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Improving Cup Positioning Using a Mechanical Navigation Instrument

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Abstract

Background Although surgical navigation reduces the rate of malpositioned acetabular cups in total hip arthroplasty (THA), its use has not been widely adopted. As a result of our perceived need for simple and efficient methods of navigation, we developed a mechanical navigation device for acetabular cup orientation.

Questions/purposes We assessed accuracy of cup orientation (mean error of cup inclination and anteversion) of a novel mechanical navigation device, percentage of outliers, length of operation, and compared the results with a series of CT-based computer-assisted THAs.

Methods Cup orientation of 70 THAs performed using the mechanical navigation device was compared with a historical control group of 146 THAs performed using CT-based computer navigation. Postoperative cup orientation was measured using a validated two-dimensional/three-dimensional matching method. An outlier was defined outside a range of ± 10° from the planned inclination and/or anteversion.

Results Using the mechanical navigation device, we observed a decrease in the errors of inclination (1.3° ± 3.4° [range, −6.6° to 8.2°] versus 3.5° ± 4.2° [−12.7° to 6.9°]), errors of anteversion (1.0° ± 4.1° [−8.8° to 9.5°] versus 3.0° ± 5.8° [−11.8° to 19.6°]), percentages of outliers (0% versus 9.6%), and length of operation (112 ± 22 [78–184] minutes versus 132 ± 18 [90–197] minutes) compared with CT-based navigation.

Conclusions Compared with CT-based surgical navigation, navigation of acetabular cup orientation using a mechanical device can be performed in less time, lower mean errors, and minimal equipment.

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Each author certifies that his institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent was obtained.
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Introduction

Acetabular component malpositioning during THA and hip resurfacing can lead to impingement, instability, accelerated wear, wear-induced osteolysis, irritation of the psoas tendon, pseudotumor in metal-on-metal bearings, and revision surgery for any of these problems [4, 8, 10, 11, 17, 19, 24]. Hip instability is the single greatest reason for revision THA in the United States, accounting for 22.5% of all revisions in the US Medicare population resulting in $504 million in charges and approximately $201 million in payments annually and acetabular component malpositioning is the single greatest cause for hip instability [2].

Acetabular component malpositioning is a primary factor associated with accelerated bearing wear as well [19]. As a result, acetabular component malpositioning is the single greatest factor determining the likelihood of both early and late revision hip arthroplasty.

The majority of acetabular components that are placed using traditional methods are malpositioned with studies showing malpositioning rates outside of the Lewinnek "safe zone" between 59% and 78% [10, 20]. These rates of malpositioning can be reduced through the use of computer-assisted surgical navigation [5, 7, 9, 12, 16], yet its use has not been widely adopted. This may be the result of many factors, including increased operative time, equipment costs, and complexity of the surgery. We therefore perceived the need for simple and efficient methods of ensuring appropriate acetabular component orientation during hip arthroplasty.

The aims of this study were to (1) assess the accuracy of cup orientation (mean error of cup inclination and anteversion) of a novel mechanical navigation device; (2) evaluate the percentage of outliers outside ± 10° of inclination or anteversion; (3) measure the length of operation using this device for navigated cup impaction during THA; and (4) compare the results of the mechanical navigation device with the accuracy, percentage of outliers, and length of operation of a series of CT-based computer-assisted THAs.

Patients and Methods

We compared the accuracy of cup orientation, percentage of outliers, and length of operation using a mechanical navigation device (study group) and CT-based navigation (control group). In the study group, we prospectively assessed postoperative cup orientation in a series of 70 patients (70 hips) who underwent THA performed using a mechanical navigation device (HipSextant; Surgical Planning Associates, Medford, MA) between April and November 2009. The study group included 36 hips (51%) in men and 34 hips (49%) in women with a mean age at operation of 59.0 ± 10.6 years (range, 25–84 years). Using our digital institutional database, we retrospectively identified all 140 patients (146 hips) who underwent CT-based computer-assisted THA performed between August 2006 and May 2008 (control group). The mean age at operation was 57.9 ± 12.5 years (range, 18–84 years) and there were 86 THAs (52%) in men and 60 THAs (48%) in women. Gender ($p = 0.88$) and age ($p = 0.76$) at operation compared with the study group did not significantly differ. The local Institutional Review Board approved this study.

