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*Original Article*

# Finite element analysis of minimally invasive osteotomy fixation using oblique hollow headed compression screws and K-wires for hallux valgus osteotomy

Yu Gan[1*], Shuai Wu[2*], Hongfei Zhang[3]

[1]*School of Clinical Medicine, Shandong Second Medical University, Weifang 261053, Shandong, China;* [2]*Department of Orthopaedics, The Second Affiliated Hospital of Xuzhou Medical University, Xuzhou 221006, Jiangsu, China;* [3]*Joint Surgery Department II, Affiliated Hospital of Shandong Second Medical University, Weifang 261000, Shandong, China.* [*]*Equal contributors and co-first authors.*

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**Abstract:** Objective: To investigate the biomechanical fixation characteristics after osteotomy for hallux valgus using K-wires and oblique hollow headed compression screws through finite element analysis (FEA). Methods: Foot computed tomography (CT) data from a female patient with hallux valgus were collected and imported into Mimics 21.0 software to create a three-dimensional (3D) model. The model was then refined using Geomagic 2021 software, followed by simulation of surgical procedures (including osteotomy and internal fixation) in SolidWorks 2021. The specimens were divided into two groups: Group A fixed with K-wires, and Group B fixed with oblique hollow headed compression screws. The models were imported into ANSYS software for meshing, material assignment, and data analysis. Displacements and stress distributions under different loading conditions were compared between the two groups. Results: Under two different load conditions, the following findings were observed: ① The maximum displacement of the first metatarsal in the hollow headed compression screw group was less than that of the K-wire group. ② The maximum displacement and maximum stress of the internal fixation device in the screw group were less than those of the K-wire group. The hollow headed compression screw provided superior lateral and vertical stability compared to K-wires. ③ The maximum stress on the osteotomy surface of the first metatarsal in the screw group was greater than that in the K-wire group, indicating better compression at the osteotomy site with the screw. Conclusion: Overall, fixation with oblique hollow headed compression screws exhibited better biomechanical performance and fixation stability for osteotomy in hallux valgus correction.

**Keywords:** Hallux valgus, finite element analysis, minimally invasive surgical procedures, osteotomy

## Introduction

Hallux valgus deformity is a common foot deformity characterized primarily by lateral deviation of the great toe and subluxation or complete dislocation of the first metatarsophalangeal joint. Clinically, it manifests as forefoot pain, deformity, difficulty in wearing shoes, and other functional impairments [1]. Hallux valgus cannot self-correct and requires treatment through conservative management or surgical intervention. When conservative treatments fail to relieve symptoms or affect daily life, surgical correction should be considered. Currently, over 150 surgical procedures have been reported for the treatment of hallux valgus [2].

According to the foundational and recent studies by Redfern and colleagues [3, 4], traditional open surgeries for hallux valgus often require extensive soft tissue stripping. This extensive dissection can lead to several disadvantages, including a higher risk of joint stiffness, delayed wound healing, severe postoperative pain, and prolonged recovery periods. In contrast, minimally invasive surgery (MIS) offers significant biomechanical and clinical advantages. Redfern's research [4] highlighted that MIS techniques minimize soft tissue disruption and preserve the periosteal blood supply. Consequently, this results in reduced postoperative pain, lower risks of wound complications, faster rehabilitation, and improved cosmetic out-

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comes, all while achieving reliable and comparable deformity correction to open techniques. In recent years, minimally invasive surgery (MIS) has been gradually applied to treat hallux valgus due to its multiple advantages, including shorter operative time, reduced postoperative pain, decreased need for anesthesia, and faster recovery [5]. Compared to open surgery, MIS has demonstrated favorable outcomes, with Bösch's procedure and Giannini's percutaneous osteotomy being among the most comprehensively reported techniques [6]. Clinical studies on the fourth-generation MIS techniques, which are newly proposed, have gradually been conducted, showing good clinical and imaging results [7]. Bösch's procedure and Giannini's percutaneous osteotomy use primarily K-wires for fixation, whereas the fourth-generation MIS employs two fully threaded screws for stabilization. Besides osteotomy, clinical follow-up evidence also exists for soft tissue reconstruction strategies [8]. For example, procedures using interosseous wire bands to correct first metatarsal varus and ligament balancing have been shown to significantly improve relevant functional scores during mid-term follow-up, with manageable complication rates, providing a non-osteotomy alternative for moderate to severe hallux valgus. Given the limitations of traditional cadaver experiments [9], such as sample heterogeneity and reproducibility of loading, finite element analysis (FEA) is increasingly becoming an effective tool to validate the biomechanical properties of different surgical designs and fixation methods [10]. The CT data used for FEA include the complete geometry of the first metatarsal and adjacent bones; image processing involves threshold segmentation (bone tissue threshold range: 226-3071 Hounsfield units) to extract cortical and cancellous bone structures; and three-dimensional reconstruction is performed based on voxel-based surface meshing at a slice thickness of 1 mm.

To investigate the effects of various minimally invasive osteotomy techniques for hallux valgus, this study employed finite element analysis to compare the fixation stability and biomechanical performance of K-wire fixation versus oblique hollow-headed compression screw fixation after distal osteotomy of the first metatarsal.

## Materials and methods

### *Study design*

Finite element analysis was used to compare the biomechanical effectiveness of fixation methods following distal osteotomy of the first metatarsal, specifically between oblique hollow headed compression screw fixation and K-wire fixation.

### *Time and location*

The experiment was conducted from June 2024 to August 2024 at the Department of Orthopedics, Second Affiliated Hospital of Shandong Medical University.

### *Subjects*

A 45-year-old female patient with hallux valgus was selected. She weighed 60 kg and was 164 cm tall. Aside from the hallux valgus deformity, the patient had no other foot or musculoskeletal injuries or symptoms. The study was approved by the Ethics Committee of the Second Affiliated Hospital of Shandong Medical University (wyfy-2024-kv-430), and the patient provided informed consent. The patient was positioned standing, and thin-slice CT scans of the right foot were performed (bone window, slice thickness 1 mm), yielding foot bone CT data stored in Digital Imaging and Communications in Medicine (DICOM) format.

