Evaluation of 2.0 mm Locking Miniplate Fixation with Minimum Adaptation for Mandible Fracture - A Clinical Study

Pracheta Ranjan[1], Atanu Bhanja[2], Piyali Poddar[3], RN Poddar[4]

ABSTRACT

Introduction: Locking miniplate is gaining popularity over standard miniplate as the modality of internal fixation method in mandible fracture due to its many advantages like, less incidence of screw loosening and postoperative complication, less requirement of plate adaptation during surgery and postoperative intermaxillary fixation etc. Our aim was to clinical evaluate 2.0 mm locking miniplate with minimum adaptation in mandible fracture.

Material and methods: A prospective study was conducted within a period of two years to clinically evaluate reliability of 2.0 mm locking miniplate fixation with minimum adaptation among patients with mandible fracture. Post operatively, intermaxillary fixation was kept only for seven days. Patients were followed up for six months for the evaluation of complication clinically and radiologically.

Results: Total 23 males and 7 female patients underwent open reduction and internal fixation with minimally adapted mandibular locking plates in 41 fractures. The age of the patients ranged from 16 – 48 years (median, 28.5). Road traffic accident was the most common etiology in 63.3%, which was followed by assault in 20%. Within a follow up period of six months, complications occurred in 2 patients (6.7%), which were all minor. One patient presented with paresthesia of lower lip, which was managed conservatively. Another patient developed wound dehiscence after three months with satisfactory osteosynthesis and implants were removed under local anaesthesia.

Conclusion: Present study reinforces the fact that, the 2.0 mm locking miniplate gives satisfactory clinical outcome with requirement of minimum adaptation and postoperative intermaxillary fixation in mandible fracture.

Keywords: Bone Plates, Bone Screws, Mandibular Fractures, Fracture Fixation, Postoperative Complications, Treatment Outcome

INTRODUCTION

The era of plate osteosynthesis in mandible started since the first reported case in 1886 by the surgeon Carl Hansmann, who used nickel coated metal strips and screws to secure fracture fragments internally after surgical exposure.[1] Since then over a period of century, enormous development happened in the field of open reduction and internal fixation(ORIF) of mandible fracture such as: metallurgy and handling characteristics of the implants; principles in the use of hardware; surgical access; complications and overall result of the treatment.[2]

Since the introduction of vitalium miniplate in mandible fracture by Michelet et al.[3] in 1973 and later its further development by Champy et al.[4,5], miniplate osteosynthesis gradually has become standard of care in mandible fracture.[6] However major disadvantage of miniplates lies in the fact that, it requires proper adaptation with the underlying bone and without it fracture fragments change position under loading.[2,6] Proper adaptation also results in transmitted pressure on the bone surface, which leads to osteolysis under miniplates and screw loosening.[1]

Guttawald[7] and Ellis[8] introduced mini locking system, where screw is locked to the threaded holes of the plate with the help of second thread under the head.[1,6] The advantage of the locking system is that, plate requires minimum adaptation and the system function as very stable mini- internal fixator due to cold wielding between threaded screw heads and plate-holes.[1,9]

Huag et al. in 2002 proved in an in-vitro study that, the degree of adaptation of plates affected mechanical behavior of non-locking system, however no effect was found in the locking system.[10] However, there is absence of any clinical study with deliberate minimum adaptation of locking plates in mandible fracture.

Therefore, a study was conducted with the purpose to clinically evaluate the result with deliberate minimum adaptation of the locking plates in mandible fracture.

MATERIAL AND METHODS

A prospective study was conducted in the Department of Oral and Maxillofacial Surgery of a dental college within a period of two years to clinically evaluate reliability of 2.0 mm locking miniplate fixation with minimum adaptation among patients with mandible fracture. Institutional ethical

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clearance was taken prior to the study.

Following proper clinical and radiological investigations, patients with mandible fracture were sequentially included in the study. Relevant data related to age, sex, etiology of trauma, site and number of fractures were documented.

Exclusion criteria for the study were:

1. Medically compromised patients
2. Concomitant fracture in either any of these regions: sub condylar, coronoid process, ascending ramus of mandible and middle third of face.
3. Grossly infected fractures
4. Patients with prior history of metal allergy
5. Failure to follow up as per the protocol.

All the patients signed an informed consent stating their willingness to participate in the study.

