

Validation and Usefulness of a Computer-Assisted Cup-Positioning System in Total Hip Arthroplasty

A Prospective, Randomized, Controlled Study

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Background: Malpositioning of the acetabular component during total hip arthroplasty increases the risk of dislocation, reduces the range of motion, and can be responsible for early wear and loosening. The purpose of this study was to compare computer-assisted with freehand insertion of the acetabular component.

Methods: A randomized, controlled, matched prospective study of two groups of thirty patients each was performed. In the first group, cup positioning was assisted by an imageless computer-assisted surgical system based on bone morphing. In the control group, the cup was placed freehand. All of the patients were operated on by the same surgeon through an anterolateral approach. Cup anteversion and abduction angles were measured on three-dimensional computed tomography reconstructions postoperatively for each patient by an independent observer using special cup-evaluation software.

Results: There were sixteen men and fourteen women in each group, and the mean body-mass index was approximately 25 in each group. The computer-assisted procedure took a mean of twelve minutes longer than the freehand procedure. Fifty-seven percent (seventeen) of the thirty cups placed freehand and 20% (six) of the thirty in the computer-assisted group were outside of the defined safe zone (outliers). This difference was significant ($p = 0.002$). There were no differences between the computer-assisted group and the freehand-placement group with regard to the mean abduction and anteversion angles, but there was a significant heterogeneity of variances, with the lowest variations in the computer-assisted group.

Conclusions: Use of an imageless navigation system can improve cup positioning in total hip arthroplasty by reducing the percentage of outliers.

Level of Evidence: Therapeutic Level II. See Instructions to Authors for a complete description of levels of evidence.

Malpositioning of the acetabular component during total hip arthroplasty increases the risk of dislocation^{1,2}, reduces the range of motion free of intra-articular impingement³, and may cause long-term wear⁴. There have been numerous reports regarding the optimal orientation of the acetabular component in total hip arthroplasty³. Lewinnek et al.¹ recommended an abduction angle of $40^\circ \pm 10^\circ$ and an anteversion angle of $15^\circ \pm 10^\circ$ as the safe zone for cup orientation in total hip arthroplasty. Use of mechanical acetabular guides for intraoperative alignment leads to variations between the actual and desired implant orientation because it is difficult to know the patient's exact position on the operating table⁵. These problems have demonstrated a need to develop more re-

liable tools in order to prevent malpositioning of the implants and to improve the reproducibility of implant alignment in total hip arthroplasty. After the initial work of DiGioia et al.⁶, a number of computer-assisted orthopaedic navigation systems have been developed. Some systems are based on computed tomography images; others are independent of preoperative imaging and are called *imageless navigation*. Computed tomography-based navigation requires intraoperative matching, which increases blood loss and surgical time⁷. Among the imageless systems, one (Praxim Medivision, Grenoble, France) is based on bone morphing, technology initially described by Stindel et al.⁸ for computer-assisted knee arthroplasty and later adapted for total hip arthroplasty. The principle is based on a

Disclosure: The authors did not receive any outside funding or grants in support of their research for or preparation of this work. Neither they nor a member of their immediate families received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, division, center, clinical practice, or other charitable or nonprofit organization with which the authors, or a member of their immediate families, are affiliated or associated.

three-dimensional reconstruction of a patient's bones from anatomical data collected intraoperatively with a three-dimensional optical localizer with use of clouds of points and a three-dimensional statistical deformable model⁸. For cup implantation in total hip arthroplasty, the anterior pelvic plane is registered intraoperatively by percutaneous palpation. Once this reference plane is determined, the cup impactor is navigated in order to achieve the safe zone described by Lewinnek et al.¹ for cup abduction and anteversion angles. This type of imageless system does not involve additional radiation exposure and is faster than the intraoperative matching with computed tomography-based navigation^{7,8}. However, the benefits of the use of such an imageless system for cup positioning have not been demonstrated in vivo, to our knowledge.

We hypothesized that the use of an imageless hip navigation system would increase the accuracy of cup orientation compared with that achieved with conventional freehand implantation methods. The first goal of this prospective randomized comparative study was to validate the system in vivo. The second goal was to compare computer-assisted with conventional freehand cup placement.

