CLINICAL ARTICLE

Usefulness of a Simple Preoperative Planning Technique using Plain X-rays for Direct Anterior Approach for Total Hip Arthroplasty

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Objective: To examine the accuracy, reliability, and reproducibility of a simple preoperative planning technique using plain X-rays.

Methods: A retrospective analysis of 96 consecutive cases of primary direct anterior approach (DAA)-total hip arthroplasty (THA) from July 2015 to December 2018 was performed. The 96 patients included 24 males and 72 females, with an average age of 70 years. The standard AP pelvis radiographs with the patients' hips extended and internally rotated were obtained pre- and postoperatively. The preoperative planning was also completed on the standardized AP pelvic radiographs. The prearranged cup positioning was radiologically measured intraoperatively using fluoroscopy. The correct leg length was assessed intraoperatively, which was compared with the preoperative planning. The component positioning was measured by three independent researchers. Two of the researchers completed the measurements three times, and intra-observer and inter-observer reliability were calculated. All patients received at least 6 months follow-up (6 months–4 years).

Results: In all cases, the median leg length discrepancy (LLD) was 4.4 mm (range 1.6–15.9 mm), and 84 patients had an LLD smaller than 10 mm, of which 58 patients had an LLD of less than 5 mm. None of the patients had a critical LLD of 2 cm or larger. The multivariable logistic regression for LLD (safe range: yes/no) with the co-variables including gender, ASA classification, type of cup, the surgeon's experience level, and the presence of a total hip arthroplasty (THA) on the contralateral side did not present statistical significance. The median angle of the inclination of the acetabular component (IA) was 42.3° (range: 28.7°–52.2°). Ninety-one patients were within the defined safe range. The hit ratio for the cup to be within the safe zone was significantly higher for the Pinnacle cups than that for the Continuum cups ($P < 0.05$). However, there was no significant difference in gender, ASA classification, the surgeon's experience level, and the presence of a total hip arthroplasty (THA) on the contralateral side. The median of its anteversion (AA) was 20.6° (range: 10.6°–40.1°). Only 41 patients were within the defined safe range. None of the co-variables presented a statistical significance affecting the AA of the cup positioning. Meanwhile, the average fluoroscopy time for the cup positioning ($n = 86$, missing data in 10 cases) was 4 seconds (range: 1–74), with most of the patients (97.9%) having a fluoroscopy time of fewer than 20 seconds.

Conclusions: The combination of correct preoperative planning and standardized intraoperative measurements can reestablish right leg length and assure the correct cup positioning.

Key words: Acetate templating; Fluoroscopy; Leg length discrepancy; Retrospective analysis; Total hip arthroplasty

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Introduction

Total hip arthroplasty (THA) is renowned for being one of the most efficient surgical procedures worldwide[1]. Successful THA not only reduces pain, it also fully restores the function of the affected limb. The survival rate of the implants has been documented to be approximately 93% at 20 years[1–3]. Preoperative templating greatly facilitates the accomplishment of surgical goals of restoration of hip biomechanics in terms of the center of rotation, the offset, and the limb length. It also allows the surgeon to choose appropriate implants and anticipate the need for special devices, allografts, or a different surgical approach. Sizing of prosthesis may also reduce the inventory and surgical time and thus the cost. Detailed preoperative planning is an essential part of THA to restore hip anatomy and biomechanics by optimal implant positioning. So, it largely contributes to the endurance of the implants[4–6]. The preoperative plan includes the calculation of many parameters, including restoration of the center of rotation, the leg length, and the femoral offset. It is also vital to avoid the malalignment of components to minimize complications such as leg length discrepancy (LLD), instability, excessive wear, and periprosthetic fractures[6–8].

