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 with cannulated screw were evolved in this study from October 2016 to December 2019, who were randomly divided into two groups (n=30/group): 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 the cannulated screw whereas the other 30 patients in the control group were underwent the implantation of the cannulated screw using the conventional FNF treatment in the inverted isosceles triangle. The success rate of one-time implantation of the cannulated screw, the postoperative shortest distance of talus cortex, and the healing of fracture, necrosis of femoral head and Harris function scores of hip joint in 12 months after operation were recorded and compared between the study and control groups.

Results: According to the finite element analysis, the biomechanics of three screws were the most stable when they were close to the bone cortex (<3mm). Further more, it was demonstrated that the patients in the study group have more effectively success rate of one-time nail placement (93.33%) and significant reduction in the distance of talus cortex of cannulated screws (3.04 ± 0.39mm) than those in the control group (66.67% and 5.38±0.71mm). At 12 months post-surgery, higher healing rate of fracture (93.33%) and Harris functional score of hip (93.67 ± 4.01), as well as lower necrosis rate of femoral head (6.67%) were underwent in the study group when compared with the control group (83.33%, 91.57±4.18 and 16.67%).

Conclusion: 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. So it is a digital orthopedic technology for clinical popularization.

1. Introduction

Recently, femoral neck fracture (FNF) is one of the common clinical fracture in elderly people with two prevalent complications of the 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 the studies on the number and layout of the applications of the cannulated screw. However, there is a consensus because of the different usage of the cannulated screw. For example, Hao Z and Dong R et al suggested that four cannulated screws could effectively resist shear force and have stronger bio-mechanical stability through finite element analysis[3, 4], while Ying W 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 when using finite element method, so in this condition, three cannulated screws with less trauma were recommended[5]. Meanwhile, In terms of spatial layout, Li Z [6] and Mei J 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 the 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 the cannulated screws to accurately place them in the ideal position, which promotes the development of minimally invasive orthopedics[10, 11]. However, it is not accurate whether our operations can insert the impaction of the 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 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 the cannulated screw whereas the other 30 patients in the control group were underwent the implantation of the cannulated screw using the conventional FNF treatment in the inverted isosceles triangle to investigate the feasibility and accuracy of combining a personalized finite element analysis with 3D-printed navigation template on the treatment of FNF with cannulated screw.

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 to 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: 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 the cannulated screw, whereas the other 30 patients in the control group were underwent the implantation of the cannulated screw using the conventional FNF treatment in the inverted isosceles triangle.

All patients in the study and control groups (≤ 65 years) were treated within 48h after the fracture with the indications for internal fixation with three cannulated screws such as the 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 the present study: the age of the FNF patients was more than 65 years old, the fracture time was more than 48 hours, 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 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.

2.2 Preoperative preparation of the finite element analysis

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 120KV, tube current was 350mAs and slice thickness was0.5mm). The data from the Dicom3.0 thin layer image was exported. Secondly, the exported Dicom image data is 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 7.3mm, the distance between the outer edge of the cylinder with femoral neck was 3mm. The other was 5mm. Thirdly, the contra-lateral model with simulated fracture was imported into the medical design software (3-MATIC), then the model surface and triangular patch was optimized and unified by smoothing, wrapping, meshing and other functions. The two groups of cylinder models (3mm and 5mm) 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 femoral model was assigned material by the material assignment module according to the mass density was $1.067\times Hu + 131$, elastic modulus was $0.01\times r^{(1.86)}$ and Poisson's ratio was 0.3. The cylindrical models of the two groups were assigned material while the mass density was 4500, elastic modulus was 55000 and Poisson's ratio was 0.33. 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 15mm was selected as the force application surface, and a force of 500N was applied on the surface when the weight of the patients was 80kg. 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.

2.3 The operation method 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 study and control groups were closed reduction under the C-arm fluoroscope, and a straight incision under the greater enchanter was taken with a length of about 5-8cm. 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 the 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 by 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 hours after 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 operation, the patients were guided to bend the hip without weight, and the affected limb was not lifted off the bed. 12 weeks after 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 the distribution of screws in the femoral neck. The patients were followed up 3, 6, 9 and 12 months after the operation. The fracture healing and femoral head necrosis were recorded during the follow-up, and Harris hip function score was also performed.

2.5 Indexes of the subjects in this study

The success rate of one-time implantation of the cannulated screw, the postoperative shortest distance of talus cortex, and the healing of fracture, necrosis of femoral head and Harris function scores of hip joint in 12 months after operation were recorded and compared between the study and control groups.

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 were considered significant.

