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| Post          |  | Prospective Study of Efficacy and Complications<br>stoperatively of Three-dimensional Miniplates in<br>xation of Mandibular Fractures. | <b>KEY WORDS:</b> mandibular fracture, 3D miniplate fixation. |  |  |  |  |  |  |
| Deepanjan Dey |  | Mch Plastic Surgery, Senior Resident, Department of Plastic Surgery, Medical College, Kolkata, India.                                  |   |  |  |  |  |  |  |
| Ma            | ainak Mallik <sup>3</sup>  | Mch, DNB Plastic Surgery, Senior Resident, Department of Plastic Surgery, Medical College,Kolkata,India.*Corresponding Author.         |   |  |  |  |  |  |  |
| Santanu Suba  |  | Mch Plastic Surgery, Residential Medical Officer and Clinical Tutor, Department of Plastic Surgery, Medical College, Kolkata, India.   |   |  |  |  |  |  |  |
| ABSTRACT      | Introduction : The treatment of mandibular fractures have evolved over time. Presently these fractures are treated by either rigid fixation or semi-rigid fixation. Some of the disadvantages of the rigid fixation methods have been addressed by the miniplates. A further refinement of the fixation system is in the form of three dimensional (3D) miniplates. These rectangular plates with their geometric configuration provide more stability to fractures against shearing, bending and torsional forces and have fewer complications.<br><b>Aims and Objectives</b> : Despite its apparent advantages in the literature, this 3D miniplating system has not been used in India quite frequently. Hence, this study was conducted to assess the efficacy of the 3D miniplates in the treatment of mandibular fractures and the postoperative complications.<br><b>Methodology</b> : This prospective institute based interventional study was carried out in the Department of Plastic and Reconstructive Surgery. Medical College & Hospital, Kolkata. Every patient meeting the inclusion criteria between August 2016 and July 2018 was included. The parameters that were studied were patient particulars in terms of age, sex, etiology, location and type of the fracture, orthopantomograms, CT scan, particular mini-plate plate chosen for fracture reduction and fixation, postoperatively mobility after fixation, complications and adequacy of reduction.<br><b>Results</b> : A total of 15 patients with mean age of 32.6 years and 73.3 % males were included. Road traffic accident was the most common etiology and parasymphysis was the most common location of the fracture. 60% of the patients had pre-operative occlusal abnormality which was corrected. None of the patients had any mobility of the fracture segments and all underwent adequate reduction as evident on radiographs. Two patients had wound infection with wound dehiscence and one patient had paresthesia of the inferior alveolar nerve postoperatively (statistically not significant). The complications.<br><b>Conclusion</b> : The 3D minipla |  |   |  |  |  |  |  |  |

# **INTRODUCTION:**

Maxillofacial trauma is a matter of grave concern due to the increasing road traffic accidents, violence and sports injury. The unique position of mandible on the face makes it one of the most commonly fractured facial bones. Mandibular fractures are classified in several categories according to the direction of the fracture to be horizontal or vertical, whether it is favourable or not, according to the severity of the fracture to be simple or closed and compound towards the oral cavity or the skin, according to the type of fracture to be greenstick fracture, complex fracture, comminuted fracture, impacted fracture or depressed fracture, according to the presence or absence of the teeth in the jaws to be dentulous, partially edentulous or edentulous and according to the location to be alveolus or symphysis or parasymphysis or body or angle or ramus or condylar process or coronoid process or a combination.<sup>[1]</sup>

The objectives in the treatment of mandibular fracture are to re-establish normal occlusion, masticatory function and facial aesthetics with minimal disability and complications. Previously the patients presenting with fracture mandible were mainly treated with MMF (maxillomandibular fixation), reconstruction plates or linear miniplates. Through the decades, various plate and screw osteosynthesis have been introduced like AO (Arbeitsgemeinschaft fur Osteosynthesefragen) plating system, miniplating system, resorbable plates and screws.<sup>[2]</sup> Transorally placed miniplates have gained wide acceptance for the treatment of mandibular fractures as described by Champy *et al.*<sup>[3,4]</sup> Noncomminuted symphyseal and parasymphyseal fractures, as well as condylar fractures, can be treated with two miniplates, and at times, favourable, undisplaced angle fractures can be treated with an upper border miniplate.

