

Pre-adjusted Three-Dimensional Plate Employing Printing versus Conventional Plate in the Management of Mandibular Fractures - A Comparative Study

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Abstract

Introduction: The aim of this study was to compare the efficacy of pre-adjusted three-dimensional (3D) plating system employing 3D printing with conventional 3D plating in the management of mandibular fractures. **Materials and Methods:** A randomised, clinical trial was conducted where the study sample ($n = 20$) was divided into two groups. In Group 1, 3D plate and in Group 2, pre-bent 3D plate was fixed to the fracture site. The parameters assessed were number of bends required for adaptation, duration of fixation, pain, occlusal stability, reduction in lingual splinting and post-operative complications. **Results:** Statistically significant difference was seen for the number of bends required ($P = 0.000$, $P < 0.01$) and duration of fracture fixation ($P = 0.001$, $P < 0.01$). There was statistically significant difference between the values of pain during the adaptation of 3D plate ($P = 0.033$, $P < 0.05$). **Discussion:** The application of pre-adjusted 3D plate is superior to conventional 3D plating in terms of reducing number of bends, duration of fixation and pain during adaptation.

Keywords: Mandibular fracture, open reduction, stereolithographic models, three-dimensional plate, three-dimensional printing

INTRODUCTION

Management of mandibular fracture has evolved from various forms of splinting, wiring, extraoral pins followed by rigid fixation technique, which has lately given way to semi-rigid fixation with miniplate.^[1] To overcome the shortcomings of semi-rigid fixation using miniplates like inability to render three-dimensional (3D) stability, Kaushik *et al.*, developed a new miniplate system, which takes advantage of biogeometry to provide a stable fixation - '3D plating system'.^[2] It uses fewer plates and screws as compared to the conventional miniplates, reducing the operation time and overall cost of the treatment. However, due to its configuration, it is required to bend it in a plane for adapting to the fracture site unlike the conventional miniplates which is bent in a line. This increases the time and number of bends. Stereolithography (STL), 3D printing was invented in the early 1980s.^[3] King *et al.*,^[4] concluded that on-site 3D model fabrication with preoperative plate decreases operative time in the management of mandibular fractures. The use of 3D models also gives an idea about the anatomy of bone and fracture pattern. Hence, we conducted a randomised clinical trial to compare the efficacy of preadjusted 3D plates on surgical models received after 3D printing with conventionally applied

intraoperative 3D plates in the management of mandibular fractures.

MATERIALS AND METHODS

This trial was approved by the Institutional Ethical Committee vide reference no. 4126/2020 and carried out in the Department of Oral and Maxillofacial Surgery from June 2020 to August 2021 (CTRI reg: 2020/06/025916). A total of 20 patients were selected from the age group, 18–45 years. The study population was randomly divided into control group (Group 1)

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and experimental group (Group 2) by software-generated randomisation sequence. Systemically healthy patients, with unilateral and/or bilateral fracture present on symphysis, parasymphysis or angle of mandible region were included. Patients excluded were those with co-morbidities, associated condylar/subcondylar/coronoid fractures, severe comminuted fractures and those not willing to participate in the study. Ours was a double blinded study to avoid operator and participant bias.

A cone-beam computed tomography (CBCT) scan using Blue Sky software was taken preoperatively [Figure 1]. For Group 2 patients, fabrication of a stereolithography (STL) model was done. The polylactic acid STL model produced was fractured using saw and was glued in anatomical position taking the reduction of inferior border into consideration. A 2-mm Titanium (Ti) 3D plate was adapted over the model preoperatively using plate bender and then sterilised [Figure 2].

Surgical procedure

Under all aseptic precautions and local anaesthesia, routine scrubbing and draping were done as per the protocol. Circumlinear vestibular incision was made as per the fracture site. Fracture site was exposed, debrided and sharp bony prominences were trimmed. Functional and anatomic reduction was achieved and intermaxillary fixation (IMF) was done. After establishment of occlusion, a 2-mm Ti 3D plate was adapted and fixed with Ti screws Group 1 patients, whereas in Group 2 patients, a pre-bent 2.0-mm 3D plate was used for fixation [Figure 3]. Both pre- and intraoperative bending of plate in Group 2 patients was done by the same surgeon.

After confirming the pre-injury occlusion and achieving complete haemostasis, the incision site was closed layer-wise using 3-0 Vicryl sutures. Postoperatively, IMF was removed and occlusion was checked. Any further development of occlusal discrepancy was treated by maxillomandibular fixation for seven days. Outcome assessed was the number of bends required for adaptation of 3D plates, time required from adaptation of plate till fixation of last screw in minutes and pain during adaptation of 3D plate by the Visual Analogue Scale (VAS).^[5]

Assessment of occlusal stability was done at the third day, seventh day, three and six months interval. A radiological examination using CBCT scan was done on the third day to assess the reduction in lingual splaying [Figure 4]. Postoperative complications such as infection, wound dehiscence, paraesthesia, trismus, occlusal derangement and hardware failure were assessed at the seventh day, three and six months interval. Analysis and measurements were performed by the same assessor twice to eliminate the intra-observer error; the mean was then calculated and recorded for further statistical analysis. Descriptive statistics such as frequencies and percentage for categorical data, mean and standard deviation for numerical data were depicted. Intergroup comparison was done using *t*-test and comparison

of frequencies of categories of variables with groups was done using the Chi-square test.

