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#### **EFFECTIVENESS** OF **STAINLESS** STEEL MINIPLATE AND TITANIUM MINIPLATE FIXATION IN THE MANAGEMENT OF MANDIBULAR COMPARATIVE FRACTURES: STUDY Α IN TERTIARY CARE HOSPITAL OF WESTERN INDIA

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#### Abstract

Background: Comparative study was done to evaluate effectiveness of stainless steel and titanium miniplate fixation in the treatment of mandibular fractures for wound dehiscence, exposure of plates, palpability of plates, pain, radiographic appearance of plates, occlusal discrepancy and evaluating stability of fracture by postoperative follow up for 6 months. Materials and Methods: Out of 20 cases of fracture, 10 were treated with stainless steel miniplates and other 10 were treated with titanium miniplates. The clinical evaluation was done at 3rd day, 1 week, 3 weeks, 3 months and 6 months. Independent't' test and Chi-square test were used to compare the parameters. Result: The age group of 20 patients ranged from 18 -45 years, mean age was 31.4 years. Our study did not show a statistically significant difference (P>0.05) in clinical outcome between the stainless steel miniplate osteosynthesis and titanium miniplate osteosynthesis in all assessed parameters. Conclusion: Clinically, titanium miniplate was found to be better than stainless steel miniplates in terms of ease of adaptability of plate, biocompatibility and stability. Studies with larger sample size are recommended to correlate the findings of the present study for their wider use in clinical practice.

# **INTRODUCTION**

The modern world of quick decisions and goaloriented living has had a significant impact on the average person. The previous few decades have seen an alarming rise in various types of accidents, including falls, sports injuries, community or other violence, and road or rail traffic accidents. All of these unplanned incidents frequently result in maxillofacial trauma, and the mandible is particularly vulnerable due to its peculiar position on the face. Hence, it is one of the facial bones that is most frequently broken. The restoration of anatomical shape and function with particular consideration for the preinjury occlusion and facial aesthetics has traditionally been the objectives of maxillofacial fracture repair. The preferred course of treatment for misplaced fractures, unstable fractures, and multiple fractures is open reduction and internal fixation (ORIF). Non compression mono-cortical miniplate fixation of the mandible is an accepted and reliable method for providing semi rigid internal fixation. In last few years, many other systems have been introduced such as locking plates, bioabsorbable plates, THORP (Titanium-coated hollow screw and reconstruction plate system), microplates, 3-D plates etc. In this study, effectiveness of stainless steel and titanium miniplate fixation (SSTM) in the treatment of mandibular fractures (MF) will be evaluated.

### Objectives

- 1. To evaluate and compare the clinical effectiveness of the SSTM and screws for ORIF of mandibular fractures
- 2. To assess the versatility of Titanium miniplates (TM) in MF in comparison with stainless steel miniplates (SSM) by evaluating the incidence of complications.

The complication mainly is palpability of plates, exposure of plates, pain, wound dehiscence, radiographic appearance of plates, occlusal discrepancy and evaluating stability of fracture which will be followed up for 6 months.

# **MATERIALSANDMETHODS**

After obtaining Institutional ethics committee approval, a prospective randomized clinical study was carried out in the Department of Oral and Maxillofacial Surgery, Jodhpur Dental College General Hospital, Jodhpur Rajasthan. A total of 20 patients were enrolled and randomly divided into two groups. Group A included the patients who were managed with SSM and screws and Group B were managed with TM and screws.

### **Inclusion** Criteria

- 1. Patients in the age groups of 18-50 years.
- 2. Fractures of the mandibular symphysis, parasymphysis, body or angle region associated or unassociated with condylar fracture.
- 3. Patients willing for follow up.
- 4. Patients who come under ASA I and ASA II category.

### **Exclusion Criteria**

- 1. Edentulous patient.
- 2. Patients with primary and mixed dentition.
- 3. Patients who come under ASA III, ASA IV and ASA V category.
- 4. Grossly comminuted fractures of the mandible.