Plating system and the specifications of implants

Arbeitsgemeinschaft für Osteosynthesefragen (AO) 2.0-mm Mandible locking plates (MLP) system was used in the study which is manufactured by SYNTHES® GmbH (Switzerland). Implant specifications is presented in Table-1

Method

The site and location of the fracture site was determined by preoperative clinical examination and radiological investigation (Figure-1A). All the patients underwent standard preoperative investigations and pre-anesthetic checkup prior to the surgery. Preoperatively arch bar fixation was done under local anaesthesia in all the patients (Figure-1B).

After general anaesthesia, extraoral region was painted with 5% Povidone and Iodine solution. Intraorally, Povidone Iodine solution wash was given along with suction. Prior to the incision, site was infiltrated with local anaesthesia containing 2% lignocaine hydrochloride along with 1:2,00,000 epinephrine.

Fracture site was exposed (Figure-2A) either intraorally or extraorally following standard surgical technique. Intraoperatively occlusion was secured with the help of intermaxillary fixation (IMF) using soft stainless-steel (SS) wires and fracture fragments were reduced anatomically.

MLP of adequate length was selected and minimally adapted with plate benders, then it was stabilized over the fracture site by plate holding instruments. Drill guide was used prior to drilling, to ensure perpendicular orientation of the drill with the holes. Drilling was done with the help of 1.5mm SS drill bit with vertical stop at 8.0 mm, under copious saline irrigation. MLP was fixed by inserting locking self-tapping screws through the holes using star drive self-holding screw drivers (Figure-2B &C). After required numbers of screws and plates were placed for securing fracture fragments, surgical site was irrigated with normal saline and closure was done with sutures in layers. Intermaxillary fixation was released after the procedure, keeping the arch-bars attached (Figure- 2D).

Postoperatively, IMF was done on 2nd postoperative day and was kept for one week. Liquid or pureed diet was advised for initial seven days during the period of IMF, which was followed by non-chew semisolid diet for another two months. Postoperatively all the patients were assessed clinically (Figure-1D) for infection, wound dehiscence, malocclusion, tooth damage and paresthesia during the initial postoperative period before discharge and subsequent follow-up visits, which were done at 1st month, 3rd month and 6th month. Postoperative orthopantomogram (OPG) during the follow up (Figure-1C) was taken to determine non-union, malunion, evidence of osteomyelitis and hardware stability.

Protocol of Ellis et al. was followed for the evaluation of complication, which were categorized as major, if that affected osteosynthesis and required either further surgeries or extended period of IMF for the treatment. All the other complications were categorised as minor. [11]

RESULT

Within a span of two years, 23 males and 7 female patients (Table-2) underwent open reduction and internal fixation (ORIF) with minimally adapted mandibular locking plates in 41 fractures, in different regions of mandible and followed up prospectively for a period of six months. The age of the patients ranged from 16 – 48 years (median, 28.5). The distribution of number of patients in different categories of age is presented in Figure-3. Road traffic accident (RTA) was the etiology of the trauma in majority of the patients (63.3%) which was followed by assault (20%).

Parasymphysis region of mandible was involved in most of the patients in our study. Thirteen patients (43.3%) presented with involvement of parasymphysis region only, whereas in eight patients (26.7%) angle of mandible was simultaneously fractured along with it. In two patients of parasymphysis fracture and one patient of angle fracture, bilateral involvement was present.

Table-3 shows region of mandible involved, approach for ORIF and implants used in 41 fracture sites. Angle fractures were treated by intraoral approach in all except in a patient with bilateral involvement, where extraoral access was used for one side. In intraoral approach for angle fracture, fixation was done with single locking plate following Champy's technique.[4] All the parasymphysis fractures were accessed through intraoral route, whereas body fractures

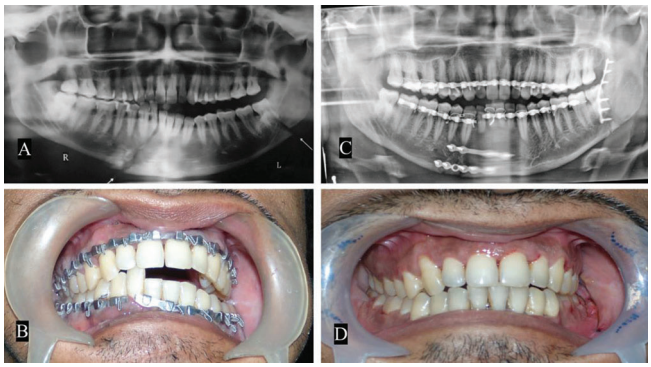

Figure-1: Pre and post-operative images (A) Pre-operative OPG showing left angle and right parasymphysis fractures (B) Pre-operative malocclusion, arch bars attached under local anaesthesia (C) Post-operative OPG in 1st month (D) post-operative occlusion in 3rd month