Since conventional planning on analog radiographs with the use of acetate templates are often available from manufacturers, it was once considered to be the gold standard. The cost of hard copy reprinting and acetate template materials used in this method is low, so it can also be considered a cost-effective planning method. Recently, digital templating has become more widespread in clinical surgery, which requires extensive IT services to install, maintain, and update the corresponding workstations and software compared with acetate templates[9]. Both techniques have their advantages and disadvantages[10–12], and similar accuracy, effectiveness, and reliability results have been reported[13–15]. Research conducted by Wako *et al.*[16] proved that three-dimensional preoperative planning software presented excellent reliability for component size and alignment in THA. Imai *et al.*[17] also considered that estimating the opposition of the metallic fit step using interoperable three-dimensional (3D) computerized planning can provide accurate interoperability planning for cementless THA. Thirion *et al.*[18] also emphasized the significance of proactive planning for THA patients in their study. Preoperative planning is one of the most crucial steps to the success of THR. It may be prudent to conference all cases with the surgical team before the surgery. Templating also helps in anticipating intraoperative difficulties and formulating an alternate plan. Thus, proactive planning may have substantial value for the operation of THA patients, post-operative recovery, and reduction of medical costs. In developing countries like China, due to economic reasons, many rural hospitals lack digital templating equipment, so conventional planning on analog radiographs with the use of acetate templates is even more important.

Apart from accurate preoperative planning, intraoperative benchmarks and measures are required to properly execute the preoperative plan, i.e. to place the implant components accurately. Regarding the cups, inclination, and anteversion, as well as the restoration of the center of rotation, the stems' insertion depth and stem alignment are fundamental factors. Bony landmarks on the femoral and acetabular side, soft tissue tension under trial reduction, as well as the assistance of intraoperative fluoroscopy are all valid options to control for correct implant positioning intraoperatively.

Surgical approaches are anatomic dissections of tissue planes that use anatomic knowledge to limit the amount of dissection required to perform the procedure while avoiding nerve and vessel damage. A variety of surgical approaches including direct anterior, anterolateral, direct lateral, transtrochanteric and posterior, have been utilized for performance of THA. Each approach has advantages and disadvantages. Depending on the surgical approach and procedure, exposure may be limited, and the assessment of clinical parameters can be challenging. Therefore, THA patients require digital imaging technology for preoperative planning. In THA, a direct anterior approach (DAA) enables the hip muscles to be accessed through inter-nerve and inter-muscle pathways, which has increased its popularity. Compared with other approaches, DAA has advantages of faster recovery, less pain, and a lower postoperative dislocation rate. For DAA, the C-arm can then be easily used to check for stem and cup sizing, positioning, restoration of leg length and offset during the surgery. Since the patient is supine, the medial malleoli can be palpated, and leg-length corroborated with the fluoroscopy. So, we can verify the accuracy of the preoperative conventional planning again during the operation and correct possible errors.

The aims of this study were as follows: (i) present a cost-effective and straightforward preoperative planning technique; (ii) confirm a reproducible and reliable method to intraoperatively measure implant orientation; and (iii) formulate a correct preoperative program. This combination helps to prevent relevant leg length discrepancy and the associated complications in total hip arthroplasty, particularly when performed *via* the direct anterior approach, which is renowned to offer limited exposure in comparison to other approaches.

Methods

Enrolment of the Patients

This retrospective study obtained the approval of the ethics committee of our institution. **Inclusion criteria were as follows:** (i) consecutive patients who underwent primary THA for the diagnosis of primary or secondary end-stage osteoarthritis between January 2016 and December 2018 in our center; (ii) patients underwent surgery with DAA; (iii) leg length discrepancy (LLD), inclination angle (IA), anteversion angle (AA) can be measured by medical imaging; (iv) clinical data are available and sufficient for retrospective studies; (v) with at least 6 months follow-up outcome. Exclusion criteria were as follows: (i) cases with significant simultaneous bilateral disease; (ii) congenital dysplasia; (iii) previous surgery on the affected side; and (iv) without complete postoperative radiographs. However, patients with an inlaying THA on the contralateral side were included in this study. Among 116 patients, 96 cases were included in this study.

