Comparison and evaluation of biomechanical stability of customized plate over monocortical screws, bicortical screws and 3d plate in mandibular fractures – An in-vitro studySailesh Kumar R^{1*}, R N Mugundan², R S Neelakandan³

^{1,2}Consultant, ³Vice Chancellor, Professor, ^{1,3}Dept. of Oral & Maxillofacial Surgery, ²Dept. of Oral and Maxillofacial Pathology, Meenakshi Ammal Dental College & Hospital, Meenakshi Academy of Higher Education & Research (MAHER) Deemed to be University, Alapakkam Main Road, Maduravoyal, Chennai, Tamil Nadu, India

***Corresponding Author: Sailesh Kumar R**

Email: drsailesh91@gmail.com

Abstract

Objective: To compare and evaluate the biomechanical stability of a customized plate over miniplate with monocortical screws, miniplate with bicortical screws, and 3D plates across the simulated fractured fragments.

Materials and Methods: This in-vitro study involves the use of 40 swine Hemi mandibles with 10 in each group. The specimens were divided into four groups. Group I: Fixation with four holed 2mm mini plates with gap and 4 monocortical screws 2x10 mm, Group II: Fixation with four holed 2mm mini plates with gap and 4 bicortical screws of dimension 2x16 mm, Group III: Fixation with 3D plate, Group IV: Fixation with the customized plate fixed with monocortical screws (2 x 10mm) at tension zone and bicortical screws (1.5 x 16mm) at the compression zone. All plates and screws used were made of stainless steel. The Instron universal Testing System is used for analyzing the test material. The maximum resistance load of these fixations was recorded.

Results: Group II showed more mechanical resistance than all other groups which is statistically significant (P-value <0.05). Group IV (customized plates) showed equivalent mechanical resistance to group III.

Conclusion: The customized plate has good biomechanical strength comparable to a 3D, it can be of great advantage especially with comminuted fractures.

Keywords: Customized plate, Concept Fracture plate, Biomechanical strength, Fractures, Invitro study.

Introduction

Among the fractures of the facial skeleton, the area most prone to fractures are in the mandible, particularly the angle, condyle, parasymphysis, and the body.^[1] In the past, the technique of mandibular fracture fixation has been modified and as underwent enormous variation. The plating systems for stable internal fixation described in the literature were performed either with an intra-oral or extra-oral approach for the effective management of mandibular fractures. The selection of a plate is purely based on the surgeon's preference and the type of fracture.

Various factors play an important role in the management of mandibular fractures like existing fracture conditions, design of the plate, surgical skill, and patient compliance. The objective of fracture management is to ensure a good reduction, fixation, and immobilization of the fractured fragments, with adequate maintenance of the blood supply and immediate restoration of function.^[2]

Recent advancements on mini plates fabrication based on Champy's principle^[3,4] and 3D plating systems has been developed to meet the requirements of functional fixation with lesser complications. Research shows that the 3D plates in mandibular fractures offer more biomechanical stability and strain resistance in compared to conventional miniplate

fixation.^[5] As a result of research in long bones, the Academy of Osteosynthesis^[2] advised absolute stability to prevent interfragmentary movement and thereby promoting primary bone healing.

Conventional treatment strategies include either closed reduction using splints or open reduction and fixation (ORIF) with mini plate fixation, wire osteosynthesis, or reconstruction plates. Open reduction of comminuted fracture could result in stripping of blood supply to the fragments leading to sequestration and infection. Such fractures are suggested to be treated in a closed manner. The stabilization of the comminuted fracture fragments is the most important factor to obtain an osseous union. In the case of reconstruction plate, bending is quite a time consuming during its adaptation to the mandible.^[6] Another challenge lies in the reliable fixation of these multiple fragments to prevent any postoperative infections.^[7] In comparison to any of the techniques mentioned above with its associated shortcomings this customized mesh plate could provide a good stabilization of displaced, undisplaced as well as comminuted fractured ends with minimal fracture site exposure thereby reducing the associated complications. In this present prospective study, we evaluated the maximum load resistance of the customized plate over the 3D plate,

miniplate with monocortical screws, and miniplate with bicortical screws, across the simulated fracture at parasymphysis, body, and angle in swine mandible.

