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ORIGINAL ARTICLE • HIP - ARTHROPLASTY

A prospective clinical trial to assess the accuracy of an MRI-based patient-specific acetabular instrument guide in total hip arthroplasty

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Abstract

Background The purpose of this study was to conduct a prospective clinical trial to investigate the accuracy of an MRI-based patient-specific acetabular instrument guide during THA.

Methods We conducted a prospective consecutive review of 14 hips in 14 patients who underwent primary THA with a posterolateral approach between September 2016 and February 2018. All preoperative planning and postoperative evaluations were completed on CT-based templating software. A pelvic MRI was taken to create a patient-specific surgical instrument guide. In order to assess the effect of increased experience on accuracy, we divided the cases into two groups according to when surgery was performed and investigated the absolute error in the acetabular component angle between preoperative planning and the postoperative state for each of the groups.

Results We did not experience postoperative complications such as implant early dislocation in any of the cases. The absolute errors of acetabular implant angle using the patient-specific instrument guide were 3.7° ± 2.2° inclination and 4.5° ± 3.9° anteversion. The absolute error of the initial group was 4.7° ± 2.1° inclination and 6.1° ± 4.0° anteversion; for the later group, it was 2.8° ± 1.8° inclination and 3.2° ± 2.9° anteversion. There was a significant difference in the absolute error of acetabular implant placement between the initial group and the later group.

Conclusions We believe this study shows that MRI-based patient-specific instrumentation may be a useful alternative to surgical tracking during THA once the slight learning curve has been overcome.

Keywords Total hip arthroplasty · Patient-specific instrument guide · MRI · Acetabular cup

Introduction

Total hip arthroplasty (THA) is a highly successful orthopedic procedure for patients with osteoarthritis (OA) of the hip [1]. Accurate preoperative planning and faithful reproduction of that planning during THA is vital for preventing postoperative complications such as excessive polyethylene wear, edge loading, implant impingement, and postoperative dislocation [2–4]. Lewinnek et al. recommended a target inclination angle of 30°–50° for the acetabular component, with anteversion of 5°–25° [5], while Widmer et al. showed that the sum of cup anteversion plus 0.7 times the stem anteversion should equal 37.3° to achieve a maximal and stable postoperative range of motion of the hip without implant-to-bone impingement [6]. Using these guidelines should enable us to minimize implant malpositioning during THA. However, past reports have shown that fifty percent of acetabular cup placement using the manual freehand technique is inaccurate, and is outside the acceptable range for both abduction and anteversion [7]. Also, intraoperative pelvic motion has been reported to be one of the critical factors in poor acetabular implant orientation using the freehand technique [8]. Therefore, preoperative planning with computed tomography (CT)-based three-dimensional templating and a CT-based surgical navigation system can be used to achieve more accurate target angles for the acetabular component [9–13]. But while these surgical support tools make it possible to place implants more accurately, they are expensive and not all institutions can use them. Some recent reports showed that a CT-based patient-specific surgical instrument

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guide made using 3D printing technology was useful in achieving a more accurate target angle for the acetabular component [14–16]. Others have noted that a CT-based or MRI-based patient-specific instrumentation guide improves the coronal alignment in total knee arthroplasty. However, no reports have investigated the accuracy of an MRI-based patient-specific acetabular instrument guide during THA.

The purpose of this study was to investigate the accuracy of an MRI-based patient-specific acetabular instrument guide during THA in a prospective clinical trial.

Materials and methods

This investigational protocol was conducted with the approval of our institutional ethical committee. In accordance with the requirements of this review, all patients were provided informed consent.

