Original Article - Comparative Study

Efficacy of Three-dimensional Locking Miniplates versus Three-dimensional Standard Miniplates in the Management of Mandibular Fractures - A Prospective Clinical Study

Ali Fathima, Girish B Giraddi, Mamthashri V, Ritika Punjabi[1], Abrar Younus A[2]

Department of Oral and Maxillofacial Surgery, Government Dental College and Research Institute, [2]Department of Orthodontics, Elegant Dental Clinic and Implant Centre, Bengaluru, Karnataka, [1]Department of Oral and Maxillofacial Surgery, Amar Clinic, Jalandar, Punjab, India

Abstract

Introduction: Fifty patients were included to compare the efficacy of three-dimensional (3D) locking miniplates versus 3D standard miniplates in the management of mandibular fractures. **Materials and Methods:** Fifty patients were randomly allocated to either 3D locking miniplate group or 3D standard miniplate group. All patients were followed for six months to compare post-operative occlusion, stability and associated clinical complications such as wound dehiscence, infection and plate/screw fracture and mental nerve paraesthesia. **Results:** All the fractures were adequately fixed when checked intraoperatively. Four patients in each group had mildly deranged occlusion, one patient in Group A and two patients in Group B had reduced stability. None of the patients had complications of non-union or malunion. In Group A, one out of 25 patients had mental nerve paraesthesia and two had wound dehiscence. Moreover, in Group B, two patients had mental nerve paraesthesia and two others had wound dehiscence. The data when compared were statistically significant (=0.05). **Discussion:** The overall result of our study led us to the conclusion that both the plating systems were satisfactory and there is no statistically significant difference when used for open reduction and fixation in mandibular fractures. Healing was satisfactory in both groups.

Keywords: Mandibular fracture, miniplate, stability, three-dimensional locking miniplates, three-dimensional standard miniplates

Introduction

Trauma to the facial skeleton results in injury to the major skeletal components of the face. Due to the prominence and anatomic position of the mandible, it is a commonly fractured site of the maxillofacial skeleton.[1] Road traffic accidents (RTAs) are the most common cause of fracture. Besides RTA and assaults, direct/indirect trauma may also occur due to sports activities, falls and gunshot injuries. Occasionally, certain pathologies such as cystic lesion, neoplasms and metabolic diseases can be a secondary cause.[2] The techniques for the management of fractures have advanced considerably in recent decades from supportive bandages, splints, extraoral pins, circummandibular wiring and transosseous wiring to rigid fixation with compression plates and recently back to semi-rigid fixation like miniplates.[3]

Miniplate osteosynthesis was first introduced by Michelet in 1973 and further developed by Champy *et al*., in 1975 and is the current standard for the treatment of mandibular fracture.[4,5] Champy *et al*., determined the ideal line of osteosynthesis on which plates must be applied to resist the torsional forces.[5,6] At present, modification in miniplates, like locking plates/screw system, has been developed.[7] The concept of three-dimensional (3D) titanium plates was developed by Farmand and Dupoirieux in 1992 to provide 3D stability of fractured bony segments.[5] The shortcomings of rigid and semi-rigid fixation led to the development of 3D plates. The stability of 3D plates is achieved by its shape that

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Quick Response Code:

Website: https://journals.lww.com/aoms

DOI: 10.4103/ams.ams_51_23

Address for correspondence: Dr. Ali Fathima, Room No. 2, Department of Oral and Maxillofacial Surgery, Government Dental College and Research Institute, Victoria Hospital Campus, Khalasipalya, Bengaluru - 560 002, Karnataka, India.
E-mail: aalifarheen135@gmail.com

Received: 17-03-2023 **Last Revised:** 05-09-2023
Accepted: 14-09-2023 **Published:** 18-12-2023

How to cite this article: Fathima A, Giraddi GB, Mamthashri V, Punjabi R, Younus AA. Efficacy of three-dimensional locking miniplates versus three-dimensional standard miniplates in the management of mandibular fractures - A prospective clinical study. Ann Maxillofac Surg 2023;13:149-53.

comprises two miniplates joined by interconnecting crossbars and fixed to the bone with monocortical screws that form a cuboid which is based on the principles of quadrangle as geometrically stable configuration for support.[8]

