Early results of the proximal femoral nail antirotation-Asia for intertrochanteric fractures in elderly Chinese patients

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ABSTRACT

الأهداف: يقدم تقريراً مبكراً لفعالية وسلامة مسمار الفخذ الداني الآسيوي المانع للدوران لكسور المدورين عند كبار السن المرضى الصينيين.

الطريقة: أجريت هذه الدراسة بأثر رجعي في المستشفى الثاني في جامعة انهوى الطبية، انهوى، الصين خلال الفترة من يونيو 2009م إلى ديسمبر 2012م. وشاركت مجموعة متاحة من 108 مريضاً كانوا يعانون من كسور المدورين لتحليل نتائج هذه الدراسة. . كان هناك 62 من الإناث و 46 من الذكور المرضى مع متوسط الأعمار 75 ± 10 عاماً. واشتملت المجموعة المستقرة على 18 حالة من الكسور A1–31، واشتملت المجموعة غير المستقرة على 68 حالة من الكسور A2–31 و 22 حالات الكسور A3–31. وقد تم إجراء تقييمات المتابعة في 1، 3، 6، 9 و 12 شهراً، وكل سنة بعد ذلك.

النتائج: كان متوسط الأشهر الأولى من فترة المتابعة هي 9±29 أشهر، فقد 4 مرضى (4%) ، وتوفي 6 مرضى (6%) في غضون 6 أشهر لأسباب لا علاقة لها بالكسر. حدث كسر في جميع المرضى، أظهر 83 مريضاً (85%) نتائج ممتازة أو جيدة. وكان متوسط درجة هاريس الورك 85.2(HHS) ± 7.5 نقطة. و لم ينظر إلى العطل الميكانيكي مثل الثني أو الكسر من عملية الزرع ولم تلاحظ القصاصات.

الخاتمة: تشير النتائج الأولية أن مسمار الفخذ الداني الآسيوي المانع للدوران فعال وآمن في علاج الكسور لدى المرضى الصينين كبار السن المصابين بالمدورين.

Objectives: To report early efficacy and safety of the proximal femoral nail antirotation-Asia for intertrochanteric fractures in elderly Chinese patients.

Methods: This retrospective study was carried out in the Second Hospital of Anhui Medical University, Anhui, China between June 2009 and December 2012. A total of 108 patients with intertrochanteric fractures were available for the outcome analysis in the study. There were 62 female and 46 male patients with a mean age of 75 ± 10 years. The stable group included 18 cases of 31 A1 fractures, the unstable group included 68 cases of 31 A2 fractures, and 22 cases of 31 A3 fractures. Follow-up evaluations were performed at 1, 3, 6, 9, and 12 months, and every year thereafter.

Results: During the average 29 ± 9 months early follow-up period, 4 patients (4%) were lost, and 6 patients (6%) died within 6 months due to causes unrelated to the fracture. Fracture union occurred in all patients, 83 patients (85%) showed an excellent, or good outcome. The mean Harris Hip Score was 85.2 ± 7.5 points. Mechanical failures, such as bending, or breaking of the implant were not seen, and cut-outs were not observed.

Conclusion: The results suggest that proximal femoral nail antirotation-Asia is effective and safe in the treatment of inter-trochanteric fractures in elderly Chinese patients.

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The incidence of intertrochanteric femoral fractures have increased markedly in recent years with societies growing continuously older.[1] Non-operative treatment of intertrochanteric femoral fractures lasts a long period, and is accompanied by serious complications and high risks of mortality.[2] As long as the systemic condition permits, an operative approach should be used. Therefore, 2 options exists: extramedullary, or intramedullary fixation.[3] Intramedullary fixation devices such as the gamma nail (GN), proximal femoral nail (PFN), and proximal femoral nail antirotation (PFNA) have become popular in elderly patients due to biomechanical advantages.[4,5] The PFNA was introduced by the Arbeitsgemeinschaft fur Osteosynthesfragen/Association for the Study of Internal Fixation (AO/ASIF) in 2003, and uses helical neck blade fixation to obtain high stability to prevent rotation and collapse.[6-8] The PFNA is one of the most effective methods in the treatment of intertrochanteric femur fractures.[9-12] However, PFNA was designed in accordance with the anatomical data of Westerners. The anatomy of Asian is different from Westerners resulting in some complications due to mismatch.[6] The average height of Chinese is less than that of Caucasians, and the proximal femoral length and femoral neck diameter are relatively shorter. Consequently, to help cope with the differences described above, an Asian version of the existing PFNA was developed and introduced into the market in 2009.[13] Few published studies in the literature systematically assessed PFNA-Asia in the treatment of intertrochanteric femoral fractures in elderly Chinese patients.[13,14] In theory, PFNA-Asia should be suitable for Chinese, and its effect should be satisfactory. This retrospective clinical study was conducted to report early efficacy and safety of the PFNA-Asia for intertrochanteric fractures in elderly Chinese patients.

