Chinese Journal of Traumatology 22 (2019) 261–269

Contents lists available at ScienceDirect

Chinese Journal of Traumatology

journal homepage: http://www.elsevier.com/locate/CJTEE

Original Article

Evaluation of labial versus labio-inferior lines of osteosynthesis using 3D miniplate for fractures of anterior mandible: A finite element analysis with a pilot clinical trial

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ARTICLE INFO

Article history:
Received 6 January 2019
Received in revised form
29 June 2019
Accepted 10 July 2019
Available online 9 August 2019

Keywords:
Mandibular fractures
Finite element analysis
Osteosynthesis
3D miniplate

ABSTRACT

Purpose: The fractures of anterior mandible are subject to severe torsional forces due to muscles acting in opposite directions. 3D miniplate has been suggested as a good alternative by some researchers. However, finite element model (FEM) studies indicate that labio-inferior positioning of two miniplates perpendicular to each other offers better stability as compared to labial positioning. This study aims at combining the advantages of a single 3D miniplate and labio-inferior positioning of two conventional miniplates, which was assessed by finite element analysis along with a pilot clinical trial.

Methods: Two FEM models were created using CT data of a 24-year-old patient with Angle class I occlusion: control model with labial plating and study model with labio-inferior plating. The models were processed with MIMICS® (materialise, Leuven, Belgium), CATIA® (Dassault Systemes) and finite element analysis softwares. Parameters adopted for analysis were (1) displacement (mm) of fracture fragments during each screw fixation, (2) lingual splay and post fixation stability of fracture fragments with masticatory load, and (3) stress distribution (MPa) across fracture fragments. Moreover, a pilot clinical trial including five patients with anterior mandible fracture was conducted. The fractures were managed by intraoral open reduction and 3D miniplate fixation in labio-inferior position. Intraoperative interfragmentary gap, post fixation lingual splay and radiographic fracture union and complications were assessed clinically.

Results: Labio-inferior plating demonstrated less displacement (mm) of fracture fragments during screw fixation (0.059 vs. 0.079) as well as after application of masticatory load (1.805 vs. 1.860). Negligible lingual splay and less stress distribution (MPa) across fracture fragments (1.860 vs. 1.847) were appreciated in the study group as compared to control group. Clinical trial support the favorable outcome related to intraoperative and postoperative assessment parameters.

Conclusion: FEM analysis and clinical trial reveal better results with labio-inferior positioning of 3D miniplate when compared to labial positioning.

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Introduction

Fractures of anterior mandible are common due to their prominent disposition, presence of canine with prominent roots and location of mental foramen.[1] The anterior mandible is subject to severe torsional forces due to the opposing action of two groups of muscles, respectively (1) muscles of mastication consisting of masseter, temporalis, medial pterygoid and lateral pterygoid which exert a superior pull, and (2) suprahyoid group of muscles including digastric, stylohyoid, mylohyoid and geniohyoid which depress the anterior mandible.[2] This inter-play of dynamic muscle forces can destabilize inadequate fixation of anterior mandible fractures which can result in numerous complications such as malunion, nonunion, delayed fracture healing, plate fracture, infection and implant failure.[2]

According to Champy's principle, two conventional miniplates are advocated at the anterior mandible for adequate stability and ideal osteosynthesis.[3] The other fixation options are dynamic compression plates and lag screws which are associated with specific indications and limitations. Alternately, 3D miniplates have

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Peer review under responsibility of Chinese Medical Association.

https://doi.org/10.1016/j.cjtee.2019.08.001
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been used in fractures of anterior mandible and proved to offer better stability and clinical benefits than the conventional miniplates.[4,5]

Traditionally two miniplates are positioned on the labial cortex for open reduction and internal fixation (ORIF) of anterior mandibular fractures. However finite element model (FEM) studies indicate that labio-inferior positioning of two conventional miniplates perpendicular to each other offers better stability as compared to parallel positioning.[6]

This study attempted to combine the advantages of using a single 3D miniplate on the labial surface (buccal cortex) and labio-inferior positioning of two conventional miniplates. This study hypothesized the usefulness of labio-inferior positioning of a single 3D miniplate, which was assessed by finite element analysis with a pilot clinical trial. There is no literature so far, which describes the use of 3D miniplate at an alternate (labio-inferior) site of osteosynthesis for fractures of anterior mandible.

The aim of the study was to evaluate the stability offered by labio-inferior fixation of 3D titanium miniplates for fractures of anterior mandible, by finite element analysis along with a pilot clinical trial.

