

Comparison of Cup Setting Angle Accuracy between Computed Tomography-Based and Computed Tomography-Free Navigation in the Same Patients with Crowe's Classification I or II Hip Dysplasia

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Background: In total hip arthroplasty, the cup setting angle may affect the postoperative results. In recent years, both computed tomography-based navigation and computed tomography-free (imageless) navigation have been reported to produce high accuracy in cup installation; however, no direct comparison between these two methods has been performed. The present study aimed to directly compare the cup installation angle accuracy between computed tomography-based navigation and computed tomography-free navigation in patients with Crowe's classification stage I or II dysplastic osteoarthritis and to examine the factors affecting the cup installation accuracy.

Methods: Using both navigation systems for the same technique, primary total hip arthroplasty was performed by the same surgeon in 36 patients. A cup was installed using computed tomography-based navigation, and the installed cup was measured again using computed tomography-free navigation. We compared the error between the target angle and the intraoperative installation angle for each navigation method by performing statistical analyses.

Results: For computed tomography-based navigation, errors in the inclination and the anteversion angles compared to the target angle were $3.14^{\circ} \pm 1.55^{\circ}$ and $1.47^{\circ} \pm 0.99^{\circ}$, respectively. For computed tomography-free navigation, the inclination and anteversion angle errors were significantly larger, i.e., $6.84^{\circ} \pm 4.78^{\circ}$ and $5.43^{\circ} \pm 5.22^{\circ}$, respectively (p < 0.01). The inclination and anteversion angles of computed tomography-free navigation were correlated, and there were no significant factors influencing the error.

Conclusions: Computed tomography-based navigation is more accurate for cup installation than computed tomography-free navigation. When using computed tomography-free navigation, it is necessary to add technical schemes before and during surgery to improve the cup installation accuracy.

Keywords: Hip arthroplasty, Computer-assisted surgery, Computed tomography, Prostheses and implants, Acetabulum

In total hip arthroplasty (THA), obtaining a wide range

Received June 8, 2020; Revised September 28, 2020; Accepted November 25, 2020 Correspondence to: Nobuhiro Kaku, MD Department of Orthopaedic Surgery, Faculty of Medicine, Oita University, 1-1 Idaigaoka Hazama-machi, Yufu City, Oita 879-5593, Japan Tel: +81-97-586-5872, Fax: +81-97-586-6647 E-mail: nobuhiro@oita-u.ac.jp of motion after surgery and preventing dislocation are important factors for improving short-term results, such as the patient being able to perform day-to-day life activities.¹⁾ Setting the implant with an appropriate angle reduces polyethylene wear and affects long-term results.²⁾ However, reports suggest that there are many errors associated with the freehand techniques of cup setting³⁾ and using a mechanical device that guides the pelvic axis also provides a very low accuracy.⁴⁾ As typified by the com-

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bined anteversion theory, the concrete cup installation angle can be calculated mathematically for appropriate implant installation.⁵⁾ A computer-assisted system was initially developed in the 1990s⁶⁾ and was reported to be highly useful for embodying the specific cup installation angle during surgery.⁷⁾ THA using navigation reduces the risk of postoperative dislocation and impingement, which in turn lowers the revision rate.⁸⁾

The navigation systems are broadly divided into computed tomography (CT)-based and CT-free, classified by the difference in the image information used as reference. In CT-based navigation, three-dimensional bone models are constructed from CT data for each patient before surgery, and registration methods, such as fluoroscopy, landmarking, and surface point matching, are used. Conversely, in CT-free navigation, registration is performed to project bone surface reference points on the bone model recorded in the computer. The CT-free navigation is referred to as "imageless" and has advantages over CT-based navigation in terms of less radiation exposure and cost because it does not require preoperative CT or preoperative planning; thus, it is widely used in orthopedic areas, such as trauma and spine.

In recent years, there have been reports of promising results using CT-free navigation;^{9,10)} however, there is no report that directly compares the cup installation accuracy between CT-free and CT-based navigation to state important points of comparison between the two techniques. The purpose of this study was to compare the accuracy of cup installation between CT-based and CT-free navigation and to examine patient factors that affect the cup installation accuracy, e.g., pelvic morphology. We hypothesized that CT-based navigation, which determines the pelvic axis by considering individual anatomical differences of patients, would be more accurate than CT-free navigation, which calculates the pelvic axis based on pelvic data of many patients.

METHODS

This study was approved by the Bioethics Committee (approval No. 1414) and was conducted based on the Helsinki Declaration revised in 1964 and thereafter. Informed consent was provided by all participants.

