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Original Article

A novel modified trochanteric entry portal and percutaneous technique for Asian patients: a prospective randomized study of the PFNA-II in China

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Abstract: The purpose of this study was to compare the clinical outcomes of a novel modified trochanteric entry portal and percutaneous technique with those of the conventional trochanteric entry portal and operative technique for the treatment of intertrochanteric fractures with the Proximal Femoral Nail Antirotation system (PFNA-II) in China. From May 2010 to December 2013, 117 elderly patients with intertrochanteric fractures treated with PFNA-II were randomized into 2 groups. Group A was treated with a modified trochanteric entry portal and percutaneous technique, and group B was treated with a standard trochanteric entry portal and operative technique. The 2 groups of patients were statistically analyzed and compared with respect to surgical trauma based on factors that included surgical time, fluoroscopy usage time, skin incision length, intraoperative blood loss, and postoperative outcomes including hospital stay duration, tip-apex distance (TAD), Harris hip score (HHS), and postoperative medical and surgical complications. The surgical times and skin incision lengths were significantly longer ($P<0.001$) in group B. The intraoperative blood loss was significantly lower in group A ($P<0.001$). However, the fluoroscopy time was significantly longer in group A ($P=0.012$). The TADs in group A (25.03±4.89) and group B (23.12±5.73) did not significantly differ ($P=0.054$). At postoperative months 1 and 3, the HHS was significantly higher in group A ($P=0.008$ and $P<0.001$, respectively). The novel modified trochanteric entry portal and percutaneous technique achieved excellent nail position, reduced surgical trauma, and enabled early hip function recovery.

Keywords: Intertrochanteric hip fracture, PFNA-II, trochanteric entry portal, percutaneous

Introduction

As the general population ages, intertrochanteric fractures have come to account for approximately 47% of all hip fractures, and this proportion is growing exponentially [1, 2]. Surgery aimed toward early rehabilitation is well accepted as the standard treatment for intertrochanteric fractures. The Association for Osteosynthesis/Association for the Study of Internal Fixation (AO/ASIF) developed the Proximal Femoral Nail Antirotation system (PFNA; Synthes, Oberdorf, Switzerland) in 2003 and the PFNA-II (the Asian version) in 2007. These systems allow for rapid and minimally invasive fracture reduction [3, 4]. Despite the biomechanical advantages of the PFNA-II and the good clinical results that have been reported [5], technical difficulties remain that are related to the insertion and ideal placement of the PFNA-II nail. These problems cause considerable bleeding, damage to the overlying soft tissues and surgical complications [6]. Moreover, although the PFNA-II has been improved to accommodate the anatomic characteristics of Asians, mismatches with the medullary canal have still been reported [5, 7, 8].

Improving PFNA-II insertion technique is key to successful stable fixation and the prevention of complications. Some investigators have suggested moving the greater trochanter starting

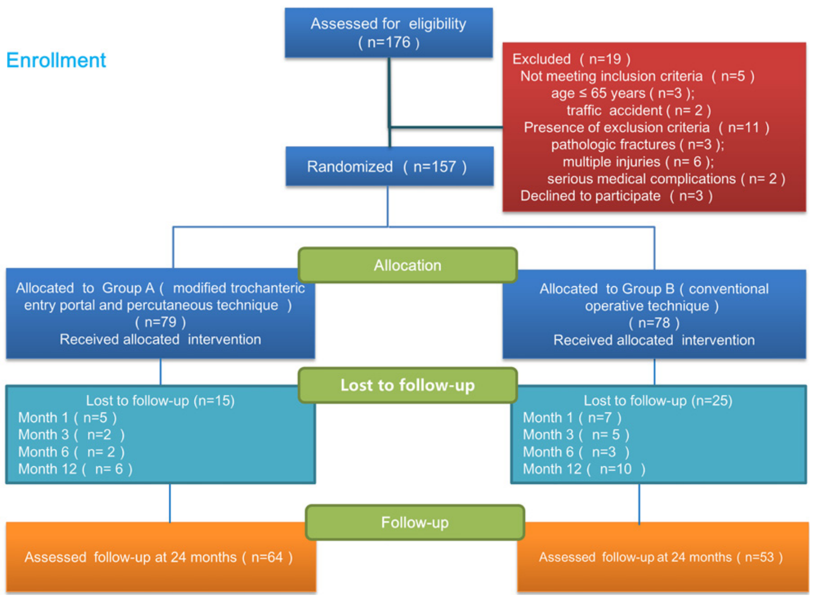

Figure 1. Flowchart of the prospective randomized study and case inclusion and exclusion.

