



COMPARISON BETWEEN STANDARD 3D TITANIUM MINIPLATES VS LOCKING 3D MINIPLATES IN THE TREATMENT OF MANDIBULAR FRACTURE

Clinical Research

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ABSTRACT

Introduction: Mandible fractures are a frequent injury because of the prominence and relative lack of support to mandible. The first description of mandibular fracture was as early as 1650 BC, when an Egyptian papyrus described the examination, diagnosis, and treatment of mandible fractures. Hippocrates was the first to describe reapproximation and immobilization through the use of circum-dental wire and external bandaging. Titanium plates have been used for over two decades to achieve internal rigid fixation of mandibular fractures. The concept of 3D Titanium plates were developed & reported first by Farmand and Duporieux. The purpose of this study is to compare the 3D titanium miniplate with the 3D titanium locking miniplates system for treatment of fractures in the mandible.

Materials and Method: 20 patients presenting with mandibular fracture with American Society of Anesthesiologists Class I & Class II, reporting to the department of Oral and Maxillofacial Surgery, Babu Banarasi Das College Of Dental Sciences, Lucknow, were randomly divided into 2 groups, Group A ;Locking 3D titanium miniplates and Group B : Standard 3D titanium miniplates of 10 patients each. The procedure was done under general anesthesia. Pre-operative and Post-operative evaluation assessment was done at regular intervals for Pain, Swelling, Infection, Surgical Ease, Hardware Failure, Bite Force.

Results: Pain and swelling was less in locking miniplate group along with no infection and hardware failure compared to non locking group. The bite force increase was more in group B than group A with mean 30.61 ± 0.95 in group B while 28.9 ± 1.6 in group A at Right molar region, 31.44 ± 1.11 in group B and 29.5 ± 1.8 in group A at Left molar region. Locking miniplate was found to have greater surgical ease compared to non locking miniplate.

Conclusion: Results suggest that 3 D locking plate/ screw system have more promising results compared with the 3 D non locking mini plate/ screw system.

KEYWORDS

3 D Non Locking Plate, 3 D Locking Plate

INTRODUCTION

The sheer paces of modern life with high speed travel as well as an increasingly violent and intolerant society have made facial trauma a form of social disease from which no one is immune. Seemingly divergent shifts in society may be responsible for recent changes in patterns of facial injuries, extent and clinical features etc. resulting in massive disfigurement of maxillofacial skeleton. Mandible being the only mobile bone of facial skeleton, there has been significant increase in number of cases of mandibular fractures in recent years.¹ The majority of facial fractures are found in males between the young ages there, mandibular fractures more common compare to other facial fracture by most common cause by road site accidents¹ where as falls and sports injuries are other common causes of mandibular fractures. Mandible fractures if not identified or inappropriately treated may lead to severe consequences both cosmetic and functional. Traditionally, fracture fragments have been reduced to satisfactory occlusion by various methods of closed reduction like direct or indirect inter-dental wiring and were immobilized in that position by maxillo-mandibular fixation. Recently so many type of treatment available for fixation of fracture but more likely the miniplate system (either locking or non-locking) has revolutionarised used the fixation of mandible fractures. The introduction of locking plate/screw system has certain theoretical advantages over conventional plates and screws which makes them superior to conventional miniplates. Titanium was first used in 1940 s and was shown to be not only biocompatible but had a tendency for osseointegration and had excellent corrosion resistance. It also has excellent ductility and tensile strengths and is totally non-toxic The treatment goal of mandible fractures allows the patient to have normal mandibular function and to achieve a normal diet earliest. The shortcomings of rigid & semi rigid fixation lead to the development of

3 dimensional (3D) miniplates ,consisting of 2 miniplates with gap which are interconnected by vertical cross struts .The concept of 3D Titanium plates were reported first by Farmand and Duporieux. Unlike compression & reconstruction plates, their stability does not derive from the thickness of plate.²

This study was undertaken with an aim to compare standard 3 D titanium miniplates with Locking 3D miniplates in treatment of mandibular fractures on the basis of ease of technique and post operative results.

AIM & OBJECTIVES:

To evaluate the mandibular fractures treatment outcomes with 3D Titanium miniplate versus locking 3D titanium miniplates and compare the 3D titanium non locking miniplate with 3D titanium locking miniplates 2mm system in mandibular fracture treatment based on various parameter also analyze and compare the advantages, disadvantages and complication.

