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The proximal femoral universal nail system (PFUN): a novel intramedullary nail for treating complex proximal femoral fractures and its biomechanical comparison with the proximal femoral nail anti-rotation (PFNA)

Fang Zhou^{1,2*}, Jixing Fan^{1,2†} and Yang Lv^{1,2}

Abstract

Aims The loss of medial and lateral wall support were the main risk factors of implant failure for proximal femoral fractures. A novel intramedullary nail, called proximal femoral universal nail system (PFUN), was proposed by our team to reconstruct the medial wall and lateral wall integrity and the biomechanical performance was evaluated in this study.

Methods The synthetic femora were assigned to three groups randomly according to three different proximal femoral fracture types. For each group, the PFUN or PFNA were implanted separately and divided into PFUN subgroup and PFNA subgroup. Biomechanical tests were separately conducted in the axial compression test, torsional test, and fatigue test in sequence. The finite element analysis (FEA) was conducted by ANSYS 14.5 and we analyzed the von Mises stress distribution and the model displacement of two implant models in three different fracture types.

Results For proximal femoral fractures with intact medial wall and lateral wall, our biomechanical results showed that the PFUN had a similar biomechanical property with the PFNA. Furthermore, the biomechanical results showed that the PFUN had a larger axial stiffness, higher torsional strength, and a similar failure load when compared with the PFNA for proximal femoral fracture with medial wall fracture. For proximal femoral fractures with broken medial wall and lateral wall, a larger axial stiffness, higher average torque and higher failure load were found in the PFUN when compared with the PFNA. The FEA results showed that the PFUN model had a higher stress concentration compared with the PFNA model, and the total displacement of the PFNA model increased by 11.63% when compared with the PFUN model in the proximal femoral fracture with broken medial wall and lateral wall.

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Conclusion Our results showed that PFUN had better biomechanical performance than PFNA, especially for complex proximal femoral fractures with medial wall fracture and lateral wall fracture, indicating that the PFUN had great potential as a new fixation strategy in future clinical applications.

Keywords Proximal femoral fracture, PFUN, PFNA, Biomechanical test, Finite element analysis

Introduction

Owing to the increasing number of the elderly population, the incidence of proximal femoral fractures increased quickly worldwide [1]. In order to help patients get early rehabilitation and avoid bed-rest complications, early surgical treatment was recommended [2, 3]. Currently, the intramedullary fixation was the first choice for proximal femoral fractures [4–6]. Although the intramedullary nail had its intrinsic biomechanical stability, implant failure could still happen, especially for complex proximal femoral fractures [7]. Furthermore, a second surgery was usually required and the reoperation itself could increase morbidity and mortality for fragile elderly patients. Therefore, it was essential to reduce the implant failure rate in the treatment of proximal femoral fractures.

Various factors had been reported to be related to the occurrence of implant failure for proximal femoral fractures after intramedullary fixation [8–11]. Among these risk factors, the loss of medial femoral support and the loss of lateral femoral wall support were current research hotspots [12, 13]. The integrity of the medial wall was very important for maintaining postoperative stability and the medial wall fracture could increase the risk of postoperative implant failure [9]. One study revealed that medial-type reduction could decrease the cut-out complications in obese intertrochanteric fracture patients [14]. Therefore, reconstruction of the medial support was necessary. Furthermore, the lateral femoral wall fracture could also increase the risk of implant failure and reconstruction of the lateral femoral wall was recommended [15]. Although a few methods had been introduced to reconstruct the medial wall or lateral wall by adding an additional fixation to nail, it could cause additional soft tissue dissection, bleeding, and increased surgical time [16, 17]. Nonetheless, the existing intramedullary nails did not have any device to reconstruct the medial support and lateral support of proximal femoral fractures separately or simultaneously.

For reconstruction of the medial support and lateral support of proximal femoral fracture, we designed a novel intramedullary nail called proximal femoral universal nail system (PFUN). In this internal fixation system, apart from the usual main nail, lag screw (or helical blade) and a lock nail, it consisted of a lesser trochanteric screw to fix the lesser trochanteric fragment and a lateral wall screw to fix the lateral femoral wall fragment (or a coronal screw to fix the coronal fracture fragment). If the

lateral femoral wall was comminuted, a lateral wall plate was used to fix the comminuted lateral wall fragment. (Fig. 1) The PFUN was designed to treat any types of the proximal femoral fractures, especially for complex proximal femoral fractures involving the medial wall and/or lateral wall. This comprehensive internal fixation could have better biomechanical stability theoretically, and the aim of this study was to evaluate the biomechanical properties of PFUN compared with the commonly used proximal femoral nails anti-rotation (PFNA).