Methods. We reviewed retrospectively 178 cases of intertrochanteric fractures treated with the PFNA-Asia (Synthes GmbH, Oberdorf, Switzerland) in The Second Hospital of Anhui Medical University, Hefei, Anhui, China between June 2009 and December 2012. Thirty-two patients with pathologic fractures, open fractures, multiple fractures, American Society of Anesthesiologists (ASA) score of V,[15] inability to work before injury, and previous implants in the fractured hip were excluded. Thirty-eight patients were excluded for being younger than 60 years. A total of 108 patients were available for the outcome analysis in the study (**Figure 1**). The study was approved by the ethics committee of The Second Hospital of Anhui Medical University, Hefei, Anhui, China. This study was conducted according to the principles of the Helsinki Declaration. Informed consent was obtained from the patients, or family members if the patients were unable to consent. According to Association for Osteosynthesis-Orthopaedic Trauma Association (AO/OTA) classification,[16] the fractures were classified as 31.A1.1-3, 31.A2.1-3, and 31.A3.1-3, 31.A1.1-3 were stable intertrochanteric fractures (stable group), and 31.A2.1-3 and 31.A3.1-3 were unstable intertrochanteric fractures (unstable group).

Surgical procedures. All patients were treated operatively according to the manufacturer's instructions of the PFNA-Asia by the same group of surgeons with over 5 years of experience. General anesthesia was used in all patients. All fractures were treated by closed reduction under C-arm fluoroscopy control. The operative time, blood loss during surgery, overall fluoroscopy time, blood transfusion volume, post-operation drainage, and duration of hospitalization were recorded.

Evaluation after treatments. In all cases, antithrombotic prophylaxis was administered using low-molecular-weight heparin sodium (Sanofi-Aventis, Paris, France) for 5 days, and prophylactic intravenous cefotiam was administered half an hour before operation, and discontinued 2 days postoperatively. Drainage tube was placed for one to 2 days. All patients were encouraged to move the hip, knee, and ankle joints on the first postoperative day under the surgeon's guidance. Continuous passive motion rehabilitation devices (Smith & Nephew, Shanghai, China) were used twice a day after the suction drain had been removed, and all patients started partial weight bearing with the aid of crutches, 2 weeks postoperatively. Follow-up evaluations were performed at 1, 3, 6, 9, and 12

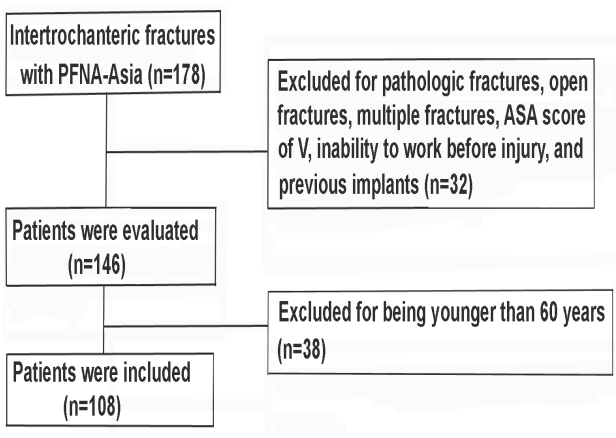

Figure 1 - Flow diagram detailing the exclusion process in this study. PFNA-Asia - proximal femoral nail antirotation Asia, ASA - American Society of Anesthesiologists

months, and every year thereafter. Plain anteroposterior and lateral radiographs were obtained at each visit. All implant position changes, the extent of the fracture union, complications, fixation failures, and final Harris Hip Score (HHS) were recorded. The HHS were categorized as excellent (90-100 points), good (80-89 points), fair (70-79 points), or poor (<69 points). The quality of fracture reduction was assessed independently by experienced surgeons, it was good if anteversion-retroversion, and/or varus-valgus was less than 5°, it was acceptable if the angle was from 5-10°, it was poor if the angle was more than 10°.[17] The position of PFNA-Asia was evaluated independently by experienced surgeons, and it was optimal if the blade was placed in the lower third of the neck on the anteroposterior radiographs, and centrally on the lateral radiographs.[16] Furthermore, the tip-apex distance (TAD) were noted. In addition, the systemic and local complications were recorded.