The quadrangular configuration of the 3D plate disseminates the forces over a wide surface area and not along a single line. This provides greater stability against torsional forces, vertical displacement, bending and shearing forces.[9,10] The introduction of locking plate systems for the treatment of mandibular fractures has offered certain advantages over other plating systems. These plates function as internal fixators, achieving greater stability by locking the screw to the plate. The most significant advantage is that the segments can be stabilised without the need to compress the bone to the plate and the screws are unlikely to loosen from the bone plate thus reducing the incidence of inflammatory complications from loosening of the hardware.[11,12]

Materials and Methods

This clinical prospective study was conducted in the Department of Oral and Maxillofacial Surgery in our institute from November 2019 to August 2021. Fifty subjects with mandibular fractures who fit in the inclusion criteria were included in the study. The study was approved by the Institutional Ethical Committee (No. GDCRI/IEC-ACM 2/19/2019-20]) and informed consent was obtained from the patients.

Inclusion criteria

- Patients under ASA-1 category
- Patients in the age group of 18–55 years
- Patients with fracture of the mandible who need open reduction and internal fixation (ORIF)
- Trauma <3 weeks.

Exclusion criteria

- Patients with comminuted fractures of the mandible
- Patients with bone pathology
- Fractures associated with infection with frank pus discharge
- Fractures in completely edentulous patients.

Patients were divided randomly into Group A (3D locking miniplates) and Group B (standard 3D miniplates). Pre-operative assessment included detailed case history to evaluate age, gender, type of fracture, aetiology and pre-surgical occlusion which was categorised as either deranged or not deranged and any associated fractures of mandible.

Subsequently, patients were subjected to radiographic investigation which included orthopantomograph (OPG) [Figures 1a and 2a]. Systemic examination, general physical examination and local examination were done to rule out associated injuries. Routine complete blood investigations were carried out. All 50 patients underwent ORIF using 2-mm locking 3D miniplates and standard 3D titanium plates under general anaesthesia/local anaesthesia.

Surgical technique

Patients were prepared, painted and draped under GA or LA according to requirement. Two percent of lidocaine with adrenaline was injected. Vestibular incision was given, and flap was raised. Fractured fragments were manipulated and reduced into the correct anatomical position [Figures 1b and 2b]. Intermaxillary fixation was done and occlusion was achieved. Plating was done with copious saline irrigation. The technique for application of the locking plates is not different than the application of any other non-compression type of miniplate. The only exception is that one should use a drill guide to 'centre' the drill hole with the centre of bone plate to facilitate screw locking with the plate. Fixed fragments are checked for mobility manually [Figures 1c and 2c]. Debridement was done. Haemostasis achieved, intermaxillary fixation (IMF) released and suturing done and pressure bandage applied. Postoperatively, patients were given medications. Advised OPG [Figures 1d and 2d] and patients were reviewed at the interval of 1st week, 1st and 6th month. Patients were assessed for occlusion and mobility of fractured fragments and any other complications. Clinical evaluation was done for the following:

Occlusal discrepancies

The post-operative occlusion was assessed by asking the patient to bite in maximum intercuspation at each follow-up. It was evaluated as intact/deranged.

Stability of fractured fragments

Evaluated intraoperatively by digital palpation, i.e., alternatively applying pressure manually across the fractured fragments. It was evaluated as follows:

1. Stable: Mobility absent.
2. Unstable: Mobility present.

Wound dehiscence

It was evaluated as present/absent in terms of wound gaping. Paraesthesia – based on information obtained from the patients and clinically by performing pinprick nociception, it was evaluated as present/absent. According to the WHO grading scale, Grade 0 corresponds to no symptoms of neuropathy, Grade 1 corresponds to paraesthesias (tingling or prickling sensation) and/or decreased tendon reflexes, Grade 2 corresponds to severe paraesthesias and/or mild weakness, Grade 3 corresponds to intolerable paraesthesia and/or marked motor loss and Grade 4 corresponds to paralysis.

Hardware failure

Based on clinical and radiographical evaluation for plate fracture and loose screws, it was evaluated as present/absent.

Statistical analysis

The data were analysed using the statistical package SPSS version 21.0 (IBM SPSS, Chicago, Illinois, USA). Descriptive statistics were given by mean, standard deviation and confidence interval. Groups were compared with independent Student's *t*-test, Chi-square test and Spearman's correlation analysis. $P < 0.05$ was considered statistically significant.