The objectives of FEM study were

(1) To assess the separation of fracture fragments across the fracture line, along the superior and inferior border during fixation, in all three planes (X, Y, Z), in millimetres.
(2) To analyze the stress distribution in mandible after fixation of 3D miniplate and during masticatory load, in Mpa.
(3) To evaluate the lingual splay following fixation, in millimeters.
(4) To evaluate the displacement of fracture fragments after fixation, during masticatory load in all three planes (X, Y, Z), in millimeters.
(5) To compare the above parameters between the study (labio-inferior plating) and control (labial plating) models.

The clinical objectives included assessment of intraoperative interfragmentary gap, postoperative fixation lingual splay and radiographic fracture union and complications.

Methods

This study, consisting of two parts: Part I- FEM analysis and Part II- a pilot clinical trial, was conducted in Central Institute of Polymer Engineering and Technology (CIPET), India. The approval has been obtained from the Institutional Review Board-SRMDC/IRB/2016/MDS/No.405.

Part I — FEM analysis

FEM analysis was executed in three stages, as represented in Fig. 1. Detailed description of each step is as follows.

Stage 1. Establishment of FEM

A. Generation of the geometric models. Computerized tomography (CT) of human head of 0.6 mm thickness was obtained from a 24 years old patient. The volunteer had a full set of dentition with Angle class I occlusion. The data were saved as Digital Imaging & Communications in Medicine (DICOM) files. The objectives of geometric modeling phase were (1) to define the model in terms of points, areas, lines and volume, and (2) to represent complicated objects as geometrically simple framework.

B. Conversion of geometric model to FEM. CT data were transferred to computer-aided design (CAD)-based medical software (MIMICS 7.0). Every tooth and bone was represented in separate slices along all three planes: coronal, axial and sagittal. By using MIMICS software, the DICOM format of CT data was converted into stereolithography (STL) files, which is the suitable format required for importing into finite element analysis software (ANSYS 15.0).

C. Material data representation. This step included design and interpretation of the properties of material in relation to the screw length and plate profile in control model with labial plate (Fig. 2) and study model with labio-inferior plate (Fig. 3) by using solid Edge® 2004 by reverse engineering technique. Data were imported to CATIA V5® (Dassault Systemes). Each element of the FEM mesh was arranged into a unit of equations which represent the properties/characteristics of the whole system. Poison's ratio and Young's modulus were the material properties required[6,7] (Table 1). The plating system used for fracture fixation was 2 mm system. The length of the screws was 2 mm × 6 mm in superior border and 2 mm × 8 mm in inferior border for both the control and study models.

D. Determination of boundary conditions. Two surface models (Model 1 and Model 2) were created and converted into solid models. Model 1 (Fig. 4) represented the control model with labial plate, and Model 2 (Fig. 5) represented the study model with labio-inferior plate. These two solid models were converted into final models by using CATIA V5. The mandible was restricted from

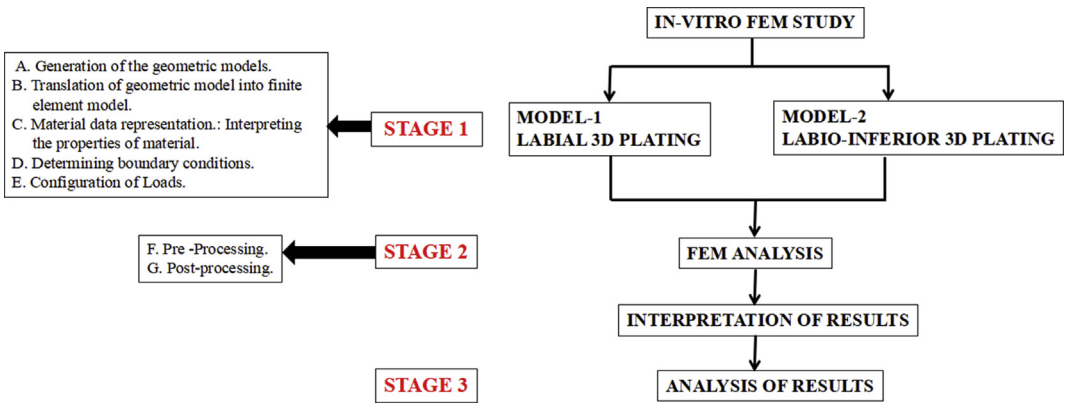


Fig. 1. Steps in FEA.

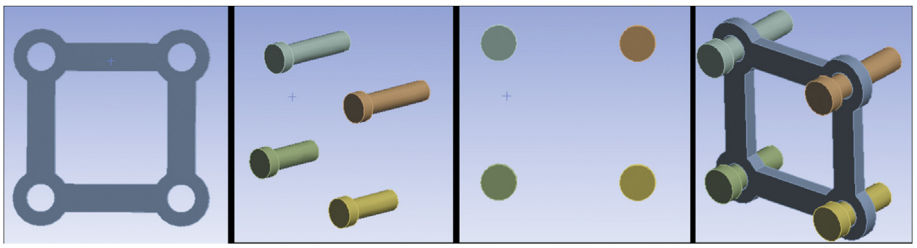


Fig. 2. Designing of 3D plate & screws for control model.