Statistical analysis. Date were performed using the Statistical Package for Social Science version 10 (SPSS Inc., Chicago, IL, USA) for Windows. All continuous data were expressed as mean ± SD. Quantitative variables between the 2 groups were analyzed using the student's t-test, or Mann-Whitney U test. Kaplan-Meier analysis was applied to analyze the fracture healing rates, and the log-rank test was used to analyze the time distribution of the 2 groups. The level of statistical significance was set at a 2-sided *p*-value of 0.05.

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Results. From June 2009 to December 2012, 108 consecutive patients with intertrochanteric fractures were included in this study. There were 62 female and 46 male patients with a mean age of 75 years (range 60-99 years). Most fractures resulted from fall (76%). The stable group included 18 cases of 31-A1 fractures, the unstable group included 68 cases of 31-A2 fractures, and 22 cases of 31-A3 fractures. Furthermore, 39 patients were classified as ASA I, 49 patients were classified as ASA II, 14 patients were classified as ASA III, and 6 patients were classified as ASA IV (**Table 1**). All fractures were treated by closed reduction, and were assessed by clinical surgeons. The detailed surgery information of the patients is given in **Table 2**. The mean operation time (skin to skin) in the stable group was 50.2 minutes, shorter than 60.0 minutes in the unstable group (p=0.000). The average blood loss of the stable group was 75.0 ml, less than 126.2 ml of the unstable group (p=0.001). The C-arm fluoroscopy mean time in the unstable group was 88.5 seconds, much longer than 48.6 seconds in the stable group (p=0.000). The average blood transfusion volume in the stable group was even more than 2 times than that in the other group (p=0.001). The average postoperative drainage was 64.4 ml in the stable group, and 66.8 ml in the unstable group (p=0.040). The mean hospital stay was 7.7 days in the stable group and 11.5 days in the unstable group (p=0.000). The differences between the 2 groups in operation time, fluoroscopy time, blood loss, transfusion volume, postoperative drainage, and hospital stay were statistically significant (**Table 2**). During the average 29 ± 9.1 months (12-36 months) early follow-up period, 4 patients (4%) were lost, and 6 patients (6%) died within 6 months due to causes unrelated to the fracture, including 3 cases of cancer, 2 cases of traffic accident, and one case of suicide. We observed that the fracture healing rates at different time in Kaplan-Meier estimate (**Figure 2**) fracture union occurred in all patients at 20 weeks postoperatively. There was no significant difference in the time distribution between the 2 groups (χ^2=1.762, p=0.184).

The HHS results were as follows: 39 - excellent; 44 - good; 10 - fair; and 5 - poor. In all, 83 patients (85%)

Table 1 - Preoperative data of patients with intertrochanteric fractures treated with PFNA-Asia at The Second Hospital of Anhui Medical University, Hefei, Anhui, China.

Characteristics	Number of cases
Age (years)	75.1 ± 9.7
Body mass index (kg/cm^2)	22.7 ± 4.3
Gender	
Male	46
Female	62
Side (left/right)	50/58
AO type	
A1.1	3
A1.2	4
A1.3	11
A2.1	25
A2.2	15
A2.3	28
A3.1	8
A3.2	7
A3.3	7
Mechanisms of injury	
Simple fall at home	82
Traffic accident	26
ASA classifications	
1	39
2	49
3	14
4	6

PFNA - proximal femoral nail antirotation,
AO - Arbeitsge-meinschaft für Osteosynthesefragen,
ASA - American Society of Anesthesiologists

Table 2 - Operative records of patients with intertrochanteric fractures treated with proximal femoral nail antirotation-Asia at The Second Hospital of Anhui Medical University, Hefei, Anhui, China.