#### **Surgical Technique**

Twenty patients who fulfilled the inclusion criteria and who gave informed consent were the study sample. After selection of the patient, a proper case history was taken. Pre-operative radiological examination was performed. Routine laboratory investigations were carried out before undertaking the surgery to evaluate any systemic conditions in these patients. Pre-operative bite force in kilograms was recorded using a bite force recorder. Prior to open reduction, Intermaxillary fixation was done. All patients were given prophylactic antibiotics intravenously before procedure. Patients were operated under general anesthesia (Naso-tracheal intubations). Strict asepsis was followed. Local anaesthesia was administered. Fracture site was exposed using standard intraoral mucosal incisions. Mucoperiosteal flap was reflected and fracture site was exposed. After proper reduction, fixation was done using either stainless steel miniplates (Group A) or titanium miniplates (Group B) using Champy's ideal osteosynthesis lines. A 3-0 vicryl stitch was used to seal the incision after attaining satisfactory hemostasis. Extra oral administration of an adhesive pressure bandage over the skin's surface. All patients were prescribed a soft diet for 30 days and given postoperative antibiotics (Amoxicilline plus Clavulanic acid and Metronodazole) and analgesics for 5 days. All of the patients were encouraged to maintain their oral hygiene by using mouthwash containing 0.2% chlorhexidine. All patients had post-operative radiographs taken.

#### Patient evaluation

After 6 months follow-up, the clinical evaluation was done at 3rd day, 1 week, 3 weeks, 3 months and 6 months. Assessment of the patients was done under following parameters – palpability of plates, pain, radiographic appearance of plates, wound dehiscence, exposure of plates, occlusal discrepancy and stability of fracture.

- 1. Wound dehiscence- It was shown by an intraoral mucosal breach at incision sites or in the area of fracture.
- 2. Exposure of plates- It was assessed clinically if the plate is visible or not intraorally in the area of fracture. t.
- 3. Palpability of plates- It was assessed by clinical palpation of the bone plate under the mucosa over the site of fracture fixation and was measured as palpability present or absent.
- 4. Pain- It was recorded on the basis of visual analogue scale. [Figure1]
- 5. Radiographic appearance of plates- It was done with Orthopantamogram to see the displacement of plates, loosening of screws or plates and the fracture of plate.
- 6. Occlusal discrepancy- It was based on clinical examination and information obtained from the patient. Stability of fracture- It was assessed using a bite force recorder. The bite force (in kilograms) at the incisor region was recorded.

In point 1, 2, 5 and 6, these were recorded by present or absent.

Bite force recorder- To evaluate the maximum biting forces preoperatively and voluntary postoperatively at each follow-up, a standardised instrument was there. Based on the Tate et al. principal, the recorder was made up of four strain gauges attached on two stainless steel bars to form a Wheatstone bridge. 1 As a display, a digital panel metre is employed. A noticeable voltage change across the four strain gauges was caused by changes in the load on the steel bars. The measurements were performed with the individual seated and in a natural, unsupported upright forward head position. At the location of the incisors, bite forces were recorded. The patient was told to use the maximum bite force setting on the bite force gauge. The bite force measurements were made. (Showing figure-2) **Statistical Analysis** 

Data were analyzed with the help of Statistical Package for Social Sciences (SPSS) version 20.0 software. Independent't' test and Chi-square test were used to compare the parameters.

### RESULTS

Graph-1 shows that road traffic accident (RTA) was the cause of fracture in 15 patients, assault in 4 patients and sports injury in 1 patient out of 20 patients. In the present study, the most common cause of fracture was road traffic accident (75%). Out of the 20 patients, 17 were male and 3 were female. The number of male patients was higher (85%) than the number of female patients (15%).

The most common age groups of patients were between 29-39 years (50%). [Table 1]

The age group of 20 patients ranged from 18 -45 years, mean age was 31.4 years. [Table 2]

[Table 3] show that two patients had post-operative wound dehiscence on 3rd day of follow up in Group A. None of the patients had wound dehiscence in both groups at 1 week, 3 weeks, 3rd month and 6th month of follow-up. There was no statistical significance in both the groups at all the follow-ups (p>.05).

[Table 4] shows that plates were exposed in one patient at 3rd month of follow up in Group A. At 6th month of follow up, plates were exposed in two patients in both Groups. There was no statistical significance in both the groups at all the follow-ups (p>.05).

[Table 5] shows that palpability of plates was present in two patients at 3rd month and 6th month of follow up in Group A. In Group B, palpability of plates was present in one patient at 3 weeks and 3rd month of follow up and in two patients at 6th month of follow up. There was no statistical significance in both the groups at all the follow-ups (p>.05).

[Table6] shows the distribution of patients in both groups according to severity of the pain at 5 different follow-ups. There was no statistical significance in both the groups at all the follow-ups (p > .05).