Table 1. Baseline data

	Group A (n=64)	Group B (n=53)	*P*-value
Age (years)	77.30±9.52	77.66±8.91	0.833[a]
Gender			0.661[b]
Male	23 (35.9%)	17 (32.1%)	
Female	41 (64.1%)	36 (67.9%)	
SPMSQ			0.741[b]
Intact	31 (48.4%)	23 (43.4%)	
Mild	22 (34.4%)	18 (34.0%)	
Moderate	11 (17.2%)	12 (22.6%)	
ASA			0.869[b]
I	10 (15.6%)	11 (20.8%)	
II	19 (29.7%)	16 (30.2%)	
III	27 (42.2%)	21 (39.6%)	
IV	8 (12.5%)	5 (9.4%)	
Cause of fracture			0.519[c]
Low-energy injury	61 (95.3%)	48 (90.6%)	
High-energy injury	3 (4.7%)	5 (9.4%)	
Fracture side			0.834[b]
Right	17 (26.6%)	15 (28.3%)	
Left	47 (73.4%)	38 (71.7%)	
Fracture classification			0.485[b]
Stable	37 (57.8%)	34 (64.2%)	
Unstable	27 (42.2%)	19 (35.8%)	
Harris Hip Score	93.28±5.80	92.96±6.30	0.938[d]

SPMSQ, Short Portable Mental Status Questionnaire; ASA, American Society of Anesthesiologists. [a]Student's T-test; [b]Chi-square test; [c]Continuity correction; [d]Mann-Whitney test.

point medially to decrease the risk of malreduction [9, 10], whereas others have suggested that minimally invasive surgery techniques should be used to reduce soft tissue trauma [11, 12]. However, no randomized, prospective, controlled studies examining these suggestions exist to date. The purpose of this investigation was to compare the clinical outcomes of intertrochanteric fractures in Chinese patients treated with a PFNA-II inserted using a novel modified trochanteric entry portal and percutaneous technique to those treated with a conventional trochanteric entry portal and operative technique with closed reduction. The null hypothesis was that no differences would exist regarding the technical ease or clinical outcomes of the improved and standard operative techniques for the treatment of intertrochanteric fractures with PFNA-II nailing.

Materials and methods

From May 2010 to December 2013, 176 consecutive patients with intertrochanteric femoral fractures treated at the 1st Hospital of Shijiazhuang were randomized for treatment either with PFNA-II via the modified trochanteric entry portal and percutaneous technique (group A) or a conventional operative technique (group B). The study plan was approved by the ethics committees of the 1st Hospital of Shijiazhuang. The inclusion criteria were an age ≥65 years, a low-energy injury and a minimum follow-up of 1 year. The exclusion criteria were

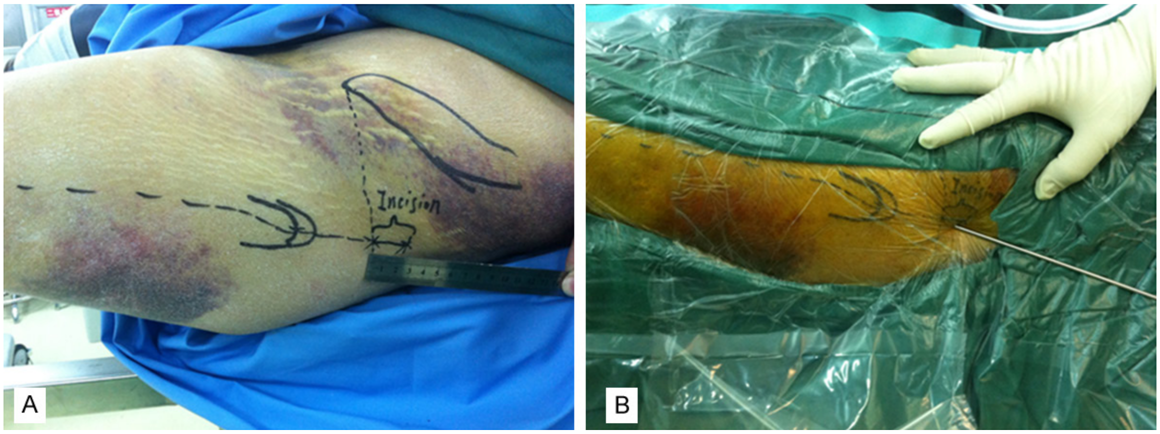

Figure 2. A. Preparation of the cutaneous entry portal. The guided pincutaneous entry portal was defined by the intersection of the femur curvature line with a vertical line 2-3 cm superior to the anterior superior iliac spine. B. Guided pin insertion. The guided pin was inserted along the femoral curvature line at an angle of 30 degrees relative to horizontal.

