Original Research Article

Comparison of the Intra and Postoperative Outcomes between 3-D Plates versus 2.0 mm Miniplates in Displaced Mandibular Angle Fractures

ABSTRACT

Aim: The aim of this study was to compare intra and post-operative outcome by using Conventional 2mm Miniplate versus 3-D plates in management of Mandibular Angle Fractures.
Study Design: Randomized control trial.
Place and Duration of Study: Department of Oral & Maxillofacial Surgery (OMFS), Liaquat University Hospital, Hyderabad over a period of 6 months.
Methodology: The study included a total of 60 patient having mandibular angle fractures randomly allocated into two groups. 30 of them were treated with 2mm conventional miniplates in group A and 30 cases were 3Dnplate in group B. Outcomes such as intraoperative time was measured in terms of minutes from start of surgery till fixation using stop watch. Stability was assessed clinically and by post-operative radiographs. Mean and standard deviation were calculated for age duration of fracture and intraoperative time. Whereas frequency and percentage were calculated for gender, occupation, type of displacement.Comparison of the said parameters was also done, subsequently. The collected data was analyzed by *SPSS version* 22.0.
Results: The average age of the patients was 29.50±6.24 years. There were 38(63.3%) male and 22(36.7%) female. Mean intraoperative time in terms of minutes was significantly low in group B than group A [45.27±7.09 vs. 50.50±7.12; p=0.006]. Rate of stability was 100% in group B and 90% in group A, however it was not statistically significant between groups (p=0.237).
Conclusion: The results of the current study showed good stability, less procedure time required with 3-D plating system. It could be concluded by the findings that 3-D plating system has advantages over conventional 2mm miniplates.

Keywords: Facial skeleton, Miniplate versus 3-D plates, Mandibular angle fractures

ABBREVIATION

OMFS: Oral and Maxillo Facial Surgery
TMJ: Temporal Mandibular Joint
NOE: Nasoorbitoethmoid
CSF: Cerebrospinal fluid
CT: Computed Tomography

1. INTRODUCTION

Injuries to facial skeleton are relatively common, and the incidence of mandibular fractures is higher compared with the other facial fractures in mandible, mandibular angle is the commonest site for fracture accounts for 23 to 42%. Inherent anatomical vulnerabilities make this location particularly prone to fractures with highest rate of complications ranging from 0 to 32% [1, 3].

Certain structural and functional peculiarities thinner compact plate, shape changes during life and frequent impacted or partially erupted teeth, bilateral muscle cover and endosseous and extra osseous blood circulation condition like peculiarities of the treatment of the fracture [2].
Various treatment modalities for angle fracture have been tried, ranging from single non-compression miniplates, lagscrew, two miniplates, one compression-type locking miniplates and a 3-D rectangular matrix fracture plate with varying levels of success [3].

The basic concept of rigid fixation is absolute stability and there are a variety of techniques advocated to achieve this goal. Champey suggests that engaging a single cortex is sufficient for rigid osteosynthesis. While the introduction of miniplates in the treatment of mandibular fractures led to notable decrease in surgical soft tissue trauma and improve ease of handling, with sufficient stability and fixation of mandibular fractures [4].

However, Luhr and AO/ASIF advocates felt that miniplates did not offer adequate stabilization of the fractures, thereby necessitating the need of further inter-maxillary fixation [5]. Fermand developed 3-D plate with quadrangular design by joining two miniplates with interlocking crossbars. The basic concept of 3-D is the stability in three dimensions. The stability is achieved by its configuration not by thickness or length. One of the advantage of 3-D plates is the simultaneous stabilization of the tension and compression zones, making the 3-D plate a time saving alternative to conventional bone plate. The locking plating system has been developed and popularized by AO/ASIF to obviate the main disadvantage of conventional plate system, which requires the plate to be perfectly adapted to the underlying bone to avoid gaping of the fracture and associated instability. This bone plate system acts as an internal-external fixator, which results in better distribution of load and prevents load concentration on a single screw, thus decreasing the risk of screws loosening and stripping. Moreover, because anatomic adaptation of the plate to the underlying bone contour is not crucial, there are theoretically a fewer interference with the adjacent vascular supply [6].

