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Research article

Biomechanical evaluation of Chinese customized three-dimensional printed titanium miniplate in the Lefort I osteotomy: A finite element analysis

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ABSTRACT

Objectives: This work aims to evaluate the biomechanical behavior of Chinese customized three-dimensional (3D) −printed miniplates by means of finite element analysis (FEA).
Methods: A 3D Lefort I osteotomy model was established by Mimics. Two models were established to compare the strain behaviors of customized miniplate and conventional L-shaped miniplate. Hypermesh and ABAQUS were used to establish computer-aided engineering finite element models. The stress distribution on the mini-plates, screws and bone and the relative displacement of the maxilla segments were analyzed by loading post-operative occlusal force.
Results: The displacements for customized mini-plate fixation were notably smaller than L-shaped mini-plate fixation. The maximum stresses on the screws, mini-plates and cortical bone for customized mini-plates were smaller than that for L-shaped miniplates.
Conclusion: Chinese customized 3D-printed miniplates provide better postoperative stability and offer a good alternative to the conventional L-shaped miniplate system.

1. Introduction

Lefort I osteotomy is a frequently used surgical technique to correct midface deformities and improve occlusal function. The procedure involves repositioning of single or multi-segment maxilla in three-dimensions. Rigid plate fixation can keep the maxillary position stable during surgery and improve long-term stability [1]. Currently, the use of titanium miniplates and screws is regarded as the gold standard for internal fixation of free segments [2].

As skeletal relapse can occur in response to an imbalance in force through alterations in biomechanics [3], restoring the physiological mechanical conduction plays an important role in postoperative healing [4]. It has been widely accepted that pterygomaxillary buttress, zygomaticomaxillary buttress and nasomaxillary buttress are the primary vertical buttresses along mid-face skeleton. Under individual canine biting, the anterior cortical wall of the maxilla around the aperture piriform experienced high compression stress [5]. While under bilateral canine biting, the stress trajectory passed through the zygomaticomaxillary buttress with much smaller involvement of the nasomaxillary buttress [6]. Under individual first molar biting, the zygomaticomaxillary buttress was the fundamental compressive load bearing structure. Besides, the region between the two buttresses also withstood relatively high stress [5]. Under full arch loading, nasomaxillary buttress, zygomaticomaxillary buttress and pterygomaxillary buttress showed high strain concentration evenly [7].

The traditional fixation methods for Lefort I osteotomy was bilaterally applying titanium miniplates in both the apertura piriformis and the zygomaticomaxillary buttress to achieve the rigid fixation of the maxilla segment [8]. Huang et al found that L-shaped mini-plates with lateral fixation provide better stability. However, the risk for mini-plate fracture increases when maxillary advancement is larger than 5 mm [9]. As the traditional titanium mini-plates demand contouring to fit maxillary geometry profiles for each individual patient, it may affect the accuracy of placement [10]. Besides, traditionally, the positioning of maxillary segment is based on preoperative model which requires oral splints to ensure the antero-posterior and transverse planes but not vertical positioning of the maxillary segment [11, 12].

Thus, customized titanium mini-plates have been investigated which can precise the positioning of upper maxilla and reduce the operation time even without the use of surgical splints [13]. Some

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customized titanium mini-plates keep the conventional L or I shape and all reported to receive desirable outcome with precise positioning but lack comparative study [14, 15]. For example, one custom-made single unit miniplate system ensured precise fixation by joining 4 L-shaped miniplates with titanium wires which functioned as a positioning guide [15]. Meanwhile, efforts have been made in designing different shapes of titanium miniplates whose design concepts usually focus on a better fit of the bone surface to maintain the fixed position. For example, Juho et al [16] used the patient-specific implants which perfectly fit the anatomical contours of the maxilla and the zygoma, while this fixation method does not ensure better postoperative stability of the maxilla segments than conventional L-shaped miniplates fixation. Another prebent 11-hole Leibinger plate shows satisfactory results with up to 5 mm advancement comparing with the standard two-plate technique while it fails in the 10 mm advancement model which causes high segmental displacements and von Mises (VM) stresses [17].

To design a titanium miniplates system suitable for maxillary occlusal mechanical conduction and postoperative stability of maxilla segments, a Chinese customized 3D−printed titanium miniplate has been well developed, with Y-shaped titanium miniplate adapted to apertura piriformis and X-shaped titanium miniplate adapted to zygomaticomaxillary buttress. Nevertheless, the biomechanical properties remain to be researched.

Finite element analysis (FEA) is a numerical approach which has been used for analyzing medical biomechanics of complex structure under various loading conditions [18, 19]. This paper aims to verify if the customized XY-shaped titanium miniplates can stand occlusal forces and maintain maxillary stabilization after Le Fort I osteotomy. The biomechanical behavior, stress distribution and segmental displacement of XY-shaped miniplates versus conventional L-shaped miniplates after Le Fort I osteotomy surgery was evaluated using FEA.

2. Materials and methods

2.1. Object selection and 3-dimensional (3D) reconstruction

Computed tomography (CT) images (0.625 mm, GE Healthcare, Buckinghamshire, England) of a skeletal class II malocclusion adult were imported into Mimics (Version 18.0, Medical, Leuven, Belgium) for 3D cranio-maxillofacial reconstruction. Conventional Lefort I osteotomy was performed on both the cortical and trabecular bone.

