

COMPARISON OF 3-D AND STANDARD MINIPLATES FIXATION IN THE MANAGEMENT OF ANGLE FRACTURE OF THE MANDIBLE

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ABSTRACT

Objectives: To compare the efficacy of the 3-D and standard miniplates fixation in the management of angle fracture of the mandible.

Materials and Methods: This randomized controlled trial was conducted from 20th December 2020 to 20th June 2021 at Department of Oral and Maxillofacial Surgery, Mardan Medical Complex Mardan. A total 336 patients between the age of 18-60 years from both the genders reporting with mandibular fractures were selected for the study through non-probability consecutive sampling and were randomized in to 2 equal groups of 168 patients each through blind balloting. In group-A, fixation was done using 3-D titanium plates while in Group-B 2 mm titanium miniplates were used. The primary outcome was set as the difference in mean operation time and mean pain post-operative pain score between the 2 groups at 2 weeks follow up.

Results: The age range was 18-60 years Mean±SD 31.178±7.86 years. Mean duration of fracture was 84.696±15.38 hour while weight was 65.059±11.97 Kg. Male and female were 78.6% and 21.4% respectively. The mean duration of operation was significantly less with 3-D titanium plates compared to standard miniplate (15.791±1.49 min. Vs 17.690±1.28 min. respectively, p=0.00). The difference between the 2 groups regarding post-operative pain score was not statistically significant as assessed on VAS at 2 weeks follow up visit (1.571±0.49 vs 1.589±0.49 respectively, p-value=0.736).

Conclusion: 3-D plate provides the advantage over standard miniplate especially in terms of less operation time in the management of angle fracture at the mandible.

Key words: Mandibular fractures, 3-D plate, Post-operative pain, miniplate. Mandibular angle

INTRODUCTION

Injury to maxillofacial region involves both soft and hard tissues of the mandible region. These injuries are common as this area is an externally exposed region of our bodies¹. Among the facial bone fractures reported in hospitals, nasal bone fractures and mandibular fractures are most common (58.7% and 23.3% respectively)². Traffic accidents (especially

the bike riders) contribute the most in maxillofacial traumas followed by falls, assaults, firearm injuries, sports, and industrial accidents. It is also reported that majority of patients facing maxillofacial trauma belongs to 21-30 years age group. The data also shows that male gender suffered from these injuries four times more than the female gender³.

The mandibular bone consists of both horizontal and vertical sections. The basal structure and the alveolar bone structure are 2 main structures of the horizontal portion. Symphysis, parasymphysis, the body, and the alveolar tooth bearing bone form the

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overall horizontal mandibular section. The angle, ramus, condylar and coronoid processes forms the vertical mandible⁴. The high prevalence of fractures is due the specific reasons like thinner cross-sectional area, unerupted 3rd molar and the muscle forces⁵. The most frequent type of mandibular fractures are the angle fractures that are reported to be around 27-30% while parasymphysis fractures are also commonly reported as frequent as 26.9%⁶. The characteristic of an angular fracture of the mandible is a fracture line that begins at the connecting point of the posterior boundary and inferior border of the mandibular body and commonly at third molar region⁷.

Hence the mandibular fractures may lead to significant functional and aesthetic effect if treatment is deficient or delayed. The surgical procedures are aimed at the insertion of the muscle, respecting the biomechanical forces at the angle, keeping in mind the restoration of anatomy, providing a stable fixation while reestablishment of the occlusion is also specifically focused^{8,9}. The methods utilized for the management of angle fracture at the mandible includes intermaxillary fixation for closed reduction, transosseous wires used for open reduction and osteosynthesis using lag screws.

Miniplates have also been used on the inferior and superior edges either by applying rigid fixation or semi-rigid fixation^{7,8}. A type of fixation introduced by Spiessl is a rigid type where compression plates are placed on the fracture segment to prevent inter fragmentary movement. Champy latter transformed intraoral fixation when he introduced ideal lines of osteosynthesis using mono-cortical, subapical and juxta-alveolar osteosynthesis. As per Champy's principles, a 2D miniplate is applied on the superior border of the external oblique ridge. The semi rigid fixation was done by utilizing miniaturized malleable plates without intermaxillary fixation and compression. The traditional and widely used 2D miniplates however did not offer sufficient stabilization of fractures and therefore occlusion disorders are observed in cases of angle fractures of mandible in 0 to 36% of cases. Therefore, further intermaxillary fixation is required^{7,10}.

