Application of a Personalized Finite Element Analysis and 3D-Printed Navigation Template in the Treatment of Femoral Neck Fracture with Cannulated Screw

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Abstract

Purpose To investigate the feasibility and accuracy of combining a personalized finite element analysis with 3D-printed navigation template on the treatment of femoral neck fracture (FNF) with cannulated screw.

Methods A total of 60 patients as unstable FNT were evolved and randomly divided into two groups. The subjects in the study group were examined using a finite element analysis according to the three-dimensional CT of hip joint before operation and then underwent 3D-printed navigation template of the femur to complete the implantation of cannulated screw, whereas the other 30 patients in the control group were underwent the implantation of cannulated screw using the conventional FNF treatment.

Results The biomechanics of three screws were more stable when they were close to the bone cortex (<3 mm). Furthermore, it was demonstrated that the patients in the study group had more effectively success rate of one-time nail placement and significant reduction in the distance of talus cortex than those in the control group. At 12 months post-surgery, higher healing rate of fracture and Harris functional score of hip, as well as lower necrosis rate of femoral head were underwent in the study group when compared to the control group.

Conclusion Totally, the combined application of a personalized finite element analysis and 3D-printed navigation template in the treatment of FNF can not only improve the effective nail placement, but also make the screw more in line with the requirements of biomechanical stability to promote the fracture healing and reduce the risk of femoral head necrosis.

Keywords Finite element analysis · 3D-printed navigation template · Cannulated screw · Femoral neck fracture · Digital orthopedic technology

1 Introduction

Recently, femoral neck fracture (FNF) is one of the common clinical fracture in elderly people with two prevalent complications of nonunion and necrosis due to the increased life expectancy, and its incidence is as high as 20–40% in China, therefore reasonable surgery is still the preferred method of treatment to improve the quality of patients, life with FNF [1, 2]. At present, the cannulated screw is the mainly surgical method for the internal fixation, so it is still the hot spot of many studies on the number and layout of the applications of cannulated screw in the surgery. However, there is a consensus because of its different usages. For example, Hao and Dong et al. suggested that four cannulated screws could effectively resist shear force and have stronger biomechanical stability through finite element analysis [3, 4].
while Ying et al. found that it was similar of the stress and displacement distribution of femur using the internal fixator under the fixation methods by the three and four cannulated screws using the finite element method, so in this condition, three cannulated screws with less trauma were recommended [5]. Meanwhile, In terms of spatial layout, Li [6] and Mei et al. [7] researchers found that the best fixation method was stable when three cannulated screws were placed in an inverted isosceles triangle and close to the angle perpendicular to the fracture line using the finite element analysis method. Through the above studies, it is found that all conclusions are based on the finite element analysis.

As we all known, the emergence of 3D printing technology is biomechanically advantageous in the clinical precision treatment [8, 9]. It builds a bridge between the virtual and actual operation. To form a personalized guide plate for the preoperative design of the placement of cannulated screws to accurately place them in the ideal positions, which promotes the development of minimally invasive orthopedics [10, 11]. However, it is not accurate whether our operations can insert the impaction of cannulated screws according to the requirements of the finite in practice. So in our hospital, a total of 60 patients as unstable FNT with cannulated screw were evolved from October 2016 to December 2019. They were randomly divided into two groups (n = 30/group). The subjects in the study group were examined using a finite element analysis according to the three-dimensional CT of hip joint before operation and then underwent 3D-printed navigation template of the femur to complete the implantation of the cannulated screw whereas the other 30 patients in the control group were underwent the implantation of cannulated screw using the conventional FNF treatment in the inverted isosceles triangle. All patients in these two groups (≤ 65 years) were treated within 48 h after the fracture with the indications for internal fixation with three cannulated screws such as Garden type I and II FNF without displacement, without nerve or vascular injury, dislocation of hip joint and acetabular fracture with the complete follow-up data. While FNF patients presenting with any of the following were excluded from this study: the age of FNF patients was more than 65 years old, the fracture time was more than 48 h, Garden type III and IV FNF with obvious displacement without the indications for internal fixation, patients with intertrochanteric fracture or pathological fracture and the follow-up data were incomplete.

All subjects in this study were provided the informed consent prior to the enrollment, and this study was approved by the ethics committee of Qingdao hospital affiliated to Shandong First Medical University (Approval number: 20160077).