Preoperative Planning

Standard AP pelvis radiographs with the patients' hips extended and internally rotated were obtained pre- and post-operatively in all cases. To guarantee an identical foot position for adequate measurement, a particular foot positioning device was used in all cases. All radiographs were stored on a Picture Archiving and Communication System (PACS; GE Medical Systems, centricity enterprise Web V3.0). The photographs were printed with a 110% scale following a standard protocol to confirm the correct amplification.

The templating was completed using the templates offered by the manufacturer.

First, an inter teardrop line (ITL), running through the inferior end of the two teardrop figures were drawn, demonstrating the horizontal reference to overcoming the possible oblique positioning of the pelvis. Secondly, the center of the rotation was marked on the contralateral hip, and a parallel line to the ITL was drawn to outline the ideal height of the center of rotation (COR) (Fig. 1). Thirdly, the contour of the affected hemipelvis was traced (Figs 1 and 2).

The size of the cup was defined from the patients' anatomy and positioned with an inclination of 40°–45°, centered on the COR line, and placed medially adjacent to the ilioischial line (Fig. 2).

Correspondingly, the size of the stem was selected according to the patients' anatomy and positioned with the center of the taper on the COR line. To reestablish the correct offset, the manufacturer's standard or the lateral offset template was selected (Fig. 2).

Finally, to determine the level of resection on the femoral neck, as well as the insertion depth of the stem component, the contour of the greater and the lesser trochanter of the contralateral side were outlined and mirrored to the affected side.

During the final step, the distance from the cranial margin of the lesser trochanter (LT) to the conus of the stem and the prearranged neck cut were measured, respectively, in mm and documented (Fig. 2).

Surgical Procedure

Anesthesia and position: The patient is positioned supine with the pelvis squared on a standard table such that a transverse line drawn through the anterior superior iliac spine is

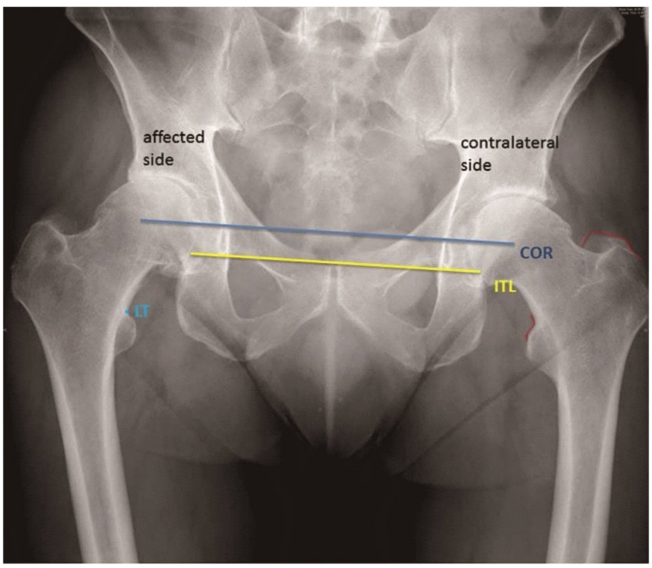

Fig. 1 Preoperative planning. The templating was completed using the templates offered by the manufacturer. First, an inter teardrop line (ITL),running through the inferior end of the two teardrop figures was drawn, demonstrating the horizontal reference to overcoming the possible oblique positioning of the pelvis. Secondly, the center of the rotation was marked on the contralateral hip, and a parallel line to the ITL was drawn to outline the ideal height of the center of rotation (COR). Thirdly, the contour of the affected hemipelvis was traced.