We enrolled a prospective consecutive review of 14 hips in 14 patients (1 man and 13 women) who underwent primary THA with a posterolateral approach between September 2016 and February 2018. We did not include patients with high dislocated hips, a prior history of reconstructive surgery of the hip which was to be treated, or those for whom THA would be performed using an anterolateral approach. The patient demographics are shown in Table 1. The mean age of the patients was 80.1 ± 6.1 years (63–86 years). There were 9 left hips and 5 right hips. The preoperative diagnosis was osteoarthritis in all cases. Secondary OA due to a developmental dislocated hip was diagnosed in 7 hips, which were Crowe group 1 [17]. Primary osteoarthritis was diagnosed in the remaining 7 hips. For the acetabular cups, the authors used G7 acetabular shells (Zimmer Biomet Inc., Warsaw, IN, USA) in all hips. For the femoral stems, Kinectiv (Zimmer Biomet Inc., Warsaw, IN, USA) was used in 5 hips, Taperlock (Zimmer Biomet Inc., Warsaw, IN, USA) in 2 hips, Taperlock Microplasty (Zimmer Biomet Inc., Warsaw, IN, USA) in 1 hip, Alloclassic (Zimmer Biomet Inc., Warsaw, IN) in 4 hips, and Heritage (Zimmer Biomet Inc., Warsaw, IN, USA) in 2 hips.

All patients were given anteroposterior hip X-rays and CT scans. An anteroposterior hip X-ray was taken immediately after the operation, and postoperatively at 3 weeks. A CT scan was taken for preoperative planning, for postoperative assessment 2 weeks after the operation, and to investigate postoperative implant alignment. All preoperative planning and postoperative evaluations were completed on the CT-based templating software ZedHip (Lexi Co., Tokyo, Japan).

Table 1 Patient demographic data

Patient characteristics ($n = 14$)	
Age	80.1 ± 6.1 (63–86)[a]
Sex (female/male)	13/1
Side (left/right)	9/5
Diagnosis	Secondary osteoarthritis 7 hips
	Primary osteoarthritis 7 hips

[a]Mean ± standard deviation (range)

Preoperative planning and description of patient-specific instrumentation

The authors performed the preoperative planning using a CT-based three-dimensional templating system in all cases, as detailed in our previous study [9]. A preoperative CT scan from the iliac wing to the femoral condyle was performed using a helical CT scanner (Lightspeed VCT; GE Medical Systems, Milwaukee, WI, USA, USA). Slice thickness was 1 mm, and pitch was 2.5 mm (160–250 slices depending on body size). The CT data was transferred to ZedHip (Lexi Co., Tokyo, Japan), which is CT-based, three-dimensional templating software. The anterior pelvic plane (APP) was defined by both the bilateral anterior superior iliac spine and pubic tubercle as a reference plane of the pelvis. If, due to spine and pelvic deformities, this plane was tilted in the sagittal plane when the patient was lying in the supine position, the correction of the anterior–posterior axis was performed during preoperative templating as described in previous studies [18]. On the APP, the *x*-axis was defined by a line connecting the right and left anterior superior iliac spines. The *z*-axis was defined as a line passing through the pubic symphysis in the APP perpendicular to the *x*-axis. The *y*-axis was defined by a horizontal line passing through the middle point of the right and left anterior superior iliac spines perpendicular to the APP.

The acetabulum component implantation site was located at the point where the original acetabulum contacted the lateral wall of the teardrop and achieved a cup CE angle of more than 0°. The planes of inclination and anteversion angle were defined as described by Murray in accordance with an anatomical assessment [19]. The target inclination or anteversion angle of the acetabular cup was determined as described by Widmer et al. [6]. The acetabular inclination and anteversion angle were planned according to the APP. The cup size was chosen so as to fill the anterior and posterior acetabular walls (Fig. 1).