Materials and Methods

Patient Selection

From April 2004 to April 2005, we performed a prospective, randomized, controlled study of two groups of thirty patients each. The study protocol (including the use of navigation and postoperative computed tomography evaluation) and consent forms were approved by the local ethical committee. The patient inclusion criteria were an age of twenty to eighty years old, a weight of <100 kg, a primary hip arthroplasty, an anterolateral approach, performance of the procedure by the senior author (J.-N.A.A.), and use of one particular cementless press-fit cup (Hillock; Symbios, Yverdon, Switzerland). The exclusion criteria were a trochanteric osteotomy or revision hip surgery. Randomization of patients into the computer-assisted group was done by the Hospital Informatics Department with use of a systematic sampling method. The first patient was randomly chosen and then one patient was selected out of every eight patients on a list of all patients meeting the inclusion criteria who were candidates for a total hip arthroplasty performed by the senior author. All of the patients provided informed consent to participate in the study. The randomization protocol was not revealed to the authors, who received the information regarding the group to which the patient was assigned in numbered, sealed envelopes. The patients assigned to the freehand-cup-placement group were matched for gender, age within five years, pathological condition, operatively treated side, and body-mass index within 3 points. The same number of patients in each group was in each of the two categories of body-mass index as defined in the French national recommendations⁹—i.e., a body-mass index of <27 or ≥ 27 . Traditional mechanical guides were used in the freehand-placement group. Before the beginning of the study, the senior author had performed more than 2000 total hip arthroplasties, which included fifty computer-assisted procedures.

Surgical Procedure

We developed a specific hip surgical procedure for the use of an imageless cup-positioning computer-based navigation system. The operation is done through an anterolateral approach with the patient supine. We performed an adaptation of the Hiplogics Universal Protocol (Praxim Medivision) for cup-positioning control. This system is based on bone morphing⁸. Preoperative planning included analysis of pelvic version on a lateral standing radiograph of the pelvis. The angle between the vertical plane and the anterior pelvic plane was calculated preoperatively for each patient and defined as the alpha angle^{5,10} (Fig. 1).

A cementless press-fit hydroxyapatite-coated titanium acetabular component and a cementless fully hydroxyapatite-coated titanium femoral stem were used. Patients were positioned so that both anterior superior iliac spines and the pubic symphysis could be palpated. The system required the placement of a tracker screw in the ilium. This tracker screw was inserted in the acetabular roof on the surgically treated side through the usual exposure for the total hip arthroplasty. The anterior pelvic plane was determined by percutaneous palpation of the anterior superior iliac spines and the pubic symphysis with a special palpation device and was registered with the computer. Then acetabular bone morphing was performed by palpation of different parts of the acetabulum. After this first step of anatomical landmark acquisition, reamer calibration was performed. During the reaming procedure, anteversion and abduction angles were measured. After calibration of the cup impactor, we navigated the cup impactor in order to determine the anteversion and abduction angles of the cup. The standard operative, radiographic, and anatomical

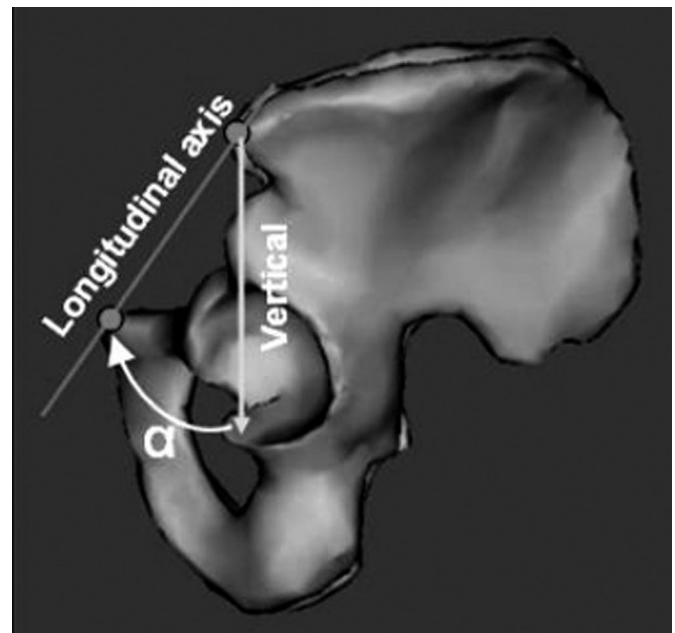


Fig. 1

The angle between the vertical plane and the anterior pelvic plane was calculated preoperatively for each patient and defined as the "alpha angle."