3. Results

3.1 Basic characteristics of the subjects

The basic characteristics of the subjects in the study and control groups was shown in Table 1 (n = 30). No significant differences were found in the indicators of sex (P = 0.793, 13 man and 17 woman in the study group, 12 man and 18 woman in the control group), age (P = 0.486, 45.63 ± 7.56 years in the study group, 46.97 ± 7.15 years in the control group), cause of injury (P = 0.787, 20 cases of fall injury and 10 cases of traffic accident injury in the study group, 19 cases of fall injury and 11 cases of traffic accident injury in the control group) and garden classification (□/□) (P = 0.739, 5 cases of Garden type I and 25 cases of Garden type II in the study group, 6 cases of Garden type I and 24 cases of Garden type II in the control group) between the 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 the 3mm model of talar cortex (maximum displacement-0.92715mm; maximum stress-64.733MPa) (Fig. 1a and c) was significantly lower than that of the 5mm (maximum displacement-0.94085mm; maximum stress-69.308MPa) (Fig. 1b and d). So the 3mm model of talar cortex has more reliable biomechanical stability. The best nail placement channel was obtained and the 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 on surgery

As shown in Fig. 3, the reduction of the 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 ± 0.39mm vs 5.38 ± 0.71mm) than those in the control group (Table 1).

3.4 Comparison of the effects on surgery

Within postoperative follow-up (one 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 and 3d), while in the study group, the femoral neck fracture had healed and the screw position was good under the X-ray (Fig. 3g and 3h). At the 12-month-follow-up, the fracture healing rate was higher (96.67% vs 80.00%) and the rate of femoral head necrosis 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 score with no significant difference 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 the hip fractures[12, 13]. Recently, it is the public method by using the closed reduction and internal cannulated screw fixation in the treatment of FNF[14]. 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[15–17]. It is conducive to the stability and healing 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 fracture fixation, which is necessary to consider the biomechanical characteristics after the implantation of the cannulated screw[18]. 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[19, 20]. 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 stability using the three cannulated screw with inverted triangular dispersion distribution[21]. However, due to the irregular anatomical structure of the femoral neck and the 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 was mostly used to discuss the researches on the biomechanical stability of FNF to evaluate the stress distribution[22, 23]. 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[24]. The results of our study demonstrated that the finite element analysis can simulate the mechanical test of the proximal femur to divide the complex whole into a collection of finite elements, which can 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 [21, 23], 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 the 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: (1) The best channel for the cannulated screw placement to meet the biomechanical stability can be determined by the finite element analysis. (2) 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. (3) Compared with the traditional method, the application of a personalized finite element analysis and 3D-printed navigation template in the treatment of FNF is more accurate and efficient on reducing the operation time, intraoperative fluoroscopy times and iatrogenic damage. In spite of the above advantages, there are a number of shortcomings as follow: (1) The finite element analysis is based on the ideal complete anatomical reduction, which is often different from the clinical complex fracture situation. (2) The finite element model is an ideal femoral neck model, not considering the soft tissue around the joint. (3) The production cost of the application of a personalized finite element analysis and 3D-printed navigation template in the treatment of FNF is relatively high and need more time to complete.

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.

Declarations

Authors' 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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Conflict of interest

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

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Tables

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 (/)	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

