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Comparing the stability of a novel h-shaped bone plate and commercial endosteal plating systems in hallux valgus correction

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Abstract

Background It is common for physicians to opt for surgical correction of hallux valgus deformities using implants, but post-operative complications are frequently reported. A novel h-shaped plate developed by the authors offers both endosteal and lateral fixation, helping to resist displacement in multiple directions. This study aims to assess the mechanical properties and stability of the h-shaped plate in comparison to various commercially available endosteal plating systems in a simulated hallux valgus correction model using finite element analysis.

Methods Finite element models of four different endosteal plates were developed and used to simulate a hallux valgus correction. The distal end of the metatarsal in each model was loaded at 87.5 N, which is the maximum load experienced during cyclic testing. The load was applied in various directions to simulate different metatarsal movements, including plantar flexion, dorsiflexion, abduction, and adduction of the first metatarsal bone. The mechanical properties and stability of each model was recorded for comparison.

Results When placed under dorsal-to-plantar loading, the model with a h-shaped plate was the most stable of all models, with a displacement of 0.278 mm, plate stress of 429.51 MPa, and screw stress of 294.97 MPa. Under medial-to-lateral loading, the model with a h-shaped plate demonstrated the lowest displacement of 0.152 mm, and plate and screw stresses of 254.27 MPa and 195.40 MPa, respectively.

Conclusion For stabilizing distal chevron osteotomies, the h-shaped bone plate showed greater resistance to displacement in the dorsal-to-plantar and medial-to-lateral directions than the commercially available implants evaluated in this study. The h-shaped plate also presented a lower risk of screw pull-out, which helps to maintain bone alignment postoperatively.

Keywords Hallux valgus, Bone plate, Endosteal, Chevron osteotomy, Finite element

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Introduction

Correcting hallux valgus can be challenging for orthopedic surgeons, particularly in cases with severe bone deformities. Hallux valgus is a multiplanar deformity in the forefoot often associated with a medial bony bump at the first metatarsophalangeal joint, which can progressively worsen over time. The bony bump can be caused by a number of factors, such as valgus phalangeal deviation, first metatarsus primus varus, and soft tissue imbalance [1].

Over the years, surgical strategies for treating hallux valgus have changed drastically. Historically, soft tissues resection was typically used to correct deformities of the forefoot, but more recently surgeons have opted for rebuilding the bone shape through osteotomy using bone plates or staples [2]. As with all implants, bone plates and staples used for osteotomies have been reported with complications such as hardware failure (breakage, loosening, dislocation), malalignment, nonunion, and recurrence of deformity [1]. Alternatively, percutaneous approaches without internal fixation have provided positive outcomes, effectively correcting deformities while significantly improving function and alleviating pain [3]. Similarly, the Bosch osteotomy has provided valuable insight into surgical indications for realigning the first metatarsal and addressing moderate to severe deformities, and thereby broadening the understanding of hallux valgus correction [4]. Minimally invasive distal metatarsal osteotomies also offer additional benefits, such as reduced operative time, faster discharge, and potential cost savings [5].

The shortcomings with traditional correction methods emphasize the importance of personalized treatment planning and highlight the need for further research and clinical trials to assess the safety and efficacy of minimally invasive surgical (MIS) techniques [6, 7]. Despite growing interest in MIS for hallux valgus correction, the efficacy of such methods is not well understood because of the limited studies and publications around this. Well-designed randomized clinical trials are essential to establish clear guidelines for the systematic application of MIS. While preliminary results are encouraging, substantial clinical heterogeneity remains a challenge to developing definitive recommendations [8].

Additionally, while revision surgery may be required to correct a complication and can yield satisfying results through accurate preoperative planning [9], some patients have reported dissatisfaction or further complications following the revision [10, 11]. As such, the initial stability of the implant and bone are important considerations when designing a fixation device.

Endosteal plating techniques developed for treating distal femoral nonunions and humeral fractures have been reported with good alignment reduction and fracture stability, even in locations with poor bone quality [12, 13]. Recently, various endosteal plating techniques have been introduced for hallux valgus correction, such as the 4.0 ChLP System Endosteal Plate (ChM sp. z o.o., Poland), 2.4 mm Av-Wiselock endosteal plating system (Auxein Medical Pvt. Ltd, India), Mini Maxlock Extreme ISO Plate (Wright Medical Group N.V., USA), Aplus Spear plate (A Plus Biotechnology Co. Ltd, Taiwan), and the V-TEK plate system (Zimmer Biomet, USA). While each of these products can be used to treat a Z-shaped shaft osteotomy and the distal end is secured using 1 or 2 screws, there are key differences in the design and fixation of the proximal end of the plate. There are three main fixation types for the proximal endosteal surface. The first type uses 2 locking bicortical screws to force the endosteal plate against the far medial or lateral endosteal surface of the first metatarsal (V-TEK plate). The second type uses a curved plate that is press-fit into the cut bone and does not require screws on the proximal end for fixation (4.0 ChLP System Endosteal Plate, Av-Wiselock endosteal plating system). The third type is fixed by 1 locking screw inserted into the plate that protrudes through the dorsal cortex (ISO Plate, Aplus Spear Plate) to push the plate against the far lateral endosteal surface of the first metatarsal.