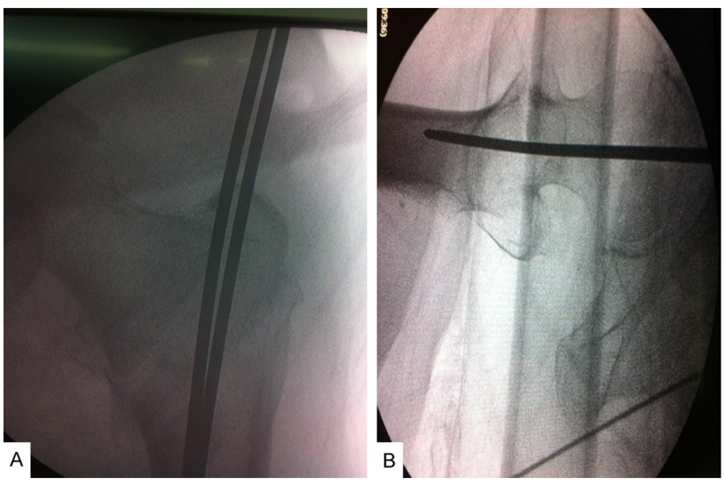

Figure 3. A. Anteroposterior radiograph. The guided pin insertion entry portal was located 0.5 mm medial to the tip of the greater trochanter on the medial edge of the greater trochanter. B. Lateral radiograph. The guided pin insertion entry portal was slightly posterior and in the center of the femoral neck.

pathologic fractures, open fractures, delayed fractures, multiple injuries, rheumatic diseases, immobility or walking difficulties prior to the fracture, serious medical complications, mental disorders and loss to follow-up. Ultimately, 117 patients (64 in group A and 53 in group B) participated in the study (**Figure 1**).

General data were collected, including the participating patients' ages, genders, American Society of Anesthesiologists (ASA) scores and Short Portable Mental Status Questionnaire (SPMSQ) scores. Hip function was recorded according to the Harris hip score (HHS). Using radiographs, the fractures were classified as stable or unstable according to the AO/ASIF classification by 2 surgeons (**Table 1**).

Surgical techniques

All patients in both groups underwent attempted closed anatomic fracture reduction and implantation of the PFNA-II nail, which were performed on a traction table under an image intensifier.

Group B (the conventional trochanteric entry portal and operative technique group) was treated using the standard protocols recommended by the PFNA-II manufacturer [3].

The novel modified trochanteric entry portal and percutaneous technique employed for group A are described below.

In group A, the guide pincutaneous entry portal was defined as the intersection of the femur curvature line and a vertical line 2-3 cm superior to the anterior superior iliac spine (**Figure 2A**). We currently use a novel trochanteric entry portal that is slightly posterior and on the medial edge of the greater trochanter rather than using the manufacturer's suggestion of an entry portal at the junction of the anterior one-third and posterior two-thirds of the tip of the

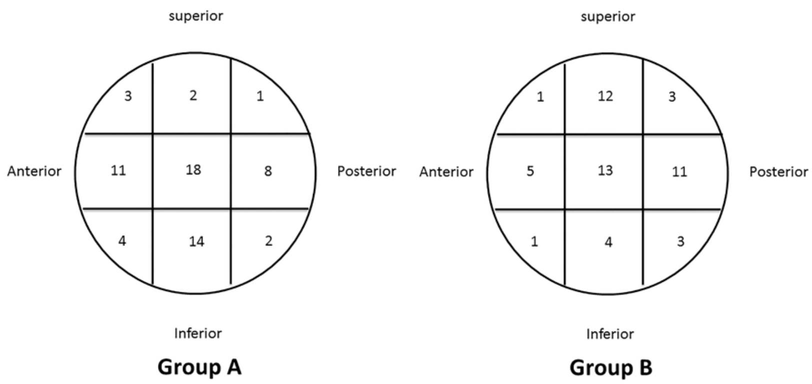

Figure 4. Helical blade position within the femoral head (groups A and B).