3-Matic Medical (Version 9.0, Medical, Leuven, Belgium) was used to generate solid 3D models of titanium miniplates and screws. The titanium plates are divided into two types: a. standard orthognathic 4-hole L-shaped miniplates, b. customized XY-shaped miniplates and the thickness of titanium plate is 1.4mm. The standard orthognathic 4-hole L-shaped miniplates were placed symmetrically on both sides near the zygomaticomaxillary buttress and apertura piriformis (Figure 1A/1B). In the other configuration, the customized XY-shaped miniplates is along the occlusal mechanical conduction trajectory of nasomaxillary buttress, zygomaticomaxillary buttress as well as pterygomaxillary buttress, with Y-shaped and X-shaped titanium miniplates adapted to apertura piriformis and zygomaticomaxillary buttress on both sides (Figure 1C/1D). The size of the screw was 2mm in diameter * 6mm in length. All the corresponding implants were then exported as stereo-lithographic (STL) files.

2.2. Establishment of 3D finite element model (FEM)

All models were smoothed with geomagic software (3D system, USA). Then, Hypermesh Software (Altair, USA) was used for pre-processing. The FEM consisted of second-order tetrahedral mesh to promote the calculation accuracy. The mesh convergence was tested by comparing the maximum von Mises stress and the strain energy (comparison error <5%). The final number of elements was about 230,000 (Figure 2). The

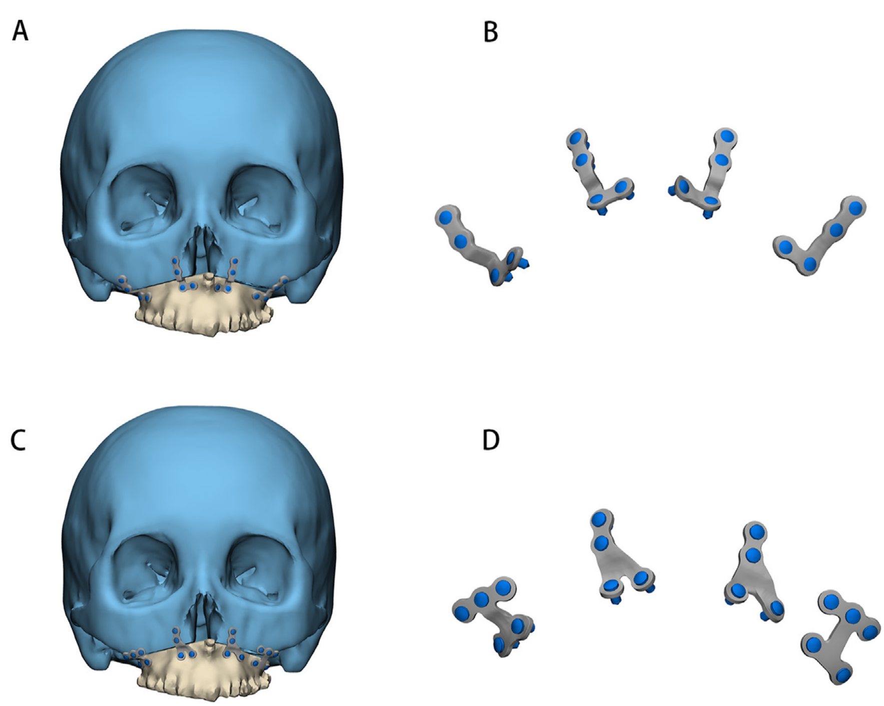

Figure 1. Fixation methods. A/B. Conventional L-shaped titanium mini-plate fixation. C/D. Customized XY-shaped titanium mini-plate fixation.

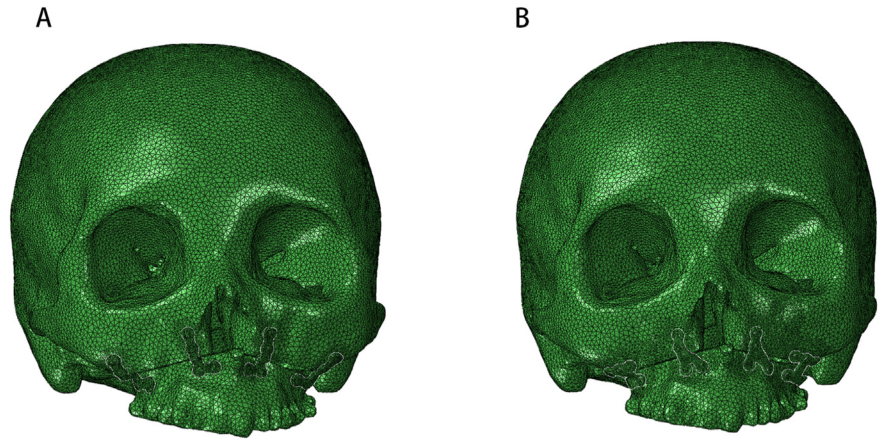

Figure 2. Pre-processing of second-order tetrahedral mesh. A. Conventional L-shaped titanium mini-plate fixation. B. Customized XY-shaped titanium mini-plate fixation.

Table 1. [20], [21]Mechanical parameters of the materials used in the modeling.

Materials	Elastic modulus (GPa)	Poisson ratio	Engineering yield strength (σs/MPa)	Engineering tensile strength (σb/MPa)
Cortical bone	14.8	0.35	135	150
Cancellous bone	1.85	0.3	7.2	7.5
Ti alloy	110	0.3	858	892

General Finite Element Analysis Software ABAQUS (DASSAULT, France) was used as the solver and processor.

2.3. Material parameters

All the titanium miniplates and screws were modelled in Ti alloy (Ti–6Al–4V). The material parameters used in the FEA were obtained from the literature and material suppliers (Table 1) [20, 21]. Linear elastic properties were adopted for all materials.

