Part IV Total Hip Arthroplasty

Part IV A Navigation: Total Hip Arthroplasty

Validation of Imageless Total Hip Navigation

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Introduction

Optimal acetabular component orientation in total hip arthroplasty is a complex three dimensional problem with failure leading to increased wear and instability [1–6]. Although the exact frequency of acetabular component mal-position and the quantitative linkage to hip re-operation is uncertain, it is clear that at least some re-operations could be avoided through more reliable acetabular component positioning at the time of surgery. Extremes of component mal-position are associated with an increased risk of dislocation and loosening. In Lewinnek's investigation, the acetabular cup »safe zone« was radiographically identified as 15 degrees of anteversion and 40 degrees of opening angle in the performance of routine hip arthroplasty. The risk of dislocation increased from 1.5% to 6.1% if the cup was placed outside of the two degree of freedom, described »safe zone« [7]. The tolerance associated with optimal cup positioning was thought to be similar for both anteversion and opening angle at +/– 10 degrees. Computed tomography studies of post-operative cup insertions have shown that a large percentage of cases have an unacceptable positioning when depending on freehand or conventional mechanical instrumentation [8, 9]. According to a recent European investigation of total hip arthroplasty cups positioned using manual instrumentation and evaluated using CT, it was found that only 27/105 (26%) fell within Lewinnek's safe zone [10].

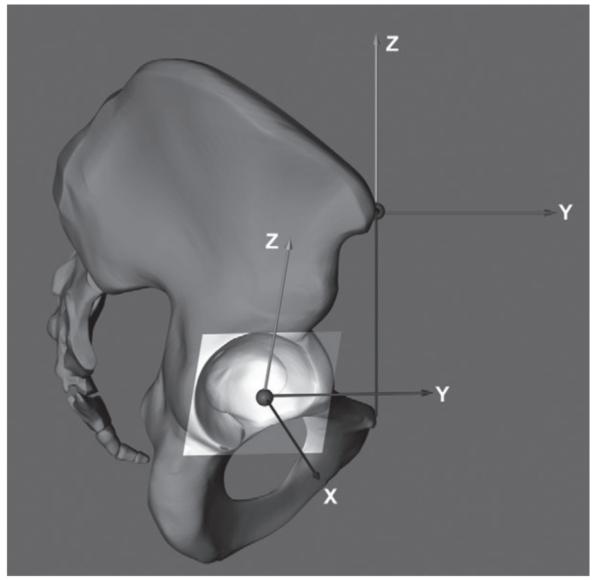
Computer-assisted orthopaedic surgery has been recently defined as the ability to utilize sophisticated computer algorithms to allow the surgeon to determine three dimensional placement of total hip acetabular implants in situ. Computer-assisted navigation for acetabular cup placement requires a registration that defines the anterior pelvic plane. McKibbin et al. first defined the anterior pelvic plane as a plane connecting the ventral surfaces of the anterior superior iliac spines and the pubic tubercles of the pubic rami [11]. Basically, a cadaver pelvis was placed »table down« with these points contacting the table. Inclination and anteversion of the acetabulum were then measured in relation to this plane.

From the beginning, computed tomography was the most accurate and reliable imaging modality to define these three dimensional relationships and has a proven precision of about one millimeter or one degree [12–15]. Other methods have been sought due to the amount of resources and time required to utilize computed tomography for navigation. One promising alternative is imageless registration where simple anatomical referencing can be done at the time of the operation [16–21]. However, the laboratory validation of this clinical application is lacking. This study compared the precision, repeatability and reproducibility of these methods against known metrological and computed tomography standards.

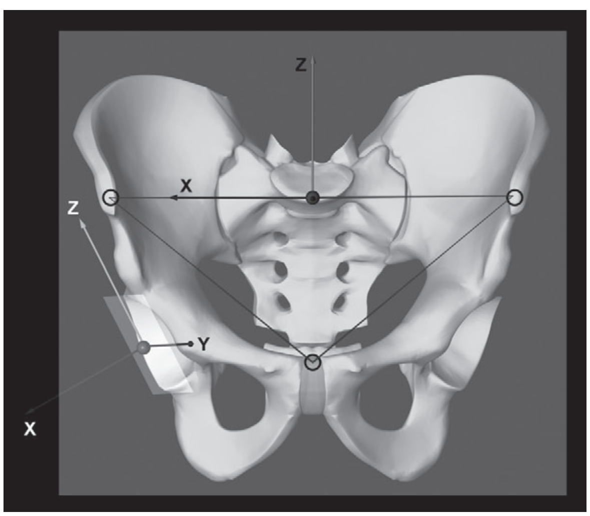
Methods

Eight surgeons were asked to clinically evaluate the position of acetabular components after having been inserted using an anterolateral, minimally invasive surgical technique. Each surgeon was asked to clinically estimate the cup position in relationship to the anterior pelvic plane (APP). For purposes of this investigation, the APP was defined as the plane defined by the most anteriorly prominent aspect of the two anterior superior iliac spines and the most prominent, anterior portion of the symphysis pubis. The origin of the APP was defined as the midpoint of the line defined by the two ASISs. A right hand coordinate system with positive X directed toward the right acetabulum (resurfaced with prosthetic cup), positive Y directed anteriorly and positive Z directed superiorly was arbitrarily chosen (▪ Figs. 42.1 to 42.3).