Most endosteal plating techniques developed for hallux valgus correction have focused on surgical technique and correction of the deformity. However, the mechanical stability of different implant designs used for correction, such as with a distal chevron osteotomy has not been reported previously. Due to the complex loading conditions, the initial stability of the fixation must resist displacement between the two bones to provide a stable environment for bone healing. To our knowledge, no published literature has compared the mechanical stability of various endosteal plating techniques used for hallux valgus correction. Besides, we considered that endosteal plating alone cannot provide sufficient mechanical support to the bone. A Taiwanese company, Bing Technology Ltd., developed a novel h-shaped plate for distal osteotomy of the first metatarsal for use in hallux valgus correction. The h-shaped plate offers endosteal plating fixation and lateral plating fixation to resist displacement in all directions. The aim of this study is to investigate the mechanical properties and stability of the h-shaped plate and compare the results to different commercially available endosteal plates in a simulated hallux valgus correction model using finite element analysis.

Methods

Model construction

A 30-year-old female patient weighing 60 kg and height of 1.67 m without any history of foot and ankle trauma, deformity, or other diseases of the lower extremities was

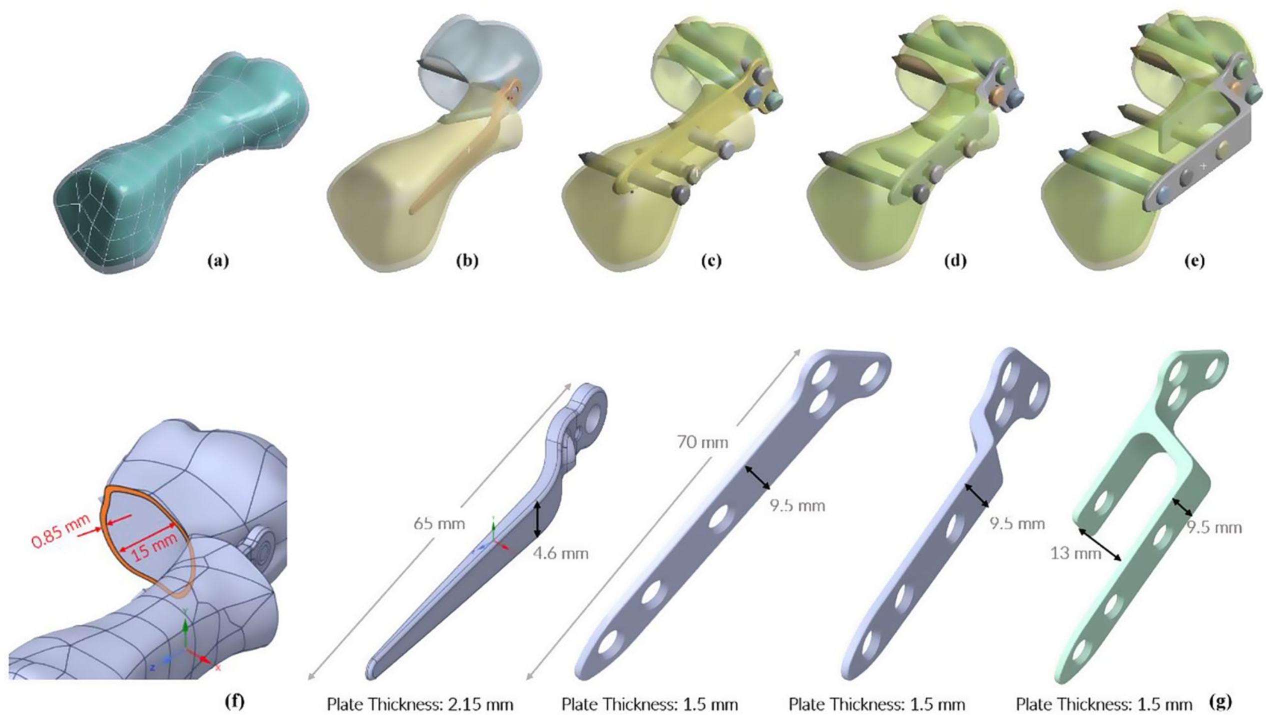

Fig. 1 Three-dimensional model of **a**) the first metatarsal of the right foot, **b**) metatarsal model with an A-Plus Spear plate, **c**) metatarsal model with a 0 mm offset T-shaped V-TEK plate, **d**) metatarsal model with a 7 mm offset T-shaped V-TEK plate, **e**) metatarsal model with a novel h-shaped plate, **f**) the dimensions of cortical and cancellous bone, **g**) the dimensions of each plate

Table 1 Material properties of the models of the first metatarsal bone and endosteal plating systems

Property	Modulus (MPa)	ν	References
Cortical bone	10,000	0.34	Shih et al., 2023 [14]
Cancellous bone	100	0.3	
Endosteal plating system (Titanium alloy screws and plate)	110,000	0.3	Song et al., 2023 [16]

enrolled in the study. The first metatarsal of the right foot was scanned by CT at intervals of 2 mm. Mimics 16.0 (Materialise, Leuven, Belgium) was used to segment the two-dimensional image, and then a three-dimensional model of bone tissue was created and smoothened using Geomagic Studio 2013 (Geomagic, Inc., Research Triangle Park, NC, United States). The model was then imported into SolidWorks 2020 (SolidWorks Corporation, Waltham, MA, United States) to form solid parts (Fig. 1a). In SolidWorks, the first metatarsal bone was cut and an endosteal plate was used to secure the bone, simulating a hallux valgus surgery. The cut surface of the first metatarsal bone was measured at a point where the cortical bone thickness was between 0.8 and 0.9 mm (Fig. 1). Models of four endosteal plates were developed and tested: (i) A-Plus Spear plate (A Plus Biotechnology Co. Ltd, Taiwan, Fig. 1b), (ii, iii) 0 mm and 7 mm offset T-shaped plate from the V-TEK plate system (Zimmer Biomet, USA, Fig. 1c and d), and (iv) a novel h-shaped plate (Fig. 1d). The dimensions of the plates are shown in Fig. 1g. Except for the A-PLUS Spear plate, which was fixed with 2.7 mm diameter screws with lengths of 20 mm and 30 mm, the other plates were fixed with 4.0 mm diameter screws, with lengths of 20 mm and 35 mm. The material properties are listed in Table 1 [14, 15].

