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THREE DIMENSIONAL BONE PLATING SYSTEM IN THE MANAGEMENT OF MANDIBULAR FRACTURES- A CLINICAL STUDY

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ABSTRACT

Over the past many years, various bone plating systems have been developed to provide stable fixation for the mandible fractures were proposed and performed. The aim of the study was to evaluate efficacy of three dimensional (3-D)titanium mini plates in the management of mandibular fractures, and to analyze structural stability of the fractured bone fragments after fixation, to evaluate the biocompatibility of the three dimensional plating system and the morbidity of three dimensional plating system.
Patients and Methods: 20 patients with mandibular fractures required open reduction internal fixation of the fractures using three dimensional mini plate osteosynthesis over a period of 2 yrs. prospectively.
Conclusions: Three dimensional titanium miniplates provide good stabilization of fractured fragments in three dimensions due to closed quadrangular geometric shape and ease of contouring and adapting. Less surgical exposure of underlying fracture site is needed, with a minimal traction of the surrounding soft tissue. They are biocompatible and no morbidity seen in our study.

KEYWORDS: Three Dimensional mini plates, Mandibular fractures, Fracture fixation. Open reduction.

INTRODUCTION

Face is window through which we perceive the world around us and the world notes us. The face is crucial , injuries to face results in divesting physical and emotional sequelae. Mandibular Fractures are the most common fractures treated by oral and maxillofacial surgeon. Fractures of mandible occur more commonly than any other fractures of facial skeleton [1,2.]. In the 21 [st] century,the near total abolition of maxillomandibular fixation in the mandibular is the major step in the evolution of maxillofacial trauma management due to advent of various plating systems.[3] The purpose of all therapy of fractures is the restoration of pre-injury anatomical form with associated aesthetics and function. Internal fixation was born of necessity, due to limitations imposed by closed reduction techniques[4]. The goal must be accomplished with less discomfort, least disability, slightest risk and shortest recovery period for the patient. Traditionally this has been achieved by immobilizing the jaws using teeth. Osteosynthesis implies functionally stable internal fixation of bone fractures, which allows the early recovery of function.

In the past four decades there has been an increasing interest in obtaining more immediate return to normal function by using different methods of direct fixation with an open approach and allowing anatomical reduction of fragments. Rigid internal fixation was initially used in the oral and maxillofacial region in the late 1970s. Since the work of Michelet et al. and later Champy et al., miniplate osteosynthesis has become an important fixation method in maxillofacial and craniofacial surgery [5, 6] . More recently, three dimensional titanium plates and screws have been developed by Farmand [7,8] .

Rigid fixation can produce three-dimensional stability of the fracture site, promoting primary fracture healing[4]. The healing is extremely susceptible to mechanical influences[9]. Mobility at the fracture site is one of the main causes of healing disturbances[10] and stability is considered the best protection against infection. The basic concept of three dimensional fixation is that a geometrically closed quadrangular plate secured with bone screws creates stability in three dimensions . The three dimensional plates are positioned parallel to fracture

line. The cross linking provides the stability to the system. Three dimensional miniplates are easy to adjust, requires minimal tissue dissectionthus least disturbance to the tissues. Its low profile design and space between plate holes permits excellent revascularization. Comparing the three dimensional plating system with conventional systems, only fewer plates and screws are needed to stabilize the bone fragments. The biomechanical and technical advantage of three dimensional miniplate system promoted the current study to evaluate the efficacy of three dimensional titanium miniplate as a viable treatment modality in the osteosynthesis of mandibular fractures. The miniplates have been the preferred fixation method in cranio-maxillofacial surgery because of their relatively small size, adaptability, ease of placement and intra oral approach. When absolute stability of the fragments is achieved, immediate postoperative jaw function is possible.[11]

Local tissue reactions have been reported for cobalt, chromium, nickel, molybdenum and aluminium and all have demonstrated some degree of cytotoxicty[6] . Titanium is considered to be the most biocompatible alloplastic material[6]. It has been shown to be well tolerated in biological tests and causes only weak local reactions [12,13]

Aim and Objectives

The aim of this prospective clinical trial was to evaluate the efficacy of 3D miniplate system for structural stability of the fracture segment after fixation, biocompatibility and morbidity. The objective was to evaluate the three-dimensional plating system, taking certain parameters of success into consideration.