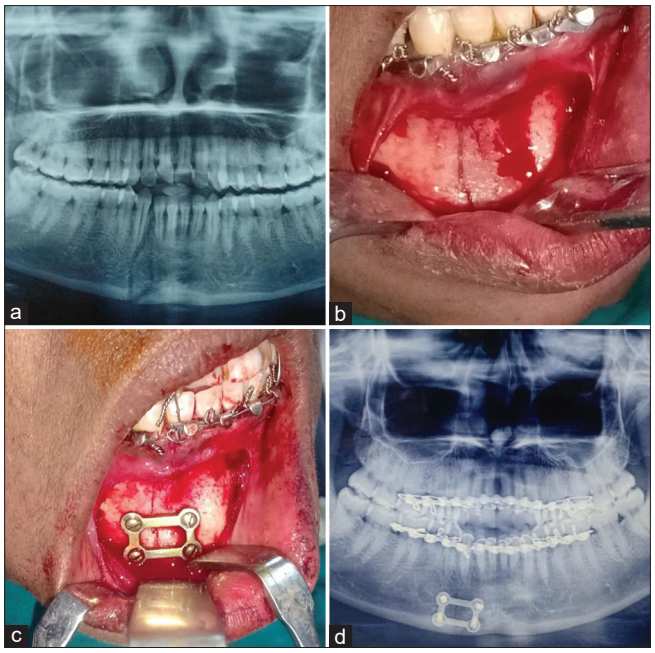

Figure 1: (a) Orthopantomograph (OPG) showing right parasymphysis fracture, (b) Intraoral view showing right parasymphysis fracture reduced into anatomic position, (c) Open reduction and internal fixation (ORIF) with three dimensional (3D) locking miniplate, (d) OPG showing ORIF with 3D locking miniplate

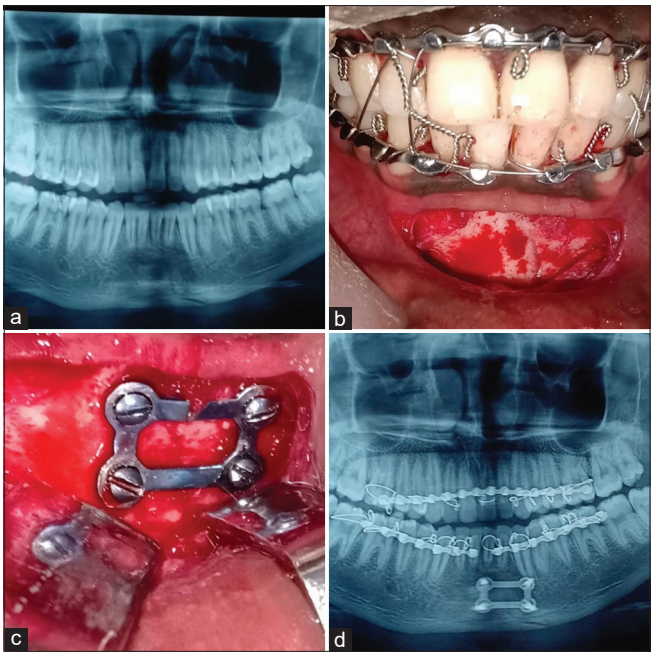

Figure 2: (a) Orthopantomograph (OPG) showing left parasymphysis fracture, (b) Intraoral view showing left parasymphysis fracture reduced into anatomic position, (c) Open reduction and internal fixation (ORIF) with three-dimensional standard miniplate, (d) OPG showing ORIF with 3D standard miniplate

Results

The age and gender distribution of the study participants in both the groups is shown in Table 1. The mean age of study participants in Group A was 27.72 ± 7.23 years and in Group B was 27.28 ± 9.32 years. Out of 50 study participants in both the groups, 39 were male and 11 were female. About 76% and 24% of the study participants in Group A were male and female, respectively. Similarly, about 80% and 20% of the study participants in Group B were male and female, respectively. The mean duration of surgery is measured in both the groups during surgery and is shown in Table 1, which is significantly higher in Group A (34.6 ± 5.18) min as compared to Group B (29 ± 2.53) min. The difference shown is statistically significant which indicates the locking 3D plate group took more operative time compared to standard 3D miniplate group.

