Six Sigma Analysis of Minimally Invasive Acetabular Arthroplasty

A Preliminary Investigation

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Abstract Minimally invasive techniques in THA may increase the difficulty of acetabular component insertion relative to the optimized position. We sought to determine the ability of eight surgeons to position an acetabular component placed using an anterior-lateral minimally invasive surgical (MIS) approach with conventional instruments or computer navigation using an optical imageless protocol compared with conventional true values determined by computed tomography (CT). We introduce a new approach, the Six Sigma process capability index, to assess outliers. Using the Six Sigma process capability index ($C_p > 1.3$) and the criteria of Lewinnek et al. of $\pm 10^\circ$ for adequate precision, three-dimensional (3D) CT was capable for inclination and anteversion. Computer navigation and visual cues with conventional instrumentation were precise for anteversion but not for inclination. We conclude image-free computer navigation was not better than conventional instrumentation with the surgeons'

visual cues for acetabular cup placement. Six Sigma analysis allows comparison of various methods of referencing with literature controls, and our data suggest CT referencing is the most precise method.

Introduction

The literature documents variable positioning of acetabular cup placement in THA [1, 5, 10, 41]. Extremes of component malpositioning are associated with an increased risk of dislocation and loosening [8, 11, 16, 18, 20, 42, 46]. 3D modeling and late implant retrievals have suggested even more subtle malpositioning is associated with edge impingement [3, 4, 22, 31–34, 45, 47]. A European investigation [31] of THA with cups positioned using manual instrumentation and evaluated using CT suggested only 27 of 105 (26%) fell within the safe zone of Lewinnek et al. [25]. Furthermore, as surgeons adopt less invasive surgical procedures, the ability of the surgeon to observe anatomic landmarks may be compromised, which might lead to an increased risk of component malposition [2, 7]. Although newer instrumentation has been developed to facilitate performance of minimally invasive procedures, the associated accuracy, reproducibility, and generalizability of these novel techniques are uncertain and may benefit by the addition of computer-assisted navigational techniques [6, 12–14, 23, 39, 43]. Fundamental to the reliable insertion of an acetabular component is whether we can improve our ability to accurately assess cup positioning while we are able to change it.

Computed navigation techniques use sophisticated computer algorithms and tracking systems to allow the surgeon to determine 3D placement of instruments and prosthetic components during surgery. Numerous reports

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suggest the ranges of accuracy with which implants can be placed using computer-assisted surgical navigation typically will have standard deviations of 1° to 10° from the control [5, 17, 19, 23, 30, 31, 43, 44, 48]. We believe the primary objective of computer-assisted surgery (CAS) is to eliminate unacceptable outliers and we discuss limitations of these prior studies.

To compare various approaches, we introduce the Six Sigma process capability index, which is a standard method to evaluate the occurrence of outliers [21, 36, 38]. Following the work of Shewart and Deming after World War II, as reported by Kotz and Johnson [21], Six Sigma has become a widely applied methodology for evaluating industrial processes [36, 37]. The Six Sigma process capability index determines an acceptable range of values for a test and then places the bell-shaped distribution (6σ) of values for the test in the denominator. Outliers diminish the ratio created. The goal of Six Sigma is to define a ratio in which the possibility of outliers is minimal or slight.

We hypothesized, with the limited exposure of a MIS approach, computer navigation would increase implant position precision compared with conventional instruments.

Materials and Methods

We asked eight surgeons to clinically evaluate the position of an acetabular component that had been inserted in a cadaver using an anterolateral, MIS technique. Using the visual cues from conventional instruments, each surgeon assessed acetabular inclination and anteversion. Computer navigation of the component insertion then was performed independently by each surgeon using an imageless referencing protocol to establish the position of the anterior pelvic plane (APP) with measurement of cup inclination and anteversion. Each surgeon performed the referencing protocol eight times. Conventional true values of the acetabular component position were established using CT [41]. We then compared the experimental values obtained from the surgeons' assessment using conventional instruments and navigation with the reference conventional true values.