2.4. Boundary conditions and loads

The screw, the cortical and cancellous bone were defined to have a binding-contact relationship. The friction coefficient was 0.5 between screw-to-plate and plate-to-bone [22]. Choi et al. [23] reported the time-dependent changes in bite force after Le fort *I orthognathic* surgery. The average occlusal force of 78 patients was 97.6N one-month post--operation, 206.9N three-month post-operation and 257N six-month post-operation. In this study, the occlusal force of these three conditions were considered as the load condition. The compressive loads were applied vertically to the bilateral molars and premolars. The occipital bone was constrained to prevent movements in all directions as the boundary conditions (Figure 3).

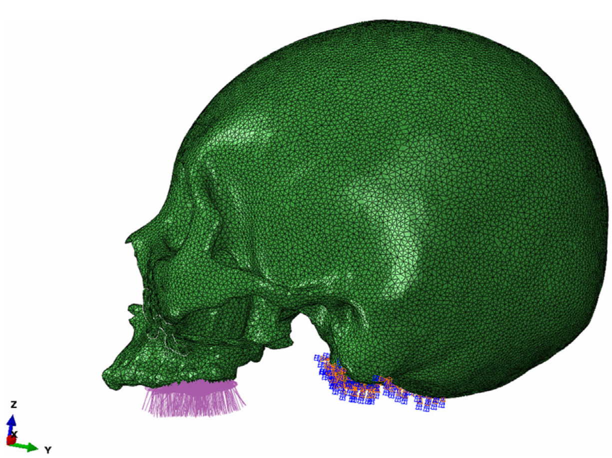

Figure 3. Boundary conditions and loads.

2.5. Data analysis

The relative displacement and the maximum von Mises stress between the two maxillary bone segments were measured. The maximum von Mises stress for the mini-plates and screw were recorded and compared.

3. Result

3.1. Relative displacement of the segments

The displacement of the maxilla segment was mainly concentrated on the posterior maxilla (Figure 4) and the separated maxilla segment had tendencies to rotate forwards (Figure 5), when the bite force was applied.

As shown in Table 2 and Figure 4, smaller relative displacements were observed when applying lighter bite force in both fixation methods. For customized XY-shaped titanium mini-plates fixation, the relative displacements were notably smaller than conventional L-shaped titanium mini-plates under all bite forces.

3.2. Stress on the screws

The screw was mainly subjected to shearing force. The stress concentration on the screws in the 2 groups occurred in the contact position of the screw with the titanium plate and cortical bone near the osteotomy line (Figure 6). The maximum von Mise stress of the screw for XY-shaped mini-plates fixation screw was only almost half that of the conventional method under three bite force conditions. The maximum stress reached 182.0 MPa in customized mini-plates fixation and 322.1 MPa in conventional mini-plates fixation with maximum bite load (Table 3, Figure 6).

3.3. Stress on the mini-plates

The stress distributions on the mini-plates were shown in Figure 7. The stress concentration of L-shaped mini-plates was found at the bending regions and the maximum von Mises stresses was 792.6MPa

