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

ABSTRACT

Aim: This study aimed to compare intraoperative and postoperative outcomes 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 6 months.
Methodology: The study included a total of 60 patients 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 3D plated in group B. Outcomes such as intraoperative time was measured in terms of minutes from the start of surgery till fixation using a stopwatch. Stability was assessed clinically and by postoperative radiographs. Mean and standard deviation was calculated for age duration of fracture and intraoperative time. Whereas frequency and percentage were calculated for gender, occupation, type of displacement. A comparison of the said parameters was also done, subsequently. The collected data were 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 in group A [45.27±7.09 vs. 50.50±7.12; p=0.006]. The 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 a 3-D plating system. It could be concluded by the findings that the 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 the facial skeleton are relatively common, and the incidence of mandibular fractures is higher compared with the other facial fractures in the mandible, mandibular angle is the commonest site for fracture accounting for 23 to 42%. Inherent anatomical vulnerabilities make this location particularly prone to fractures with the highest rate of complications ranging from 0 to 32%". [1, 3].

"There are certain structural and functional peculiarities such as thinner compact plate, shape changes during life and frequent impacted or partially erupted teeth, bilateral muscle cover, and endosseous and extraosseous blood circulation condition like peculiarities to consider for the treatment of the fracture" [2]. "A variety of 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 a notable decrease in surgical soft tissue trauma and improved 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 for further inter-maxillary fixation" [5]. "Fermand developed a 3-D plate with a quadrangular design by joining two miniplates with interlocking crossbars. The basic concept of 3-D is stability in three dimensions. The stability is achieved by its configuration, not by thickness or length. One of the advantages of 3-D plates is the simultaneous stabilization of the tension and compression zones, making the 3-D plate a time-saving alternative to a conventional bone plate. The locking plating system has been developed and popularized by AO/ASIF to obviate the main disadvantage of the 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 the anatomic adaptation of the plate to the underlying bone contour is not crucial, there are theoretically fewer interferences with the adjacent vascular supply" [6].

"Both conventional miniplates and 3D plates have adequate stability after the fixation of a fracture. The stability of the 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 plates can be used as an alternative to conventional miniplates. The system is a reliable and effective treatment modality for mandibular fractures. 3-dimensional miniplates in mandibular parasymphysis and symphysis fractures are 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 of Sudheer R et al. (2019) suggests that a 3D rectangular grid plate is a feasible alternative to conventional miniplate systems with good clinical outcomes 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 defects 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 Yadav et al, the mean intraoperative time was estimated as 2.80 in mini plates and 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 this study aims to compare intraoperative and postoperative 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. METHODOLOGY

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 genders, and patients having mandibular angle fracture. 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 through the outpatient department or emergency department of Liaquat University Hospital, Hyderabad, and were divided into two groups i.e.; Group A and Group B by simple random sampling (port chit method). Group A comprised of candidates for the 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 the 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. The total sample size was 60.

2.1 Data Collection Procedure

Diagnosis of the fracture was done based on clinical examination and radiographical evaluation. Every patient was admitted to the hospital for the evaluation and baseline investigations and general anesthesia fitness. 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. The patient was given local anesthesia (xylocaine 2%adrenaline 1:100000, medicine, HUONS CO.LTD made in Korea) and five eyelets on the upper and lower jaw were passed for achieving normal functional occlusion. After achieving maximum occlusion, a mucoperiosteal flap was raised intra-orally as needed by the case with blade #15 to visualize and reduce the fracture, and occlusion was rechecked after reduction; the fracture was fixed with the implant by surgical drill bit using a 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 7mm monocortical screw.

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

Outcomes such as intraoperative time were measured in terms of minutes from the start of the surgery with incision till fixation followed by closure using a stopwatch. Stability was assessed clinically by manipulation of mandibular fragment after fixation and by postoperative digital orthopantomogram

radiographs. The responses were recorded after treatment of fractures and then at follow-ups of patients which was at an interval of 1 week from treatment to 1 month afterward.

2.1.1 Data Analysis

The data was analyzed by Statistical Software Packages SPSS version 22.0. Mean and standard deviation was 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, the status of third molar, and stability at first month were also measured. Comparison between both groups was done using an 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, the 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 statistically significant.