Both conventional miniplates and 3D plates have adequate stability after fixation of fracture. The stability of 3D plate is gained over a defined surface area and is achieved by its configuration and not by thickness or length. The large free areas between the plate arms and minimal dissection permit good blood supply to the bone. The 3D system is easy to use and cost effective. Further, it uses lesser hardware as compared to conventional miniplates. Thus 3D plate can be used as an alternative to conventional miniplates. The system is reliable and effective treatment modality for mandibular fractures. 3-dimensional miniplates in mandibular parasymphysis and symphysis fractures is efficacious enough to bear masticatory loads during the osteosynthesis of fracture as it gives the advantage of reduced implant material and 3 dimensional stabilities with almost similar results as seen in 2 dimensional miniplate osteosynthesis [7].
The study suggest that 3D rectangular grid plate is feasible alternative to conventional miniplate systems with good clinical outcome and fewer complications related to paresthesia, infection and hardware failure [8].

The 3D plate and two straight miniplates were equally effective for the surgical management of mandibular sub condylar fractures. Although a 3D plate is sufficient for a typical simple fracture, in cases with bone defect around the fracture, selection of the plate fixation method should be carefully

considered [9]. The results of this meta-analysis showed that the use of 3D miniplate fixation had lower complication rates when compared with the use of standard miniplate fixation in the management of mandibular fractures.[10] In the study about Yadev at al the mean intraoperative time was estimated as 2.80 in mini plates and as 3D plates as 2.90 in 3D plates. Similarly, the stability reported by them among both groups was 100% [7].

The clinical outcome of both the 3D and standard miniplate systems in the study was similar; however, the following advantages with the use of three-dimensional miniplates can be highlighted: i) relatively lesser operating time due to simultaneous stabilization at superior and inferior borders. ii) Three-dimensional stability of the fracture site. iii) Easy and simple to use [11].

There is no local data available on this topic so the aim of my study is to compare intraoperative and post-operative outcomes between mini plates and 3D plates for the management of mandibular angle fracture this study will help in identifying the technique which will provide better stability with compact size and decrease torsional movement improving overall treatment outcomes and it will lessen the operating time.

2. MATERIALSANDMETHODS

The Non-probability consecutive trial technique was used to recruit patients for this randomized trial study. The inclusion criteria consisted of: age group 18-40 years of both gender, and patients having mandibular fracture as per operational definition. The exclusion criteria included: patients unwilling to participate in the study, having hypertension & diabetes mellitus, unfit for general anesthesia and, suffering from mental retardation.

The patients fulfilling the inclusion criteria were admitted throughout patient department or emergency department of Liaquat University Hospital, Hyderabad and were divided into 2 groups i.e.; group A and B by simple random sampling (port chit method). Group A comprised of candidates for 2.0 mm mini plates procedure while Group B for 3D miniplates. The sample size was estimated using open EPI by taking statics of intraoperative time in 3D plates as 13.90 ±2.56 and 19.0 ±2.21 in mini plates, power of test was 80% and confidence level 95% [68]. The estimated sample size came out as 4 in each group but it was taken as 30 patients in each group. Total sample size was 60.

2.1 Data Collection Procedure

Diagnosis of the fracture was done on the basis of clinical examination and radiographical evaluation. Every patient was admitted in hospital for the evaluation and base line investigations and for general anesthesia fitness. A written informed consent was taken and they were advised for NPO (nil per orally) for 6 hours before the surgery. On the day of surgery, every patient was prepared according to the standard universal protocols. Patient was given local anesthesia (xylocaine 2%adrenaline 1:100000, medicine, HUONS CO.LTD made in Korea) and five eyelets on upper and lower jaw were passed for achieving normal functional occlusion. After achieving maximum occlusion, muco-periosteal flap was raised intra-orally as needed by the case with blade #15 to visualize the fracture, fracture was reduced and occlusion was checked again after reduction; the fracture was fixed with implant by surgical drill bit using surgical drill. During drilling, copious irrigation through normal saline was maintained (0.9% serial, made in Pakistan) and fixation of fracture was done by 2.0mm conventional miniplates in group A and a single 3D plate in group B (main international, made in Pakistan) with screw of 7mm cortical/monocortical otherwise (as needed by the case).