Table 2. Intraoperative outcomes

	Group A (n=64)	Group B (n=53)	*P*-value
Surgical time (minutes)	43.59±11.76	51.34±11.29	0.000[a]
Skin incision length (cm)	3.53±0.81	6.56±1.29	0.000[a]
Fluoroscopy time (seconds)	64.09±10.76	58.49±12.89	0.012[a]
Blood loss (ml)	105.30±28.66	140.13±33.41	0.000[a]

[a]Student's T-test.

greater trochanter. The guide pin insertion entry portal was located 0.5 cm medial to the tip of the greater trochanter on anteroposterior radiographs and 0.5 cm posterior to the tip of the greater trochanter on lateral radiographs (**Figure 3A**, **3B**). When the ideal insertion entry portal had been identified, the guide pin was inserted along the femoral curvature line at an angle of 30 degrees relative to horizontal (**Figure 2B**). Satisfactory positioning of the guide pin was verified on anteroposterior and lateral radiographs. Subsequently, a 3-cm skin incision was made in line with the guide pin to split the tensor fascia lata using a separator. After reaming of the proximal femur, an appropriate nail was inserted into the femur. Next, the PFNA-II blade and distal screw were inserted according to the manufacturer's recommendations.

Perioperative management

All patients received prophylactic second-generation cephalosporin antibiotics 30 minutes preoperatively, and the antibiotics were continued for 48 hours postoperatively. The patients in both groups were given spinal or general anesthesia. Subcutaneous low-molecular-weight heparin was administered as thromboembolic prophylaxis for a total of 10 days.

All patients underwent follow-up assessments at 1, 3, 6, 12 and 24 months after surgery.

Intraoperative outcomes

The following intraoperative data were recorded: surgical time, fluoroscopy usage time, skin incision length, and intraoperative blood loss. Surgical time was defined as the number of minutes from skin incision (group B) or guide pin insertion (group A) until skin closure.

Blood loss calculation

The following blood loss data were recorded: postoperative and intraoperative blood loss amounts, number of blood transfusions, and calculated total blood loss amount (visible blood loss plus hidden blood loss). Total blood loss was calculated based on the hemoglobin level and the estimated blood volume, which was estimated using Nadler's formula and Mercuriali's formula.

Postoperative outcomes

The 2 groups were compared in terms of the length of hospital stay after the surgery, reoperations, and postoperative medical and surgical complications. All patients underwent follow-up assessments at 1, 3, 6, 12 and 24 months after surgery. Anteroposterior and lateral X-rays, physical examinations, and clinical follow-up data were obtained at each follow-up assessment. Functional outcomes were evaluated using the HHS.

Radiographic review

The quality of the reduction and the tip-apex distance (TAD) were assessed according to the system of Baumgaertner et al. [13], which is based on postoperative anteroposterior and lateral radiographs. As described by Cleveland

Figure 5. Skin incision length. The mean incision length was significantly shorter in group A (3.53±0.81 cm) than in group B (6.56±1.29 cm; P=0.000).

et al. [14], all the postoperative radiographs were assessed to determine the position of the helical blade within the femoral head (**Figure 4**). The positioning of the nail in the femoral canal was evaluated, and a distance of zero to the lateral cortex on the anteroposterior view was defined as impingement. Fracture union was defined as the presence of visible bone trabeculae between the bone fragments on the anteroposterior and lateral radiographs and as the ability to bear full weight on the extremity.

Statistical analysis

Descriptive statistics generated using SPSS 20.0 (SPSS, Inc., Chicago, IL, USA) were utilized for data analysis. Kolmogorov-Smirnov tests were used to evaluate the Gaussian distributions of continuous variables. Comparisons of the 2 groups were performed using T-tests for continuous variables with Gaussian distributions and Mann-Whitney U tests for continuous variables that did not show Gaussian distributions. For categorical variables, Pearson chi-square tests were used to evaluate the significance of differences. All *P*-values were 2-sided, and *P*-values below 0.05 were considered significant.

