Finite-Element Analysis of a Novel Cephalomedullary Nail for Restricted Sliding to Reduce Risk of Implant Failure in Unstable Intertrochanteric Fractures

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Objective: How to restrict sliding of cephalomedullary nail and rigid reconstruct medial support for unstable intertrochanteric fractures remains a challenge. This study aims to explore the feasibility of a novel cephalomedullary nail for restriction sliding and reconstruction of medial femoral support to prevent failure in unstable trochanteric fractures through finite element analysis.

Methods: The DICOM files of a unilateral femur spiral computed tomography (CT) scans from a elderly female were converted into STL files, and the most common clinical trochanteric fracture model with the absence of medial support, AO/OTA 31-A2.3 was simulated by removing the posterior medial femur. The model of a novel medial sustain nail (MSN-II) and a widely used nail (proximal femoral nail anti-rotation PFNA-II) were modeled according to the manufacturer-provided engineering drawing. Different loads were applied to the femoral head to simulate the postoperative weight bearing gait. The sliding distance of helical blade in femoral neck, maximum stress of femur and nail, displacement of proximal fragment were analyzed to revealing the mechanical stability of unstable trochanteric fracture stabilized by different implant.

Results: The sliding distance of helical blade in the femoral neck, the maximum stress on the femur and nail, the displacement of proximal fragment in MSN-II under 2100N axial load were 0.65 mm, 689 MPa, 1271 MPa, 16.84 mm respectively, while that were 1.43 mm, 720.8 MPa, 1444 MPa, 18.18 mm, respectively in PFNA-II. The difference between the two groups was statistically significant ($P < 0.05$) and the stress was mainly distributed in medial distal side of nail but helical blade and the proximal aperture for the nail in MSN-II. Compared to PFNA-II, MSN-II demonstrates biomechanical merit against femur medialization, cut-out and coax varus.

Conclusion: The sliding distance of helical blade in femoral neck, the maximum stress on the femur and nail, and the displacement of proximal fragment of MSN-II were less than those of PFNA-II in the treatment of unstable intertrochanteric fractures. Therefore MSN-II has better stability than PFNA-II and it may have the potential to avoid femur medialization and cut out. It might be an option in unstable trochanteric fracture because of its superiority in restricted sliding and medial support reconstruction.

Key words: Finite element analysis; Medial support; Proximal femoral nail anti-rotation; Sliding; Unstable trochanteric fracture
Introduction

The incidence of hip fractures is predicted to rise by 12% from 2010 to 2030, and more than 50% of it will occur in Asia by 2050. More than half of hip fractures are trochanteric fractures in older patients, with 1 year mortality rate up to 36% because of immobilization, so surgical stabilization and early mobilization is the keystone in the treatment. Cephalomedullary nailing is the mainstream in trochanteric fractures, especially for unstable fractures, as its axial fixation and the ability of earlier weight bearing. But the implant failure has been reported as high as 22.3%, that mainly due to the mechanical conduction structure of the medial femur cannot be reconstructed after the unstable trochanteric fractures and the excessive sliding or femoral medialization.

Restoring medial cortical support is important in unstable intertrochanteric fractures but is often difficult to achieve in clinical practice. The comminuted trochanteric fractures (especially AO/OTA 31-A2.3) account for more than 80% of unstable trochanteric fractures, which are the main component of implant failure. Comminuted medial wall fractures are difficult to maintain reduction due to the muscle traction. Moreover, the proximal femur is prone to loss of reduction and implant failure due to swing effect when it is fixed by cephalomedullary nail as the wide medullary cavity caused by osteoporosis and the advanced age.

Chen et al. reported that the postoperative reduction loss rate due to comminuted medial wall was as high as 20%. Song et al. found that calcar fracture gapping (comminuted medial wall) is a reliable predictor of implant failure after cephalomedullary nailing for trochanteric fractures. None of the existing cephalomedullary nails can effectively reconstruct the medial femoral support. Therefore, reconstruction and maintenance of medial femoral cortical support is a key factor in reducing the risk of implant failure and seems unavoidable as confirmed in our previous research.