TABLE I Deviation Between Perioperative and Postoperative Abduction and Anteversion Angles in the Patients in the Computer-Assisted Group with a Body-Mass Index of <27

	Abduction (deg)		Anteversion	
	Deviation* (deg)	P Value	Deviation* (deg)	P Value
Operative	3 ± 2	0.30	4 ± 3.8	0.125
Radiographic	4 ± 2.8	0.23	3.4 ± 3.6	0.063
Anatomical	4 ± 2.9	0.09	4.8 ± 4	0.234

*The values are given as the mean and standard deviation.

definitions of cup orientation (anteversion and abduction angles) described by Murray¹¹ were used and were registered for each patient in the computer-assisted group. The extra time needed for the cup navigation with the computer guidance system was noted. Once the cup was inserted in the acetabulum, the abduction and anteversion angles were estimated, with the cup impactor still in place, by the surgeon. The correlation between the surgeon's estimation and the value given by the computer-assisted system was graded as "high" (complete agreement), "weak," or "poor" (not in agreement). The postoperative protocols were the same in the two groups, with full weight-bearing recommended.

Postoperative Evaluation

The position of the cup in each patient in each group was evaluated on a postoperative computed tomography scan by an independent observer using special cup-evaluator software¹² (Cup Evaluator 1.0; Praxim Medivision). Full pelvic computed tomography scans, including both anterior superior iliac spines, were performed one month after surgery for all patients with the same protocol in the same radiographic center. A virtual three-dimensional model of the pelvis was reconstructed with use of this software. Changing window parameters of the postoperative computed tomography scans made the implanted cup visible with a minimum amount of metal artifact. The three points defining the anterior pelvic plane were identified on each computed tomography scan. A virtual implant model generated by the evaluator software was aligned and fitted, by one of the authors (S.P.) familiar with the software, to the contour of the real prosthetic cup in the frontal, sagittal, and transverse computed tomography cuts. The software then calculated the resulting operative, radiographic, and anatomical anteversion and abduction angles of the cup according to the definitions given by Murray¹¹. According to these definitions, operative anteversion is measured around a transverse axis; anatomical anteversion, around a longitudinal axis; and radiographic anteversion, around an oblique axis. According to Murray's normogram¹¹, 45° of radiographic inclination and 15° of radiographic anteversion are equivalent to 43° of operative inclination and 21° of operative anteversion and to 47° of anatomical inclination and 21° of anatomical anteversion. Murray recommended using the operative definition during the procedure, the anatomical definition for computed tomography analysis, and the radiographic

definition for standard radiographic analysis. In our study, the angles were expressed according to the three definitions, automatically given by the system perioperatively and by the cup evaluator software postoperatively.

Statistical Analysis

We first analyzed the accuracy of the navigation system through a two-group pair comparison of the perioperative and postoperative abduction and anteversion angles in the patients in the computer-assisted group with a body-mass index of <27 and in those with a body-mass index of ≥27; the latter group was considered to be overweight according to the French national recommendations⁹. Means and variances of the cup position achieved with the computer-assisted technique were compared with those achieved with the freehand method. Then we determined, within each group, the percentage of cups outside the safe zone (outliers) as described by Lewinnek et al.¹. The percentages of outliers were compared between groups with use of a chi-square test. Finally, a gender comparison was performed in order to analyze the effect of anatomical differences as well as body fat distribution. Statistical analysis was performed, with SPSS software (version 12; SPSS, Chicago, Illinois), as a two-group pair comparison with use of the t test for the means comparisons and a variance comparison test for link data. $P < 0.05$ was considered to be the level of significance.