A relatively newly introduced technique is 3-dimensional (3-D) titanium plating for mandibular fracture treatment. These new 3-D miniplates provide 3dimensional stability with more number of screws.

The benefits of these 3-D miniplates are expressed as providing fixing stability, reduced operation time and less rate of complication¹¹.

Studies comparing the efficacy and clinical experiences of standard miniplate fixation and 3-D miniplates are limited. Al-Moraissi EA et al. compared single 1-mm 3-D miniplate with single 2.0-mm standard miniplate. The mean operation time for the procedure was 39.7 ± 9.1 min for 3D miniplate while 33 ± 4.6 min for standard miniplate with no statistically significant difference ($p=0.141$). They however mentioned that the 3D plate as an effective treatment for such angle fracture⁸. El Nakeeb NA compared 3D plate in 10 patients versus two miniplates in 10 patients in the management of these fractures. The fixation time for the 3D plate was less (5 to 10 min) compared to conventional miniplates (10-15 min). The mean postoperative pain score was 1.60 ± 1.07 with 3-D plates and 1.90 ± 0.88 with standard miniplate fixation¹².

The work done on 3-D miniplate is also limited in Pakistan. This study was therefore planned to determine whether 3-D plates (3-D titanium plates) or standard miniplates (2 mm titanium miniplates) are more useful in the management of angle fracture at the mandible. The results of our study will help in establishing a standard protocol for the future recommendations of managing these frequently reported fractures in our hospitals.

MATERIALS AND METHODS

This study was conducted over a period of 6 months from 20th December 2020 to 20th June 2021 at Department of Oral and Maxillofacial Surgery, Mardan Medical Complex Mardan. Study design was Randomized controlled trial and sample size was calculated with 95% confidence level with power = 80% and $\alpha= 5\%$. By using mean postoperative pain score of 1.60 ± 1.07 with 3-D plates and 1.90 ± 0.88 with standard miniplate fixation. The sample size was $n= 336$ patients (168 patients in each group)¹². (Add line about Ethical approval and its number).

A total of 336 patients between 18-60 years of age from both the genders reporting with mandibular fractures (when X-Ray reveals a hair line gap/discontinuation fracture of mandibular that involves the anterior region) were selected for the study through non- probability consecutive sampling. The patients

were randomized in to 2 equal groups of 168 patients each through blind balloting.

The exclusion criterion was set as patients with diabetes, renal disease, mal-union, non-union, pathological fractures, edentulous patients and pregnancy.

In group-A, 168 patients underwent fixation with 3-D titanium plates and screws while in Group-B fixation was done with 2 mm titanium miniplates and screws.

In Group-A, the titanium 3-D plate was used and held with plate holding forceps. Holes for the screw were made through drill bits of 1.5 mm. Fixation with titanium 3-D was done with the use of one 8 holed 3-D plate and monocortical screws. In Group-B fixation was done using 2-mm titanium miniplates using Champy’s principle of osteosynthesis (four holes with gap). Titanium (2x10 mm) screws were used for stabilization of plates.

All the fixation procedures were performed under general anesthesia. A standard intraoral surgical technique was adopted to expose and reduce the fractures. Fracture site was exposed using the extra-oral approach in case where extra-oral laceration was present.

The primary outcome was set as the difference in mean operation time (starting from plate adaptation up to the time when fixation was completed) and mean pain score (evaluated at 2 weeks using visual analogue scale 0-10) between the 2 groups at the 2 weeks follow up visit.

All the data was noted and recorded on pre-designed proforma.

Ethical approval of conducting the study was taken from the ethical committee of the hospital.

The study purpose was explained and consent was taken from the participants on written forms.

Data was analyzed using SPSS version 22. Variables like age, weight, duration of fracture, operation time and post-operative pain score were presented in form of means and standard deviations while frequency and percentage was calculated for qualitative variables like gender. Both groups were compared for operation time and postoperative pain score. The differences in the operation time and postoperative pain score was calculated by applying independent t- test with $p \leq 0.05$ was considered

statistically significant.