Figures

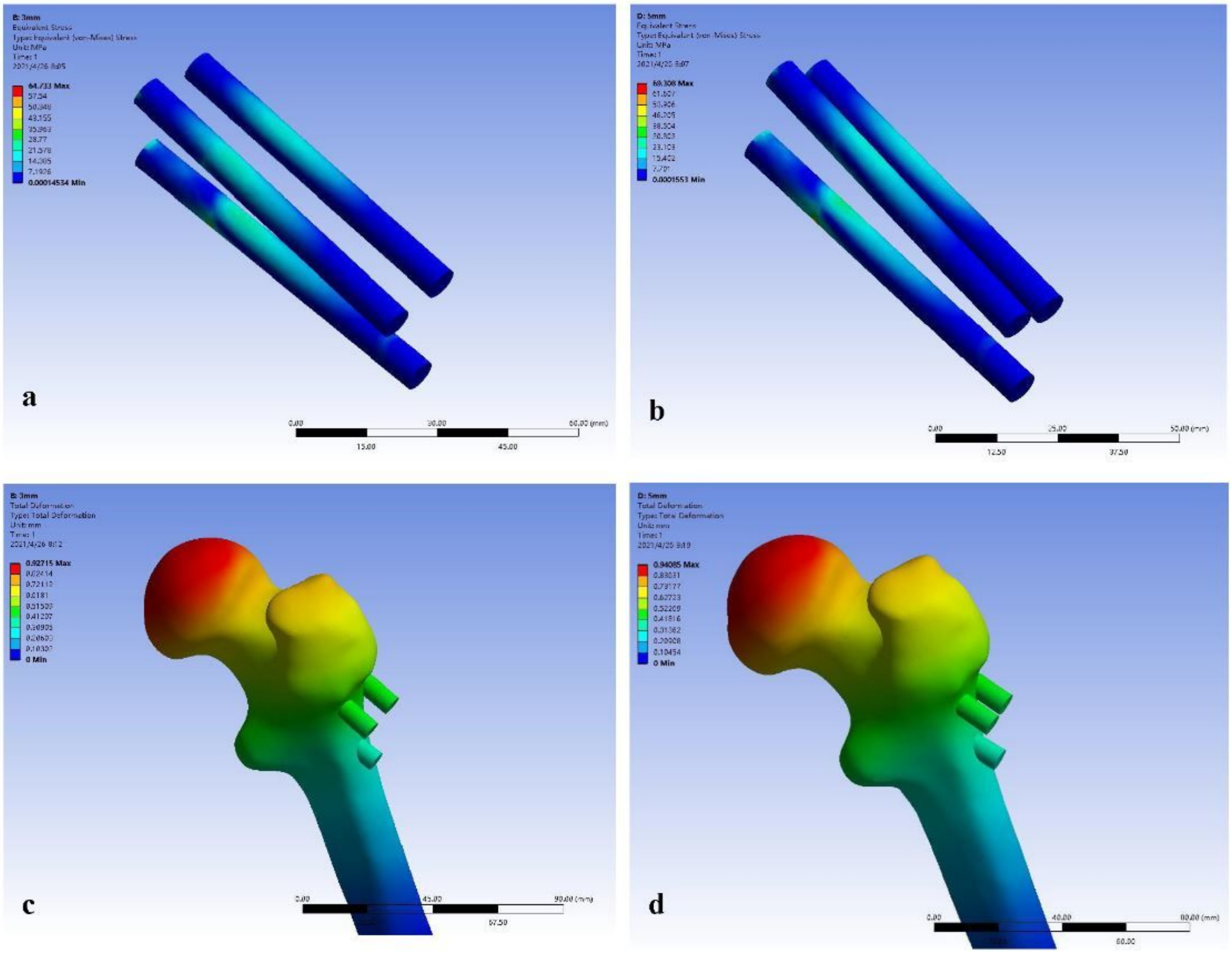

Figure 1

Cloud diagram of maximum stress and displacement analysis Note: a: maximum stress of the 3mm model of talar cortex, b: maximum stress of the 5mm model of talar cortex, c: maximum displacement of the 3mm model of talar cortex, d: maximum displacement of the 5mm model of talar cortex.

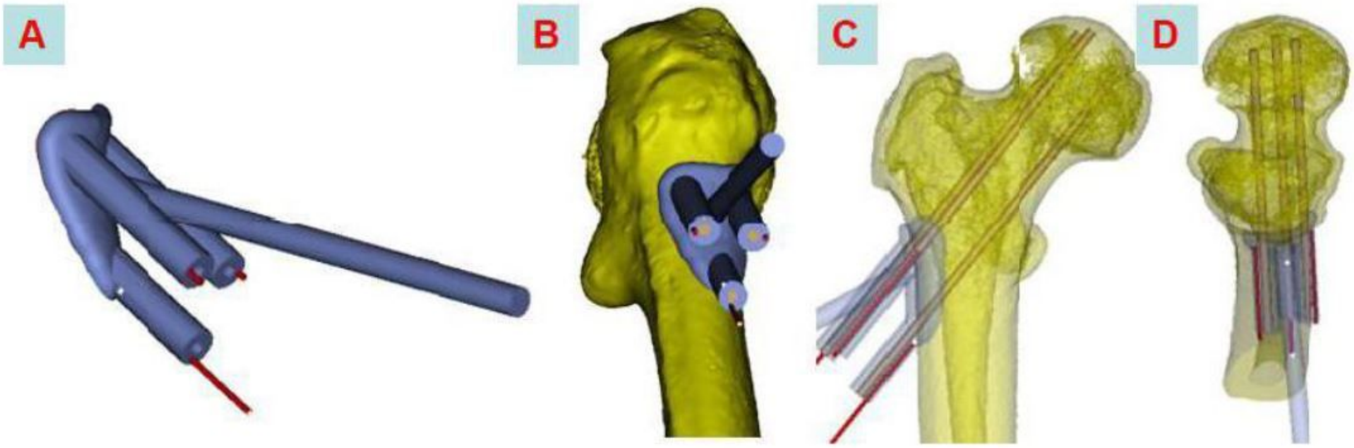

Figure 2

The appropriate 3D-printed navigation template based on the results from the finite element analysis Note: 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.