The use of a single patient's anatom data to construct the finite element model is a standard and widely accepted approach in computational biomechanics. This method acts as a strict internal control, eliminating confounding variables such as inter-individual differences in bone geometry, bone mineral density, and soft tissue volume. Consequently, any differences observed in the biomechanical outcomes (stress and displacement) can be exclusively attributed to the different internal fixation methods (K-wires vs. screws) rather than anatomic variations.

### *Methods*

*Data collection and 3D model construction:* Data collection involved scanning the right foot of a female volunteer with hallux valgus using a 64-slice spiral CT scanner from the distal tibia

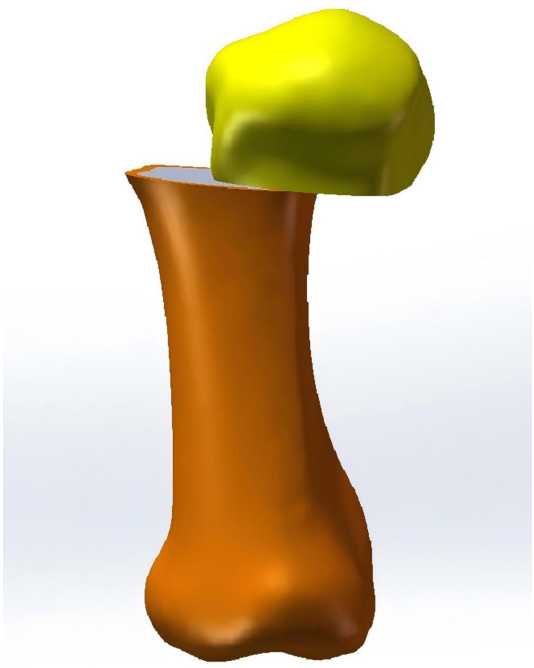

**Figure 1.** Distal osteotomy model of the first metatarsal. The model was obtained following completion of the osteotomy procedure in SolidWorks. The post-osteotomy first metatarsal model comprises the proximal bone segment and the laterally translated distal bone segment, interfaced by partial contact at the osteotomy surface. This osteotomy model serves as the shared skeletal base for both internal fixation groups.

to the toe. The resulting two-dimensional cross-sectional images, with a slice thickness of 1.0 mm, were saved in DICOM format. The obtained foot CT data were imported into Mimics 21.0 software for threshold segmentation (bone tissue threshold range: 226-3071 Hounsfield units), mask editing, region growing, and removal of artifacts. A complete, homogeneous 3D model of the first metatarsal was reconstructed and saved as an STL file. This STL file was then imported into Geomagic Wrap 2021 for surface processing and feature optimization, including modeling of cortical and cancellous bone. After finalization, the model was saved in STEP format and imported into SolidWorks 2021 for assembly, creating a detailed 3D model of the first metatarsal.

*Establishment of the osteotomy and internal fixation models:* A distal first metatarsal osteotomy model was established using SolidWorks 2021 through a simulated surgical procedure. A transverse osteotomy was created approximately 2 cm distal to the first metatarsal head by defining an osteotomy plane oriented at 10°relative to the longitudinal axis of the metatarsal. The metatarsal head was subsequently translated laterally by approximately 8 mm to obtain the distal osteotomy model (**Figure 1**). Based on clinical practice, internal fixation constructs were developed in SolidWorks 2021. Two K-wires with a diameter of 2.0 mm were modeled; for simplification, they were represented as two parallel cylindrical rods and assembled with the distal first metatarsal osteotomy model (**Figure 2**). Additionally, two obliquely oriented cannulated compression screws (3.5 mm and 4.0 mm in diameter) were created and similarly simplified as cylindrical structures for assembly with the osteotomy model (**Figure 2**). The insertion points of the screws were defined to coincide with those of the K-wires to ensure consistency and comparability of fixation trajectories.

*Material property definitions:* The first metatarsal was assumed to be a continuous, homogeneous, isotropic linear elastic material. Based on previous literature [11], the elastic modulus and Poisson's ratio for cortical bone, cancellous bone, and internal fixation devices (K-wires and screws) were set as shown in **Table 1**.

*Mesh generation:* Finite element meshing was performed using Ansys 2021 software. The mesh size for the cortical and cancellous bone of the first metatarsal model was set to 1 mm. The K-wire and screw meshes had average element sizes of 0.2 mm and 0.75 mm, respectively. All meshes were set as tetrahedral elements. The mesh was further refined for the first metatarsal and the internal fixation components. The final mesh consisted of approximately 118,752 to 151,463 elements, with 189,681 to 238,596 nodes (**Figure 3**).

*Contact conditions setup:* Contact conditions were defined for different parts of the model based on typical finite element modeling principles for orthopedic biomechanics [11, 12]. The cancellous and cortical bones at the same site were set as bonded contacts, assuming no relative motion. Different bone regions were set as frictional contacts with a coefficient of friction of 0.60, simulating physiological sliding between bone fragments. The interface between the K-wire and bone was set as a fric-

