Three Dimensional Titanium Mini Plates in Oral & Maxillofacial Surgery: A Prospective Clinical Trial

Gaurav Mittal · Ramakanth Reddy Dubbudu ·
K. M. Cariappa

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Abstract

Aim The purpose of the study was to evaluate the efficacy of three dimensional titanium miniplates as treatment modality for the stabilization of the fractured or osteotomized bone fragments in maxillofacial region.

Patients and Methods 24 patients with maxillofacial trauma and one patient who underwent orthognathic surgery constituted the sample of the study. All the patients with maxillofacial injuries required open reduction internal fixation of the fractures and the orthognathic surgery patient required stabilization of the osteotomized segments.

Conclusions Three dimensional plates provide good stability of bone fragments due to closed quadrangular geometric shape, and the ease of contouring and adapting. Because of better inter fragmentary stability; supplemental fixation is not necessary, thereby enhancing the overall comfort, convenience and well being of the patient.

Introduction

The purpose of all therapy of fractures is the restoration of the original form and function. An important requirement to this end is immobilization. Failure to achieve these

conditions of healing results in infection, malocclusion, nonunion or malunion [20]. Internal fixation was born of necessity, due to limitations imposed by closed reduction techniques [13]. Osteosynthesis implies functionally stable internal fixation of bone fractures, which allows the early recovery of function.

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 [1, 2, 10]. Later several systems have been developed. The rigid systems were replaced by more functionally oriented systems, and the term “semi-rigid” has gained more importance.

Rigid fixation can produce three-dimensional stability of the fracture site, promoting primary fracture healing [16]. The healing is extremely susceptible to mechanical influences [7]. Mobility at the fracture site is one of the main causes of healing disturbances [3, 17] and stability is considered the best protection against infection.

For years, many surgeons felt the necessity to change the traditional long period of maxillo-mandibular fixation thought to be essential for successful treatment of mandibular fractures. Dispensing the intermaxillary fixation allows the patient to protect their airway more effectively and facilitates postoperative function and nutrition with an early return to work. When absolute stability of the fragments is achieved, immediate postoperative jaw function is possible [8].

The requirements of an ideal implant material used for osteosynthesis are biocompatibility, possibility of easy adaptation and stabilization of the osteotomized or fractured segments without dislocation of the fragments and impairment of blood supply. Local tissue reactions have been reported for cobalt, chromium, nickel, molybdenum

G. Mittal (✉)
Department of Dentistry, VCSGMSRI, Pauri Garhwal,
Srinagar, Uttarakhand, India
e-mail: drgauravmittal@rediffmail.com

R. R. Dubbudu
Department of Oral & Maxillofacial Surgery,
Arrowe Park Hospital, Wirral, UK

K. M. Cariappa
Department Of Oral & Maxillofacial Surgery, Manipal College
of Dental Sciences, Manipal, Karnataka, India

and aluminium and all have demonstrated some degree of cytotoxicity [4].

In the quest for an ideal implant material, maximum research has been directed towards titanium in the current century. Titanium is considered to be the most biocompatible alloplastic material [3]. It has been shown to be well tolerated in biological tests and causes only weak local reactions in vivo [14, 15].

More recently, three dimensional titanium plates and screws have been developed by Farmand [5, 6]. Their shape is based on the principle of the quadrangle as a geometrically stable configuration for support [5, 6].

The biomechanical and technical constraints of the conventional rigid internal fixation devices have prompted the current study to evaluate the efficacy of the three dimensional titanium miniplates as a viable treatment modality.

Aims and Objectives

The aim of this prospective clinical trial was to test the efficacy of three dimensional titanium mini-plates as treatment modality, for the stabilization of the fractured or osteotomized bone fragments.

The objective was to evaluate the three-dimensional plating system, taking certain parameters of success into consideration. All the cases were evaluated for surgical procedure, osteosynthesis technique, interfragmentary stability, postoperative complications and fate of the implant.

Patients and Methods

The clinical trial was carried out in the department of oral and maxillofacial surgery (CODS), Manipal.

25 cases were selected for the evaluation of three-dimensional titanium plating system. The study design and purpose was presented to an institutional review board before starting the research work. The plates and screws for the study were designed and manufactured in collaboration with Non Ferrous Materials Technology Development Centre (NFTDC) Hyderabad, an autonomous Research and Development organization. 24 cases of trauma, and 1 case of orthognathic surgery constituted the sample for the study. The surgical technique closely followed the guidelines developed by Champy et al. The sample constituted 18 male and 7 female patients. No relevant medical history was noted in any of the patients.