The four implanted bone models were imported into Workbench 2021 (ANSYS, Inc., Canonsburg, PA, USA) for meshing and contact settings. All solid parts were meshed using tetrahedral elements (Fig. 2). Frictionless contact was applied at the interfaces between the plate and bones using surface-to-surface contact elements (CONTA174 and TARGE170). Additionally, the interface between the osteotomy faces of the metatarsal bone was also assumed to have a frictionless contact and was modeled using surface-to-surface contact elements (CONTA174 and TARGE170) [14]. Interfaces between bone screw/bone and screw/plate were set to bonded.

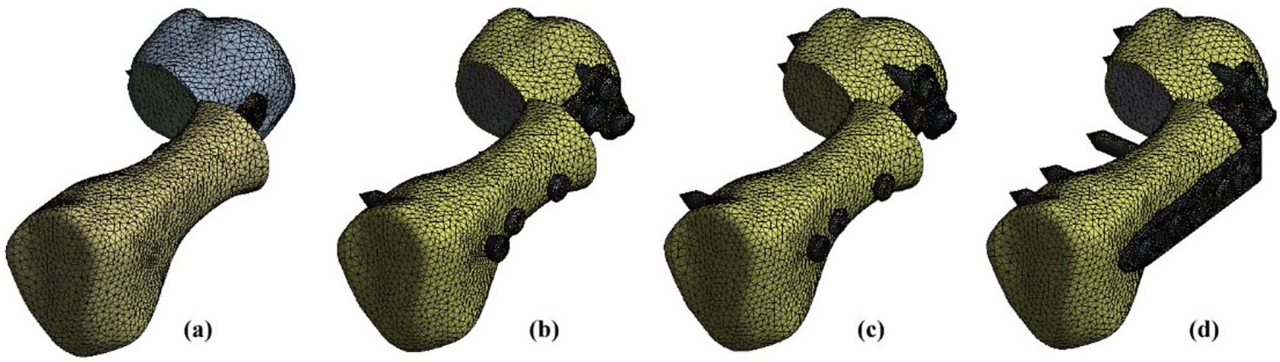

Fig. 2 Meshed first metatarsal model with **a**) A-Plus Spear plate, **b**) 0 mm offset T-shaped V-TEK plate, **c**) 7 mm offset T-shaped V-TEK plate, **d**) novel h-shaped plate

Boundary conditions, loading conditions and convergence test

Finite element analysis was used to analyze the mechanical properties and stability of the implanted models. The proximal surface of the first metatarsal bone was fixed as shown in Fig. 3. A load of 87.5 N [15] was applied to the distal end of the bone in different directions to simulate various metatarsal movements, such as plantar flexion, dorsiflexion, abduction, and adduction of the first metatarsal bone. The load was based on the maximum load experienced during cyclic testing [15]. Convergence testing was performed by assessing the stress changes in the bone model implanted with a A-Plus Spear plating system. The convergence graphs are presented in Fig. 3c. Based on these results, the optimal element sizes were determined to be 1.6 mm for the bone models and 0.6 mm for the screws and plates. The final mesh with 108,865 elements and 174,758 nodes was chosen because further refinement resulted in a less than 0.4% change in bone stress.

Validation of the FE models

The finite element model was validated by comparing the displacement of the metatarsal head after hallux valgus correction against measurements from mechanical testing. A hallux valgus correction was performed on a sawbone model of the first metatarsal (#3422, Sawbones USA) using the A-Plus Spear plating system, as shown in Fig. 4. Each specimen was secured in an MTS 858 mini Bionix II instrument and subjected to axial loading. An initial preload of 1 N was applied to each specimen, followed by a test load at a rate of 5 mm/min acting parallel to the dorsal-plantar axis. The axial displacement of the bone was recorded and compared with the results from the finite element model. The comparison showed an error percentage of less than 10% between the experimental model and finite element model.

Results

Validation result

The axial displacement of the metatarsal head recorded from the mechanical testing was compared against the data from the finite element model. The results showed an error percentage of less than 10% between the data sets, which confirmed the validity and accuracy of the finite element model (Fig. 5).

Stress on the models

The maximum displacement at the osteotomy site, as well as the maximum stress on the implanted bone plate and screws under different loading directions, are summarized in Table 2.

Flexion/extension moment (dorsal to plantar loading)

Under dorsal to plantar loading, the A-Plus model exhibited the highest displacement of the metatarsal head of 0.746 mm, while the next highest was the VTEK model with a 7 mm offset with a maximum displacement of 0.358 mm. The VTEK model with 0 mm offset had the highest maximum screw stress of all models (725.49 MPa) (Fig. 6a). The highest maximum fractional stress (Fig. 7a) at the bone/screw interface occurred in the A-Plus model, with 70.61 MPa at the distal screw (screw no. 1) and 36.841 MPa at the proximal screw (screw no. 2). The model with the novel h-shaped plate had the lowest displacement of the metatarsal head (0.278 mm), and the lowest maximum von Mises on the screws (294.97 MPa). The A-Plus model exhibited the highest displacement at the osteotomy head, whereas the New Design models displayed the lowest displacement, as shown in Fig. 8a. The maximum compressive stress at the osteotomy interface of the bone occurred in the A-Plus model (21.2 MPa), whereas the other models exhibited similar values, all less than 4 MPa, as shown in Fig. 9a.