There are two fundamentally different philosophies for the treatment of mandible fracture using plates and screws which are the concept of rigid fixation<sup>[5]</sup> using compression plates, rigidly fixed along the lower border of fractured mandible using bicortical screws to prevent inter-fragmentary movement and provide healing by primary intention and the concept of semi-rigid fixation which consisted of juxtaalveolar, subapical osteosynthesis without compression and intermaxillary fixation using miniaturized malleable plates. <sup>[3,4,6]</sup>Both the techniques are associated with disadvantages. In semi-rigid fixation a doubt arises whether miniplate fixation is sufficiently stable for fractures that cannot be adequately reduced. These shortcomings of rigid and semi-rigid fixation led to the development of three dimensional (3D) miniplates,

consisting of two miniplates interconnected by vertical cross struts. Unlike compression and reconstruction plates their stability is not derived from the thickness of the plate. With the screws monocortically fixed to outer cortical plate, these rectangular plates form a cuboid which possess 3D stability. The 3D plating system, first introduced by Mustafa Farmand in 1992, is based upon the principle of obtaining support through geometrically stable configuration. The quadrangle geometry of plates assures a good stability in three dimensions of the fracture sites since it offers good resistance against torque forces.<sup>[7]</sup>

The newly introduced 3D plating system provides definite advantages over conventional miniplates. The 3D plating system uses fewer plates and screws as compared to conventional miniplates to stabilize the bone fragments. In case of conventional miniplates, two plates are recommended in symphysis and parasymphysis region, while only one 3D plate is necessary for the same. Thus, it uses lesser foreign material, and reduces the operation time and overall cost of the treatment.<sup>[7-10]</sup>

In spite of the apparent advantages, these 3D miniplates have still not been widely used in our country. Hence this prospective study was carried out to assess the postoperative complications and efficacy of 3D miniplates in fixation of mandibular fractures. FIG.1 shows the 3D miniplates used in our study.

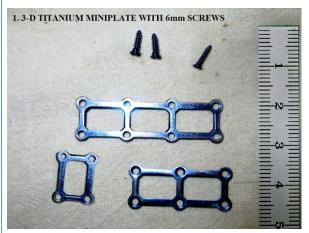


FIG.1- showing titanium quadrangular 3-D miniplates with 6mm screws used by us.

#### **METHODOLOGY**:

This prospective, descriptive, institutional study with convenience sampling was carried out in the Department of Plastic and Reconstructive Surgery, Medical College, Kolkata over 2 years duration (August 2016 to July 2018). No randomization of patients was done. Patients aged between 18 and 60 years with fractures in mandible, indicated for open reduction and fixation (excluding comminuted, infected fractures, coronoid and condylar fractures and those with haemodynamic instability, brain injury and severe comorbidities like uncontrolled diabetes, hypertension and bleeding disorders) attending the Plastic Surgery OPD/ ER and similar referred cases from other specialities of General Surgery, Orthopedics and Otorhinolaryngology, were included in this study.

The study parameters included patient particulars in terms of age, sex, etiology, location of the fracture and a careful history, diagnostic modalities like clinical examination, photographs, radiographs, CT scans, operative procedure performed and

postoperative monitoring in terms of mobility after fixation, adequacy of reduction and fixation on radiographs and complications. The study tools used were patients' informed consents, proforma for relevant history & clinical examination and data tabulation.

All patients who met our inclusion criteria were admitted for surgery. A detailed history, clinical and radiological evaluation was done, noting any paraesthesia in the distribution of inferior alveolar nerve, status of dental occlusion, any associated temporomandibular joint (TMJ) dislocation, or any other functional deficits. Radiological evaluation in the form of orthopantomograms and/or CT scans was done preoperatively. All patients were optimized for surgery and Erich arch bars were applied preoperatively. Prophylactic antibiotics were administered.