Results

There were no significant differences in demographic data between the two study groups, with the numbers available. There were sixteen men and fourteen women and fourteen right hips and sixteen left hips in each group. The mean age (and standard deviation) of the patients was 61.2 ± 13.15 years (range, twenty-four to eighty years) in the computer-assisted group and 62.6 ± 9.6 years (range, twenty-six to seventy-eight years) in the freehand-placement group ($p = 0.29$). The mean body-mass index was 25.6 ± 4.53 (range, 17 to 37) in the computer-assisted group and 25.2 ± 4.1 (range, 19.53 to 38.2) in the freehand-placement group ($p = 0.28$). The mean alpha angle measured preoperatively on a standing lateral pelvic radiograph was $-1.72^\circ \pm 7.5^\circ$ (range, -15° to 14°) in the computer-assisted group and $0.6^\circ \pm 7.8^\circ$ (range, -22° to 11°) in the freehand-placement group ($p = 0.29$). The etiologies were primary osteoarthritis in twenty-seven hips and osteonecrosis in three hips in the computer-assisted group and primary os-

TABLE II Deviation Between Perioperative and Postoperative Abduction and Anteversion Angles in the Patients in the Computer-Assisted Group with a Body-Mass Index of ≥ 27

	Abduction (deg)		Anteversion	
	Deviation* (deg)	P Value	Deviation* (deg)	P Value
Operative	2.8 ± 2	0.28	11 ± 6.2	<0.001
Radiographic	3.3 ± 3.06	0.18	11.6 ± 6.1	<0.001
Anatomical	5.3 ± 3.8	0.08	11.5 ± 8.4	0.002

*The values are given as the mean and standard deviation.

teoarthritis in twenty-six hips and osteonecrosis in four hips in the freehand-placement group. The mean diameter of the acetabular cup was 52 mm in both groups. No additional skin incision had to be made to accommodate navigation. The mean additional time for the computer-assisted procedure was twelve minutes (range, eight to twenty minutes). The correlation between the surgeon's intraoperative subjective estimation of the abduction and anteversion angles and the angles provided by the computer-assisted system was graded as high in twenty-three cases, weak in six, and poor in one.

No patient had a neurovascular complication and no dislocation occurred in the first year after surgery.

The angles of abduction and anteversion recorded by the imageless navigation system in the computer-assisted group perioperatively were compared with the position of the acetabular component postoperatively. The results of the comparison for the patients with a body-mass index of <27 and for the patients with a body-mass index of ≥ 27 are detailed in Tables I and II.

In the freehand-placement group, the mean operative, radiographic, and anatomical abduction angles, as calculated with

the postoperative software, were, respectively, $32^\circ \pm 7.1^\circ$ (range, 21° to 48°), $34^\circ \pm 7.62^\circ$ (range, 24° to 50°), and $38^\circ \pm 8^\circ$ (range, 28° to 55°) and the mean operative, radiographic, and anatomical anteversion angles were $16.6^\circ \pm 10.4^\circ$ (range, 0° to 37°), $16.2^\circ \pm 9.6^\circ$ (range, 2° to 35°), and $20.6^\circ \pm 10^\circ$ (range, 2° to 39°). In the computer-assisted group, the respective abduction angles were $32^\circ \pm 4.8^\circ$ (range, 25° to 45°), $34^\circ \pm 5.7^\circ$ (range, 25° to 45°), and $40^\circ \pm 5.0^\circ$ (range, 27° to 47°) and the respective anteversion angles were $14.8^\circ \pm 4.6^\circ$ (range, 6° to 23°), $14.4^\circ \pm 4.5^\circ$ (range, 7° to 25°), and $18.6^\circ \pm 5.0^\circ$ (range, 9° to 27°). There was no difference between the computer-assisted group and the freehand-placement group with regard to the mean abduction angles ($p = 0.668$, $p = 0.113$, $p = 0.316$) or the mean anteversion angles ($p = 0.243$, $p = 0.311$, $p = 0.312$). According to these results and with use of a 0.80 test power, a minimal difference of 3.5° in abduction and 5.5° in anteversion would have been detected. A smaller variation in the positioning of the acetabular component in the computer-assisted group than in the freehand-placement group was indicated by the lower standard deviations in the computer-assisted group for the abduction ($p = 0.025$, $p = 0.066$, $p = 0.028$) (Fig. 2-A) and anteversion angles ($p < 0.001$ in the three referentials) (Fig. 2-B). The percentage