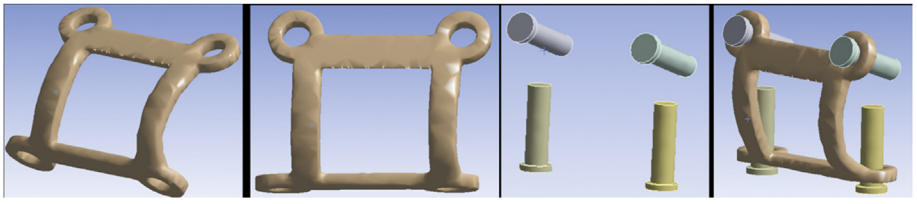


Fig. 3. Designing of 3D plate & screws for study model.

Table 1
Material data representation.

Item	Poisson's ratio (v) (%)	Elastic modulus (E) (Mpa)
Cortical bone	0.3–0.33	8700–15000 (13700)
Cancellous bone	0.3	500–1500
Medullary bone	0.3	7930
Teeth	0.33	80350
Periodontal ligament	0.49	0.666
Plates and screw (Titanium)	0.34–0.35	105000–110000 (115000)

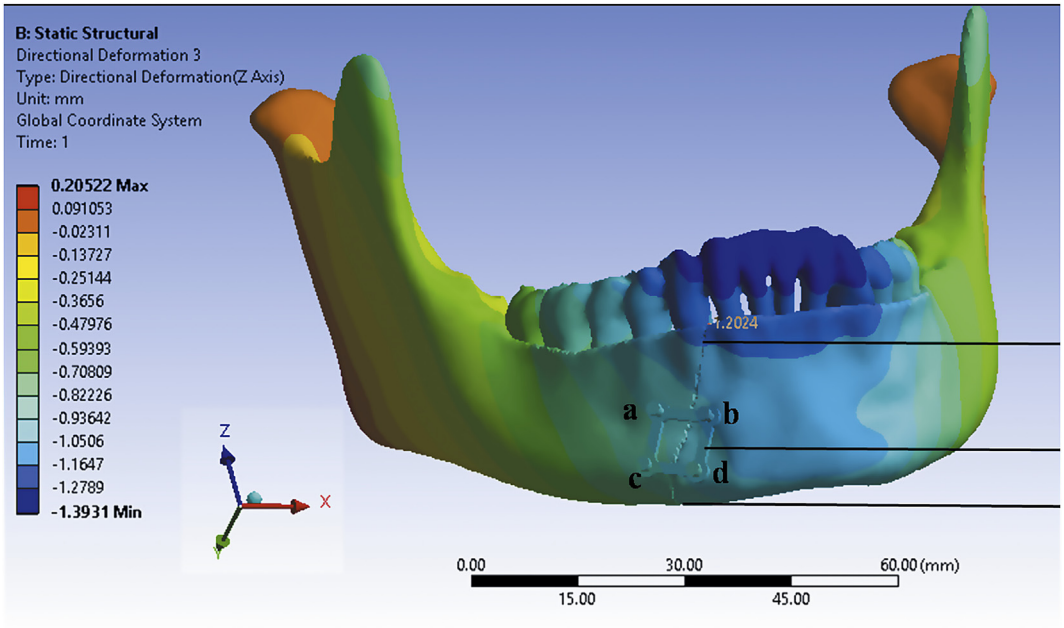


Fig. 4. Control final model—labial plating. 1: Superior border; 2: 3D miniplate in labial position, 3: Inferior border; a–d: 1st-4th screw.

movement in all planes (X, Y, Z) during masticatory load, which was fixed to zero displacement. The restriction was important to study the deformation of an object at a stationary state without any translatory or rotatory motion. These restrictions are named as boundary conditions.