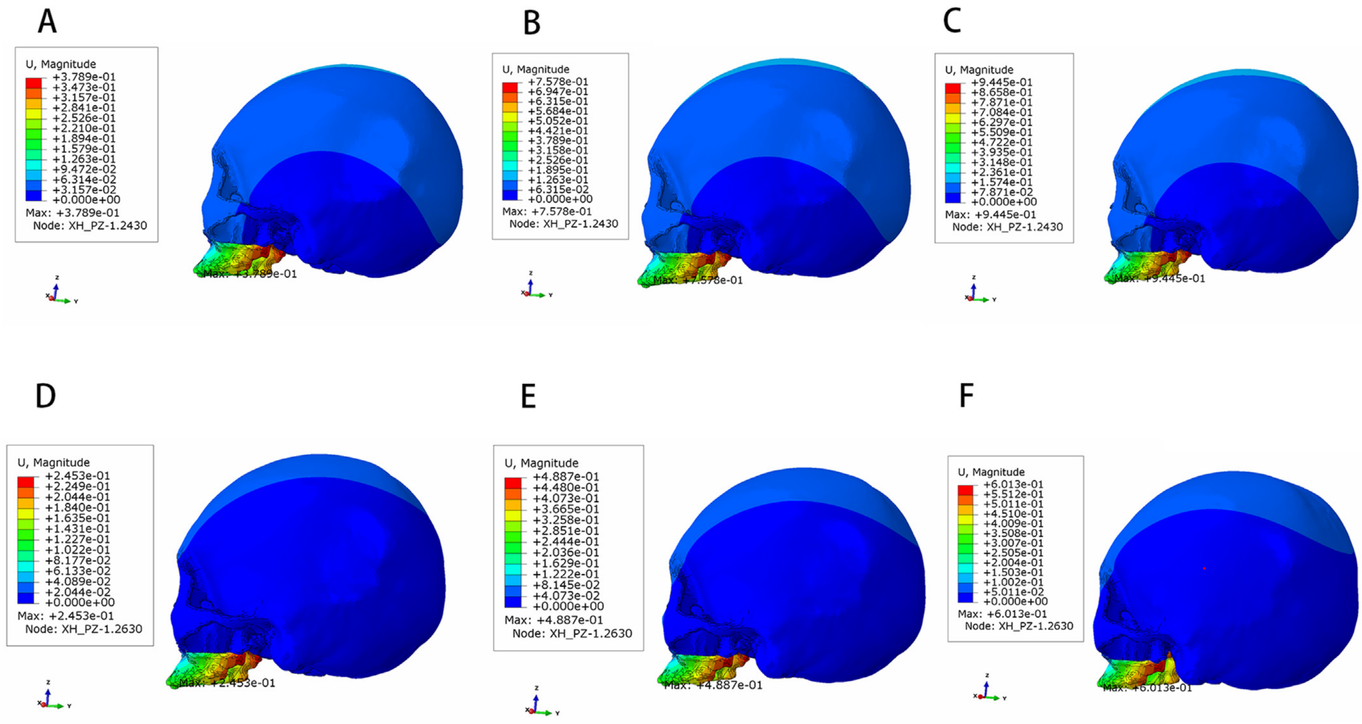

Figure 4. The relative displacements. A. L-shaped mini-plate with 98N bite load. B. L-shaped mini-plate with 207N bite load. C. L-shaped mini-plate with 257N bite load. D. XY-shaped mini-plate with 98N bite load. E. XY-shaped mini-plate with 207N bite load. F. XY-shaped mini-plate with 257N bite load.

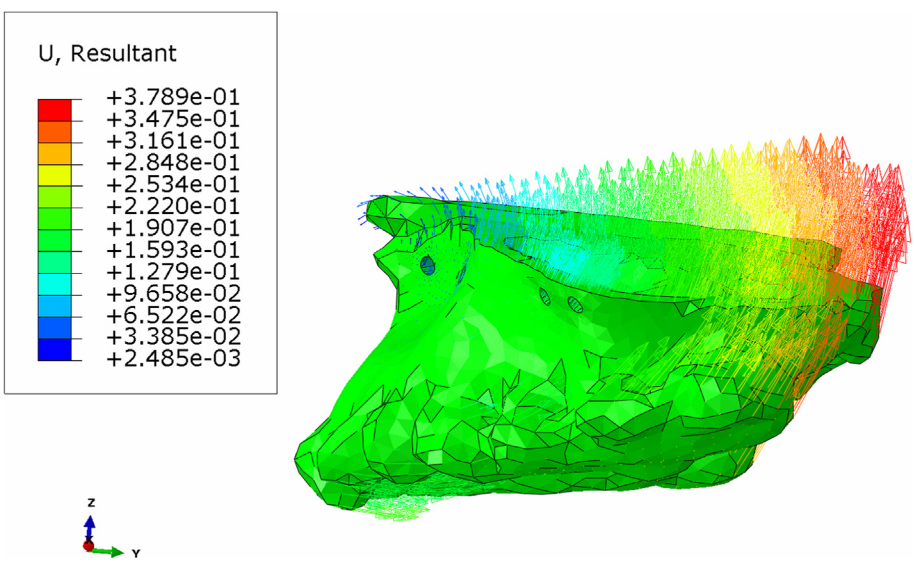

Figure 5. The displacement direction of the maxilla segment. L-shaped mini-plate with 98N bite load (The displacement direction under different fixation methods and loads was the same.).

Table 2. Maximum displacement of osteotomy segment with different fixation methods.

Bite force / Fixation Method	98N	207N	257N
L-shaped titanium mini-plates	0.379mm	0.758mm	0.945mm
XY-shaped titanium mini-plates	0.245mm	0.489mm	0.601mm

when applying 257N bite force. While the stress was smaller and distributed relatively more evenly on the customized XY-shaped titanium mini-plates, with highest von Mises stresses close to the osteotomy line on the right when adding 257N bite force, namely 655.0MPa (Table 4 and Figure 7).

3.4. Stress on the cortical bone

The stress distribution of the cortical bone under the two fixation methods was similar. The stress was more concentrated around the screw holes, followed by zygomaticomaxillary buttress and apertura piriformis (Figure 8). Compared with conventional L-shaped titanium mini-plates

