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Novel Design Of Miniplate For Fixation Of Fractures At Transition Zone Of Parasymphysis-Body Region Of Mandible – A Clinical Randomised Study

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NOVEL DESIGN OF MINIPLATE FOR FIXATION OF FRACTURES AT TRANSITION ZONE OF PARASYMPHYSIS-BODY REGION OF MANDIBLE – A CLINICAL RANDOMISED STUDY

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Summary

Fractures through the mandible at the level of the parasymphysis extending obliquely and traversing through the transitional zone to body region are relatively common. Therefore, a surgeon should have an appropriate understanding of the biomechanics of different plating techniques to fix these fractures. There is always a dilemma for the surgeon as to whether to fix these mandibular segments with one or two miniplates, and the presence of mental neurovascular bundle makes it more challenging. A study was planned in the Department of Oral and Maxillofacial Surgery to evaluate a novel twin-fork design of a miniplate used for fracture fixation at the transition zone of parasymphysis and body region of mandible after an in-vitro study of same design, and provided encouraging results. A total of 30 patients (10 patients in three groups each) were included in the study. All patients were evaluated preoperatively and postoperatively for operating time, ease of placement of miniplate, occlusion, reduction of fracture, neurosensory disturbances and infection. The novel design of twin-fork−shaped miniplate proved to be superior to the conventional miniplate in terms of neurosensory (Fisher exact test 17.40; $p = 0.003$) and functional outcome. There was statistically significant difference ($\chi^2 = 13.895$, $p = 0.031$) in postoperative reduction of fracture at week 4, indicating superiority of the twin-fork miniplate among the other conventional designs. The study concludes that the use of newly designed twin-fork−shaped miniplate should be encouraged in the fractures of transitional zone of parasymphysis-body region involving mental neurovascular bundle.

Keywords: novel design; twin-fork miniplate; transition zone, mental nerve paresthesia

INTRODUCTION

Fractures through the mandible at the level of the parasymphysis extending obliquely and traversing through the transitional zone to body region are relatively common. Parasymphysis/body fractures of the mandible have reported to occur with a frequency of 9% to 57%.[1] Therefore, a surgeon should have an appropriate understanding of the biomechanics of different plating systems and techniques used to fix these fractures.

The anatomy of the mandible, presence of long roots and vector of forces exerted by the pterygomasseteric sling makes mandibular parasymphysis/body fractures particularly problematic. The presence of mental neurovascular bundle poses additional complications during reduction and fixation of the fracture segments in this zone of transition at the parasymphysis and body region, and frequently results in mental nerve paresthesia if manipulated too much.[2] The fixation of mandibular fractures has been an evolutionary process that, over time, has included many different concepts. Although each of the techniques or philosophies for reconstruction offer unique advantages or disadvantages, the transition zone at the parasymphysis and body region harboring mental nerve has not yet been explored.

For these reasons, the purpose of this study is to evaluate the biomechanical behavior of a newly designed twin-fork−shaped miniplate for the fixation of fractures involving the transition zone of parasymphysis and body region, involving the mental neurovascular bundle, and to compare the same with the conventional single and two miniplates. The in vitro study was conducted using finite element model analysis, and the study results are very encouraging.[3]
Subsequently, an in-vivo evaluation of the same novel design of the miniplate was planned in the Department of Oral and Maxillofacial Surgery. The miniplate was assessed clinically and radiographically in terms of discrepancy in the occlusion, anesthesia or paresthesia due to mental

nerve injury, evidence of infection at the operated site, intra-operative time taken for the procedure and reduction status of fracture fragments. The objective was to assess and compare the results with the conventional techniques used for the repair of such fractures.

Since a modified single miniplate is used instead of two plates, it is economical for the patient, reduces the risk of infection and reduces wound dehiscence. Moreover, the design reduces the incidence of mental nerve injury.

The aim of this study is to evaluate the clinical performance of the novel design of the miniplate for mandibular fractures at transition zone of parasymphysis/body region.

MATERIALS AND METHODS

This is a clinical prospective study conducted in the Department of Oral and Maxillofacial Surgery. A total of 30 patients (10 patients in each of three groups) were included. A standard pro forma was used to collect the necessary information regarding each case. The patients after inclusion were randomly divided into three groups, as depicted in Table 1. The randomization was performed by assigning each number to the patient as they first reported to the department, and allocation of the subject's number to their group was performed by the computer-generated system.

Table 1. Study patient group allocation

Group	Configuration of miniplate
Group A	Patients undergoing fixation with the conventional design of the single miniplate
Group B	Patients undergoing fixation with the conventional design with two miniplates
Group C	Patients undergoing fixation with the newly designed twin-fork−shaped miniplate

The procedure to be performed was explained, and written informed consent was obtained from the patients.