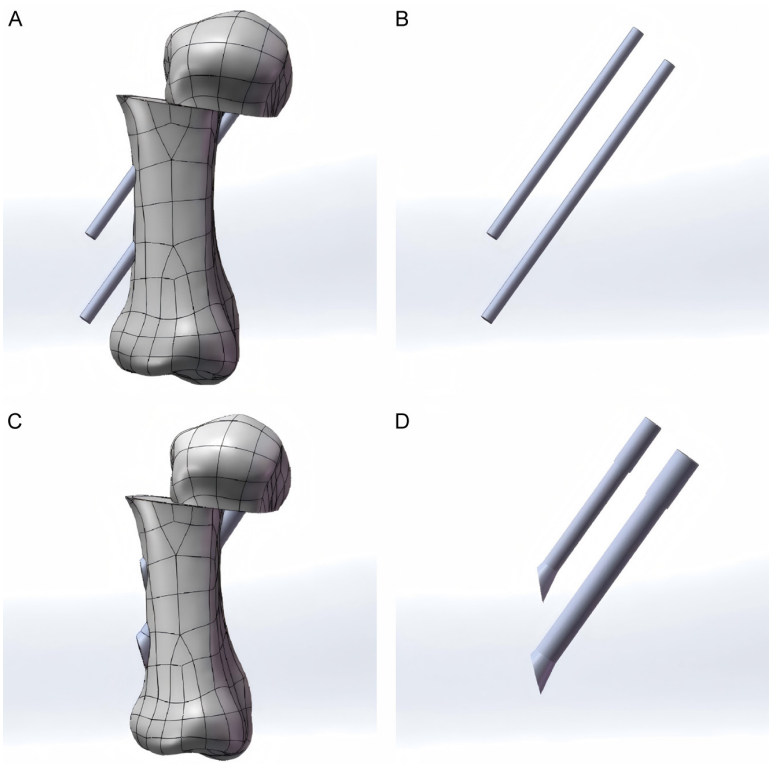


**Figure 2.** Internal fixation models - K-wire fixation and oblique hollow headed compression screw fixation. A. K-wire distal osteotomy model of the first metatarsal; B. Oblique hollow headed compression screw distal osteotomy model of the first metatarsal; C. K-wire model; D. Equivalent model of the oblique hollow headed compression screw.

**Table 1.** Material properties of the first metatarsal and internal fixation devices [10, 11]

| Material | Elastic Modulus (MPa) | Poisson's Ratio |
|---|---|---|
| Cortical Bone | 7300 | 0.3 |
| Cancellous Bone | 100 | 0.3 |
| K-wire | 187500 | 0.3 |
| Screw | 200000 | 0.3 |

tional contact with a coefficient of 0.2, reflecting typical metal-bone friction. The contact between the oblique hollow-headed compression screw and the proximal end of the metatarsal was set as bonded, while the contact between the screw and the distal fracture site was set as frictional with a coefficient of 0.4 to allow controlled micromotion.

*Load application:* Based on previous biomechanical analyses of the first metatarsal [13-15], the loading conditions were approximated as follows: 1) The proximal articular surface of the first metatarsal was fixed, constraining the degrees of freedom in the X, Y, and Z directions. 2) In Group A, the load application point was located on the bottom surface of the head of the first metatarsal, forming a 75° angle with the axis of the first metatarsal, simulating the upward force experienced during standing, with a magnitude of 90 N (**Figure 4**). 3) In Group B, the load application point was on the medial surface of the head of the first metatarsal, perpendicular to its longitudinal axis, simulating lateral forces exerted by ligaments, muscles, and other soft tissues, with a magnitude of 90 N. Mechanical analysis was performed using Ansys Workbench 2021R1 software (**Figure 5**).

*Main observation indicators*

The following indicators were extracted from the finite element analysis results using the post-processing module of Ansys Workbench (von Mises stress and total deformation outputs): (1) Peak displacement of the osteotomy site in Groups A and B; (2) Peak displacement of the internal fixation devices in Groups A and B; (3) Stress distribution and peak stress values in the internal fixation devices in Groups A and B; (4) Stress distribution and peak stress values on the osteotomy surface in Groups A and B. These data were used to evaluate and compare the fixation effectiveness.

*Statistical analysis*

As the present study was based on finite element simulation analysis, statistical hypothesis testing was not performed. All results were derived from numerical outputs of the computational model. Descriptive statistics were used for analysis, and differences of less than 5% were considered comparable. Future clinical investigations with appropriate statistical methods will be conducted to validate these biomechanical findings.

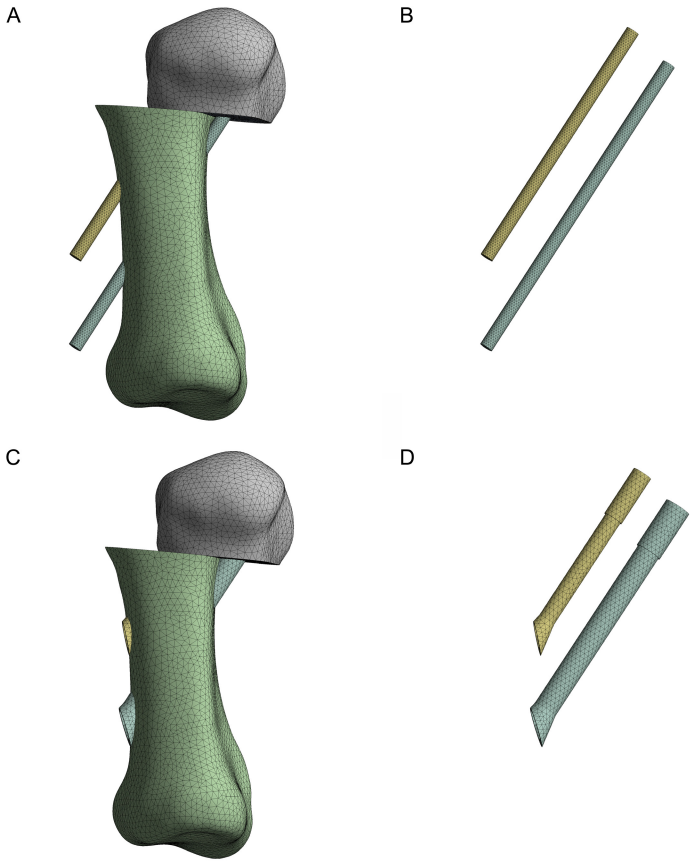


**Figure 3.** Finite element mesh models. A. Mesh model of the first metatarsal osteotomy with K-wire fixation; B. Mesh model of the K-wire; C. Mesh model of the first metatarsal osteotomy with oblique hollow headed compression screw fixation; D. Mesh model of the oblique hollow headed compression screw.