E. Configuration of loads. This step included (1) fixation of screws and (2) application of muscle forces. Firstly screws were fixed in a systematic order in the study and control model as shown in Fig. 4. The next process included application of muscle forces and occlusal forces in the study and control model at various points. The

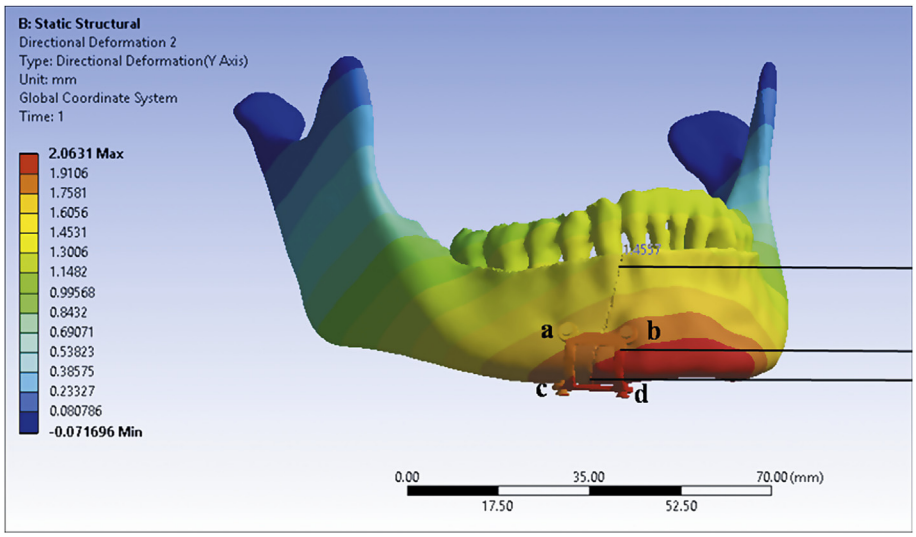


Fig. 5. Study final model—labio-inferior plating. 1: Superior border; 2: 3D miniplate in labio-inferior position, 3: Inferior border; a–d: 1st-4th screw.

magnitude of muscle and occlusal forces were 135 N in anterior mandible and 300 N respectively.

Stage 2. Analysis of the model

Analysis of the model included pre-processing and post-processing procedures.

F. Pre-processing. The mathematical equation for model analysis was solved by deriving stresses from strains by Hooke's law and calculating strains from displacement functions within the element, along with Hooke's law.

G. Post-processing. The output of analysis was expressed in the numerical form which consisted of nodal values of the field variable. Graphic outputs of field variables were displayed in the form of curves and contours. Color coded maps were used to depict the outcome. Quantitative analysis was evaluated by interpreting these maps.

Stage 3: analysis of the results

The study and control models were evaluated and compared for

(1) Displacement of fracture fragments during screw fixation along the superior and inferior border, in mm (Fig. 4) in all three axes (X—anteroposterior, Y—superoinferior, and Z—transverse).
(2) Displacement of fracture fragments after screw fixation and during application of masticatory load, in mm (Fig. 5) in all three axes.
(3) Assessment of lingual splay, in mm (Fig. 6) in all three axes.
(4) Assessment of stress distribution in all three axes using von Mises analysis, in Mpa (Figs. 7 and 8).

Part II — Clinical trial

Inclusion and exclusion criteria

Patients with anterior mandibular fractures and no systemic disease (American Society of Anesthesiologists I patients) were selected for the pilot clinical trial. Patients with systemic disease or comminuted fractures of mandible were excluded.

Surgical treatment

ORIF was done using an intraoral approach with vestibular incision and fractures were reduced and fixed with 3D miniplate (1.5 mm system-LeFort plates) in labio-inferior position. Fracture reduction & fixation was done under general anesthesia. Standardized surgical protocol was followed by a single surgeon. The vestibular incision was used to expose the fracture. Intermaxillary fixation was achieved with arch bar. Titanium 3D miniplate was fixed in the labio-inferior position with 2 mm × 6 mm screws in upper border and 2 mm × 8 mm screws in the lower border (Fig. 9).

Outcome assessment

Lingual splay preoperatively and 1 week after operation, inter-fragmentary gap duration operation, as well as radiographic fracture healing were adopted to assess patients' outcomes. Lingual splay, defined as separation of the lingual cortices across the fracture line, was assessed using occlusal radiograph (Fig. 10) and Claude Guimond criteria.[4] Inter-fragmentary gap, i.e. separation between fracture fragments, was measured in millimeter using a caliper before and after reduction. Radiographic healing of fracture at 1 week after operation (Fig. 11) was assessed using Orthopantomogram and Kawai et al[8] criteria (Grade 1–4).

Results

FEM analysis

Displacement of fracture fragments during screw fixation

The detailed results of fracture displacement during fixation of screws are listed in Table 2. During the fixation of the first screw, maximum displacement/separation was noted in X axis along the inferior border, i.e. 0.094 mm in control group and 0.080 mm in study group. Fixation of the 2nd screw revealed maximum separation in Y axis along the inferior border, i.e. 2.009 mm in control group and 1.962 mm in study group. During the 3rd screw fixation, maximum displacement was found in relation to lingual splay along the X axis, i.e. 0.079 mm in control group and 0.059 mm in study group. Maximum displacement was noted in X axis along the inferior border, i.e. 0.081 mm in control group and 0.065 mm in study group during 4th screw fixation.