Under general anesthesia with nasotracheal intubation the approach was either intra or extra oral depending on the location of the fracture and the presence of external scars. After adequate exposure of fracture fragments, debridement and curettage was done and the malunited fractures were refractured. The fracture fragments were reduced to their anatomical form (ascertained by normal occlusion manually) and jaws were placed into maxillomandibular fixation (MMF) with Ivy loops or arch bars. The 2.0 mm titanium 3D miniplates (designed by AO or Orthomax) were adapted and bent adequately and placed over surface. The 3D plates were placed in such a way that horizontal cross bars were perpendicular to the fracture line and vertical cross bars were parallel to the fracture line. They were fixed with 6.0 mm and 8.0 mm screws. The lower border screws were fixed first, followed by upper border screws. Once the hardware was placed, the occlusion was checked and the fixed fracture fragments were checked manually for adequacy of reduction and fixation. The 4 hole plates were preferred in general but 6 hole or 8 hole plates were used in cases with unfavourable and grossly displaced fractures. After copious irrigation, the incisions were closed. A watertight closure of the mucosa was achieved with 4-0 polyglactin sutures in intraoral approach. Skin incisions when used were closed in layers by 3-0 polygalactin to muscles, 4-0 polygalactin to dermis and 6-0 polypropylene to skin. Pressure pack was applied and patients were prescribed antibiotics and analgesics for 5 days with liquid diet. The MMF was removed subsequently and the patients were advised to maintain the oral hygiene and to perform oral rinses with mouthwash on regular intervals. They were prescribed soft diet for the next six weeks. Panoramic radiographs for evaluation of adequacy of surgical reduction and plate localization were taken as soon as the patients were ambulatory. They were discharged and followed up in the out patients department at weekly interval for the first month, fortnightly in the second month and then monthly for up to six months.

## **RESULTS AND OBSERVATIONS :**

Statistical Analysis was performed with help of Epi Info (TM) 3.5.3. [a trademark of the Centers for Disease Control and Prevention (CDC)]. Descriptive statistical analysis was performed to calculate the means with corresponding standard deviations. Test of proportion was used to find the Standard Normal Deviate to compare the different proportions and chi-square test was performed to find the associations. Corrected chi-square test was used where any one of the cell frequencies was less than zero. t-test was used to compare the means. p<0.05 was taken to be statistically significant. The total number of patients in this study was 15. The patient characteristics including age and gender, etiology and location of fracture mandible, occlusal

abnormality present preoperatively and the short term complications at 1 week postoperatively have been described in Table 1.

Table 1- showing the patient characteristics including age and gender, etiology and location of fracture mandible, occlusal abnormality present preoperatively and the short term complications at 1 week postoperatively.

| S.<br>No. | Age<br>(yrs) | Gender | Etiology<br>of<br>fracture  | Location<br>of<br>fracture   | Preoper<br>ative<br>occlusal<br>abnorm<br>ality | ations (at<br>mean  |
|-----------|--------------|--------|-----------------------------|------------------------------|---|---|
| 1         | 45           | М      | Road<br>traffic<br>accident | Body                         | Present   | Nil   |
| 2         | 35           | F      | Assault                     | Angle +<br>parasym<br>physis | Absent  | Paraesthe<br>sia along<br>inferior<br>alveolar<br>nerve<br>distributi<br>on |
| 3         | 21           | М      | Road<br>traffic<br>accident | Parasym<br>physis            | Present   | Nil   |
| 4         | 43           | М      | Road<br>traffic<br>accident | Angle                        | Present   | Infection<br>and<br>discharge   |
| 5         | 33           | F      | Road<br>traffic<br>accident | Parasym<br>physis            | Present   | Nil   |
| 6         | 23           | F      | Road<br>traffic<br>accident | Parasym<br>physis            | Absent  | Nil   |
| 7         | 55           | М      | Road<br>traffic<br>accident | Body                         | Present   | Infection<br>and<br>discharge   |
| 8         | 34           | М      | Road<br>traffic<br>accident | Parasym<br>physis            | Absent  | Nil   |
| 9         | 27           | F      | Road<br>traffic<br>accident | Angle +<br>parasym<br>physis | Present   | Nil   |
| 10        | 44           | М      | Road<br>traffic<br>accident | Angle                        | Absent  | Wound<br>dehiscen<br>ce   |
| 11        | 31           | М      | Road<br>traffic<br>accident | Angle +<br>parasym<br>physis | Present   | Nil   |
| 12        | 23           | М      | Assault                     | Angle +<br>parasym<br>physis | Present   | Nil   |
| 13        | 22           | М      | Sports<br>related<br>injury | Angle +<br>parasym<br>physis | Present   | Nil   |
| 14        | 28           | М      | Road<br>traffic<br>accident | Ramus +<br>parasym<br>physis | Absent  | Wound<br>dehiscen<br>ce   |
| 15        | 25           | М      | Road<br>traffic<br>accident | Parasym<br>physis            | Absent  | Nil   |