Inclusion criteria were as follows: minimally displaced or unfavorable fractures of mandibular parasymphysis−body region only requiring open reduction with rigid internal fixation for treatment; patient above 18 years of age; patient medically fit for general and/or local anesthesia; non-comminuted and non-infected fractures.

Exclusion criteria were as follows: patients with systemic disease contraindicating general anesthesia; patients with fracture comminution; patients with frank infection.

Subjects of the study underwent open reduction and internal fixation under local anesthesia. The placement of the novel miniplates was according to the conventional method as suggested by Champy.[4] Throughout the study, these patients were evaluated preoperatively, intraoperatively and postoperatively for various parameters. Preoperatively OPG was taken and compared with the postoperative OPG to check the adequacy of reduction and fixation.

Routine blood and radiological investigations done. The intravenous line was secured and an injectable antibiotic (amoxicillin−clavulanic acid 1.2 g intravenously) was given 1 hour prior to the operation. Surgical approach was either through an intraoral or extraoral transbuccal approach, if an extraoral contused lacerated wound was present.

The titanium miniplate according to the patients' respective groups was pre-bent according to the shape of the mandible and fixation achieved using titanium screws (Figures 1−3)

All patients were discharged on the same day as the operation. All patients were prescribed oral antibiotics and analgesics with anti-inflammatory agents for 5 days postoperatively. All patients were evaluated postoperatively on day 5, 1 month, and 3 months. Clinical utility and outcome of the novel design of the twin-fork−shaped miniplate was evaluated in terms of the following:

1) Operative time: The operative time for the surgery was calculated as commencing of the incision and ending with the completion of wound closure. This excluded the time to place IMF. It was recorded in minutes.
2) Ease of placement of miniplate: This was based on operator's evaluation of the degree of difficulty in adapting and placing the miniplate in the transition zone of parasymphysis−body region in close proximity to the mental neurovascular bundle. It was assessed as easy, mildly difficult, moderately difficult and severely difficult based on operator's experience.
3) Occlusion: The preoperative and postoperative occlusion was graded based on the surgeon's evaluation. The scoring was allotted as 0 to stable (all occlusal contacts preset between maxillary and mandibular teeth on both sides). A score of 1 indicated mildly derangement (ie, a slight gap is present between one or two cusps on unilateral or bilateral sides). A score of 2 indicated unstable and grossly deranged occlusion (ie, no occlusal contacts between maxillary and mandibular teeth is present.)
4) Postoperative reduction of fracture: Patients were evaluated radiologically at 1-week, 4-week and 12-week intervals with OPG. The reduction of the fracture segments was determined on a panoramic radiograph by assessment of the inferior border of mandible. Whenever alignment of the inferior border of mandible was maintained across the fracture line, it was considered as excellent reduction. If a discrepancy of 1−3 mm was

noted, it was considered as good reduction. If discrepancy of 3−5 mm was noted in OPG, it was labeled as fair reduction. If the discrepancy was >5 mm, it was considered poor reduction.

5) Neurosensory disturbances: The patients were asked for their subjective impression of any alteration in sensory function. Then extraoral and intraoral examinations were performed to determine whether there was any abnormality or a biting scar on lip. At the last stage, clinical neurosensory testing was performed in the area of distribution of the mental nerve. A pin-prick test using a probe over the area of distribution of the mental nerve was used for evaluation.

   All patients were evaluated preoperatively after the trauma and at each recall visit on the 7th day, 4th week, and 12th week postoperatively. The sensation at the opposite side of the fracture acted as the control area. All the neurosensory tests were performed by the same person in a room free of acoustic or visual stimuli.

   a. Postoperative infection: Criteria for infection were based on either of the following conditions on follow-up visits: purulent discharge from the incision; pain in the operated region; and serosanguinous drainage and a positive wound culture for a known pathogen.

Statistical analysis

All the data were entered in custom-written software in Excel (MS Office 2010, Windows XP; Microsoft Corp., Redmond, WA, USA). The statistical analyses were performed using SPSS version 22.0 (IBM Corp., Armonk, NY, USA) software, and statistical significance was tested at 5% level. Statistical analysis of the comparison of operative time, ease of placement of miniplate, postoperative reduction of the fracture, neurosensory disturbances and postoperative infection was carried out to find any significant difference between those values. Furthermore, pre- and postoperative occlusion were also compared using repeated-measures analysis of variance. Since the data did not follow normal distribution, non-parametric tests were used, such as the Chi-square test of association for nominal and ordinal data, Mann−Whitney test, Wilcoxon signed rank test, Kruskal−Wallis test and Friedman test. Descriptive statistical analysis (i.e., mean, standard deviation and standard error) was carried out for this study.