Results

Baseline data

Between May 2010 and December 2013, 176 cases of osteoporotic intertrochanteric fractures were treated with PFNA-II at the 1st Hospital of Shijiazhuang. Nineteen cases were excluded, and 40 cases were lost to follow-up. The baseline data are presented in **Table 1**. Follow-up was completed by 64 of the initial 95 patients (67.3%) treated with the modified trochanteric entry portal and percutaneous technique (group A) and by 53 patients of the initial 81 patients (65.4%) treated with the conventional technique (group B). The mean follow-up time was 26.9 months. No significant differences between the 2 groups were observed regarding age (group A, 77.30±9.52 years; group B, 77.66±8.91 years; P=0.833), gender (group A, 41 females [64.1%]; group B, 36 females [67.9%]; P=0.661), SPMSQ score (P=0.741), American Society of Anesthesiologists score (P=0.869), cause of fracture (group A, 61 low-energy injuries [95.3%]; group B, 48 low-energy injuries [90.6%]; P=0.519), or fracture side (group A, 47 left [73.4%]; group B, 38 left [71.7%]; P=0.834). The fracture classifications of the 2 groups were homogeneous (P=0.458). The preinjury HHSs (group A, 93.28±5.80; group B, 92.96±6.30) were not normally distributed; thus, the between-group difference was examined using the Mann-Whitney U test (1682.000), which revealed no significant difference (P=0.938).

Intraoperative outcomes

The intraoperative outcomes are listed in **Table 2**. The surgical time of group B (51.34±11.29 minutes) was significantly longer than that of group A (43.59±11.76 minutes; P=0.000). The difference in surgical time was primarily due to the incision and suture times. The mean incision length was significantly shorter in group A (3.53±0.81 cm) than in group B (6.56±1.29 cm; P=0.000) (**Figure 5**). The fluoroscopy time was significantly longer in group A (64.09±10.76 seconds) than in group B (58.49±12.89 seconds; P=0.012). The intraoperative blood loss was significantly lower in group A (105.30±28.66 ml) than in group B (140.13±33.41 ml; P=0.000).

Blood loss

The blood loss values are listed in **Table 3**. There were no significant differences between the 2 groups in total blood loss, postoperative blood loss, hidden blood loss or mean blood transfusion volume. However, the volume of visible blood loss was significantly lower in group A (181.70±31.66 ml) than in group B (214.34±40.33 ml).

Table 3. Blood loss data

	Group A (n=64)	Group B (n=53)	*P*-value
Intraoperative blood loss (ml)	105.30±28.66	140.13±33.41	0.000[a]
Postoperative blood loss (ml)	76.41±14.07	77.17±16.10	0.785[a]
Visible blood loss (ml)	181.70±31.66	214.34±40.33	0.000[a]
Hidden blood loss (ml)	472.11±138.61	466.66±145.28	0.837[a]
Total blood loss (ml)	653.78±170.51	680.96±185.63	0.411[a]
Transfused blood volume (units)	3.67±2.06	3.34±2.02	0.382[a]

[a]Student's T-test.

Table 4. Radiographic review

	Group A (n=64)	Group B (n=53)	*P*-value
Quality of reduction			0.344[a]
Acceptable	57 (89.1%)	44 (83.0%)	
Poor	7 (10.9%)	9 (17.0%)	
Distance to the lateral cortex			0.036[a]
=0	11 (11.2%)	18 (34.0%)	
>0	53 (82.8%)	35 (66%)	
TAD	20.03±3.89	18.60±3.03	0.054[b]
Helical blade position overall			0.351[a]
Helical blade position (anteroposterior)			0.007[a]
Superior (1.2.3)	6 (9.4%)	16 (30.2%)	
Middle (4.5.6)	38 (59.4%)	29 (54.7%)	
Inferior (7.8.9)	20 (31.2%)	8 (15.1%)	
Helical blade position (lateral)			0.058[a]
Anterior (1.4.7)	18 (28.1%)	7 (13.2%)	
Middle (2.5.8)	35 (54.7%)	29 (54.7%)	
Posterior (3.6.9)	11 (17.2%)	17 (32.1%)	

TAD, tip-apex distance. [a]Chi-square test; [b]Student's T-test.