MATERIALS AND METHOD:

20 Consecutive Patients presenting with mandible fracture attending the OPD of Department of Oral and Maxillofacial Surgery, Babu Banarasi Das College Of Dental Sciences, Lucknow requiring open reduction and internal fixation as treatment of choice were included in this study. Detailed information consisting of age, sex, chief complaint, history of present illness, past medical history, etiology and associated injuries were recorded on a specially designed history sheet for this purpose then after taken consent, a thorough clinical examination as well as radiological interpretation was done for each

patient, diagnosis and all related investigation done before surgical procedure of each individual. In our study included age group >18 years old, Symphyseal, Parasymphyseal & Body fracture of mandible with dentulous patients. All patients were randomly categorized into two groups with 10 patients each. Group 1 consist Conventional or standard 2 mm Non-Locking 3D Titanium Miniplate system and another group 2 consist 2 mm locking 3D Titanium Miniplate plate/screw system.

SURGICAL TECHNIQUE:

Patients were operated under General Anaesthesia (Following Naso-Tracheal intubation)/Local Anaesthesia as per need. Strict asepsis was followed. The fracture site was exposed through intra oral, sub labial approach is required. Mucosal incision was given approximately 5 mm below the attached gingiva. Mucoperiosteal flap reflected and fracture site was exposed. Following reduction of the fragments and temporary Maxillo-mandibular fixation was done using stainless steel wire. A suitable plate (Locking or Non Locking) was selected and bent with a plate bending pliers to confirm the proper adaptation of plates to bone surface. Drilling was performed at slow speed along with the copious saline irrigation to prevent damage to the bone by heat. To avoid injury to the dental roots the holes were drilled strictly mono-cortical, and directed into the space between the roots. Later screws of suitable length were selected for fixation of

the plate. For screw tightening the rotations were executed using the screw- holding screw driver and then the conventional screw driver used for tightening the screws. Inter-maxillary fixation was released and passive occlusion was checked by moving the lower jaw. The incision site was closed in layers with 3-0 vicryl suture material in interrupted fashion. After surgery, assessment of the patients was done under following parameters, Pain, Swelling, infection, surgical ease, hardware failure and Bite force.

Follow up: Done from the day of operation up to 3 months. Assessment will be done according to the parameters mentioned above at postoperative day 2, 1 week, 1 month, and 3 months.

STATISTICAL ANALYSIS AND RESULTS:

The data was statistically analyzed by chi square and student t test using SPSS Statistical Analysis Software. In our study 20 sample size considered each group has 10 samples content. The mean age of study population in group A was 29.20 6.44 and of group B was 33.20 5.80. There were 90% males and 10% females in group A and 80% males and 20% females in group B. In our study, the pain, swelling and hardware failure was compared between group A and group B on 2nd day, 1st week, 1 month and 3 months post-operatively as mentioned in table 1, 2, 4 and infection evaluated on the day of 1 week, 1 month and 3rd month of the post operation as mention in table 3.

Table 1: Comparison of group A and B according to post-operative pain

PAIN											
2 nd day of post operate			1 week of post operate			1 Month of post operate			3 Month of post operate		
	Mild	Moderate		No pain	Mild		No pain	Mild		No pain	Mild
N (%)	2 (20%)	8 (80%)	N (%)	0 (0%)	10 (100%)	N (%)	9 (90%)	1 (10%)	N (%)	10 (100%)	0 (0%)
N (%)	6 (60%)	4 (40%)	N (%)	1 (10%)	9 (90%)	N (%)	10 (100%)	0 (0%)	N (%)	10 (100%)	0 (0%)
X ² =2.400; p= <0.041			χ ² = 2.667P = 0.446			χ ² = 1.053; P = 0.305			χ ² = ---; P = ---		

The pain was compared between group A and group B on 2nd day post-operatively. There were 20% cases who experience mild pain and 80% moderate pain in group A compared to 60% mild and 40% moderate pain in group B and the difference not statistically significant ($p=0.041$), after 1 week there were 100% cases who experience mild pain in group A compared to 10% with no pain and 90% mild pain in

group B and but the difference not statistically significant ($p=0.446$). After 1 month post-operatively there were 10% cases who experience mild pain and 90% no pain in group A compared to 100% no pain in group B and the difference was not statistically significant ($p=0.305$). The pain was evaluated on 3 months post-operatively. There were no cases of pain in either of the groups.