Plates		**Screws**	
Material	Commercially pure titanium	Material	Commercially pure titanium
Shape	Straight with or without centre space, notches between holes	Type	Locking; Star drive; Self Tapping
Number of Holes	04 holes/ 06 holes with centre space; 06 hole continuous	Length	8 mm
Thickness	1.0 mm	Thread Diameter	2 mm
Length	04 holes with centre space- 28 mm; 06 holes with centre space- 40 mm; 06 holes continuous- 35 mm	Core Diameter	1.35 mm
Width	4.8 mm	Head Diameter	2.95 mm
Distance between holes	3.0 mm	Thread Pitch	0.75 mm
Hole diameter	2.0 mm		
Bevel at Hole	30 degrees		

Table-1: Implant specifications

Criteria	**N (%)**
Age	
Range (Median) in years	16-48 (28.5)
Sex	
Male	23(76.7%)
Female	7(23.3%)
Etiology	
RTA	19(63.3%)
Assault	6(20%)
Fall	3(10%)
Work related	2(6.7%)
Region of mandible involved	
Parasymphysis*	13(43.3%)
Parasymphysis + Angle	8(26.7%)
Body of Mandible	5(16.7%)
Angle#	4(13.3%)
Number of fractures	
Single fracture site	19(63.3%)
Two fractures sites	11(36.7%)
Total numbers of fractures	41
In two patients of *parasymphysis fracture and one patient of #angle fracture, bilateral involvement was present.	

Table-2: Patient and fracture related characteristics

Region of mandible: number of fractures	**Type of approach: number of fractures treated**	**Type of implant (number of implants): number of fractures treated**
Angle:13	Intraoral: 12	4 holes with space (1):07
		6 holes with space (1): 05
	Extraoral: 1	4 holes with space (2): 01
Parasymphysis:23	Intraoral:23	4 holes with space (2):16
		4 holes with space (1) + 6 holes (1):06
		4 holes with space (1) + 6 holes with space (1): 01
Body:05	Extraoral:05	4 holes with space (2): 02
		4 holes with space (1) + 6 holes with space (1): 03

Table-3: Region of mandible, approach for ORIF and implants (41 fracture sites)

Complications (Minor)		**n (%)**
No		28(93.3%)
Yes		2(6.7%)
Type	Intervention	
Wound Dehiscence/plate exposure	Plate removal	1(3.3%)
Paraesthesia	Conservative	1(3.3%)

Table-4: Complications (n=30 patients)

were plated extraorally and in both the regions, two locking plates were used in parallel to the lower border of mandible.

Among 30 patients, within a follow up period of six months, overall complications (Table-4) occurred in 2 patients (6.7%), which were all minor and major complication was nil in our study.

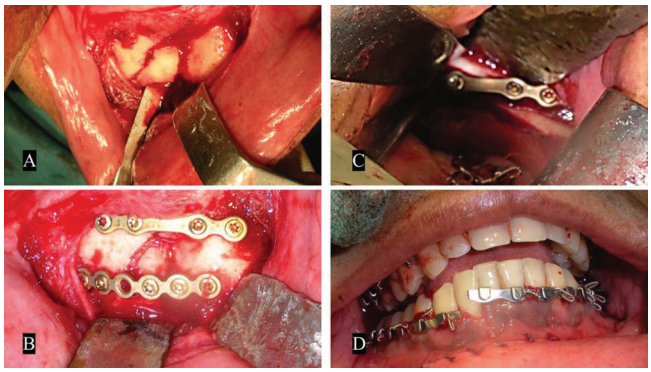

Figure-2: Intra and immediate post-op images (A) Exposure of the fracture site (B) Locking mini plates fixed at parasymphysis region (C) Fixation at angle region (D) Immediate post-operative occlusion after release of IMF

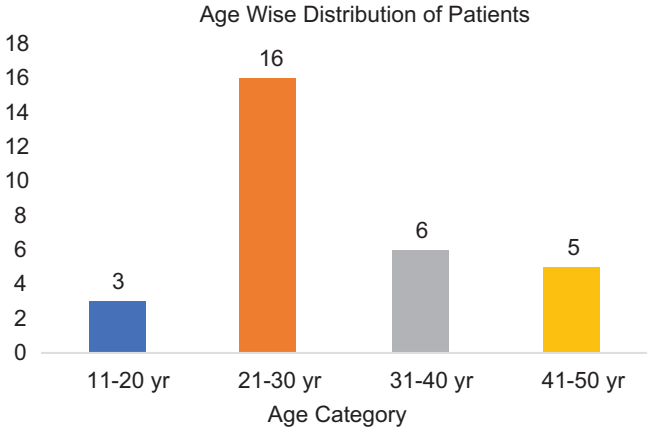

Figure-3: Age wise Distribution of Patients

DISCUSSION

Research related to osteosynthesis aims to give better surgical outcome and focus on many aspects like, size, shape, number and biomechanical principle of the plate and screw system.[12] The technology of locking mini plates are available for more than three decades and there is increasing interest among surgeons due to its multiple benefits over standard miniplates.[13,14]