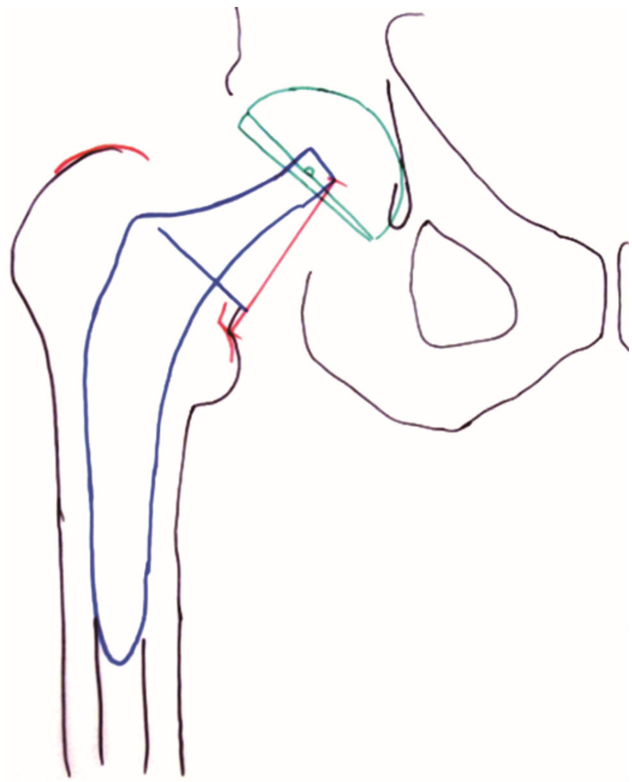

Fig. 2 Preoperative templating. Green line: size of Acetabulum. Blue line: size of femoral stem. Red line: the distance from the cranial margin of the lesser trochanter (LT) to the conus of the stem. The size of the cup was defined resultant from the patients' anatomy and positioned with an inclination of 40°–45°, centered on the COR line, and placed medially adjacent to the ilioischial line.

perpendicular to the long axis of the table. The operating table should be capable of attaining a Trendelenburg's position and lowering its foot-end at the level of the break. We have been performing this surgery using DAA without the use of the special table. The same surgical technique, as described by Unger *et al.*[19], was used for all the patients.

All patients underwent general anesthesia with intubation. During the operation, the anesthesiologist cooperated with giving adequate muscle relaxation drugs to reduce muscle damage risk, especially the flexor fascia lata.

Approach and exposure: Instead of entering the interval between the fascia of the tensor and sartorius muscles, the DAA involves a more lateral entry to avoid damage to the lateral femoral cutaneous nerve. After a standardized T-shaped anterior capsulotomy was completed, the direct access to the femoral neck was acquired so that the osteotomy of the femoral neck could be done safely. This was not necessarily completed at the level of the planned neck cut, but more cranially. After the extraction of the femoral head, the acetabulum was prepared for reaming and trialing for the planned cup. The decisive cup positioning, with particular prominence on the insertion depth, cranialization/caudalization, and anteversion/retroversion, was radiographically controlled and confirmed using a C-arm. Finally, the fluoroscopy time for the cup positioning was documented.

Resection: During the femoral shaft bone preparation, the neck cut was at the correct level was checked according to the preoperative planning. If required, a second neck cut was performed during this stage.

Placement of prosthesis: The shaft was reamed and the trial component was inserted again according to the preoperative planning. The precise stem positioning was determined by measuring the distance between the LT and the conus of the stem and adjusted according to the planned distance. To acquire the scheduled distance, either an up- or down-sizing of the stem component or a variation of the femoral head component (−3.5 mm, 0, +3.5 mm) was accepted.

Reconstruction: The soft tissue tension after the joint reduction with the trial implants was also measured to double check for the correct implant positioning. Based on the agreement of the operating surgeon, the decisive implant components were inserted.

Every operation was performed by an expert surgeon or a trainee under the supervision of an experienced surgeon. An experienced surgeon was outlined as one that had completed at least 100 total hip arthroplasties per year. The implants used were mainly (n = 92) Pinnacle cups with cement-less Corail (DePuy) and (n = 4) R3 cups with stems (Smith & Nephew). Early postoperative full weight-bearing as tolerated was encouraged in all the patients.

Radiological Measurement

The measurements were made by three independent researchers using a standardized digitalized technique. Two of the investigators completed the measurements three times and intra-observer and inter-observer variations were calculated for reliability. The parameters are as follows.