Four to 6 weeks before surgery, a preoperative MRI image of the entire pelvis was taken in order to create a patient-specific surgical instrument guide in the axial, coronal, and sagittal planes. Slice thickness was 2 mm, and the acquisition matrix was 256 × 256 according to Hip Signature protocol (Zimmer Biomet Inc., Warsaw, IN, USA). The imaging data were then provided to Materialise (Leuven, Belgium). The technician segmented the data and determined reference points in the MRI image. Bilateral

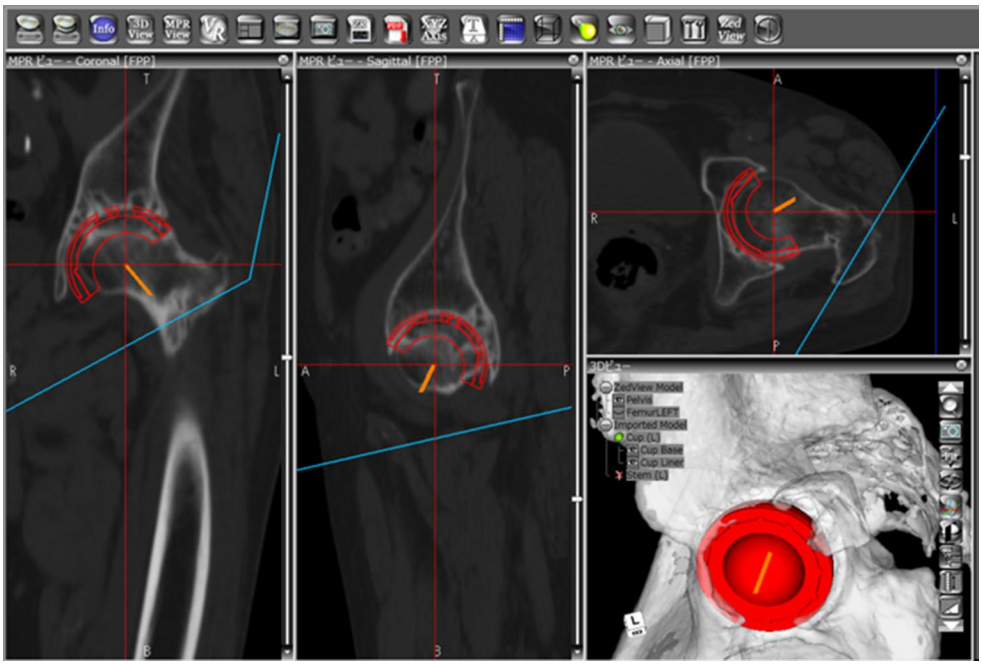

Fig. 1 Preoperative planning for the acetabular component in a CT-based surgical preoperative planning system. Acetabular inclination and anteversion angle were planned according to APP. The cup size was chosen so as to fill the anterior and posterior acetabular walls

anterior superior iliac spine (ASIS), 2 mm or 4 mm superior and inferior ASIS, pubic symphysis, and 2 mm or 4 mm superior and inferior pubic symphysis were identified to provide an accurate reference of the APP plane. After these processes, the three-dimensional data set of the entire pelvis was input to the Signature planning software. The Signature planning software utilizes MRI images to provide a consistent three-dimensional data set and visualization of the patient's anatomy to enhance efficiency. The intuitive layout of the software provides a number of preoperative visualization options for implant size and position; the preoperative planning using CT-based templating software was then reproduced with this MRI planning software (Fig. 2). The planned implant inclination and anteversion angles were defined anatomically as described by Murray [19]. After the surgeon's approval of the preoperative plan, a patient-specific surgical guide was designed to give the planned implant angle or orientation.