Patients and Methods:

The study comprises of 20 patients having non-comminuted, isolated fracture mandible were selected. Informed consent was taken from all patients to participate in the study. Mandibular fractures (single/multiple)were treated with open reduction and internal fixation using 2 mm 3-D miniplate system. All patients were systematically monitored 6 months postoperatively. The parameters recorded were pain, infection, paresthesia, occlusion, mobility of fracture fragments, and hardware failure.

Armentarium

Armentarium used in the study is shown in **Fig 1**.

Plating System

Plates Design: **(Fig.2, Fig.3 and Fig.4)**

1. Square plate (1 cm 9 1 cm)
2. Rectangular plate (1 cm 9 0.5 cm)
3. Continuous Square or Double Square (2 cm 9 1 cm)
4. Continuous rectangle or double rectangle (2 cm 9cm)
5. Double rectangle with an intervening square (2 cm 9 1 cm)
6. Diameter of plate hole: 2 mm Thickness: 1 mm (Standard plates)

Screws

Non compression, self-tapping, monocortical screws withround head as shown in **Fig. 5.**

Diameter: 2 mm

Length: 5, 7 and 9 mm

Correction screws: 2.3 mm

Drill Bit : Titanium coated,Diameter:1.6 mm

Accessories

1. Screw drivers
2. Bone plate holding forceps
3. Bone plate bending forceps
4. Plate cutting pliers
5. Trochar and cannula for transcutaneous drilling

Radiographs: OPG (Fig.6)

Surgical Technique

All the procedures were carried out under general anesthesia (Naso-tracheal intubation). The three dimensional titanium miniplate was positioned so that the horizontal cross-bars are perpendicular to the fracture line and the vertical ones are parallel to it. In the symphysis and parasymphysis region the upper cross-bar was placed in a sub apical position.Posterior to the mental foramen the plates were placed with the superior cross-bar between the roots andthe inferior alveolar nerve and the lower cross-bar below the nerve. To treat fractures near the mental foramen the lower bar of the plate was bent and placed above the mental nerve. A rectangular plate is preferred in these cases as is depicted in a post operative radiograph in Figure (**Fig. 7)** . In the mandibular angle region the plate was bent over the oblique line so that the vertical crossbars are aligned perpendicular to the external oblique ridge. **Fig. 8** shows a square plate in position over the fracture. All the basic principles of internal fixation were followed. In mandible fractures, the plates were placed along the ideal lines of osteosynthesis as described by Champy et al. At least two screws were placed on each segment in all the cases.

Results

All the results were tabulated and analyzed with statistical analysis to find significance.(**Table I to Table-VII**). Among the 20 cases treated 16 were males(80%)