The navigation system used in the control group was the Vector Vision from BrainLab (BrainLAB AG, Feldkirchen, Germany) with preoperative surgical planning based on three-dimensional pelvic models from CT scans and the anterior pelvic plane (APP) as the pelvic coordinate system. Intraoperative registration was carried out using a combined paired points and surface matching algorithm with points on the lateral aspect of the anterior superior iliac spine (ASIS), iliac wing, and within the acetabulum and on the acetabular rim. Navigated cup impaction was performed using an optical tracking system with reflective spheres on the skeletal reference frames and tools.

In both groups, the components used were a press-fit titanium shell (Lineage® cups; Wright Medical Technology, Arlington, TN) combined with a cementless femoral stem and a modular neck design to correct femoral deformities (Profemur renaissance®; Wright Medical Technology). For all hips, a less invasive approach, the superior capsulotomy [13], was performed with the patient in the lateral decubitus position. The cups were impacted using an angled impactor and all the operations were performed by one surgeon (SBM).

The HipSextant (Surgical Planning Associates) was developed by the authors of the study (SBM, JHK, SDS) for mechanical navigation of acetabular cup orientation (Fig. 1A–B). The instrument is adjusted for each patient based on patient-specific three-dimensional models from CT imaging using a preoperative planning software application. The HipSextant itself has two adjustable orthogonal protractors (in-plane and offplane angle) and two adjustable arms (Fig. 1A–B). A direction indicator points in the direction of the planned cup orientation.

In planning surgery, the APP and the sextant planes are defined on the three-dimensional model from CT imaging using the planning application. The sextant plane is defined by three points (Fig. 1A–B): the first point (base point) is just outside of the posterior wall of the acetabulum 20 mm above the infracotyloid notch. This point is defined with the help of distance guide (Fig. 2A). The second point (ASIS point) is located on the lateral ilium just adjacent to the ASIS. The third point (landing point) is on the surface of the ilium, anterior to the sciatic notch, and equidistant from the first two points. The arm lengths of the HipSextant are then calculated to fit this sextant plane preoperatively by the software. The surgeon then designates the desired cup orientation relative to the APP and the software planning application, then determines the angles on the two adjustable orthogonal protractors so the resultant direction indicator on the HipSextant instrument points in the direction of the surgeon's planned cup orientation (Fig. 1A–B). Furthermore, if the surgeon determines intraoperatively that a different cup orientation is desired (as a result of femoral version or pelvic tilt considerations for example), the angles on the instrument can be instantaneously recalculated to allow for intraoperative instrument adjustment.

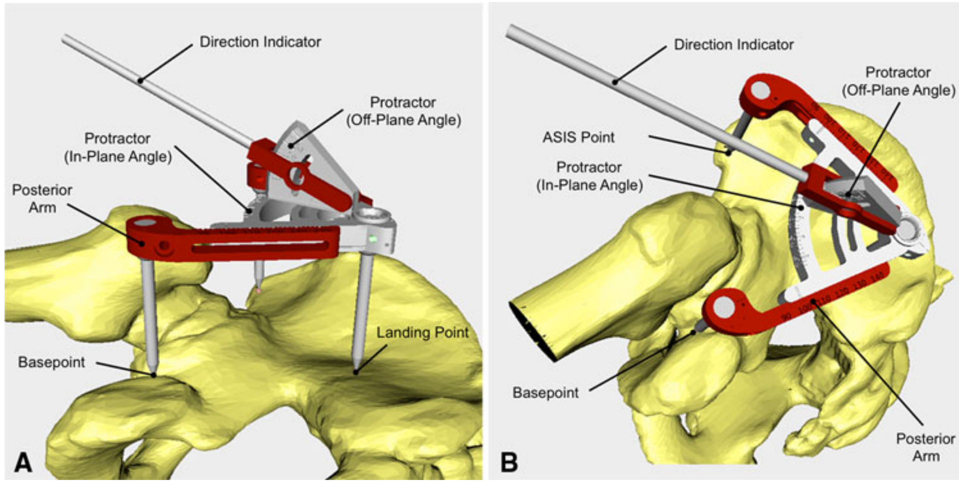

Fig. 1A−B The mechanical navigation device (HipSextant; Surgical Planning Associates, Medford, MA) has two adjustable orthogonal protractors (in-plane and off-plane angle), two adjustable arms, and a direction indicator pointing in the direction of the desired cup orientation. The HipSextant plane is defined by three points: the base point, the ASIS (anterior-superior iliac spine) point, and the landing point.

