Accuracy of acetabular component positioning with a fluoroscopically referenced CAOS system

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Abstract
Objective: This study evaluated the accuracy, repeatability, and reproducibility of a fluoroscopic referenced system used for guiding acetabular component positioning.
Methods: Calibration of the Medtronic StealthStation Treon Plus system was performed using a Weber gage block to assess linearity. Metrologic validation of repeatability and reproducibility was done using a cadaveric pelvis with an uncemented cup placed in the target position of 45° inclination and 17.5° anteversion. A baseline assessment was done with a National Institute of Standards and Technology (NIST) traceable coordinate measuring machine (CMM).
Results: Weber gage block analysis revealed a mean bias of 0.69 mm. For the cadaveric pelvis, the anterior pelvic plane was determined using the bilateral anterior superior iliac spines with the symphysis pubis as the inferior landmark. The mean CMM measurement was inclination of 46.023° (SD = 1.075; range: 43.318–46.844°) and anteversion of 15.787° (SD = 0.411; range: 15.068–16.384°). One surgeon performed a repeatability assessment (n = 8), finding mean inclination of 42.8° (SD = 1.5; range: 39.5–44.5°) and anteversion of 17.5° (SD = 3.0; range: 14.5–22.5°). Three surgeons performed a reproducibility assessment (n = 24), finding mean overall inclination of 48.5° (SD = 0.9; range: 46–50°) and anteversion of 17.8° (SD = 2.5; range: 13.5–23.5°). All measurements were within a predefined acceptability range of ±5°.
Discussion: The accuracy and reproducibility of the fluoroscopic referencing method was found to be suitable for determination of cup position in the surgical setting. Anteversion measurements were more variable for the fluoroscopic method and this may be related to the difficulty for the surgeon in predictably picking the anatomical points from the fluoroscopic image.

Keywords: Treon Plus, acetabular component, fluoroscopic referencing, cup position

Introduction
Optimal acetabular component orientation in total hip arthroplasty (THA) is a complex three-dimensional (3D) problem, with failure leading to increased wear and instability [1–6]. Although the exact frequency of acetabular component malpositioning and the quantitative linkage to hip reoperation 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. Computed tomography (CT) studies of postoperative cup insertions have shown that a large percentage of cases have unacceptable positioning when depending on freehand or conventional mechanical instrumentation [7, 8]. Recent publications have demonstrated a connection between positioning of the prosthesis and frequency of dislocation. Lewinnek et al. noted an increase in hip dislocation rate from 1.5 to 6.1% if a safe range of 15 ± 10° radiographic anteversion or 40 ± 10° acetabular inclination was exceeded [9]. Recent computer simulations have studied the relationship between range of motion and cup position. They found that the greatest range of hip motion was noted with anatomical acetabular anteversion of 20–25°, acetabular inclination of 45°, and femoral stem anteversion of 15° [9–11].

Computer-assisted orthopaedic surgery has recently been defined as the ability to use
sophisticated computer algorithms to allow the surgeon to determine 3D placement of total hip implants in situ. Multiple technologies are currently being used in the laboratory and in early clinical implementation. Technical implementations range from the use of preoperative CT of the patient’s hip joint to systems that use physical point identification fluoroscopy for point identification and hybrid techniques. In THA, several reports have cited the accuracy with which implants can be placed using computer-aided robotic devices or surgical navigation [12–25].

A focus group surveying US orthopaedic surgeons in 2004 concluded that surgeons did not trust existing commercial computer-based intraoperative positioning systems. They were concerned about the lack of information relating to system calibration, referencing, accuracy, repeatability, reproducibility, reliability, usability, and cost. We therefore elected to determine whether surgeons’ concerns about several of these characteristics in one commercial system (StealthStation Treon Plus, Medtronic, Louisville, Colorado) were justified. This investigation used NIST traceable calibration blocks and a single cadaveric pelvis study to assess the accuracy, repeatability, and reproducibility of a fluoroscopic navigation system used for acetabular component orientation.

**Methods**

**System calibration**

Using artifacts with traceability to the National Institute of Standards and Technology (NIST), the repeatability and linearity of the Treon Plus system were evaluated (Figure 1). A Weber gage block with equally spaced reference platforms 2.54 cm apart across a range of 25.4 cm was used as the primary artifact. The block was placed first parallel and then perpendicular to the plane of the imaging bar. The perpendicular attitude was established by using a NIST traceable triangular artifact. Each position of the Weber block was referenced using the point indicator six times in a random order with varying probe attitudes. Ambient temperature was constant during the short period of data acquisition.