The present study used a prospective design to investigate the cup setting angle accuracy during THA for patients with dysplastic osteoarthritis of Crowe's classification stage I or II using CT-based and CT-free navigation. The registration was performed for both CT-based and CT-free navigation by the same manufacturer preoperatively and intraoperatively; the surgeon (NK) used a common antenna during surgery for the same patient placed in the lateral decubitus position. Immediately after cup installation with CT-based navigation, the installed angle of the same cup was measured intraoperatively with CTfree navigation. We measured the difference between the cup angle obtained from postoperative CT data and the angle obtained from the intraoperative display using CTbased navigation. We also investigated the factors that affected the installation cup angle of CT-based and CT-free navigation. Unlike cohort studies with different subject groups, our study design minimized the influence of interindividual differences, such as anatomical factors and surgical position.

When comparing the cup installation angles between the two matched groups, a difference of 3° in the installation angle was defined as a clinically meaningful difference. The standard deviation was set to 6.2 based on our past cases. With an α error of 0.05 and a β error of 0.20, the required sample size was 36 hip joints. The participants of this study were recruited for approximately 1 year to obtain the number of joints needed for adequate power and for significance in statistical analysis. Of the 117 hip joints that were eligible for primary THA within the same period in our hospital, 65 were available after excluding non-osteoarthritis cases, such as rheumatoid arthritis, osteonecrosis of the femoral head, and cases after osteotomy. Twenty-one hip joints with Crowe type III or IV dysplasia showing obvious subluxation were also excluded. Of the total Crowe type I and II osteoarthritis cases, 8 cases with a Sharp's angle of less than 40° on the surgical side and without osteophytes, such as an acetabular double-floor, were excluded. Therefore, the Sharp's angle on the surgical side of the 36 target joints averaged $48.79^\circ \pm 3.56^\circ$ (range, 43°-59°). The study included 36 patients (7 men and 29 women) who underwent a primary THA for dysplastic osteoarthritis of the hip at our hospital between June 2018 and July 2019. The mean age of the patients at surgery was 65.6 ± 11.1 years (range, 37–84 years), and the average height, weight, and body mass index (BMI) were 154.7 ± 10.6 cm (137.0–181.5 cm), 56.9 ± 11.9 kg (39.0–86.6 kg), and $23.7 \pm 3.4 \text{ kg/m}^2$ (18.3–31.6 kg/m²), respectively. As per the Crowe's classification of osteoarthritis, 26 and 10 joints were in groups I and II, respectively; no cases were in group III or higher. CT images from the iliac wing to the knee joint were acquired using a helical CT scanner (Aquilion CX; Toshiba Medical Systems Corp., Tokyo, Japan) with a slice thickness of 1 mm. CT data were transferred to the planning module, which was then used to determine the optimal component size, angle, and position.

The installation target radiographic angles were 40° inclination and 20° anteversion based on the functional pelvic plain (FPP) standard for the preoperative plan of CTbased navigation. We used two navigation systems: Vector Vision Hip (Vector Vision compact hip CT ver. 3.5.2) for CT-based navigation and Hip-Ver 6.0 for CT-free navigation from the same manufacturer (Brainlab, Munich, Germany) (Table 1).

Fluoro-matching was used for registration during CT-based navigation. We performed bone surface registration after the induction of general anesthesia. We inserted two screws and placed the antenna on the iliac crest in the lateral decubitus position. Two fluoroscopic pelvic images were recorded from angles greater than 20° using a mobile fluoroscopy system (PhilipsBV-29 C-Arm; Koninklijke Philips, Eindhoven, the Netherlands). Next, 1 point of the superior anterior iliac spine and 2 points of the iliac crest on the surgical side were touched with a probe for registration because a metal mark was affixed at the superior anterior iliac spine opposite to the surgical side with an adhesive tape during CT-free navigation before surgery. The superior anterior iliac spines were touched as reference points with a probe bilaterally, and the acetabular fossa was run across with another probe during the operation in the same position for the registration of CT-free navigation.

All operations were performed by the same surgeon (NK) using a posterior approach in a lateral decubitus position, with an approximately 10° posterior tilt. An SQRUM/HA cementless cup (Kyocera, Kyoto, Japan) was used as the implant in all patients. The cup sizes were 42, 46, 48, 50, 52, and 56 mm for 1, 3, 12, 8, 7, and 5 hip joints, respectively. Although the cup was installed using CT-based navigation for all hip joints, the final operative angle of the cup was recorded on each hip joint at the same time. The operative angle was also immediately measured and recorded in one shot before removing the setting rod with an antenna using CT-free navigation. Therefore, it was possible to obtain the operative angles for cup installation

in CT-based and CT-free navigation of the same model for the same joint concurrently. After confirming cup fixation using the press-fit technique, two screw fixations were performed for all patients.