Table 2: Comparison of group A and B according to post-operative swelling

GROUP	SWELLING											
	2 nd day of post operate			1 week of post operate			1 Month of post operate			3 Month of post operate		
		Mild	Moderate		Absent	Mild		Absent	Mild		Absent	Mild
A	N (%)	9 (90%)	1 (10%)	N (%)	1 (10%)	9 (90%)	N (%)	10 (100%)	0 (0%)	N (%)	10 (100%)	0 (0%)
B	N (%)	9 (90%)	1 (10%)	N (%)	5 (50%)	5 (50%)	N (%)	10 (100%)	0 (0%)	N (%)	10 (100%)	0 (0%)
$\chi^2 = ---; P = --$			$\chi^2 = 3.810; P = 0.049$			$\chi^2 = ---; P = ---$			$\chi^2 = ---; P = ---$			

The swelling was compared between group A and group B on 2nd day post-operatively. There were 90% cases that experience mild swelling and 10% severe swelling in both the groups. When we were evaluate after 1 week then found there were 50% cases who experience no swelling and 50% mild swelling in group B compared to 10% no

swelling and 90% mild swelling in Group A and the difference is statistically significant ($p=0.049$). After 1 month post-operatively, there were no cases of swelling in either of the groups. The swelling was evaluated on 3 months post-operatively. There were no cases of swelling in either of the groups.

Table 3: Comparison of group A and B according to post-operative infection

GROUP	INFECTION								
	1 week of post operate			1 Month of post operate			3 Month of post operate		
		Present	Absent		Present	Absent		Present	Absent
A	N (%)	0 (0%)	10 (100%)	N (%)	1 (10%)	9 (90%)	N (%)	0 (0%)	10 (100%)
B	N (%)	0 (0%)	10 (100%)	N (%)	0 (0%)	10 (100%)	N (%)	0 (0%)	10 (100%)
$\chi^2 = 1.053; P = 0.305$		$\chi^2 = ---; P = ---$		$\chi^2 = ---; P = ---$					

The infection was evaluated on 1 Week post-operatively; there were no cases of infection. After 1 month post-operatively, There were no cases of infection in group B but 10% cases of infection in group A

subjects but the difference was not statistically significant ($p=0.305$). When we were evaluated on 3 months post-operatively, there were no cases of infection.

Table 4: Comparison of group A and B according to post-operative hardware failure

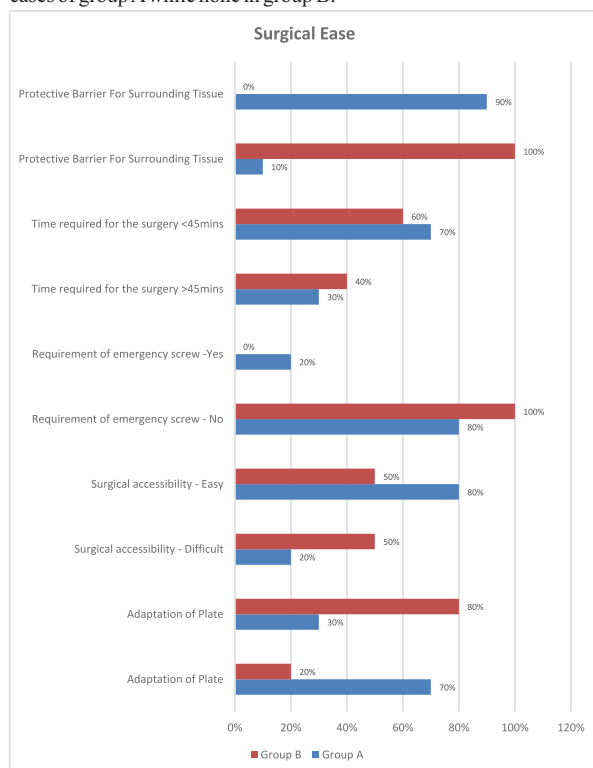
GROUP	HARDWARE FAILURE											
	2 nd day of post operate			1 week of post operate			1 Month of post operate			3 Month of post operate		
		Present	Absent		Present	Absent		Present	Absent		Present	Absent
A	N (%)	0 (0%)	10 (100%)	N (%)	0 (0%)	10 (100%)	N (%)	1 (10%)	9 (90%)	N (%)	0 (0%)	9 (90%)
B	N (%)	0 (0%)	10 (100%)	N (%)	0 (0%)	10 (100%)	N (%)	0 (0%)	10 (100%)	N (%)	0 (0%)	10 (100%)
	² = ---; P = ---			² = ---; P = ---			² = 1.053; P = 0.305			² = ---; P = ---		

The hardware failure was evaluated on 2nd day, 1st week and 3rd month of post-operatively there were no cases of hardware failure in either of the groups. The hardware failure was evaluated on 1 month post-operatively. There were 10% of hardware failure in group A compared to 0% hardware failure in group B but the difference was not statistically significant ($p=0.305$).

