A Prospective Randomized Clinical Trial Comparing 3D and Standard Miniplates in Treatment of Mandibular Symphysis and Parasymphysis Fractures

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Abstract

Purpose To compare the efficacy of the 3D miniplates to standard miniplates in the osteosynthesis of mandibular symphysis and parasymphysis fractures on the basis of clinical parameters and radiographic evaluation.

Patients and Methods A prospective randomized clinical trial was conducted to treat consecutive mandibular symphysis and parasymphysis fractures. The patients were randomly divided into 2 groups. The patients underwent osteosynthesis in group A with 3D titanium miniplates and in group B with conventional titanium miniplates. The cause of trauma, the number of days from injury to surgery, average age and gender were all reviewed. The assessment of the patients was done at 1, 3, and 6 weeks and 3 months using the clinical parameters and radiographic evaluation.

Results Eighty patients with isolated symphysis or parasymphysis fracture met the inclusion criteria. In our study, a statistically significant difference was not found in the clinical parameters such as pain, swelling, infection, paresthesia, hardware failure, and mobility between the fracture segments. Similarly Radiological evaluation did not show any statistically significant difference in reduction between the 2 groups. 3D plates are difficult to adapt and use sometimes, but operative time is less with them in treatment of symphysis and parasymphysis fractures.

Conclusion The use of 3D miniplates for symphysis and parasymphysis fracture fixation was efficacious enough to bear the masticatory load during osteosynthesis of the

fracture. Although 3D miniplate system is difficult to adapt and difficult to use in cases of fractures involving the mental nerve, they provide the advantage of less operative time and less implant material in treatment of symphysis and parasymphysis fracture, with clinical results almost similar to those seen with conventional miniplate osteosynthesis.

Keywords 3D plates · 3D miniplates · Mandible fracture · Mandibular symphysis · Symphysis and parasymphysis fracture

Introduction

Face is the window through which we perceive the world around us and the world perceives us. In the era of increasing automobilization and industrialization, the treatment of mandibular fractures has attained a prominent position. The main goal in the treatment of fracture is to predictably restore preinjury anatomical form, with associated aesthetics and function. The goal must be accomplished by means that will produce the least disability, smallest risk, and shortest recovery period for the patient. Traditionally this has been achieved by immobilising the jaws using teeth. 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 the fragments [1].

Methods of open reduction and internal fixation have changed and diversified enormously in the past few years [2]. Through the decades various plate and screw osteosynthesis have been introduced like AO bicortical plating system; monocortical miniplating system, resorbable plates and screws, locking miniplates and 3-dimensional miniplating

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system. Miniplate osteosynthesis, first introduced by Michlet in 1973, and further developed by Champy in 1975, is today's standard for the treatment of mandibular fractures [3–5]. In 1913, Lambotte [6] recommended an aluminum-made geometrically closed quadrangular plate secured with bone screws at the lower border of the mandible for the treatment of fractures of the mandibular body via an extraoral approach. He found that, provided that the fragments were repositioned properly, this specially designed plate offered sufficient stability without further immobilization, and that this system was superior to that in use at that time using wiring osteosynthesis. However, this method did not gain further popularity that might be assumed to be because of the lower biocompatibility of the material and because treatment methods using closed reduction were preferred. More recently, three dimensional titanium plates and screws have been developed by Farmand [7–9]. Their shape is based on the principle of the quadrangle as a geometrically stable configuration for support. Because 3D stability is achieved by the geometric shape that forms a cuboid, compared with standard miniplates and reconstruction plates, the thickness of these plates is reduced to 1 mm. The plates are adapted to the bone according to Champy's principles and are secured with monocortical self-cutting screws. Although experimental studies on biomechanics have confirmed sufficient stability of the 3D plating system [10–12] only a few clinical studies [13–16] are reported in the literature. Also, to the best of our knowledge, very few studies have compared standard miniplates and 3D miniplates in treatment of fracture of a particular site i.e., symphysis and parasymphysis of mandible. Hence a prospective randomized clinical trial was carried out to compare the standard and 3D miniplate fixation in the management of mandibular symphysis and parasymphysis fractures.