For the MIS, we used an 8-cm anterior incision made from a point over the anterior margin of the greater trochanter extending oblique and cephalad to a point three fingerbreadths posterior to the anterior-superior iliac spine (ASIS) [2, 7]. The fascia of the gluteus maximus was incised and we identified the anterior margin of the gluteus medius muscle. A lighted retractor then was passed over the anterosuperior hip capsule but inferior to the gluteus minimus tendon at the insertion to the greater trochanter. We then incised the hip capsule over the superior insertion into the greater trochanter and along the anterior femoral

neck. A Z-shaped incision of the anterior capsule was made by extending the incision along the anterior femoral neck to the acetabular margin and then superior along the superior rim of the acetabulum. We completed exposure of the acetabulum by placing two retractors over the anterior and posterior rims of the acetabulum and by incising the inferior transverse acetabular ligament, which mobilizes the proximal femur. Through this approach, an acetabular component was inserted using a conventional cup insertion device at a target position of 45° inclination and 17° anteversion.

The surgeons ranged in age from 39 to 55 years. All surgeons were male. They averaged 19 years (range, 2–32 years) from completion of residency training. Four of the surgeons had used CAS techniques previously. Seven of the eight were certified by the American Board of Orthopaedic Surgery (ABOS). One of the surgeons had completed osteopathic training and was not ABOS-certified. Seven of the eight respondents were experienced in performing minimally invasive THA. The surgeons stated they had performed 84 (range, 30–250) THAs and 123 (range, 30–290) TKAs during the past year.

We asked each surgeon to clinically estimate cup inclination and anteversion in relationship to the longitudinal and transverse planes of the body using conventional instruments (Fig. 1). For computer navigation, the APP was determined. Recent studies have advanced the use of this structure because of the definable landmarks presented [19, 26, 29, 35, 37, 43]. For purposes of this investigation, the APP was defined as the plane defined by the most anteriorly prominent aspect of the two ASISs and the most prominent anterior portion of the symphysis pubis. For cup anteversion and inclination of all tests, including CT assessment, we used the operative definition described by Murray [27]. Operative anteversion is the angle between the longitudinal axis of the patient and the acetabular axis

Fig. 1 An example of touch-point referencing of the pubic tubercle of registration is shown.

as projected onto the sagittal plane. Operative inclination is the angle between the acetabular axis and the sagittal plane. These relationships accurately define what the surgeon is assessing in the operative field. Each surgeon was asked to provide these data independently. Each surgeon was masked from the assessments of the other surgeons.

On the reference cadaver, eight surgeons then used the imageless referenced TREON[®] Plus system (Medtronic, Inc, Louisville, CO) and a custom software package to measure the component position. The software was designed to allow a more comprehensive display of positional information than is available in commercially available, US FDA-approved software. The APP was established by touch-point referencing, and cup position

Fig. 2 This photograph shows placement of the acetabular component in the pelvis with a navigated cup inserter.

was determined by attaching a referenced cup inserter to the acetabular component. Specifically, the two ASISs and the pubic symphysis were referenced by percutaneous puncturing to touch point the chosen reference points (Fig. 2). The digital values created by the computer protocol followed the operative definition as defined by Murray [27]. We randomly asked each surgeon to rereference the APP and to determine the position of the acetabular cup with eight independent repetitions.

To establish the true acetabular component position, post hoc CT analysis was performed by an independent observer (KB) who did not participate as a surgeon. The conventional true value is the mean value determined after a limited or finite number of trials by a method considered accurate and precise enough for benchmarking [42]. Using a Philips Brilliance 16 series CT machine (Royal Philips Electronics NV, Eindhoven, The Netherlands), 1-mm-thick slices were obtained at 0.5-mm increments. The machine was set at 140 kVp and 450 mAs. The 3D reconstruction was performed using the image reconstruction filter B before measurement. During measurement, the CT images were positioned such that the two reference planes were perpendicular to the plane of the monitor [10, 15, 25, 27] (Fig. 3). This isolated the measurement plane to that being viewed. The angles calculated followed the operative definition as described by Murray [27] and were identical to those measured by the conventional visual cues. The Philips angle and ruler image tools were used for measurement. This strategy allowed direct measurement of independent degrees of freedom without the need for projectional or magnification correction. The observer performed eight measurements in a masked fashion.