Table 1: Age, gender distribution and mean duration of surgery of the study participants

Category	Mean±SD	
Locking (*n*=25)	27.72±7.23	
Non-locking (*n*=25)	27.28±9.32	
t	0.18	
P	0.85	
Category	**Male, *n* (%)**	**Female, *n* (%)**
Locking (*n*=25)	19 (76)	6 (24)
Non-locking (*n*=25)	20 (80)	5 (20)
χ^2	0.46	
P	0.49	
Category	**Mean±SD**	
Locking (*n*=25)	34.6±5.18	
Non-locking (*n*=25)	29±2.53	
t	4.85	
P	0.0001*	

*The difference shown is statistically significant which indicates the locking 3D plate group took more operative time compared to standard 3D miniplate group. SD: Standard deviation

The complications such as infection, paraesthesia and wound dehiscence are measured at the interval of one week, one month and sixth month. Table 2 shows the distribution of complications in both the groups of the study participants. A total of seven study participants got the complications. One out of 25 patients of Group A had mental nerve paraesthesia and two had wound dehiscence. Out of 25, four participants in Group B had complications, out of which two had mental nerve paraesthesia and two had wound dehiscence. No cases of infections and hardware failure were noted. Group A reported complications amongst 4% and 13.1% of the participants at one week and one month, respectively. Group B reported complications amongst 13.1% participants at both first week and first month. No complications were reported after six months in both the groups ($P = 0.05$). Four patients in each group had mildly deranged occlusion during the follow-up at the end of one week [Table 2]. Satisfactory occlusion was achieved by guiding elastics. One patient in Group A and two patients in Group B showed reduced stability of fracture fragments intraoperatively. They were placed on IMF for a week. Table 2 shows that there was no significant difference

related to the distribution of the intraoperative stability of the study participants between both the groups ($P \geq 0.05$).

Discussion

The primary goal of treatment of mandibular fracture is to restore normal occlusion and masticatory function. Mandibular fractures can be treated with closed reduction and ORIF. Closed reduction is attained by immobilising the jaws by intermaxillary fixation which is achieved by arch bars, dental wiring, cap splints in dentulous and in edentulous patients using gunning splints. ORIF of mandibular fracture includes intraoral and extraoral approach of the fracture site and direct osteosynthesis with transosseous wires, lag screws or miniplates.[3,13]

With the introduction and popularity of plate and screw systems over the past 30 years, a number of fixation methods have been advocated for the treatment of mandibular fractures. In open osteosynthesis, there has been a metamorphosis and change in trend from rigid fixation (1968) using compression plates to semi-rigid fixation (1973) using non-compression monocortical miniplates.[13] Mandible fracture fixation with miniplates along the 'ideal lines of osteosynthesis' has become the extensively used technique. Champy *et al*., have performed several studies to substantiate this technique.[14] Miniplates provide functionally stable fixation. Functionally stable fixation applies to internal fixators that allow bone alignment and permit healing during function.[15] The conventional miniplates are smaller, easier to handle and avoid extraoral procedures. However, conventional bone plate/screw systems stand in need of precise adaptation of the plate to the underlying bone. Without this intimate contact, tightening of the screws will draw the bone segments towards the plate, resulting in variations in the position of the osseous segments and the occlusal relationship.[9]

Table 2: Distribution of the complications of the study participants at week 1, 1st month and 6th month, distribution of deranged post-operative occlusion and intraoperative stability of the study participants

Category	Locking (*n*=25)		Non-locking (*n*=25)	
	Present, *n* (%)	Absent, *n* (%)	Present, *n* (%)	Absent, *n* (%)
1st week	1 (4)	24 (96)	2 (13.1)	23 (86.9)
1st month	2 (13.1)	23 (86.9)	2 (13.1)	23 (86.9)
6 months	0	25 (100)	0	25 (100)
χ^2	16.58		14.23	
P	0.0001*		0.0001*	
Category	**Absent, *n* (%)**		**Present, *n* (%)**	
Locking (*n*=25)	21 (84)		4 (16)	
Non-locking (*n*=25)	21 (84)		4 (16)	
χ^2	0			
P	1			
Category	**Present, *n* (%)**		**Absent, *n* (%)**	
Locking (*n*=25)	24 (96)		1 (4)	
Non-locking (*n*=25)	23 (92)		2 (8)	
χ^2	1.41			
P	0.23			

*The difference shown is statistically significant which indicates the locking 3D plate group took more operative time compared to standard 3D miniplate group

The modification of miniplates like titanium 3D plating system was developed by Farmand and Dupoirieux[5] to meet the requirements of semi-rigid fixation with lesser complications. Principles of 3D locking design depend on principles of two plating systems, i.e., 3D miniplates system and locking system. The primary forces of concern when the mandible is in function are bending, vertical displacement and shearing. In 3D plate, the vertical bars connecting the two horizontal bars resist bending forces. The quadrangular configuration of the 3D plate disseminates the forces over wide surface area and not along a single line, this provides greater stability against torsional forces, vertical displacement, bending and shearing forces. Thus, the stability is gained in 3D.[9] The plate and screw become a single rigid functional unit in the locking plate system that does not depend on the bone to plate interface for stabilisation.