RESULTS

There were a total of 20 patients in our study [Figure 5], with age ranging from 21 to 44 years with a mean age of 28.10 years. A total number of male patients were 18 (90%), compared to female patients 2 (10%). Amongst 20 patients, 6 (30%) were having left parasymphysis fracture, 8 (40%) were having right parasymphysis fracture, 2 (10%) were having symphyseal fracture, 3 (15%) were having left

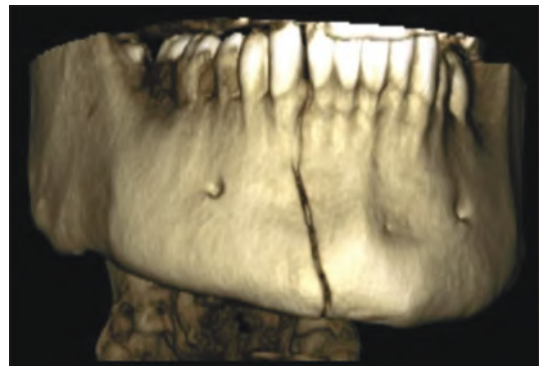


Figure 1: Three-dimensional-computed tomography reconstruction image showing right parasymphyseal fracture with mandible involving the inferior border



Figure 2: Adaptation of three-dimensional plate to the fracture site preoperatively on the stereolithography model



Figure 3: Pre-adjusted plate adapted and fixated to the fracture site

parasymphyseal and right-angle fracture and 1 (5%) was having left parasymphysis and right body fracture. Single fracture was present in 16 patients while more than one fracture was present in 4 patients. Fall was the leading cause of fracture in 10 (50%) patients followed by road traffic accident in 8 (40%) patients and assault in 2 (10%) patients. 3D plate was applied in 10 (50%) left parasymphysis regions, 8 (40%) right parasymphysis regions and 2 (10%) symphyseal regions. The mean number of bends in Group 1 was 5.3, whereas in Group 2 was 3. There was a statistically highly significant difference seen for the values between the groups ($P < 0.05$) for pain, 188 (VAS) with higher values in group 1 [Table 1].

Statistically non-significant difference was seen in the frequencies between the groups ($P > 0.05$) for occlusal stability on the third-day, seventh-day, third and sixth-month follow-up [Table 2]. There was significant/acceptable reduction of lingual splaying in all the patients with score of +1. The frequency for complications at various time intervals in between the groups was statistically non-significant ($P > 0.05$) [Table 3].

DISCUSSION

Open reduction and internal fixation (ORIF) is considered as the 'gold standard' for the fixation of maxillofacial fractures.^[6-8] 3D plating system was developed to render greater stability against torque forces, simultaneous stabilisation at both superior and inferior borders of the mandible and to decrease the operative time. The use of 3D STL models made with 3D printing has become a routine practice for majority of craniofacial surgeons for orthognathic surgeries, distraction osteogenesis, dental implant surgeries and various trauma and reconstruction surgeries.^[3] The purpose of this study was to validate our hypothesis that the use of 3D printed models and preoperatively bent 3D plates decreases number of plate bending, operating time, pain and post-operative complications.

The main cause for mandibular fracture in our study was fall followed by road traffic accident. It is not in accordance with the given literature,^[9] where road traffic accident (RTA) accounts for most of the mandibular fractures (83.3%). The reduced incidence of fracture with RTA is attributed to increased use of

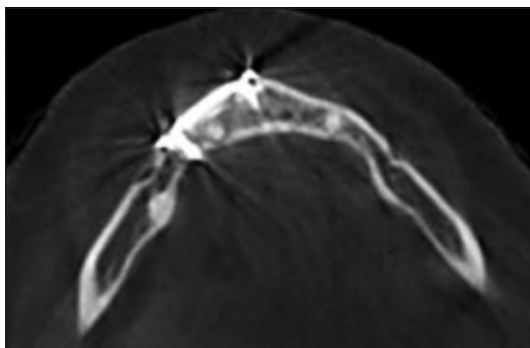


Figure 4: Third day cone-beam computed tomography scan was taken to assess the reduction in lingual splay is checked on the axial view, complete reduction in lingual splay can be seen