Dynamic sliding implants such as Dynamic Hip Screw (DHS) or Proximal Femoral Nail Anti-rotation (PFNA-II) is the golden standard in trochanteric fractures as it did yield a lower risk of unplanned return to theater. However, excessive sliding or femoral medialization of those implants is a risk factor for implant failure and is a unique complication that occurs almost exclusively in the treatment of unstable trochanteric fractures with cephalomedullary nailing. Law et al. found that intramedullary nailing of unstable intertrochanteric fractures is inherently predisposed to femoral neck element medial migration making it more susceptible to consequent cut-out compared to fixation with the DHS. A large number of studies have confirmed that excessive sliding may lead to implant-related complications such as cut-out, which contributes significantly to the overall failure rate of implants. In order to limit the excessive sliding, non-cylindrical and more blade-like head fixation devices have been developed to prevent, or at least reduce, the failure rate in the latest implant generation. But excessive sliding is reported as sliding of ≥8mm, which occurs in approximately 40% of cases.

Some techniques are available to enhance cephalomedullary nailing for unstable trochanteric fractures to reduce the risk of implant failure by restoring mechanical conduction of the medial femur and limiting excessive sliding. Cerclage cable is the most common medial support reconstruction technique in cephalomedullary nailing for trochanteric fractures, but whether cerclage can improve fixation is still controversial. Ceynowa et al. confirmed that medial wall reconstruction with a cerclage cable does not improve axial stability of the fixation through biomechanical study. Cement augmentation for trochanteric fractures is considered viable to limit the excessive sliding by enhancing the implant anchorage within the head and neck fragment and lead to promote patient early mobilization. However, evidence regarding the effect of cement augmentation on fixation failures was very uncertain. Cement augmentation did not reduce the risk of loss of reduction, implant loosening and malunion. However, catastrophic leakage complications are another reason for caution. To our best knowledge, restoring medial support and limiting excessive sliding are still pending problems in the treatment of intertrochanteric fractures.

The theory of triangular stability was proposed based on the triangular-stable mechanical in the proximal femur in our earlier study and a novel medial sustain nail (Medial Sustain Nail-MSN, Fig. 1A) was designed by that which could restored the triangular-stable mechanical in the proximal femur by reconstructed the femoral medial support. It was found that MSN was superior to PFNA-II in reducing displacement and anti-rotation performance in early biomechanical tests, however, the defect of excessive sliding of helical blade still exists. The design of MSN was improved by adding a limited slide groove and changing the structure of the helical blade (MSN-II, Fig. 1B), and satisfactory results of medial support reconstruction were confirmed by biomechanics. It is not clear whether the excessive sliding is restricted. The aim of this study was to determine by finite element analysis: (i) whether the novel nail can reduce risk of cut out by restriction sliding? (ii) whether the novel nail can reduce risk of coxa varus by reconstructing the medial support? And (iii) whether the novel nail has potential risks?

Materials and Methods

Materials and Subjects

A healthy elderly female, 160 cm in height, 70 kg in weight and 70 years old, underwent a CT scan with a slice thickness of 1mm of the femur after examination to rule out hip disease and deformity but osteoporosis. This 3D finite element model has been used in a previous study.

This study was approved by the ethics committee of the PLA General Hospital and written informed consent was obtained from a healthy volunteer.
Methods