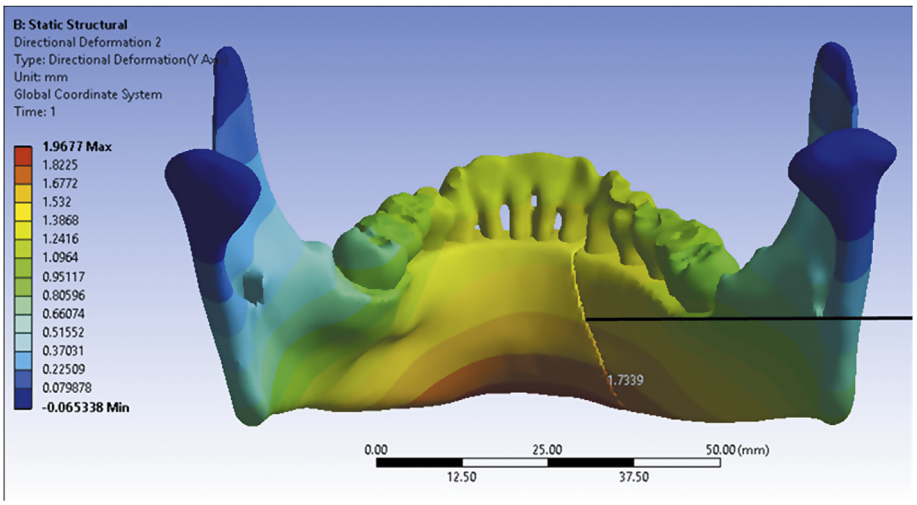


Fig. 6. Lingual splay (1 refers to the lingual splay).

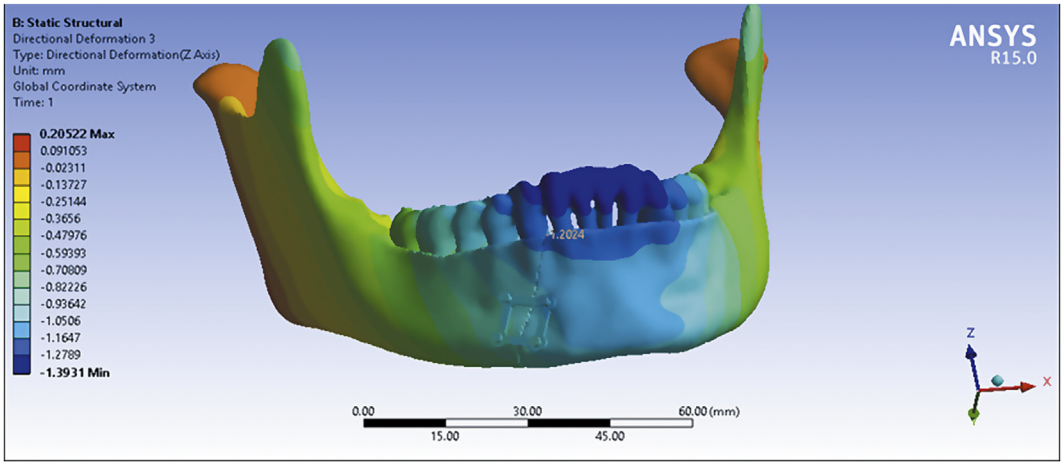


Fig. 7. Stress distribution in control model.

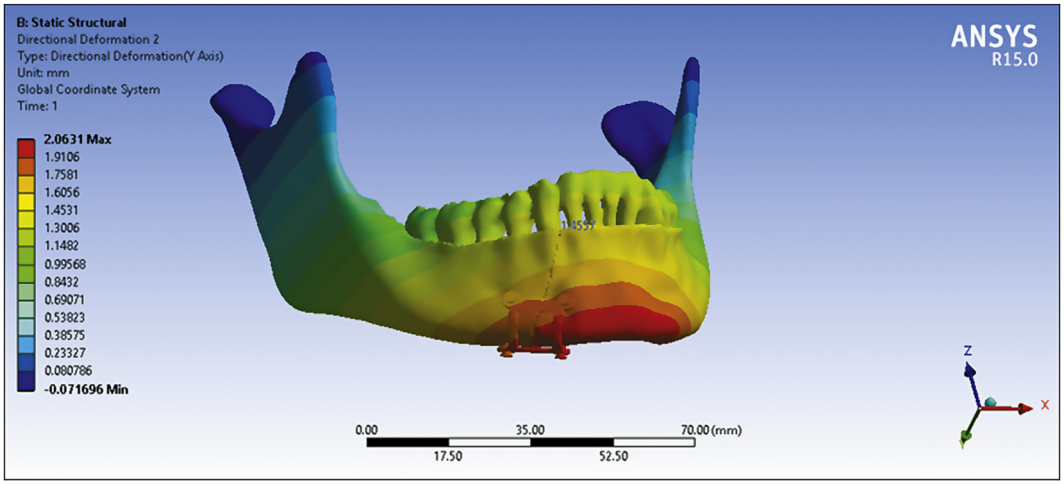


Fig. 8. Stress distribution in study model.