Materials and methods

Biomechanical study

Specimen Preparation and fracture simulation

In this study, a total of 36 left fourth-generation synthetic femora (Model 3406; Sawbones Worldwide, WA, USA) were used. Femora were assigned to three groups randomly according to the fracture type (Group A, a simple proximal femoral fracture (AO/OTA 31 A 1.2); Group B, a proximal femoral fracture with a medial wall fracture (AO/OTA 31 A 2.2); Group C, a proximal femoral fracture with medial wall fracture and lateral wall fracture (AO/OTA 31 A 3.3); $N=12$ per group). In each group, 12 femora were randomly assigned into two subgroups, namely the PFUN subgroup and PFNA subgroup. To ensure accurate and anatomical reduction and fixation, a PFUN or a PFNA nail was inserted to the femora before osteotomy. To ensure consistency of all specimens, a 3D-printed osteotomy guide was designed. (Fig. 2A) In this study, a fracture type of AO/OTA (the AO Foundation/Orthopaedic Trauma Association) 31-A3.3 was simulated according to the model described by Meinberg et al. [18], with a major intertrochanteric fracture line, associated with a free lesser trochanteric fragment and a free bone fragment of the LFW. For simple proximal femoral fracture (AO/OTA 31 A 1.2), an intertrochanteric fracture line was created from the greater trochanter to the lower border of the lesser trochanter. For a proximal femoral fracture with a medial wall fracture (AO/OTA 31 A 2.2), apart from the basic fracture line, a fracture line above the lesser trochanter was created. The lateral wall area and the lateral fracture were referred to the definition of Haq et al. [19] To ensure accurate and anatomical reduction and fixation, the specimens were first fixed using two different methods and then osteotomized. The nail was re-inserted in the specimen according to the operation manual after the fracture model was made. All procedures were performed by the same orthopedic

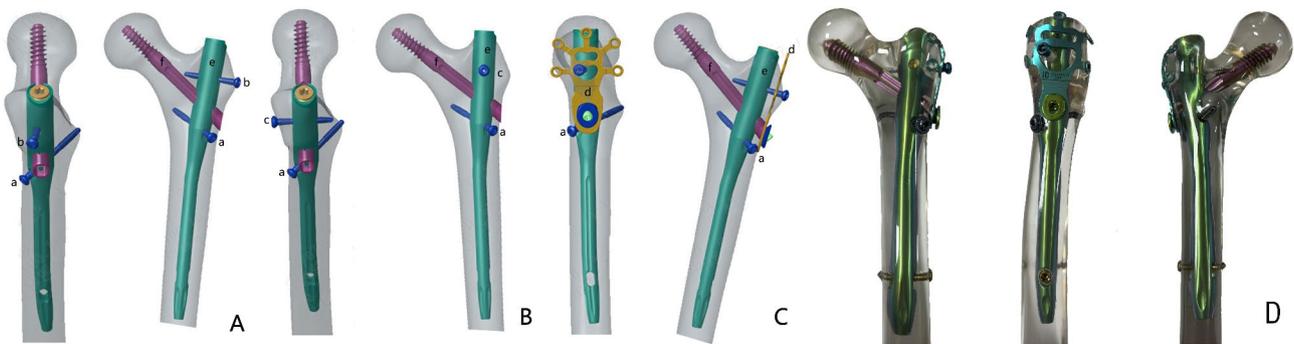


Fig. 1 The schematic diagram of the proximal femoral universal system (PFUN) for intertrochanteric fracture fixation. **(A)** Intertrochanteric fracture fixed by lesser trochanteric screw and lateral wall screw; **(B)** Intertrochanteric fracture fixed by lesser trochanteric screw and coronal screw; **(C)** Intertrochanteric fracture fixed by lesser trochanteric screw and lateral wall plate; **(D)** The general view of the PFUN. a, lesser trochanteric screw; b, lateral wall screw; c, coronal screw; d, lateral wall plate; e, main nail; f, lag screw (or helical blade)

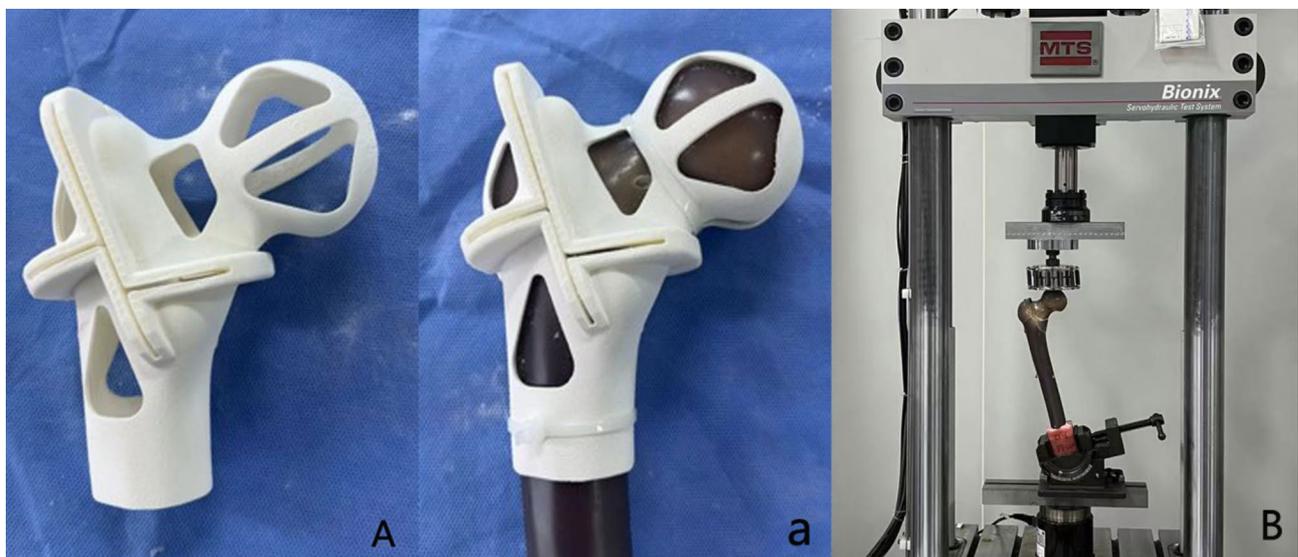


Fig. 2 (A-a) 3D-printed osteotomy guide of AO/OTA type 31-A3.3 intertrochanteric fracture; **(B)** Illustration of the mechanical test setup

surgeon according to standard surgical technique and the X-ray was used to make sure that the inserted implants were appropriate. (Fig. 3)

Biomechanical test

Before biomechanical testing, 5 cm length of the distal diaphysis was embedded with the dental acrylic resin powder. To simulate the human standing with one leg in physiological state, the specimen was loaded axially with the femurs positioned at 10° of adduction and 9° of flexion [20]. Biomechanical testing was performed using the MTS 858 Bionix materials test system (Bionix 858; MTS Systems, Minneapolis, MN, USA). (Fig. 2B) For all specimens, the axial compression test, torsional test, and finally fatigue test were carried out in sequence.