Incision was closed by 2 layers' technique using vicryl surgical sutures 3/0 (jonson and jonson international). After procedure, intermaxillary fixation was released, patient was shifted to the recovery area and when patient got stable, was shifted to the ward with maintained I/V line and patient's attendants were asked to keep patient on NPO for next 6 hours while standard antibiotic and pain killer were administered.

Outcome such as intraoperative time was measured in terms of minutes from start of the surgery till fixation using stop watch. Stability was assessed clinically and by post-operative radiographs. The responses were recorded after treatment of fractures and then at follow ups of patients which was at interval of 1 week from treatment to 1 month afterwards.

2.1.1 Data Analysis

The data was analyzed by Statistical Software Packages SPSS version 22.0. Mean and standard deviation were calculated for age duration of fracture and intraoperative time. Whereas frequency and percentage were calculated for gender, occupation, type of displacement. Statics of occlusion, cause of fracture, status of third molar and stability at first month were also measured. Comparison between both the groups was done for using independent T test. Whereas comparison of stability between both groups was done using chi square/fissure exact test.

Effect modifiers like age, gender, occupation, duration of fracture, type of displacement, status of occlusion, cause of fracture, and status of third molar were addressed through stratification. Post stratification independent T test was applied for intraoperative time and fissure exact test/chi square test was applied for stability. P value less than and equal to 0.05 was considered as statistically significant.

3. RESULTS

A total of 60 patient having mandibular angle fractures were randomly allocated into groups 30 were treated with 2mm conventional miniplates in
group A and 30 cases were of 3Dnplate in group B. The average age of the patients was 29.50±6.24 years and mean duration of fracture was 3.52±1.24 days (table 1). There were 38(63.3%) male and 22(36.7%) female. Male to female percentage between groups is shown in figure 1. Occupation status of the patients is also shown in figure 2. Regarding type of displacement, horizontally was most common in both groups (figure 3). Rate of malocclusion was 80% in group A and 60% in group B as shown in figure 4. Most common cause of fracture was road traffic accident in both groups.

Comparison of outcome in terms of time and complication by using conventional 2mm miniplate versus 3-d plates in management of mandibular angle fractures are reported in figure 7 and table 2 respectively. Mean intraoperative time in terms of minutes [from start of surgery till fixation using stop watch] was significantly low in group B than group A [45.27±7.09 vs. 50.50±7.12; p=0.006]. Rate of stability was 100% in group B and 90% in group A, however it was not statistically significant between groups (p=0.237).

Stratification analysis was done to control the univariate effect of confounding variables like age, gender, occupation, duration of fracture, type of displacement, status of occlusion, cause of fracture, status of third molar to observe the difference in time and stability. Intraoperative mean time difference was significant between groups for some specified categories of modifier but rate of stability difference was not statistically significant between groups for all stratified variables as presented in table 3 to 6.

Table 1. Physical, chemical and biological properties of experimental soil (0-20 cm)

Variables	Group An=30		Group Bn=30		Total	
	Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation
Age(Years)	28.60	6.42	30.40	6.02	29.50	6.24
Duration ofFracture(days)	3.47	1.07	3.57	1.40	3.52	1.24

Table 2. Comparison of complication between groups

Complication Stability	Group A n=30	Group B n=30	Total	P-Value
Yes	27(90%)	30(100%)	57(95%)	0.237
No	3(10%)	0(0%)	3(5%)	