[Table 7] shows that radiographic appearance of plates was normal in both the groups at all follow ups. No displacement of plates, loosening of screws/plates or the fracture of plates was seen in the OPG of any patient of both groups at different

follow ups. There was no statistical significance in both the groups at all the follow-ups (p>.05).

[Table 8] shows that three patients of Group A had occlusal discrepancy at 3 weeks, 3 months and 6 months follow up. No occlusal discrepancy was seen in any of the patient of Group B at different follow ups. There was no statistical significance in both the groups at all the follow-ups (p>.05).

[Table9] shows the mean bite force in kilograms at the incisor region in both groups preoperatively and post operatively at 5 different follow ups. No statistically significant difference was seen in incisor bite force of both the groups at different follow ups.

0 - 1 0	v	AS	Nun	neric	Pain	1	Dist	ress	s S c	al	
No pain		Moderate pain					Unbearable pain				
		1			1	1	1				
0 1		2	3	4	5	6	7	8	9	10	

Figure1: visual analogue scale



Figure 2: Bite force recorder



Graph 1: Distribution of patient according to Gender and Etiology of fracture

Table 1: Distribution of patient according to age.								
Age groups (in years)	Number of patients							
18-28	7							
29-39	10							
40-50	3							
Total	20							

Table 2: Table showing mean age of the patients										
Group	Cause	Ν	Mean	Std. Deviation	Anova	P- value				
Group A	Assault	2	26.00	5.657	.114	.740				
	RTA	8	32.00	10.677						
Group B	Assault	2	28.00	1.414						
	RTA	7	34.00	5.033						
	Sports Injury	1	26.00	-						

\*RTA-Road Traffic Accident

Table 3: C	Table 3: Comparison between Group A and Group B in terms of wound dehiscence using Chi-square test.												
FOLLOW UP		3rd day		1 Week	3 Weeks	3 Months	6 Months						
		Absent	Present	Absent	Absent	Absent	Absent						
Group	GROUP A	8	2	10	10	10	10						
	GROUP B	10	0	10	10	10	10						
Total		18	2	20	20	20	20						
Chi-Square	Гest	2.222		No statistics are	No statistics are	No statistics are	No statistics are						
P-Value		.136		computed.	computed.	computed.	computed.						

Table 4: C	Table 4: Comparison between Group A and Group B in terms of exposure of plates using Chi-square test												
FOLLOW UP		3rd Day	1 Week	3 Weeks	3 Months		6 Months						
		Absent	Absent	Absent	Absent	Present	Absent	Present					
Group	GROUP A	10	10	10	9	1	8	2					
	GROUP B	10	10	10	10	0	8	2					
Total		20	20	20	19	1	16	4					
Chi-Square Test N		No statistics	No statistics	No statistics	1.053		.000						
P-Value		are computed	are computed	are computed	.305		1.000						

Table 5. Commentant between Comm	A and Case	. D : 4	almahilitan af	-lates Chi serve	
Table 5: Comparison between Grou	p A and Grou	ры in terms oi p	alpadinty of	plates using Chi-squar	e test.

FOLLOW UP		3rd Day	1 Week	3 Weeks	3 Weeks			6 Months	
		Absent	Absent	Absent	Present	Absent	Present	Absent	Present
Group	GROUP A	10	10	`10	0	8	2	8	2
	GROUP B	10	10	9	1	9	1	8	2
Total		20	20	19	1	17	3	16	4
Chi-Square	Test	No statistics	No statistics	1.053		.392		.000	
P-Value		are computed	are computed	.305		.531		1.000	

Table 6: Distribution of Patients according to severity of pain in both groups using Chi-square test.											
FOLLOW UP	3rd Day	1 Week		3 Weeks			3 Mon	ths	6 Months		
No pain (0)	Moderate Pain	Mild	Moderate	No	Mild	Moderate	No	Mild	No Pain		
Mild (1-4)		Pain	Pain	Pain	Pain	Pain	Pain	Pain			
Moderate (5-7)											
Severe (8-10)											
Group A	10	5	5	4	6	0	10	0	10		
Group B	10	4	6	4	5	1	9	1	10		
Total	20	9	11	8	11	1	19	1	20		
Chi-Square Test	No statistics are	.202		1.091			1.053		No statistics are		
P-Value	computed.	.653		.580			.305		computed.		