Fig.1 Armamentarium

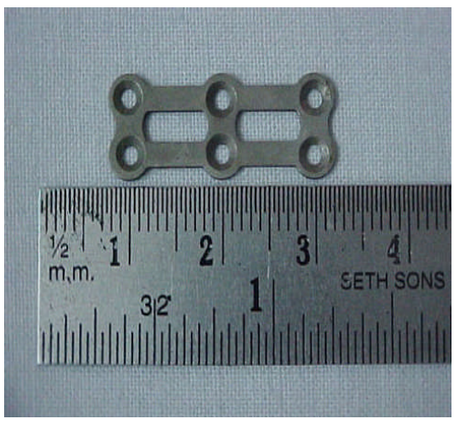

Fig .2 Double rectangle plate

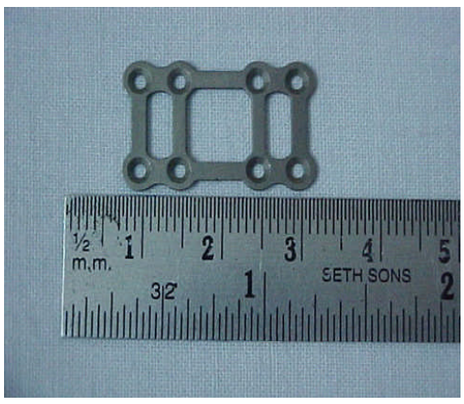

Fig-3 Double rectangle with a square 8 holed plate

Fig.4 Screws

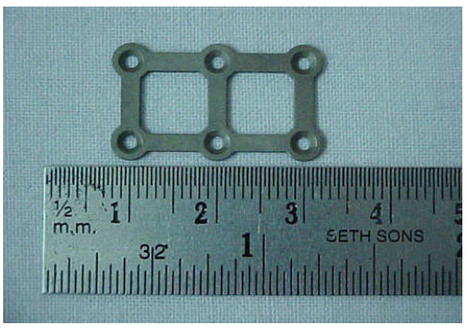

Fig.5 Double Square Plate

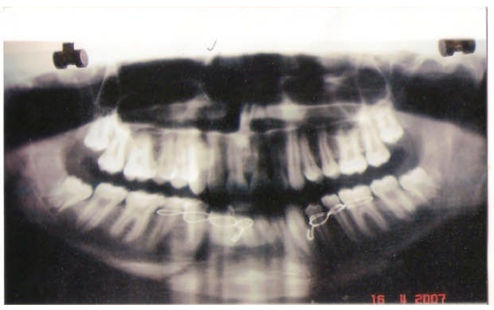

Fig.6 Preoperative O.P.G

and 4 were females (20%).Age distributions of the patients were 16-60 yrs. In the present study most common cause of injury was road traffic accident and the maximum numbers of patients were treated within time gap of 1 week. Site distribution was parasymphysis alone or in combination with other sites was the most commonly involved.

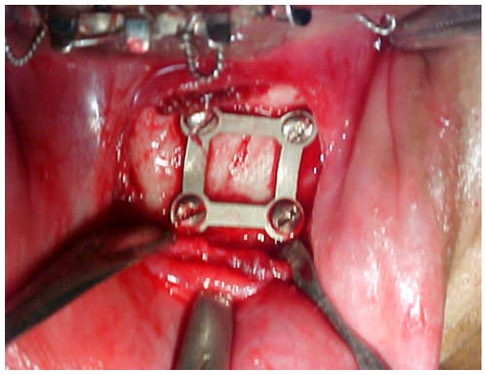

Fig.7 Square plate at fracture site

Clinical evaluation

1. **Post-Operative Pain**

At 3rd day follow up all patients showed moderate pain (VAS score 5-7).Patients with moderate pain decreases to VAS score 6-8 respectively in all patients at 1st week. At 3 rdweek follow-up, there were 8 patients showing no pain (VAS score 0). By 3rd month onwards follow-up reported none with pain. Severe pain was not seen in any patient. (Table VI).There is significant decrease in pain from follow up 3rd day to 6th week in all the patients. No significant difference was seen at different follow up visits in regard to pain.

2. Post-OperativeSwelling

On 3rd day follow-up,swelling was present in all the patients. By 3rd week follow up swelling was present in 20% of patients only, but the difference is non-significant. At 6thweek follow up, the swelling was present in 10% patients only. No swelling was present at 3rd month and 6th month follow ups.

3. Post-Operative Infection:

Post-operative infection was not seen in any of the patients during follow up visits.

4. Post-OperativeParasthesia:

Post-operative transient parasthesia was seen in all the patients treated for parasymphysis fracture, which had resolved by 6th week.No parasthesia was observed at 3rd month and 6th month follow up.

5. Post-Operative Malocclusion

Post-operative malocclusion was not seen in any of the patient at different follow ups.No malocclusion was observed in any patient at 3rd and 6thwks follow ups.

6. **Mobility of Fracture Fragments and Bone Plate Failure:**

There were no mobility and plate failure in our case series.

Table.1 Etiology of Fractures

Etiology	No. of patients	percentage
Road traffic accidents	15	75
Assault	1	5
Others	4	20
Total	20	100

Table.2 Age distribution among the treated cases.

Age group(in years)	No. of patients	percentage
1-15	----	----
16-30	14	70
31-45	4	20
46-60	2	10
TOTAL	20	100

Table 3. Sex distribution among the treated cases

Sex	No. of patients	Percentage
Males	16	80
Females	4	20
Total No. of cases	20	100

Table.4.Time Lapse between Injury and Definitive Management.