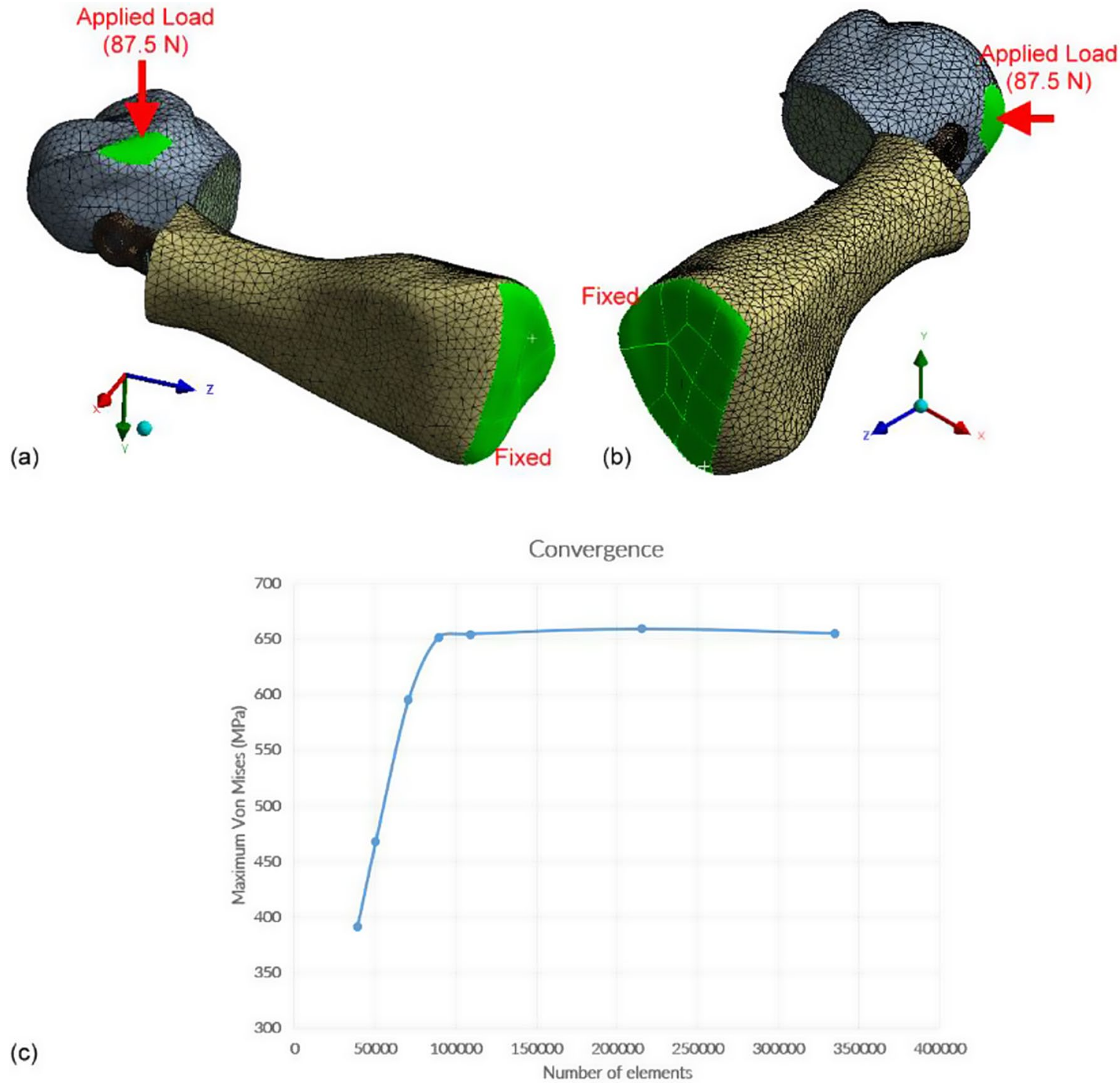

Fig. 3 **a**) loading direction to simulate plantar flexion/dorsiflexion; **b**) loading direction to simulate abduction/adduction; loading areas are marked in green. **c**) graph showing model convergence

Abduction/adduction moment (medial to lateral loading)

Under medial to lateral loading, the greatest displacement of the metatarsal head, von Mises on the plate, von Mises on the screws, and fractional stress at the distal screw (screw no. 1) were recorded in the model with an A-Plus plate. The maximum fractional stress at the proximal screw (screw no. 2) occurred in the VTEK (0 mm offset) model. The model with h-shaped plate had the lowest displacement of 0.152 mm, and plate and screw stresses of 254.27 MPa and 195.40 MPa, respectively (Figs. 6b and 7b). The A-Plus model exhibited the highest displacement at the osteotomy head, while the New Design models recorded the lowest displacement, as illustrated in Fig. 8b. The VTEK (0 mm offset) model showed the highest compressive stress at the osteotomy interface on the bone (13.45 MPa), while the New Design models recorded the lowest value of 4.92 MPa, as illustrated in Fig. 9b.