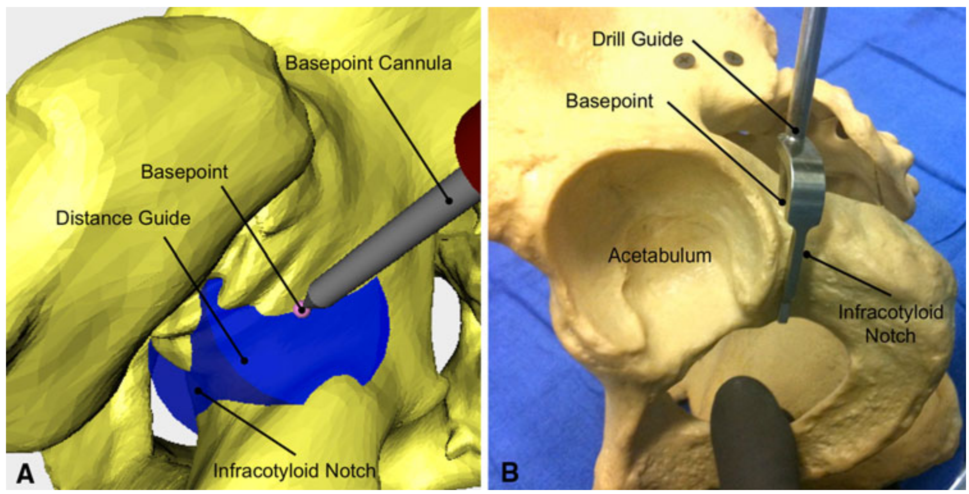

Fig. 2A–B In planning surgery (**A**) the base point outside of the posterior wall of the acetabulum and 20 mm above the infracotyloid notch is defined using a distance guide. Intraoperatively (**B**) the base point is identified using a calibrated drill guide.

All surgery was performed by a single surgeon (SBM). The patient was placed in the lateral decubitus position. We identified the base point using a calibrated drill guide and threaded guidewire (Fig. 2B). The cannulated base point leg of the HipSextant was then placed over the guidewire. A sharp trocar was placed through another cannula and percutaneously onto the surface of the ilium to determine the second sextant plane point (ASIS point) adjacent to the ASIS. The appropriate location of this point was confirmed by the surgeon by percutaneously probing the lateral ASIS using the trocar. Finally, another trocar was placed through a third cannula and percutaneously onto the surface of the ilium to determine the landing point. With the HipSextant docked on the ipsilateral hemipelvis, we applied a removable direction indicator to demonstrate the planned cup orientation during component implantation. The surgeon then impacted the acetabular component with the insertion handle aligned visually with the direction indicator (Fig. 3).

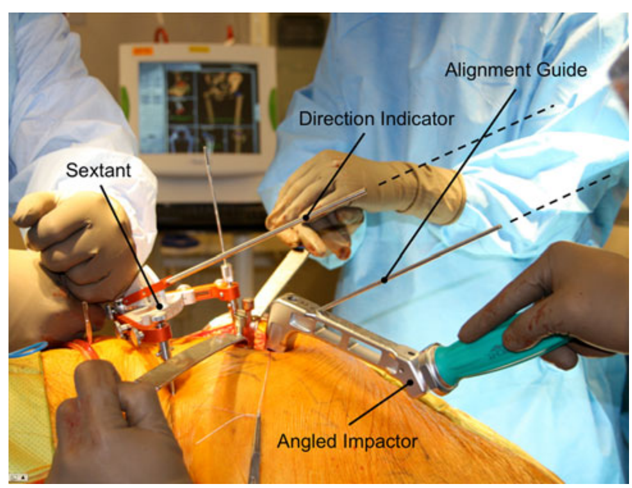

Fig. 3 Intraoperatively, the surgeon visually aligns the cup impactor handle or the alignment guide in angled instruments with the direction indicator to implant the cup in the desired orientation. Although this figure depicts an angled cup impactor, a straight cup impactor may be used as well.