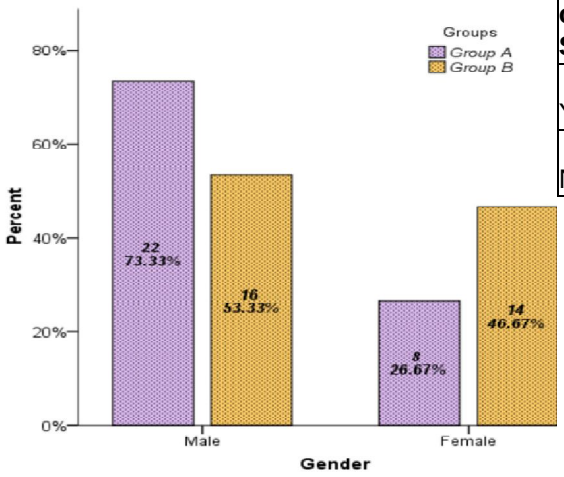

Figure 1. Gender distribution of the patients according to groups n=60

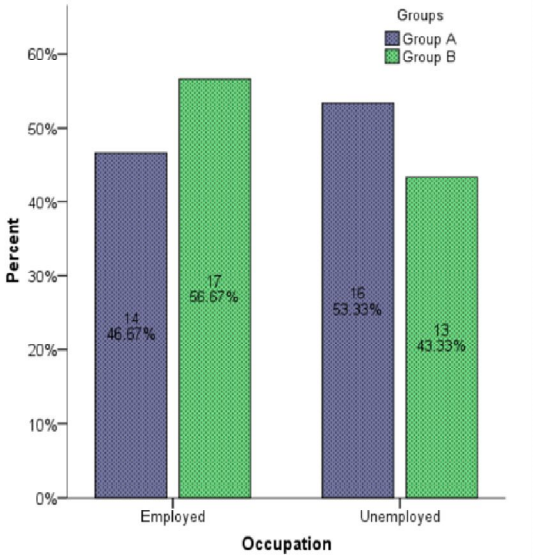

Figure 2. Occupation status of the patients according to groups n=60

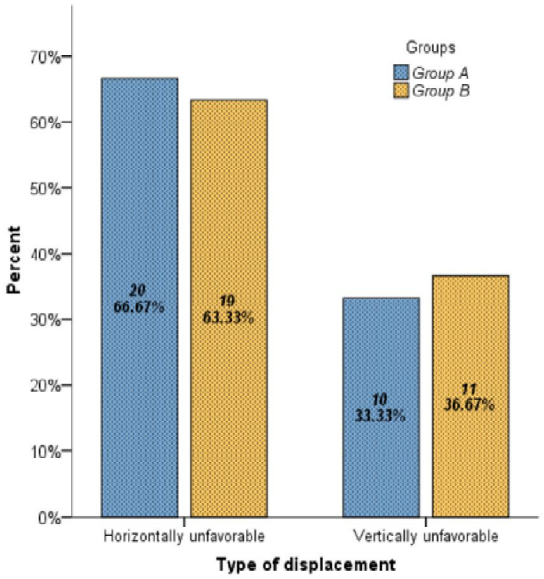

Figure 4. Type of displacement according to groups

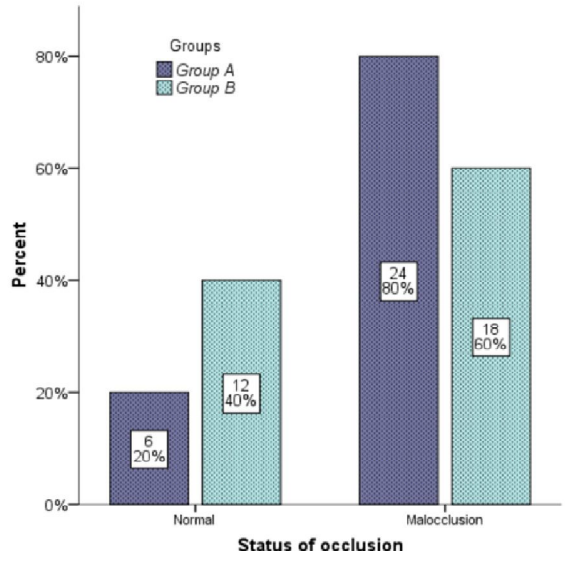

Figure 3. Occlusion statusof the patients according to the groups n=60

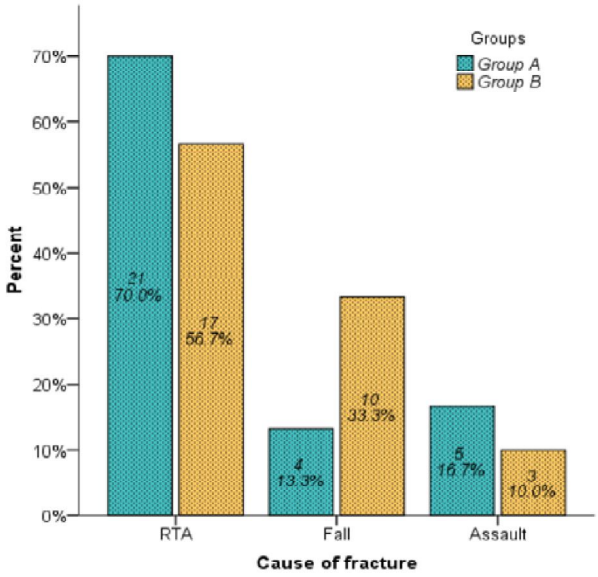

Figure 5. Cause of fracture of the patients according to groups n=60

Table 3. Comparison of outcome in terms of time by using Conventional 2mm Miniplate versus 3-D Plates in management of mandibular angle fracture by effect modifiers

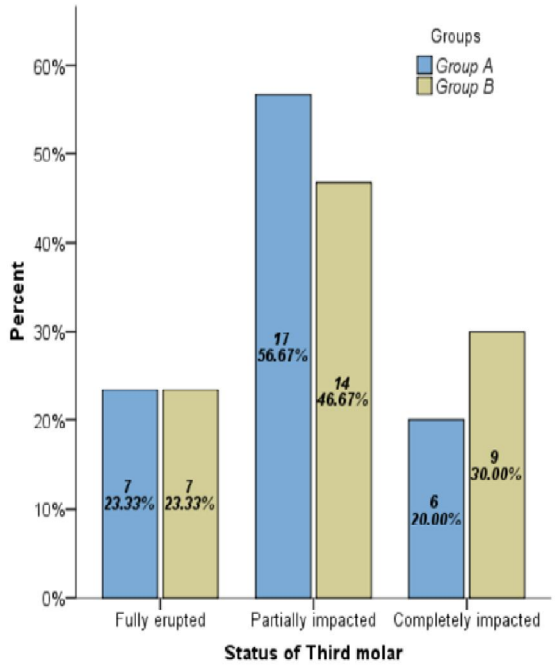