RESULTS

A total of 30 patients were enrolled in the study, divided into three groups. The mean age of the patients was 31.50±07.86 years and ranged from 18 to 50 years. There was a higher incidence of fractures in the age range of 20−30 years. Twenty-four (80.0%) of the patients were male and six (20.0%) were female. The data show that the incidence of trauma was higher in male than in female patients. The most common etiology was road traffic accidents, followed by assault (interpersonal violence) and fall from a height. All the patients were treated exclusively for the fractures of transition zone of parasymphysis−body region of mandible with open reduction and internal fixation using different plating configuration according to their respective groups using following parameters.

Operative time

The mean operative time for Group A was 26.50±5.79 minutes, Group B was 42.00±5.67 minutes and Group C was 36.50±28.98 minutes. There was a statistically significant difference (Kruskal–Wallis test = 9.007, p = 0.011**)** between patients and mean intraoperative time. This indicates that Group B had the longest time for fracture fixation, followed by Group C, which had a longer intra-operative time than Group A.

Ease of placement of miniplate

There was a statistically significant difference (Kruskal−Wallis test: 7.50, p = 0.002) between patients and mean intraoperative ease of placement of miniplate. The miniplate in Group A is the most easy to use, followed by that in Group C.

Occlusion

The results show a significant difference between the Group C and the mean postoperative occlusion at week 12, with Group C showing the most stable occlusion at postoperative week 12.

Postoperative reduction of the fracture

In group A, 6 patients had excellent, 3 good, 1 fair, and no patients poor reduction of fracture at the end of week 4. In group B, 3 had excellent, 6 good, none fair, and 1 had poor reduction of fracture at the end of week 4, whereas in group C all 10 patients had excellent reduction of fracture at the end of week 4.

There was statistically significant difference (χ^2 =13.895, p = 0.031**)** between patients and postoperative reduction of fracture at week 4. This indicates the superiority of group C in postoperative reduction of fracture at week 4.

On comparison of postoperative reduction of fracture at different time using the Friedman test, the following were observed. In group A, mean postoperative reduction of fracture at weeks 1, 4, and 12 was 0.70±0.67, 0.50±0.71 and 0.40±0.52 respectively. There was no statistically significant difference (p=0.097). In group B, mean postoperative reduction of fracture at weeks 1, 4, and 12 was 0.90±0.87, 0.90±0.87 and 0.40±0.69 respectively. There was a statistically significant difference (p=0.007). In group C, mean postoperative reduction of fracture at weeks 1, 4, and 12 was 0.30±0.48, 0.00±0.00 and 0.00±0.00 respectively. There was no statistically significant difference (p=0.05).

Neurosensory disturbances

The association between patients from each group and neurosensory disturbance at postoperative week 12 was evaluated using Fisher exact test. A total of 22 patients (7 from group A, 6 from group B and 9 from group C) were free from any neurosensory deficit at the end of week 12. Six patients (2 from group A, 3 from group B and 1 from group C) were recovering from their previous neurosensory disturbance. The remaining 2 (1 from group A and 1 from group B) still had neurosensory disturbances at the end of week 12. There was a statistically significant difference (Fisher exact test= 17.40, $p = 0.003$**)** between patients and postoperative neurosensory disturbance. Group C showed the most positive neurosensory response.

Postoperative infection

1. In all the groups, all 10 study participants had no postoperative infection across weeks 1, 4, and 12.

DISCUSSION

In accordance with the dynamic biomechanics, behavior of various patterns of stresses and the forces generated in the transition zone of body and parasymphysis of mandible, there is always a dilemma for the surgeons as to whether to fix the mandibular segments with one or two miniplates.

According to Champy et al .,[4] the location of the plates may be precisely determined by the study of the stress distribution, photo-elasticity, and calculation of moments.

A plate screwed at the lower border does not re-establish the stress distribution existing before the section. At the level of the horizontal ramus, there are almost only flexion moments, the value of which increases from the front backwards. In the anterior part of the mandible, in front of the first premolar, there are mainly moments of torsion. They are higher the nearer they are to the mandibular symphysis. Therefore, the principle of osteosynthesis is to re-establish the mechanical qualities of the mandible, taking into account the anatomical conditions. Proximal to the first premolar, one plate is sufficient. In front of the first premolar, one can place a strong solid plate on the lower border; however, one risks an adaptation of the cortical surfaces to the shape of the plate. Alternatively, one can place two miniature plates separated by 4-5 mm in order to neutralize the moments of torsion.

However, the zone of transition at the mental foramen region is also constantly subjected to various types of occlusal and muscular forces as well as tension forces on its superior border and compression forces on its inferior border. Furthermore, this zone is complicated by the presence of long roots and the change in the pattern and direction of the bony trabeculae. The presence of the mental nerve in this region makes it more challenging for the surgeon to fix the fracture segments without dissecting and damaging the nerve. Thus, this new miniplate is designed to overcome all these shortcomings and sources of confusion.