Radiographic review

The radiographic reviews are shown in **Table 4**. On the postoperative anteroposterior and lateral radiographs, the reduction quality was not significantly different between the 2 groups (P= 0.344). The distance to the lateral cortex was classified as zero (11 in group A [11.2%] and 18 in group B [34.0%]) or as greater than zero (53 in group A [82.8%] and 35 in group B [66.0%]), and the difference in classification between the 2 groups was significant (P=0.036). The TADs in group A (20.03±3.89) and group B (18.60±3.03) did not significantly differ (P= 0.054). The helical blade positions were recorded and are shown in **Figure 4**. No significant differences in helical blade position were observed between the 2 groups either overall or on the lateral radiographs (P=0.351 and P=0.058, respectively). However, a significant difference existed between the 2 groups in the helical blade position on the anteroposterior radiographs (P=0.007).

Postoperative outcomes

The hospital stays were not significantly different (P= 0.507) between groups A (12.11±4.12 days) and B (11.56±4.78 days). Additionally, the HHSs at 6 and 12 months were not significantly different (P=0.342 and P=0.602, respectively). However, at postoperative months 1 and 3, the HHSs of group A (61.36±7.57 and 68.58±7.68, respectively) were significantly higher than those of group B (57.81±6.32 and 63.38± 6.01; P=0.008 and P= 0.000, respectively) (**Table 5**).

Discussion

Among elderly patients, intertrochanteric fractures are the most common osteoporotic fractures and are associated with high morbidity and mortality. The results of PFNA-II for the treatment of intertrochanteric fractures are satisfactory due to the biomechanical advantages of the intramedullary nail and the helical blade [3, 6, 15]. However, certain technical problems persist, such as the relatively complex operation, perceived lengthy surgical duration, expansive learning curve, and inappropriate entry portals and blade positions that may result in cutouts and iatrogenic fractures in the lateral cortex [5-8, 15, 16]. Several studies [9, 10, 17, 18] have recommended improvement of the insertion technique to ensure stable fixation and prevent major complications.

A precise starting point is the first criterion for ensuring the accurate reduction of proximal fractures. Impingement of the soft tissues or operative drapes may lead to eccentric lateral

Table 5. Postoperative outcomes

		Group A (n=64)	Group B (n=53)	*P*-value
Harris Hip Score	1 month	61.36±7.57	57.81±6.32	0.008[a]
	3 months	68.58±7.68	63.38±6.01	0.000[a]
	6 months	74.92±8.87	76.36±7.08	0.342[a]
	12 months	78.94±8.23	78.13±8.36	0.602[a]
Hospital stay (days)		12.11±4.12	11.56±4.78	0.507[a]

[a]Student's T-test.

reaming, which may in turn lead to a more lateral entry portal and a more lateral placement of the intramedullary nail than intended. Incorrect placement of the entry portal may result in fracture propagation, proximal fractures, varus reduction of the proximal fragment and a high blade position in the femoral head [9, 15]. Iatrogenic lateral proximal fractures likely result from the geometry of the PFNA-II and from impingement of the proximal femoral lateral cortex during insertion. Despite the flat proximal lateral surface of the PFNA-II, which was designed for Asians with the goal of preventing impingement of the femoral lateral cortex, a mismatch with the narrow proximal canal persists [5, 7, 8]. With the intention of resolving this mismatch, we moved the entry portal slightly medially from the trochanteric tip and subsequently observed significantly reduced impingement of the femoral lateral cortex in group A (11 [11.2%], modified entry portal) compared with group B (18 [34.0%], conventional entry portal). In group B, 2 iatrogenic lateral proximal fractures occurred during the PFNA-II insertion process, whereas none occurred in group A, in which the entry portal was slightly medial from the trochanteric tip.

TAD is widely recognized as an essential index for predicting fixation failure with the use of lag screws or blade cutouts from the femoral head following surgical fixation with intramedullary nailing [13]. However, the optimal lag screw position and the resultant TAD remain a subject of debate. For the PFNA, the manufacturer suggests inserting the blade 5-10 mm from the subchondral bone in the anteroposterior and lateral planes, which would yield a TAD of 10-20 mm in the case of center-center positioning. However, the latest biomechanical research suggests that the TAD for the PFNA should be 20-30 mm and that the blade position should be low in the anteroposterior plane and in the center of the lateral plane to achieve the best stability [19, 20]. Because the femoral geometry of Asians involves shorter femoral necks, the smaller femoral neck angles and shorter proximal canals increase the difficultly of obtaining the ideal blade position, particularly in elderly Asian women [10, 21, 22]. To insert the blade lower in the anteroposterior plane, the nail must be inserted deeply, which causes the nail to impinge on the lateral cortex in cases of short proximal canals. Simultaneously, small femoral neck angles also result in higher blade positions with a high risk of cutout. In the present study, we found that the use of an entry portal slightly medial to the trochanteric tip allowed the nail to be inserted deeper and more medially, which in turn enabled the helical blade to be placed in a lower position in the femoral head. The TADs of group A (modifiedentry portal) were greater than those of group B (conventionalentry portal); however, this difference was not significant. In the Cleveland zone, the blade position was lower in group A than group B, and 2 cutouts requiring revision surgery occurred in group B.