Materials and Methods

This prospective in-vitro study on animal (swine) bone was done with the approval of Meenakshi University Ethical committee, virtual designing of the plates were performed at Central Institute of Plastic and Engineering Technology (CIPET), Chennai and the in-vitro test was done at MICRO LABS, Ambattur, Chennai, during the year 2015 - 2017.

Designing of the customized plate

The design of the plate came up when there was a necessity of using a universal plate for all kinds of mandibular fractures. Plate customization was performed virtually using computer-aided designing (CAD) software (Figure 1) in the central institute of plastic and engineering technology (CIPET), Chennai. The dimension of the plate was 2mm profile superiorly with 2mm diameter screw holes and a 1mm profile mesh continues below the lower border of the mandible with a pore size of 1.5 mm diameter. The length of the mesh plate is placed at 15mm.

Fabrication of the customized plate

The STL format of the plates was made and 3D printing (Figure 2). The plates were fabricated by a technician in stainless steel according to the desired dimensions and the mesh was made in such a fashion that, it was malleable and could easily adapt to the anatomical contours of the bone when placed.

Twenty wet swine mandibles were selected for the study. They were cut in the midline to produce 40 Hemi mandibles (N=40). Four study groups (n=10) were selected according to the type of plate fixation at the various proposed site of virtual fracture namely, parasymphysis, body, and angle (Figure 3,4).

Group I: Fixation stabilized using four holed 2mm mini plates with gap and 4 monocortical screws 2x10 mm.

Group II: Fixation stabilized using four holed 2mm mini plates with gap and 4 bicortical screws of dimension 2x16 mm.

Group III: Fixation done using the 3D plate.

Group IV: Fixation done using the customized plate fixed with monocortical screws (2 x 10mm) at tension zone and bicortical screws (1.5 x 16mm) at the compression zone. (Figure 6 (a), (b)). All the screws and plates used were made of stainless steel.

A virtual fracture was created at parasymphysis, body, and angle of the swine mandible in each group with displacement stress compared between the customized plate over mini plates and 3D plate by exerting a compressive force through a universal testing machine in the laboratory.

The plating technique of miniplates was based on Champy's technique^[4] and AO/ASIF2 technique for parasymphysis, body & angle region. After plate fixation, the proximal segment of each specimen were mounted on a custom made fixture. The swine mandibles were then

sectioned accordingly to fit the fixture and were locked using a fixation screw before application of the load.

The Universal mechanical testing machine tests specimens in tension and compression while meeting international standards. After fixation, all groups were subjected to compression load in the Universal testing machine. The point of load application was fixed for all the specimens. The machine was calibrated and maximum resistance/displacement load (MRL) at 10mm displacement is recorded for each group and tabulated. The Acquired data from the two different groups were analysed using SPSS for windows version 16.0 (SPSS Inc., Chicago, Illinois, USA) with One Way ANOVA followed by Tukey's Post Hoc Test. P-value <0.05 was considered significant.

Figure 1: Virtual design of buccal and lingual adaptation of the customized plates

Figure 2: 3D printed plate prototype

Figure 3: Simulated fractures on swine mandible fixed using respective plates for the study

Table 1: Intergroup comparison at parasymphysis region

Parameter	Groups Compared					
Maximum Load resistance at 10mm displacement	Group I V/s Group II	Group I V/s Group III	Group I V/s Group IV	Group II V/s Group III	Group II V/s Group IV	Group III V/s Group IV
	0.0001 ^s	1.000 ^{ns}	0.785 ^{ns}	0.0001 ^s	0.007 ^s	0.778 ^{ns}

The mean difference is significant at the 0.05 level, s – Significant, ns – Non significant