All the trauma patients included in this study had a history of road traffic accident; the orthognathic surgery patient had a skeletal class III malocclusion. Table 1 shows the fractures site, the surgical approach and the type of plating system used in each case. 31 fracture sites—16 parasymphysis, 7

LeFort I level, 4 mandibular angle, and 4 mandibular body were treated. 4 of the patients had additional condylar fractures. In the orthognathic case the LeFort I osteotomy site was fixed with three dimensional titanium plates. The average time interval between trauma and surgery was 4 days. No trauma case had a tooth in the line of fracture.

The surgical approach for trauma cases was intraoral, sub labial, except for mandibular angle where a transbuccal approach was used for fixation. In 21 cases a rectangular three dimensional titanium plate was used. A square plate, was used in 8 cases, and a double rectangle, was used in 2 cases. 7 mm long, 2 mm diameter titanium screws were used in the maxillary region and 9 mm long, 2 mm diameter screws were used in the mandible. In the orthognathic surgery case, an intraoral approach was used and the osteotomized fragments were stabilized with a double rectangle three dimensional titanium plate. 7 mm long, 2 mm diameter screws were used.

Table 2 shows the hardware complications if any, the occlusion recorded after treatment and supplemental fixation if any for every case included in the study. Data regarding the average time taken for the adaptation and fixation of a three dimensional titanium plate was also recorded. Any hardware complications like broken plates, screws or screws heads, if any were promptly recorded. Degree of stability of the fragments, occlusion at the end of the surgical procedure and the need for any form of supplemental fixation were also taken into consideration.

Post operatively the patients were evaluated for Inter-fragmentary stability, complaints of trigeminal dysfunction, maximal mouth opening and signs of infection.

Recall intervals were at 1, 3, 5, 8, 16 and 32 weeks. Later the patients were evaluated on a yearly basis for the next 5 years.

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. Figure 1 shows a double rectangle plate in position used in a Le Fort level I fracture. In the symphysis and parasymphysis region the upper cross-bar was placed in a sub apical position. Figure 2 shows post operative OPG with a double rectangular plate in position. Posterior to the mental foramen the plates were placed with the superior cross-bar between the roots and the 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 Fig. 3. In

Table 1 Fracture site and the plating system used

No.	Age/sex	Diagnosis	Surgical approach	Plating system	
				Plates	Screws
1.	21/F	Left parasymphysis fracture and undisplaced right condylar fracture	Intra oral, sub labial	4 hole (2 × 2), rectangular (1 cm × 0.5 cm)	4 screws, 2 mm diameter, 9 mm length
2.	20/M	Right parasymphysis fracture and bilateral condylar fracture	Intra oral, sub labial	4 hole (2 × 2), square (1 × 1 cm)	4 screws, 2 mm diameter, 9 mm length
3.	20/M	Right parasymphysis	Intra oral, Sub labial	6 hole (3 × 2), rectangular (1 × 0.5 cm)	4 screws, 2 mm diameter, 9 mm length
4.	20/F	Left mandibular parasymphysis and right angle fracture	Intraoral, sub labial and transbuccal	Two plates, 4 holed (2 × 2), rectangular (1 × 0.5 cm)	8 screws, 2 mm diameter, 9 mm length
5.	21/F	Bilateral Le Fort level I fracture	Intra oral, Sub labial	Two plates, 4 holed (2 × 2), rectangular (1 × 0.5 cm)	8 screws, 2 mm diameter, 7 mm length
6.	21/M	Left angle and right body fracture	Intra oral, sub labial and transbuccal	Two plates, 4 holed (2 × 2), square (1 × 1 cm)	8 screws, 2 mm diameter, 7 mm length
7.	38/M	Left zygomaticomaxillary complex fracture	Intra oral, Sub labial	6 hole (3 × 2), double rectangle (2 × 0.5 cm)	4 screws, 2 mm diameter, 7 mm length
8.	24/M	Right parasymphysis fracture	Intra oral, sub labial	4 hole (2 × 2), rectangular (1 × 0.5 cm)	4 screws, 2 mm diameter, 9 mm length
9.	29/M	Left mandibular parasymphysis and condylar fracture	Intra oral, sub labial	4 hole (2 × 2), rectangular (1 × 0.5 cm)	4 screws, 2 mm diameter, 9 mm length
10.	44/M	Left parasymphysis fracture	Intra oral, Sub labial	4 hole (2 × 2), rectangular (1 × 0.5 cm)	4 screws, 2 mm diameter, 9 mm length
11.	40/M	Right angle fracture	Transbuccal	4 hole (2 × 2), square (1 × 1 cm)	4 screws, 2 mm diameter, 9 mm length
12.	19/F	Left parasymphysis fracture	Intra oral sub labial	4 hole (2 × 2), rectangular (1 × 0.5 cm)	4 screws, 2 mm diameter, 9 mm screws
13.	16/M	Right body mandible fracture	Intra oral, sub labial	4 hole (2 × 2), rectangular (1 × 0.5 cm)	4 screws, 2 mm diameter, 9 mm length
14.	17/F	Left parasymphysis fracture	Intra oral, sub labial	4 hole (2 × 2), rectangular (1 × 0.5 cm)	4 screws, 2 mm diameter, 9 mm length
15.	29/M	Bilateral parasymphysis fracture	Intra oral, sub labial	Two plates, 4 holed (2 × 2), rectangular (1 × 0.5 cm)	8 screws, 2 mm diameter, 9 mm length
16.	31/M	Left Le Fort level I fracture	Intra oral, sub labial	4 hole (2 × 2), rectangular (1 × 0.5 cm)	4 screws, 2 mm diameter, 7 mm length
17.	46/F	Right parasymphysis and left condylar fracture	Intra oral, sub labial	4 hole (2 × 2), rectangular (1 × 0.5 cm)	4 screws, 2 mm diameter, 9 mm length
18.	33/M	Right body mandible fracture	Intra oral, sub labial	4 hole (2 × 2), square (1 × 1 cm)	4 screws, 2 mm diameter, 9 mm length
19.	22/M	Mid symphysis and bilateral condylar fracture	Intra oral, sub labial	4 hole (2 × 2), rectangular (1 × 0.5 cm)	4 screws, 2 mm diameter, 9 mm length