The short, straight PFNA-II requires a slightly posterior entry portal to accommodate the proximal medullary canal due to the greater anterior bowing of the femoral shaft in Asians, and the nail should be inserted at a 30-degree angle with respect to horizontal [5]. With a posterior entry portal, some studies have indicated that the blade position will be more anterior and cut out. In contrast, we observed no significant differences between the 2 groups on the lateral radiographs (P=0.058), and no cutouts occurred in group A. We believe this phenomenon was due to the medial shifting of the entry portal, which allowed deeper insertion of the nail and lower positioning of the blade.

McConnell et al. [23] emphasized that the lateral trochanteric portal recommended by the manufacturer resulted in an average 27% damage to the gluteus medius tendon during the reaming for intramedullary (IM) nail insertion. The authors proposed that gluteus medius tendon injury should be recognized as a cause of postoperative morbidity. In a cadaver study, Perez et al. [24] described a modified trochanteric portal that used an entry portal slightly medial to the trochanteric tip along the trochanteric ridge and did not damage the gluteus medius tendon during reaming; they recommended the clinical application of this technique. However, in that study, a 14-mm reamer was used rather than the 16-mm reamer recommended by the manufacturer. Tao et al. [10] also suggested modifying the entry portal to decrease postoperative morbidity. In the present study, we observed that the HHS was significantly greater in group A than group B at postoperative months 1 and 3; however, at 6 and 12 months, there were no significant differences between the groups. In group B, the recovery from hip abductor weakness was observed after 6 months. This phenomenon confirmed that the novel modified entry portal reduced the damage to the gluteus medius tendon and that the restoration of the gluteus medius was achieved by 6 months.

Due to iliac wing and soft tissue impingement, the process of inserting the IM nail is difficult, and the guide pin often pierces the canal from the medial calcar region, particularly in obese patients and patients with spacious pelvises. Although longer incisions were used for these individuals, we nonetheless found it difficult to obtain an ideal entry portal and to smoothly insert the IM nail. Siddiqui et al. [11] introduced a technique to facilitate an IM insertion that was less disruptive to the soft tissues and to reduce the intraoperative time. Ziran et al. [12] described a percutaneous technique for IM nail insertion that involved a minimal incision and minimal tissue dissection, and they vaguely defined a cutaneous entry portal from which an IM nail may be inserted and directed toward the piriformis fossa. In our study, we defined an exact cutaneous entry portal to reduce the soft tissue barrier and prevent its disruption, such that the ideal entry portal could be easily reached. We observed that the percutaneous technique used in group A resulted in a shorter surgical time, a smaller incision, and lower volumes of visible and intraoperative blood loss than the values that have been reported in the literature [4, 6]. However, in the percutaneous technique group, we found that the fluoroscopy time was significantly longer, indicating that the percutaneous insertion technique requires more fluoroscopy. We believe that the learning curve was primarily responsible for this observation and that increases in the number of surgical cases will reduce the fluoroscopy time; however, this hypothesis must be verified by further research.

This study has several limitations. First, all the patients in this study were local residents of northern China; thus, whether our results may be generalized to southern Chinese patients with shorter stature requires further multicenter studies. Second, in this study, obtaining optimal anteroposterior and lateral views was difficult from the intraoperative fluoroscopic views. However, in a recent anatomical study [25], Farhang found that mild rotation in the proximal femur had little effect on the placement of the trochanteric entry portal. Third, we did not classify the greater trochanteric morphologies, although the number of patients may have been sufficient to include all types of greater trochanters.

This randomized, prospective, controlled study demonstrated that the novel modified trochanteric entry portal and percutaneous technique may reduce the PFNA-II mismatch with the femoral geometry of Asians and achieve excellent nail positions with fewer complications, shorter operation times, and reduced surgical blood loss and trauma. Finally, the most significant improvement was in early hip function recovery, an improvement that may result in reduced morbidity.

Disclosure of conflict of interest

None.

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