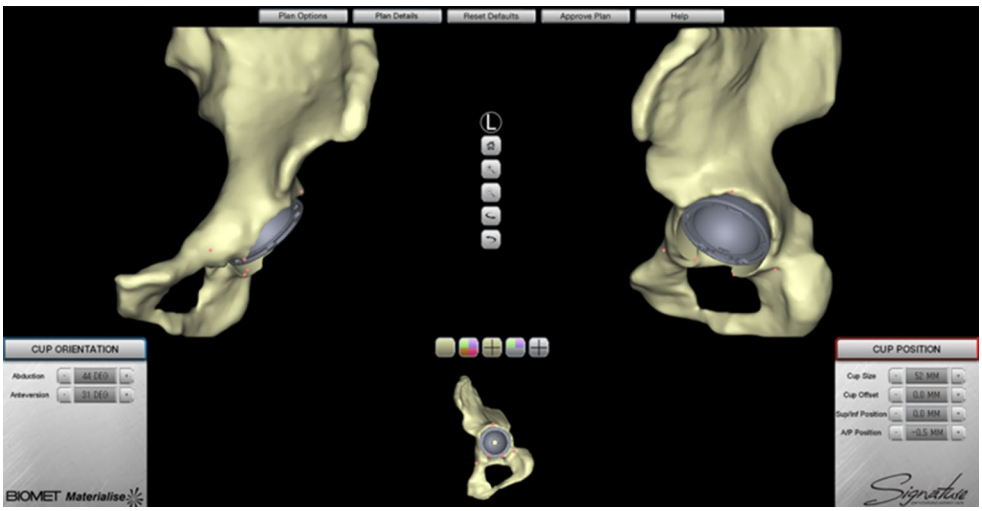

Fig. 2 Preoperative planning for the acetabular component in MRI planning software. The planned implant inclination and anteversion angle were described in accordance with the CT-based surgical preoperative planning

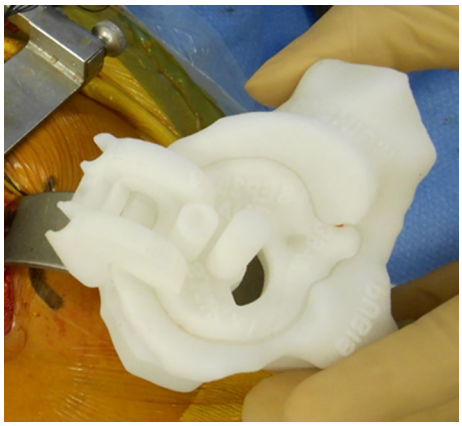

Fig. 3 Digital photograph of 3D acetabular bone model

Hip Signature positioning guides or acetabular 3D bone models were manufactured (Zimmer Biomet). We used the acetabular bone model to accompany positioning guides for preoperative surgeon evaluation and intraoperative verification (Fig. 3).

Surgical technique

All surgeries were performed using a posterolateral approach in a lateral decubitus position by a single surgeon (D.I.). After cutting the femoral head, the anterior joint capsule was released in order to enlarge the field on the acetabular side. Then, the synovia and acetabular labrum were resected. To place the patient-specific instrument (PSI), the superior part of the acetabulum was released in order to insert the guide pin, and finally the acetabulum fossa was exposed to hook the surgical guide to the acetabulum fossa. The surgical guide was placed on the acetabulum by hooking it to the acetabulum fossa, and fitting it into the acetabular joint surface and superior part of the acetabulum (Fig. 4a). Two surgical guide pins were inserted into the superior part of the acetabulum to finish the surgical guide placement (Fig. 4b). The surgical guide was removed after insertion of the guide pins. Next, the surgeon reamed the acetabulum to the lateral wall of the teardrop according to the alignment of the surgical guide pins and reproduced the preoperative acetabular implant position. The acetabular implant was press-fit to the acetabulum according to the guide pins (Fig. 4c). After acetabular implant fixation, we performed a gentle rasping technique to help prevent femoral diaphyseal fractures, and the femoral implant was inserted in the femur. The joint capsule was repaired to its original site after final implantation. The postoperative rehabilitation schedule was free weight bearing after the operation.