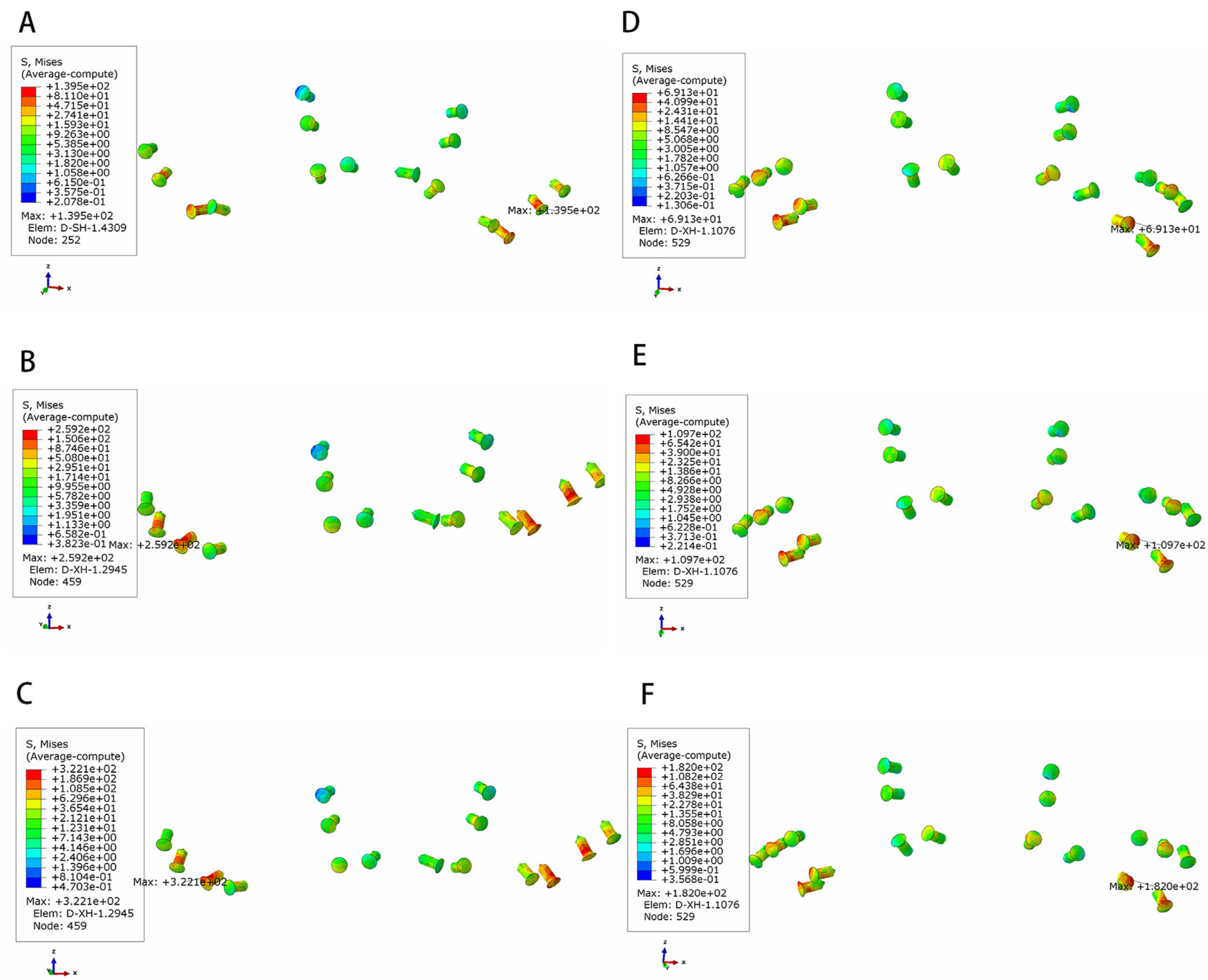

Figure 6. Stress distribution on the screws. A. L-shaped mini-plate with 98N bite load. B. L-shaped mini-plate with 207N bite load. C. L-shaped mini-plate with 257N bite load. D. XY-shaped mini-plate with 98N bite load. E. XY-shaped mini-plate with 207N bite load. F. XY-shaped mini-plate with 257N bite load.

Table 3. Maximum Mises stress of screws with different fixation methods.

Bite force	98N	207N	257N
Fixation Method			
L-shaped titanium mini-plates	139.5MPa	259.2MPa	322.1MPa
XY-shaped titanium mini-plates	69.1MPa	146.3MPa	182.0MPa

fixation, customized XY-shaped titanium mini-plates fixation effectively reduced the stress level on cortical bone (Table 5 and Figure 8).

4. Discussion

This study used FEA to validate the biomechanics of the customized XY-shaped titanium mini-plates by comparing the displacements of the maxilla segment and the stress on the implanted materials and bone after Lefort I osteotomy. Two FE models using conventional L-shaped titanium mini-plates and customized XY-shaped titanium mini-plates were generated for simulations under bite load condition. 98N, 207N and 257N force were applied vertically to bilateral molars and premolars which represented occlusal loads one month, three months and six months after Lefort I osteotomy respectively [23]. Sugiura et al. [24] reported that peak stress levels of miniplates occurred 2–4 weeks after surgery, so 98N occlusal force was also considered as the loading condition.

The reliability of the method was tested under 98N as loading condition by comparing the maximum von Mises stress and the strain energy. 0.8, 0.7, 0.6, 0.5, 0.4, 0.3 were selected as the element size of the plate and the screw (Table 6). To ensure comparison error <5%, 0.5 was finally chosen as the element size with about 230,000 elements in total.

Studies have shown that physical environment exerts regulatory influences on skeletal healing that requires mechanical loading under the physiological direction dictated by the musculoskeletal function [4]. Researchers attempt to optimize skeletal reconstruction by creating a variety of biophysical environments which includes improvement of internal fixation [25]. Therefore, restoring occlusal mechanical conduction of maxillary in physiological stress state, plays an important role in maxillary reconstruction and stability after Lefort I osteotomy. As the gap created between the alveolar and maxillary segment reduced bone contact, Albert [26] et al. found that the skulls plated with conventional L-shaped miniplate fixation after the LeFort I osteotomy displayed a strain pattern greatly differed from the intact pattern. The maximum and

