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ORIGINAL ARTICLE

Portable imageless navigation system and surgeon's estimate for accurate evaluation of acetabular cup orientation during total hip arthroplasty in supine position

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Abstract

Background This prospective study aimed to clarify whether this novel device can evaluate the cup orientation during total hip arthroplasty (THA) more closely to that measured in postoperative computed tomography (CT) compared to the surgeon's estimate using a manual goniometer.

Methods We prospectively performed 30 cementless THAs via the anterolateral approach in supine position between October 2018 and July 2019, wherein cup orientation was evaluated by both a portable imageless navigation system (HipAlign) and a manual goniometer during surgeries. Primary outcome was the absolute estimate error [the absolute value of the difference between cup angles measured by postoperative CT and those measured by HipAlign (group H) or surgeon's estimate using the manual goniometer (group S) during surgery]. The number of outliers of the absolute estimate error (> 10°) in each group was also estimated.

Results The absolute estimate error of cup inclination in groups H and S was 3.3° ± 2.7° and 3.0° ± 2.5°, respectively ($p = 0.51$), whereas that of cup anteversion was 3.8° ± 3.4° and 6.0° ± 3.7°, respectively ($p = 0.0008$). The number of outliers of the estimate error in groups H and S was one case (3.3%) and six cases (20.0%), respectively ($p = 0.04$). In all six outlier cases, surgeons underestimated cup anteversion during surgeries.

Conclusions This portable imageless navigation system was a useful method, especially for avoiding incorrect cup anteversion. Underestimation of cup anteversion during THA in the supine position with the conventional alignment assisting device should be given attention.

Keywords Acetabular cup orientation · Total hip arthroplasty · Portable imageless navigation system · Range of motion

Introduction

The orientation of the acetabular cup in total hip arthroplasty (THA) is a critical factor for the prevention of postoperative dislocation, accelerated wear and loosening, reduced range of motion, and patient dissatisfaction [1–3]. Although the ideal cup orientation is still controversial, most surgeons target an inclination angle of 30°–50° and an anteversion angle of 5°–25°, taking into consideration the patients' demographics, especially femoral neck anteversion [4–6].

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To achieve the targeted cup positioning, various conventional alignment assisting devices, such as manual goniometers and mechanical alignment guides, have been used, and computer-assisted navigation systems have been developed recently [7–9]. On the other hand, although it has been clarified that some computer-assisted navigation systems can provide far more accurate cup positioning than conventional alignment assisting devices, Aoude et al. [10] reported that approximately 97% of THAs in the USA are still performed with conventional alignment assisting devices, not with any computer-assisted navigation system because of its cost, longer surgical time, and potential complications.

The imageless computer-assisted navigation system is one of the common computer-assisted navigation systems and has been reported to be a useful device to improve the accuracy of cup positioning for THAs compared to conventional alignment assisting devices [11, 12]. HipAlign (Orthalign

Inc, Aliso Viejo, California, USA) was used as an accelerometer-based portable imageless device, which consists of a disposable computer display unit and a reference sensor. This portable system aims to integrate the accuracy of large-console imageless computer navigation systems with the convenience of the conventional alignment techniques. In fact, this system enables surgeons to shorten the surgical time compared to other computer-assisted navigation systems, and its considerable accuracy of cup positioning in THA via the minimally invasive anterolateral approach in supine position has been reported [13]. On the other hand, a previous report indicated that the accuracy of cup positioning of an imageless computer navigation system was possibly similar to that of a conventional alignment assisting device [12]. Besides, few studies have evaluated the accuracy of cup positioning of this new portable device [13]. Therefore, we conducted this study to clarify whether the HipAlign can evaluate the cup orientation during surgery more closely to that measured in postoperative computed tomography (CT) compared to the surgeon's estimate using a manual goniometer.

Materials and methods

This study was conducted as a part of a prospective multicenter study approved by our institutional research ethics committee according to the principles of the Declaration of Helsinki. The protocol of the multicenter study was registered on the University Hospital Medical Information Network Clinical Trials Registry before enrolment of the first participant.