In the present study, we have designed a novel shape of the miniplate that follows the exact configuration of the Champy osteosynthesis lines for better stability and osteosynthesis.
The in vitro study[3] confirms the study of Kroon et al [5] and Choi et al,[6] who found that the single miniplate is not able to provide stability to the fractured segments in this highly dynamic region and one more plate is required that acts as tension band. Our twin-fork−shaped miniplate has an upper horizontal arm that acts as a tension band and lower horizontal arm as the compression arm. Both the arms are connected to a single horizontal arm that coincide with the lines of osteosynthesis distal to mental foramen region (Figure 4).

Another mechanical advantage of this specific design is the distribution of the forces and stresses along the three arms in equal direction and vector. As a result, the forces along the inner zone of the broad end of the Y shape is neutralized. The miniplate is hence adapted in the specific manner that the neutral zone overlies the anatomical location of the mental nerve. It can be achieved by either adapting the lower horizontal arm at the inframental region (Figure 5) or the suprarenal region, depending on the orientation of the fracture line and root configuration of teeth. All three regions around the central point of the twin-fork miniplate are neutral zones. This configuration in turn allows preservation of the mental neurovascular bundle.
The literature[7] indicates that the prevalence of postinjury/pretreatment inferior alveolar nerve (IAN) injury ranges from 5.7% to 58.5%. The prevalence of IAN neurosensory deficit after fracture treatment ranges from 0.4% to 91.3%.[8]
In our study, the neurosensory disturbance has definitely improved over the follow-up period after proper reduction of the fracture segment was performed. In cases in which the reduction

was not adequate, the result was delayed recovery or long-term paresthesia of the mental nerve region. The results of our study suggest that for most patients, the neurosensory status improved after treatment of mandibular fracture. Group C had the most favorable result, in which 9 of 10 patients were symptom free at month 3 follow-up and one patient was recovering. The data were statistically significant (Fisher exact test 17.40; p= 0.003), showing the superior behavior of the twin-fork miniplate with mean postoperative neurosensory disturbance for group C to be the least among the three groups.

The mean operating time analysis in our clinical study shows that the new designed twin-fork−shaped miniplate took slightly more time to adapt and the fixation of the fracture longer than the single miniplate but less than when using two miniplates, and the result was statistically significant. The reason may be due to the new design of the twin-fork miniplate, which took a little more time for the surgeon to become familiar with it. However, the twin-fork−shaped miniplate was easier to place intraoperatively. Since it is a one-unit miniplate with three arms, adaptation is easy, and hence the mean operating time is less than with the two-miniplate configuration. Thus, this novel miniplate is operator as well as patient friendly.

According to Michelet et al,[9] the function of the masticatory apparatus is determined by the state of the dental occlusion. Malocclusion has been reported in many previous studies as a postoperative complication after fracture treatment. In our study, the twin-fork−shaped miniplate proved to be more suitable for fixation of the fracture segments in the transition zone. Group C proved to be statistically significantly better in postoperative reduction of fracture than group A and group B. None of the patients needed a prolonged period of intermaxillary fixation, and hence patient-friendly and cost-effective treatment could be provided to the patients with group C, whereas two patients in group A required 10 days of intermaxillary fixation. The preoperative occlusion was deranged in all the patients in all groups. However, functional occlusion was achieved postoperatively in all patients. Better occlusion and primary bone healing contribute to the superior functional result achieved with the novel miniplate approach.

It was suggested earlier that the use of metal plates for mandibular fractures increases the incidence of postoperative infection. Conversely, several studies,[4] have shown low rates of infection associated with the use of miniplate osteosynthesis. In our experience, none of the patients reported any sign of postoperative infection such as pain, purulent discharge or a draining sinus. However, the patients with oral submucous fibrosis had experienced delayed healing following facial trauma.

The intraoral approach, which avoids skin scars, and the easy manipulation of the plates contribute to the suitability of this technique for a teaching unit.

The limitations of this design is that the twin-fork−shaped miniplate required a longer incision and exposure to access intraorally longer than the conventional miniplate. However, the “extension for prevention” principle well applies here, since this new twin-fork−shaped miniplate was observed to be superior in terms of fracture reduction, postoperative maintenance of occlusion and better neurosensory outcome.

CONCLUSION

This study aimed to evaluate the novel twin-fork design of a miniplate used for fracture fixation at the transition zone of parasymphysis and body region of mandible. The following conclusions can be drawn from this study:

1. The novel design of the twin-fork miniplate is better than the conventional design and applicable for rigid fixation of the mandibular fractures at the transition zone of para-symphysis to body region.
2. The twin-fork−shaped miniplate is better in regard to handling, ease of use and postoperative occlusal stability.
3. The postoperative reduction of the fractured fragments has been significantly good, and this miniplate provides better stability in the transitional zone of mandible.
4. The twin-fork−shaped miniplate proved to be superior to the conventional miniplate in terms of neurosensory and functional outcome.