Advantages of locking system are requirement of less adaptation of implants; less incidence of screw loosening; greater stability across the fracture sites leading to less incidence of postoperative malocclusion with minimum requirement of IMF.[12,15]

Screw head of standard non-locking system compress the plate against the bone for getting stability by friction, causing compromised vascularity of cortical bone and increased osteolysis leading to screw loosening and infection of the fracture site. In comparison, locking system gets the stability forming a 3- dimensional internal framework which function like external fixator placed closer to the bone but without intimate contact.[1] Because of the above fact, the technique of locking system has been termed as minimally invasive plate osteosynthesis (MIPO).[16]

Post-operative complications in mandible fracture has been reported to be 20% -25% in a recent meta-analysis by Batbayar et al.[17] and according to this study, it happens mostly due to infection which results in malunion, non- union or osteomyelitis. Locking system is designed to prevent many of such issues by improved technique.

Wusiman et al.[18] in 2017 in a meta-analysis have shown that, no significant benefit exists of locking plates over standard plates in terms of short term complications in mandible fractures however they commented requirement of postoperative IMF is significantly less in the locking group. The same finding is also supported by the meta-analysis of Batbayar et al.[17]

However the comparative study of complications in mandible fracture are often difficult to design and interpret as it is multifactorial in nature and can be affected by different variables like age; sex; associated co-morbidities and habits(e.g. alcoholism; smoking etc.) of the patient; delay for surgery; type and location of the fracture; principle and type of internal fixation method used; duration of IMF; compliance of the patient with post-operative instructions like food restrictions, maintenance of oral hygiene, follow-up period, etc. [17]

Systematic review by An et al.[19] in 2018 gives strong evidence for the use of locking plates as it decreases postoperative complication by nearly 55% over non-locking system. Recent meta-analysis by Wusiman et al. in 2019 showed significant differences in overall complications, postoperative infection, incidence of malocclusion, lower postoperative IMF rate in locking group compared to non-locking group in angle fracture. Apart from this, literature reports increased bite force in postoperative patients where locking system is used.[6]

In our study, overall complications rate was found to be only 6.7% which were all minor. We kept the patient in IMF only for seven days following the protocol of Chritah et al.[20] Rate of wound dehiscence/ plate exposure, which required hardware removal under local anaesthesia, was only 3.3%. However, in all patients osteosynthesis was satisfactory. Only in one patient (3.3%) where plating was done in para symphyseal region, paresthesia of lip was detected postoperatively, which might have occurred due to neuropraxia from the stretching of mental neurovascular bundle during surgery. Methylcobalamine capsule was prescribed 1500 mcg daily for six weeks and gradually problem decreased over a period of three months. The period of IMF was only for one week which was less than our institute's protocol of at least 14 days of immobilization in case of mini plates. The findings of our study corroborate with the study of Chritah et al.[20]; Collins et al.[12] and Ellis et al.[8]

Our study is unique in the sense that, to the best of our knowledge, this is the first reported clinical study on locking miniplates with deliberate minimum adaptation. Earlier only one in-vitro study was reported by Haug et al.[10] in 2002. The limitations of the present study are small sample size and to keep the study simple, all possible variables were not recorded. Only noted disadvantage of locking system is the cost of the implant, however the system was used in those patients, who could afford the cost of it.

AO/ASIF 2.0 mm locking mini plate system, supplied by

SYNTHES® was found to be comfortable to use; it does not require any special expertise compared to the use of standard miniplates and the system also gives very reliable result.[21]

CONCLUSION

Over a century, treatment of mandible fracture has evolved, presently multiple options are available for plate-osteosynthesis. Recent literature supports the use of the locking system due to multiple advantages over standard mini plates, which remained as the standard of care for many years. Present study reinforces the fact that even with minimum adaptation of plates, the locking system gives good clinical outcome and there is less requirement of postoperative intermaxillary fixation.

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