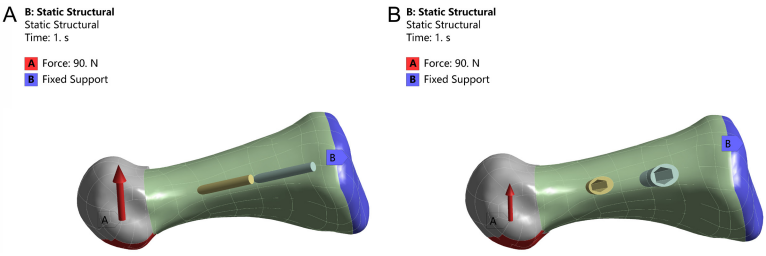


**Figure 4.** Group A - First metatarsal models under vertical load with boundary conditions. A. Group A1: Loading and boundary condition model for K-wire fixation under vertical stress applied to the first metatarsal; B. Group A2: Loading and boundary condition model for oblique hollow headed compression screw fixation under vertical stress applied to the first metatarsal.

## Results

After finite element analysis of models in Groups A and B under two different mechanical loading conditions, a total of four data sets were obtained. The results demonstrated that K-wires and oblique hollow headed compression screws exhibited different internal fixation effects under the two force conditions (**Table 2**).

*Displacement of the first metatarsal and stress distribution on the osteotomy surface*

In all four models, both fixation methods effectively reduced the peak displacement of the first metatarsal osteotomy. Models B1 and B2 showed smaller vertical and lateral displacements of the first metatarsal osteotomy, indicating superior fixation stability. Displacement mainly concentrated at the top of the metatarsal head joint surface, with similar locations across models; stress on the osteotomy surface was primarily distributed around the force application area. The peak stress on the osteotomy surface in B1 and B2 models was higher than in A1 and A2 models, indicating better compression and stability of the osteotomy site (**Figures 3-8**).

*Displacement and stress distribution of internal fixation devices*

In all four models, the peak displacement of internal fixation devices was concentrated mainly at the distal end of the device, gradually decreasing toward the proximal end. The screws in B1 and B2 models exhibited smaller displacements, showing advantages in maintaining vertical and lateral stability. Stress concentrations in the fixation devices occurred at the fracture gap and at contact points between K-wires or screws and bone, related to the direction of applied forces. The peak stresses in screws in B1 and B2 models

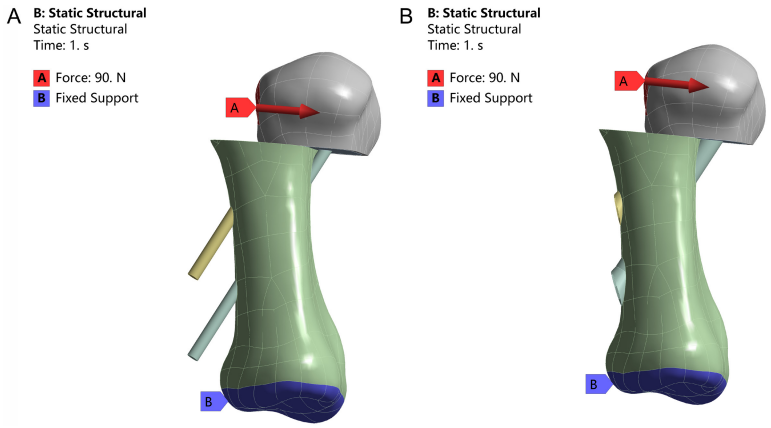


**Figure 5.** Group B - First metatarsal models under lateral load with boundary conditions. A. Group B1: Loading and boundary condition model for K-wire fixation under lateral stress applied to the first metatarsal; B. Group B2: Loading and boundary condition model for oblique hollow headed compression screw fixation under lateral stress applied to the first metatarsal.

were higher than in K-wires in A1 and A2 models, demonstrating more effective resistance to shear forces and better stress dispersion (**Figures 6**-**11**).

## Discussion

The primary goal of treating hallux valgus is to correct the deformity and restore foot function. In recent years, MIS and percutaneous procedures have become increasingly popular with advances in technology and auxiliary devices. Significant progress has also been made in the minimally invasive treatment of hallux valgus. Based on studies of the fourth-generation MIS [16], the surgical method using K-wires involves making an incision on the medial side of the first metatarsal head, performing transverse osteotomy at the neck of the metatarsal head with a drill, moving the head laterally to correct the deformity, and then fixing the osteotomy segment with K-wires. This approach aims to achieve deformity correction with small incisions, minimal trauma, and mild postoperative pain. However, the recurrence rate with K-wire fixation is relatively high, possibly because the stress at the osteotomy ends is low during fixation [17]. After 4-6 weeks of healing and removal of the K-wires, the force on the osteotomy ends may suddenly increase, which could be a reason for the high recurrence rate [18]. Clinically, some cases have shown K-wire loosening or backing out, likely related to friction and bending moments between the K-wire and the bone within the osteotomy structure. The fourth-generation MIS [7] represents a significant recent advancement in hallux valgus correction. It combines the transverse osteotomy technique from the second-generation MIS and the internal fixation system using screws from the third-generation MIS [19], enabling strong fixation of the first metatarsal osteotomy segment and achieving reliable deformity correction. Compared to traditional open surgery or earlier minimally invasive procedures, the fourth-generation MIS offers notable improvements in surgical trauma, postoperative recovery, and clinical outcomes [7]. FEA with its high repeatability, reliable data, low experimental costs, and shorter duration, has been widely applied in orthopedic biomechanical research [20]. This study utilized FEA to analyze the biomechanical differences between K-wire and oblique hollow headed compression screw fixation in minimally invasive hallux valgus osteotomy. The quantitative results provide meaningful reference information for surgeons in selecting appropriate implants in clinical practice.

*Results analysis under different loading conditions*

Under a 90 N axial load simulating standing posture, both fixation methods exhibited relatively uniform stress and displacement distributions, with a low overall load level and displacements ranging from 0.5 to 0.7 mm, indicating stable fixation efficacy. Among them, the screw fixation group under vertical load (Type B1) achieved the smallest displacement (0.377 mm) with a peak stress of 92.988 MPa, demonstrating favorable anti-displacement capacity and homogeneous stress distribution. Compared to Kirschner wire fixation, screw fixation reduced femoral displacement by 18.49% and internal fixation device displacement by 21.72%.