Model Establishment
The DICOM data of the full length of the left femur (unilateral femur) from CT were imported into Mimics 16.0 software (Materialise, Leuven, Belgium), and the coronal plane, sagittal plane and horizontal plane were defined respectively to reconstruct the femoral model. Cortical bone and cancellous bone were modeled as two separate sections. With the method of dynamic region growth of software, the human bone threshold value was selected, and the femur model was established, that was saved as a binary STL format file. The file was imported into Geomagic 12.0 (Geomagic co, Cary, NC, USA) for surface construction. The burrs and voids were repaired and then the surface triangular patches were repaired, and noise reduced to realize the smoothing of the femoral model. A standardized posteromedial unsupported intertrochanteric fracture (AO-A2.3; the most unstable and most common type in comminuted trochanteric fracture) was created by two simulated fracture line and has been used in the previous studies. The anatomical axial of femoral shaft was established in 3-Matic 12.0 (Materialise NV, Leuven, Belgium). And a plane through the femoral axis that was perpendicular to the XZ-plane of the world coordinate system (WCS) was obtained. Then the plane was rotated 20° clockwise around Y-axis of the WCS through the rotation center of red point (P in Fig. 1C) on the trochanteric anterior cortex. So we got the first osteotomy plane. Then we created second osteotomy plane which was determined by three points: P point, the apex of the greater trochanter (P3 in Fig. 1C,D), and the upper end of the less trochanter (P4 in Fig. 1C,D). The intertrochanteric crest and the lesser trochanter between the two osteotomy lines were completely removed, and part of greater trochanter, especially the posterior part, was removed. The models of implant (MSN-II and PFNA-II) were modeled by UG 8.5 (Siemens, Saint Paul, MN, USA) according to the manufacturer-provided engineering drawing. Assemblage of the implants and the posteromedial unsupported intertrochanteric fracture models were accomplished in 3-matic. The helical blades were located in the middle and lower third of the femoral neck. The entry point was located at the apex of the greater trochanter in anteroposterior radiographic fluoroscopy and the extension of the femoral shaft in lateral. Parameters of PFNA-II were as follows: nail length 240mm with proximal diameter 16mm and distal diameter 10mm, helical blade length 110mm with the diameter 9.9mm and spiral blade length 30mm, distal lock screw length 45mm with diameter
4.9mm. Parameters of MSN-II were as follows: nail length 240mm with proximal diameter 16mm and distal diameter 10mm, medial support screw length 61.5mm with the diameter 4.9mm, helical blade length 110mm with the diameter 9.9mm and spiral blade length 30mm.

Assignment and Boundary Setting
The surface of the femur was selected as cortical bone with a thickness of 2mm and the remainder as cancellous bone, and HyperMesh 12.0 (Altair, Maple Grove, MN, USA) was used to complete the pre-calculation process, including meshing, definition and assignment.

Boundary conditions were set in Abaqus11.0 (Abaqus, Providence, RI, USA), binding was set between the support nail and the main nail, friction coefficient between fracture blocks was 0.46, friction coefficient between internal fixation was 0.23, and coefficient between bone and internal fixation was 0.3, and the internal fixation was made of titanium alloy. Parameters of internal fixation and femur are listed in Table 1.

Load Settings
The distal femur was set as binding and the axial stress of the model was applied to the femoral head, with the force direction was 10° adduction on the coronal plane and 9° adduction on the sagittal plane. The axial loads were 300N, 600N, 900N, 1200N, 1500N, 1800N, and 2100N, respectively, to simulate the process from partial to complete weight-bearing after surgery, and the stress distribution and displacement of femur were recorded.

Assessment Criteria
After the finite element simulation test, the sliding distance of the helical blade in the femoral neck (mm), the maximum stress (MPa) of the femur, the MPa of the implant and the maximum displacement (mm) of the proximal fragment were measured and recorded. The displacement difference

| Material            | Elasticity modulus | Poisson’s ratio |
|---------------------|--------------------|-----------------|
| Cortical bone       | 12.4 GPa           | 0.3             |
| Cancellous bone     | 77 MPa             | 0.3             |
| Titanium alloy      | 114 MPa            | 0.28            |

Fig. 2 Diagram of sliding distance of helical blade in femoral neck in two kinds of implants under different loads

Fig. 3 Pressure cloud diagram of the sliding distance of helical blade in femoral neck in MSN-II and PFNA-II under different loads
between the proximal fragment and the helical blade on the anatomical axis of the femoral neck was defined as the sliding distance of the helical blade in the femoral neck (Fig. 1E). The maximum stress of the femur was defined as the maximum stress on the femoral head. The maximum stress of the implant was indicated by the maximum stress below the junction between the helical blade and the nail. The displacement difference of the proximal fragment on the coronal plane before and after loading was defined as the maximum displacement of proximal fragment (Fig. 1F).

