Evaluation of customized plate in mandibular angle fracture: Randomized clinical trial

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Abstract---Background: A customized plate design is an appropriate plate structure for mandibular angle fracture using the minimum output values for stress of plate. Methods: To evaluate the effect of customized plate fixation versus a conventional superior-inferior miniplates fixation of mandibular angle fracture on patient satisfaction. Results: Most patients were males (92%) while (8%) were females. (69 %) of patients’ age ranged from 17-35 years old, and (31%) patients were aged between 35.1-45 years old. There was a statistical difference (p=0.000) in the postoperative sensory dysfunction in both groups. Conclusion: Customized plate is a proper plate structure for mandibular angle fracture, it ensured a proper
alignment of the fracture with good fixation without any post-operative sensory dysfunction.

**Keywords**---customized plate design, angle fracture, conventional superior-inferior miniplates fixation, virtual planning, mandibular angle fracture.

**Introduction**

Mandibular angle is located at the junction of the ramus and the lower body of the mandible, the bone here is very weak, so it is easily fractured from violent crimes, sport, traffic accidents, or pathological processes. The definition of a MAF consists of a fracture line that begins where the anterior border of the mandibular ramus meets the body of the mandible, extending inferiorly through the inferior border or posterior towards the gonial angle. The mandibular angle is one of the most common sites for fractures, accounting for 23–42% of all cases of mandibular fractures (Ellis, 2010; Suer et al., 2014; Yamaji et al., 2015 and Wallner et al., 2017).

Moreover, mandibular angle fractures have the highest postoperative complications among all mandibular fractures, loosening of screws and fracturing of plates are the main reasons for the complications (Lim et al., 2017). The most widely used treatment modality for mandibular angle fracture is the use of one miniplate fixation following the principles described in 1975 by champy. Champy recommended a single non-compression miniplate on the superior border of mandible which corresponds to the tension band of the mandible (Champy technique) (Siddiqui et al., 2007; Yong Liu et al., 2017 and Yamaguchi et al., 2017). The other one uses two mini-plates, with superior mini-plate fixed at the same place of previous treatment which corresponds to the tension band of the mandible, and the inferior mini-plate fixed at the inferior border of the mandible which corresponds to the compression band of the mandible, however, based on recent experimental and clinical studies, the stability provided by the miniplate fixation of mandibular angle fractures has become a point of contention among surgeons (Monnazzi et al., 2017).

Authors have argued that internal fixation with a passive manipulates produces a tension effect that may yield a failure of osteosynthesis or a compromise in stability (Kroon et al., 1991 and Rudman et al., 1997). This non-compression standard and straight manipulates need to be bent to bone surface before fixation, which will increase the time of the operation and may lead to mismatching between the bone surface and titanium plates (Woo et al., 2017). There are complications associated with the use of this type of fixation which are bony gaps along the inferior border, malocclusion, infection, wound dehiscence, sensory disturbances of the inferior alveolar nerve and plate exposure (Vajgel et al., 2013).

In order to decrease the need for plate removal, reduce the operative time and improve the stability of the fixation system, a customized plate design is an appropriate plate structure for fractured mandible using the minimum output
values for stress of plate and displacement of bony segments to seek maximum reduction volume on an original plate (Liu et al., 2017). Radio graphical evaluation is also an important parameter to assess adequate reduction of the fractured segments. Orthopantomogram (OPG) can be used before patient discharge to assess adequate reduction of the fractured segments. CT scan or Cone beam CT are used postoperatively for assessment of progressive healing of the fracture and for radio densitometry measurements to analyze the mean bone density in Hounsfield unit at the site of fracture (Al-Bishri et al., 2005). The customized fixation system designed directly from the specific patient is much fitter to the bone surface when compared with the standard mini-plate, which will reduce the time of bending and fixing the plate during operation (Yamaji et al., 2015)

**Materials and Methods**

This Randomized Clinical Trial was conducted at the Faculty of Dentistry / Cairo University, and Ahmed Maher Teaching Hospital / Egypt, from January 2019 to January 2020. 26 patients were included with a mean age of 28.19 years. Inclusion criteria were dentate patients suffered from displaced unilateral mandibular angle fracture which needed open reduction and internal fixation. The exclusion criteria were patients with systemic disease (may affect normal healing), patients with old and/or malunited fractures (affect accuracy of reduction of the fractured segments) and patients who cannot tolerate follow up intervals (affect accuracy of study results). Preoperative evaluation included clinical examination were assessed. Preoperative paresthesia of the lip was recorded in five patients. Routine preoperative CT scan was performed to reach a diagnosis. Planning was done for surgical planning, surgical simulation and modeling of custom-made plate and surgical guide design. Standard intra-oral approach was performed to reach the mandibular angle fracture. The fractured segments were mobilized and aligned to obtain proper reduction, then maxillomandibular fixation was applied to obtain appropriate occlusion. Fixation of the angle fracture was achieved by applying custom made plate by using surgical guide. In control group mandibular angle fracture fixation was done with the conventional superior –inferior miniplates fixation. After fixation of the fracture in both groups the stability of the fixation was checked, the occlusion was checked. Then the wound was sutured back using continuous suture with 4.0 vicryl suture. Follow up period was determined to be 3 months and 6 months during this period assessment of sensory function of the inferior alveolar nerve subjectively by asking the patient about any alteration in sensation in addition to objective examination by using a dental probe to assess the sensory changes along the distribution of the mental nerve (lower lip and chin) through examining lip sensation in comparison to the contralateral side.