Leg Length Discrepancy (LLD)

Like the preoperative planning, the ITL was drawn on every postoperative AP pelvis radiograph. A parallel line passing through the lesser trochanter of the contralateral side was used as a femoral landmark (LTL). The leg length difference was then depicted as the vertical distance between the LTL and the ipsilateral lesser trochanter (Fig. 3). A leg length discrepancy (LLD) of less than 10 mm was thought to be within the safe range to attain good reconstruction of the leg length without causing any gait disturbance for the patient.

Inclination Angle (IA)

The angle of inclination of the acetabular component (IA) was measured between the long axis of the ellipsoid projection of the acetabular component and the ITL (Fig. 4) in the AP radiograph.

Anteversion Angle (AA)

The angle of its anteversion (AA) was measured on the lateral radiograph according to the angle formed by the long axis of the ellipsoid projection of the acetabular component and a vertical line. This technique was previously described by Woo *et al.*[20] (Fig. 5). The values between 30° and 50° of inclination and 5° and 25° of anteversion were considered as the "safe zone," according to Lewinnek's definition[21].

Implant malposition, especially the wrong IA and AA, is a significant contributor to instability, dislocation, impingement, accelerated wear, and failure of the THR.

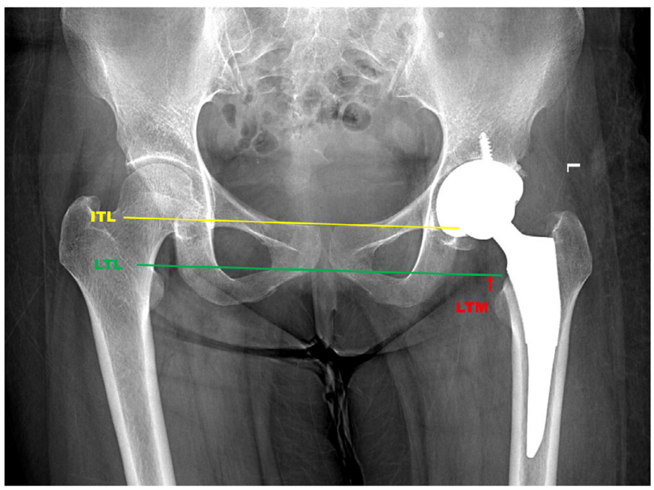

Fig. 3 Postoperative measurement of LLD. A parallel line passing through the lesser trochanter of the contralateral side was used as a femoral landmark (LTL). The leg length difference was then depicted as the vertical distance between the LTL and the ipsilateral lesser trochanter.

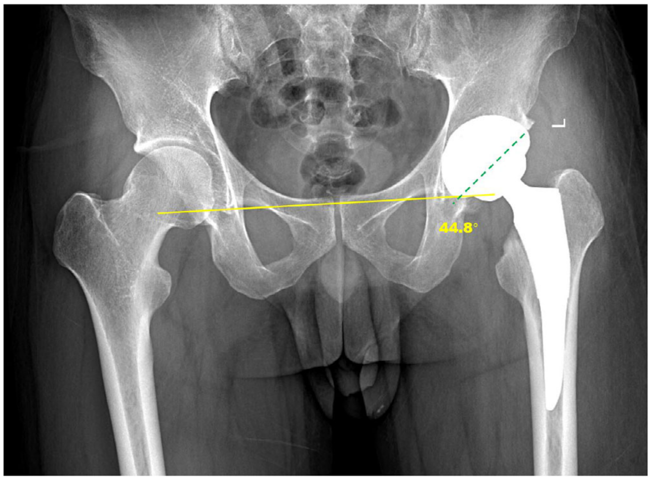

Fig. 4 The IA was measured between the long axis of the ellipsoid projection of the acetabular component and the ITL. The angle of inclination of the acetabular component (IA) was measured between the long axis of the ellipsoid projection of the acetabular component and the ITL in the AP radiograph.