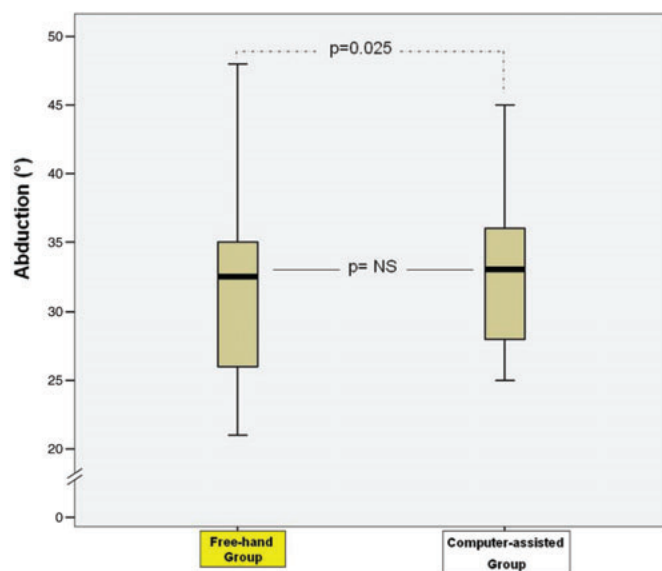


Fig. 2-A

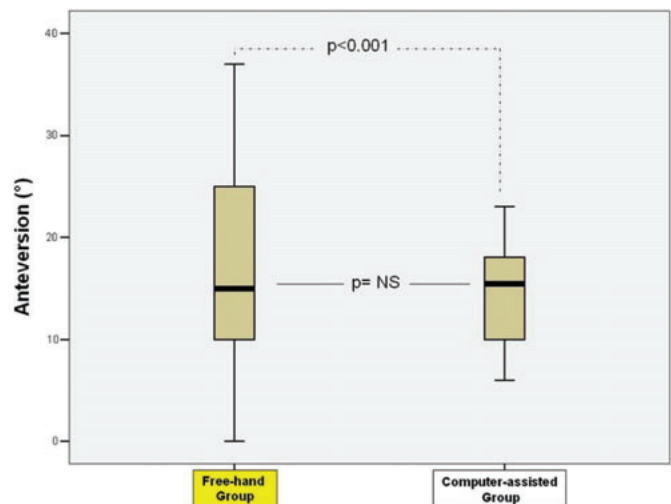


Fig. 2-B

Operative abduction (Fig. 2-A) and anteversion (Fig. 2-B) angles of the acetabular component in the computer-assisted and the freehand-placement groups. The boundaries of the boxes indicate the twenty-fifth and seventy-fifth percentiles, and the black lines within the boxes mark the mean values. The whiskers above and below the boxes indicate the ninetieth and tenth percentiles.

of outliers was 57% (seventeen of thirty) in the freehand-placement group and 20% (six of thirty) in the computer-assisted group. This difference in the percentage of outliers between the two groups was significant ($p = 0.002$).

The gender comparisons revealed no significant differences in the abduction or anteversion angles, with the numbers available.

Discussion

The first goal of this study was to validate this imageless navigation system in vivo, and the second goal was to compare conventional cup placement with computer-assisted cup placement. The results of our study demonstrated a good correlation between intraoperative and postoperative measurements for patients with a body-mass index of <27 . The results did not show any differences between treatment groups with regard to the mean cup abduction and anteversion angles, but the computer-assisted-surgery system significantly reduced the percentage of outliers according to the criteria described by Lewinnek et al.¹, from 57% (seventeen of thirty) in the freehand-placement group to 20% (six of thirty) in the computer-assisted group. One of the limitations of this study was the absence of variation in surgeons' levels of skill in the use of computer-assisted technology for cup positioning. However, we chose two groups that were strictly comparable with regard to all parameters, including surgical approach, surgeon, type of implant, gender, age, body-mass index, operatively treated side, and disease etiology.