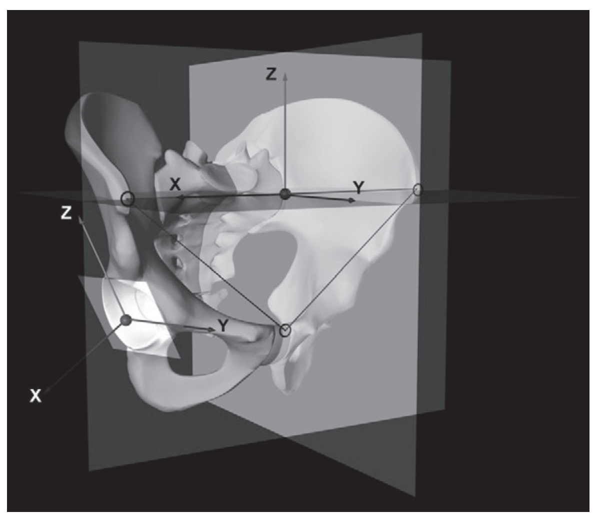
On a single reference cadaver eight surgeons then used the Medtronic Treon Plus[1] system and a custom software package to measure the component position. For the assessment of repeatability and reproducibility, each surgeon was randomly asked to re-reference the APP and to determine the position of the acetabular cup with eight independent repetitions. The cadaver was then assessed clinically using computed tomography (CT). Each cadaver was repositioned prior to each scan. CT scanning was performed using a Phillips' Brilliance 16 series computerized tomographic machine. One millimeter thick slices were obtained at 0.5 mm. increments. The machine was set at 140 KVP and 450 MAS. 3D reconstruction was carried out using the image reconstruction filter B, prior to measurement. During measurement, the CT images were positioned such that the two reference planes were perpendicular to the plane of the monitor. This isolated the measurement plane to that being viewed (▪ Figs. 42.4, 42.5) The Phillips angle and ruler image tools were used



▪ **Fig. 42.2.** Schematic pelvic diagram demonstrating calculation of anterior pelvic plane and the acetabular inclination and anteversion from lateral view



▪ **Fig. 42.1.** Schematic pelvic diagram demonstrating calculation of anterior pelvic plane and the acetabular inclination and anteversion from anterior posterior view



▪ **Fig. 42.3.** Schematic pelvic diagram demonstrating calculation of anterior pelvic plane and the acetabular inclination and anteversion from oblique view

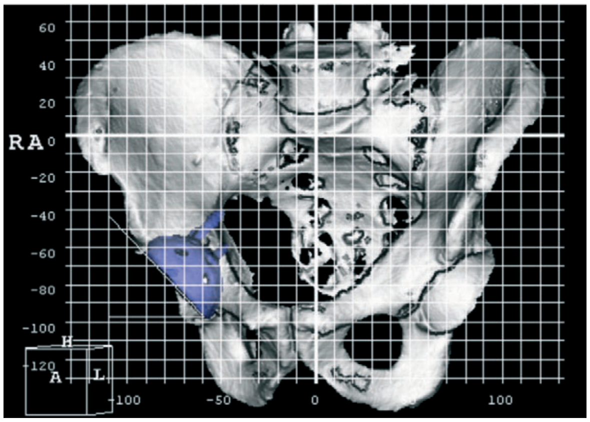


Fig. 42.4. Grid used for assessment of CT reconstruction for measuring acetabular inclination

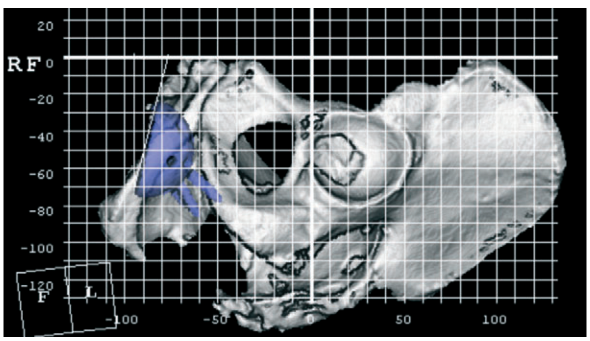


Fig. 42.5. Grid used for assessment of CT reconstruction for measuring acetabular anteversion

for measurement. This strategy allowed the direct measurement of independent DOFs without the need for projectional or magnification correction. A single trained, observer performed these multiple measurements in a masked fashion.

Surgeon Characteristics

The surgeons, who participated in the trial, ranged in age from 39 to 55 years of age. All surgeons were male. They averaged 19 (2–32) years from completion of their residency training. Four (44%) of the surgeons had previously used CAOS techniques previously. Seven of the eight American Board of Orthopaedic Surgery (ABOS) eligible surgeons were certified by the American Board of Orthopaedic Surgery. One of the surgeons had completed Osteopathic training and was not ABOS certified. Seven of the eight respondents used minimally invasive surgical techniques in the performance of total hip arthroplasty. The surgeons stated that they had performed 84 (30–250) total hip arthroplasties and 123 (30–290) total knee arthroplasties in the past year.