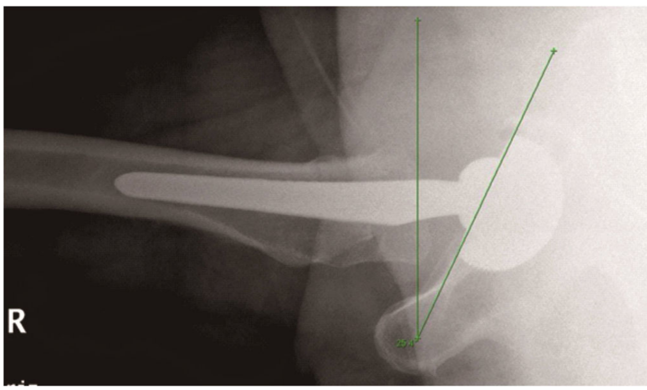

Fig. 5 An axial radiograph of the pelvis showing the measurement of the anteversion (AA). It is the angle formed by the long axis of the ellipsoid projection of the acetabular component and a vertical line. The angle of its AA was measured on the lateral radiograph according to the angle formed by the long axis of the ellipsoid projection of the acetabular component and a vertical line.

Statistical Analysis

Statistical analysis was performed using R (The R Foundation for Statistical Computing) statistical software (version 2.13.1 with the package "irr"). The proportion of patients within the safe ranges of leg length discrepancy (LLD) (less than 1 cm) was supplemented by an exact two-tailed 95% confidence interval by Agresti[22]. A binary logistic regression model was used to examine the association between LLD (safe range: yes/no) and the predictor variables. Intraclass correlation (*ICC*) was measured and estimated using the grouping recommended by Landis and Koch[23]. Scores between 0.61 and 0.8 indicated substantial agreements, and those greater than 0.81 indicated near-perfect agreements. As a measure of consistency, Kendall's coefficient of concordance "W" also was calculated[24]. A *P* value less than 0.05 was considered statistically significant.

Results

General Data of Patients

The 96 patients included 72 females (75%) with an average age of 70 years. The median leg length discrepancy (LLD) was 4.4 mm (range: 1.6–15.9 mm). The median cup inclination angle (IA) was 42.3° (range: 28.7°–52.2°), and median cup anteversion angle (AA) was 25.6° (range: 10.6°–40.1°) (Table 1).

Measurement of LLD

Eighty-four patients (88.5%) had an LLD smaller than 10 mm (95% *CI*: 80.9%–94.0%), of which 58 patients had an LLD of less than 5 mm. None of the patients had a critical LLD of 2 cm or larger. The multivariable logistic regression for LLD (safe range: yes/no) with the co-variables including gender, ASA classification, type of cup, surgeon's experience level, and the presence of total hip arthroplasty (THA) on the contralateral side did not present statistical significance (Table 2).

Measurement of IA

The median IA was 42.3° (range: 28.7°–52.2°) (Table 1). Ninety patients (94.3%) were within the defined safe range (95% *CI*: 88%–97.9%). There was a high agreement for the intra-observer measurement (*ICC*: 0.958–0.919). "W" was 0.951 and 0.949 for the two observers. There was a low agreement for the inter-observer measurement (*ICC*: 0.42). A substantial consistency was found (W = 0.625). The hit ratio for the cup to be within the safe zone was significantly higher for the Pinnacle cups than for the other cups ($P = 0.028$). Other variables such as gender, ASA classification, the surgeon's experience level, and the presence of a THA on the contralateral side did not show statistical significance (Table 3). There was a high agreement for the intra-observer measurement (*ICC*: 0.965–0.933; "W" was 0.971 and 0.943 for the 2 observers) and for the inter-observer measurement (*ICC*: 0.826), respectively. Also, high consistency was found (W = 0.864).