Statistical Analysis
SPSS 22.0 software (IBM Corp., Armonk, NY, USA) was used for statistical analysis in this study. Finite element analysis data such as sliding distance and maximum stress between MSN-II and PFNA-II were statistically compared using the paired t-test. The significance was measured according to a P value of 0.05.

Results
Sliding Distance of Helical Blade in Femoral Neck
Under different loads of 300 N, 600 N, 900 N, 1200 N, 1500 N, 1800 N and 2100 N, the sliding distance of MSN-II and PFNA-II helical blade in femoral neck were 0.1 mm, 0.19 mm, 0.29 mm, 0.37 mm, 0.47 mm, 0.54 mm, 0.65 mm respectively and 0.2 mm, 0.41 mm, 0.62 mm, 0.82 mm, 1.05 mm, 1.23 mm, 1.43 mm respectively. The sliding distance of MSN-II helical blade in femoral neck is less than that of PFNA-II at different loads and the increasing trend of the sliding distance was also significantly smaller than PFNA-II. The sliding distance of helical blade in femoral neck of the two groups under continuous loading was compared...
Maximum Stress of Femur
Under different loads of 300 N, 600 N, 900 N, 1200 N, 1500 N, 1800 N and 2100 N, the maximum stress of femur in MSN-II and PFNA-II were 98.4 MPa, 196.8 MPa, 295.3 MPa, 393.7 MPa, 492.1 MPa, 590.6 MPa, 689 MPa respectively and 103 MPa, 205.9 MPa, 308.9 MPa, 411.9 MPa, 514.8 MPa, 617.8 MPa, 720.8 MPa respectively. The increasing trend of the maximum stress of femur in MSN-II was less than that of PFNA-II under different loads. The maximum stress of the two implants under continuous increasing axial load is shown in Fig. 6 and the pressure cloud diagram is shown in Fig. 7.

Displacement of Proximal Fragment
Under different loads of 300 N, 600 N, 900 N, 1200 N, 1500 N, 1800 N and 2100 N, the displacement of proximal fragment in MSN-II and PFNA-II were 2.41 mm, 4.83 mm, 7.24 mm, 9.64 mm, 12.05 mm, 14.45 mm, 16.84 mm respectively and 2.61 mm, 5.21 mm, 7.81 mm, 10.41 mm, 13.01 mm, 15.6 mm, 18.18 mm respectively. The increasing trend of the displacement of MSN-II was less than that in PFNA-II under different loads. The maximum stress distribution on the femur of the two groups under continuous increasing axial load is shown in Fig. 8 and the pressure cloud diagram is shown in Fig. 9.

Comparison of Biomechanical Characteristics and Statistical Analysis
The sliding distance of helical blade in the MSN-II group decreased by 0.45 mm compared with the PFNA-II group, and the difference was statistically significant ($t = -4.774$, $P < 0.05$). The maximum stress of femur in the MSN-II group decreased by 18.2 MPa compared with the PFNA-II group, and the difference was statistically significant ($t = -4.911$, $P < 0.05$). The maximum stress of nail in the MSN-II group decreased by 18.2 MPa compared with the PFNA-II group, and the difference was statistically significant ($t = -4.796$, $P < 0.05$). The displacement of proximal fragment in the MSN-II group decreased by 0.8 mm.
compared with the PFNA-II group, and the difference was statistically significant ($t = -4.917, P < 0.05$). (Table 2).

**Discussion**

It was found that MSN-II had less sliding distance than PFNA-II in the fixation of medial comminuted intertrochanteric fracture by the finite element analysis. In addition, the maximum stress of femur, the maximum stress of nail and the displacement of proximal fragment in MSN-II group was less than that of PFNA-II group. Therefore, MSN-II may reduce the risk of implant failure by limiting sliding distance and resisting femur medialization.