The mean age of the patients was 32.60 years with range 21-55 years. The maximum number of patients was in the age group of 20-29 years (46.7%). There were 4 patients each in the age groups of 30-39 years and  $\geq$ 40 years respectively (26.7%). Test of proportion showed that proportion of males (73.3%) was significantly higher than that of females (26.7%) (Z=6.59; p<0.0001). The ratio of male and female was 2.8:1.0. Test of proportion showed that the proportion of the patients with road traffic accident (80.0%) was significantly higher than other etiologies (Z=9.45; p<0.0001). Only 2(13.3%) and 1(6.7%) of the patients were having assault and sports related injuries respectively. A total of 73.3% and 46.6% of the patients had location at parasymphysis and angle respectively. Thus proportion of patients with location parasymphysis was significantly higher (Z=3.85;p<0.001). Of all the patients, 60% had pre-operative occlusal abnormality which was significantly higher (Z=2.82;p=0.0048). No patient had pre-operative paresthesia in the distribution of inferior alveolar nerve. No patient had mobility after fixation. All the patients had postoperative adequacy of reduction and fixation on radiographs. No patient had occlusal abnormality postoperatively. No patient had hardware failure at any time after surgery and during follow-up. One (6.7%) patient had post-operative paresthesia at 1<sup>st</sup> week which was not significant (Z=1.03;p=0.30). Only 2 (13.3%) patients had infection and wound dehiscence at 1<sup>st</sup> week after surgery which was not significant (Z=1.13;p=0.26). The mean duration of hospitalization postoperatively was 3 days. FIG. 2 and 3 shows the preoperative malocclusion, X-rays of the fractures, the operative details with the 3-D miniplates used and the postoperative restoration of normal occlusion and reduction of fracture in 2 of our study patients.



FIG.2- shows a 23 year old male patient with traumatic fracture of left parasymphysis, A- preoperative malocclusion, B- fracture line seen in X-ray, C- occlusion achieved with arch bars with exposed fracture line, D- 8 hole 3-D miniplate used to fix the segments in reduction, E- 2 weeks postoperative X-ray showing reduced fracture segments aligned and normal occlusion, F- clinically occlusion normal at 2 weeks postoperatively.

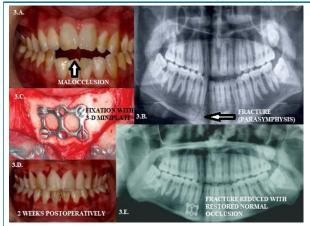


FIG.3- shows a 33 year old female patient with traumatic fracture of right parasymphysis, A- preoperative malocclusion, B- fracture line seen in X-ray, C- exposed fracture fixed with 6 hole 3-D miniplate in reduction after achieving occlusion, D- clinically occlusion normal at 2 weeks postoperatively, E- 2 weeks postoperative X-ray showing reduced fracture segments aligned and normal occlusion.

### **DISCUSSION:**

Champy et al advocated transoral placement of small, thin, malleable, stainless steel miniplates with monocortical screws along an ideal osteosynthesis line of the mandible, believing that compression plates were unnecessary because of masticatory forces that produce a natural strain of compression along the inferior border.<sup>[3,4]</sup> Subsequently Farmand et al.<sup>[7]</sup> developed the concept of 3D miniplates.