## 2 Materials and Methods

### 2.1 Patients

According to strict inclusion and exclusion criteria, a total of 60 patients as unstable FNT with cannulated screw were evolved in this study between October 2016 and December 2019 in Qingdao hospital affiliated to Shandong First Medical University. They were randomly divided into two groups (n = 30/group) based on the patients preference such as the control group and study group. To be exact, the subjects in the study group were examined using the a finite element analysis according to the three-dimensional CT of hip joint before operation and then underwent 3D-printed navigation template of the femur to complete the implantation of cannulated screw, whereas the other 30 patients in the control group were underwent the implantation of cannulated screw using the conventional FNF treatment in the inverted isosceles triangle. All patients in these two groups (≤ 65 years) were treated within 48 h after the fracture with the indications for internal fixation with three cannulated screws such as Garden type I and II FNF without displacement, without nerve or vascular injury, dislocation of hip joint and acetabular fracture with the complete follow-up data. While FNF patients presenting with any of the following were excluded from this study: the age of FNF patients was more than 65 years old, the fracture time was more than 48 h, Garden type III and IV FNF with obvious displacement without the indications for internal fixation, patients with intertrochanteric fracture or pathological fracture and the follow-up data were incomplete.

All subjects in this study were provided the informed consent prior to the enrollment, and this study was approved by the ethics committee of Qingdao hospital affiliated to Shandong First Medical University (Approval number: 20160077).

### 2.2 Preoperative Preparation of a Personalized Finite Element Analysis

As the fracture type of each FNF patient among the 60 subjects was not exactly the same. So the finite element analysis of simulated reduction and implant nail was carried out for each different patient to obtain common mechanical changes, which was not analyzed the simulation using a standard model. So the preoperative preparation of a personalized finite element analysis was as follows [12, 13]. Firstly, the natomical and dual source force third generation spiral CT was used to scan the middle and upper segments of bilateral femurs (the tube voltage was 120 kV, tube current was 350mAs and slice thickness was 0.5 mm). The data from Dicom3.0 thin layer image was exported. Secondly, the exported Dicom image data was imported into the medical modeling software (Mimics21.0). According to the CT values in the different tissues, the three-dimensional masks of different femoral fracture blocks were obtained using the threshold segmentation, pruning, intelligent filling and other tools in the segment module. Based on the three-dimensional mask calculation, the three-dimensional model was generated, the fracture was accurately and anatomically reduced using the model movement and rotation tools. The model after the reduction was copied into the contra-lateral position by the mirror function, and the model was accurately registered with the contra-lateral model. The simulated fracture line formed on the contra-lateral model was deleted. Meanwhile, the first group of three cylinders was a diameter of 7.3 mm, the distance between the outer edge of cylinder with femoral neck was 3 mm, the other was 5 mm. Thirdly, the
conducted the verification to ensure the accuracy of the FE model and convergence. The two groups of cylinder models (3 and 5 mm) were imported into 3-MATIC, and the optimized fracture models were respectively copied and assembled with non-manifold, and then the volume mesh was generated for the assembled model. Fourthly, the generated volume mesh was led back to the MIMICS. Then the femoral model was assigned material by the assignment module according to the following conditions, in which the mass density was 1.067×Hu + 131, the elastic modulus was 0.01×r^3(1.86) and the Poisson's ratio was 0.3. The cylindrical models of these two groups using the simulated implant nails were that the mass density was 4500, the elastic modulus was 55,000 and Poisson’s ratio was 0.33. The volume mesh was assigned with material and exported to the cbd format. The volume mesh assigned to the material was exported to cbd format for standby. Fifthly, the generated cbd format file was imported into the finite element analysis software ansys (ANSYS19.0) to set various imposed conditions. Taking the contact point between the top of femoral head and acetabulum as the center, the circular surface with a diameter of 15 mm was selected as the force application surface, and a force of 500 N was applied on the surface when the weight of the patients was 80 kg. The bottom surface of the femur model was completely constrained. The contact area between each simulated implant nail and femur was set as the friction, the friction coefficient was set as 0.6, and the friction coefficient was set as 0.3.

Meanwhile, the information about FE mesh convergence was included before the study. We should set up the mesh size at 0.01 m and mesh elements about 782 to apply the force and torque T on the component. In addition, the holes were fixed since it was connected to the ground to record the distribution of the total deformation and normal stress on the component, which was clear that the range of total deformation is from 0 to 1.2328×10^{-5} and the maximum deformation existed at the top surface of cylinder, which had been proved by the other researchers [12–14], in which ite mesh quality had also been verified. What is more, we had also used a small sample size follow-up study before this research and conducted the verification to ensure the accuracy of the FE model and convergence.