Under a 90 N lateral load simulating soft tissue traction, the screw fixation model (B2) still

**Table 2.** Comparison of peak displacement, stress of internal fixation, and osteotomy surface stress under two mechanical loads

| Model (Group) | Peak displacement of the first metatarsal osteotomy (mm) | Peak displacement of internal fixation devices (K-wire, screw) (mm) | Peak stress of internal fixation devices (MPa) | Peak stress on osteotomy surface (MPa) |
|---|---|---|---|---|
| A1 | 0.518 | 0.456 | 256.95 | 36.597 |
| A2 | 1.870 | 1.305 | 574.140 | 21.07 |
| B1 | 0.377 | 0.352 | 92.988 | 50.659 |
| B2 | 1.063 | 0.863 | 145.720 | 46.111 |

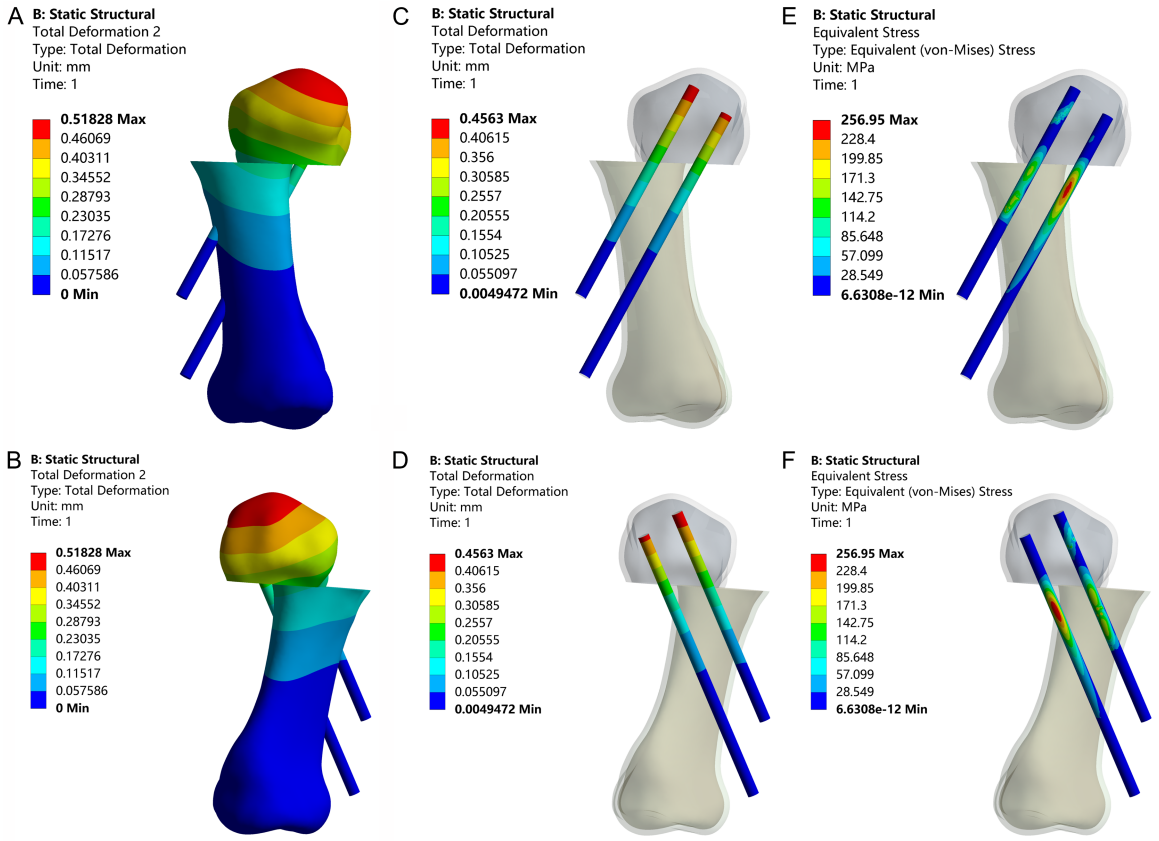


**Figure 6.** Group A1 - Displacement and stress distribution contour maps under vertical load. A, B. Displacement contour maps of the first metatarsal; C, D. Displacement contour maps of the K-wires; E, F. Von Mises stress distribution contour maps of the K-wires.

maintained excellent stability. The peak displacement of the first metatarsal was 1.063 mm, which was 43.2% lower than that of the K-wires fixation model (A2, 1.870 mm). The maximum stress of the internal fixation device in the screw group (145.720 MPa) was significantly lower than that of the Kirschner wire group (574.140 MPa), suggesting superior stress dispersion effect and stronger shear resistance.

*Interpretation of mechanical findings*

Through the experiments, we found that the peak displacement of the first metatarsal in models A1 and A2 fixed with K-wires was 0.518 mm and 1.870 mm, respectively. The peak displacements of the K-wires were 0.456 mm and 1.305 mm. The locations of maximum displacements, as well as the average stress values at multiple points on the osteotomy sur-