In a study conducted by Zix J et al.,  $^{\scriptscriptstyle [10]}$  non-comminuted mandibular angle fractures were treated using straight and curved 3D miniplates and it was found to be suitable for fixation of simple mandibular angle fractures and an easy-touse alternative to conventional miniplates. The system may be contraindicated in patients in whom insufficient interfragmentary bone contact causes instability of the fracture. Mahmoud E. Khalifa et al.[11] conducted a study comparing titanium 3D miniplate versus conventional titanium miniplate in fixation of anterior mandibular fractures to find a statistically significant reduction in operative time in the 3D plate group and similar complication rates in both groups, concluding that 3D miniplate system is a better and easier method for fixation of mandibular fractures, compared with the conventional miniplate. The 3D miniplate system provides good stability in most cases and operative time is shorter because of simultaneous stabilization at both superior and inferior borders. Al-Moraissi EÀ et al.<sup>[12]</sup> did a systematic review and metaanalysis of 3D versus standard miniplate fixation in the management of mandibular angle fractures which revealed statistically significant differences for the incidence of hardware failure and postoperative trismus between the two groups. There were no significant differences in the incidence of postoperative infection, malocclusion, wound dehiscence, non-union/malunion, or paresthesia. The results also showed lower postoperative complication rates with the use of 3D miniplates. Other studies also corroborated these facts.<sup>[13-16]</sup>

In our study of a total of 15 patients the mean age was 32.6 years, similar to that in other studies such as Zix J et al.<sup>[10]</sup> with 33.9 years, Gokkulakrishnan S et al.<sup>[15]</sup> with 30.95 years, Khalifa M et al.<sup>[11]</sup> with 32.5 years and Barde DH et al.<sup>[13]</sup> with 35 years.

In our study 73.3% of the patients were males. Similar gender distributions were also seen in other studies such as Zix J et al.

 $^{\scriptscriptstyle (10)}$  with 85% males, Khalifa M et al. $^{\scriptscriptstyle (11)}$  with 70% males, Barde DH et al. $^{\scriptscriptstyle (13)}$  with 85% males and Kumar BP et al. $^{\scriptscriptstyle (17)}$  with 100% males.

Most of the patients in our study (80%) had trauma due to road traffic accidents, significantly more than other eitiologies. Similar findings were also reported by Gokkulakrishnan S et al.<sup>[18]</sup>, Parmar et al.<sup>[9]</sup> and Jain MK et al.<sup>[18]</sup> Conversely, assault or interpersonal violence was the most common etiology in the studies by Zix J et al.<sup>[10]</sup> and Guimond C et al.<sup>[19]</sup>

We had 5 patients who had fracture at the parasymphysis alone, another 5 patients had fracture at the parasymphysis along with the angle (2 ipsilateral and 3 contralateral ones), one patient with fracture of the ramus along with the ipsilateral parasymphysis and 1 patient each with fractures at the angle and body alone. Hence parasymphysis alone or in combination with other sites was most commonly involved (73.3%). As per literature, Kumar BP et al.<sup>[13]</sup>, Barde DH et al.<sup>[13]</sup> and Khalifa M et al.<sup>[11]</sup> also reported similar findings.

A total of 9 patients (60%) had occlusal abnormality due to the fractures preoperatively. Gokkulakrishnan S et al.<sup>[15]</sup> reported a preoperative occlusal defect in 90% of their patients. We did not have any patient with any sensoryneural abnormality preoperatively similar to the study by Gokkulakrishnan S et al.<sup>[15]</sup>. Kalifa M et al.<sup>[11]</sup> had 15 % of their patients presenting with paresthesia of the lower lip in their study.

Mobility after fixation was assessed intraoperatively and post-operatively at various intervals. None of the patients had any mobility of the fracture fragments after fixation at any point of time indicating stability of the fixation with the 3D miniplates. The adaptability of the miniplates to the bone surface contour also contributed to the precise screw placements for optimum fixation. All the patients were dentate and no tooth needed extraction during the procedure. Six and eight hole plates were used only in the cases with unfavourable grossly displaced fractures. The minimally displaced fractures were fixed with four hole quadrangular plates thus reducing the overall implant material used. Plate fixation was very convenient and less time consuming as two horizontal plates were effectively being fixed at the same time as they were connected by the vertical cross bars. We did not evaluate the operating time in our procedures as no control group was included in our study for comparison. But other comparative studies by authors like Kumar BP et al.<sup>31</sup>, Barde DH et al.<sup>28</sup>, Jain Mk et al.<sup>26</sup> and Zix J et al. comparing the two plating systems showed statistically significant reduced operative time in case of the 3D miniplates.