2.3 The Operation and Treatment

All patients were operated by the same group of physicians using the combined spinal epidural anesthesia. After the anesthesia, the patients were lay flat on the operating bed, in which the affected limb was connected to the orthopedic traction bed in the straight and mild internal rotation position, and the healthy hip joint was fixed in the flexion abduction external rotation position. The patients in the study and control groups were closed reduction under the C-arm fluoroscope, and a straight incision under the greater enchancer was taken with a length of 5–8 cm.

The details were as follows: In the study group, after separating the cortical bone below the greater trochanter, the 3D-printed navigation template was tightly attached to the lateral side of cortical bone, and then the Kirschner wire was implanted with the help of the guide hole, and the Kirschner wire was finally drilled and nailed. While in the control group, the angle of cannulated screw was evaluated according to the CT image data of hip joint among the FNF patients, and then the cannulated screw placement was completed with the help of common guide device under C-arm fluoroscope according to the experience of the operators.

2.4 Postoperative Treatment

After the operation, the affected limb was immediately kept in the abduction neutral position with anti rotation device to reduce the stress on the fracture. The antibiotics were used to prevent infection within 24–48 h after the operation, while the routine administration of analgesic drugs and low molecular weight heparin sodium was used to prevent the thrombosis. After the anesthesia, quadriceps isometric contraction training and ankle pump functional exercise were started. On the second day after the operation, the patients were guided to bend the hip without weight, and the affected limb was not lifted off the bed. 12 weeks after the operation, the affected limb began partial weight-bearing exercise and gradually increased to full weight-bearing activity. The X-ray and CT of hip joint were reexamined on the third day after the operation to analyze the fracture reduction and distribution of screws in the femoral neck.

2.5 Indexes of the Subjects in this Study

The success rate of one-time implantation of cannulated screw, the postoperative shortest distance of talus cortex, and healing rate of fracture, necrosis rate of femoral head and Harris function scores of hip joint were recorded by following up 3, 6, 9 and 12 months after the operation, in which the criteria of fracture healing was that the fracture end was bridged and callus was formed by X-ray, which could be free movement and slight tenderness at the fracture end. The criteria of delayed fracture healing was that the fracture end had not healed and the formation of callus was not obvious by X-ray at 4–6 months after operation. The criteria of not fracture healing was that the fracture was not healed and there was tenderness at the fracture end by X-ray at 9 months after operation. In this condition, the healing rate of fracture was that (fracture healing patients + delayed healing patients)/total number of patients×100% [14].
2.6 Statistical Analysis

All data were expressed as Mean ± Standard deviation and percentage (%) using the SPSS 21.0 software. Normality of the distributions was assessed using the Kolmogorov–Smirnov test. Differences between the two groups were analyzed using t test and Chi square test, while the Mann–Whitney U test was used for the data that was not normally distributed. P values < 0.05 was considered significant.

3 Results

3.1 Basic Characteristics of the Subjects

The basic characteristics of the subjects in this study was shown in Table 1 (n = 30). No significant differences were found in the indicators of sex (P = 0.793), age (P = 0.486), causes of injury (P = 0.787) and garden classification (I/II) (P = 0.739) between these two groups.

3.2 Suitable Model of Talus Cortex Edge Using the Finite Element Analysis

According to the results on the displacement and stress of the finite element analysis by observing the cloud image results of 3 mm and 5 mm models of talus cortex edge under the same mechanical conditions, the stress was mainly concentrated in the fracture area to the cannulated screw. As shown in Fig. 1, the maximum displacement and stress of 3 mm model of talar cortex (maximum displacement-0.92715 mm; maximum stress-64.733 MPa) (Fig. 1a and c) was significantly lower than that of the 5 mm (maximum displacement-0.94085 mm; maximum stress-69.308 MPa) (Fig. 1b and d). So the 3 mm model of talar cortex had more reliable biomechanical stability. The best nail placement channel was obtained and 3D-printed navigation template on the outer side of the upper femur was made based on the results of the above finite element analysis (Fig. 2).

3.3 Comparison of the Effects of the Operation

As shown in Fig. 3, the reduction of FNF was good under the X-ray both in the control (Fig. 3a) and study groups (Fig. 3e). However the position and angle of the cannulated screw placement was better using the 3D-printed navigation template technology (Fig. 3f) than that by the traditional surgery method (Fig. 3b). Besides, the success rate of the first vertebral screw (93.33% vs 66.67%) were higher in the study group with shorter distance between cannulated screw and cortex D (3.04 ± 0.39 mm vs 5.38 ± 0.71 mm) than those in the control group (Table 1).