Patients and Methods

After obtaining ethics and research committee approval, a prospective randomized clinical trial was carried out in the Department of Oral and Maxillofacial Surgery, Government Dental College, Jaipur, India. We have read Helsinki declaration and have followed the guidelines in this investigation. Informed consent was obtained, and patients of both genders with isolated mandibular symphysis and parasymphysis fracture were included. Preoperative infected or medically compromised patients and those not willing to return for follow-up were excluded. Patients were randomly divided into 2 groups. A standardized data sheet was formulated, and demographic variables and relevant clinical and radiological findings were noted. All patients were given prophylactic antibiotic cefotaxime 2 g intravenously 1 h before the procedure, followed by 1 g 2 times per day

Fig. 1 Fracture site exposed

for 5 days. Procedures were carried out under general anesthesia. Following strict aseptic, an intraoral translabial incision was given; fracture site was identified (Fig. 1), reduced, and after obtaining satisfactory occlusion, temporary maxillomandibular fixation was placed using Erich's arch bar wiring. Fixation was done using either 3D 2-mm titanium plates (group A) or standard titanium miniplate (group B) using Champy's principle of osteosynthesis.

Fixation of the 3D plate was done in such a way that a horizontal bar is perpendicular and a vertical bar is parallel to the fracture line (Fig. 2). In our study in symphysis and parasymphysis regions, the upper bar was placed in the subapical position (Fig. 2). To treat fractures near the mental foramen (involving the mental nerve), the plate was placed above the nerve and, to avoid injury to the dental roots, holes were drilled monocortically directing them into the space between the roots. A rectangular plate and short screws were used. A watertight wound closure was done. Duration of the procedure was noted. Patients were followed for a period of 3 months at intervals of 1, 3, 6, and 3 months by a blinded senior oral surgeon for pain (Visual Analogue Scale) (0–10), swelling, infection, paresthesia, hardware failure, Mobility between fracture fragment, Occlusion and radiographic reduction. Chi square test and 't' test were used for comparison of two groups. A value of *P* less than 0.05 was considered statistically significant.

Results

Eighty patients with isolated symphysis or parasymphysis fracture were enrolled in both the groups, with 40 patients

Fig. 2 3D plate fixed at fracture site

in each group. Patients were divided into four age groups—1–15, 16–30, 31–45 and 46–60 years. In the present study most common age group of patients who underwent surgery were between 16 and 30 years (70 %). Road traffic accident was the most common cause of injury (75 %). Number of male patients was higher (95 %) than the number of female patients (5 %) (Table 1). According to time lapse between injury and definitive treatment, patients were divided into four groups—less than 1, 1–3, 4–7 and 8–11 days. Maximum number of patients were treated within time lapse of 4–7 days (60 %). Mean time lapse between injury and definitive management was seen to be 5.2 days. Mean duration of procedure for group A was 38 min and for group B 49 min (Table 2).

Preoperative occlusion was found to be deranged in all the patients in both the groups. The occlusion improved to satisfactory status post-operatively in all the patients. Post-operative pain was measured using VAS Scale (0–10), where score of 0 was given for no pain, score of 1–4 was considered mild pain, score of 5–7 was considered moderate pain and score of 8–10 was considered severe pain. At 1st week follow-up, there were 12 patients with mild pain and 28 patients were with moderate pain in group A and 8

Table 2 Comparison of clinical and radiographic parameters in group A and group B

Clinical/radiographic parameter	Group A (N = 40)	Group B (N = 40)
Duration of operation (minutes)	38 min	49 min
Infection	2	0
Paresthesia	0	0
Hardware failure	0	0
Deranged post-operative occlusion	0	0
Mobility between fracture fragments	0	0
Unsatisfactory radiographic reduction	0	0