Fig. 3A–B (A) CT reconstruction shows grid orientation of the APP in the coronal plane. The angle assessed is the operative inclination angle (see text). (B) Sagittal plane orientation of the grid with the

ASISs and pubic symphysis is shown in this CT reconstruction. The angle assessed is the operative anteversion (see text).

Descriptive statistics were calculated using Excel[®] 2003 (Microsoft Corp, Redmond, WA) and Minitab[®] Version 14.2 (Minitab Inc, State College, PA) (Table 1). Verification of the null hypothesis, that the distributions were not different from normality, was performed using Minitab's implementation of the Anderson-Darling test (empiric cumulative distribution function) [41]. We calculated Six Sigma process capability indices for each group [22, 36, 38]. This method has been widely developed for quality control in many sectors of manufacturing and has been used to improve outcomes in medical applications. The process capability index (Cp) is a ratio created by dividing the projected acceptable range of values for a given test by the actual bell-shaped distribution (6σ) of values for that test. Outliers are values that are outside the acceptable range or specifications limits for a test. By example, a Cp of 1.33 will have 0.06% outliers or 63 unacceptable parts per million. A Cp of 0.66 will have 4.55% outliers or 45,500 parts per million. It would appear any method producing a Cp of 1.3 or better is a reasonable goal and has been achieved in other manufacturing processes.

The process capability index is mathematically formulated as follows:

$$Cp = \frac{(USL - LSL)}{6\sigma}$$

where USL is the upper specification limit, LSL is the lower specification limit, and σ is the standard deviation. In this study, we used the criteria established by Lewinnek et al. [25] for determining the ideal target mean and

outliers, ie, $\pm 10^\circ$ for the upper and lower specification limits. However, Cp may not adequately reflect the capabilities of the process when the distributional mean is offset; ie, when the mean of the test group is not coincident with the conventional true value, a problem with calibration is present. If the distribution is sufficiently wide such that the tails of the bell-shaped curve intersect either of the specification limits, calculation of the offset capability index, or Cpk, is required:

$$Cpk = \min \left[\frac{(USL - \bar{x})}{3\sigma}, \frac{(\bar{x} - LSL)}{3\sigma} \right]$$

For further clarification, Cpk measures the minimum value of the specification limit to the mean assuming the mean is either above or below the conventional true value for the test. By convention, the Cpk must be equal to or less than the Cp. For elimination of outliers, we believe the Cpk also should be above a minimum value of 1.3.

Results

Using process capability comparisons, we rejected our hypothesis suggesting an advantage of optical tracking. Optical tracking offered no clear improvement identified for determining implant cup anteversion as compared with conventional instrumentation using visual cues with similar Cp values (Table 2). However, there was a slight advantage of optical tracking, because the Cpk for conventional instrumentation fell below the acceptable limit (Cpk = 1.11). The mean values of the opening angle ranged from 43° to 44° . Mean assessed values for anteversion ranged from 12.3° to 18.76° . Based on the analyses performed, the variations were most dependent on the surgeon performing the assessment and ranged from 0.877 to 7.63. The only method with adequate capability for cup inclination and anteversion was that using 3D CT for assessment of cup position. With 3D CT in the assessment of acetabular inclination, the Cp was 2.81. In the assessment of anteversion, Cpk was 4.36, optical tracking (Cp = 3.30) and

Table 1. Descriptive statistics of all groups

Technique	Abduction	Anteversion
Conventional	$44^\circ \pm 5.4^\circ$	$12.3^\circ \pm 1.06^\circ$
CAOS	$43.6^\circ \pm 3.6^\circ$	$17^\circ \pm 1.01^\circ$
CT	$44^\circ \pm 1.0^\circ$	$12.8^\circ \pm 0.31^\circ$

Values are expressed as mean $\pm$ standard deviation; CAOS = computer-assisted orthopaedic surgery; CT = computed tomography.