Discussion

With moderate to severe hallux valgus deformities, it is difficult to stabilize the bone structure after corrective osteotomy/reduction, and progressive deformities often emerge during the rehabilitation period. An osteotomy of the distal 1st metatarsal is often performed during hallux valgus correction, and internal fixation is achieved with bone plate systems which are used to stabilize the bone interface at the osteotomy site [17–20]. Due to the complex anatomical correction required for hallux valgus deformities, reconstruction plates may not sufficiently stabilize the surgical site and often cannot restore full functionality to the surrounding joints. Although various

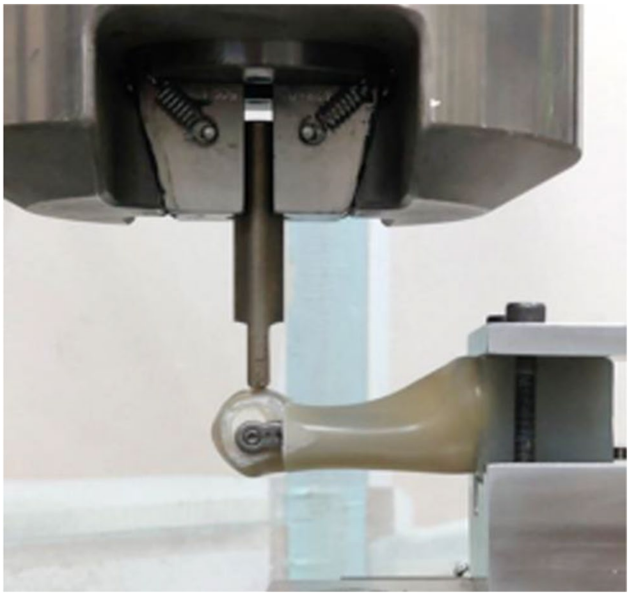

Fig. 4 A simulated bone of a first metatarsal implanted with an A-Plus Spear plating system was secured in an MTS 858 mini Bionix II instrument and subjected to axial loading

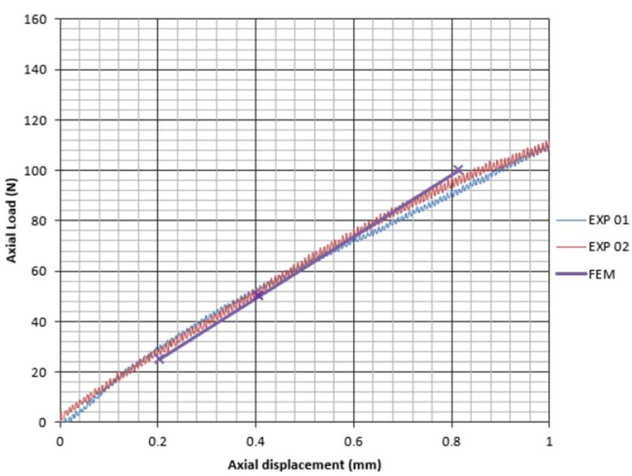

Fig. 5 The error percentage of axial displacement was less than 10% when comparing the results of mechanical testing against the finite element model

endosteal plating techniques have been developed for correcting hallux valgus, the limited studies on these devices means it is still unclear whether these techniques can sufficiently stabilize the bone. In this study, the rigidity of a novel h-shaped plate for hallux valgus correction and reconstruction was compared against other common endosteal plating techniques using the FE method. The results showed that the h-shaped plate was stiffer and stronger than its counterparts.

With a distal chevron osteotomy, a section of the distal bone is moved in the medial direction to correct hallux valgus. However, if the distal bone part is pushed too far to the lateral border, this can destabilize the construct and cause further complications. Through mechanical testing, the h-shaped plate in this study was recorded with the highest stiffness and was found to have the lowest deformation under loading, which can help reduce excessive lateral displacement. The seesaw phenomenon could be observed in all groups during medial-lateral loading because of the cantilever effect with the corrected bones, but this phenomenon was least noticeable with the h-shaped plate (Table 2). Similar techniques have been applied to fractures of the proximal humerus, with Braman et al. [12] indicating that a lateral locking plate in combination with an endosteal plate could offer sufficient support and a stable reduction in patients with displaced proximal humeral fractures because the hybrid construct provides support to both the lateral and medial column. Accordingly, the design of the h-shaped plate incorporates a bilateral support structure which we considered could provide sufficient stability for hallux valgus correction and avoid displacement of the bone sections under loading.

The maximum fractional stress at the bone/screw interface occurred at the distal region in all implants secured with screws. The maximum fractional stress at the bone/screw interface was defined as a stress required to pull-out (+) or push-in (-) from the bone model. Among all groups, the highest pull-out stress of the distal screw was found in the A-Plus group when placed under a flexion/extension moment. This is possibly because the distal part of the A-Plus implant is secured with only one screw in the horizontal orientation and the single plane/direction fixation cannot sufficiently constrain motion, such as those experienced due to horizontal tensile loading. The h-shaped plate is secured with three multi-directional screws in the distal region of the plate, and one central screw is inserted through the two plates to increase the pullout strength. Hence, the screws in the h-shaped plate demonstrated the lowest maximum pull-out stress of all groups. Using an FE model, Kong et al. [21] assessed the fixation strength of a double-plated internal fixation with distal transverse screws inserted through the two plates, and found lower screw displacement under different loading conditions when compared to single-plated internal fixation. We considered that two locking plates with a single screw passing through them could improve the pullout strength, which was supported by the low maximum fractional stress at the bone/screw interface with the h-shaped plate. With the A-Plus Spear plate, the proximal screw was inserted obliquely into the medial board of the proximal bone, but the maximum fractional stress at the bone/screw interface was still higher than the other groups. This is likely due to the thin walls of the medial cortical bone. Generally, the thickness of the medial cortical of the 1st metatarsal is less than the lateral