This study aimed to evaluate the efficacy between 3D locking miniplates and 3D standard miniplates in mandibular fractures. The objectives of the study was to compare the duration of procedure, intraoperative stability of the fracture fragments manually, post-operative occlusion, complications such as infection, paraesthesia and wound dehiscence and hardware failure. In this study, 17 and 16 patients were under 30 years of age and 8 were equal or greater than 30 years old in Group A and Group B, respectively. The mean age of patients in Group A was 27.72 ± 7.23 years and the mean age of patients in Group B was 27.28 ± 9.32 years. Out of 50 patients, 39 were male and 11 were female. About 76% and 24% of the study participants in Group A were males and females, respectively. Similarly, about 80% and 20% of the study participants in Group B were males and females, respectively.

Operating time in minutes was recorded in both the groups from starting of incision till the closure. The mean duration of surgery in our study was found to be 34.6 ± 5.18 min in Group A and in Group B, it was found to be 29 ± 2.53 min. The locking group took more operating time because the drill guide had to be used to attain a perpendicular drill to fix the screw head precisely into the threaded plate holes. Preoperatively, all the patients of Group A and Group B had mobility of the fracture fragments. Out of 50 patients in Group A, 4.0% lacked stability intraoperatively and in Group B, 8.0% lacked stability intraoperatively. The data when compared were not statistically significant. Four patients (16%) in each group had mildly deranged occlusion during the follow-up at the end of one week. Satisfactory occlusion was achieved by guiding elastics. The data when compared were not statistically significant.

In our study, the complications such as infection, paraesthesia and wound dehiscence are measured at the interval of one week, one month and sixth month. Three participants in Group A had complications, out of which one (4%) had mental

nerve paraesthesia and two (13.1%) had wound dehiscence. Wound dehiscence was corrected by antibiotics, irrigation with betadine and saline. Patient with paraesthesia was put on methylcobalamin 1500 mcg and was found to be satisfactory after a month of surgery. Out of 25, four participants in Group B had complications, out of which two (13.1%) had mental nerve paraesthesia and two (13.1%) had wound dehiscence. No cases of infections were noted. No complications were reported after 6 months in both the groups.

To interfere with the results of our study, there was no statistically significant difference in parameters such as post-operative occlusion, stability, wound dehiscence, paraesthesia and infection. However, operative time was found to be considerably more in locking miniplate group as it demands precision in making a hole exactly in the centre of plate necessitating the use of drill guide. Healing was satisfactory in both the groups. One of the difficulties noted in both the groups was when fractures are oblique passed through the mandibular foramen; the adaptation of 3D plate was difficult. Studies on fixation of the mandibular anterior fracture with 3D locking plates provide 3D stability and carry low infection rates and shorter operative time because of simplified adaptation to the bone and simultaneous stabilisation at both superior and inferior borders.[9,16] The 3D plating system is reliable and effective treatment modality for mandibular fractures. The need for precise adaption with the incorporation of locking system in 3D plate precluded and it is unnecessary for the plate to have intimate contact with bone. Thus, the 3D plate could now be considered as the better option for the management of mandibular anterior fractures.

Conclusion

The overall result of our study led us to the following conclusion:

- The 3D system is economical and easy to use
- Of all the parameters, we studied, intraoperatively locking group consumed more time in fixation as it demands precision in making a hole exactly in the centre of plate necessitating the use of drill guide
- Both the plating systems were satisfactory and there is no statistically significant difference when used for open reduction and fixation in mandibular fractures
- However, as the screws 'lock' to the plate in locking plate system, the segments can be stabilised without the need to compress the bone to the plate and the screws are unlikely to loosen from the bone plate thus reducing the incidence of inflammatory complications from loosening of the hardware.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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