Table 2. Six Sigma analysis of groups using the criteria of Lewinnek et al. ($\pm 10^\circ$)

Technique	Attitude	SD	Mean	UCL	LCL	Cp (95% CI)	Cpk (95% CI)
Clinical	Inclination	5.35	40	50	30	0.62 (0.30, 0.94)	0.56 (0.19, 0.93)
	Anteversion	1.06	15	25	5	3.14 (1.54, 4.75)	1.11 (0.48, 1.74)
Optical tracking	Inclination	3.56	40	50	30	0.93 (0.46, 1.41)	0.88 (0.36, 1.40)
	Anteversion	1.01	15	25	5	3.30 (1.34, 4.73)	2.73 (1.28, 4.18)
3D CT	Inclination	1.06	40	50	30	3.13 (1.34, 4.73)	2.81 (1.34, 1.73)
	Anteversion	0.31	15	25	5	10.75 (5.28, 16.26)	4.36 (2.06, 6.66)

The optimal mean, upper control limit (UCL), and lower control limit (LCL) are based on these criteria; SD = standard deviation; CI = confidence interval; Cp = process capability index; Cpk = offset capability index; 3D = three dimensional; CT = computed tomography.

conventional instrumentation ($C_p = 3.14$) were capable in the assessment of acetabular component anteversion but not for acetabular inclination.

Discussion

For THAs, surgeons have strived to limit the surgery in terms of incision and exposure. One of these methods is the minimally invasive anterolateral approach, which exposes the hip anteriorly without incision in the gluteus medius muscle. Computer navigation methods of insertion of the acetabular component have been advocated to optimize cup position. We designed this study to determine, in an experimental setting, if computer navigation could improve precision of cup positioning compared with conventional instruments.

This study is subject to certain limitations. Only one cadaver was used. However, published studies and our prior study used only limited numbers of cadaver specimens [17, 29, 35, 38, 40]. In clinical practice, there undoubtedly would be more variability for imageless referencing if more specimens would have been used. We inserted only one optimized cup and that served as the baseline example in all tests. Cup insertion can be a source of variation. The surgeons in this study were quite experienced with THA but were new to the MIS anterior approach and to the computer methods. Therefore, we cannot rule out the possibility that the observations have an associated learning curve. A fully developed experiment would require consideration of individual patient factors, surgical factors, surgeon factors, image processing/analysis factors, greater numbers of repetitions, and creation of dummy variables to model other potential interactions.

Sufficient numbers of representative cadaveric specimens, volunteer surgeons, and technicians to fully explore these potential factors on process capability were not in the budget of this preliminary investigation. Nevertheless, we believe conclusions of this study could be considered a reasonable approximation of measurement precision.

We found CT assessment of acetabular inclination and anteversion was precise enough to avoid outliers based on specification limits associated with dislocation avoidance as defined by Lewinnek et al. [25]. The imageless referenced optical tracking system and conventional instrumentation with visual cues were precise for acetabular anteversion but not for acetabular inclination. We believe most surgeons using conventional instrumentation should be able to perform acetabular cup positioning as reliable as currently available imageless referenced computer navigation systems. If more rigorous specification limits such as those that have been proposed to avoid edge impingement were set as boundary conditions, surgeons and these more advanced tools currently are unable to achieve the desired level of precision [47].