Table 2: Intergroup comparison at body region

Parameter	Groups Compared					
Maximum Load resistance at 10mm displacement	Group I V/s Group II	Group I V/s Group III	Group I V/s Group IV	Group II V/s Group III	Group II V/s Group IV	Group III V/s Group IV
	0.0001 ^s	0.006 ^s	0.004 ^s	0.004 ^s	0.005 ^s	0.999 ^{ns}

The mean difference is significant at the 0.05 level, s – Significant, ns – Non significant

Table 3: Intergroup comparison at angle region

Parameter	Groups Compared					
Maximum Load resistance at 10mm displacement	Group I V/s Group II	Group I V/s Group III	Group I V/s Group IV	Group II V/s Group III	Group II V/s Group IV	Group III V/s Group IV
	0.000 ^s	0.403 ^s	0.001 ^s	0.000 ^s	0.050 ^s	0.050 ^s

The mean difference is significant at the 0.05 level, s – Significant, ns – Non significant

Figure 4: Customized mesh plate fixated on the Simulated fracture

Graph II: Mean Load Resistance of different plates at Mandibular Body region

Graph I: Mean Load Resistance of different plates at Parasymphysis region

Graph III: Mean Load Resistance of different plates at Mandibular Angle region

Results

The values of maximum resistance load in KN (kilo Newtons) at 10mm displacement is recorded.

Comparison of the maximum load resistance based on the fracture region

Mandibular Parasymphysis

At the parasymphysis fracture site is illustrated in graph 1 and table 1, the miniplate with bicortical screws (group II) displayed maximum load resistance followed by the customized plate (group IV) in comparison with the other groups.

Mandibular Body

On intergroup comparison at the mandibular body fracture site given in table 2 and graph 2, the miniplate with bicortical screws (group II) displayed maximum load resistance followed by the customized plate (group IV) in comparison with the other groups.

Mandibular angle

On comparing the mandibular angle fracture site in table 3 and graph 3, the miniplate with bicortical screws (group II) displayed maximum load resistance followed by the customized plate (group IV) in comparison with the other groups.

Group II showed significant mechanical load resistance than other groups (P-value <0.05). Group IV demonstrated better mechanical resistance than group I which had a significant difference (P-value <0.05) in most of the areas of fracture studied. Group IV showed mechanical resistance which was statistically insignificant (P-value >0.05) over group III in most of the areas of fracture studied.

The least mechanical resistance was seen in group I and the highest mechanical resistance was seen in group II. Thereby the in-vitro results prove that miniplate with bicortical screw fixation provides better rigid fixation than the other plating systems. The customized plate with mesh is found to be as efficient as the 3D plates in different fracture sites at the mandible.

Discussion

The incidence of facial bone fractures in Indian population was studied in 2015 in which mandibular fractures (60%) had the highest rate of incidence, this study was done to introduce a customized mesh plate that effectively manages such fractures with a functionally stable fixation.^[1] In India, the mandibular parasymphysis (27%) has the highest incidence followed by the mandibular angle (25%), condyle (22%), dentoalveolar fractures (16%), body (8%) and symphysis (2%).^[8]

Such fractures are managed either by closed reduction or by open reduction. Closed reduction is achieved by interdental wiring, arch bars, cap/gunning splints, and external pin fixation. Open reduction utilizes transosseous wiring, plating, lag screws, and titanium mesh. The technique of mandibular osteosynthesis was introduced by Michelet et al^[10] (1973) and later improved and popularized by Champy^[3,11] (1975) the latter is followed till date. The champys lines represent the tension and compression zones in the mandible caused by the load exerted during muscle function.

These lines of osteosynthesis represent the area of the mandible that resists functional stresses and thus are the ideal

location for miniplate fixation. Miniplate fixation with monocortical screws provides functional stability when there is an interfragmentary movement present on loading and results in gap healing, in contrast to bicortical screws where there is rigid fixation without the interfragmentary gap. The Strasbourg group of research^[2] has advised rigid fixation to prevent interfragmentary movements which thereby promote primary fracture healing, as opposed to Champy et al^[3,11] who have advised functional stability rather than rigid fixation to prevent the stress shielding effect. This mini plate with monocortical screw fixation which provides functional stability lacks 3-dimensional resistance of forces, to overcome that 3D plating system was devised.