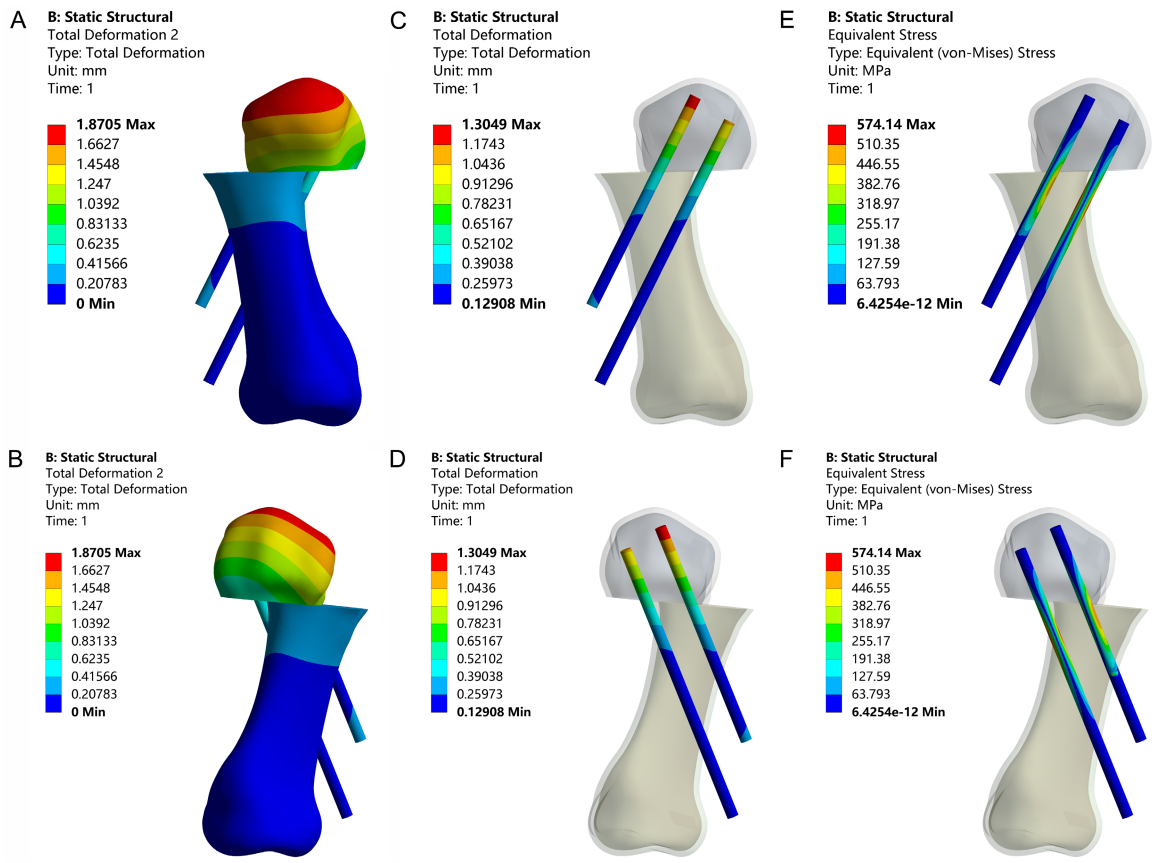


**Figure 7.** Group A2 - Displacement and stress distribution contour maps under lateral load. A, B. Displacement contour maps of the first metatarsal; C, D. Displacement contour maps of the K-wires; E, F. Von Mises stress distribution contour maps of the K-wires.

face, were recorded. For the screw-fixed models B1 and B2, the peak displacements of the first metatarsal were 0.377 mm and 1.063 mm, respectively; the peak displacements of the screws were 0.352 mm and 0.863 mm. These results indicated that under both loading conditions, the oblique hollow headed compression screw and fixation of the first metatarsal osteotomy resulted in smaller relative displacements compared to K-wire fixation. These findings are consistent with the experimental conclusions of Xie et al. [11] and Thomas et al. [7]. Therefore, we believe that the bicortical fixation and compression design of the bevelhead cannulated compression screw confer distinct advantages in maintaining osteotomy stability.

In our study, applying vertical and lateral stresses to the apex of the first metatarsal, the maximum stress in the four models appeared primarily around the fixation devices and the osteotomy perforation sites, suggesting a higher risk of fixation failure due to fracture or damage to the distal cancellous bone. The results also showed that the peak stresses in K-wire fixation were higher than those in oblique hollow headed compression screw fixation. Stress concentration indicates potential risks of internal fixation failure. However, the peak stresses in K-wires did not reach the yield strength of medical titanium alloy implants, and their excellent fatigue resistance and durability under high-cycle fatigue conditions suggest that all constructs are fundamentally safe and reliable [21]. Nonetheless, excessively high stress peaks imply that the cancellous bone at contact points must withstand corresponding destructive forces, which could damage the cancellous bone and lead to fixation failure.

From the results, the magnitude of stress on the fixation devices was influenced mainly by the insertion position. Fixation devices near the