Although descriptive statistics are available from most reports, meaningful and generalizable comparisons are lacking. For that reason, we have calculated Six Sigma process capability indices for each measuring method. In the first place, accuracy is not what we are looking for because accuracy is a fixed measure to a reference point and must be determined individually for each trial. We really want to know how precise a computer system is in eliminating measurement outliers. The Six Sigma formula determines the precision of a system by comparing the maximum tolerable spread of values in the numerator with the bell-shaped variation of actual values (6σ) in the denominator [21]. Outliers will disturb and diminish this

Table 3. Reported precision of acetabular component positioning reproducibility of different navigation systems using process capability analysis (upper and lower specification limits, $\pm 10^\circ$)

Study	Modality	Object	Number	Control measurement	Inclination	Anteversion	Cp inclination	Cp anteversion
Grützner et al. [9]	Fluoroscopy, digitizing	Patients	50	CT	1.5° (SD, 1.1°)	2.4° (SD, 1.4°)	2.22	1.38
Nogler et al. [29]	Imageless	Cadaver	12	Digitizing arm	−3.8° (SD, 3.4°)	−4.8° (SD, 4.55°)	0.98*	0.36*
Tannast et al. [40]	Fluoroscopy	Cadaver	14	CT	0.7° (SD, 2.8°)	−6.6° (SD, 6.0°)	1.19*	0.55*
Jolles et al. [17]	CT	Plastic bones	50	Electromagnetic digitizing	Mean SD, 2.5°	Mean SD, 1.5°	1.33	2.2
Stiehl et al. [38]	Fluoroscopy	Cadaver	24	CT, CMM	0.6° (SD, 0.9°)	3.2° (SD, 2.5°)	3.7	1.3*
Spencer et al. [35]	Imageless	Cadaver	10	CT	Mean SD, 6.3°	Mean SD, 9.6°	0.52*	0.34*
Current study	CT	Cadaver	1	CT	Mean SD, 1.0°	Mean SD, 0.31°	3.13	10.75
	Conventional	Cadaver	8	CT, CMM	Mean SD, 5.4°	Mean SD, 1.1°	0.62*	3.14
	Imageless	Cadaver	8	CT	Mean SD, 3.6°	Mean SD, 1.1°	0.93*	3.30

* Below acceptable limits for process capability, which is greater than 1.3; C_p = process capability index; CT = computed tomography; CMM = coordinate measuring machine; SD = standard deviation.

ratio. The most important consideration for using the Six Sigma formula is setting the proper upper and lower specification limits. In our example, we chose 10° above and below the reference position based on the historical comparison of Lewinnek et al. [25]. To analyze the comparative ability of the Six Sigma ratio, we evaluated other similar computer navigation acetabular studies that adequately reported descriptive statistics [9, 17, 29, 35, 37, 40] (Table 3). CT for navigation referencing provided satisfactory precision, whereas fluoroscopy was capable in some studies but not in others. Imageless navigation referencing techniques do not appear to be process-capable using Six Sigma formulas and those findings held up in the current study.

Although studies have shown pelvic tilt may be an equal factor determining functional acetabular component positioning, the goal of the current study was to assess the effectiveness of various methods to position the acetabular component with two degrees of freedom in relation to the APP [24, 26, 28]. In practice, the imageless CAS referencing technique currently uses a direct anatomic point matching method. The surgeon palpates or makes small stab wounds to place the reference probe directly onto the ASISs and the pubic symphysis. We believe the reference points of the ASISs are relatively broad surfaces and considerable error may be added by touch-point referencing [36, 38]. Although some studies suggest this error is tolerable, Spencer et al. [35] reported substantial variation using this approach [38]. From our prior work, we predicted the error with imageless referencing would be greater for inclination because this measurement is made in the coronal plane, which is colinear with the APP. Anteversion, however, is measured in the transverse plane, a different plane from the APP. For example, subtle differences for ASIS referencing would not alter anteversion considerably as long as these points remained in the APP. Spencer et al. [35], however, reported higher variation for anteversion than for inclination, and substantial interobserver variability.

Based on our data, we are not convinced imageless referencing methods currently available for CAS improve the results of acetabular cup placement. We were encouraged by the inherent ability of the experienced surgeons in our study to match or exceed the results of computer navigation using conventional instrumentation for determining anteversion with a MIS approach. We believe, if optical computer assessment of the surgery were to be combined with precise referencing tools such as 3D CT, it may be possible to incorporate this technology to make additional improvements in component positioning.

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