Table 1 continued

No.	Age/sex	Diagnosis	Surgical approach	Plating system	
				Plates	Screws
20.	41/M	Bilateral Le fort level I fracture	Intra oral, sub labial	Two plates, 4 holed (2×2), rectangular (1×0.5 cm)	8 screws, 2 mm diameter, 7 mm length
21.	25/M	Left parasymphysis and right body fracture	Intra oral, sub labial	Two plates, 4 holed (2×2), square (1×1 cm)	8 screws, 2 mm diameter, 9 mm length
22.	34/M	Bilateral Le fort level I fracture and mandibular parasymphysis fracture	Intra oral sub labial	Three plates, 4 holed (2×2), rectangular (1×0.5 cm)	8 screws, 2 mm diameter, 7 mm length, 4 crews of 9 mm length
23.	54/M	Right parasymphysis fracture	Intra oral, sub labial	4 hole (2×2), rectangular (1×0.5 cm)	4 screws, 2 mm diameter, 9 mm length
24.	45/M	Left body fracture	Intra oral, sub labial	4 hole (2×2), square (1×1 cm)	4 screws, 2 mm diameter, 9 mm length
25.	16/F	Skeletal Class III malocclusion	Intra oral, Sub labial	2 plates, 8 hole (4×2), double rectangle with intervening square (2×0.5 cm)	8 screws, 2 mm diameter, 7 mm length

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. Figure 4 shows a single rectangular plate where as Fig. 5 shows a square plate in position over the fracture.

All the basic principles of internal fixation were followed. In mandibular 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.

Plating System

Plates

Design:

Square plate ($1 \text{ cm} \times 1 \text{ cm}$)

Rectangular plate ($1 \text{ cm} \times 0.5 \text{ cm}$)

Continuous Square or Double Square ($2 \text{ cm} \times 1 \text{ cm}$)

Continuous rectangle or double rectangle ($2 \text{ cm} \times 0.5 \text{ cm}$)

Double rectangle with an intervening square ($2 \text{ cm} \times 1 \text{ cm}$)

Diameter of plate hole: 2 mm

Thickness: 1 mm (Standard plates)

Figure 6 shows the armamentarium used whereas Figs. 7, 8 and 9 shows the different designs of plates used in the present study.

Screws

Non compression, self-tapping, monocortical screws with round head as shown in Fig. 10.

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

Discussion

In osteosynthesis, the requirement of a minimum of implant material with maximum stability should always be

Table 2

No.	Hardware complication	Occlusion after treatment	Supplemental fixation
1.	None	Stable	None
2.	None	Mild anterior open bite	Correction/training elastics
3.	None	Stable	None
4.	None	Stable	None
5.	None	Stable	None
6.	None	Mild cross bite	Correction/training elastics
7.	None	Stable	None
8.	None	Stable	None
9.	None	Stable	None
10.	None	Stable	None
11.	None	Stable	None
12.	None	Stable	None
13.	None	Stable	None
14.	None	Stable	None
15.	None	Mild anterior open bite	None
16.	None	Stable	None
17.	None	Mild cross bite	Correction/training elastics
18.	None	Stable	None
19.	None	Mild anterior open bite	Correction/training elastics
20.	None	Stable	None
21.	None	Stable	None
22.	None	Stable	None
23.	None	Stable	None
24.	None	Stable	None
25.	None	Stable	None

Fig. 1 Double rectangle plate at LeFort level I fracture **Fig. 2** Post operative radiograph showing double rectangle plate

considered. The three dimensional titanium miniplates seem to fulfill this requirement ideally. Due to the closed quadrangular geometric configuration of the plates, less foreign material is needed to stabilize the fragments.