Table 5: Summarization of surgical ease

Surgical ease			Group A	Group B	P- value
Adaptation of plate	Difficult	N	7	2	0.068
		%	70.0%	20.0%	
	Easy	N	3	8	
		%	30.0%	80.0%	
Surgical accessibility	Difficult	N	2	5	0.160
		%	20.0%	50.0%	
	Easy	N	8	5	
		%	80.0%	50.0%	
Requirement of emergency screw	No	N	8	10	0.136
		%	80.0%	100.0%	
	Yes	N	2	0	
		%	20.0%	0.0%	
Time required for the surgery	>45 min	N	3	4	0.639
		%	30.0%	40.0%	
	<45 min	N	7	6	
		%	70.0%	60.0%	
Protective barrier for surrounding tissue	No	N	1	10	<0.001
		%	10.0%	100.0%	
	Yes	N	9	0	
		%	90.0%	0.0%	

The surgical ease was compared between group A and group B on the basis of Adaptation of plate, which was easier in 80 % cases of group B as compared to 30% cases in group A. The surgical accessibility was 80% easy in group A while it was 50 % in group B. 20 % cases of group A required emergency screws while none in group B. The time required for surgery was >45 minutes for group B in 40 % cases while in group A it was 30 % cases. Protective barrier was required in 90 % cases of group A while none in group B.



DISCUSSION AND CONCLUSION

Fractures of the mandible occur more frequently than the fractures of other facial bones, making up approximately two thirds of all maxillofacial fractures. Although the mandible is dense and strong, but as it occupies the prominent peripheral position around the lower third

of the facial skeleton hence, it is exposed to frequent trauma. The treatment of mandible fractures has been studied over the past 40 years and has evolved significantly in the past few decades as rigid internal fixation has become increasingly popular with both patients and surgeons. Two general treatment philosophies emerged for plate and screw fixation of mandibular fractures in the 1970s and 1980s. Miniplate fixation of mandibular fractures along the “ideal lines of osteosynthesis” has become the most widely used technique. Champy et al have performed several studies to validate this technique. Studies continue to cite high complication rates using these traditional methods. Research continues to focus on the size, shape, number, and biomechanics of plate/screw systems to improve surgical outcomes. Locking plate/screw systems have certain advantages over conventional plates and screws. 3 D miniplate system works on the following principle: when the mandible is in function, primary forces of concern are bending, vertical displacement and shearing. In 3D plate, the vertical bars connecting the two horizontal bars resist bending forces. The box configuration of the plate distributes the forces over a surface area and not along a single line; this provides more stability in three dimensions; against torsion forces, vertical displacement, bending and shearing forces. In the locking system, the screw and plate becomes a single rigid functional unit that no longer relies on the bone to plate interface for stabilization. The locking system combines two principles: first, the locking system prevents stripping of screws and prevents movement and loosening of screws; and second, fixator principle simplifies bending of plates and decreases torsion or opening at the fracture site.

The incidence of mandibular fracture in this study was between the age of 23 to 28 years. This could be explained as children till the age of 6 years are under parental care thereby prevented from afflicting injuries making them less prone to fracture. The susceptibility of fracture is further reduced by the inherent property of the elasticity of the bones. With increasing age they are more involved in physical activities, by the time they reach adulthood they are involved in fast and rash driving, interpersonal violence, alcohol abuse, contact sports etc, while the people beyond 40 years of age people are less afflicted by incidence of fracture as they lead a more calm, peaceful and disciplined life. Male are predominating with 85% while female constitute a meager percentage of 15% i.e. in a ratio of 5.6:1. This is in conformity with, **Dongas et al (2002)**³, **Al ahmed et al (2004)**⁴, **Ogundare (2003)**⁵, **Sakr (2006)**⁶, **Brasilierio et al (2006)**⁷ with a slight variation from this study. This is probably due to higher level of physical activity among men as being the bread winners in this part of the country. There was significant decrease in the incidence of swelling in group-A and group-B respectively. All cases but 1 in both the groups had severe swelling on 2nd day post-operatively owing to the fact that inflammatory reaction sets in response to the surgical insult. While incidence of swelling was less in group-B when compared to group-A at 1st week follow up. No case presented with swelling at 1st and 3rd month follow up in both groups. This is supported by **Edward ellis(2002)**⁸, **Ayman chrith(2005)**⁹, **Chandan prabhakar (2011)**¹⁰. There was significant reduction in pain score in both the groups at postoperative follow up. Pre-operative pain in patients having fracture of bone is due to the mobility between the fracture fragments as a result the periosteum rubs against each other. Significant difference in pain score on 2nd day post-operative was due to proper reduction and stabilization of fracture fragment. But reduction of pain score was always more in group-B than group-A as in case of locking miniplates screws are locked into the plate as well as into the bone resulting in a frame construct with high stability. The functional forces on mandible are transmitted directly from the bone to the screws, from there to the plate and on the opposite side of the fracture again through the screws into the bone. These forces are more favourably distributed over the whole thread contour in case of locking miniplates as compared to conventional miniplates. This was very well supported by **Gutwald ralf (2002)**¹¹. At 1st month follow up, one patient in group A reported mild pain which could be attributed to the development of infection around hardware. At 3rd month follow up, the patient who reported with pain at 1st month follow up had underwent surgery & the hardware was removed as the fracture was properly healed with no mobility at 1st month follow up. The patient was having pain because of infection around failed hardware & not because of unhealed fracture; removal of hardware with subsequent resolution of infection relieved him of pain at 3rd month follow up.