3. RESULTS

A total of 60 patients having mandibular angle fractures were randomly allocated into two groups: 30 were treated with 2mm conventional miniplates in group A and 30 cases were treated with a 3D plate in group B. The average age of the patients was 29.50±6.24 years and the mean duration of fracture was 3.52±1.24 days (table 1). There were 38(63.3%) males and 22(36.7%) females. The male to a female percentage between groups is shown in figure 1. The occupation status of the patients is also shown in figure 2. Regarding the type of displacement, horizontally was most common in both groups (figure 3). The rate of malocclusion was 80% in group A and 60% in group B as shown in figure 4. The most common cause of fracture was a 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 the 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]. The rate of stability was 100% in group B and 90% in group A. However, it was not statistically significant between the two 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, the status of occlusion, cause of fracture, the status of third molar to observe the difference in time and stability. The intraoperative mean time difference was significant between groups for some specified categories of modifier but the rate of stability difference was not statistically significant between groups for all stratified variables as presented in tables 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 complications 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%)	

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

Effect Modifiers	Cutoff	Group A			Group B			P-Value
		n	Mean Time	Std. Deviation	n	Mean Time	Std. Deviation	
Age Groups	<=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

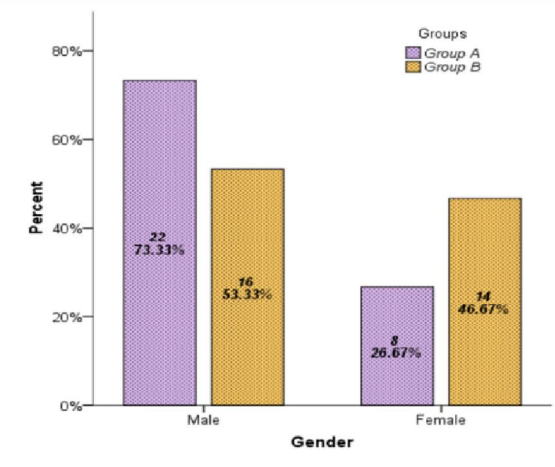

Figure 1. Gender distribution of the patients according to groups n=60

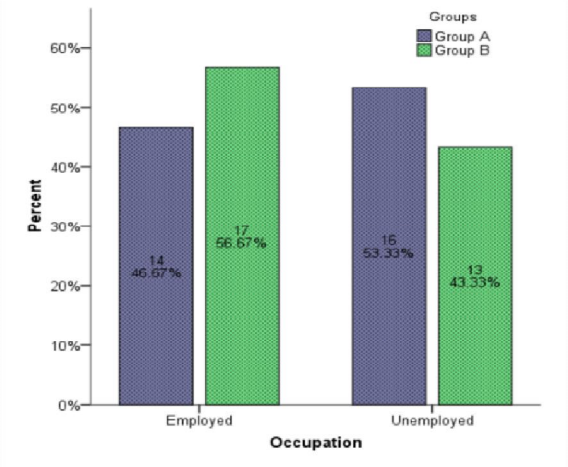

Figure 2. Occupation status of the patients according to groups n=60

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

Effect Modifiers	Cutoff	Group A			Group B			P-Value
		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