Figure 6. Status of third molar of thepatients according to groups n=60

EffectModifiers	Cutoff	Group A			Group B			P-Value
		n	Mean Time	Std. Deviation	n	Mean Time	Std. Deviation	
AgeGroups	<=30	17	50.35	8.21	15	44.80	7.32	0.054
	31-35	10	50.20	6.25	8	47.13	8.28	0.382
	>35	3	52.33	3.78	7	44.14	5.58	0.052
Gender	Male	22	51.82	7.47	16	45.06	7.13	0.008
	Female	8	46.88	4.67	14	45.50	7.30	0.639
Occupation	Employed	14	52.79	7.11	17	47.59	6.62	0.044
	Unemployed	16	48.50	6.71	13	42.23	6.73	0.019

Duration ofFracture(Days)	1-3	17	50.71	7.89	15	43.87	7.03	0.015
	>3	13	50.23	6.26	15	46.67	7.09	0.174

Effect		Group A	Group B	

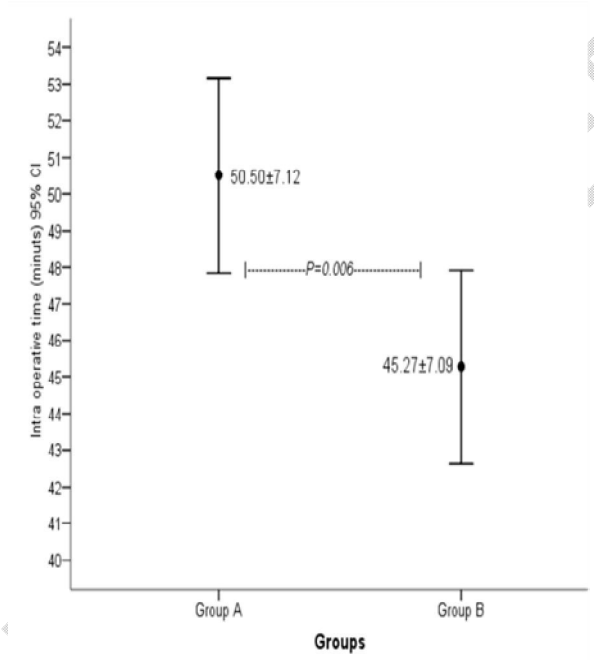

Figure 7. Comparison of outcome in term of time by using Conventional 2mm Miniplat eversus 3-D Plates in management of Mandibular angle fractures n=60