The operative angle obtained during the surgery using CT-based navigation was converted to a radiographic angle. For CT-free navigation, as the operative angle during surgery was based on the anterior pelvic plain (APP) standard, it was converted to the FPP standard by referring to the methods of Babisch et al.¹¹⁾ and then converted to a radiographic angle. The radiographic angles for cup inclination and anteversion were measured using LEXI's ZedHip ZedView 11.5.3 (LEXI Co., Tokyo, Japan) from the CT image obtained 1 week after the surgery. The accuracy of the CT-based navigation for the cup setting was initially measured to compare with the installation cup angles measured after surgery. Next, the difference between the radiographic angle measured intraoperatively and the target installation angle was compared between the CTbased and the CT-free navigation techniques.

In addition, BMI (kg/m²), the bilateral superior anterior iliac spine distance (mm), absolute value of pelvic tilt angle (°), Crowe's classification, and presence or absence of double-floor osteophytes were examined to determine the clinical factors affecting the cup installation accuracy. All measurements were performed by the same observer (NK) and were repeated in a blinded manner during the course of two sessions with at least 1 month apart. Intraobserver reliability evaluated using intraclass correlation coefficients (ICC) was excellent (range, 0.93–0.98). The reproducibility of the measurement was tested by two independent observers (HT and HT) who performed measurements in 31 randomly selected hip joints in a blinded manner. Interobserver reliability, which was evaluated using ICCs, was excellent (range, 0.92–0.98).

A paired *t*-test, Pearson correlation, multiple regression analyses, and ICCs were used for statistical analyses in IBM SPSS ver. 25 (IBM Corp., Armonk, NY, USA). A *p*-value of less than 0.05 was considered statistically sig-

Table 1. Characteristics of Both Navigation Systems			
Variable	CT-based navigation	CT-free navigation	
Software	Vector Vision compact hip CT version 3.5.2	Hip-Ver 6.0	
Registration	Fluoro-matching	Surface-matching	
Timing of registration	Preoperative	Intraoperative	
Reference	Two fluoroscopic pelvic images and 3 reference points	Two reference points and stroking of acetabular fossa	

CT: computed tomography.

nificant. A paired *t*-test was performed to compare the target installation radiographic angle errors that occurred during surgery using CT-based navigation as well as CT-free navigation. A Pearson correlation was used to examine the association between the inclination angle and the anteversion angle within the CT-free navigation group. Multiple regression analyses were performed to examine the role of perioperative factors in introducing angle errors during the surgery for the target angle between CT-based navigation and CT-free navigation. ICCs were determined to compare the interobserver error and assessment of the measurement method.

RESULTS

Compared to the installed cup angle measured after the surgery, the intraoperative radiographic inclination and anteversion angles on CT-based navigation had errors of $2.40^{\circ} \pm 2.01^{\circ}$ and $2.43^{\circ} \pm 1.81^{\circ}$, respectively. The target installation radiographic angle error during surgery was $3.14^{\circ} \pm 1.55^{\circ}$ for inclination and $1.47^{\circ} \pm 0.99^{\circ}$ for anteversion in CT-based navigation (Fig. 1). Conversely, CT-free navigation had angle errors of $6.84^{\circ} \pm 4.78^{\circ}$ for inclination and $5.43^{\circ} \pm 5.22^{\circ}$ for anteversion, which were significantly different from those observed in CT-based navigation (p <0.01). In the CT-free navigation group, the inclination angle increased significantly as anteversion angle increased, indicating a positive correlation (r = 0.37, p < 0.01) (Fig. 2). A multiple regression analysis revealed that factors, such as BMI, bilateral superior anterior iliac spine distance, absolute value of pelvic tilt angle, Crowe's classification, and presence of double-floor osteophytes, did not contribute to the errors in intraoperative angles of navigation accounting for the target installation angle value (Tables 2-5). However, the anteversion angle and pelvic tilt had lower *p*-values compared to other factors in the CT-free navigation group.

DISCUSSION

This study concurrently and directly compared CT-based and CT-free navigation systems of the same model for the same hip joints and found that CT-based navigation was more accurate than CT-free navigation for cup installation. Considering that the inclination and anteversion angles in CT-free navigation increased/decreased proportionally, it is highly possible that the pelvic axis (e.g., APP) on the computer after registration was likely different from the actual pelvic axis in the sagittal plane. Blendea et al.¹²⁾ compared the cup setting accuracy of CT-free navigation



Fig. 2. Scatter plots of inclination and anteversion angles. The inclination and anteversion angles of the computed tomography (CT)-free navigation group are significantly correlated (r = 0.37, p < 0.01).