Measurement of AA

The median AA was 25.6° (range: 10.6°–40.1°) (Table 1). Only 46 of the patients (43.8%) were within the defined safe range (95% *CI*: 34.1%–53.8%). None of the co-variables showed a statistical significance affecting the AA of the cup positioning (Table 4). There was a high agreement for the intra-observer measurement (*ICC*: 0.992–0.988) and "W" was 0.988 and 0.987 for the two observers. There was also a very high agreement for the inter-observer measurement (*ICC*: 0.873). Furthermore, very high consistency was found

TABLE 1 Patient characteristics

Characteristics	*n* (%)	Median (range)
Age (years)	96	56 (42–78)
Gender		
Male	24 (25.0)	
Female	72 (75.0)	
ASA Classification		
I	9 (9.3)	
II	70 (72.9)	
III	17 (17.7)	
IV	0 (0.00)	
Leg length discrepancy (LLD) (mm)	96	4.4 (1.6–15.9)
Cup inclination angle (IA) (°)	96	42.3 (28.7–52.2)
Cup anteversion angle (AA) (°)	96	25.6 (1.6–40.1)
Intraoperative fluoroscopy time (seconds)	86 (89.6)	4 (1–74)

TABLE 2 Factors affecting LLD

Factors	*n* (%)	Odds ratio	*P* value*
Gender			
Male	24 (25.0)	1.27	0.580
Female	72 (75.0)		
ASA Classification			
I/II	79 (75.2)	0.65	0.214
III/IV	17 (17.7)		
Cup			
Pinnacle	86 (89.6)	1.21	0.922
Other	10 (10.4)		
Surgeon			
Experienced	81 (84.3)	1.03	0.230
Trainee	15 (15.7)		
Contralateral prosthesis			
Yes	9(9.3)	1.21	0.609
No	87 (90.7)		

* Wald test.

TABLE 3 Factors affecting IA

Factors	*n* (%)	Odds ratio	*P* value*
Gender			
Male	24 (25.0)	0.45	0.425
Female	72 (75.0)		
ASA Classification			
I/II	79 (75.2)	0.08	0.180
III/IV	17 (17.7)		
Cup			
Pinnacle	86 (89.6)	0.11	0.028
Other	10 (10.4)		
Surgeon			
Experienced	81 (84.3)	1.33	0.782
Trainee	15 (15.7)		
Contralateral prosthesis			
Yes	9(9.3)	2.74	0.461
No	87 (90.7)		

* Wald test.

TABLE 4 Factors affecting AA

Factors	*n* (%)	Odds ratio	*P* value*
Gender			
Male	24 (25.0)	1.40	0.420
Female	72 (75.0)		
ASA Classification			
I/II	79 (75.2)	0.66	0.425
III/IV	17 (17.7)		
Cup			
Pinnacle	86 (89.6)	1.23	0.702
Other	10 (10.4)		
Surgeon			
Experienced	81 (84.3)	0.69	0.402
Trainee	15 (15.7)		
Contralateral prosthesis			
Yes	9(9.3)	0.27	0.065
No	87 (90.7)		

* Wald test.

(W = 0.917). The average fluoroscopy time for the cup positioning (n = 96, missing data in nine cases) was 4 seconds (range: 1–74) (Table 1) with most of the patients (97.9%) having a fluoroscopy time of fewer than 20 seconds.

Discussion

The study showed a simple, safe, fast, and reproducible system to optimize implant positioning and to prevent leg length discrepancy in the DAA for THA. The preoperative standard templating combined with intraoperative single shot fluoroscopy and simple measurements of two distances also provided exceptional results.

Given the importance of preoperative planning, we are convinced that its main purposes are the calculation of parameters like the restoration of the center of rotation, the leg length, and the femoral offset, rather than the determination of the exact sizes of the definitive components. Many studies have focused on this aspect and have reported good planning methods if the rate of up- or down-sizing the components intraoperatively was low[10,14,15,25,26]. We did not examine the ratio of the correct size of the implants according to these terms. Rather, we highlighted the importance of the right implant positioning instead of sticking to the planned component sizes. For an acetabular cup, it must be placed adjacent to the ischial line at the level of the original center of rotation with a precise ("safe") anteversion and inclination.