Patients

We prospectively performed 30 THAs in 29 patients between October 2018 and July 2019 at our institution, wherein cup orientation was evaluated by both HipAlign and the manual goniometer during surgeries. The inclusion criteria were as follows: patients who were indicated for THA, were older than 20 years, and agreed to provide informed consent to participate in this study. The exclusion criteria were as follows: patients with dementia, metabolic disorder, and severe neuromuscular disease.

Methods

Cementless THA was performed under spinal anesthesia with intravenous sedation in all cases. The patients were placed on the standard operating table without a leg traction device, which was positioned in the horizontal axis to the floor. All surgeries were performed through a minimally invasive anterolateral approach in the supine position by two senior surgeons who had had more than 100 cases of experience on this approach prior to this study. This anterolateral approach modifying the Watson–Jones approach, which is called the Rottinger approach when performed in the lateral position, is a technique separating the inter-muscular plane between the tensor fascia lata and the gluteus medius muscles [14]. An initial incision was made on the anterolateral aspect of the hip (10 cm), and the interval between the tensor fascia lata and gluteus medius was bluntly created without muscle cutting or detachment, and the exposed plane was not created too proximally to minimize the risk of superior gluteal nerve injury [15]. After capsulotomy, cementless implantation with ceramic-on-highly cross-linked polyethylene bearings was performed in all cases. Femoral preparation was done prior to acetabular preparation. TaperLoc Microplasty (Zimmer Biomet, Warsaw, IN) and G7 acetabular cup (Zimmer Biomet) were used as femoral and acetabular components, respectively. The acetabular cup was inserted in a press-fit fashion. In two cases, two screws were used for each cup fixation.

The cup orientation after insertion was finally evaluated using the HipAlign portable navigation system and by the surgeon's estimate using the manual goniometer. The surgeons had had the experience of using the HipAlign in several cases before this study began. The navigation unit of the HipAlign was calibrated on a flat table. Two fixation pins were placed parallel to each other on the ipsilateral iliac crest, and the pelvic unit's base was fixed on both pins. The bilateral anterior superior iliac spines and pubic symphysis were registered as anatomical landmarks to define the functional pelvic plane. These procedures were finished before surgeries. The radiographic inclination and anteversion were basically targeted as 40° and 15°, respectively. These targeted angles were individually arranged considering patients' demographics, especially stem neck anteversion measured during surgery [4, 6]. The cup was inserted manually with a steel hammer. HipAlign was not used during the cup insertion. After the cup insertion, the cup inclination and anteversion angles based on functional pelvic plane were evaluated by attaching a navigation sensor to a cup impactor (Fig. 1). The manual goniometer was also used to evaluate those angles after the evaluation by the HipAlign system [8]. The cup inclination was measured using both anterior superior iliac spines to define the horizontal line by using the manual goniometer (Fig. 2). The cup anteversion was measured based on the horizontal axis to the floor. Intraoperative X-rays, fluoroscopy, and other computer-assisted devices were not used.

Outcome

Patients' background data (age, sex, side of surgery, body mass index, and diagnosis) and surgical data (operative time,