Fig. 1. Comparison of angles converted to the radiographic angle in both navigation systems. (A) Median inclination angle of the cup was $36.9^{\circ} \pm 1.6^{\circ}$ (range, $33.8^{\circ}-39.5^{\circ}$) for the computed tomography (CT)-based navigation group and $35.1^{\circ} \pm 6.5^{\circ}$ (range, $18.9^{\circ}-53.3^{\circ}$) for the CT-free navigation group. (B) The median anteversion angle of the cup was $21.2^{\circ} \pm 1.2^{\circ}$ (range, $19.0^{\circ}-23.7^{\circ}$) for the CT-based navigation group and $20.8^{\circ} \pm 7.3^{\circ}$ (range, $10.4^{\circ}-41.6^{\circ}$) for the CT-free navigation. Whiskers indicate the maximum and minimum values excluding outliers.

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Table 2. Multiple Regression Analysis with Radiographic Inclination of the Cup Using Computed Tomography-Based Navigation					
Independent variable	Standardized beta coefficient	Standard error coefficient	<i>t</i> -value	<i>p</i> -value	
Body mass index	-0.008	0.096	-0.043	0.966	
Bilateral superior anterior iliac spine distance	-0.113	0.022	-0.496	0.623	
Absolute value of pelvic tilt angle	0.128	0.058	0.533	0.598	
Crowe's classification	-0.28	0.852	-0.126	0.901	
Presence or absence of double-floor osteophytes	-0.99	0.732	-0.518	0.608	

Table 3. Multiple Regression Analysis with Radiographic Anteversion of the Cup Using Computed Tomography-Based Navigation

Independent variable	Standardized beta coefficient	Standard error coefficient	t-value	<i>p</i> -value
Body mass index	0.117	0.128	0.637	0.529
Bilateral superior anterior iliac spine distance	0.224	0.029	1.002	0.324
Absolute value of pelvic tilt angle	0.294	0.078	1.240	0.225
Crowe's classification	0.027	1.144	0.123	0.903
Presence or absence of double-floor osteophytes	0.015	0.983	0.078	0.939

Table 4. Multiple Regression Analysis with Radiographic Inclination Using Computed Tomography-Free Navigation					
Independent variable	Standardized beta coefficient	Standard error coefficient	t-value	<i>p</i> -value	
Body mass index	-0.195	0.254	-1.083	0.287	
Bilateral superior anterior iliac spine distance	-0.003	0.066	-0.010	0.992	
Absolute value of pelvic tilt angle	-0.45	0.132	-0.190	0.851	
Crowe's classification	0.184	2.190	0.886	0.383	
Presence or absence of double-floor osteophytes	0.080	2.051	0.409	0.685	

Table 5. Multiple Regression Analysis with Radiographic Anteversion Using Computed Tomography-Free Navigation

Independent variable	Standardized beta coefficient	Standard error coefficient	t-value	<i>p</i> -value
Body mass index	0.058	0.261	0.343	0.734
Bilateral superior anterior iliac spine distance	0.053	0.068	0.225	0.824
Absolute value of pelvic tilt angle	0.414	0.136	1.853	0.074
Crowe's classification	0.075	2.254	0.381	0.706
Presence or absence of double-floor osteophytes	0.084	2.111	0.459	0.649

with both saw bone models and the actual clinical results. They reported that the accuracy was unacceptably low in a so-called real-life clinical surgical setting, although the accuracy in a so-called machine ideal setting was acceptable. Mor et al.¹³⁾ found that accurate cup installation angles were obtained with CT-based navigation with similar veri-

fications.

Although there is a possibility that the accuracy will be improved by simply adding reference points, such as pubic symphysis, in the registration of CT-free navigation, multiple factors affect the accuracy. The present study failed to show whether factors, such as BMI, bilateral su-