Characteristics	Stable (n=18)	Unstable (n=90)	Total	*P*-value
Operation time (minutes)	50.2 ± 5.8	66.0 ± 13.9	63.4 ± 14.2	0.000
Blood loss (ml)	75.0 ± 49.4	126.2 ± 71.7	117.7 ± 70.9	0.001
Fluoroscopy time (seconds)	48.6 ± 31.6	88.5 ± 24.5	81.9 ± 29.7	0.000
Blood transfusion volume (U)	1.3 ± 0.5	2.7 ± 0.7	2.4 ± 0.8	0.001
Post-operation drainage (ml)	64.4 ± 7.8	66.8 ± 26.8	66.4 ± 25.5	0.040
Hospitalization duration (days)	7.7 ± 1.2	11.5 ± 3.0	10.8 ± 3.1	0.000

Figure 2 - Kaplan-Meier estimate of fracture union in the 2 groups included in this study at The Second Hospital of Anhui Medical University, Hefei, Anhui, China.

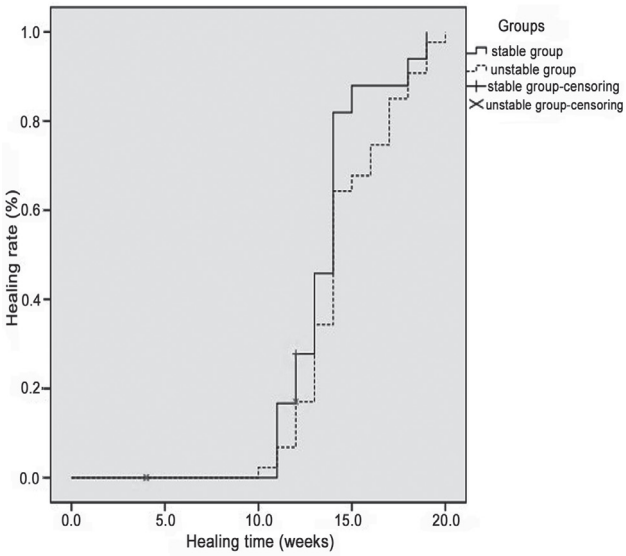

Table 3 - Postoperative radiographs measurement of patients with intertrochanteric fractures treated with proximal femoral nail antirotation-Asia at The Second Hospital of Anhui Medical University, Hefei, Anhui, China.

Characteristics	Number of cases
Reduction	
Good	85
Acceptable	19
Poor	4
Implant position	
Optimal	95
Suboptimal	13
Tip apex distance	
<10 mm	12
10-20 mm	76
>20 mm	20

Table 4 - Postoperative complications of patients with intertrochanteric fractures treated with proximal femoral nail antirotation-Asia at The Second Hospital of Anhui Medical University, Hefei, Anhui, China.

Complications	Number of cases
Systemic complications	
Pneumonia	2
Myocardial infarction	3
Urinary tract infection	3
Hypoproteinemia	6
Deep vein thrombosis	1
Local complications	
Superficial infection	1
Fat liquefication	4
Hematoma	8
Cut-out	0
Thigh pain	7

showed an excellent, or good outcome. The mean HHS was 85.2 ± 7.5 points (range; 53-93 points). On postoperative radiographs, fracture reduction was considered anatomical, or acceptable in 104 patients (96%), and implant position was optimal in 95 patients (88%), TAD in 88 patients (82%) was less than 20 mm (**Table 3**). The systemic and local complications are reflected in **Table 4**. During the postoperative period, systemic complications occurred in 15 patients including 2 cases of pneumonias, 3 cases of myocardial ischemia, 3 cases of urinary tract infections, 6 cases of hypoproteinemia, and one case of deep vein thrombosis. Four main postoperative local complications occurred in this study, including superficial infection, fat liquefication, hematoma, and thigh pain due to proximal end of the nail. Eight cases of hematoma of the surgical wound resolved satisfactorily by detumescence. Seven cases of thigh pain disappeared after fracture union.

Four cases of fat liquefication resolved by changing the dressing. One case of superficial infection also resolved favourably by appropriate antibiotic treatment. Mechanical failures such as bending, or breaking of the implant were not seen and cut-outs were not observed (**Table 4**).