Table 7:	Comparison	between	Group	A and	Group	B in	terms	$\boldsymbol{o}\boldsymbol{f}$	radiographic	appearance	of plates	using	Chi-
square tes	t.												

FOLLOW UP	3rd Day	1 Week	3 Weeks	3 Months	6 Months
	Absent	Absent	Absent	Absent	Absent
Group A	10	10	10	10	10
Group B	10	10	10	10	10
Total	20	20	20	20	20
Chi-Square Test	No statistics are				
P-Value	computed.	computed.	computed.	computed.	computed.

Table 8: Com	parison between Grou	p A and Grou	p B in terms of occlusal	discrepancy using	g Chi-square test.
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FOLLOW UP	3rd Day	1 Week	3 Weeks		3 Months		6 Months		
	Absent	Absent	Absent	Present	Absent	Present	Absent	Absent	
Group A	10	10	7	3	7	3	7	3	
Group B	10	10	10	0	10	0	10	0	
Total	20	20	17	3	17	3	17	3	
Chi-Square Test	No statistics are	No statistics are	3.529		3.529		3.529		
P-Value	computed.	computed.	.060		.060		.060		

 Table 9: Comparison between Group A and Group B in terms of stability of fracture using Independent Students' T test.

	Group A			Group B			Independent	<b>P-Value</b>
	Ν	Mean	Std.	Ν	Mean	Std.	Students' T Test	
			Deviation			Deviation		
Pre Operative	10	1.8450	.59899	9	1.3856	.49217	1.814	.087
Third day	10	4.9290	.84683	9	4.1322	1.82213	1.244	.230
1 week	10	8.7200	1.84502	9	8.0311	2.09307	.763	.456
3 weeks	10	12.4400	2.32799	9	12.2689	1.79314	.178	.861
3 Months	10	16.4620	2.49343	9	16.5422	2.21259	074	.942
6 Months	10	19.2180	2.54869	9	18.6278	3.05485	.459	.652

## DISCUSSION

Mandible bone needs immediate attention whenever it is fractured.<sup>[2]</sup> One of the earliest metals utilised for semirigid fixation in maxillofacial surgery was stainless steel (SS). The SS implants are affordable and widely accessible. The primary argument in favour of removing SS miniplates after fracture healing is tissue reactivity caused by metallic plate corrosion and metal particle release in the nearby soft tissues. Stainless steel plates are toxic and produce both local and systemic reactions since they are allergenic and corrosive. As a result, metal ions penetrate and aggregate in tissues.<sup>[3]</sup> Palpability, sensitivity, interference temperature with radiographic imaging, and the consequent necessity for a second surgery to remove the plate are drawbacks of stainless steel miniplates.<sup>[4]</sup>

According to research by French HG et al., SS miniplates are generally not very hazardous to human tissue, are well tolerated, and do not require routine implant removal.<sup>[5]</sup> All of the stainless steel plates that were removed exhibited mechanical flaws such surface roughness, which could be linked to handling techniques, according to a study by Arun Dugal and Gagan Thakur. Corrosion was not frequently observed, however it was discovered in one patient who had a plate-related infection.<sup>[6]</sup>

Due to the unique characteristics of titanium devices compare to other metals; reflection of X-rays by this metal is smaller than some other alloys, as a result the image (contour) is clearer.<sup>[3]</sup>

There were 17 male and 3 female participants in this study. Haug et al, who conducted a 5-year retrospective assessment of face fractures, also noted this male dominance.<sup>[7]</sup> This may be explained by the fact that guys are typically more vulnerable to trauma-prone circumstances. Mandibular fractures were caused by assault in 4 cases (20%), sports injuries in 1, and road traffic accidents in 15 cases (75%) each. This is in accordance to the findings of B. Pawan et al., who discovered that road traffic accidents were the root cause in 17 (85%) instances, falls in one case, and interpersonal violence in 2 (15%) cases. To lower the rate of road traffic accidents, the traffic laws must be developed and carefully enforced.<sup>[2]</sup>

Both groups were compared for seven parameters. The patients were evaluated pre-operatively, third day, 1 week, 3 weeks, 3 months, and 6 months postoperatively. In our study, patients were checked clinically for wound dehiscence post operatively at all follow-ups. Two patients in Group A showed wound dehiscence on third day after surgery due to poor oral hygiene habit. Both the patients were cared properly with antibiotics and continuous follow up done in the OPD with normal saline (NS) and Povidone lotion irrigations, which made satisfactory secondary healing in following visits. B. Pavan et al in a study compared 3-D miniplates with Champy's miniplates. According to a study by Deepak S. and Manjula S., titanium bone plates had a wound dehiscence rate of 0%, while stainless steel bone plates had a rate of 20% for every five patients.<sup>[8]</sup>