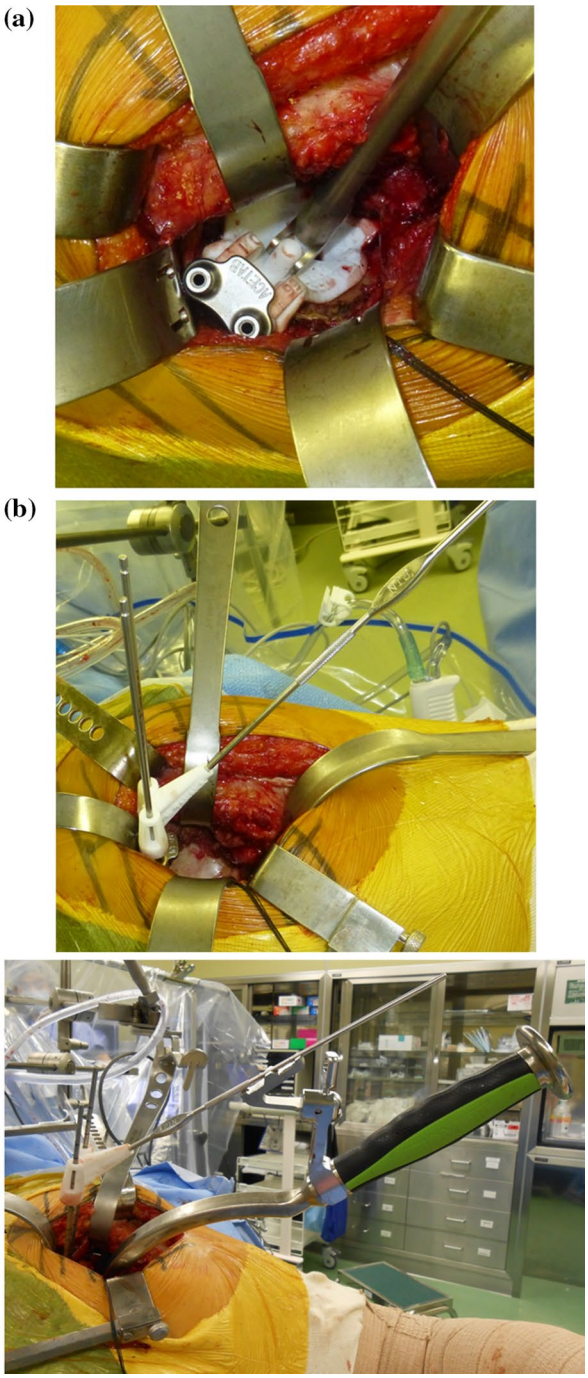

Fig. 4 Steps for clinical use of the MRI-based surgical guide. **a** The surgical guide is placed on the acetabulum by hooking it to the acetabulum fossa and fitting it into acetabular joint surface and superior part of acetabulum. **b** Two surgical guide pins were inserted to the superior part of the acetabulum. **c** The acetabular implant was press-fit to the acetabulum according to the surgical guide pins

Postoperative evaluation

For postoperative evaluation, a CT scan was taken about 2 weeks after the operation using the preoperative protocol. The

postoperative pelvic coordinate system was adjusted to match the preoperative pelvic coordinate system. Using postoperative CT data, we measured the acetabular implant insertion angle (cup anteversion and inclination) by manually superimposing computer-aided design (CAD) models on the postoperative multiplanar reconstruction CT images with ZedHip, as described in previous reports [9]. We determined the absolute error in the acetabular component angle between preoperative planning and postoperative state. We divided the patients into two groups in order to compare the absolute error between the two. The first 7 hips comprised the initial group; the later group contained the last 7 hips.

Statistical analysis

We used SPSS software (PASW Statistics Base version 19; SPSS, Chicago, Illinois) for the statistical analysis. The absolute error of acetabular component angle was expressed as mean ± standard deviation. An unpaired t test was used to assess the difference between the initial and the later groups. A p value < 0.05 was considered statistically significant.

Results

Complications

No patients were lost during the follow-up period. In this study, there were no postoperative surgical site infections, intraoperative nerve or vessel injuries, or intraoperative acetabular or femoral fractures. We also did not experience early dislocation of the postoperative implant in any of the cases.