**Restriction Sliding and Cut out**

Cut out is a common complication of intramedullary nailing, mainly related to the excess sliding of the helical blade or femoral medialization. Goffin et al. found that the part of the femoral head with highest bone density was located in the middle and lower part of the femoral head, and he suggested that the helical blade should be placed in the middle and lower part of the femoral neck, in order to resist the axial pressure to prevent cut out. Kwak et al. conducted a comparative study on Gamma3, Gamma 3 with U-shape blade and PFNA-II by biomechanics, and found that PFNA-II and U-shape blade had better anti-rotation ability. However, even if the blade is placed in the middle and lower 1/3 of the femoral head, the proximal fragment is prone to varus and the blade is cut out. That may be due to the excessive sliding and cutting during weight bearing. The modified MSN (MSN-II) blade, with the addition of a limited sliding groove and the removal of the upper blade which reduced the sliding distance and increasing varus resistance so that the risk of cut out is reduced. In this study, the sliding distance of the MSN-II blade in femoral neck was smaller than that of PFNA-II (Fig. 2), indicating that MSN-II achieved the purpose of avoiding excessive sliding. Meanwhile, less proximal fragment displacement of MSN-II (Fig. 9) also suggested that MSN-II has a better ability to resist varus. The stress concentration on the MSN-II helical blade was less than that of PFNA-II (Fig. 7), indicating that MSN-II achieved the purpose of avoiding excessive sliding. Meanwhile, less proximal fragment displacement of MSN-II (Fig. 9) also suggested that MSN-II has a better ability to resist varus. The stress concentration on the MSN-II helical blade was less than that of PFNA-II in the stress cloud diagram (Fig. 7) suggested that the stress distribution of the helical blade was dispersed because of the proximal triangular configuration. All of these lead to a reduced risk of cutting out or cutting through.

**Medial Support and Coax Varus**

Cephalomedullary nailing is the main treatment for intertrochanteric fracture, in which PFNA-II is the mainstream.

| Biomechanical characteristics          | MSN-II   | PFNA-II | $t$     | $p$     |
|----------------------------------------|----------|---------|---------|---------|
| Sliding distance of helical blade      | 0.37 ± 0.2 | 0.82 ± 0.44 | -4.774  | 0.003   |
| Maximum stress of femur               | 393.7 ± 212.6 | 411.9 ± 222.4 | -4.911  | 0.003   |
| Maximum stress of nail                 | 734.5 ± 390.2 | 831.4 ± 443.6 | -4.796  | 0.003   |
| Displacement of proximal fragment     | 9.6 ± 5.2 | 10.4 ± 5.6 | -4.917  | 0.003   |

**Fig. 9** Pressure cloud diagram of the displacement of proximal fragment in MSN-II and PFNA-II under different loads.
implant, but the complications associated with PFNA-II are as high as 8%–40%, among which the most common is coxa varus, which is also the most serious complication. Once the varus occurs, the success rate of revision is less than 50%. Coxa varus is caused by the comminution of the posteromedial cortex of the femur and the inability to maintain the medial femoral support structure. In addition, PFNA-II could not effectively restore the support of the femoral posteromedial and therefore could not resist coxa varus during weightbearing. That leads to the failure of secondary stability of fracture and the proximal fragment prone to varus. Not only PFNA-II, but existing hip implants are also unable to effectively reconstruct the medial support in an early minimally invasive way. Therefore, many scholars added surgical incision during surgery and used steel wire or additional steel plate for fixation, but increased operative and anestheisa time resulted in more bleeding and increased risk of infection. MSN-II can prevent coxa varus by simply adding medial support screws to fulfill the void between nail and femoral medial cortex without additional incision and forming support for the medial cortex of the proximal fragment. Moreover, the medial support screw is placed under the middle part of the helical blade to disperse the pressure on the helical blade. Part of the stress is transmitted to the distal femur where the bone cortex is thicker and stronger thereby reducing the stress of the helical blade hole in nail and the risk of implant fracture. In this study, the stress on the femur and the nail of MSN-II is smaller than that in PFNA-II (Figs 4 and 6), besides that, the stress on the medial of MSN-II nail is larger than that of PFNA-II and the stress in the proximal of MSN-II nail is less than that of PFNA-II in stress nephogram (Fig. 7) which mean the stress on the proximal femur has been transmitted to distal of nail. In the majority of cases, breakage occurs at the proximal aperture for the cervicocephalic screw. The stress of the proximal aperture for the cervicocephalic screw decreases as the support screw disperses stress to the distal medial side of the nail. As a result of that, the risk of implant breakage is reduced and the pressure distribution between the long reamer and the intramedullary nail of MSN-II was higher than that in the PFNA group (see Fig. 7). In terms of proximal fragment displacement, the MSN-II was smaller than PFNA-II, which also suggested that the risk of coxa varus was lower than that of the PFNA-II in the posteromedial no support intertrochanteric fractures with MSN-II fixation after adjustment of fixation structure.