The 3D plating system was introduced by Mostafa Farmand, which has two-plates with interconnecting crossbars.^[12,13] It is quadrilateral in shape thereby providing a geometrically stable configuration for support. It also increases the resistance to shear forces along the long axis of the plate. This provides simultaneous stabilization over tension and compression forces in comparison to the conventional miniplates.^[14,15]

The stainless steel plates and screws are recommended, depending on the patient's economic status and they are advised to be removed after the healing period of the fracture site, as the nature of the implant material can cause a reaction to the surrounding tissues which may further lead to infection.^[11,16] The titanium plates which are inert in nature, does not cause adverse tissue reactions or infection at the implanted site and are the most preferred material.^[11] Biodegradable plates are opted depending on the growth status of the patient, whereas the choice of non-biodegradable plates can restrict the growth in the region of fracture. In our study, the customized plate was made in stainless steel material for in-vitro trial and compared with three other stainless steel plating system.

Our study was done in fresh swine mandibles, which were opted as their bone densities were similar to that of the human mandible.^[13] In the current study, the choice of wet swine mandibles was to maintain the wet strength and yield toughness of the bone, as most of the in-vitro studies used dry mandibles of human or animal bones. Nyman JS et al^[17] analyzed that the loss of water from the extracellular matrix of bone tissue, by drying, reduces the mechanical properties of bone and thereby reduces yield toughness of bone. The swine mandibles were kept fresh by freezing them and by doing so, they do not lose their biomechanical resistance property.^[18]

In this study, we fabricated a customized universal mesh plate for all types of fractures that could occur in different regions of the mandible and compared its efficiency against other available plating systems. The fractures were simulated at parasymphysis, body, and angle region of swine mandibles, and the customized plate was manually contoured to adapt it to the simulated fracture site.

Champy et al^[3,11] put forth the most accepted "lines of osteosynthesis" in mandible, where he had suggested two plates in symphysis and parasymphysis region of the mandible to resist the tension and compression forces acting

at the fracture site due to muscle action, and one plate fixation with monocortical screws for fractures along the body of the mandible. According to the Strasbourg osteosynthesis research group (SORG) or AO/ASIF,^[2] the miniplate with bicortical screw fixation was suggested for rigid fixation. In our study group, only one customized mesh plate fixation was done in parasymphysis, body, and angle regions of the swine mandibles.

The angle is the second most frequent site for fracture on the mandible and several fixation methods have been advocated till date. Champy et al^[3,11] has suggested single miniplate monocortical fixation at external oblique ridge region, Ellis et al^[19] has also evaluated and proved the efficacy of single miniplate in mandibular angle fracture. They both concluded that the use of a single miniplate is a simple and reliable technique with reduced complications.^[20] Strasbourg osteosynthesis research group (SORG or AO/ASIF) has advised rigid fixation for mandibular angle fracture using two plates (bipolar) with bicortical fixation.

In this study, once these simulated fractures were reduced and plated using different plating systems, they were subjected to mechanical load by a computer-controlled universal testing machine. de Olivera et al^[21] had evaluated the biomechanical resistance of three different stable internal fixation techniques for fixation of sagittal split osteotomies in sheep mandibles using the universal testing machine. Medeiros et al^[22] also reported an in vitro study using polyurethane mandibles to evaluate the mechanical resistance of bilateral mandibular angle and body fractures by different plating systems using a universal testing machine.

The average adult human mandible may generate between 300 – 400 N of maximal bite force. Haug et al^[23] in his study has proved that at the incisal edge, loading forces range from 0 to 100 N, and for the contralateral molars, they range from 0 to 200 N, by biomechanical evaluation using polyurethane mandible replicas.