The absolute error of acetabular implant angle

In our study, the absolute errors of acetabular implant angle using the patient-specific instrument guide were 3.7° ± 2.2° inclination and 4.5° ± 3.9° anteversion. In the inclination angle, all cases had planned target angles within ± 10°. However, in the anteversion angle, 3 of 14 cases had out of target angles within ± 10° (Fig. 5). The absolute error of the initial group was 4.7° ± 2.1° inclination and 6.1° ± 4.0° anteversion; for the later group, it was 2.8° ± 1.8° inclination and 3.2° ± 2.9° anteversion (Table 2). There was a significant difference in the absolute error of acetabular implant placement between the initial group and the later group.

Discussion

Achieving a safe target angle for the acetabular implant is a very important factor in the prevention of postoperative complications such as excessive polyethylene wear, edge loading, implant impingement, and postoperative dislocation [2–4]. Callanan et al. showed that the manual freehand technique is inaccurate, with fifty percent of acetabular cup placements falling outside a modification of the Lewinnek safe zone for both abduction (30°–45°) and anteversion (5°–25°) in the radiographic manner [7]. Krismer et al. found that the target angle was achieved within 10° in 61% of cases and within 5° in 21% with the freehand technique, aiming for a target inclination of 40° and anteversion of 20° in the radiographic manner [20]. Implant malpositioning with the freehand technique is thought to result from the fact that the index of preoperative planning or inserting implant depends only on bony landmarks, while the actual implant angle also was affected by intraoperative pelvic motion [8]. In addition, several reports have demonstrated that inserting the acetabular implant in the desired position and angle is imprecise regardless of the surgeon's skill or experience [21, 22]. Therefore, more detailed preoperative planning and a surgical guide that is not dependant on intraoperative pelvic

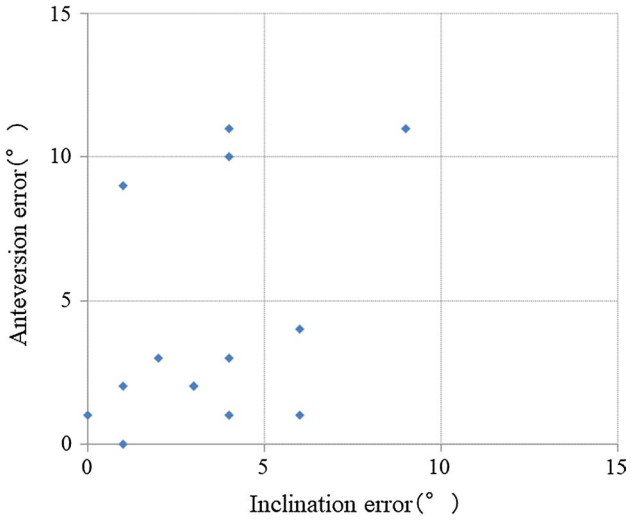

Fig. 5 Scatter plot showing the absolute error of acetabular implant inclination and anteversion angle

Table 2 The planned and actual implant angle

	Pre-op	Post-op	Absolute error
(a) The initial group ($n = 7$)			
Inclination	42.0 ± 1.1°	44.4 ± 4.7°	4.7 ± 2.1°
Anteversion	25.2 ± 2.9°	27.4 ± 6.0°	6.1 ± 4.0°
(b) The later group ($n = 7$)			
Inclination	43.1 ± 1.0°	45.6 ± 2.6°	2.8 ± 1.8°
Anteversion	28.3 ± 2.2°	27.4 ± 4.5°	3.2 ± 2.9°

Implant angle or absolute error is expressed in mean ± standard deviation. Inclination and anteversion angle are expressed in the anatomical manner

motion may help prevent implant malpositioning if a surgical navigation system cannot be used during THA. The advantages of a patient-specific instrumentation guide are as follows: (1) it can be used by institutions that do not have a surgical navigation system. (2) Surgical procedure is relatively simple and straightforward. (3) Intraoperative indexes are increased. (4) It reduces the effect of intraoperative pelvic motion. Considering these advantages, we investigated the accuracy of an MRI-based, patient-specific acetabular instrument guide during THA in a prospective clinical trial.