Axial compression test

The axial compression test was applied to simulate the stress experienced by patients with 60 kg body weight

at 4~6 weeks postoperatively [21]. Before compression test, each specimen was preloaded with 100 N at a speed of 5 mm/min three times to eliminate the gap and creep between the model bone and the implant. Then the specimen was loaded with axial loading pressure starting from 0 N to 600 N (the body weight of a 60 kg adult) with a rate of 5 mm/min. The data of axial load and displacement were recorded in the computer file connected to the testing machine, and the axial stiffness, ultimate displacement was calculated according to the axial load-displacement curve.

Torsional test

Next, a torsional test was performed with the following parameters: Starting from 0°, the maximum torsion angle set to 3° with a loading rate of 0.5°/s. The direction of the torsion to twist the femoral shaft was laterally (simulating the abduction movement of the human hip joint). The

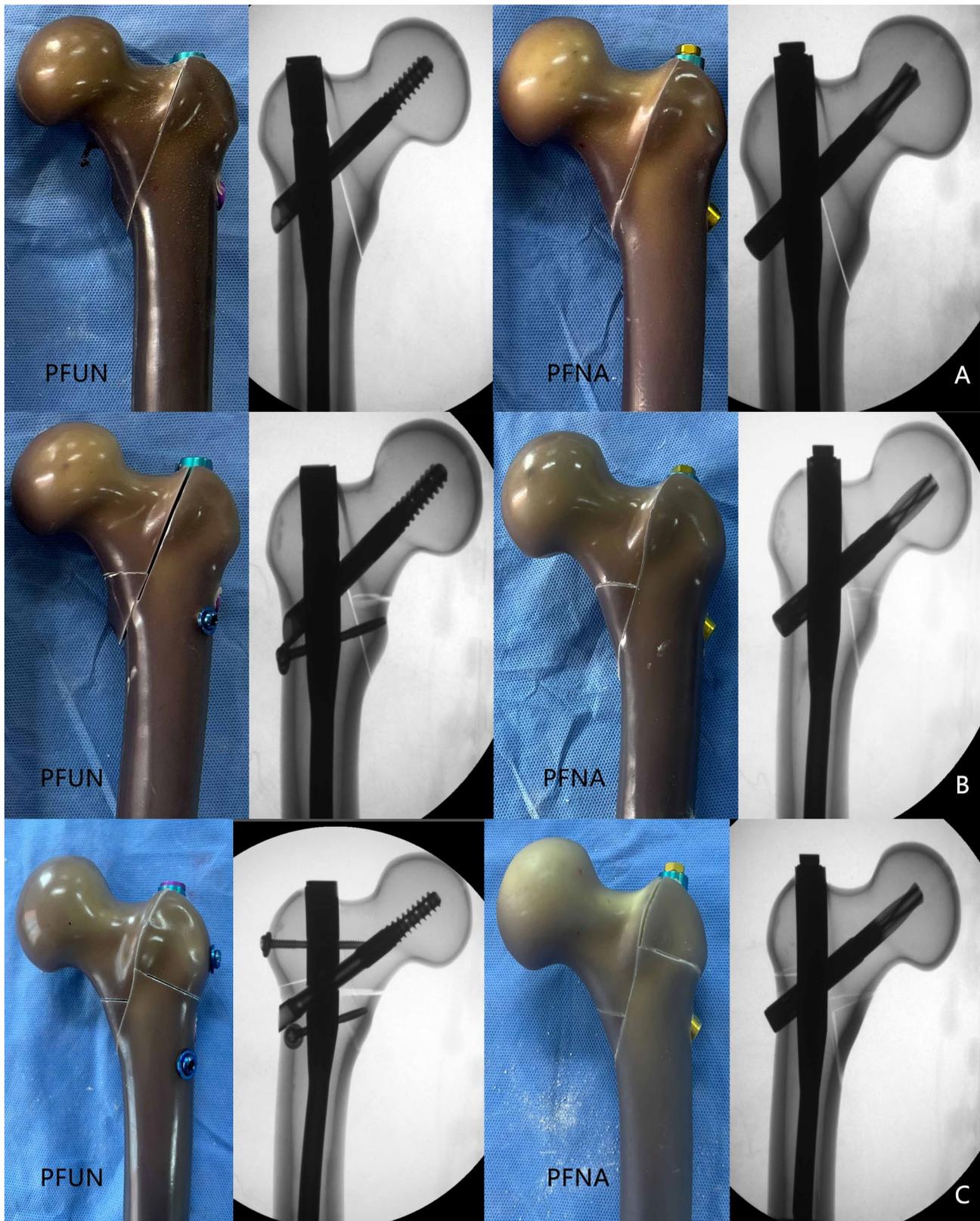


Fig. 3 Establishment of different fracture types of the intertrochanteric fracture model. (A) Group A, a simple intertrochanteric fracture (AO/OTA 31 A 1.1); (B) Group B, an intertrochanteric fracture with a medial wall fracture (AO/OTA 31 A 2.2); (C) Group C, an intertrochanteric fracture with medial wall fracture and lateral wall fracture (AO/OTA 31 A 3.3)

torque-angle curve and related data were saved in the computer file connected to the testing machine.