As the three dimensional plates are of miniature size, they can be placed easily through an intraoral approach and

as the horizontal crossbars of the three dimensional titanium miniplates are placed perpendicular to the fracture line, and the vertical cross bars parallel to, only a minimal amount of surgical exposure is necessary for the placement of plates and screws. Periosteal stripping is minimal, when compared to other conventional miniplate osteosynthesis techniques.

Fig. 3 Post operative radiograph showing rectangle plate

Fig. 4 Single rectangle plate at fracture site

Fig. 5 Square plate at fracture site

Fig. 6 Armamentarium

Fig. 7 Double rectangle plate

The average time period for adaptation and fixation of three dimensional plates was found to be less. These findings concur with that of Hughes who evaluated three dimensional plates against lag screw technique for treatment of fractures of the anterior mandible [14]. Wittenberg [23] also reported about the advantage of rapid reduced time for transoral application of three-dimensional titanium miniplates in the treatment of mandibular angle fractures. No hardware complications were noted. In all the cases the fractured or osteotomized 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.

Fig. 8 Double square plate

Fig. 9 Double rectangle with a square 8 holed plate

Fig. 10 Screws

Even the most biocompatible implant material is still a foreign body and the potential adverse tissue reactions in human body due to its prolonged/life long retention should be considered in any osteosynthesis technique. Though not ideally, three dimensional titanium miniplates come close to addressing this problem because of their 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 [18, 21]. As the miniature plates could be placed through small incisions, with minimal traction of the surrounding soft tissues, surgical morbidity was less. Post operative soft tissue swelling though cannot be attributed solely to the above mentioned factors, was minimal.

Since it provides stability of the fractured or the osteotomized fragments in the third dimension as well, supplemental fixation is not needed. In all the cases evaluated in this trial, a stable occlusion was achieved at the end of the procedure. Satisfactory functional occlusion was achieved in all cases, except a few with bilateral condylar or, mandibular body with angle fractures. In these cases correction/training elastics were used post operatively. In all the remaining cases, no other form of supplemental fixation was used.

These findings are similar to other clinical trials. Farmand M reported a good stability against traction forces (90 N) and torsion forces (30 N) with three-dimensional plating system [5, 6]. Wittenberg et al. [24] also reported that three-dimensional plating system may provide adequate fixation for mandibular fractures. The fixation of a 4-holed square plate for mandibular angle fracture is supported by studies by Kroon et al. and Choi et al. who reported that two non compressive miniplates can effectively stabilize a mandibular angle fracture. The placement of a single plate at the superior border was not stable enough according to their studies. Hughes reported that three-dimensional plating system is as effective as lag screw technique for treatment of fractures of the anterior mandible [14].

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. None of the patients had any complaints of trigeminal dysfunction, signs of infection, discoloration of overlying soft tissues or complaints of temperature sensitivity. These findings correlate with low postoperative complications with three dimensional plating system evaluated in other clinical studies.

Although the general recommendation by the AO/ASIF school of thought is that metallic fracture fixation implants should be removed [19], Luhr claimed that with miniplates do not need routine removal [9]. Titanium is generally

considered to have low toxicity and to be biocompatible, although there have been a few reports of symptomatic metallosis caused by titanium dioxide [12]. Moberg et al. [11] recommended that titanium miniplate should not be removed, although aluminum was found to be released to some degree. Addressing the question whether titanium miniplates should be removed after bone healing is complete, 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 [18]. 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. All the patients were followed post operatively for 5 years and none of them developed any late complications.

Conclusions

Three dimensional plates stabilize the bone fragments in three dimensions because of the closed quadrangular geometric shape, and the ease of contouring and adapting. Due to better interfragmentary stability, supplemental fixation in the form of intermaxillary fixation/maxillo-mandibular fixation is not necessary, thereby enhancing the overall comfort, convenience and well being of the patients.

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. With the three dimensional titanium miniplate osteosynthesis technique, less surgical exposure of the underlying fracture or osteotomy site is needed, with a minimal traction of the surrounding soft tissue. Hence, the chances of a compromised blood supply due to excessive periosteal stripping, surgical morbidity due to excessive exposure and inadvertent traction, and chances of temporary nerve dysfunction due to excessive traction of surrounding soft tissue are decreased. The time taken for the contouring, adaptation and fixation of a three-dimensional titanium miniplate was less in comparison to other conventional miniplate osteosynthesis techniques.

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