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perior anterior iliac spine distance, absolute value of pelvic tilt angle, Crowe's classification, or the presence or absence of double-floor osteophytes, contributed to the error significantly. It was suggested that a significant difference might be obtained in the association between the anteversion angle and pelvic inclination (p = 0.074) by increasing the number of cases. Lin et al.¹⁴⁾ showed from clinical results that the accuracy of cup placement by CT-free navigation is significantly affected by the pelvic tilt. Furthermore, Lembeck et al.¹⁵⁾ experimentally demonstrated that pelvic tilt interferes with APP settings. It has been reported in the past that the error that occurs in touching reference points with a probe for the registration are affected by obesity.¹⁶⁾ Since CT-based navigation using fluoro-matching needed a total of 3 points from the iliac crest (2 points on the iliac bone of the affected side and 1 point on the superior anterior iliac spine) and CT-free navigation had a total of 3 points as references (2 points on the bilateral superior anterior iliac spine and 1 point on the acetabular fossa) in this study, we speculate that there was no difference in touching reference points between both navigation systems. Currently, the virtual pelvis in CT-free navigation by Brainlab has been mainly created from the global data of primary osteoarthritis, and the pelvic axis has also been set on its basis. It was reported that anatomical measurements of the pelvis, such as the distance between the superior anterior iliac spines, were different between the dysplastic and normal hip joints.¹⁷⁾ However, the bilateral superior anterior iliac spine distance did not significantly contribute to the error in the present study, which was limited to the groups with Crowe's classification stages I and II without severe subluxation. In addition, double-floor osteophytes, which covered and narrowed the acetabular fossa, also did not contribute to the error.

As more specific angles are required for the installation of the cup for THA in recent years, the accuracy of freehand procedures is limited.¹⁸⁾ The navigation system is useful for improving the installation accuracy. Sugano et al.⁸⁾ showed that the accuracy of cup installation was superior in CT-based navigation over that in freehand techniques in primary THA, with 80 out of 111 cases using freehand techniques and all 60 cases using CT-based navigation including the Lewinnek safe zone. The dislocation rate was 0 out of 60 for CT-based navigation cases and 7 out of 111 freehand cases over a 3-year period.¹¹⁾ It has also been reported that the cup position and angle have a high accuracy of 2 mm and 2° or less, respectively.¹⁹⁾ CTbased navigation can maintain the implant placement accuracy without being affected by surgical approaches that are minimally or less invasive.²⁰⁾ It has also been reported that the high accuracy for cup installation can be maintained for patients with Crowe's classification stage III or IV disease, severe pelvic tilt, and obesity.²¹⁻²³⁾ These results suggest that the use of CT-free navigation for severe hip dysplasia with specific anatomical features requires attention for maintaining the accuracy of the cup setting angle. CT-based navigation is also effective for stem-side orientation and leg length correction.^{24,25)}

According to a report by Kalteis et al.,²⁶⁾ 28 out of 30 cases in CT-free navigation and 14 out of 30 freehand cases for primary THA included the Lewinnek safe zone for cup installation, which was a significant difference (*p* = 0.003) between them. The results of CT-free navigation also showed a comparable accuracy with CT-based navigation in 25 of 30 cases that included the Lewinnek safe zone. Snijders et al.²⁷⁾ also performed a systematic review and meta-analysis comparing CT-free navigation (imageless) and freehand techniques and stated that the accuracy improved at p = 0.002 for anteversion and at p = 0.01 for inclination. However, Hohmann et al.²⁸⁾ reported that the results of 32 joints, in which CT-free navigation was used, showed high accuracy in the inclination angle of the cup, but not in the anteversion angle. Inaccurate cup installation angles due to large errors from the bone model in cases with severe deformity have also been reported.¹⁴⁾ In addition, obesity with a BMI greater than 27 further reduces accuracy.²⁹⁾

The present study has some limitations. First, the sample size was small, but it met the required calculated size to compare the two navigation techniques. It is worth noting that the results obtained in this study are specific to THA using navigation systems for Crowe type I or II dysplastic osteoarthritis of the hip. However, it may be possible to determine factors that affect the clinical placement accuracy, such as the absolute value of the pelvic tilt angle, if the sample size was larger. Patients with other hip disease and Crowe type III and IV dysplastic osteoarthritis were excluded from this series because the anatomical factors involved in APP were expected to be largely different from those noted in dysplastic osteoarthritis with Crowe classification stage I and II. Therefore, it is not clear whether these results may be generalized to Crowe type III and IV dysplastic osteoarthritis. Second, the same number of patients when the cup was actually installed with CTfree navigation should be compared against the results of the present study to evaluate both navigation systems more in-depth using a cohort study design. To improve the accuracy of CT-free navigation, the intraoperative installation cup angle should also be measured in the supine position with easier pointing for bilateral superior anterior

iliac spine, and not the lateral position, in which there is a three-dimensional increase in the pelvic tilt.³⁰⁾

Although there were some limitations, CT-based navigation resulted in more accurate cup installation than CT-free navigation in THA for Crowe type I and II dysplastic osteoarthritis. It is recommended that the surgeon should select and use one of the two techniques after sufficiently understanding their characteristics and patient's condition. When using CT-free navigation, clinical procedures, such as pelvic fixation with the same tilt during surgery, are usually required to improve the installation accuracy of the cup for even Crowe type I and II dysplastic osteoarthritis.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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