We also used a C-arm during the cup implantation that caused certain exposure to radiation for the patient, which is undoubtedly a point that needs to be discussed. The fluoroscopy time in our study was as short as possible to avoid radiological hazards. The average time was 4 seconds, which we consider to be acceptable. Other reports using intraoperative X-ray for the acetabular positioning did not mention the fluoroscopy time at all[27,28]. Also, in our daily practice, we observe a shorter fluoroscopy time with an increase in the experience level of the surgeon. Although we could not measure a statistical significance, there appears to be a type of a learning curve in terms of handling the products and instrumentation devices depending on the caseload.

According to the "safe zones" defined by Lewinnek *et al.*[21], the majority of the cup positions expected in the present study fell within these ranges (median IA 42.2°, median AA 24.7°) with very good inter- and intra-observer reliability. The broader range for AA in our patient collective could either represent a valid higher AA due to the surgical technique and limited exposure of the acetabulum that misguides the surgeon to a higher anteversion position; alternatively, it could be related to an inferior radiological measuring technique (Fig. 5). The method of Woo and Morrey[20] perhaps does not consider the variability of pelvic tilting as patients lay in a supine position on the X-ray table. For a femoral component, a correct insertion depth besides the right rotation and alignment with the neck and shaft is key for restoring leg length. The femoral offset is typically restored by using standard or lateral offset components provided by the manufacturers. In this study, we only focused on reporting the insertion depth and an intraoperative measuring method to control for the corresponding restoration of the leg length. The distance between the lesser trochanter and the conus of the stem in combination with the distance of the lesser trochanter to the level of the neck that is cut are reproducible, reliable, and simple methods.

According to the current literature, a leg length discrepancy (LLD) within 10 mm of the contralateral limb would be acceptable since it does not appear to affect the functional parameters of gait while producing satisfactory outcomes in most patients[29–31]. A successful total hip arthroplasty (THA) should not only relieve the pain for the patient but always aim for the full restoration of functions[5]. In our study, the average LLD was 4.4 mm, with only 11.4% of patients presenting an LLD of 10 mm or greater. We consider this an excellent result.

Furthermore, no accidental shortening of the operated leg occurred in any of our patients. The low inter-observer reliability of the corresponding measuring method on the postoperative radiographs was likely due to some difficulties in identifying the proximal end of the lesser trochanter in a 2D image.

The preoperative planning method used in this study is based on hard-copy radiographs. Considering that the costs for the hard-copy reprint and acetate templating material are low, this technique can be regarded as a cost-effective planning method. As reported in the current literature, the advantage of this conventional method is that the image does not need to be calibrated because it is produced with a fixed magnification factor. In comparison, digital templating requires a high amount of IT service for installing, maintaining, and updating the corresponding workstations and software. For both techniques, similar results of accuracy, validity, and reliability are reported[4,5]. However, since digitalization is progressing, perhaps a hybrid planning technique as suggested by Petretta *et al.*[6] should be considered in the future.

There are some limitations in this research. Our study is limited since there was no clinical evaluation of the patients, and no long-term follow-ups were conducted. Also, it was a retrospective analysis. One crucial issue that occurs in all observational studies is selection bias. Due to the sample size of the study, the next subgroup analysis cannot be performed. However, despite these limitations, our findings are clinically important since they present well-founded inter- and intra-observer reliability.

Conclusion

Our results showed that our preoperative planning combined with intraoperative measurement techniques are safe, reproducible, and reliable for achieving optimal implant positioning intraoperatively and for minimizing LLD in THA through the minimally invasive DAA. This simple method can be applied to any femoral stem or acetabular cup system.

Ethics approval

This study and manuscript, including related data, figures, and tables, comply with the Good Clinical Practice (GCP) and Declaration of Helsinki principles. This study was approved by the Institutional Review Board of our hospital [No.S-K999].

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