Table 4.Comparison of outcome in terms of time by using Conventional 2mm Miniplate versus 3-D Plates in management of mandibular angle fracture by using other effect modifiers

		n	Mean Time	Std. Deviation	n	Mean Time	Std. Deviation	
Type of displacement	Horizontally unfavorable	20	48.75	7.15	19	44.79	7.12	0.092
	Vertically unfavorable	10	54.00	5.91	11	46.09	7.30	0.014
Status of Occlusion	Normal	6	51.17	5.30	12	45.83	7.25	0.132
	Occlusion	24	50.33	7.59	18	44.89	7.16	0.023
Cause of Fracture	RTA	21	50.57	7.53	17	46.06	6.56	0.060
	Fall	4	48.75	4.99	10	45.00	8.51	0.431
	Assault	5	51.60	7.76	3	41.67	5.77	0.106
Status of Third Molar	Fullyerupted	7	47.86	9.26	7	43.71	8.93	0.411
	Partially impacted	17	52.29	6.96	14	47.00	7.00	0.044
	Completely impacted	6	48.50	3.20	9	43.78	5.71	0.091

Variables	Age groups	Complication [Stability]	Group A	Group B	P-Value

Table 5. Comparison of outcome in terms of complication of in Conventional 2mm Miniplate versus 3-D Plates in management of mandibular angle fracture

Age groups	≤30	Yes	17(100%)	15(100%)	NA
		No	0	0	
		Total	17	15	
	31-35	Yes	8(80%)	8(100%)	0.477
		No	2(20%)	0(0%)	
		Total	10	8	
	>35	Yes	2(66.7%)	7(100%)	0.300
		No	1(33.3%)	0(0%)	
		Total	3	7	
Gender	Male	Yes	21(95.5%)	16(100%)	0.387
		No	1(4.5%)	0(0%)	
		Total	22	16	
	Female	Yes	6(75%)	14(100%)	0.121
		No	2(25%)	0(0%)	
		Total	8	14	
Occupation	Employed	Yes	12(85.7%)	17(100%)	0.107
		No	2(14.3%)	0(0%)	
		Total	14	17	
	Unemployed	Yes	15(93.8%)	13(100%)	0.359
		No	1(6.3%)	0(0%)	
		Total	16	13	
Duration of Fracture	1-3days	Yes	16	15	0.340
		No	1	0	
		Total	17	15	
	>3days	Yes	11	15	0.206
		No	2	0	
		Total	13	15	

Variables	Agegroups	Complication[Stability]	GroupA	GroupB	P-Value
Type of Displacement	Horizontally unfavorable	Yes	18(90%)	19(100%)	0.157
		No	2(10%)	0(0%)	
		Total	20	19	
	Vertically unfavorable	Yes	9(90%)	11(100%)	0.476
		No	1(10%)	0(0%)	
		Total	10	11	
Status of Occlusion	Normal	Yes	6(100%)	12(100%)	NA
		No	0	0	

Table 6. Comparison of outcome in terms of Conventional 2mm Miniplate versus 3-D Platesin management ofmandibular angle Fracture by other effect modifiers

		Total	6	11	
	Occlusion	Yes	21(87.5%)	18(100%)	0.247
		No	3(12.5%)	0(0%)	
		Total	24	18	
Cause of Fracture	RTA	Yes	19(90.5%)	17(100%)	0.191
		No	2(9.5%)	0(0%)	
		Total	21	17	
	Fall	Yes	3(75%)	10(100%)	0.101
		No	1(25%)	0(0%)	
		Total	4	10	
	Assault	Yes	5(100%)	3(100%)	NA
		No	0(0%)	0(0%)	
		Total	5	3	
Status of Third Molar	Fully erupted	Yes	7(100%)	7(100%)	NA
		No	0(0%)	0(0%)	
		Total	7	7	
	Partially impacted	Yes	15(88.2%)	14(100%)	0.488
		No	2(11.8%)	0(0%)	
		Total	17	14	
	Completely	Yes	5(83.3%)	9(100%)	