RESULT

Out of total 336, the mean age of total patients in this study was 31.178 ± 7.86 years with a range of 18-60 years. Mean duration of fracture was 84.696 ± 15.38 hours while the mean weight was 65.059 ± 11.97 Kg. The percentage of males in total study population was 78.6% while females were 21.4%. The group wise demographics are shown in Table 1.

The duration of operation was significantly less in Group-A as compared to Group-B. Moreover, there was no difference in the mean pain score among the 2 groups at 2 weeks follow up visit, as shown in Table 2.

DISCUSSION

The 3-D plate allows a 3 - dimensional stability to the angle fracture and adjusts to torque forces present there and guarantee malleability¹³. The tension and compression forces are neutralized as it is a modification of Champy’s system where 2 plates are connected using vertical bars¹⁴.

The benefit of 3-D plates in shape of reduced operation time has been mentioned by the surgeons in different studies. As mentioned in a randomized

Table 1: Details of demographics and clinical characteristics n=336

Demographics		Group-A (n=168)	Group-B (n=168)
Age Mean±SD (years)		31.178±7.86	30.214±7.11
Gender n(%age)	Male	135 (80.4%)	132 (78.6%)
	Females	33 (19.6%)	36 (21.4%)
Duration of fracture Mean±SD (hours)		84.696±15.38	85.011±18.65
Weight Mean±SD (Kg)		65.059±11.97	65.488±10.79

Table 2: Study outcomes in both the groups n=336

Study Outcomes	Group-A n=168	Group-B n=168	p-value
Duration of Operation Mean±SD (min)	15.791±1.49	17.690±1.28	0.002
Postoperative pain score on VAS Mean±SD (1-10)	1.571±0.49	1.589±0.49	0.001

control trial, operation time was reduced while managing parasymphysis and symphysis fractures with 3-D plates compared to traditional miniplates. The suggested reason for this reduced operative time was concurrently providing stabilization at both the superior and inferior borders. There was also lesser implantation material needed in using these 3-D plates¹⁵.

Mittal Y et al. in their study of 30 patients with mandibular fractures compared 2 mm 3-D and 2-D miniplates. The majority of patients in their study were males (80%), 43% of the patients belonged to less 30 years of age and 73% of the patients were treated within 3-7 days of incidence. The results showed that 3-D miniplates were better in ease of surgical procedure, cost and were with lesser operation time. However they reported that the difference in pain score was not statistically significant between the 2 groups¹⁶.

Singh R, et al. compared the efficacy of 3-D plates and 2 mm standard miniplates for managing mandibular fractures. Out of 70 patients included in this study 82.85% were males and 77.14% belonged to age group less than 30 years. The results have shown that mean operative time (adaptation and fixation) was significantly low in 3-D plates group compared to standard miniplates (15.12 ± 5.20 min. vs 15.33 ± 5.91 min. respectively)¹⁷.

A Comparative study of 2-Dimensional miniplates Vs 3-Dimensional Miniplates by Sarepally G. in the management of symphysis and parasymphysis areas mandibular fractures mentioned 40.62 ± 2.134 min. operation time with 3-D plates and 54.88 ± 1.642 min in 2-D miniplates (statistically significant difference, $p < 0.05$). The researchers therefore concluded that 3D plates are better than standard 2-mm miniplates in patients with these types of mandibular fractures¹⁸.

The results of our study are in line with studies discussed above. Similar results for the mean operation time and mean pain score were shared in some previous studies conducted with 3-D plates for the same procedures^{15,16,17,18}.

Hence the results show that these 3-D plates provide the advantage over standard miniplate especially in terms of less operation time and therefore ease of usage for the surgeons. There is also no difference

in post-operative pain after two weeks among both groups ensuring a good patient's compliance. More studies from other centers are required which will help to establish proper protocol for the management of mandibular angle fractures.

CONCLUSION

3-D plate is effective in the management of angle fracture at the mandible. The lesser time taken in fixation provides a major benefit of ease of use for the surgeons. More studies are required to establish a proper protocol for the management of mandibular fractures

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