**Pelvic cadaveric validation**

An embalmed cadaveric pelvis was used for the anatomical validation. The test conditions reproduced an operating room (OR) set-up to duplicate the operative procedure, including the use of a radiolucent OR table, lateral decubitus positioning of the pelvis, and typical room positioning of the system camera and the C-arm for image acquisition (Figure 2).
An acetabular component (Modular Trilogy Metal Cup, Zimmer Inc., Warsaw, IN) was securely fixed into the cadaveric pelvis with two screws. An instrumented insertion device was attached to the cup using the threaded hole in the cup apex. Initially, the target position of insertion was 45° cup inclination and 17.5° anteversion. The insertion device could then be removed and re-attached after the referencing protocol had been repeated. The Treon Plus system was evaluated with the software protocol for fluoroscopic navigation of acetabular component insertion. The important navigational references for this system are the anterior pelvic plane (APP) and the anatomical center of the affected acetabulum. For each trial, the APP was determined which represented the coronal plane of the anterior pelvis in the standing position or the longitudinal axis of the patient. The APP’s three reference points included the two anterior superior iliac spines and the most anterior surface of the pubic symphysis. For all trials of computer navigation, the APP was established radiographically using bi-planar fluoroscopic images.

To assess the accuracy of the system, the position of the cup in the cadaveric pelvis was measured by a NIST traceable Brown and Sharpe coordinate measuring machine (CMM) (accuracy = 0.038 mm). This was done using a direct point-matching protocol, as all soft tissues covering the anterior pelvis were removed and the reference points for the APP were directly visible. The specific coordinate system used was the acetabular anatomical pelvic plane reference, which measures the acetabular inclination angle at the center of the cup relative to the coronal plane. Similarly, acetabular anteversion is the angle at the center of the cup relative to the transverse axis. Five trials were used to calculate the acetabular position.

Repeatability of the referencing system was assessed by one experienced surgeon, who performed the entire referencing protocol for the Treon Plus fluoroscopic system, including fluoroscopic image acquisition. This protocol required the use of a grid on the fluoroscopic C-arm to calibrate the image to compensate for errors resulting from the earth’s gravitational forces. Images were acquired to represent each of the reference points in two perpendicular radiographic planes, including the contralateral side anterior superior iliac spine (ASIS), the pubic symphysis, and the acetabular cup center. Comparable to the surgical setting, the affected side ASIS was determined by a direct point-matching method. The acetabular center was referenced on the computer screen from the concentric center of the acetabular component. Once the system had been referenced, the acetabular cup insertion instrument was calibrated using a reference block and geometric

Figure 2. OR setup of the cadaveric pelvis, C-arm and cup positioner to perform the acetabular insertion study.
data for the specific cup. The navigation system uses an anatomical measurement scheme similar to those of prior CT methods. For the purposes of this investigation, acetabular inclination was defined as the angle between the Z-axis and the line of intersection of the plane parallel to the face of the acetabulum with the APP (‘frontal’) plane. The anteversion angle was defined as the angle between the Y-axis and the line of intersection of the plane parallel to the face of the acetabulum with the APP (‘frontal’) plane. The cup inserter was then securely inserted into the fixed component in the cadaveric pelvis and measurements were made for eight consecutive trials.

Reproducibility of the cup insertion method was assessed by three surgeons who independently referenced one set of fluoroscopic images that had been acquired in the computer system. Specifically, this required each of the reference points to be picked on the computer screen, including the ipsilateral ASIS, the contralateral ASIS, the pubic symphysis, and the acetabular cup center. As noted earlier, the affected side ASIS point could be determined by direct point matching. The most prominent aspect of the midpoint of the ASIS was referenced. For each trial, the instrumented cup inserter was referenced using an identical cup and the inserter attached to the fixed pelvic cup for measurement.

Statistics

MS Excel 2003, SP1, and Minitab, version 14.13, were used for statistical analysis. Basic descriptive and the Pearson r regression models were used for data analysis and presentation. Assumption of distributional normality was verified prior to modeling by assessment of the goodness of fit. Absolute dimensions are reported with variability measures of one standard deviation and the absolute range. Probabilities are reported as two-sided.

Results

System calibration accuracy and repeatability

The Treon Plus system was found to have small but statistically systematic biases in comparison to the fiducial block in both parallel and perpendicular attitudes relative to the imaging bar (Figures 3a and 3b, respectively). The mean bias for the parallel condition was 0.26 mm. Regression analysis demonstrated a fixed bias of 0.52 mm (P = 0.00). The mean bias varied inversely according to the distance from the center of the imaging bar. The further the point of measurement from the center of the imaging bar the greater the deviation from the known artifact. The slope of the deviation was small at −0.00232 mm and was statistically different (P = 0.01). The mean bias for the perpendicular condition was 0.69 mm. Regression modeling demonstrated a fixed bias of 0.79 mm (P = 0.00). The mean bias varied inversely according to the distance from the imaging bar. The further the point of measurement from the imaging bar the smaller the deviation from the known distance. The slope of the deviation was small at −0.00085 mm and was not statistically different from zero (P = 0.33).