Table 2 Maximum displacement at the osteotomy site of each model and maximum stress on the implanted bone plate and screws under different loading directions

Loading Direction on the 1st metatarsal bone	implant	Maximum displacement of head (mm)	Maximum von Mises of Plate (MPa)	Maximum von Mises of screws (MPa)	Maximum Fractional Stress between bone/screw interface (MPa) / [screw no.]	
					At distal	At proximal
from dorsal to plantar (flexion/extension moment)	A-Plus	0.746	447.94	694.82	70.61 [1]	36.841 [2]
	VTEK (0 mm offset)	0.289	359.71	725.49	15.48 [1]	27.24 [5]
	VTEK (7 mm offset)	0.358	623.21	456.67	54.91 [1]	18.41 [6]
	New Design	0.278	429.51	294.97	28.21 [3]	28.33 [4]
from medial to lateral (abduction/adduction moment)	A-Plus	0.553	603.43	709.66	61.95 [1]	35.76 [2]
	VTEK (0 mm offset)	0.345	567.76	520.60	15.15 [1]	67.79 [5]
	VTEK (7 mm offset)	0.293	328.72	349.41	14.17 [1]	35.67 [5]
	New Design	0.152	254.27	195.40	24.61 [3]	31.90 [5]

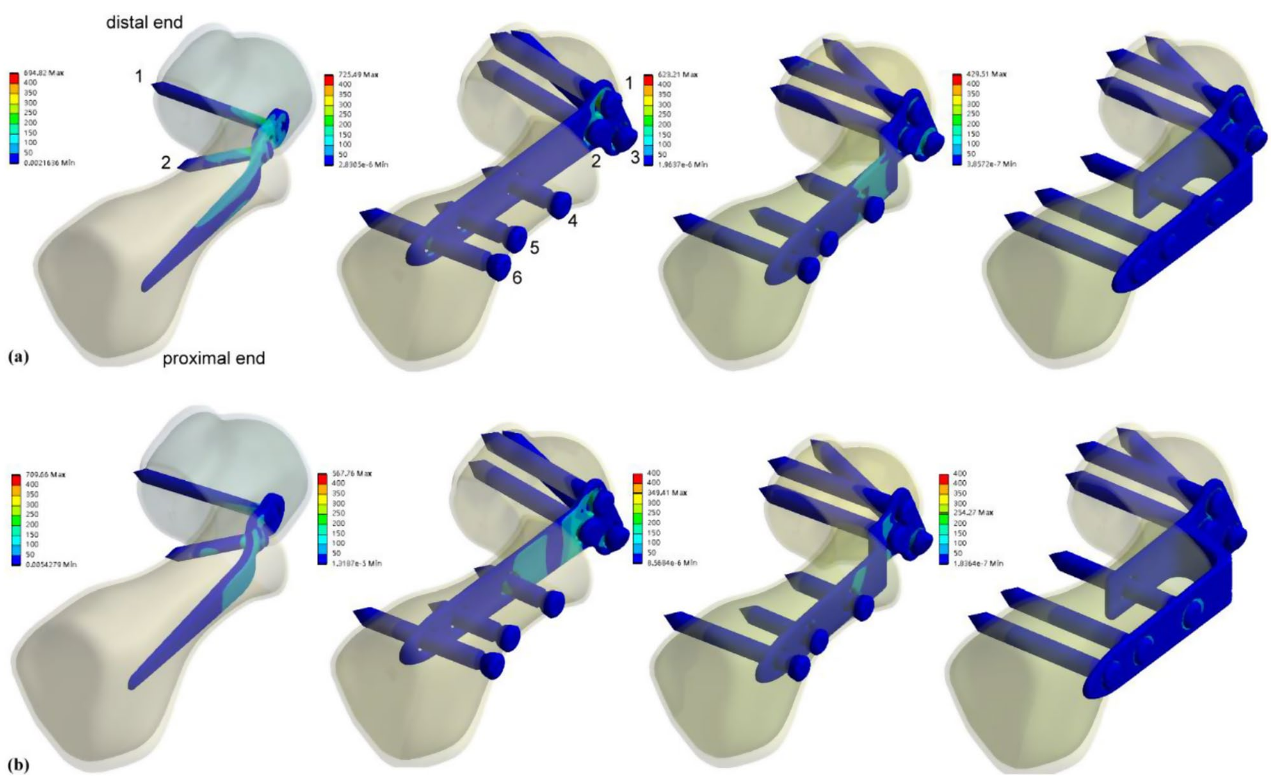

Fig. 6 von Mises distribution on models placed under **a**) dorsal to plantar, and **b**) medial to lateral loading applied to the proximal end of the metatarsal head

cortical thickness [22], and so an oblique screw insertion captures less cortex than a vertical screw insertion.