Because of peculiarities of mandibular fractures of the symphyseal or body region,<sup>[9,10]</sup> there may be a greater chance of complications such as plate exposure or infection.<sup>[11]</sup> In our study, two patients in Group A after six months, one patients after three months and two patients in Group B after six months both experienced plate exposure.

In our study, palpability was present after 3 and 6 months in two patients respectively in Group A and in one patient after 3 months and two patients after 6 months in Group B. Adaptation of the miniplate to contour of mandible and maintenance of reduction of the fractured segments play important role in palpability of the miniplates through overlying tissues. Naiva V. Pathak et al in a study observed adaptation of stainless steel miniplate was fair in 5 out of 10 patients while it was good in all 10 patients treated with titanium miniplates. Due to its excellent compression strength and lower modulus of elasticity, titanium gives better adaptation to contour of the skeletal surface. In this study palpability of the miniplate was present in three patients treated with stainless steel miniplates and in only one patient who was treated with titanium miniplate.<sup>[12]</sup>

The pain scores decreased subsequently at all follow ups in both the groups. Not a single patient of both groups had pain after 3 months. The pain parameter showed insignificant difference.

The imbalance between the masticatory muscles' muscular activity following the trauma and the postoperative edoema at the TMJ area led to the occlusal disparity that was observed. Three patients from Group A in our study experienced occlusal disparity. Giving guiding elastics provided a solution to this issue. However, when a tooth is involved in the fracture line, it can cause a little amount of tooth displacement that can be fixed with selective grinding. The findings revealed no statistically significant correlation between the two groups. Naresh et al in a study reported postoperative malocclusion in one patient out of ten patients treated with titanium miniplates.<sup>[13]</sup> Pavan et al in a study also use the same technique for 7 days followed by selective coronoplasty.<sup>[2]</sup>Naiya V. Pathak etal in a study observed occlusal derangement in five out of twenty patients. Three in titanium group while two in stainless steel group. It was related with presence of associated subcondylar fracture or parafunctional movements developed by the patient.<sup>[12]</sup>

Radiographic appearance of plates was evaluated with Orthopantamogram to see the displacement of plates, loosening of screws or plates and the fracture of plate. No such complication was seen in both the groups in our study.

The considerable decrease in biting forces that occurred after the treatment of a MF may have been

caused by traumatic or surgical damage to the chewing muscle or to its protective neuromuscular mechanisms. The patient's ability to bite strongly especially at early weeks of post-surgery might be due to psychological discomfort.<sup>[13,14]</sup> This may be the cause of the extremely low bite force values seen in this study's first postoperative week.<sup>[15]</sup>

In our investigation, the biting force values start to slowly rise after the first postoperative week. After six months, the maximum bite forces for both groups were almost 60% higher than previously reported normal bite forces. According to a study by Rajesh et al., healthy Indian persons can bite with a maximal voluntary force of about 15 kg on the incisor and 36 kg on the molar. Bite forces were abnormal in parasymphyseal fracture cases until 4 weeks, and by 8 weeks, maximum biting forces had been recovered. After 8 weeks, there was no discernible increase in biting forces.<sup>[16]</sup>

Cost is an important factor in choice of the miniplates. In our study, we found that titanium miniplates are costlier then stainless steel miniplates; but at the same time with its higher bio-compatibility becomes a favorable option.

Titanium miniplates were found to be superior to stainless steel miniplates in terms of ease of adaptability of the plate, biocompatibility, and stability, even though the results of our study did not show a significant difference in clinical outcome between the stainless steel miniplate osteosynthesis and titanium miniplate osteosynthesis. Miniplates made of titanium are more expensive, nevertheless.

#### **CONCLUSION**

In the open reduction and internal fixation of mandibular fractures, there is no statistically significant difference between the stainless steel miniplate and titanium miniplate osteosynthesis. In terms of clinical performance, titanium miniplates outperformed stainless steel miniplates. For wider application in clinical practise, studies with bigger sample sizes are advised to correlate the findings of the current study.

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