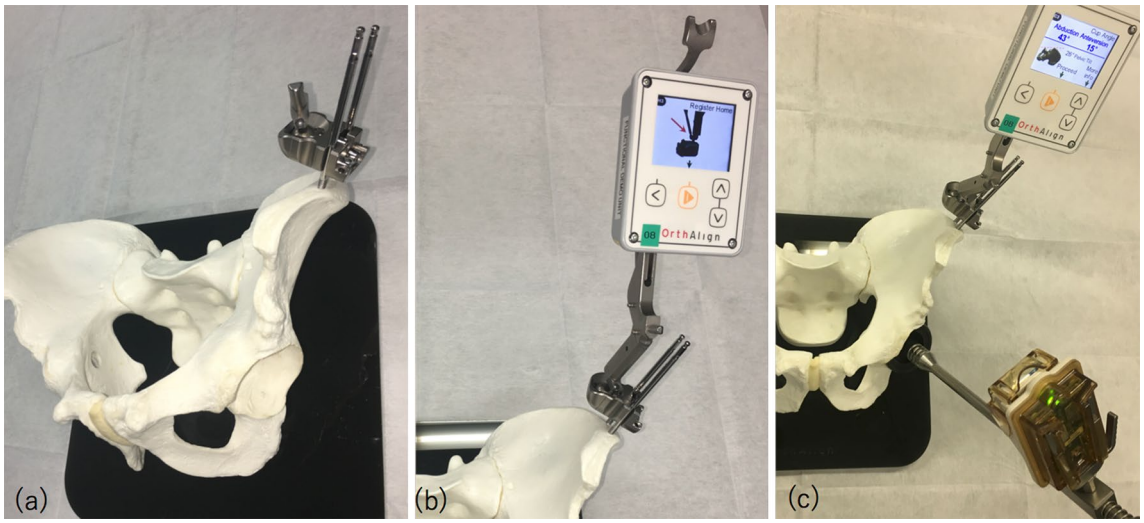

Fig. 1 **a** Two fixation pins are placed parallel to each other on the ipsilateral iliac crest, **b** a navigation sensor with a base unit is set on the fixation pins, **c** a monitor showing radiographic cup inclination and anteversion angles by attaching a navigation sensor to a cup impactor

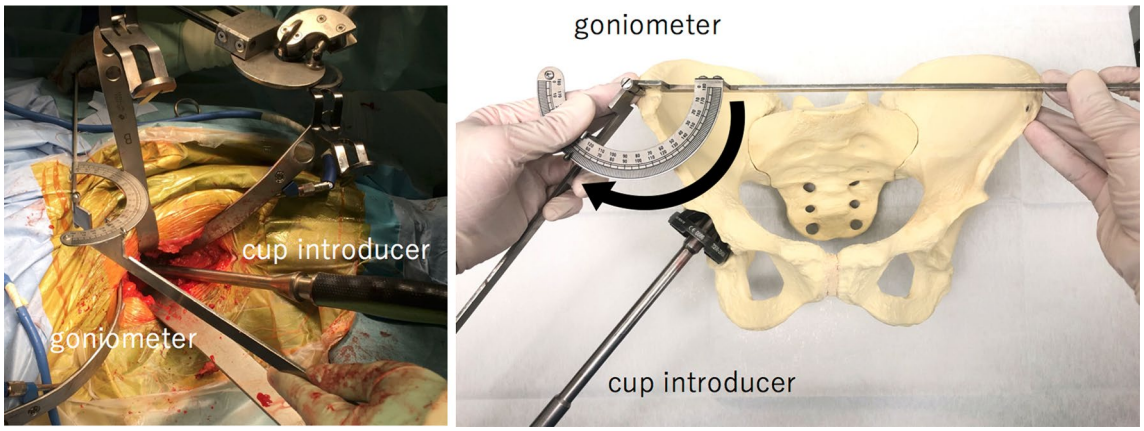

Fig. 2 Radiographic cup inclination during surgery is evaluated. In the supine position, bilateral anterior superior iliac spines are palpable to determine the pelvic horizontal line

intraoperative blood loss, any complication regarding the navigation system) were obtained. The time for preparing the fixation rod and the landmark registry for HipAlign before surgery was also recorded (preparation time for navigation). Computed tomography (CT) for hip in the supine position is the most accurate method for determining the postoperative acetabular component position [7, 12]. We assessed the postoperative inclination and anteversion using CT, which was performed within 3 months postoperatively. The pelvic incline in supine position during CT examination was used to define functional pelvic plane [7, 8]. The functional pelvic plane was used as a reference plane for the cup orientation. This assessment was performed by one surgeon. To clarify the intra- and inter-observer reliability of this assessment, a second assessment was performed 4 weeks later by the same surgeon, and another surgeon performed the same assessment in the first 20 cases. We defined the difference between the angles measured during surgery and those measured by postoperative CT measurement as *estimate error* (positive value of the estimate error means that the angles measured during surgery are larger than those measured in CT) and the absolute value of the estimate error as *absolute estimate error*. For all analyses, the radiographic angle values were used based on the definitions by Murray [16] because these definitions have been used most commonly in other studies [7, 8].

Primary outcome was the absolute estimate error of cup inclination and anteversion for both HipAlign (group H) and surgeon's estimate using the manual goniometer (group S). The number of the outliers of the absolute estimate error (the absolute estimate error > 10°) in each group was also estimated.

