICC values and large maximum differences for change in posterior slope and tibial torsion suggest poor accuracy in the sagittal and axial planes. Notably, in six of 13 trials the navigation system measured a change in tibial torsion in the direction opposite to that reported by CT. The poor correlation between navigation and CT in measuring changes in tibial slope and tibial torsion may be due to errors in skin contact registration or inaccurate definition of the tibial A-P axis that would lead to a misaligned coordinate system. Other navigation protocols rely on percutaneous registration of bony anatomy and/or kinematic registration to characterize 3D long leg alignment, including the tibial A-P axis. These other protocols may permit more accurate monitoring of 3D alignment in the sagittal and axial planes.

References: 1. Hernigou et al., JBJS, 1987. 2. Sprenger et al., JBJS, 2003. 3. Hankemeier et al., Knee Surg Sports Traumatol Arthrosc, 2006. 4. Jenny et al., Comput Aided Surg, 2004. 5. Yau et al., J Arthroplasty, 2005.

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