The authors conclude that the use of novel design of twin-fork miniplate should be encouraged in trauma cases, especially in the fractures of the transition zone of parasymphysis−body region involving the mental neurovascular bundle.

Further studies with larger sample sizes and longer follow up periods should be performed. Future studies should also include the associated maxillofacial trauma in order to evaluate the clinically utility of this newly designed twin-fork miniplate in multiple trauma cases.

Conflict of interest

None.

Ethics approval

Institutional Ethical Committee Number: GDCHN/SS/PG/Ethic.Com.Meet/10575/2016 with reference No. MUHS/PG/E2/2386/2016

REFERENCES

1. Scolozzi P, Richter M. Treatment of severe mandibular fractures using AO reconstruction plates. Journal of Oral and Maxillofacial Surgery. 2003 Apr 1;61(4):458-61.
2. Kevin A. Shumrick, Md, Facs: Complications of Facial Plating. Operative Techniques in Otolaryngology. Head and Neck Surgery. 1995 Jun:6(2) 135-141
3. Datarkar A, Tayal S, Thote A, Galie M. An in-vitro evaluation of a novel design of miniplate for fixation of fracture segments in the transition zone of parasymphysis-body region of mandible using finite element analysis. Journal of Cranio-Maxillo-Facial Surgery. 2018 Nov 12.
4. Champy M, Lodde JP, Schmitt R, Jaeger JH, Muster D. Mandibular osteosynthesis by miniature screwed plates via a buccal approach. Journal of Maxillofacial Surgery. 1978 Jan 1;6:14-21.
5. Kroon FH, Mathisson M, Cordey JR, Rahn BA. The use of miniplates in mandibular fractures: an in vitro study. Journal of Cranio-Maxillo-Facial Surgery. 1991 Jul 1;19(5):199-204.
6. Choi BH, Yoo JH, Kim KN, Kang HS. Stability testing of a two miniplate fixation technique for mandibular angle fractures. An in vitro study. Journal of Cranio-Maxillo-Facial surgery. 1995 Apr 1;23(2):122-5.
7. Goodday RH. Management of fractures of the mandibular body and symphysis. Oral and Maxillofacial Surgery Clinics. 2013 Nov 1;25(4):601-16.

8. Thurmuller P, Dodson TB, Kaban LB. Nerve injuries associated with facial trauma: natural history, management and outcomes of repair. Oral and Maxillofacial Surgical Clinics of North America 2001;13:283–94.

9. Michelet Fx, Deymes J, Dessus B: Osteosynthesis With Miniaturized Screwed Plates in Maxillofacial Surgery. J Maxillofac Surg 1:79, 1973

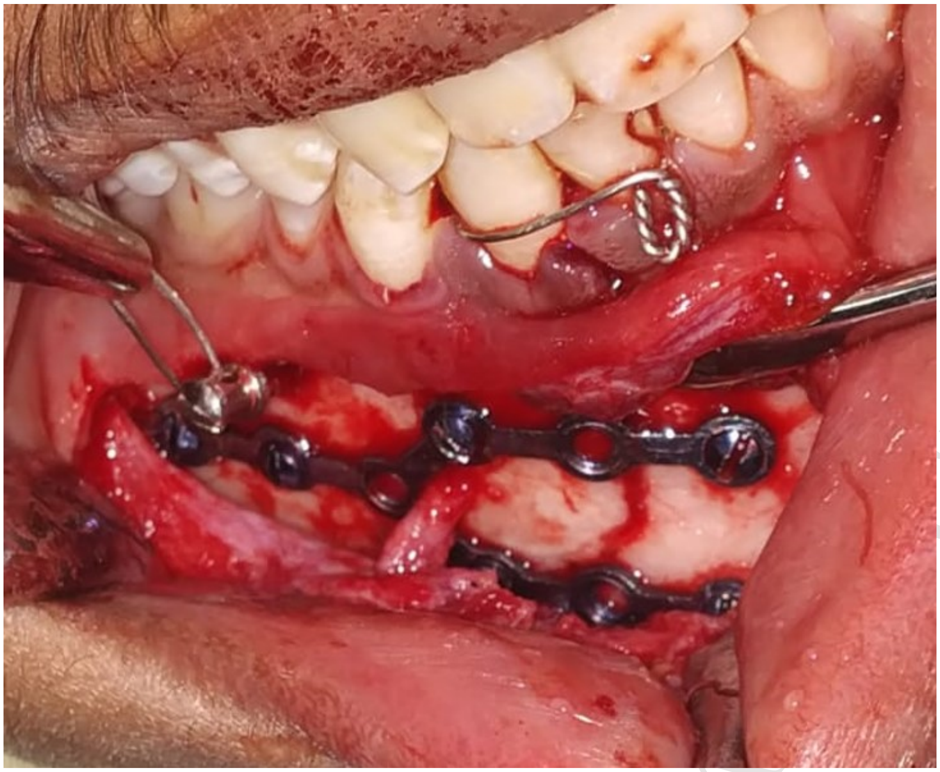
Figure 1. Single miniplate fixation. A. Preoperative clinical photograph showing existing contused lacerated wound. B. Preoperative OPG showing fracture at left transition zone of parasymphysis-body of mandible. C. Single miniplate fixation. D. Postoperative OPG. E. Postoperative occlusion. F. Postoperative clinical photograph.