The results revealed that 3D labio-inferior plating provided better rigidity as compared to 3D labial plating in the superior as well as inferior border.

Displacement of fracture fragments after masticatory load

After applying masticatory load and occlusal force of 300 N in molar region[6] and 135 N in anterior mandible,[9] maximum

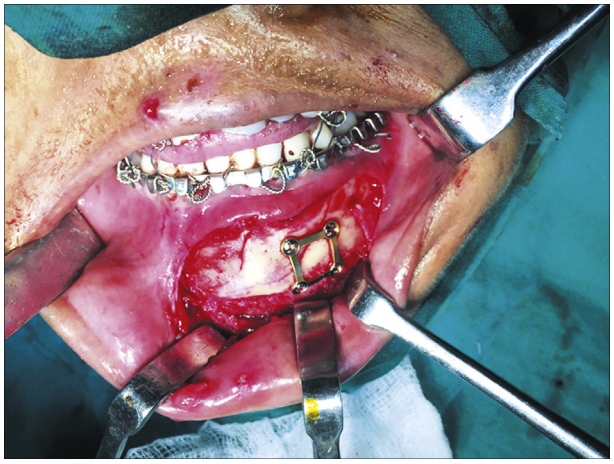


Fig. 9. Intraoperative picture demonstrating 3D miniplate in labio-inferior position.

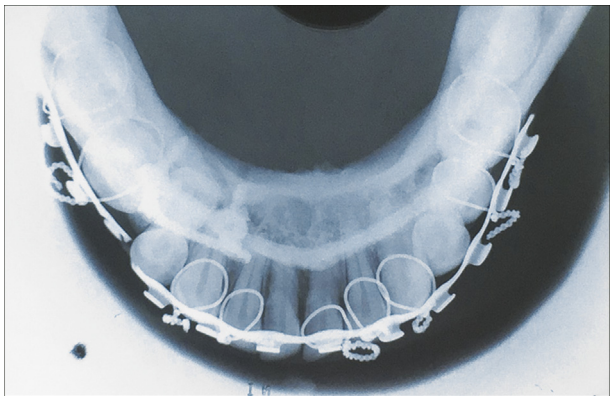


Fig. 10. One week postoperative occlusal radiograph.

displacement was seen in inferior border along the Y axis, i.e. 1.805 mm in study group and 1.860 mm in control group (Table 3). Analysis revealed that 3D labio-inferior plating demonstrated less displacement during masticatory load as compared to 3D labial plating.

Stress distribution

Von Mises stress analysis demonstrated that when 3D miniplate was fixed on the labial surface of fractured parasymphysis region, there was a slightly increased stress distribution along the inferior border in Y axis (1.860 Mpa in control vs. 1.847 Mpa in study). In some planes, the evaluated values were neutral. Lingual splay along the X axis was 0.057 Mpa in study group and 0.057 Mpa in control group. In Y axis along the superior border, the tension noted was 1.456 Mpa in study group and 1.456 Mpa in control group. Table 4 displays the data of stress analysis.

Clinical trial

None of the five clinical cases demonstrated interfragmentary separation after fracture reduction and fixation. The correction of lingual splay was also appreciated in all cases. The radiographic fracture healing was evaluated based on Kawai et al criteria[8] using orthopantamogram which revealed good clinicalresults (Table 5).

No complications such as postoperative infection, pain and paresthesia or implant failure were observed in any of the patients.

Discussion

The general options for fixing the anterior mandible are transosseous wiring, miniplates, lag screws and dynamic compression plates.[4] Currently, the most commonly used method of fixation for anterior mandibular fractures is miniplates. According to Champy's principle, two miniplates are advocated at anterior mandible for adequate stability and ideal osteosynthesis.[3] However, this will not correct lingual splay which is frequently observed in fractures of anterior mandible. Hence 3D miniplates are popularized as they offer 3D stability as well as correction of lingual splay. Further, this method reduces the number of hardware; 2 plates and 8 screws for conventional miniplates vs. 1 plate and 4 screws for 3D miniplate.[5]

The present study was designed to assess the feasibility of combining the advantages of a single 3D miniplate on the labial cortex and labio-inferior positioning of two conventional miniplates. This study hypothesized the usefulness of labio-inferior positioning of a single 3D miniplate and assessed the same by finite element analysis. This is the first study which has assessed the differences in stability offered by fixation of 3D miniplate at two different positions for anterior mandibular fractures, i.e. labial and labio-inferior by FEM analysis. The study has also compared the stress distribution across the fracture line and displacement of fracture fragments in X, Y and Z axes during screw fixation and in response to masticatory load, between the control and study group.