Pelvic cadaveric validation

Accuracy. The acetabular cup position after insertion using the Treon fluoroscopic referenced system was assessed by comparing its position with measurements from the NIST-traceable CMM. The mean CMM abduction measurement of the acetabular cup position was 46.02° (SD = 1.075; range: 43.32–46.84°). The mean CMM anteversion measurement of the acetabular cup position was 15.79° (SD = 0.411; range: 15.07–16.38°).

Repeatability. Using the fluoroscopic referencing system, repeatability of the acetabular component position was assessed by one surgeon repeating eight trials with complete image acquisition and cup insertion. The mean inclination was 42.8° (SD = 1.5; range: 39.5–44.5°). The mean anteverision was 17.5° (SD = 3.0; range: 14.5–22.5°).

Discussion

Variability in the measurement process can potentially be a function of multiple random or systematic errors. Systematic errors include variation in ambient temperature and physical limitations of the measurement system. Physical limitations of an optical measuring system, for example, include the number and density of pixels available in the active field of view, the distance from the measurement plane, the size of the measurement zone, the attitude of the zone being measured relative to the measurement plane, variability in target positioning, the processing software, and design characteristics of the measurement probe. Experimentally, errors may be associated with the measurement system itself or the user, or may be due to errors relating to the specific
application. For example, factors such as obesity or anatomic variation may interfere with the user’s ability to reliably perform the referencing tasks.

This study addresses several questions that a surgeon might have regarding the use of computer-assisted navigation in clinical practice. The systems assessed were both precise and accurate. The measurement system must be designed and calibrated such that there is minimal error in the measurement of a single point’s absolute position. Furthermore, the position of a measured point should be accurate throughout the system’s field of view. This implies that any errors should be consistent across linear distance in any direction. From the current study, the system tested produced very small deviations, or bias, from the ‘ground truth’ measurements of the calibration bar. Mean biases were less than 1 mm across the measured field of view. However, bias did vary across the field of view: At the extremes of the measurement field, the deviation from ‘truth’ increased, but still remained small in terms of absolute deviation.

The potential success of improvements in positioning through the use of computer-assisted surgery will...
depend upon multiple factors. The basic accuracy of the computer system in providing numerically correct output data and the ability of the referencing protocol to reliably create the virtual operating field for the surgeon’s interpretation are fundamental requirements.

Numerous studies have attempted to define limits that appear to be acceptable for clinical usage of surgical navigation in placing the acetabular component in THA. Grützner et al. evaluated a different hybrid system that used a C-arm fluoroscopic bi-planar landmark reconstruction and point matching similar to that used in the Treon Plus system. They compared CT-based navigation with fluoroscopic inclination and 6° for anteversion, with a maximum error of 5°. 1.71° after fluoroscopy-based navigation [17]. Hube et al. evaluated CT-based navigation with 350 observations, finding a maximal inclination error of 5° in 99% of cases and a maximal anteversion error of 5° in 97% of cases [13]. Jolles et al. evaluated imageless navigation in plastic pelvic bones, finding a mean accuracy of 1.5° for inclination and 2.5° for anteversion, with a maximum error of 8° [19].

The computer navigation referencing protocol in this study used fluoroscopically acquired images to establish the APP and to determine the affected cup center. For the system tested, the APP was defined as the plane that was defined by the two ASISs and the most anterior point of the pubic symphysis. The pubic symphysis was chosen as the pubic tubercles are not easily identified fluoroscopically. The fluoroscopic system determined cup position using the anatomical position definition [28]. This scheme is typically applied by CT protocols for measuring cup position [26,27]. This is an important distinction, as other radiographic methods for determining cup positioning have been described in the literature [28].

From the current study, we found that the accuracy of one surgeon, as compared to the CMM control, demonstrated that the system deviated by 3.22° from the reference standard in the assessment of inclination. In the assessment of anteversion, the bias was 1.71°. The repeatability was found to be 1.5° for component inclination and 3.0° for anteversion.

Future investigations should address other clinically important degrees of freedom. In particular, the ability of navigation systems to determine the three translational degrees of freedom associated with cup position should be considered as additional feature requirements. Extremes of translational malpositioning have additional clinical relevance in allowing the surgeon to optimize hip kinetics, avoid intrapelvic protrusion, achieve leg-length equality, and avoid eccentric columnar reaming. In this study, repeatability assessment was designed to evaluate the full system referencing protocol, while reproducibility assessment focused on determining cup position variation between surgeons without new image acquisition for each trial. Future studies should consider assessing repeatability and reproducibility using an identical referencing protocol.

In summary, accuracy, repeatability, and reproducibility of two degrees of rotational freedom while using the Medtronic StealthStation Treon Plus system were characterized in an ex vivo system. In the assessment of accuracy, systematic measurement errors were identified and characterized. In the repeatability measurements of inclination and anteversion, the magnitude of these errors was found to lie within the predefined error believed to be of clinical significance. In the assessment of reproducibility, only one anteversion measurement lay outside the range believed to be of clinical significance.

References