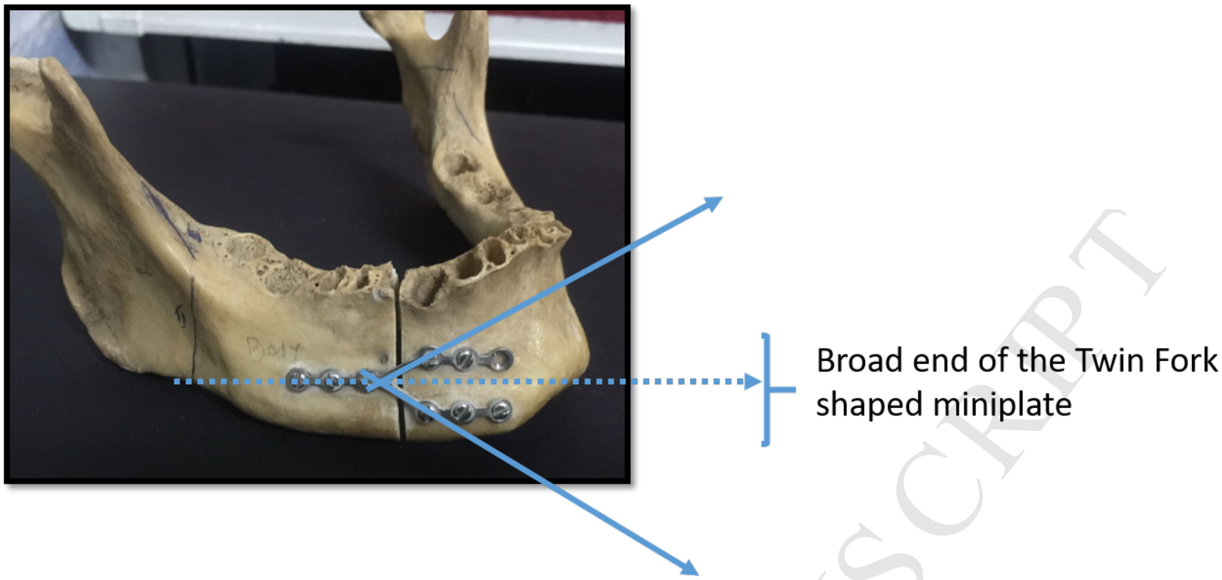
Figure 2. Two-miniplate fixation: A. Preoperative OPG showing left parasymphysis of mandible. B. Fixation of two-miniplates and their relationship with the mental neurovascular bundle. C. Postoperative OPG.