In comparison to the 3D plate and miniplate monocortical fixation, our customized plate showed better biomechanical stability but not greater than miniplate with bicortical fixation at various sites after evaluation using a computer-controlled universal mechanical testing device. Thus we hypothesize that the customized mesh plate is as equivalent to the 3D plate and miniplate monocortical fixations in providing functional stability to the fractured fragments, promoting secondary bone healing. However, customized plates have an edge over the 3D plates in compound fractures in not involving the comminuted fractured fragments to take stability from. This is a laudable feature as most of the authors [6, 24] have highlighted the high incidence of secondary infection and osteomyelitic changes taking place with a comminuted fracture site that otherwise requires constant monitoring.

Jun li ma et al^[7] suggested the use of 3D printed customized titanium mesh for management of such fractures, where the mesh holds the comminuted segments together and provides the anatomical contour. The author has also suggested removal of the mesh after the fracture healing which was constantly monitored using CT scans. Thomas

Schug et al^[24] in his prospective study used titanium mesh for management of fracture in atrophic mandibles. He has stated that the mesh can also be shaped into a tray and used for the placement of bone graft material. The rate of complication was also relatively low.

The use of the customized plate with mesh has the potential to maintain the anatomical contour more closely. Similarly, the customized mesh plate can also be used in case of comminuted fractures, where the malleable nature of our mesh plate can be easily utilized to fit the contour of the defect area, as well as to be used as a tray for bone grafting in such defects. The anatomical contour of the lower border can also be maintained by our design.

The plating systems available in the market cannot be universally used for all fracture types as it requires different shape and profile thickness based on the anatomy of the area. This in-vitro study was done to prove the efficacy of the customized mesh plate at various fracture sites and it showed significant biomechanical stability than the 3D plate and miniplate monocortical fixation. The results of this in-vitro study encourage this customized plate to be utilized in any type of mandibular fracture for it could be easily contoured because of its malleability, all the more so in mandibular comminuted fractures as it does not interfere with its periosteal blood supply and still have stability equivalent to the 3D plate, providing functional fixation. Its use in human subjects is to be validated through clinical trials.

Conclusion

The customized plate has biomechanical strength comparable to that of 3D plate but lesser than that of the miniplate bicortical fixation screws. There is also an additional laudable feature of near-normal bone contouring and bone holding property due to its adaptability and meshed network design that can be of great advantage especially with comminuted fractures.

Abbreviations

ORIF - Open Reduction and Internal Fixation

CIPET - Central Institute of Plastic and Engineering Technology

CAD - Computer-aided Designing software

AO/ASIF - Association for Osteosynthesis/Association for the Study of Internal Fixation

KN – Kilo Newtons

SORG - Strasbourg Osteosynthesis Research Group

Funding

None.

Conflict of Interest

None.

References

1. Olson RA, Fonseca RJ, Zeitler DL, Osborn DB. Fractures of the mandible: a review of 580 cases. *J Oral Maxillofac Surg.* 1982;40(1):23-8.