	impacted	No	1(16.7%)	0(0%)	0.400
		Total	6	9	

4. DISCUSSION

Injuries related to maxillofacial fractures are mostly traumatic in nature. Literature says the most universal etiological factor related to maxillofacial injuries is road traffic accident (RTA) which shows a round 45.3% involvement [69]. Causes other than RTA include falls (42.6%), assaults (0.89%), sport injuries (2.2%), and gunshot wounds (0.89%) [70]. The most common cause of fracture in this study was road traffic accidents in both groups. To improve the surgical outcome of fixation with 3D plating system a continuous research is underway to spot light the dimension, profile, number and mechanics of plate/screw systems [71]. Around 2 decades ago in 1993, a 3-D plate with quadrangular was designed by Farmad. He did it by uniting two miniplates with interlocking crossbars [70, 72]. Stability by three dimensions was the basic concept thought in the development of 3-D plates [73].

And when it comes to stability, it is solely achieved by its configuration not by thickness or length [70, 71, 73, 74]. Nowadays, 3D plate system is one of the most standard alternate to conventional plating system, because it has advantage of providing concurrent in the tension and compression zones, and this property makes the 3- D plate a time saving method too [71].

In this study the average age of the patients was 29.50±6.24 years and mean duration of fracture was 3.52±1.24 days. Data of this study in terms of mean age is widely supported by Zafar KJ [75] where he reported mean age with 32.4. Gokkulakrishnan et al [76] showed in his study mean age of 30.9. One study carried out by Al-Tairi et al [77] came with mean age with less than 25 years i.e. 24.5 years. In Kumari et al study [78] the mean age of patients in group A and group B was 31.38±9.03 years and 30.10±9.35 years, respectively.

Findings of this study have shown that males were predominantly affected from anterior mandibular fractures as compared to females. Our data is widely supported by various similar studies performed in world like Zafar KJ [75] where he encountered 71.9% cases with male gender. Sadhwani BS [72] also showed male predominance with 64.29% cases. El Nakeeb [79] et al stated that Incidence in males compared with that of females was 4:1.
Average operating time was less with the 3-D miniplate system in comparison with conventional miniplates in the symphysis/parasymphysis region because placement of one plate puts another plate in place, thus reducing the manipulation for two individual plates. In the angle region, the 3-D miniplate took more time as compared with conventional miniplates. Intra-oral placement of the 3-D miniplate is also more difficult. In bilateral fracture of mandible, the operating time for 3-D miniplate was less compared to miniplates. Overall operating time was slightly higher with the 3-D miniplate system as compared with conventional miniplates.

In this study mean intraoperative time in terms of minutes [from start of surgery till fixation using stop watch] was significantly low in group B (3-d plates) than group A (Conventional 2mm miniplate). According to the studies by Zafar KJ [75], Kumar [80], Kinra [81] and El Nakeeb [79] they also reported decreased operating with 3-D plates as compared to 2 conventional miniplates for the fixation of anterior mandibular fracture. In Kumari et al study [78] the operating time needed in group A (Conventional 2mm miniplate) was < 30minutes in 22(46.8) cases and >30 minutes in 25(53.2%) cases, while in group B all 47 (100%) cases were found with intra operative time<30 minutes.

In this study, though there was no statistical difference between the two groups in terms of fracture stability. Similar results were obtained by Jain et al. [82] and Vineeth et al. [83]. Three-dimensional miniplate system uses lesser implant material in the symphysis and parasymphysis region, as only one plate and four screws are fixed as compared to miniplates, where two plates and eight screws are fixed. Overall cost of the treatment is reduced to half for 3-D miniplate in comparison with miniplates of the same manufacturer. However, cost of the implant used in other areas of mandible is comparable for both the systems [84].

5. CONCLUSION

The results of the current study showed good stability, less procedure time required with 3-D plating system. It could be concluded by the findings that 3-D plating system has advantages over conventional 2mm miniplates.

CONSENT

Written informed consent form was obtained from the patients in their medical file before filling up the Performa to use their data for any research purpose.

ETHICAL APPROVAL

The ethical permission was sought from the Ethical Review Committee (ERC) of the Liaquat University of Medical and Health Scienes. In addition, departmental permission was also sought from Department of Oral and Maxillofacial Surgery, Liaquat University Hospital, Hyderabad.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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