Table 1 Patients' demographics and surgical data

Variable	$n=30$
Age (years)	65.0 ± 10.6 (35–82)
Sex (female/male)	24/6
Side (right/left)	14/16
Body mass index (kg/m^2)	24.2 ± 4.1 (16.8–30.3)
Diagnosis	
Osteoarthritis	25
Osteonecrosis	5
Preparation time for navigation (min)	4.2 ± 1.4 (3–7.5)
Operative time (min)	95.3 ± 18.7 (66–147)
Intraoperative blood loss (ml)	266.9 ± 122.8 (101–550)

Values are given as mean ± standard deviation (range)

Statistical analysis

Statistical analysis was performed using JMP software version 13.0.0 for Mac (SAS Institute, Cary, NC, USA). Unpaired *t* test and the Chi-square test were utilized to evaluate statistical differences between the continuous and categorical data, respectively. To compare the primary outcome between groups H and S, the differences in each error and 95% confidence intervals were calculated. All tests were two-sided, and $p<0.05$ was considered statistically significant.

Results

Patients' demographics and surgical data are shown in Table 1. There was no complication during surgery in all cases. Postoperative CT and analysis were performed in all cases. The postoperative radiographic inclination and anteversion were 37.6° ± 3.9° (mean ± standard deviation (SD), range 31.9°–45.6°) and 17.9° ± 4.1° (mean ± SD, range 10.2°–24.6°), respectively. As primary outcome, the absolute estimate error in both groups H and S is shown in Table 2. Although there was no significant difference in the cup inclination between the two groups ($p=0.51$), the absolute estimate error of cup anteversion was significantly lower in group H than in group S ($p=0.0008$). The numbers of outliers of the estimate error in groups H and S were one case (3.3%) and six cases (20.0%), respectively ($p=0.04$) (Fig. 3). Figure 3 also shows that the surgeons underestimated cup anteversion in all outliers during surgeries. Intra- and inter-observer reliabilities are shown in Table 3.

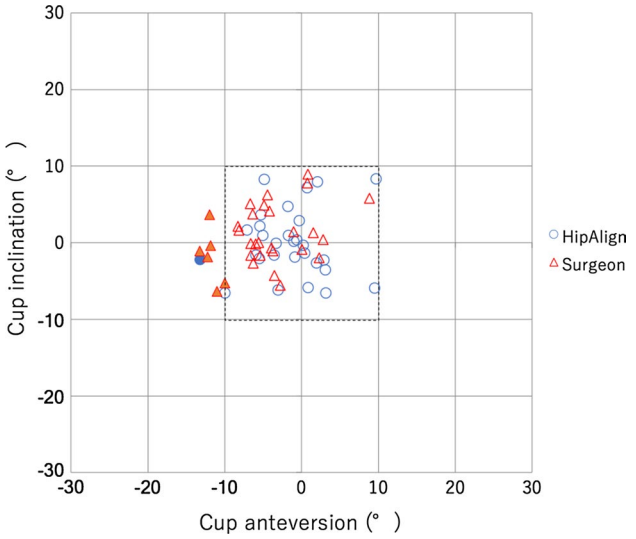

Fig. 3 Distribution of the estimate error for the HipAlign and surgeon. One outlier by the HipAlign (3.3%) and six outliers (20.0%) by surgeon's estimate were found in our study. This figure also indicates that the surgeons underestimated the cup anteversion in all outliers

Table 3 Intra- and inter-observer reliabilities using intraclass correlation coefficients (ICC) in each parameter measured postoperatively

Reliability	Cup inclination	Cup anteversion
Intra-observer reliability	0.96	0.92
Inter-observer reliability	0.84	0.87

Discussion

In this study, the HipAlign evaluated the cup orientation during surgery significantly more correctly than the surgeon's estimate using the manual goniometer in terms of cup anteversion and significantly decreased the number of outliers. On the other hand, surgeon's estimate for cup inclination during surgery was not inferior to that of the HipAlign. This is the first study to investigate the superiority of this new portable imageless navigation system compared to the surgeon's estimate with the conventional alignment assisting device.