2. Iizuka T, Lindqvist C, Rigid internal fixation of mandibular fractures. An analysis of 270 fractures treated using the AO/ASIF method. *Int J Oral Maxillofac Surg.* 1992;21:65-69.
3. Champy MP, Haeger L, Wilk A, Gerber C, Osteosyntheses mandibulaires selon la technique de Michelet. I. Bases biomécaniques. II. Présentation d'un nouveau matériel. *Résultats Rev Stomat.* 1976;77:569.
4. Champy M, Loddé JP, Schmitt R, Jaeger JH, Muster D. Mandibular osteosynthesis by miniature screwed plates via a buccal approach. *J Maxillofac Surg.* 1978;6(1):14-21.
5. Ellis E 3rd. A study of 2 bone plating methods for fractures of the mandibular symphysis/body. *J Oral Maxillofac Surg.* 2011;69(7):1978-87.
6. Dai J, Shen G, Yuan H, Zhang W, Shen S, Shi J et al. Titanium Mesh Shaping and Fixation for the Treatment of Comminuted Mandibular Fractures. *J Oral Maxillofac Surg.* 2016;74(2):337.e1-337.e11.
7. Ma J, Ma L, Wang Z, Zhu X, Wang W. The use of 3D-printed titanium mesh tray in treating complex comminuted mandibular fractures: A case report. *Med (Baltimore).* 2017;96(27):e7250.
8. YA Agrawal A, Chandel S, Singh N, Singhal A, Maxillofacial Fracture Patterns in North Indian Urban Population. *J Dent Sci Res.* 2013;4(1):1-4.
9. Silajiding K, Wusiman P, Yusufu B, Moming A. Three dimensional versus standard miniplate fixation in the management of mandibular fractures: A meta-analysis of randomized controlled trials. *Kaohsiung J Med Sci.* 2017;33(9):464-72.
10. Michelet FX, Deymes J, Dessus B. Osteosynthesis with miniaturized screwed plates in maxillo-facial surgery. *J Maxillofac Surg.* 1973;1(2):79-84.
11. Gilardino MS, Chen E, Bartlett SP. Choice of internal rigid fixation materials in the treatment of facial fractures. *Craniomaxillofac Trauma Reconstr.* 2009;2(1):49-60.
12. Farmand M. The 3d plating system in maxillofacial surgery. *J Oral Maxillofac Surg.* 1993;51:166-7.
13. Powell K, Atkinson PJ, Woodhead C. Cortical bone structure of the pig mandible. *Arch Oral Biol.* 1973;18(2):171-80.
14. Vineeth K, Lalitha RM, Prasad K, Ranganath K, Shwetha V, Singh J. A comparative evaluation between single noncompression titanium miniplate and three dimensional titanium miniplate in treatment of mandibular angle fractured randomized prospective study. *J Craniomaxillofac Surg.* 2013;1:103e9.
15. Choi BH, Yoo JH, Kim KN, Kang HS. Stability testing of a two miniplate fixation technique for mandibular angle fractures. An in vitro study. *J Craniomaxillofac Surg.* 1995;23(2):123-5.
16. Abdelfadil E, Salem AS, Mourad SI, Al-Belasy FA, Infected Mandibular Fractures: Risk Factors and Management. *J Oral Hyg Health.* 2013;1:102
17. Nyman JS, Roy A, Shen X, Acuna RL, Tyler JH, Wang X et al. The influence of water removal on the strength and toughness of cortical bone. *J Biomech.* 2006;39(5):931-8.
18. Bouwman JPB; Tuinzing DB, Kostense PJ. A comparative in vitro study on fixation of sagittal split osteotomies with Würzburg screws, Champy miniplates and Biofix (biodegradable) rods. *Int J Oral Maxillofac Surg.* 1994;23:46-8.
19. Ellis E 3rd, Walker LR. Treatment of mandibular angle fractures using one noncompression miniplate. *J Oral Maxillofac Surg* 1996;54:864-71.
20. Marentette L. Miniplate Osteosynthesis of Mandible Fractures. Operative Techniques In Otolaryngology. *Head Neck Surg.* 1995;6(2):86-8.
21. Olivera LB, Sant' Ana E, Manzato AJ, Guerra FL, Arnett GW. Biomechanical in vitro evaluation of three stable internal fixation techniques used in sagittal osteotomy of the mandibular ramus: a study in sheep mandibles. *J Appl Oral Sci.* 2012;20(4):419-26.
22. de Medeiros RC, Sigua EA, Navarro P, Olate S, Albergaria Barbosa JR. In Vitro Mechanical Analysis of Different Techniques of Internal Fixation of Combined Mandibular Angle and Body Fractures. *J Oral Maxillofac Surg.* 2016;74(4):778-85.
23. Haug RH, Street CC, Goltz M. Does plate adaptation affect stability? A biomechanical comparison of locking and nonlocking plates. *J Oral Maxillofac Surg.* 2002;60(11):1319-26.
24. AO Surgery <https://surgeryreference.aofoundation.org/cmf/trauma/mandible/body-simple/orif-two-plates?searchurl=%2fSearchResults>