Statistics

Descriptive statistics were calculated using Excel 2003 and Minitab version 14.2. A probability of less than 0.05 was selected for statistical significance. Process capability analysis was done with a threshold of $Cp>1.3$; $Cpk>2.0$. This method is described elsewhere.

Results

Absolute Assessment Measures and Variability

For eight surgeon, assessment of clinical cues from the conventional instruments yielded mean acetabular inclination of 44° (SD = 5.35°) and anteversion of 12.29 (SD = 1.06°). Using the imageless optical tracking referencing surgical navigation, mean acetabular inclination was 43.59° (SD = 3.56°) and anteversion was 17.03° (SD = 1.01°). For one observer with 3D computed tomography, acetabular inclination was 44.05° (SD = 1.07) with anteversion of 12,8° (SD = 0.087°). Based upon the modeling performed, the variations were most dependent upon the surgeon performing the assessment and ranged from 0.877 to 7.63.

Process Capability

Using the data from this experiment and clinical component specification limits associated with the avoidance of dislocation, C_p and C_{pk} were determined. (Table 42.1) The only process that consistently approaches very high quality manufacturing process capability is that using 3D CT for assessment of cup position. With 3D CT in the assessment of acetabular inclination the C_{pk} was 2.81. In the assessment of anteversion C_{pk} was 4.38. The optical tracking system ($C_{pk} = 2.73$) was six sigma process capable in the assessment of acetabular component anteversion.

Table 42.1. Data from assessment of acetabular inclination and anteversion with process capability analysis. (Note: Upper and lower limits of +/– 10º; acceptable limits: Cp.1.3; Cpk>2.0) * Denotes below of process capability

Technique	Attitude	Standard Deviation	Mean	UCL	LCL	Cp	Cpk
Clinical	Inclination	5.35	40	50	30	0.62*	0.56*
	Anteversion	1.06	15	25	5	3.14	1.11*
Optical Tracking	Inclination	3.566	40	50	30	0.93*	0.88*
	Anteversion	1.01	15	25	5	3.30	2.73
3D CT	Inclination	1.065	40	50	30	3.13	2.81
	Anteversion	0.31	15	25	5	10.75	4.36

Surgeons, as a group, using visual cues alone, were unable to meet process specification associated with current definitions of high quality, rigorous manufacturing processes. The point picking surgical navigation technologies did not improve the surgeons' capabilities in the determination of acetabular inclination.

Discussion

Computed tomographic assessment of both acetabular inclination and anteversion was found to be process capable for the specification limits associated with dislocation avoidance based upon the measurements taken by one observer. The imageless referenced optical tracking surgical navigation system was process capable in the assessment only of acetabular anteversion. Unfortunately, when using clinical assessment alone, the participating surgeons' were not able to meet the rigorous process capabilities as used in other industries to address Lewinick's criteria for dislocation avoidance associated with cup mal-position. If more rigorous specification limits, such as those that have been proposed to avoid edge impingement, were set as boundary conditions, surgeons and imageless hip CAS applications are currently unable to achieve the desired level of accuracy or process capability.

It is possible that with improvements in the definition and determination of the pelvic plane, additional surgeon training and experience, that the effectiveness of these assessment systems may improve. It is also probable that with additional technical innovation, especially in approaches that will allow referencing improvement, that these systems may be able to have further improvement in their process capabilities. If the surgeon had a wider field of view, such as that associated with more extensile surgical approaches, it is possible that the ability to assess position might have been improved. However, based upon the single report of using conventional open surgical approaches in-vivo, it was found that the use of a CT based CAOS was required to improve both of the two degree of freedom accuracy and process capability in acetabular inclination and anteversion [22].

The findings of our current study are consistent with other recent work with imageless applications for the hip, and that is that point picking is problematic, especially for determining the transverse plane of the pelvis [16–19]. Anatomically, the anterior superior iliac spine is a relatively broad zone, and hitting a point that matches on both sides is difficult. Additionally, certain currently available systems have recommended that superficial skin surface point matching is suitable for referencing. We would disagree based on our current study. Recent studies have suggested that the error from these superficial methods approaches 0.5 degrees for one millimeter of discrepancy. For the pubic symphysis with a layer of fat that approximates 10 millimeters, this could for an error of at least 5°.

In conclusion, we believe that computer-assisted surgical applications will be needed to improve the overall precision of acetabular component positioning. From our analysis, computed tomography applications for CAS are currently process capable and this remains consistent with recent prior literature that confirms a precision of 1°/1 mm of reproducibility measures with these systems. We found determination of cup anteversion to be process capable for imageless hip applications but not for determining cup inclination. This most likely reflects the inability to accurately establish a transverse plane from point picking of the anterior superior iliac spines, at least done by current methodologies. In the future, it is possible that combinations of technologies will be needed to accurately reference the target anatomy.

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