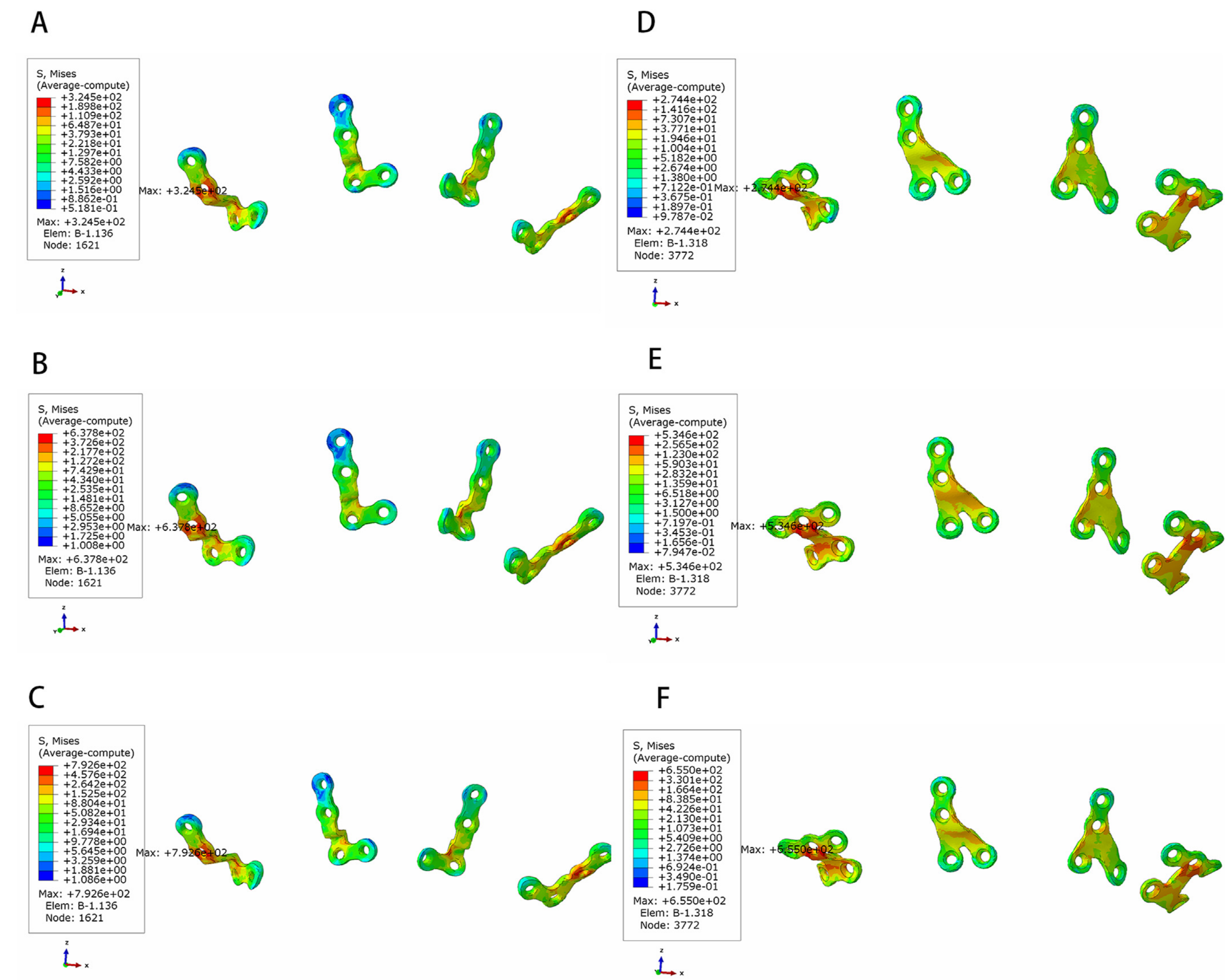

Figure 7. Stress distribution on the mini-plates. A. L-shaped mini-plate with 98N bite load. B. L-shaped mini-plate with 207N bite load. C. L-shaped mini-plate with 257N bite load. D. XY-shaped mini-plate with 98N bite load. E. XY-shaped mini-plate with 207N bite load. F. XY-shaped mini-plate with 257N bite load.

Table 4. Maximum Mises stress of mini-plates with different fixation methods.

Bite force	98N	207N	257N
Fixation Method			
L-shaped titanium mini-plates	324.5MPa	637.8MPa	792.6MPa
XY-shaped titanium mini-plates	274.4MPa	534.6MPa	655.0MPa

minimum strains were less linear over the incremental compressive loads and the standard deviations were much greater. Thus, the design concept of customized XY-shaped titanium plate aims at collecting and transmitting maxillary occlusal force along the trajectory in a physiological way (Figure 9).

A firm and stable fixation is prerequisite for optimal osteotomy healing. Sertan [27] et al. have proved that a single Y-shaped miniplate or a single double-Y-shaped miniplate could provide better stability and greater resistance to displacement than L-shaped miniplate after mandibular corpus fracture. Besides, when using Y and L-shaped miniplates for Lefort I fracture fixation, the tension in the L-shaped miniplate increased significantly which could cause great deformation [28]. The possible reason may be that at posterior maxilla, L-shaped miniplate can only transmit the force upwards along the single arm of L-shaped miniplate. While the X-shaped miniplate can distribute the bite force both upwards and backwards along the two arms extending to zygomaticomaxillary buttress and pterygomaxillary buttress. Less deformation of the miniplate can ensure lower displacement, as the fixation is more fixed. Thus, the customized XY-shaped titanium miniplate was developed to provide a more stable fixation alternative.