Postoperative measurements on three-dimensional computed tomography reconstructions allowed comparison between intraoperative and postoperative abduction and anteversion angles. The anterior pelvic plane, known as the *Lewinnek plane*¹, was the basis for all angle measurements during the procedure with the navigation software and after the procedure with the postoperative evaluation software. Thus, three osseous landmarks—the two anterior superior iliac spines and the pubic symphysis—are necessary in this system. The angles can be calculated irrespective of the patient and pelvic position. Tannast et al.¹³ showed that measurements of the version of the prosthetic cup on postoperative anteroposterior radiographs or standard computed tomography scans without accurate definition of the position of the pelvis are highly inaccurate as a result of pelvic tilt, rotation, and obliquity. Currently, in almost all computer-assisted orthopaedic surgery systems that rely on definition of the anterior pelvic plane, the plane is derived by percutaneously identifying three osseous landmarks: the anterior superior iliac spines and the pubic symphysis¹⁴⁻¹⁶. Considering that the registration of the anterior pelvic plane is modified by subcutaneous fat tissue, we call it the *cutaneous Lewinnek plane*. Using a kinematic model, Wolf et al.¹⁴ showed how to examine the effects of these inaccuracies on the final orientation of the acetabular cup. Simulation results indicated that if, for example, a surgeon aimed for 45° of abduction and 20° of anteversion a total error of 4 mm in the measurement of the anterior superior iliac spine and the pubic tubercles would result in a final cup orien-

tation of 47° and 27° of abduction and anteversion, respectively, which would be a 2° abduction error and a 7° anteversion error. Thus, the poor correlation between intraoperative and postoperative measurements in patients with a body-mass index of ≥ 27 observed in our study was probably due to the limits of the percutaneous registration of the Lewinnek plane¹. This is probably one of the most obvious technical limitations of an imageless anatomical navigation system based on bone morphing in total hip arthroplasty. Perioperative echographic morphing of the anterior pelvic plane may overcome this limitation in the future.

The second purpose of our study was to compare computer-assisted acetabular component positioning with conventional freehand placement. Our study did not show any differences between the computer-assisted group and the freehand-placement group with regard to the mean abduction and anteversion angles, but there were significantly smaller standard deviations in the computer-assisted group. Furthermore, the use of a computer-assisted surgery system significantly reduced the percentage of outliers in our study from 57% (in the freehand-placement group) to 20% ($p = 0.002$), which is in agreement with previously reported findings¹⁷⁻²⁰. In the study by Wixson and MacDonald¹⁸, 30% (twenty-five) of eighty-two hips in the computer-assisted group were in the combined zone of 40° to 45° of abduction and 17° to 23° of anteversion, whereas only 6% (three) of fifty hips in the freehand-placement group were. However the postoperative evaluations in these previous studies were based on conventional radiographic analysis¹⁷⁻¹⁹, which may prevent direct comparison with our study⁸. Kalteis et al., in a prospective randomized study comparing freehand placement with computed tomography-based and imageless navigation in total hip arthroplasty, demonstrated with postoperative computed tomography that navigation significantly reduced cup orientation outliers²⁰. According to Jolles et al., the differences between computer-assisted and freehand cup placement are greater for less skilled surgeons¹⁷. Thus, the lack of differences in the mean abduction and anteversion angles between the two groups in our study could be explained by the senior author's experience with total hip arthroplasty. We did not observe any complications related to computer-assisted surgery, and no dislocation or neurovascular complication was recorded in the two groups. It would be interesting to replicate this study with a variety of surgeons with different skill levels to identify differences in cup positioning and calculate complication rates.

The computer-assisted surgery system used in this study, which was based on bone morphing, reduced the percentage of outliers for cup positioning in total hip arthroplasty. The next challenge for computer-assisted cup positioning is threefold. The first, technical concern involves registration of the anterior pelvic plane during the procedure, especially in obese patients. Echographic morphing could be a good alternative, and it needs to be validated in a prospective randomized study. The second challenge is the definition of optimal cup orientation in terms of abduction and anteversion angles for each patient. Analysis of the pelvic tilt in our study showed important inter-individual differences, which should be considered preoperatively to pro-

vide the best anteversion angle intraoperatively. The third issue is the clinical impact of reducing outliers during cup positioning. The clinical differences, especially with regard to the dislocation rate, range of motion, and wear, between patients treated with the computer-assisted system and those treated with free-hand cup positioning need to be evaluated at intermediate and long-term follow-up time-periods in order to evaluate the additional costs and operative time involved with these systems. ■

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doi:10.2106/JBJS.F.00529

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