The accuracy for absolute estimate error in both cup inclination and anteversion by the HipAlign in our study was consistent with that in a previous study. Kamenaga et al. [13]

Table 2 The absolute estimate error

	HipAlign ($n=30$)	Surgeon's estimate ($n=30$)	Difference (95% CI)	*p* value
Cup inclination (°)	3.3 ± 2.7 (0.1–8.3)	3.0 ± 2.5 (0–8.9)	0.31 (−0.6 to 1.2)	0.51
Cup anteversion (°)	3.8 ± 3.4 (0.3–13.1)	6.0 ± 3.7 (0.1–13.2)	−2.2 (−3.5 to −0.9)	0.0008

CI confidence interval

reported that their absolute estimate error of cup inclination and anteversion by HipAlign was 2.6° ± 2.7° and 2.8° ± 2.7°, respectively. They also demonstrated that their accuracy by the HipAlign was almost equal to that achieved by using other imageless computer-assisted navigation systems with relatively short surgical time. In fact, only a few minutes were required for HipAlign preparation before surgeries in our study. Moreover, this portable imageless navigation system has also been used for total knee arthroplasty and can provide more accurate implant orientation compared to free-hand surgery [17]. As mentioned previously, the HipAlign can be a useful simple method for improving the accuracy of cup positioning similar to other imageless computer-assisted navigation systems.

Some authors have explained that the supine position allows for better pelvic stability and landmark availability during surgery, which can help achieve accurate cup positioning, compared to the lateral position [18, 19]. The previous randomized controlled study of Takada et al. [20] showed that the supine position provided more accurate cup positioning, especially cup inclination, because of its better landmark availability. In the supine position, accurate cup inclination can be achievable because both anterior superior iliac spines are palpable to recognize the pelvic horizontal plane (Fig. 2). This can be a considerable reason why we achieved good accuracy of cup inclination using the manual goniometer as well as using the HipAlign.

Although only one outlier was produced by the HipAlign, six outliers by the surgeon's estimate were found in our study. Moreover, those outliers were because of the surgeon's underestimation of cup anteversion. This underestimation can cause joint instability for postoperative dislocation and be related to postoperative implant impingement that can cause early implant failure [1, 2]. This can be explained by the findings of previous studies [21, 22]. They indicated that this underestimation of cup anteversion in the anterolateral approach is caused by the retractor placed at the posterior acetabular wall, which retracts the femoral bone and rotates the ipsilateral pelvis posteriorly during cup preparation. It can be suggested that cup preparation in minimally invasive anterolateral approach should be done with high attention to the ipsilateral posterior rotation of the pelvis. In other words, on the basis of our results, the HipAlign is a useful method for avoiding underestimation of cup anteversion during surgery.

There are several limitations in our study. First, surgeon's estimate during each surgery was performed after the evaluation of the HipAlign. This order of the procedure can influence the surgeon's estimate in each surgery. Second, we did not consider the learning curve of the use of the HipAlign. Two senior surgeons had not had much experience in using the HipAlign before starting this study. However, Kamenaga et al. reported that there was no considerable learning curve in terms of absolute estimate error in their study [13]. Therefore, the effect of this limitation is considered limited. Further studies by experienced surgeons should be conducted in the future. Third, we did not conduct power analysis for this study because this study was part of a multicenter study. Although we did not find significant difference of the accuracy for cup inclination between HipAlign and surgeons' estimate, it might be found in a study with a larger number of subjects.

In conclusion, the imageless portable navigation system was a useful method, especially for avoiding incorrect cup anteversion. Underestimation of cup anteversion during THA via the minimally invasive anterolateral approach in the supine position could be prevented using this portable navigation system [13, 20].

Author's contribution RT performed study design and data collection, analysis, and interpretation, and wrote the article. TJ contributed to study design and data interpretation. KM contributed to data collection and interpretation. MH contributed to data collection and the analysis of inter-observer reliability. TY contributed to restructuring and revision of article. AO contributed to study design and data interpretation.

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Compliance with ethical standards

Conflict of interest Dr. Takada reports personal fees from Stryker, Medtronic Sofamor Danek, and HOYA, outside the submitted work. Dr. Jinno reports grants and personal fees from Stryker and personal fees from Zimmer Biomet and Depuy Synthes, outside the submitted work. Dr. Miyatake, Dr. Hirao, Dr. Yoshii, and Dr. Okawa declare that they have no conflict of interest.

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