3.4 Comparison of the Effects on the Postoperative Follow-Up

Within the postoperative follow-up (1 month or 12 months), the fracture healing was poor and the femoral head had cystic changes under the CT scan in the control group (Fig. 3c, d), while in the study group, the femoral neck fracture had healed and the screw position was good under the X-ray (Fig. 3g, h). At the 12-month-follow-up, the healing rate of fracture was higher (96.67% vs 80.00%) and the necrosis rate of femoral head was lower (3.33% vs 20.00%) in the study group than those in the control group. All patients in these two groups exhibited the similar Harris scores with no significant difference were observed (Table 1).

4 Discussion

FNF is a common intra-articular fracture in elderly people, with the 3.6% of total fractures and 48%-54% of hip fractures [14, 15]. Recently, it is the public method by using the closed

| Table 1 | Comparison of observation indexes between the study and control groups |
|-----------------|-----------------------------|---------------------|---------------------|
|                | Control group (n = 30) | Study group (n = 30) | t/x^2  | P        |
| Sex (man, %)   | 12 (40.00%)            | 13 (43.33%)          | 0.069  | 0.793   |
| Age (year)     | 46.97 ± 7.15           | 45.63 ± 7.56         | 0.702  | 0.486   |
| Cause of injury (fall/accident) | 19/11                  | 20/10                | 0.073  | 0.787   |
| Garden classification (I/II) | 6/24                   | 5/25                 | 0.111  | 0.739   |
| Success rate of the first vertebral screw (%) | 20 (66.67%)           | 28 (93.33%)          | 6.667  | 0.010   |
| The shortest distance between cannulated screw and cortex D (mm) | 5.38 ± 0.71            | 3.04 ± 0.39          | 15.853 | <0.001  |
| Follow-up in 12 months Fracture healing rate (%) | 24 (80.00)             | 29 (96.67)           | 4.043  | 0.044   |
| The rate of femoral head necrosis (%) | 6 (20.00)              | 1 (3.33)             | 4.043  | 0.044   |
| Harris score   | 91.57 ± 4.18           | 93.67 ± 4.01         | 1.985  | 0.052   |
Fig. 1 Cloud diagram of maximum stress and displacement analysis. 
\(a\) Maximum stress of the 3 mm model of talar cortex, \(b\) maximum stress of the 5 mm model of talar cortex, \(c\) maximum displacement of the 3 mm model of talar cortex, \(d\) maximum displacement of the 5 mm model of talar cortex

Fig. 2 The appropriate 3D-printed navigation template based on the results from the finite element analysis. \(a\) Overall view of 3D-printed navigation template with the side hole, \(b\) the 3D-printed navigation template was attached to the outside of the upper end of the femur, \(c\) the position of the screw was simulated by the anteroposterior display, \(d\) the position of the screw was simulated by the lateral position
reduction and internal cannulated screw fixation in the treatment of FNF [16]. Due to a significant poor closed reduction and unstable fixation, the curative effect of FNF is still not satisfactory and the probability of postoperative nonunion and necrosis of femoral head fluctuates are 20–40% although the bio-mechanical research of FNF and the improvement of fixation methods are constantly improved [17–19]. It is conducive to the stability and healing rate of fracture only when the fracture surface is compressed and the implanted internal fixation meets the requirements of uniform stress distribution and minimum fracture displacement under the maximum stress after the fixation of the fracture, which is necessary to consider the biomechanical characteristics after the implantation of cannulated screw [20]. As we all known, a good stable internal environment can promote the fracture healing and the evenly distributed stress of internal fixation can be effectively fixed to avoid the loosening and fracture of the internal fixation [21, 22]. There are many factors influencing the stress after the implantation of cannulated screws, such as the number, angle, position and etc. of the implantation. In the present study, it is considered the stability using the three cannulated screw with inverted triangular dispersion distribution [23]. However, due to the irregular anatomical structure of the femoral neck and complexity of human mechanics experiments, it is difficult to guarantee whether the angle and position of cannulated screw can meet the characteristics of biomechanical stability, so the reliability of fixation is also difficult to guarantee.