Our model showed stress concentrations on the plate-screw system were primarily located on the distal part of the plate that was in direct contact with the distal bone fragment and the cutting line, indicating the resistance to displacement provided by the plate. The stress concentrations tended to be located around the screw holes on the distal plate and, as expected, the screw holes were the weakest point in all plates in this study. The VTEK (0 mm offset) group had the highest von Mises stress of all groups when placed under a flexion/extension moment, and the A-Plus group had the highest von Mises stress in abduction/adduction. We found that the dual medial and lateral supports in the proximal region of the h-shaped plate could reduce the stress concentrations on the implant, which was evident by the maximum von Mises stress being the lowest of all groups. A higher stress on the implant may put it at greater risk of failure. A finite element study by Tuminoh [23] showed that increasing the number of screws in the bone plate lowered the maximum von Mises stress on the plate and, conversely, reducing the number of screws increased the stress concentrations on the bone and plate. The lower construct

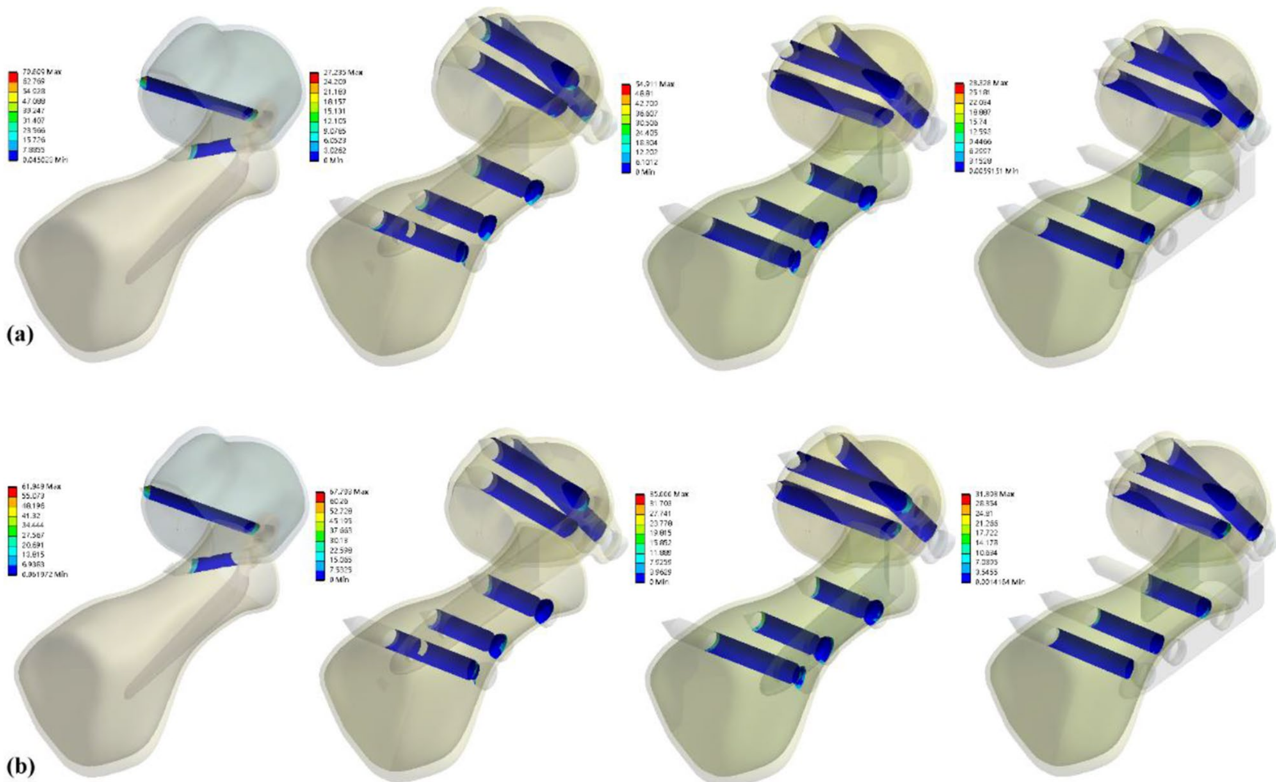

Fig. 7 Maximum fractional stress at the bone/screw interfaces in models placed under **a**) dorsal to plantar, and **b**) medial to lateral loading applied to the proximal end of the metatarsal head