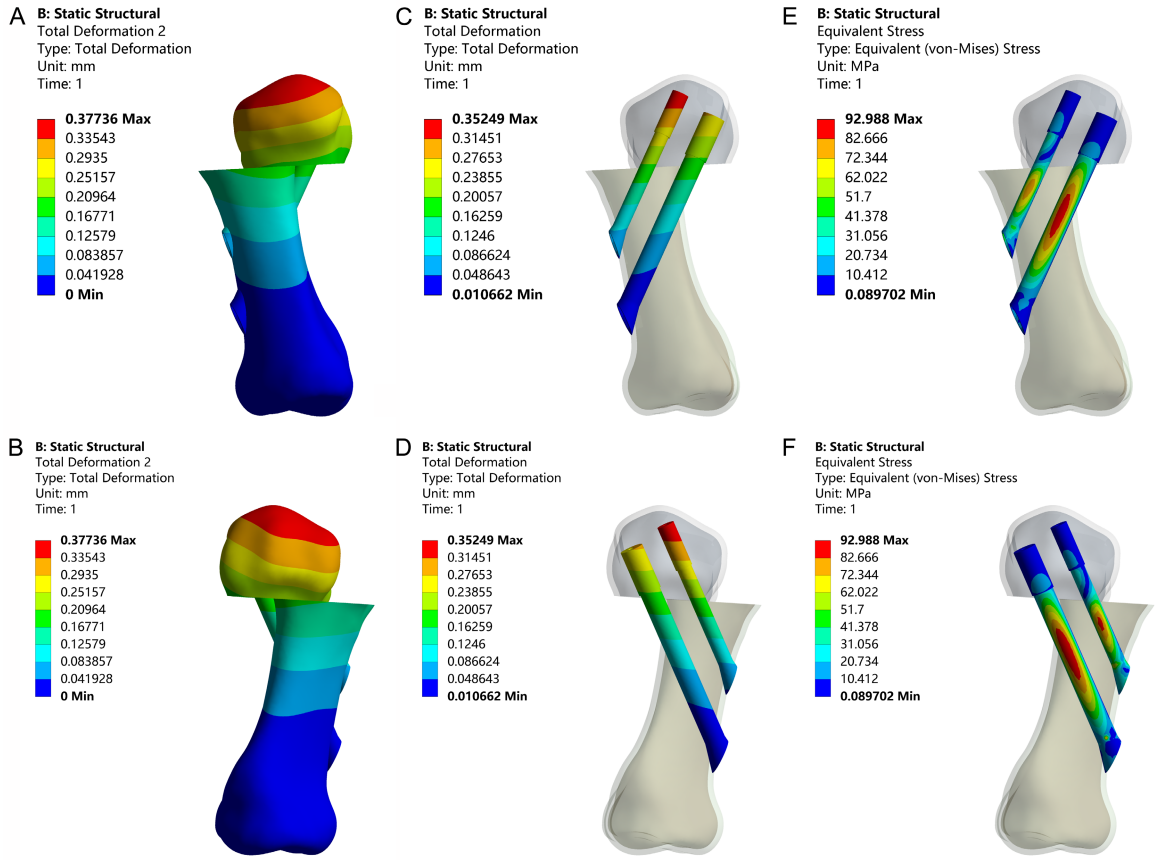


**Figure 8.** Group B1 - Displacement and stress distribution contour maps under vertical load. A, B. Displacement contour maps of the first metatarsal; C, D. Displacement contour maps of the oblique hollow headed compression screws; E, F. Von Mises stress distribution contour maps of the oblique hollow headed compression screws.

proximal end of the first metatarsal could bear more stress. The fourth-generation fixation devices penetrate two layers of cortical bone at the proximal end, increasing stability. The oblique hollow headed compression screw, due to its structural design, provided strong support after osteotomy, exerting better compression and stabilization at the osteotomy site. In our experiments, under a 90 N load in two directions, the maximum stress on the osteotomy surface was concentrated on the side bearing the load. Among the four models, the peak stresses on the osteotomy surface in groups A1 and A2 exceeded those in groups B1 and B2, indicating that the oblique hollow-headed compression screw has greater compression force and higher stability compared to K-wire fixation.

In summary, we conclude that the bevel-head cannulated compression screw provides superior overall fixation, with stronger resistance to vertical and lateral loads, better anti-displacement performance, and distinct advantages in fixation strength and stability. Because the screw fixation achieves better functional outcomes, patients can resume functional activities earlier, accelerating recovery. Additionally, the screw's oblique head design allows it to be buried within the tissue, reducing infection risk and easing postoperative management [11]. However, implanting the oblique screw requires high surgical skill, may prolong operative time, and some patients might need a second operation for screw removal [22]. There is also a risk of cortical bone splitting during surgery. Therefore, screw fixation is more costly and technically demanding, increasing the surgical burden and financial costs for patients. K-wire surgery, with its lower difficulty and cost, is suitable for mild to moderate hallux valgus correction, especially in osteoporotic patients, where K-wire fixation may be more effective [15].

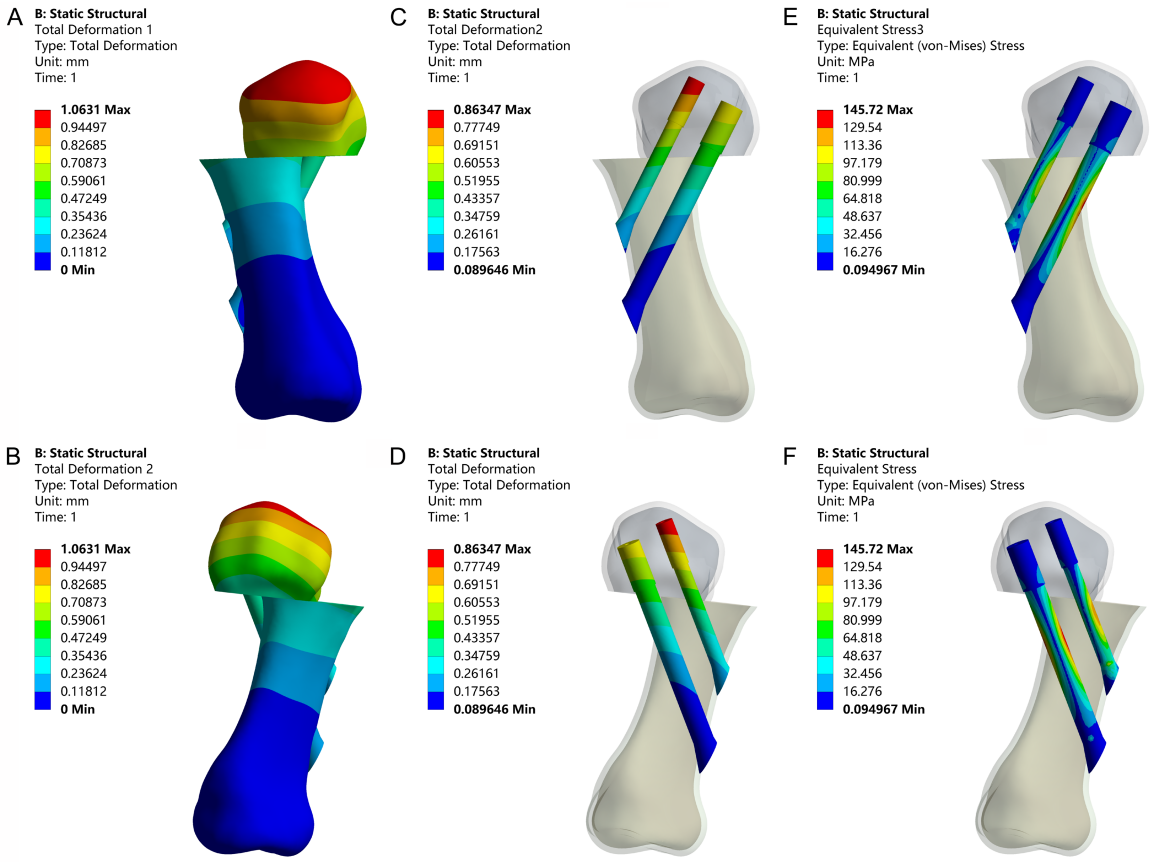


**Figure 9.** Group B2 - Displacement and stress distribution contour maps under lateral load. A, B. Displacement contour maps of the first metatarsal; C, D. Displacement contour maps of the oblique hollow headed compression screws; E, F. Von Mises stress distribution contour maps of the oblique hollow headed compression screws.