In both groups, cup orientation was planned according to the individual anatomy with a mean radiographic inclination of 41.9° ± 0.4° (range, 39°–42°) and radiographic anteversion of 23.3° ± 0.1° (range, 23°–25°) in the study group and a mean radiographic inclination of 40.8° ± 1.3° (range, 38°–45°) and radiographic anteversion of 30.5° ± 2.9° (range, 23°–37°) in the control group [14]. To determine accuracy (mean error with standard deviation and range) of cup inclination or anteversion of the mechanical navigation device (study group) or CT-based navigation (control group), the preoperative planned values were compared with postoperative measured cup orientation. Because of the inability to measure exact cup orientation out of postoperative pelvic radiographs as a result of pelvic malorientation [1, 22, 23], a noncommercial two-dimensional/three-dimensional matching application (HipMatch; Institut for Surgical Technology and Biomechanics, Bern, Switzerland) [21, 25] was used. This software application uses a fully automated registration procedure that can match the three-dimensional model of the preoperative CT with the projected pelvis on a postoperative radiograph. This allows one to calculate cup radiographic inclination and radiographic anteversion relative to the APP corrected for individual pelvic malpositioning [14]. This method has been validated and showed a mean accuracy of 1.7° ± 1.7° (range, −4.6° to 5.5°) for inclination and 0.9° ± 2.8° (range, −5.2° to 5.7°) for anteversion compared with postoperative CT measurements [21]. The software showed a good consistency with an intraclass correlation coefficient (ICC) for inclination of 0.96 (95% confidence interval [CI]: 0.93 to 0.98) and for anteversion of 0.95 (95% CI: 0.91 to 0.98). A good reproducibility and reliability for both inclination and anteversion was found with an ICC ranging from 0.95 to 0.99. No systematic errors in accuracy were detected with the Bland-Altman analysis [21]. For the current study, an outlier was defined outside a range of ± 10° of inclination and/or anteversion from the planned orientation [10]. Length of operation was defined as the time from incision to dressing and was recorded for both groups.

Nominal parameters were tested for normal distribution using the Kolmogorov-Smirnov test and all parameters showed normal distribution. To compare error of inclination and anteversion, length of operation, or age at surgery between the study and the control groups, the independent t-test was used. To test binominal data (percentage of outliers or gender distribution), the Fisher's exact test was used. A power analysis for the primary research question (error of inclination) with a known error of 3.5° ± 4.2° in the control group and an assumed minimal detectable difference of 2° resulted in a minimal sample size of 55 for a level of alpha of 0.05 and beta of 0.2.

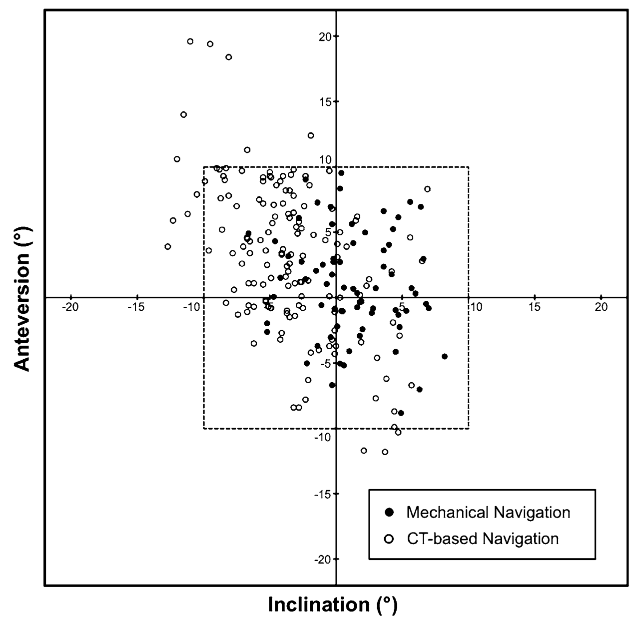

Fig. 4 Scatterplot showing cup orientation using mechanical navigation and CT-based navigation. There were no outliers using mechanical navigation. The control group of CT-based navigation had a higher percentage (9.6%, p = 3.4%) of outliers.

Results

In the study group, the mean error for inclination using the mechanical navigation device was 1.3° ± 3.4° (range, −6.6° to 8.2°) and 1.0° ± 4.1° (range, −8.8° to 9.5°) for anteversion. The mean error for inclination for the control group was greater ($p < 0.001$) than that for the mechanical navigation group (3.5° ± 4.2°; range, −12.7° to 6.9°) and greater ($p = 0.003$) for anteversion (3.0° ± 5.8°; range, −11.8° to 19.6°). There were no outliers for either inclination or anteversion in the study group. The percentage of outliers in the control group was 9.6% (13 of 146), which differed significantly (p = 3.4%) compared with the study group (Fig. 4). The mean length of operation was lower ($p < 0.001$) in the mechanical navigation than control group: 112 ± 22 minutes (range, 78–184 minutes) versus 132 ± 18 minutes (range, 90–197 minutes), respectively.