In this study, larger displacements were observed at the posterior maxilla segment, which is consistent with Wu et al. that the region at the back of maxilla (pterygomaxillary pillar) was blind spot of I-shaped fixation and was quite unstable [19]. In addition, this displacement pattern is similar to Huang [9]'s research that when adding oblique loads of each premolar and molar, maxilla segment had tendency to rotate forward. The possible mechanical reason is that with Le Fort I fractures, the clenching position acts as a fulcrum while the bone mass is tilted under the loaded muscle [28]. Besides, the center of resistance for the nasomaxillary complex is located posteriorly on the pterygomaxillary fissure [29], thus when applying force to the premolars and molars, the maxilla segment has a tendency to rotate counterclockwise and results in greater posterior displacement. Moreover, the relative displacements of XY-shaped mini-plate were smaller than that of L-shaped mini-plate, which suggests that customized XY-shaped miniplates can better

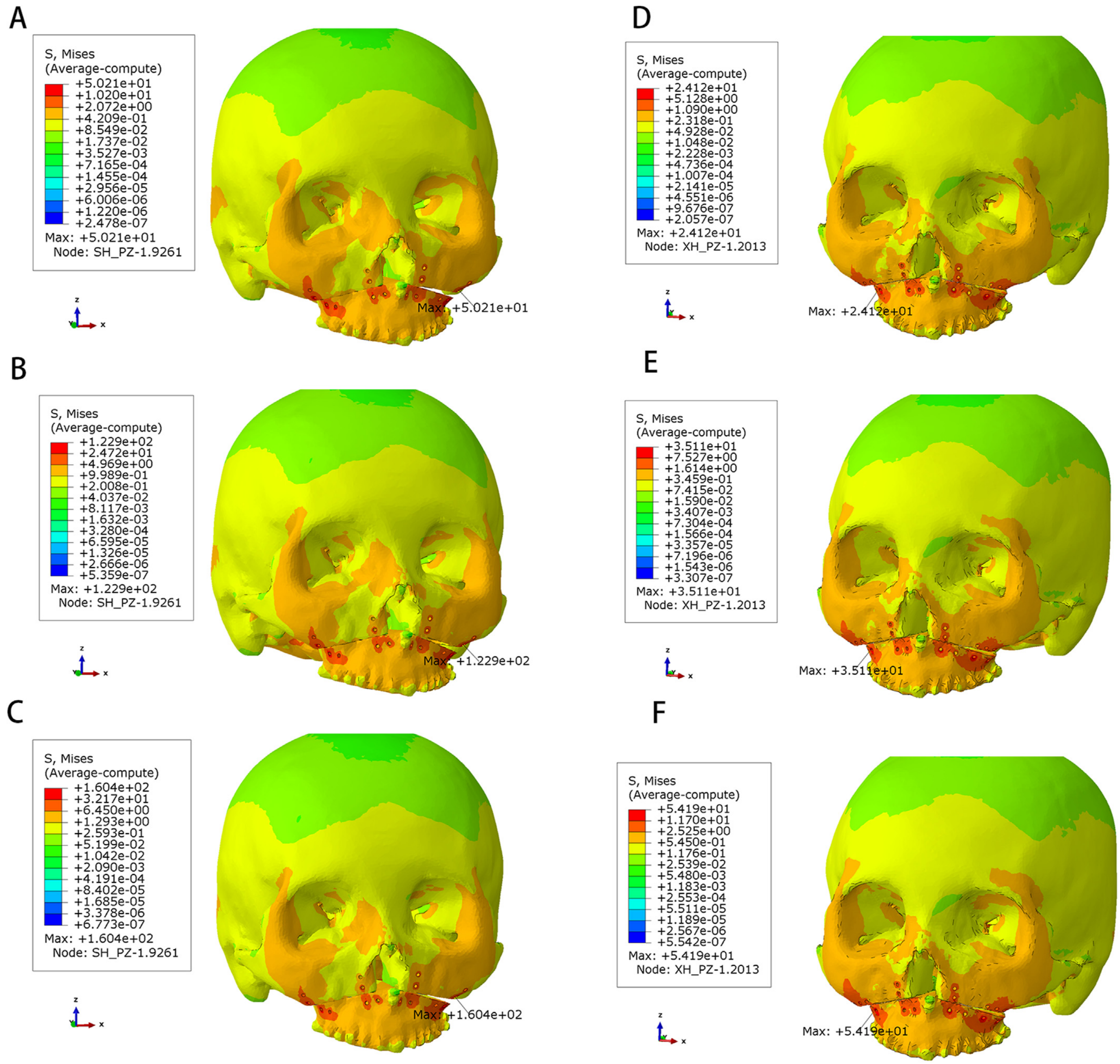

Figure 8. Stress distribution on the cortical bone. A. L-shaped mini-plate with 98N bite load. B. L-shaped mini-plate with 207N bite load. C. L-shaped mini-plate with 257N bite load. D. XY-shaped mini-plate with 98N bite load. E. XY-shaped mini-plate with 207N bite load. F. XY-shaped mini-plate with 257N bite load.

Table 5. Maximum Mises stress of cortical bone with different fixation methods.

Bite force Fixation Method	98N	207N	257N
L-shaped titanium mini-plates	50.2MPa	122.9MPa	160.4MPa
XY-shaped titanium mini-plates	24.1MPa	48.8MPa	54.2MPa

ensure short-term postoperative stability. Intermaxillary elastics are frequently worn after orthognathic surgery to immobilize the maxilla segment in the proper position [30]. Due to the better postoperative stability by XY-shaped mini-plate, it's likely that the time for intermaxillary elastics can be shortened, which provides the patients with comfort and better oral hygiene. The significant resistance to displacement detected between loads of 207 and 257 N shows that the strong fixation of XY-shaped mini-plate may help to reduce the relapse between 3 and 6 months postoperatively.

Table 6. Element size and the relative error.