Fatigue tests

Finally, the axial failure test was performed with a loading rate of 4.6 mm/s continuously until fatigue failure. The failure was defined as fracture gap > 20 mm, nail cutting-out, breakage, or fracture line found near the distal locking screw [21]. The load level at which failure occurred was identified as the ultimate failure load.

Statistical analysis

The data were analyzed by SPSS 21.0 software (SPSS, Chicago, Illinois, USA). Normal distribution was investigated using the one-sample Kolmogorov-Smirnov test. Mechanical parameters were compared by using the independent samples *t*-test and the results were presented as mean \pm SD. The $p < 0.05$ was defined as a statistically significant difference.

Finite element analysis (FEA)

Finite element model establishment

In present study, the computed tomography images of a Sawbone femur (Model 3406, 4th Generation Sawbone, Vashon, WA, USA) were obtained and imported into Mimics 19.0 (The Materialise Group, Leuven, Belgium) to create a three-dimensional model. This 3D finite element model was created and had been used in a previous study [22]. Three different proximal femoral fracture models (Group A, a simple proximal femoral fracture (AO/OTA 31 A 1.1); Group B, a proximal femoral fracture with a medial wall fracture (AO/OTA 31 A 2.2); Group C, a proximal femoral fracture with medial wall fracture and lateral wall fracture (AO/OTA 31 A 3.3)) were created in the SolidWorks software (Dassault Systemes SolidWorks Corp., USA). Then, the models of implant (PFUN and PFNA) were modeled by SolidWorks according to the size of the intramedullary nail provided by the manufacturer. The implants were virtually inserted into the proximal femur. Subsequently, the models were imported into ANSYS Workbench 14.5 (ANSYS Inc., Canonsburg, PA) for analysis.

In present study, all materials were assumed to be homogeneous, isotropic, and with linear elastic behavior [23]. The material properties of the femur and implant materials used in the models were summarized in Table 1 [24]. According to the well-established and approved test contact setup method described in previous studies,

binding contact was formed between the internal fixation screw and the femur [25]. Friction contact was used on the fracture surface with a friction coefficient of 0.46.

For boundary conditions, the distal end of the femur was constrained in all degrees of freedom. The loading forces acting on the femur presented the loads at the heel strike of normal walking [26]. A joint reaction force of 2967.7 N ($\{x, y, z\} = \{1234.8, -352.8, -2675.4\}$) was applied at the femoral head. To reduce bending moments at the proximal femur, an abductor force was applied on the greater trochanter. An abductor muscle load of 1288.3 N ($\{x, y, z\} = \{-460.6, 634.34, 1022.28\}$) was applied at the greater trochanter [27]. In this finite element analysis, the peak von Mises stress on the proximal femur and implant, the total displacements of the models were selected as indices of the stability.

Results

Biomechanical results

Axial compression test

In group A, the PFUN subgroup had a similar average maximum displacement when compared with the PFNA subgroup and no significant difference was found between the two subgroups ($P > 0.05$). In group B, the PFUN subgroup had a significantly lower average maximum displacement and higher axial stiffness compared with the PFNA subgroup ($P < 0.05$). In group C, the average maximum displacement of the PFUN subgroup was significantly lower when compared with the PFNA subgroup ($P < 0.05$). Furthermore, the average axial stiffness of the PFUN subgroup was significantly higher than that of the PFNA subgroup ($P < 0.05$). (Fig. 4)

Torsional test

In each type of proximal femoral fractures, the torque was gradually increased with a twist angle of 1°, 2° and 3° in the PFUN and PFNA subgroups. In group A, the mean torsional strength of PFNA in the twist angle of 1°, 2° and 3° were similar to those of PFUN and no significant difference was found ($P > 0.05$). In group B, the mean torsional strength of PFNA in the twist angle of 1°, 2° and 3° were significantly lower than those of PFUN ($P < 0.05$). In group C, the average torque of PFNA subgroup in the twist angle of 1°, 2° and 3° were 3.04 \pm 0.97Nm, 4.63 \pm 1.35Nm and 6.07 \pm 1.05Nm, respectively; while those of PFUN subgroup were 5.35 \pm 2.19Nm, 7.92 \pm 3.02Nm and 9.45 \pm 2.50Nm, respectively. Furthermore, significant differences were found between the PFNA subgroup and PFUN subgroup in group C ($P < 0.05$). (Fig. 5)

Fatigue test

In group A, the PFNA subgroup a similar average failure load when compare with the PFUN subgroup and

Table 1 Material properties used in the simulations in this study

Material	Young's modulus (Mpa)	Poisson's ratio
Cortical bone	17,000	0.33
Cancellous bone	1000	0.3
Implant (Ti-6Al-7Nb)	110,000	0.35