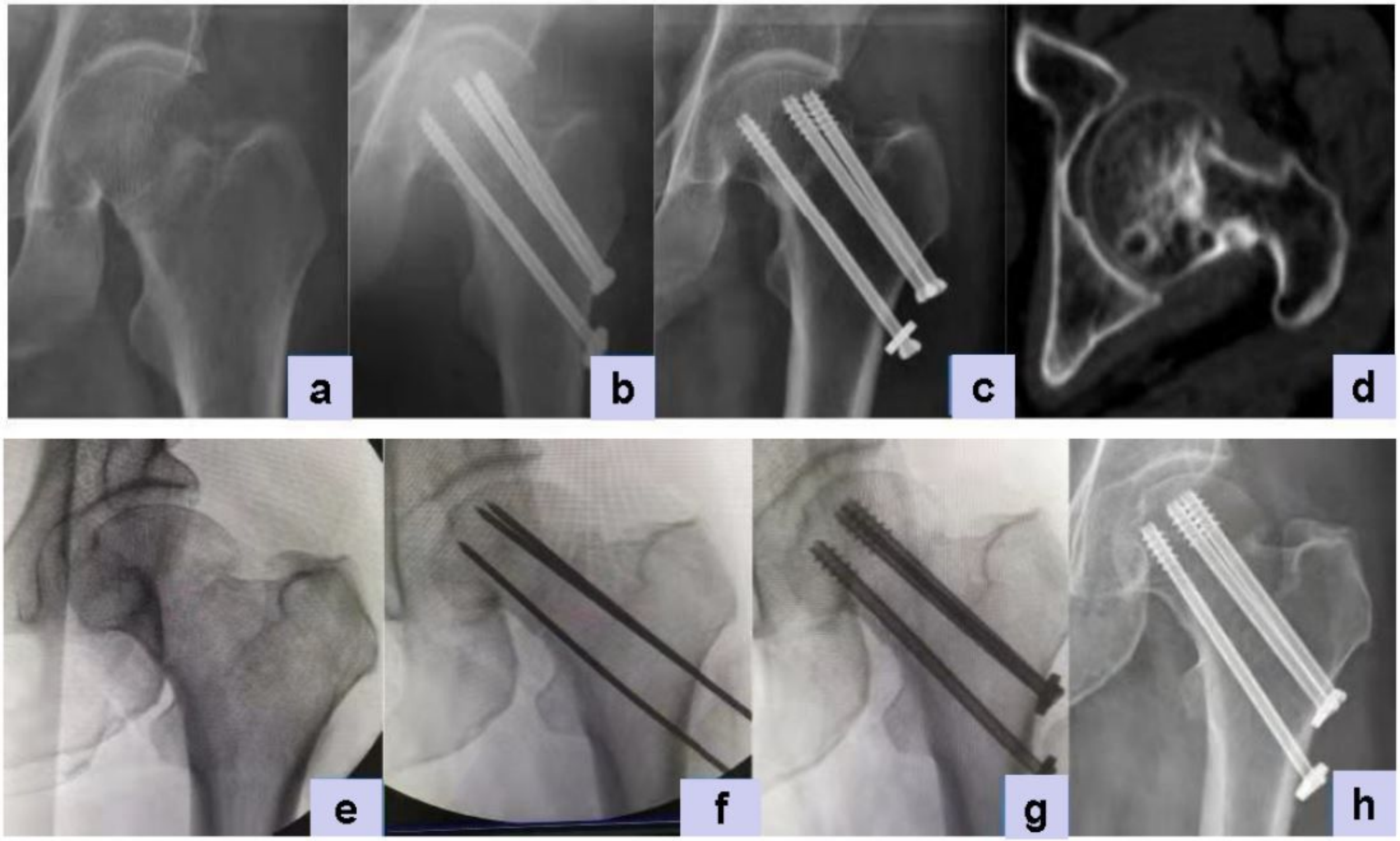

Figure 3

The implantation of the cannulated screw placement between these two groups Note: a, b, c and 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 one month, d: The fracture healing was poor and the femoral head had cystic changes under the CT scan within postoperative 12 months. e, f, g and 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.