Element size/mm	Maximum von Mises stress/ MPa	Relative error of maximum von Mises stress	Maximum strain energy/ mJ*mm^{-3}	Relative error of maximum strain energy
0.8	124.6	/	0.082	/
0.7	219.6	43.3%	0.264	68.9%
0.6	279.4	21.4%	0.443	40.4%
0.5	324.5	13.9%	0.603	26.5%
0.4	330.5	1.8%	0.627	3.8%
0.3	330.8	0.0%	0.628	0.0%

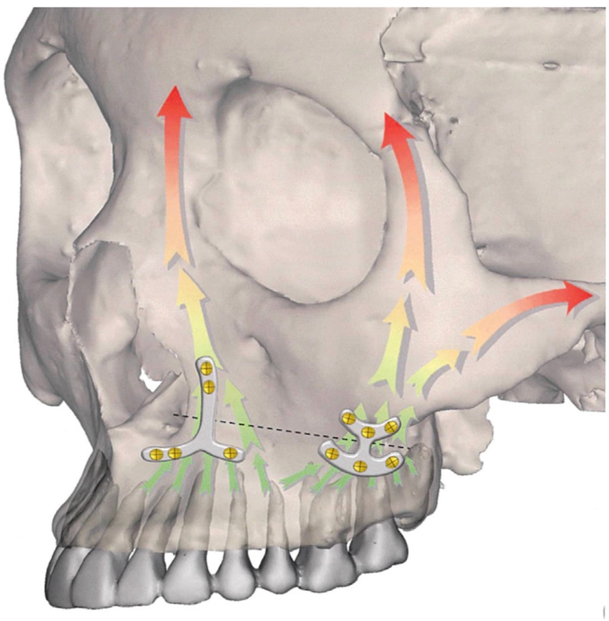

Figure 9. The design of XY-shaped mini-plate.

Studies [9, 10, 22] have found that the stress concentration of miniplates were located at the bending regions, which is consistent with the present result. In addition, customized XY-shaped miniplates fixation effectively reduced the stress on the miniplate and screws as well as met the mechanical requirements of the implanted materials. This was an expected outcome because the XY-shaped configuration leads to a larger contact surface and cross-sectional areas, thus more uniformly distributing the bite forces. As the maximum stress being significantly lower than the yield strength of Ti alloy, plastic deformities and cracks were unlikely to occur. In addition, the even stress distribution of the customized XY-shaped miniplates can reduce the potential breaking risk caused by metal fatigue.

In terms of stress on the bone, stress was concentrated around the screw hole with L-shaped miniplate fixation. While with XY-shaped miniplate fixation, larger red region at posterior zygomaticomaxillary buttress region and larger orange region at nasomaxillary buttress were shown (Figure 8). It has been reported that under loading of the full maxillary dental arch in the intact skull, high VM stress was observed in the area around the upper border of the nasal cavity and at lower part of the zygomatic arch [7]. Besides, Alber at al have found that in the osteotomy skulls with conventional L-shaped miniplate fixation, the strain at posterior zygomaticomaxillary buttress region and nasomaxillary buttress region were decreased compared with the intact skull [26]. In the present study, although smaller stress was observed on the bone with XY-shaped miniplate fixation than L-shaped miniplate fixation, the stress distribution on the bone of XY-shaped miniplate tends to be more concentrated at the two buttresses, which indicate the stress distribution was much closer to the physiological state. Besides, as the von Mises stresses on the cortical bone are more intensified around screw-bone interface, this may cause relapse [31]. In the case of conventional L-shaped titanium miniplate fixation with 257N bite force, the stresses on the cortical bone (160.4MPa) exceeded the tensile limit (150MPa), suggesting that bone micro-fractures may occur around the screw and lead to screw loosening. However, under same bite load, the maximum stress of cortical bone fixed with customized XY-shaped titanium miniplates was only 54.2MPa. Hence, customized XY-shaped mini-plate provide long-term stability and better safety than conventional L-shaped titanium miniplate.

The existing studies on maxillary fixation focused on its stability for Lefort I maxillary advancement [32, 33] and little has been conducted on maxillary setback, while the postoperative stability after maxillary setback is more difficult to obtain due to insufficient bone contact between the posterior maxilla segment and the pterygoid plates and inappropriate grafting [34]. As Asians generally have a protrusive maxilla facial type [35], patient with skeletal class II deformity was selected in this study and setback was included in the surgical procedure. Present study shows that the customized XY-shaped titanium miniplate can achieve better stability and mechanical properties in maxilla setback than conventional L-shaped miniplate, indicating that the customized XY-shaped titanium miniplate can serve as a stable fixation alternative for maxillary repositioning.

This study has several limitations. First, the forces of muscles facial expression were omitted from this study. Second, the analysis is based on a 3D model of conventional Lefort I osteotomy without multi-segmentations. In the future study, we will optimize the design concerning whether a larger XY-shaped titanium plate is necessary to stabilize the muti-pieces for advancement, impaction or downgraft, as larger contact surface distribute forces more uniformly [36]. In the follow-up study, further clinical trials and personalized biomechanical analysis are needed to verify the results of this study.

5. Conclusion

The presented customized XY-shaped titanium miniplates is an innovative product due to its attempt to distribute the bite force closer to the physiological state after Lefort I osteotomy. The comparative study proved the ability to reduce segment displacement and the efficacy of stress distribution on the screw, miniplate and bone, which better ensure the maintenance of both short-term and long-term postoperative stability. For extensive clinical application in the future, such a design needs further clinical trials.

Declarations

Author contribution statement

Zixian Jiao: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Jiayi Li: Analyzed and interpreted the data; Wrote the paper.

Qianyang Xie and Xiaohan Liu: Contributed reagents, materials, analysis tools or data; Wrote the paper.

Chi Yang: Conceived and designed the experiments; Performed the experiments.

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Data availability statement

Data included in article/supp. material/referenced in article.

Declaration of interest's statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

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