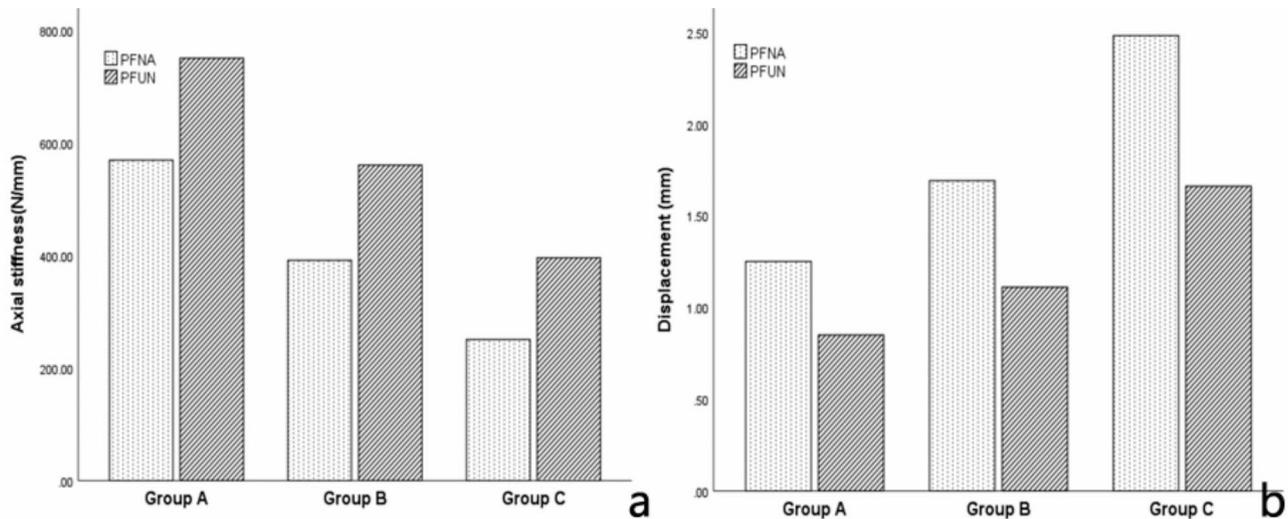


Fig. 4 Comparison of axial stiffness and displacement at different fracture types between PFUN subgroup and PFNA subgroup. (A) The axial stiffness; (B) The displacement. Group A, a simple intertrochanteric fracture (AO/OTA 31 A 1.1); Group B, an intertrochanteric fracture with a medial wall fracture (AO/OTA 31 A 2.2); Group C, an intertrochanteric fracture with medial wall fracture and lateral wall fracture (AO/OTA 31 A 3.3)

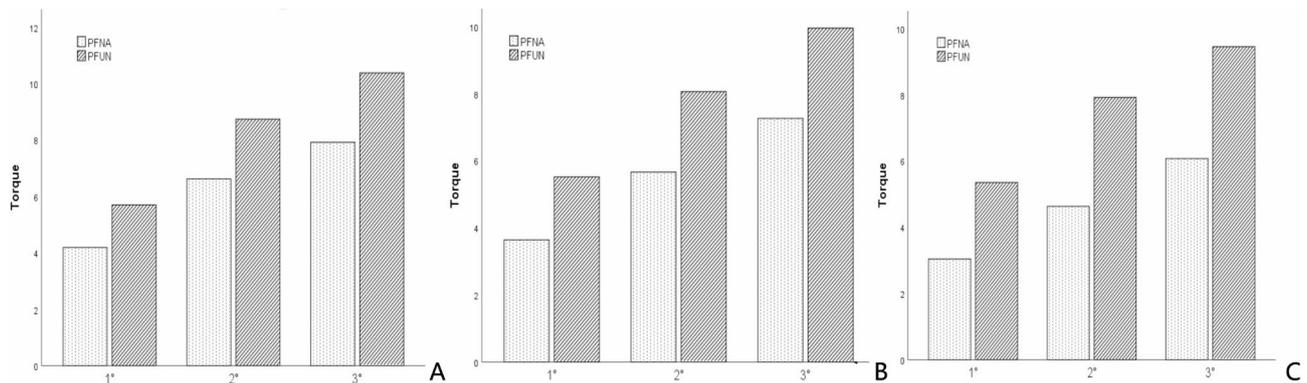


Fig. 5 Comparison of torque at different twist angles between PFUN subgroup and PFNA subgroup at different fracture types. (A) Group A, a simple intertrochanteric fracture (AO/OTA 31 A 1.1); (B) Group B, an intertrochanteric fracture with a medial wall fracture (AO/OTA 31 A 2.2); (C) Group C, an intertrochanteric fracture with medial wall fracture and lateral wall fracture (AO/OTA 31 A 3.3)

no significant difference was found ($P > 0.05$). In group B, the failure loads of PFUN were 7.52% larger than that of PFNA, while there was no significant difference between the two subgroups ($P > 0.05$). In group C, the average failure loads of PFNA and PFUN subgroups were 3455.86 ± 635.03 N and 4418.77 ± 467.17 N, respectively, and there was significant difference between two subgroups ($P < 0.05$). (Fig. 6)

FEA results

The von mises stress distribution of the proximal femur

In group A and group B, the PFNA subgroup and PFUN subgroup had a similar maximum von Mises stress. In group C, the stress concentration area was located at the medial-inferior part of the proximal femur in both the PFNA and PFUN subgroups. The magnitude of peak von Mises stress of the PFNA subgroup was 139.14 MPa,

which was larger than the 92.94 MPa of the PFUN subgroup. (Fig. 7A).