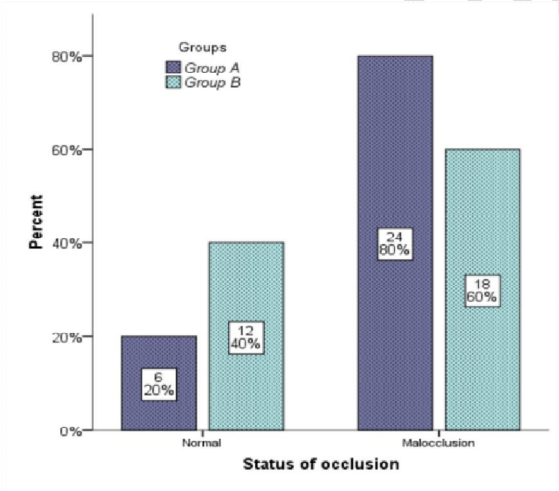

Figure 3. Occlusion status of the patients according to the groups n=60

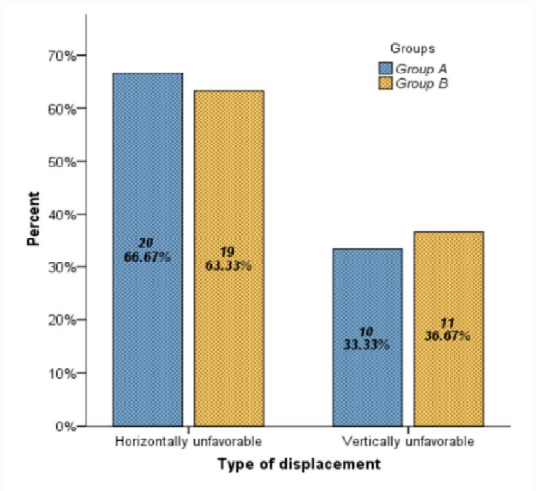

Figure 4. Type of displacement according to groups

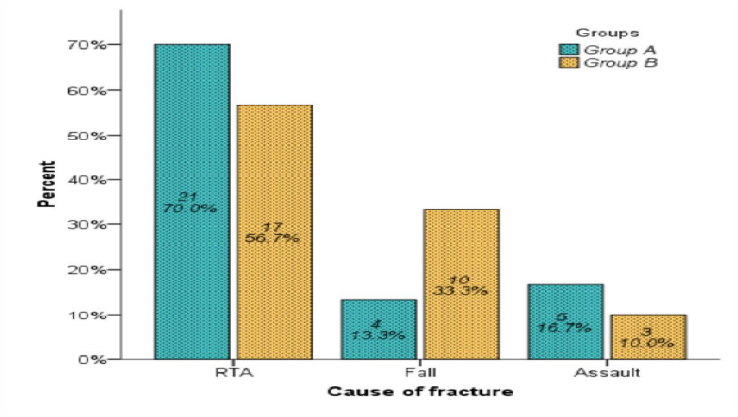

Figure 5. Cause of fracture of the patients according to groups n=60

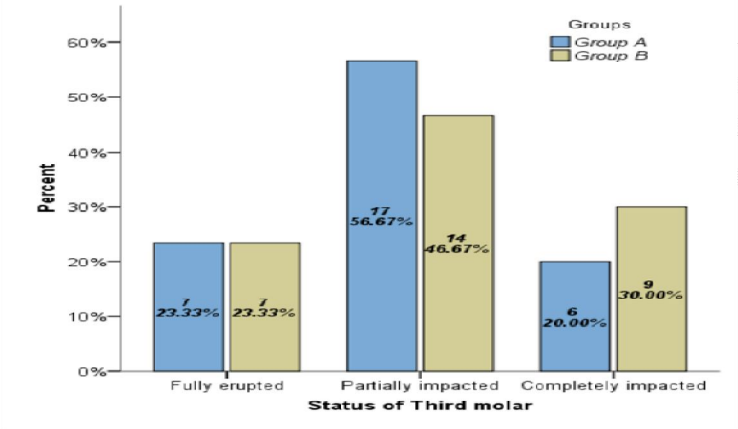

Figure 6. Status of third molar of the patients according to groups n=60

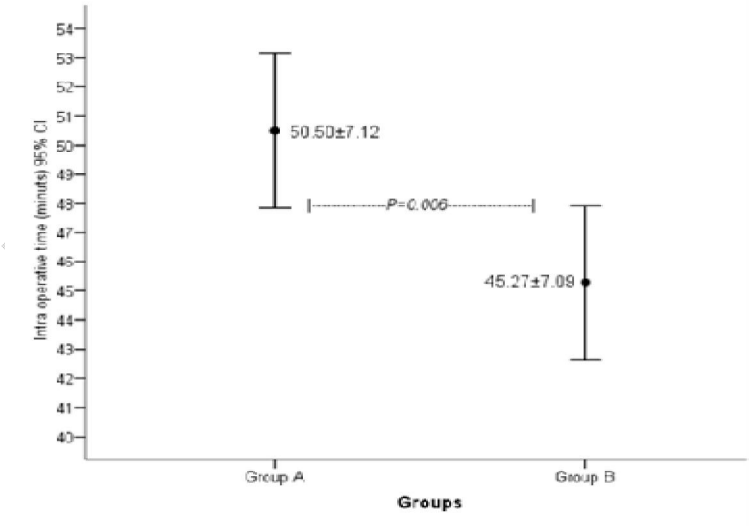

Figure 7. Comparison of outcome in terms of time by using Conventional 2mm Miniplate versus 3-D Plates in management of Mandibular angle fractures n=60