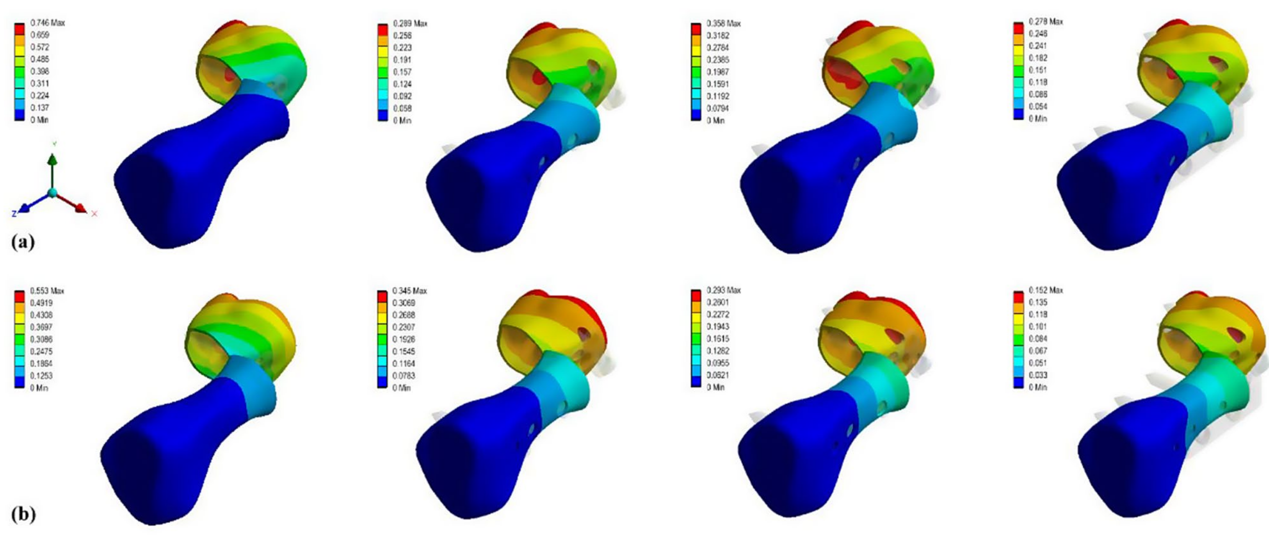

Fig. 8 Bone displacement in models placed under **a**) dorsal to plantar, and **b**) medial to lateral loading applied to the proximal end of the metatarsal head

stiffness and higher displacement observed with the A-Plus plate in our study may affect bone healing alignment and increase the risk of plate failure over time. It is noteworthy that the maximum von Mises stress on the VTEK (0 mm offset) plate and A-Plus plate was over 700 MPa, which is approaching the yield strength of 825–860 MPa for titanium alloy Ti6Al4V (ASTM F136 [24]). This may lead to breakage, screw loosening or bone nonunion.

When used on a distal chevron osteotomy for hallux valgus correction, the results showed that the novel h-shaped plate had a higher stiffness and lower stress concentrations than the other designs, which is beneficial for supporting the postoperative alignment of the bones.

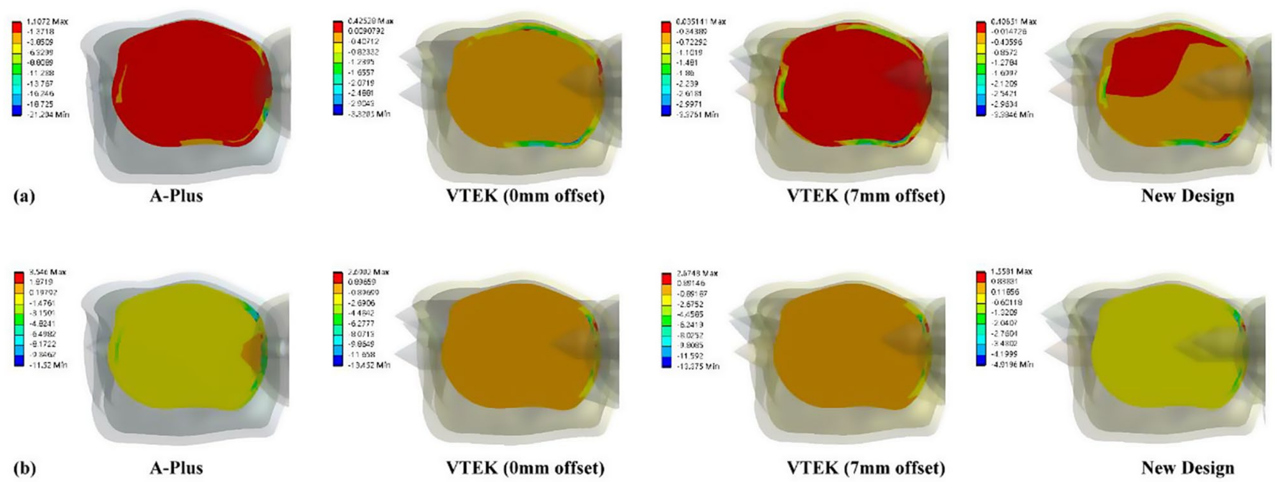

Fig. 9 Compressive stress at the bone osteotomy interfaces in models placed under **a**) dorsal to plantar, and **b**) medial to lateral loading applied to the proximal end of the metatarsal head

The h-shaped plate is still a prototype and may have some disadvantages commonly associated with bone plates in such applications, such as reduced blood supply to the bone beneath the plate and potential skin irritation [25]. Therefore, we plan to optimize our design by incorporating features such as a low-contact surface, a low-profile structure, and a limited number of fixation screw holes to mitigate these clinical risks. There are some limitations to this study to be considered. Firstly, to simplify the model and speed up processing, all materials were modeled with isotropic, linear and homogeneous properties. Natural bone exhibits anisotropic and inhomogeneous properties. Nevertheless, the results of this study are still valid because all bone plates were implanted in the same bone model and the intent of the study was to make a direct comparison of the stability of various plate designs. Variations in material properties, such as with diseased bone, were not considered in this research but may be evaluated in future studies. Second, only the 1st metatarsal bone was modeled, rather than a whole foot, because the focus of this study was the fixation relationship between the implant and osteotomy bones. Third, the loading conditions were referenced from literature, but these conditions may not reflect true physical activities. Future studies may consider different loading conditions to represent a variety of activities, and it would also be beneficial to consider in vitro testing.

Conclusion

For stabilizing distal chevron osteotomies, this FE study found that the h-shaped bone plate offers greater resistance to displacement in the dorsal-to-plantar and medial-to-lateral directions and a lower screw pull-out risk to maintain bone alignment postoperatively, in comparison to other commercially available endosteal plating techniques.

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Author contributions
YT: Conceptualization, Investigation, Writing– original draft. YT, YH, CC: Data curation, Visualization, Writing– review & editing, Formal analysis. YT: Resources, Methodology. YH, CC: Validation, Software, Supervision. CC: Project administration, Resources. All authors read and approved the final manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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