Time Lapse	No. of Patients	Percentage
With In 24 Hours	6	30
With In 1 Week	10	50
More Than 1 Week	4	20
Total	20	100

Table.5-Site of Distribution

Fracture site	No. of Patients	Percentage
Symphysis alone	1	5
Parasymphysis	6	30
Angle fracture alone	2	10
Angle and parasymphysis	8	40
Bilateral parasymphysis	3	15
Total	20	100

Discussion

A Total 20 Patients with Isolated Mandibular Fracture were Selected. All patients underwent osteosynthesis using 3-D manipulates. In osteosynthesis, the requirement of a minimum of implant material with maximum stability should always be considered. Monocortical miniplate osteosynthesis has been used successfully for the management of facial fractures.

The original goal of miniplate osteosynthesis was to provide stable mandibular fracture reduction without requiring inter-fragmentary compression or maxillomandibular fixation.

. The reduced size of the miniplate system offers several advantages over the larger mandibular plates.Smaller incisions and less soft tissue dissection are required for their placement.In addition,miniplates can often be placed intraorally,thereby avoiding an external scar. The average time period for adaptation and fixation of three dimensional plates was found to be less.

Wittenberg [15] also reported about the advantage of rapid reduced time for transoral application of three-dimensional titanium miniplates in the treatment of mandibular angle fractures. These findings concur with that of Hughes who evaluated three dimensional plates against lag screw technique for treatment of fractures of the anterior mandible [16]

Because of the smaller size and thinner profile of the miniplates, they are less likely to be palpable, As the horizontal crossbars of the three dimensional titanium miniplates are placed perpendicular to the fracture line, and the vertical cross bars parallel ,Periosteal stripping is minimal, when compared to other conventional miniplate osteosynthesis technique. They may decrease the degree of stress shielding seen following rigid fixation. Finally,because the screws are monocortical, the plates may be placed in the areas of mandible adjacent to tooth roots with minimal risk of dental injury.The rationale of using monocortical plate in mandibular fracture is that osteosynthesis by the plate screwed on the outer cortical plate is solid enough to support the strain developed by the masticatory muscles.

No hardware complications were noted. In all the cases the fractured fragments were found to be stable after plate fixation. No interfragme ntary mobility was seen. The maximal mouth opening/interincisal distance after the surgical procedure was satisfactory in all the patients.

The three dimensional titanium miniplates are superior size strength or size, stability ratio. Since titanium is the most biocompatible implant material available at present with minimal of adverse tissue reactions, the indication for removing the titanium miniplates can be defined by individual patient's complaints[10,17] . Posterior to mental foramen the plates are placed with the upper cross-bar between the roots and the inferior alveolar nerve and lower cross-bar below the nerve.To treat the fractures near mental foramen the lower bar of the plate can be bent and placed above the mental nerve.A rectangularplate is preferred in these cases.At the angle the plate can be bent over the oblique line so that the vertical crossbars are aligned perpendicular tothe external oblique ridge. for patients with mandibular fracture and found uneventful healing. Since it provides stability of the fractured fragments in the third dimension as well, supplemental fixation is not needed. In all the cases a stable occlusion was achieved at the end of the procedure. These findings are similar to other clinical trials. Farmand M reported a good stability against traction forces and torsion forces with three-dimensional plating system [7,8]. Wittenberg et al[18] also reported that three-dimensional plating system may provide adequate fixation for mandibular fractures. Satisfactory functional occlusion was achieved in all cases, In our study. Intermaxillary fixation was done pre-operatively in all the patients to achieve the stable occlusion was achieved at the end of the procedure. Intra-oral and extraoral approach was used as per the case.A minimum of 2 screws,on each side of fracture were used to prevent rational movement of fractured fragments which was in correlation with study of Champy[4](1978).Post-operatively intermaxillary fixation was done for 7-10 days in all patients ,following the principles of delayed osteosynthesis given by Nakamura(1994).The growing number of automobiles on the road has led to increase in number of accidents which often end up in oral and maxillofacialinjuries.In this study majority of patients received trauma due to road traffic accidents(75%)which also correlates with the study of Rowe and Killey(1968).Incidence of mandibular fractures was more in males (80% compared to females and age group commonly affected was 16-30 years (70%)which can be attributed to more socially active life led by this group of individuals. The time lapse between injury and definitive management seems to be important because delay in seeking treatment increases the possibility of infection. In our study,(30%) of the patients were given definitive management within 24 hrs, were as in 50%, within 1 week after the injury. This relatively longer period of delay could be owing to the fact our setup due to its wide coverage. This was one of the surprising findings because the preliminary management of the patients was performed at different centers which included PHCs as well as district hospitals. This finding correlates with findings of Smith WP [(28)] who effectively used miniplates in delayed treatment of mandibular fractures (up to 7 to 11days).No patient reported with any sign of infection at different follow up, near the fracture site. There was no mobility at fracture site and fracture was united uneventfully. discoloration of overlying soft tissues or complaints of temperature sensitivity.