The usefulness of CT-based surgical navigation systems for reducing acetabular implant angle errors has already been documented. Kajino et al. reported that the mean deviations between preoperative planning and postoperative measurement were 1.5° ± 1.2° inclination and 2.9° ± 2.8° anteversion for severe pelvic deformities, and 2.0° ± 1.7° inclination and 3.2° ± 1.8° anteversion for mild dysplastic patients. Their report showed that the accuracy of a CT-based surgical navigation system does not depend on the degree of pelvic deformity, and the system is also useful for identifying acetabular orientation and for precise component implantation [10]. Inaba et al. reported the absolute errors of acetabular implant angle were 3.5° ± 2.6° inclination and 4.0° ± 3.5° anteversion for primary THA [11]. Other reports also have shown improvements of acetabular implant angle due to the use of surgical navigation systems [12, 23]. In our study, the absolute error of acetabular implant angle using the patient-specific instrument was 3.9° ± 2.2° inclination and 4.5° ± 3.9° anteversion for primary THA. In other words, compared with past reports of results achieved with a surgical navigation system, the accuracy of inclination angle when using the PSI was almost the same, but the accuracy of anteversion angle was inferior. Hananouchi et al. reported that the absolute error of acetabular implant angle using a patient-specific guide was 3.2° ± 2.3° inclination and 3.7° ± 2.7° anteversion [14]. Spencer et al. also showed that the absolute error of acetabular implant angle using a patient-specific guide was 3.5° ± 2.6° inclination and 4.0° ± 3.5° anteversion [24]. Compared to these reports, the absolute error with an MRI-based PSI was not inferior to the results achieved with a CT-based PSI in primary THA.

The disadvantages of using this PSI were as follows. In our study, the absolute error was 3.7 ± 2.2° for the inclination angle and 4.5 ± 3.9° for the anteversion angle. Furthermore, 3 of the 14 cases had out of target anteversion angles within ± 10°. In our opinion, the accuracy may depend on how this PSI was put on the obturator foramen. If the PSI compatibility for the obturator foramen was not so good, it could possibly have produced the error in anteversion angle. Accuracy also depended on the learning curve for putting the PSI on the acetabulum. In our study, the absolute error in the later group was lower than in the initial group, indicating that acetabular implant placement accuracy improved with practice. Finally, using a PSI for the placement of the acetabular implant typically requires more total operating time than the manual free hand technique. Past reports show that the mean additional time for using the PSI was 3–5 min, but the slight increase in time can be justified by the increased accuracy. On the other hand, the use of surgical navigation, while more accurate than using PSI, increased the time by 15–46 min [14, 24].

There were two limitations to this study. First, the number of patients was small. There were two reasons why the number of enrolled patients was small. First, the study design was prospective. Second, this surgical guide used in this study is a new device that has not reported the clinical result in the past. For two reasons, some of the patients did not approve using this new surgical guide in the operation. It will be necessary to investigate the accuracy of this patient-specific instrument guide using a larger sample size based on this study result. Second, this study lacked a control group for which the manual freehand technique was utilized, for a direct comparison of the two techniques, despite the fact that past reports have shown that using this PSI during THA is more accurate than using the free hand technique. Despite these limitations, we believe this study shows that MRI-based patient-specific instrumentation may be a useful tool during THA once the slight learning curve has been overcome.

Conclusion

Once we achieved the slight learning curve, the accuracy of using this PSI during THA was almost comparable to surgical navigation techniques. We conclude, therefore, that an MRI-based patient-specific instrumentation guide may be a useful tool during THA.

Compliance with ethical standards

Conflict of interest The author(s) declare that they have no competing interests.

Ethical approval All procedures performed in studies were in accordance with the ethical standards of our institutional ethical committee. In accordance with the requirements of this study, all patients were provided informed consent.

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