**Potential Risk**
The medial support screw did not increase the risk of fracture of the lateral femoral wall. The lateral femoral wall is the part of the lateral femoral cortex between the extensions of the superior and inferior femoral neck. The medial support screw is located below this area. That is an increased risk of subtrochanteric fracture after femoral neck fixation with cannulated screws when the distal most screw is placed distal to the lesser trochanter. Kim et al. found that peri-implant atypical femoral fracture may develop through the screw hole at the subtrochanteric or diaphyseal area due to femoral fragility and stress riser effect of the implant. In this study, concentration of stress was not in the femur around the supporting screw but the fracture site in the stress cloud map. Since the function of sliding compression was maintained in the design of MSN-II, such stress concentration can compress at the fracture end and accelerate fracture union. The stress of the lateral femoral cortex in MSN-II is higher than that in PFNA-II, but the stress was evenly distributed in the lateral and lateral cortex of the femur. MSN-II does not have the same stress concentration around the proximal helical blade hole as PFNA-II and is therefore less at the risk of femoral fracture. That maybe since the support screw hole is in the cortical thick region rather than the gradient area of cortical thickness and the small diameter of the support screw which has little influence on the overall stability of the femur. Moreover, the stress of the helical blade hole is transmitted to the distal of the femur. All of the above conditions may be the reason why the support screws did not increase the risk of femoral fracture, however, the actual effect of MSN-II needs further clinical verification.

**Strengths and Limitations**
This study also has some limitations. First, this is simulated mechanical study even though.

simulate the gradual loading of the hip by applying different loads and more studies are needed to confirm this conclusion to ensure that it is not exaggerated. Second, Although the femur model was derived from an elderly woman with osteoporosis, we assumed that the femur was composed of homogeneous and elastic material, and that this homogeneity was sufficient for the purpose of comparing biomechanical properties. So we believe that this study can still provide a reference for clinical treatment.

**Conclusions**
The sliding distance of helical blade in femoral neck, the maximum stress on the femur and nail, and the displacement of proximal fragment of MSN-II were less than those of PFNA-II in the treatment of unstable intertrochanteric fractures. Therefore MSN-II has better stability than PFNA-II and it may have the potential to avoid femur medialization and cut out. It might be an option in unstable trochanteric fractures because of its superiority in restricted sliding and medial support reconstruction.

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**Authors’ Contributions**
All authors had full access to the data in the study and take responsibility for the integrity of the data and the
accuracy of the data analysis. Study concept and design: Licheng Zhang and Peifu Tang. Acquisition of data: Shaobo Nie and Jianhao Li. Analysis and interpretation of the data: Shaobo Nie, Ming Hao and Kun Wang. Drafting of the manuscript: Shaobo Nie and Ming Li. Critical revision of the manuscript for important intellectual content: Licheng Zhang and Peifu Tang. Statistical analysis: Shaobo Nie and Jianhao Li. Obtained funding: Jianhao Li. Administrative, technical and material support: Ying Xiong and Xuewan Gan. Study supervision: Peifu Tang.

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