Discussion

Although surgical navigation reduces the rate of malpositioned acetabular cups [5, 7, 9, 12, 16], its use has not been widely adopted, possibly as a result of increases in cost, operating time, complexity, and capital equipment. As a result of our perceived need for simple and efficient methods of navigation, we developed a mechanical navigation device for acetabular cup orientation. The aims of this study were to (1) assess the accuracy of cup orientation (mean error of cup inclination and anteversion) of this novel mechanical navigation device; (2) evaluate the percentage of outliers outside ± 10° of inclination or anteversion; (3) measure the length of operation using this device for navigated cup impaction during THA; and (4) compare the results of the mechanical navigation device with the accuracy, percentage of outliers, and length of operation of a series of CT-based computer-assisted THAs.

This study has several limitations. First, it is a single-surgeon series, which does not allow one to evaluate intersurgeon variability. Second, the surgeon (SBM) is the inventor of the tool and the study was performed after the benefit of prior experience with a prototype of this navigation device. Therefore, a surgeon may have inferior results at the beginning of the learning curve. Third, a prospective and randomized study design comparing the two methods of navigation would have been preferable to the current study design (comparative case-series). A prospective randomized study was not performed largely because the additional time, cost, and potential risk associated with continuation of the prior methods for the sole purpose of research did not seem justifiable.

The accuracy of this mechanical navigation device depends on repeatability of finding anatomic landmarks. Although the posterior point is aided by the use of a calibrated drill guide, the ASIS point is determined by percutaneous probing, much like traditional navigation registration techniques. There may be more variation in the determination of this landmark. Still, resulting cup orientation in the entire study group measured within a range of ± 10° for both inclination and anteversion. This may be the result of the widely based legs of the tool, which results in smaller angular errors for a given linear error in landmark determination. Also, because the third leg is determined entirely by the instrument and the surface of the bone, user error is further reduced.

A limitation of the mechanical device, as used in this study, is that it was only used to navigate cup orientation, whereas conventional navigation can also measure cup location, leg length change, and offset change. Although the mechanical device may also be used as a registration device to accomplish the same tasks, it was used in this study in its simplest form, to measure cup orientation only, because acetabular component malorientation is the primary technique factor associated with revision surgery. A further limitation of the mechanical device, as used in the current study, is that it is based on preoperative CT imaging. Although the true cost of a CT for hip planning is only 53 Euros and requires only a body mass index-dependent mean effective dose of 4.0 mSv for the bone detail [6], the use of plain radiographs for three-dimensional planning would certainly be more practical. The ability to predict the docking of the mechanical instrument in individual patients based on two plain radiographs is a primary focus of our current research.

There is a need for simple, accurate methods of achieving appropriate cup orientation during hip arthroplasty. This need may be greatest for surgeons who perform fewer than 50 hip arthroplasties per year, yet these surgeons are the least likely to gain access to expensive and complex equipment to solve this problem. Because malposition of the pelvis during surgery may be the single greatest factor contributing to component malposition, the current mechanical navigation instrument was designed to quickly determine the position of the pelvis during surgery.

Mechanical navigation of acetabular cup orientation can be performed in less time with minimal equipment and an accuracy that is equivalent to a more complex, expensive, and time-consuming method of performing navigation. The findings suggest the primary obstacles to the use of navigation methods during surgery can be removed. These findings further suggest the greatest factor contributing to revision for both instability and accelerated wear can be addressed. The instrument "registers" the pelvis using a technique that is referred to as "paired-point matching" in the navigation literature with the addition that the three paired points are physically linked to each other by the instrument, thereby further reducing potential registration errors.

Controversies remain concerning the optimal positioning of the acetabulum in individual patients, and certainly femoral offset, version, leg length change, and spinopelvic flexibility and orientation may all affect the desired goal of acetabular orientation. The concept of combined anteversion must always be considered so that the goal of cup anteversion should be reduced in cases of excessive uncorrected femoral anteversion [3]. Similarly, the goal of cup anteversion should also be reduced in patients with rigid negative spinopelvic tilt even with normal femoral anteversion [15]. Fortunately, the mechanical navigation device can be adjusted both preoperatively and intraoperatively to handle these clinical circumstances. In addition, a patient's pelvic orientation during activity before surgery can change after surgery [18] and it is understood that the APP is not a perfect reference coordinate system for the pelvis. Nonetheless, the mechanical navigation device can be used with any pelvic coordinate system, can accommodate a wide range of implantation goals, and can incorporate any improvements in our understanding of optimal goals of cup orientation for hip arthroplasty.

Compared with CT-based surgical navigation, navigation of acetabular cup orientation using a mechanical device can be performed in less time with lower mean errors and minimal equipment. This may address the single greatest intraoperative technical challenge that currently affects hip arthroplasty.

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