precautionary gears such as seat belts and helmets in the recent years. The mean number of bends in Group 1 was 5.30, while in Group 2 was 3. The reduced number of bends in Group 2 can be attributed to the use of 3D, STL model preoperatively for adaptation of plate, which is in accordance with those given in the literature by King *et al.*^[4] However, in contrast to his study where he calculated only corrective intraoperative bends, we have also calculated the number of bends given preoperatively. It is important to minimise the number of bends for adaptation of the plate as it may lead to decreased strength of plate, more fatigue and stress-induced fracture.^[10] In Group 1 and Group 2, the mean score for pain was 5.60 and 4.60, respectively showing statistically significant difference between their values ($P = 0.033$, $P < 0.05$). This increased value for pain in Group 1 can be attributed to increased surgical time leading to more discomfort to the patient. The mean time required for plate adaptation and fixation in Group 1 was 22.70 minutes, whereas in Group 2, it was 15.50 min, showing statistically highly significant difference ($P = 0.001$, $P < 0.05$). Our results can be correlated with the study done by King *et al.*^[4] The reduced number of bends given intraoperatively can be a major reason for the reduction of time required in Group 2.

There was no loss of molar relationship in all the patients in Group 1. However, in Group 2, there was unilateral loss of molar relationship in two patients. These two patients were kept under elastic traction. In the first patient, satisfactory occlusion was achieved at the seventh day following which IMF was left intact for another one month. The second patient showed complete loss of molar relationship of one side. Occlusal stability assessed in this study was in accordance with that given in the literature.^[11,12] Significant reduction of lingual splaying was achieved in all the patients (100%) in contrast to the study done by Prasad *et al.*,^[13] he achieved significant reduction of lingual splaying in 72.2% of his cases. There was no clinical evidence of complications in Group 1 patients at follow-up visits. While in Group 2, one patient presented with paraesthesia with the left side of the

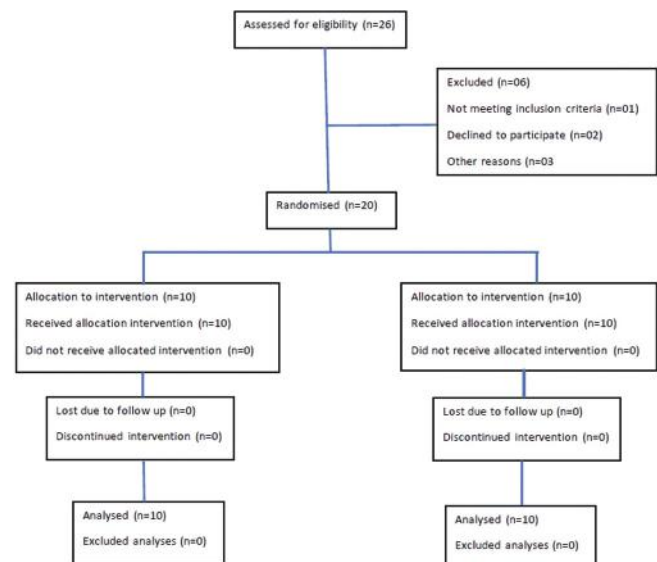


Figure 5: Participant flowchart

Table 1: Comparison of frequencies of subjects between groups for number of bends, time and pain

Parameter	Group 1 (n=10)	Group 2 (n=10)	P*
Number of bends	5.30	3	0.000
Time	22.70	15.50	0.001
Pain	5.60	4.60	0.033

*Statistically significant when, $P < 0.05$ **Table 2: Comparison of frequencies of subjects between groups for occlusal stability at various time intervals**

Time	Scores/outcome	Group 1	Group 2	χ^2	P*
Day 3	-1	0	0	2.222	0.136
	0	2	0		
	1	8	10		
Day 7	-1	0	0	1.053	0.305
	0	1	0		
	1	9	10		
3 rd month	-1	0	0	1.053	0.305
	0	1	0		
	1	9	10		
6 th month	-1	0	0	1.053	0.305
	0	1	0		
	1	9	10		

*Statistically significant when, $P < 0.05$ **Table 3: Comparison of frequencies of subjects between groups for complication at various time intervals**

Duration	Complication	E**	C***	χ^2	P*
7D	Deranged occlusion with right side	0	1	2.222	0.329
	Transient Paraesthesia with lower lip	0	1		
3M	Deranged occlusion with right side	0	1	1.053	0.305
6M	Deranged occlusion with right side	0	1	1.053	0.305

*Statistically significant when, $P < 0.05$. **E=Experimental group, ***C=Control group

lower lip at the seventh day and another patient with deranged occlusion with the right side. The results of our study are in agreement with those reported in the published literature;^[12,13] however, to correctly define all these parameters, a randomised controlled trial with larger sample size needs to be done.

CONCLUSION

Our study compared pre-adjusted 3D plate employing 3D printing with conventional 3D plate in the management of mandibular fractures and concludes that the application of

pre-adjusted plates is superior than conventionally applied plate in terms of reducing the number of bends, duration of fracture fixation and pain during adaptation of 3D plate.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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