The methods commonly used to study the stability of various materials of fixations are physical biomodelling and computer biomodelling. The former includes cadaveric bone study, animal



Fig. 11. One week postoperative orthopantamogram image.

Table 2
Analysis of displacement during screws fixation (mm).

Site of separation during screws fixation	X plane (anteroposterior)		Y plane (superoinferior)		Z plane (transverse)	
	Study	Control	Study	Control	Study	Control
During 1st screw fixation						
Inferior border	0.080	0.094	1.952	2.046	0.871	0.878
Superior border	0.048	0.054	1.519	1.574	1.251	1.274
Lingual splay	0.059	0.059	1.807	1.831	0.831	0.884
During 2nd screw fixation						
Inferior border	0.080	0.087	1.962	2.009	0.865	0.870
Superior border	0.048	0.055	1.520	1.565	1.232	1.236
Lingual splay	0.059	0.060	1.794	1.806	0.833	0.859
During 3rd screw fixation						
Inferior border	0.080	0.084	1.937	1.939	0.814	0.852
Superior border	0.048	0.053	1.513	1.522	1.221	1.221
Lingual splay	0.059	0.079	1.763	1.779	0.828	0.833
During 4th screw fixation						
Inferior border	0.065	0.081	1.883	1.900	0.798	0.799
Superior border	0.048	0.053	1.483	1.485	1.245	1.253
Lingual splay	0.056	0.057	1.776	1.782	0.819	0.822

Table 3
Analysis of displacement after masticatory load (mm).

Site of separation	X plane (anteroposterior)		Y plane (superoinferior)		Z plane (transverse)	
	Study	Control	Study	Control	Study	Control
Inferior border	0.069	0.080	1.805	1.860	0.785	0.798
Superior border	0.047	0.052	1.434	1.448	1.195	1.202
Lingual splay	0.058	0.073	1.717	1.718	0.810	0.811

Table 4
Analysis of stress distribution (MPa).

Site of separation	X plane (anteroposterior)		Y plane (superoinferior)		Z plane (transverse)	
	Study	Control	Study	Control	Study	Control
Inferior border	0.062	0.063	1.847	1.860	0.797	0.802
Superior border	0.048	0.053	1.456	1.456	1.184	1.190
Lingual splay	0.057	0.057	1.728	1.734	0.809	0.811

Table 5
Clinical assessment of parameters.

No.	Age (year)/sex	Involved parasymphysis	Interfragmentary gap (mm)		Lingual splay (occlual radiograph)		Radiographic union*
			Before Reduction	After Reduction	Preoperative	Postoperative	Postoperative
1	40/F	Left	3	0	−1	+1	3
2	23/M	Right	4	0	−1	+1	3
3	41/M	Right	3	0	−1	+1	3
4	35/M	Right	3	0	−1	+1	3
5	29/M	Left	2	0	−1	+1	3

Note: for lingual splay assessment, "−1" means increase in lingual splay, "0" minimal/no change and "+1" significant reduction.
* Radiographic union is assessed by Kawai et al criteria[8] using orthopantamogram. Grade 1–4: 1–unchanged, 2–resorption, 3–osteogenesis, 4–union.
All of the postoperative data are obtained at 1 week after operation.

study and various bone-substitute modelling. While the latter comprises of virtual models, computational biomodels and rapid prototypes.[9] FEM was chosen for this study because of its numerous advantages: (1) FEM biomodelling is more accurate and reliable; (2) it is a noninvasive technique; (3) generation of 3D models is possible; (4) surgeons can repeat the analysis as many times as possible and (5) material properties of implants, physical and biological properties of bone, teeth and muscles can be replicated in FEM with utmost accuracy.[10]

In maxillofacial scenario, FEM has been used to determine the stability of internal fixation in implant surgery,[11] orthognathic surgery,[12] panfacial trauma[11,13,14] and reconstruction procedures.[15] FEM has also been used effectively by numerous authors to compare the different types of plates in different fracture patterns of mandible. Akiko et al[6] studied the stress analysis in symphyseal fracture and concluded that the perpendicular double (one labial and one inferior) plating was the most satisfactory in terms of stability. However, this technique requires 2 conventional miniplates and 8 screws which increases the intraoperative time and cost of hardware. It also increases the amount of hardware which may lead to implant-related complications. The above mentioned disadvantages may be negated by the use of a single 3D miniplate, as revealed by our study.