Discussion. Patients with intertrochanteric fractures should be treated operatively with internal fixation, although a controversy continues to surround the preferred implant for intertrochanteric femoral fractures.[18] Intramedullary fixation device has become a mainstream trend in treating trochanteric fractures because of advantages from the biomechanical point of view,[5,19] but serious implant-related complications have been reported.[20] In 2003, PFNA was designed by the AO/ASIF group, which increased stability using a single element. However, PFNA does not match with the anatomy of some short elderly Chinese patients. Some researchers reported lots of complications, when PFNA was used in elderly Chinese patients, including femoral shaft fracture, lateral cortex splitting during operation, hip and thigh pain, and lateral blade migration. To address these problems, PFNA-Asia was developed. [6,21] The PFNA-Asia size has a better fit to the smaller trochanteric area and narrower intramedullary canal of the Asian population. It features a lateral flat surface which makes insertion easier and lowers the pressure on the lateral cortex. The spiral blade diameter has been reduced to 10.3 mm versus 11 mm compared to the PFNA, and the bend has been reduced to 5° for the anatomy of Asians. The stable type 31-A1 fractures usually were excluded in the previous literatures concerning the PFNA-Asia for stabilization of intertrochanteric femoral fractures, because excellent results can be obtained with the dynamic hip screw (DHS). However, 18 cases of stable type fractures were included in our study. The average operative time in the stable group was 50.2 minutes, the average blood loss was 75 ml, C-arm fluoroscopy mean time was 88.5 seconds, average postoperative drainage was 64.4 ml, and the mean hospital stay was 7.7 days. Anatomic reduction and optimal implant position were obtained in 18 cases of stable type fractures. Setiobudi et al[22] reported 61 patients with stable intertrochanteric fractures were treated with DHS, the average duration of surgery was 59 minutes, and the mean hospital stay was 13.4 days. Therefore, PFNA-Asia is convenient, safe and effective in the treatment of type 31-A1 fractures, although the cost of this implant is more than DHS in China.

The mean operation time, C-arm fluoroscopy time and hospital stay in the stable group were shorter than those in the unstable group. The average blood loss, blood transfusion volume, and postoperative drainage of the stable group were less than those of the unstable group. The differences between the 2 groups in operation time, fluoroscopy time, blood loss, transfusion volume, postoperative drainage, and hospital stay were significant. It is easy to understand the differences, because the stable type 31-A1 fractures is less injury and rapid recovery. The average blood loss and blood transfusion volume of the unstable group were more than those of the stable group, so patients in the unstable group need longer hospital stay to observe and recover. However, the differences of sample number can affect the results.

As far as we know, Lv et al[13] reported the early clinical results of using PFNA-Asia in 84 consecutive elderly Chinese patients to stabilize AO type 31-A2 and 31-A3 fractures. In this article, no patients showed complication related to the mismatch between the nail and femora, 90% of the patients regained pretrauma mobility, 63 patients (78%) had an excellent or good outcome. Pu et al[6] reported a prospective study of 87 elderly Chinese patients with unstable intertrochanteric fractures treated with PFNA, pre-injury activity level was recovered in 77% of the patients, fractures united in all patients, mechanical failure and cut-out were not observed, a technical problem related to the mismatch of the proximal end of the nail was observed in 11 cases. However, in our study, the early results of the PFNA-Asia fixations were satisfactory. Eighty-three patients (85%) showed an excellent or good outcome. There was no postoperative complication associated with mismatch between the nail and femora. Thigh pain is a common complication in previous reports.[14,23,24] Seven cases of thigh pain disappeared after fracture union in our study, the rate of thigh pain was lower than that in previous reports.[24] The PFNA-Asia size has a better fit to the trochanteric area and intramedullary canal of the Chinese, which may reduce the rate of thigh pain due to mismatch.

Compared with the PFNA, PFNA-Asia had better results in the treatment of intertrochanteric fractures in elderly patients by closely matching Asian femoral anatomy, and thereby reducing complications related to the implants.[13] Although PFNA-Asia has many advantages, we should pay attention to the following in the surgery: to treat underlying health problems actively, which shorten the time of preoperative preparation; and to realize classification of fracture and the size of the medullary cavity, a detailed examination should be carried out. The blade should be placed into the lower half of the neck on the anterior-posterior view, and

centrally on a lateral view, the TAD should be less than 10 mm.[25] To protect the blood supply, open reduction and internal fixation should be avoided if possible.

Study limitations. First, the number of the patients included in our study was small and lacked a control group. Second, this is a retrospective study with all the problems inherent with the methodology, a series of prospective randomized controlled multicentric trials on comparing PFNA and PFNA-Asia should be required for further evaluation.

In conclusion, significant differences were found in operation time, fluoroscopy time, blood loss, transfusion volume, postoperative drainage, and hospital stay between the stable and unstable group. These results suggest that PFNA-Asia is effective and safe in the treatment of intertrochanteric fractures in elderly Chinese patients. We recommend PFNA-Asia for unstable intertrochanteric fractures, however, there are several good options for stable intertrochanteric fractures, PFNA-Asia could be an alternative plan.

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