Recently, the finite element analysis is mostly used to discuss the researches on the biomechanical stability of FNF to evaluate the stress distribution [24, 25]. As a theoretical method, it can simulate geometric models of various structures and endow various tissue biomaterials with properties to reflect their biomechanical properties under non-invasive condition. The finite element analysis has its unique advantage on completing the complex intra-articular fractures which are difficult to complete the biomechanical research through human mechanical experiments [26]. The results of our study demonstrated that the finite element analysis could simulate the mechanical test of the proximal femur.

Fig. 3 The implantation of cannulated screw placement. a–d were shown the implantation of the intraoperative screw placement in the control group by hands. a The reduction was good under the X-ray, b the position and angle of the cannulated screw placement was not good by the traditional method, c the screw was withdrawn under the X-ray within postoperative 1 month, d the fracture healing was poor and the femoral head had cystic changes under the CT scan within postoperative 12 months. e–h were shown the implantation of the intraoperative screw placement in the study group using the 3D-printed navigation template technology. e The reduction was good under the X-ray, f the placement of Kirschner wire was completed with 3D-printed navigation template technology, and the display position, depth and angle were good, g the screw was inserted after drilling along the Kirschner wire, h the femoral neck fracture had healed and the screw position was good under the X-ray within postoperative 12 months.
to divide the complex whole into a collection of finite elements, which could provide help for the mechanical analysis of the proximal femur. Although there is a theoretical basis on discussing the best angle and position of cannulated screw implantation by the finite element analysis, it is still a difficulty that how to estimate the best position of cannulated screw implantation because of the instability of the operator, which needs to be completed through the nail channel. In this way, the emergence of 3D-printed navigation template can perfectly solve the above problem. The present study, as well as the results from the previous study [23, 25], 3D-printed navigation template was made at the proximal lateral femoral nail placement to complete the nail placement through the personalized finite element analysis of every FNF patient, which can not only shorten the operation time, reduce the number of intraoperative fluoroscope and improve the efficiency of the operation, but also be closer to the femoral neck cortex in the position and angle of the nail placement. In the line with the results of finite element analysis, the stress distribution was more diffuse, with smaller displacement peak under the maximum stress, so the biomechanics was more stable. Within the 12-month follow-up of all patients, it was also confirmed that the healing rate of FNF treated with 3D printing guide plate was higher and the necrosis rate of femoral head was lower in the study group than that in the control group. The reasons were that the angle and position of the cannulated screw needed to be constantly adjusted by the traditional surgical method to aggravate the trauma and destroy the blood supply of the fracture end and femoral head. Meanwhile, the replacement of cannulated screw further destroyed the cancellous bone to reduce the holding strength of the screw to result in decreasing the fixation strength and increasing the fretting of the fracture end, which could affect the fracture healing. Based on the experience of our study, we can summarize the advantages as follows: Firstly, the best channel for the cannulated screw placement to meet the biomechanical stability can be determined by the finite element analysis. Secondly, the cannulated screw placement can be completed at one time to reduce the secondary trauma by combined with 3D-printed navigation template, which is conducive to fracture healing and reduce the rate of femoral head necrosis. Thirdly, compared with the traditional method, the application of a personalized finite element analysis and 3D-printed navigation template in the treatment of femoral neck fracture with cannulated screw can not only improve the effective nail placement, but also make the screw more in line with the requirements of biomechanical stability to promote the fracture healing and reduce the risk of femoral head necrosis. In this condition, Individualization and accuracy are the development direction of the orthopedics in the future. The continuous improvement and optimization progress of digital orthopedic technology such as finite element analysis and 3D-printed navigation technology will promote the development of the clinical popularization.

5 Conclusion

In summary, the results of this study suggest that combined application of a personalized finite element analysis and 3D-printed navigation template in the treatment of femoral neck fracture with cannulated screw can not only improve the effective nail placement, but also make the screw more in line with the requirements of biomechanical stability to promote the fracture healing and reduce the risk of femoral head necrosis. In this condition, Individualization and accuracy are the development direction of the orthopedics in the future. The continuous improvement and optimization progress of digital orthopedic technology such as finite element analysis and 3D-printed navigation technology will promote the development of the clinical popularization.

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Author Contributions  Sizhe Wang designed this study, interpreted the data and wrote the manuscript. Bin Wang, Xiaoquan Lan and Zhenzhen Xu did all the experiments and interpreted all the results. Haoran Huang and Xiaolong Wang performed the operation. Shibin Shen and Jianlin Ma supervised the manuscript. All authors read and approved the final manuscript.

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Declarations

Conflict of interest  The authors had not received any funding or benefits from industry or elsewhere to conduct this study.

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