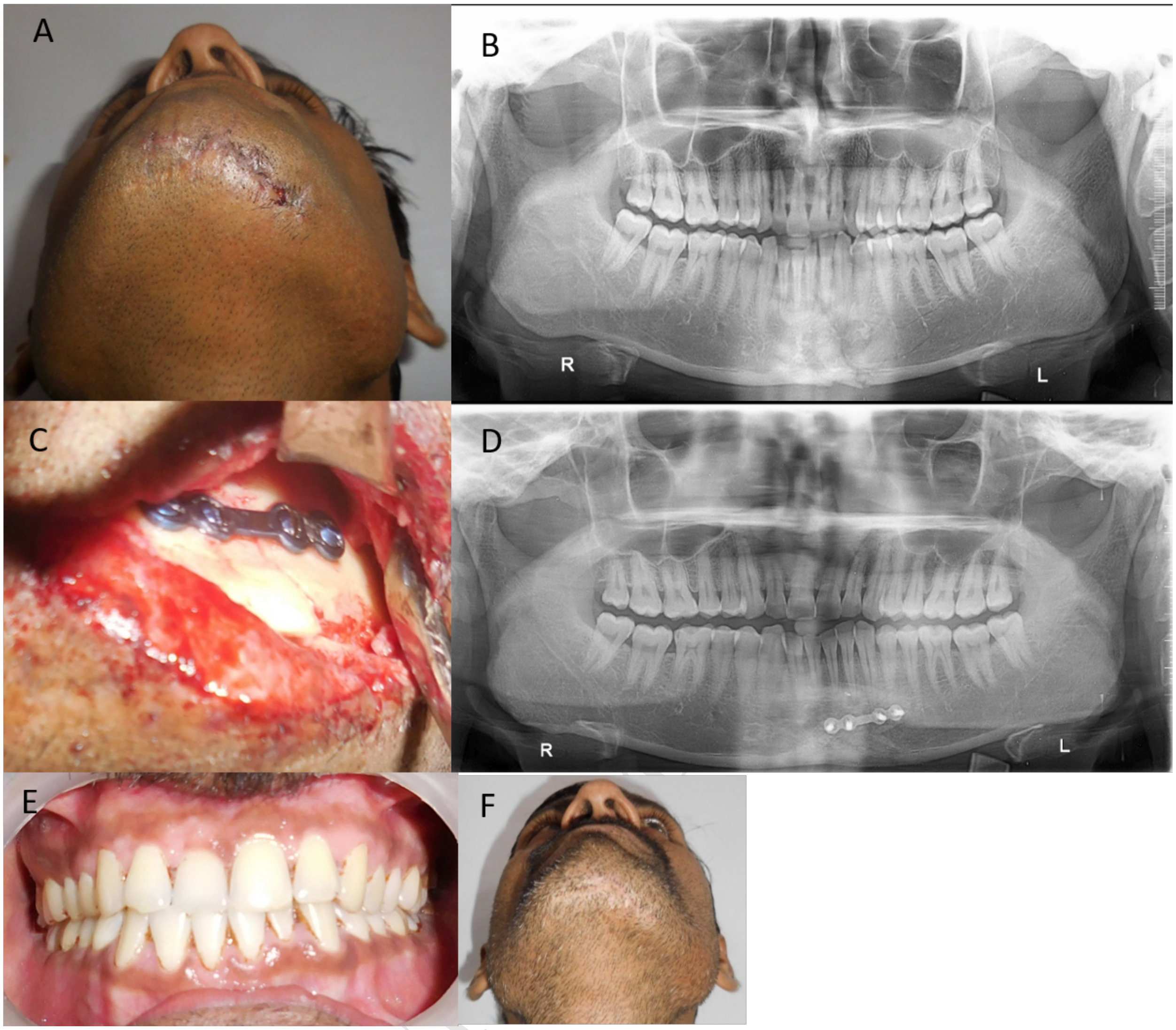
Figure 3. Twin-fork miniplate fixation. A. Intraoperative view of twin-fork−shaped miniplate fixation. B. Preoperative OPG showing fracture at left parasymphysis fracture at transition zone to body region. C. Postoperative occlusion D. Postoperative OPG.

Figure 4. Design and configuration of the twin-fork−shaped miniplate.

Figure 5. Adaptation of the twin-fork miniplate around the mental nerve.