Adequacy of reduction was evaluated on post-operative panoramic radiograms. For simplicity in assessment, the baseline control orthopantomograms were compared to the postoperative ones to look for the position of the fractured fragments and the fracture lines. All the patients showed evidence of adequate reduction (100%). It was especially more evident in patients who had gross displacement of the fragments preoperatively with changes in occlusion (60%). The plates and the surrounding bone did not show any adverse changes and the fracture lines were barely visible in the long term follow up X-rays after 6 months.

Pretraumatic occlusion was restored in all the patients after the surgery and was maintained subsequently in the follow up.Kalifa M et al.<sup>[11]</sup> reported a few patients with slight occlusal abnormality after fixation that was corrected by orthodontic treatments. Malocclusion rate of 4.4 % were reported by Moreno JC et al.<sup>[20]</sup> who had used linear plates. Similar to us, no malocclusion was reported by others like Jain MK et al.<sup>[18]</sup> and Gokkulakrishnan S et al.<sup>[19]</sup> who had used the 3D miniplates.

The patients were evaluated for complications. 2 patients had evidence of wound infection at the 1st week post-operatively (13.3%). Both the patients had discharges from the wounds (one at intraoral incision and another at the percutaneous incision site) along with wound dehiscence. Both of them were put on oral antibiotics (as per culture sensitivity of wound swab) for 3 weeks and had complete resolution subsequently after 3 weeks of follow up. These complications were not statistically significant. The infection rates in various other studies were quite diverse such as 0% with Zix J et al.  $^{\scriptscriptstyle [10]},1\%$ with Barde DH et al.<sup>[13]</sup>, 5% with Gokkulakrishnan S et al.<sup>[16]</sup> 10% with Jain MK et al.<sup>[18]</sup> and 11.6% with Kumar M et al.<sup>[21]</sup> Though all our patients were selected carefully so as to exclude any adverse wound healing factors, those like poor oral hygiene and tobacco use could have been a reason for wound infection in the two patients in our study. More data with an increased sample size will be needed to find out statistical correlations.

One patient developed paresthesia in the distribution of the inferior alveolar nerve in the early postoperative period. It recovered spontaneously after the first month of follow up. The fracture line in this patient passed through the mental foramina and manipulations during the procedure might have been a reason for neuropraxia that recovered over time. We had to place the plate inferior to the foramina. A similar difficulty while fixing 3-D miniplates in fractures involving the mental foramina was also reported by Kumar BP et al.<sup>[17]</sup>. The post-operative paresthesia rates show a lot of variation in other studies from as low as 0% with Gokkulakrishnan S et al.<sup>[15]</sup> to as high as 60% with Guimond C et al.<sup>[19]</sup> Al Tairi NH et al.  $^{\scriptscriptstyle [16]}$  in their study reported an increase in the paresthesia rate from 37% in the preoperative period to 50% postoperatively with the use of linear miniplates. The screws being monocortical, the chance of damage to the inferior alveolar nerve is reduced, hence it explains for the statistically insignificant paresthesia rate in our study.

There were no patients with hardware failure at any point of time in the follow up period. Plate fracture was reported to be about 5.8% by Zix J et al.<sup>[10]</sup> According to them multiple bending and improper placement of the plate, as well as insufficient fracture reduction or overdrilling of the screw holes, have negative effects on the stability of the fixation, resulting in a plate fracture. Hardware failure rates of 0% similar to us were also reported by authors like Jain MK et al.<sup>[18]</sup> and Gokkulakrishnan S et al.<sup>[18]</sup>

Therefore, our study showed good post-operative outcomes with acceptable and statistically insignificant complications with the use of 3D miniplates for treating mandibular fractures. Though the titanium 3D miniplates were relatively more expensive than the linear plates, the overall favourable outcomes and low complication rates might be cost effective in the long run. The adaptability, convenience and ease of application are added advantages of this system.

### **CONCLUSION:**

The 3D miniplates are efficacious in the treatment of mandibular fractures. They produce stable fixation of fractures with very few complications and so are cost effective in the long run. Their application is convenient and their use involves relatively less implant material, avoids the need for prolonged MMF (maxillomandibular fixation) in the postoperative period. The only drawback is that they are difficult to fix in case the fracture line passes through the mental foramina.

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