The von mises stress distribution of the internal fixation

In group A and group B, the PFNA subgroup and PFUN subgroup had a similar maximum von Mises stress. In group C, the stress concentration area of the PFNA group was located near the junction of the spiral blade and nail, and the value was 231.01 MPa. The maximum stress of the PFUN group was 252.96 MPa, which was located at the junction of the lateral wall screw and nail. (Fig. 7B).

The model displacement

The maximum displacement was located at the top of the femoral head for all models. In group A, the PFNA subgroup and PFUN subgroup had a similar maximum displacement (6.81 mm VS 6.77 mm, respectively). In group B, the PFNA model had a larger displacement than

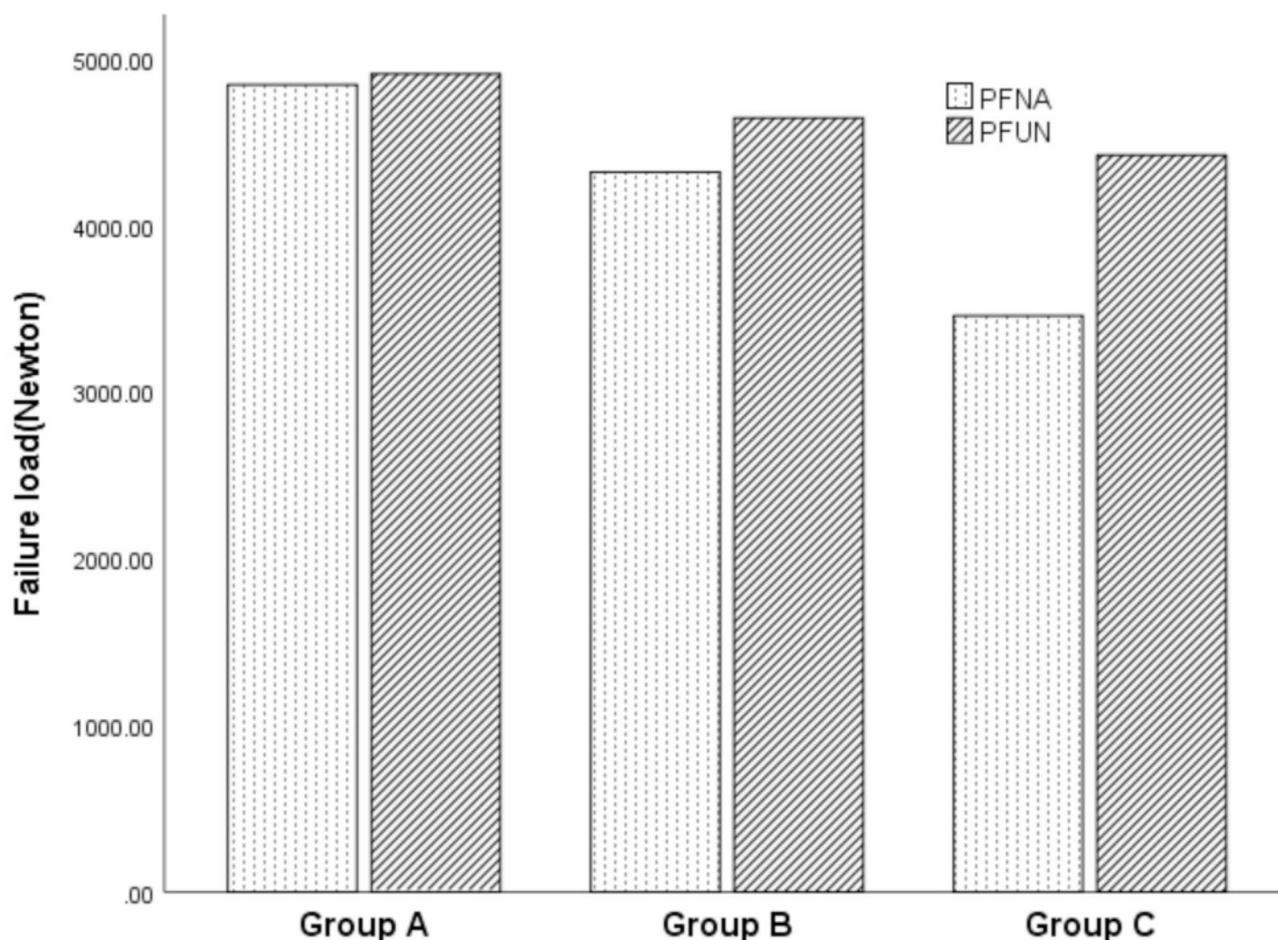


Fig. 6 Comparison of failure load between PFUN subgroup and PFNA subgroup at different fracture types. Group **A**, a simple intertrochanteric fracture (AO/OTA 31 A 1.1); Group **B**, an intertrochanteric fracture with a medial wall fracture (AO/OTA 31 A 2.2); Group **C**, an intertrochanteric fracture with medial wall fracture and lateral wall fracture (AO/OTA 31 A 3.3)

the PFUN model (7.18 mm VS 7.08 mm, respectively). In group C, the maximum amount of displacement of the PFNA model and PFUN model was 8.12 mm and 7.28 mm, respectively. (Fig. 7C)