Table. 6 Distribution of patients according to severity of pain number of patients

S.no	Severity of pain equivalent To (vas)	3rd day	1st week	3rd week	6th week	3rd month	6th month
1.	No pain((0)	**0**	0	4	9	10	10
2.	Mild pain	**0**	0	4	6	0	0
3.	Moderate pain(5-7)	10	6	0	0	0	0
4.	Severe pain (8-10)	0	0	0	0	0	0

Table.7 Post Operative Swelling

Follow Up	Present	**Absent**	'T"	'P'
3rd day	10	**0**	99.9	0
1st week.	7	**3**	-0.49	0.31
3rd week	2	8	-0.59	0.48
6th week.	0	10	-1.0	0.165
3rd month	0	10	-	-
6th month	0	10	-	-

These findings correlate with low postoperative complications with three dimensional plating system evaluated in other clinical studies. All the patients were followed up regularly at 1, 3, 5, 8,16 and 32 weeks postoperatively, following which they were recalled on a yearly basis. Because of the low profile design of 3D miniplates provide larger space between plate holes thus permitting excellent revascularization.3 D miniplates utilize optimal instruments and implant design to avoid complications during handling. Technically too, use of 3D miniplate could be considered better as it need minimal tissue dissection near fracture site. On the economic point of view to,3-D miniplates could be adjudged better because of its low cost owing to fewer number of plates and screws used in the technique. In all the cases in this study, routine removal of plates was not contemplated. Although the general recommendation by the ASIF school of thought is that metallic fracture fixation implants should be removed[19], Luhr claimed that with miniplatesdo not need routine removal[12]. Due to short duration of the study, the question of whether to remove or not remove the plate doesn't arise. Since the implant material was titanium which is considered to be the most biocompatible implant material available, we did not plan for routine removal of the plates and screws even at a further date . At the end of the study we found that 3-D miniplate was superior in respect of stability . Although there have been a few reports of symptomatic metallosis caused by titanium dioxide[20] . Moberg et al[13] recommended that titanium miniplate should not be removed, although aluminum was found to be released to some degree. No hardware complications were noted. In all the cases the fractured fragments were found to be stable after plate fixation. No interfragmentary mobility was seen. The maximal mouth opening/interincisal distance after the surgical procedure was satisfactory in all the patients. Rosenberg et al. stated that the demonstrated changes in soft tissue near titanium miniplates should not be interpreted as a clear indication to remove the plates [21] The indication for removing titanium miniplates should be defined by patient's complaints. None of the subjects in this clinical study had color changes in the surrounding soft tissues or any symptoms of metal hypersensitivity.

CONCLUSION

Based on the findings of our study, the following conclusions were derived: Because of the closed quadrangular geometric shape,and the ease with which it can be contoured and adapted to the bony fragments,the 3-D titanium miniplates provide better stabilization of fractured fragments in three dimensions.Use of 3-Dtitanium miniplates is more cost effective as lesser number of plates and screws are needed for fixation.With3-Dtitanium miniplate osteosynthesis technique, less surgical exposure of the underlying fracture site is needed, with a minimal traction of the surrounding soft tissue.The implant was able to counteract forces along the fracture site, thus precluding hardware failure. So the 3-D miniplate is efficient enough to bear masticatory load during the osteosynthesis of fracture. Because of better inter fragmentary stability; supplemental fixation is not necessary, thereby enhancing the overall comfort, convenience and well being of the patient. As titanium is the most biocompatible material, with very few adverse tissue reactions, a secondary operative procedure for the removal of the implant may not be necessary.

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