Broad end of the Twin Fork
shaped miniplate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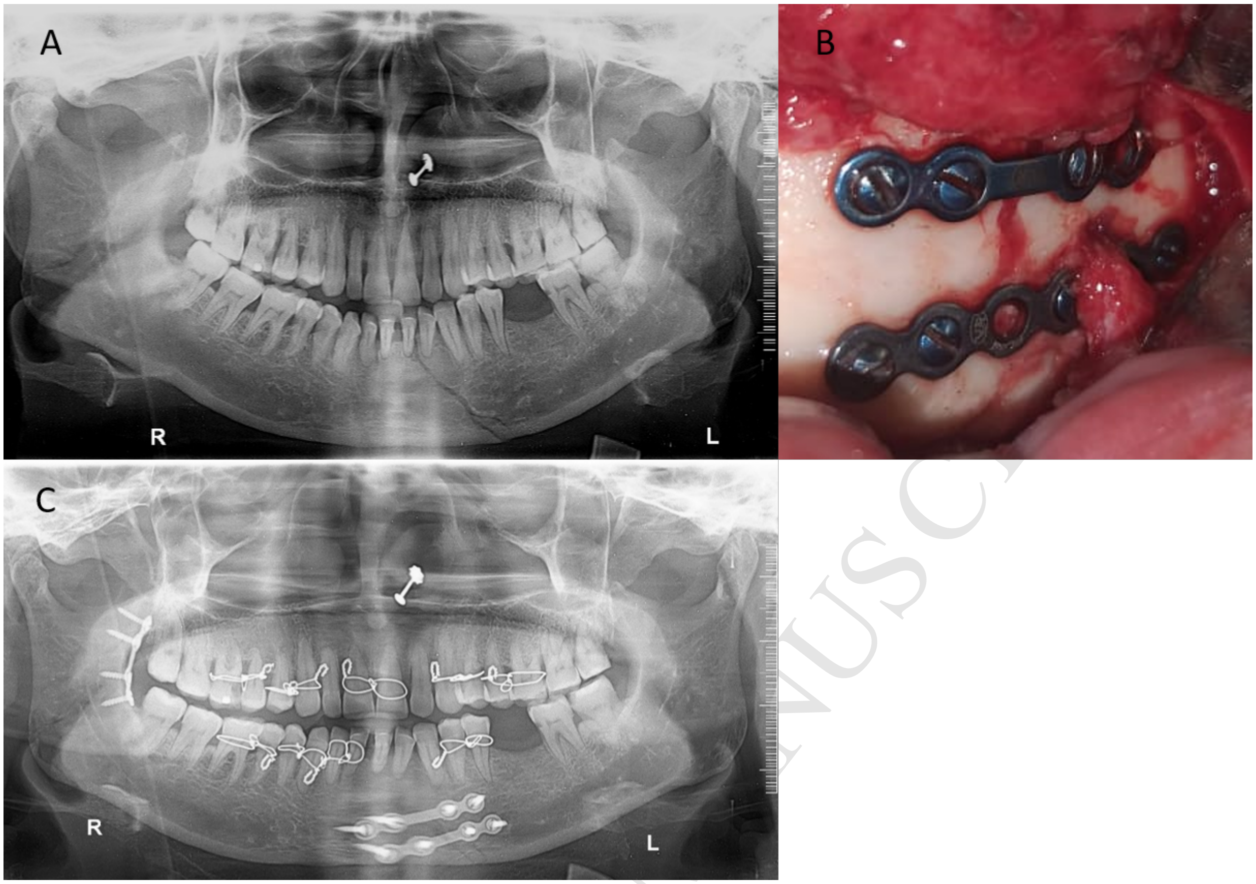
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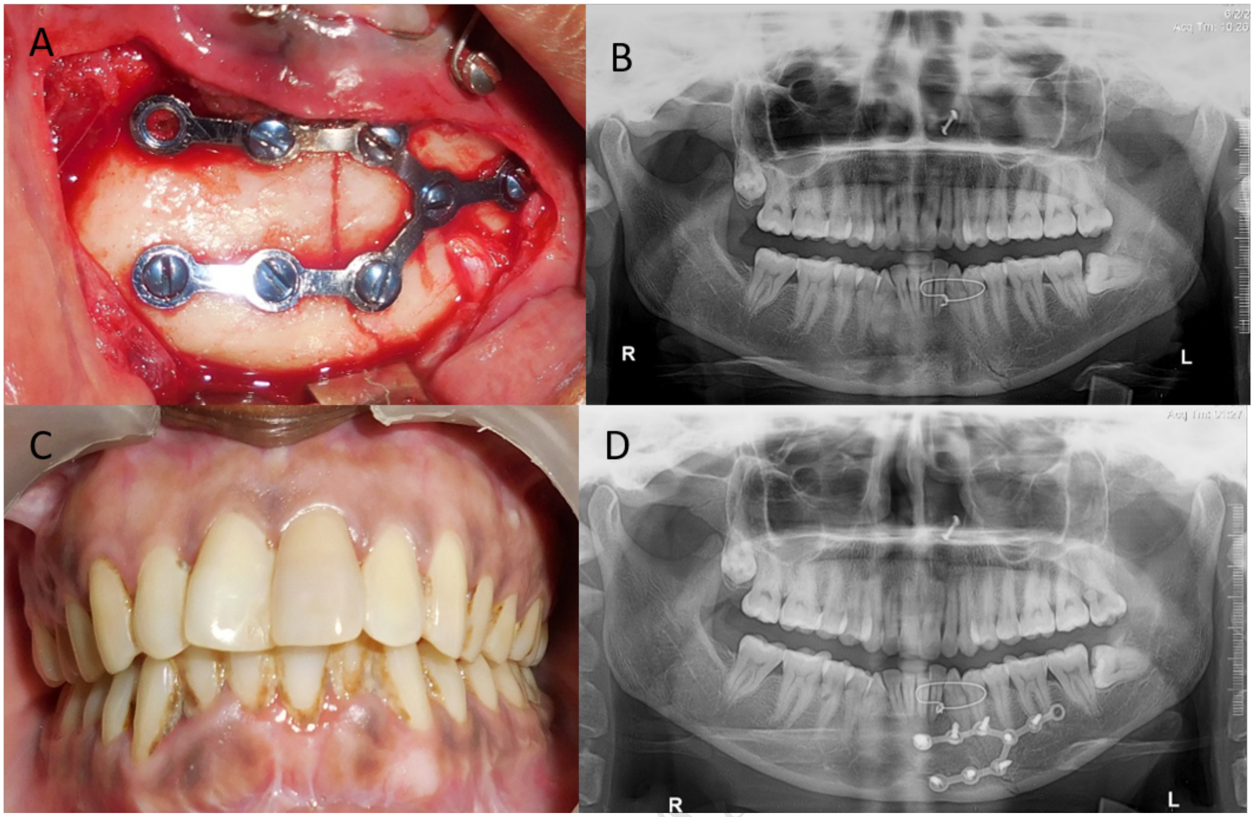
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