Discussion

Currently, early surgical treatment was recommended for proximal femoral fractures and intramedullary nail fixation was the first choice [2, 28]. However, implant failure remained one of the main complications and might carry significant morbidity. It had been reported that intramedullary nail fixation had a failure rate between 3 and 20% [8, 29–31]. Both the medial wall cortex and the lateral wall cortical buttress contributed to the stability of proximal femoral fractures [17, 32]. Previous studies had demonstrated that the medial wall defect and lateral wall fracture could increase the risk of postoperative implant failure in proximal femoral fractures [9, 10]. Although the intramedullary nail fixation was a central fixation and nail itself could act as a lateral buttress, there was nothing designed to fix the medial wall fracture fragment

and lateral wall fracture fragment. A few surgical techniques had been introduced to fix the lesser trochanter fragment (such as the circumferential wiring with a cerclage cable) and the lateral femoral wall fragment (such as the trochanter stabilizing plate) [16, 17]. Furthermore, another study reported that poller screws applied around the lag screw could increase fixation stiffness and reduce varus collapse [33]. However, all of these methods might increase the operation time, blood loss and soft tissue injury. Currently, none of the existing intramedullary nail system was designed to fix the medial wall fracture fragment and lateral wall fracture fragment of proximal femoral fractures separately or simultaneously with a minimally invasive surgical technique.

As we know, the closer the fracture reduction was to the normal anatomical structure, the more stable the fracture was. Therefore, the designed internal fixation should make use of the inherent anatomic mechanical structure of the proximal femur to restore the normal bone structure and stress conduction. The proximal femur was mainly affected by compressive stress and

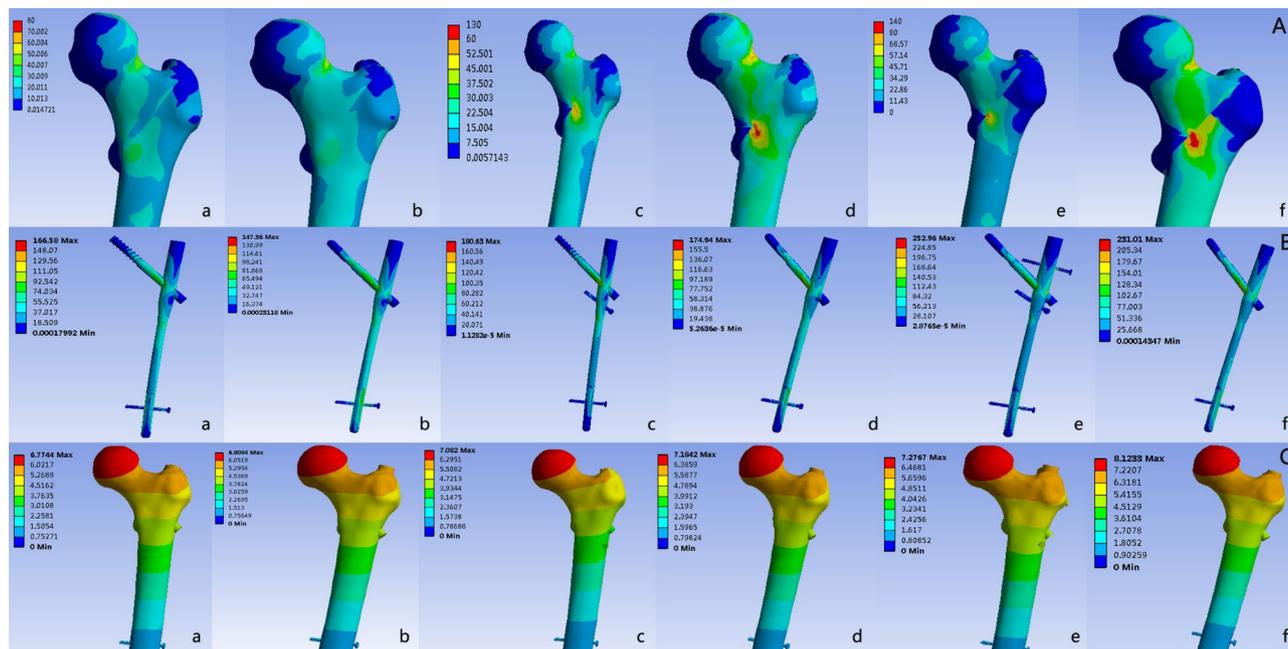


Fig. 7 Contour plots of von Mises stress and displacement in PFUN subgroup and PFNA subgroup at different fracture types. (A-a) The von Mises stress of the proximal femur in Group A; (A-b) The von Mises stress of the proximal femur in Group B; (A-c) The von Mises stress of the proximal femur in Group C; (B-a) The von Mises stress of the internal fixation in Group A; (B-b) The von Mises stress of the internal fixation in Group B; (B-c) The von Mises stress of the internal fixation in Group C; (C-a) The model displacements in Group A; (C-b) The model displacements in Group B; (C-c) The model displacements in Group C

tensile stress [34]. Under weight-bearing conditions, the medial wall of the proximal femur was mainly subjected to the compressive stress, while the lateral cortical bone provided buttress for the tensile stress [34]. As a new generation intramedullary implant, the PFUN was specifically designed for complex proximal femoral fractures, which could reconstruct the normal bone structure of the proximal femur. The PFUN consisted of the lesser trochanteric screw to reconstruct the medial wall, and lateral wall screw to reconstruct the lateral wall integrity (or a coronal screw to fix the coronal fracture fragment or a lateral wall plate to fix the comminuted lateral wall fragment), which could rebuild the compressive stress support and tensile stress support simultaneously with a minimally invasive surgical procedure. Therefore, the PFUN was theoretically an ideal internal fixation in line with the biomechanical characteristics of the proximal femur.