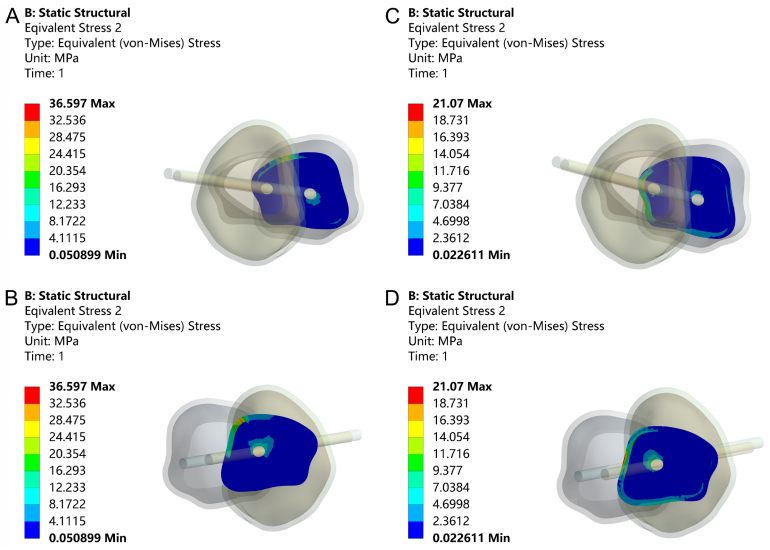


**Figure 10.** Von Mises stress distribution contour maps of the first metatarsal osteotomy surface under vertical load. A. Stress distribution on the metatarsal head osteotomy surface in Group A1; B. Stress distribution on the metatarsal shaft osteotomy surface in Group A1; C. Stress distribution on the metatarsal head osteotomy surface in Group B1; D. Stress distribution on the metatarsal shaft osteotomy surface in Group B1.

*Limitations of this study*

FEA was used to simulate the biomechanical effects of forces on the first metatarsal during hallux valgus deformity, aiming to ensure the accuracy and reliability of the internal fixation models. Considering the differences in size and shape among the first metatarsal, K-wires, and screws, we adjusted the mesh sizes for each component accordingly. Given the irregular shape of the first metatarsal, tetrahedral meshing was chosen for dense discretization, resulting in a total of 118,752-151,463 elements and 189,681-238,596 nodes, with validation of mesh quality to ensure the results'

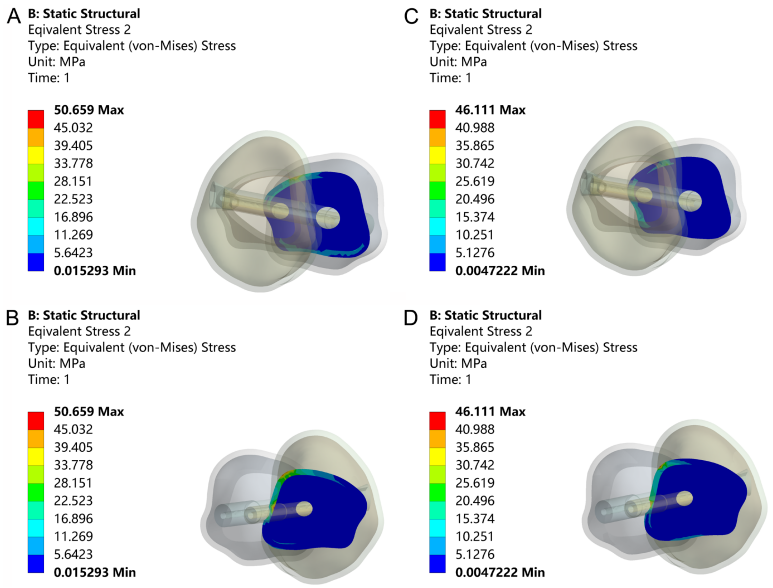


**Figure 11.** Von Mises stress distribution contour maps of the first metatarsal osteotomy surface under lateral load. A. Stress distribution on the metatarsal head osteotomy surface in Group A2; B. Stress distribution on the metatarsal shaft osteotomy surface in Group A2; C. Stress distribution on the metatarsal head osteotomy surface in Group B2; D. Stress distribution on the metatarsal shaft osteotomy surface in Group B2.

authenticity. The four finite element models of the first metatarsal internal fixation established in this study are reliable and can provide a theoretical basis for selecting suitable implants, offering clinical reference. However, real surgical conditions, such as soft tissue coverage over the first metatarsal surface and individual anatomical variations, cannot be perfectly simulated. Moreover, this study only examined hallux valgus in a single individual subjected to vertical and lateral forces, without exploring multi-dimensional force scenarios or dynamic loading. Although single-patient models are standard in finite element analysis to isolate and compare the mechanical properties of different fixation methods, the generalizability of the absolute stress values to the broader population is limited. However, the primary objective of this study was to perform a controlled, head-to-head relative biomechanical comparison. By applying different fixation methods to the exact same bone geometry, we effectively eliminated inter-subject anatomic variability as a confounding factor, thereby isolating the mechanical effects of the implants. Future studies incorporating multi-patient statistical shape modeling or probabilistic finite element analysis are necessary to confirm the generalizability of these findings. Therefore, the findings have limitations and require further validation through clinical trials and long-term follow-up. Finally, *in vitro* biomechanical experiments and clinical studies should validate the FEA results. While FEA provides a robust framework for comparing different fixation methods, experimental data are needed to confirm these findings under real world conditions.

The simulation results indicate that, under both load conditions, the choice of fixation method directly affects the stability of the osteotomy. Oblique hollow headed compression screw fixation exhibits superior biomechanical stability. While these results aim to provide a theoretical basis for clinical practice, they are limited by the study's constraints and should be considered only as a reference.

## Disclosure of conflict of interest

None.

**Address correspondence to:** Hongfei Zhang, Joint Surgery Department II, Affiliated Hospital of Shandong Second Medical University, No. 2428 Yuhe Road, Kuiwen District, Weifang 261000, Shandong, China. E-mail: zhf131@126.com

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