**Results and Discussions**

**Gender and age distribution**

Most patients were males (92%) while (8%) were females. (69 %) of patients’ age ranged from 17-35 years old, and (31%) patients were aged between 35.1-45 years
old. The mean age of patients was (28.19) years old. The results were graphically drawn in Figure (1, 2)

![Figure (1): Gender distribution](image1)

![Figure (2): Age distribution](image2)

**Pre-& post-operative sensory dysfunction distribution**

Pre-operative sensory dysfunction of the lower lip presented in 2 patients of study group (8%) while presented in 3 patients of control group (12%). There was a statistical difference (p=0.000) in the postoperative sensory dysfunction in both group, postoperative sensory dysfunction persisted in 2 patients of the study group (8%) while in the control group the affected patients were increase to involve (19.%) of patients with sensory dysfunction. The results were presented in Table (1, 2) and figure (3, 4, and 5).
Table (1): Study &Control group * Pre operative sensory dysfunction
Crosstabulation

<table>
<thead>
<tr>
<th>Study &amp;Control group</th>
<th>Study Group</th>
<th>Control Group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>no</td>
<td>Yes</td>
</tr>
<tr>
<td>Study Group</td>
<td>2</td>
<td>11</td>
<td>8%</td>
</tr>
<tr>
<td>Control Group</td>
<td>3</td>
<td>10</td>
<td>11%</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>21</td>
<td>19%</td>
</tr>
</tbody>
</table>

Figure (3): Study &control group * pre. operative sensory dysfunction crosstabulation

Table (2): Study &control group * Post. operative sensory dysfunction crosstabulation

<table>
<thead>
<tr>
<th>Study &amp;Control group</th>
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<th>Total</th>
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<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td>Study Group</td>
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<td>11</td>
</tr>
<tr>
<td>Control Group</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>19</td>
</tr>
</tbody>
</table>
Discussion

Fracture of the mandibular angle is common, it is difficult to treat as there is no universal standard protocol to treat angle fractures. Various types of plates have been designed, claiming to be superior to other types in terms of stability and complications (Pal et al., 2013). When mandibular angle fracture is treated appropriately and with patient compliance, the outcome of both methods has been successful and resulted in proper bone healing. Semi rigid internal fixation has been shown to have certain advantage in the treatment forming a “stronger bone” as well as requiring little or no maxillomandibular fixation and thus allowing earlier physical rehabilitation and function for the patient (Mukerji et al., 2006 and Cawood, 1985).

In this study, 26 angle fractures were presented in 26 patients. Out of which majority of patients were males (92%) while (8%) were females. (69%) of patients' age ranged from 17-35 years old, and (30.8%) of patients were aged between 35.1-45 years old. The mean age of patients was (28.19 yrs). The results of this study are in agreement with other studies which concluded that the mean age of the patients was 28.6 years by Guimond et al., (2005), 26.5 years by Bui et al., (2009), 29 years by Zix et al., (2007) Sensory deficit is a problem frequently seen in connection with mandibular fractures. In this study pre-operative sensory...
dysfunction of the lower lip presented in (8 %) of study group while presented in
(11 %) of control group. There was a statistical difference (p=0.000) in the
postoperative sensory dysfunction in both group, postoperative sensory
dysfunction in control group increased to involve (19 %) while in study group
there was not increase in sensory dysfunction (8%).

Absence of postoperative sensory dysfunction in study group due to correct
placement of the customized plate away from the inferior alveolar nerve, this
occurred by correct virtual planning and designing of the customized plate and
correct placement of plate at the site of the fracture by using the surgical guide
that guided the exact positioning of screw holes along the fracture site without
endanger the inferior alveolar nerve so this result in the absence of iatrogenic
postoperative sensory dysfunction in the study group. This result was in
agreement with Hochuli-Vieira et al., (2011) who found that 33.3% of patients
presented with hypoesthesia of the inferior alveolar nerve before surgery, and
8.88% had this change until the last follow-up at 6 months, Melek et al., (2015)
concluded that sensory deficit was related to the injury in 30% of the observed
cases, with no incidence of postoperative iatrogenic sensory disturbance.

On the other hand the reason for increased the incidence of postoperative sensory
dysfunction in control group (19%) was due to the presence of displacement of
the fracture, difficult intraoperative fracture manipulation, uncontrolled drilling
and screw placement of the inferior miniplate along the inferior border specially
during the intraoral approach. Al-Tairi et al., (2015) found that 37% of patients
had sensory deficits due to their nerve injury. After operation, the rate of
neurosensory deficits increased to 50% of cases. Fox & Kellman, (2003) stated
that 4.4% of cases were noted to have nerve impairment. Those patients were
followed up for several weeks after surgery, without improvement.

**Conclusion**

A customized plate design as comparable to the conventional superior -inferior
miniplates is a proper plate structure for mandibular angle fracture, it ensured a
proper alignment of the fracture with good fixation without any post-operative
sensory dysfunction

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**References**

Disturbance after Sagittal Split and Intraoral Vertical Ramus Osteotomy: As