In a prospective clinical trial by Barde et al,[5] the clinical efficacy of one 3D miniplate in ORIF of fractured anterior mandible has been established. The study assessed the operating time, post-operative infection, pain, wound dehiscence, neurosensory deficit & postoperative mobility and concluded that 3D plates were clinically superior due to its quadrangle geometry. The results of our study indicate that clinical benefits of 3D plate in a labial position may be further compounded by labio-inferior positioning of 3D miniplate.

A total of two models created from CT scan helped to objectively compare the biomechanical stability of labial (control) vs. labio-inferior (study) plating using 3D plate. During screw fixation and application of masticatory force, displacement of fracture fragments and stress distribution were checked in X, Y and Z axes. During loading, maximum displacement was seen in inferior border along the Y axis in study group as compared to control group. Similarly, during screw fixation maximum displacement/separation was noted in control group as compared to study group. On von Misses stress analysis, lower distribution of stress was found for the labio-inferior 3D plate as compared to labial 3D miniplate. The above mentioned findings demonstrate the superiority of the labio-inferior plating in fractures of the anterior mandible.

Though numerous FEM studies have been conducted to analyze the stability and stress distribution of different types of plates, lingual splay pertaining to mandible fractures has not been assessed in detail. On the contrary, this study objectively ascertains the correction of lingual splay during labio-inferior fixation of 3D miniplate. Correction or elimination of lingual splay is very important clinically because fractures of the anterior mandible with lingual splay can lead to unaesthetic widening of the face post-operatively.[16]

Joshi and Kurakar[17] assessed plate fixation in mandible with 15 different designs of miniplates and compared the various parameters such as stress concentration, maximum bite force and inter-fragmentary stability between these miniplates. The various parameters mentioned above were assessed only after fixation of all the screws but in our study we have compared displacement of fracture fragments and inter-fragmentary mobility during every screw fixation, which is clinically important. The reduced stress distribution observed in the study model as compared with control model implies that labio-inferior plating may negate the pressure-related resorption of bone which may be clinically significant.

This FEM analysis was further validated by a pilot clinical trial, which revealed identical results to FEM study in terms of stability of the 3D miniplate and elimination of lingual splay. Intraoperative application of the plate was found to be convenient and less time-consuming because of the reduction in the number of screws by 50%.

Agarwal et al[18] in his prospective randomized clinical trial compared the effectiveness of 3D miniplates to standard miniplates for fractures of parasymphysis and symphysis. The authors concluded that use of 3D miniplate in anterior mandibular fractures have added benefits like reduced intraoperative time,[19] occlusal stability during masticatory load, reduced hardware as compared to standard conventional two miniplates. Our study also demonstrated similar results. Further, in the postoperative period, palpability of the plate was found to be minimal due to the lesser thickness of 3D miniplate in compared to the conventional miniplate.[20]

This study has the limitation of small sample size for clinical trial. However the following findings are exclusive to this study.

(1) Assessment of lingual splay after labio-inferior positioning of 3D miniplate.
(2) Assessment of inter-fragmentary mobility and displacement of fracture fragments during every screw fixation.
(3) Simulation of the clinical impact of masticatory load on the fracture fragments after screw fixation.
(4) FEM study does not mimic the exact clinical scenario in various aspects and hence limit the clinical assessment in the following aspects: (a) the technical ease of application of 3D plate in labio-inferior position in a patient, (b) the severity of postoperative tissue response such as swelling and pain and (c) bone resorption or complications such as infection cannot be assessed. So, this study included a clinical trial to validate the FEM results. The clinical results also coincided with the FEM results.

In conclusion, this is the first study describing the use of a single 3D miniplate at an alternate (labio-inferior) site of osteosynthesis for fractures of anterior mandible and the results have significant clinical implications. Fixing the 3D plate in the labio-inferior position of the mandible may ensure favorable clinical outcomes such as accurate 3D reduction of fracture with minimal stress on the fracture fragments. Clinically stable fixation would translate to better fracture healing and minimal postoperative complications.

Funding

Nil.

Acknowledgements

The authors would like to thank the SRM Institute of Science And Technology, Tamil Nadu, India for support to carry out this research and Mr. Santhosh from Advanced Research School for Technology and Product Simulation (ARSTPS) R&D wing of CIPET, for all his support and permitting me to do the study analysis in Central Institute of Polymer Engineering & Technology (CIPET).

Ethical statement

Ethical approval of this study has been obtained from the Institutional Review Board-SRMDC/IRB/2016/MDS/No.405.

Conflicts of interest

All of the authors declared no conflicts of interest.

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