patients with mild pain and 32 patients with moderate pain in group B respectively. Thirty-two patients had no pain and 8 patients had mild pain. There was no pain in 24 patients but mild pain was there in 16 patients respectively in group A and group B at 3rd week. There was significant decrease in pain from follow up I (1st week) to follow up II (3rd week) in both the groups. No pain was observed in follow up III (6th week) and IV (3rd month) in any group. There was no significant difference in pain in group A and group B at different follow-ups. At follow-up I (1st week), swelling was present in 100 % of patients in group A and group B. At follow-up II (3rd week), swelling was present in 10 % patients in group A and 20 % in group B, but difference was not significant. No swelling was present at follow ups III (6th week) and IV (3rd month). Mobility at fracture site was not observed in any of the patients of group A and group B at different follow-ups. No paresthesia was observed in any patient of group A and group B. Implant failure i.e., breakage of plate or screws was not observed in any of the patients of group A and group B at different follow-ups. Infection was observed in two patients of group A at 1st follow-up at 1 week. This conditions were treated by draining of pus, wound debridement and antibiotics for 5 days (IV cefotaxime and metronidazole). But difference was not statistically significant. Radiological evaluation (Fig. 3) did not show any statistically significant difference in reduction between the 2 groups.

Discussion

Very few studies in the literature have compared standard miniplate to 3D plate in treatment of a particular site of mandible. A preliminary report in their biomechanical experiment by Feledy et al. [10], found better bending stability and more resistance to out-of-plane movement in the 3D plating system. The use of 3D miniplates in mandibular fracture has not yet become established. Only a few follow-up series are presented in the literature, with few

Table 1 Demographic Data

Demographic data	Group A (N = 40)	Group B (N = 40)
Mean age (years)	24.72	22.62
Gender		
Male	39	37
Female	1	3

Fig. 3 Post-operative radiograph

studies [8, 10, 13, 14], emphasizing the hardware-related advantages over conventional miniplates and reconstruction plates. These advantages include easy application, simplified adaptation to the bone without distortion or displacement of the fracture, simultaneous stabilization at both superior and inferior borders, and hence less operative time. We agree with them in terms of less operative time, as mean duration of procedure for 3D plate was 38 min and for conventional plate it was 49 min. But we do not agree with simplified adaptation, a 3D plate has to be bent in 3 dimensions, whereas a conventional plate has to be bent only in 2 dimensions, so a 3D plate is much more difficult to perfectly adapt than a conventional plate. Another said advantage of the 3D plates is their improved biomechanical stability compared with conventional miniplates, because of extra vertical arms. In our study, stability was adequate in all cases of both groups, as there were no cases of segmental mobility and implant failure. Some studies [16] claim, that 3D plates has excessive implant material resulting from extra vertical bars incorporated for countering the torque forces. But this is not true for symphysis and parasymphysis fracture, as 2 plates has been advocated by Champy in symphysis and parasymphysis region, and implant material for 2 plates and screws will be more than a single rectangular 3D plate and 4 screws. Infection rates in the clinical studies on 3D plates for angle fractures are 5.4 [12] and 9 % [10]. In this study, there was temporary infection in two case and difference was not statistically significant. Farmand and Dupoirieux [7] also treated 95 fractures of the mandibular body using 4 holed square plates; among the complications, only one late infection and one plate fracture were recorded. Plate fracture was again a most important complication in the study by Zix et al. [17] in which reduced interfragmentary cross-sectional bone surface at the fracture site was cited as the most likely reason. No such plate fracture was seen in this study. As per the principle of a 3D plate to treat fractures near the mental foramen, the plate should be placed above the nerve, and, to avoid injury to the dental roots, holes should be drilled monocortically, directing them into the

space between the roots. We did not face any mental nerve paresthesia in both groups, but in our opinion its difficult to place a 3D plate near the mental foramen and it needs skill, time and patience. Since its introduction, the potential effectiveness of the Champy miniplate has been demonstrated in many clinical follow-up series [3–5, 18, 19]. Its use has been associated with a low number of complications, such as infection, plate fracture and malocclusion. In our study, no such significant complications were noted in both conventional and 3D miniplates.

To conclude, these findings suggest that the use of 3D miniplates for symphysis and parasymphysis fractures fixation was efficacious enough to bear the masticatory load during osteosynthesis of the fracture. Morbidity and Infection rate is comparable to conventional miniplates. The 3D miniplate system is difficult to adapt and difficult to use in cases of fractures involving the mental nerve. However, operative time is shorter because of simultaneous stabilization at both superior and inferior borders and less implant material is used in symphysis and parasymphysis region. Studies with a larger sample size are necessary to corroborate the findings of the present study for their wider use in clinical practice.

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