Due to the lack of clear clinical evidence on the optimal surgical treatment, the selection of implants was often based on biomechanical properties [35]. As we all know, good therapeutic effect was closely related to its biomechanical stability for the treatment of proximal femoral fractures. For proximal femoral fractures with intact medial femoral wall and lateral femoral wall, our biomechanical results showed that the PFUN had a similar biomechanical property with the PFNA. The possible reason might be that the intact medial wall could provide

a medial support and the intact lateral wall could offer a lateral buttress. Furthermore, the biomechanical results showed that the PFUN had a larger axial stiffness, higher torsional strength, and a similar failure load when compared with the PFNA for proximal femoral fracture with medial wall fracture. Moreover, the lateral femoral wall could provide a lateral buttress for the proximal fragment, and its deficiency might lead to excessive collapse and varus mal-positioning [36]. For proximal femoral fractures with medial wall fracture and lateral wall fracture, the axial stiffness of the PFUN increased by 57.82% more than the PFNA. With respect to the torsional stability, the average torques of the PFUN were 75.98%, 71.06%, 55.68% higher than that of the PFNA with the twist angle of 1°, 2° and 3°. For fatigue test, the average failure load of the PFUN was 1.28-times of the PFNA. This result demonstrated that the PFUN had a better anti-torsion capability and anti-fatigue performance than the PFNA for complex proximal femoral fractures.

The coxa varus was one of the most common and serious postoperative complications for the treatment of proximal femoral fractures [37]. The possible reason for the coxa varus was the breakage of the medial femoral cortex or the broken lateral wall, which could result in the inability to maintain the medial femoral support structure and lateral buttress structure. It had been demonstrated that lack of medial cortical support appeared as an important risk factor for implant failure in treating

unstable intertrochanteric fractures with intramedullary nail [38, 39]. One of our previous studies enrolled 394 cases of AO31-A2 intertrochanteric fractures to identify the relationship between the loss of the posteromedial support and implant failure [38]. The results showed that the loss of posteromedial support was an independent risk factor if implant failure for AO31-A2 intertrochanteric fractures. Furthermore, we classified the medial fracture fragment into three types according to the degree of involvement of the posterior cortex and found that medial wall fragment involving large posterior cortex intertrochanteric fractures was a notable preoperative risk factor of implant failure [9]. Therefore, we hypothesized that the additional lesser screw fixation could improve the postoperative stability for unstable intertrochanteric fractures. In this finite element analysis, we found that the stress concentration area was located at the medial-inferior part of the proximal femur. For proximal femoral fractures with medial wall fracture, the additional of the lesser trochanteric screw could decrease the model displacement. Moreover, we found that a broken LFW was a risk factor of implant failure for unstable intertrochanteric fractures and the comminution extent of the LFW fracture might influence the stability of intertrochanteric fractures [12, 22]. For proximal femoral fractures with medial wall fracture and lateral wall fracture, the PFUN model showed a higher stress concentration compared with the PFNA model, and the total displacement of the PFNA model increased by 11.63% when compared with the PFUN model. Thus, the PFUN was shown to be biomechanically superior to the commonly used PFNA, especially for proximal femoral fractures with medial wall fracture and lateral wall fracture. Therefore, the PFUN was a reliable internal fixator for the treatment of proximal femoral fracture.

However, several limitations existed in this study. First, this study didn't simulate soft tissues, which were crucial for stabilizing the fracture. Furthermore, the lesser trochanter could be detached and displaced by the tractional deforming force of iliopsoas tendon. In this study, the iliopsoas was not simulated and the osteotomy of minor tubercle remained perfectly at its place without any traction. Second, the sample size was six in each subgroup, corresponding to other studies in the literature [21]. Third, the femur and implants were anisotropic materials. However, in this study, in order to reduce complexity of analysis during the FEA, they were simplified into homogenous, isotropic and elastic materials. Although this study underwent some simplification and used conditions that might have differences with actual situations, it showed a clear trend for the topic being investigated. Furthermore, the purpose of this study was to compare relative values under the same loading environment and boundary conditions. As such, the simplification could

be accepted. Forth, the dynamic hip screw (DHS) was a commonly used method for stable proximal femoral fractures, while we didn't compare the biomechanical stability between the DHS and PFUN/PFNA in present study. Further study was necessary to evaluate the biomechanical stability and surgical outcome between the DHS and PFUN/PFNA.

Conclusions

For proximal femoral fractures with intact medial wall and lateral wall, either the PFUN or PFNA was a suitable implant choice. For proximal femoral fractures with medial wall fracture or broken lateral wall, it was necessary to reconstruct the medial wall structure by lesser trochanteric screw or rebuild the lateral wall integrity by lateral wall screw (or a coronal screw to fix the coronal fracture fragment or a lateral wall plate to fix the comminuted lateral wall fragment). In summary, the PFUN was biomechanically superior to the commonly used PFNA, especially for complex proximal femoral fractures with medial wall fracture and lateral wall fracture. Therefore, the PFUN might be a new advanced internal fixator for the treatment of proximal femoral fracture.

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Author contributions

Fang Zhou: Conceptualization, Methodology, Writing—original draft, Writing—review & editing; Jixing Fan: Methodology, Investigation, Formal analysis, Writing—original draft; Yang Lv: Methodology, Investigation, Formal analysis.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Our study does not involve human or animal data and requires no ethical board approval.

Conflict of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

AI and AI-assisted technologies in the writing process

The authors declare that no AI and AI-assisted technologies are used, and the languages in this study are manually polished by a specialist who has studied and worked in English-speaking country for many years.

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