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

Variables	Age groups	Complication [Stability]	Group A	Group B	P-Value
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	1-3 days	Yes	16	15	0.340
		No	1	0	
		Total	17	15	
	>3 days	Yes	11	15	0.206
		No	2	0	
		Total	13	15	

Table 6. Comparison of outcome in terms of Conventional 2mm Miniplate versus 3-D Plates in management of mandibular angle fracture by other effect modifiers

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	
		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 impacted	Yes	5(83.3%)	9(100%)	0.400
		No	1(16.7%)	0(0%)	
		Total	6	9	

4. DISCUSSION

"Injuries related to maxillofacial fractures are mostly traumatic. The literature says the most universal etiological factor related to maxillofacial injuries is road traffic accidents (RTA) which show around 45.3% involvement" [12]. "Causes other than RTA include falls (42.6%), assaults (0.89%), sport injuries (2.2%), and gunshot wounds (0.89%)" [13]. "The most common cause of fracture in this study was road traffic accidents in both groups. To improve the surgical outcome of fixation with a 3D plating system continuous research is underway to spotlight the dimension, profile, number, and mechanics of plate/screw systems" [14]. "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" [13, 15]. "Stability by three dimensions was the basic concept thought in the development of 3-D plates" [16].

"And when it comes to stability, it is solely achieved by its configuration, not by thickness or length" [13, 14, 16, 17]. "Nowadays, the 3D plate system is one of the most standard alternative to conventional plating system, because it has the advantage of providing concurrent tension and compression zones, and this property makes the 3-D plate a time-saving method too" [14].

In this study, the average age of the patients was 29.50±6.24 years and the 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 [18], where he reported mean age of 32.4. Gokkulakrishnan et al [19] showed in his study mean age of 30.9. "One study carried out by Al-Tairi et al [20] came with a mean age of fewer than 25 years i.e. 24.5 years. In Kumari et al study [21] 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 by anterior mandibular fractures as compared to females. Our data is widely supported by various similar studies performed in the world like Zafar KJ [18] where he encountered 71.9% cases with the male gender. Sadhwani BS [15] also showed male predominance with 64.29% cases". "El Nakeeb [22] et al stated that Incidence in males compared with that of females was 4:1".
The average operating time was less with the 3-D miniplate system in comparison with conventional miniplates in the symphysis/parasymphysis region because the 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 the start of surgery with incision till closure 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 [18], Kumar [23], Kinra [24], and El Nakeeb [22], they also reported "decreased operating with 3-D plates as compared to 2mm conventional miniplates for the fixation of anterior mandibular fracture" . In Kumari et al study [21], "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 intraoperative 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. [25] and Vineeth et al. [26]. The 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. The overall cost of the treatment is reduced to half for a 3-D miniplate in comparison with miniplates of the same manufacturer. However, the cost of the implant used in other areas of the mandible is comparable for both systems [27].

5. CONCLUSION

The current study's findings indicated good stability and shorter process times utilising a 3-D plating system. The results suggest that the 3-D plating system has advantages over conventional 2mm miniplates. The large free regions between the plate arms, combined with the minimal dissection, allow for adequate blood supply to the bone. The 3D system is simple to use and inexpensive. Moreover, it employs less hardware than conventional miniplates, resulting in fewer complications such as paresthesia, infection, and hardware failure.

CONSENT

A 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

Ethical permission was sought from the Ethical Review Committee (ERC) of the Liaquat University of Medical and Health Sciences.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that they have no known competing financial interests OR non-financial interests OR personal relationships that could have appeared to influence the work reported in this paper.

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