The forces that must be countered in mandibular body fracture have been derived from maximum voluntary bite force measurement, which

in healthy adult may be in the order of 48.3 kpa and 49.3 kpa in left and right molar regions respectively (Ellis and Throckmorton, 1994)¹². The amount of force the subjects with fractures can generate is much less. Ellis and Throckmorton (1994)¹² stated that sufficient internal fixation hardware be applied to resist the maximum force of mastication. By doing so, they hypothesized that stability of fracture segment is assured even under full function of the masticatory system.

In our study there was increase in bite force in both the groups at subsequent follow up but the increase of bite force left molar region, right molar region was more in group-B than group-A, taking 2nd day bite force as base line compared to 1st month bite force. It is supported by the fact that the screws, plate, and bone form a solid framework with higher stability in case of locking miniplate than the traditional miniplate system. Following observation of our study is supported by Ayman chritah (2005)⁹, Mohit agarwal and Shadab mohammad (2011)¹³. But bite force achieved in patients of mandibular fracture treated either by locking or non- locking miniplates failed to meet the reported maximum voluntary bite force of a healthy adult. This could be attributed to the fact that neuromuscular protective mechanism occurs throughout the body. Moreover bite force is related to a number of factors such as tactile impulses, pain and pressure reception in periodontal ligament and number of residual teeth thereby limiting the patient's ability to apply pre trauma bite force. Gerlach et al (2002)¹⁴ stated that maximum bite force in patient with mandibular fractures treated with miniplate osteosynthesis reaches only 31% at 1 week postoperatively, compared to healthy control group. These value increases to 56% at the 1st month postoperatively. In group A there was 1 (i.e 10 %) patient who reported with infection, it was confirmed on surgical exploration that it happened become screw loosening with eventual hardware failure. Which is in accordance with Rajendra Prasad et al(2015)¹⁵ Manoj Goyal (2011)¹⁶, Neelima J et al (2018)¹⁷ who reported no incidence of infection and hardware failure in 3 D Locking mini plate group. While Sebastian et al (2010)¹⁸ in his study reported 1 case with screw loosening and infection due to incorrect depth of drilling and screw placement in locking mini plate group. Screw loosening in non locking 3D miniplates could be due to tortional forces between bone fragments leading to loss of frictional lock between bone and screw or, might have been possible due to improper osteotomy procedure, while in case of locking 3 D miniplates the thread on the screw head locks into the congruent thread of the plate, transforming the screws and plate into a unit, creating a rigid splint with higher mechanical stability. In present study surgical ease was evaluated under following parameters: Adaptation of plate during drilling, surgical accessibility, requirement of emergency screw, time required for the surgery, protective barrier for surrounding tissue during drilling. Adaptation of plates was all time easier in group B compare to group A. While surgical accessibility was found to be lot more easier in group A as the drill guide attached to the pate for drilling holes, in case of 3 D locking miniplates at times lead to hindered placement because of limitations of stretched of corner mouth. Secondly 3 D non locking miniplates allows angulated screw placement to a certain degree which is not feasible with 3 D locking miniplates. There by having difficulty in screw drillings in premolar region due to corner of mouth. In group A two cases required placement of emergency screws, owing to the play or less stable hands while drilling holes. While drill guide attached to 3 D locking miniplates does not allow play to sufficient degree which dictates placement of emergency screw. Owing to more armamentarium required for drilling holes in 3 D locking miniplates. General time required for surgery was lesser in 3 D non locking miniplate group as compare to 3 D locking miniplate group. This is in contrast to chad. P. Collins (2004)¹⁹, ayman chritah et.al. (2005)²⁰. While drilling holes one must ensure proper retraction of surrounding soft tissue so as to prevent injury & achieve uneventfull healing. The drill guide of 3 D locking miniplates acts as self protective barrier while in 3 D non locking one assistant is required to stabilize & protect the surrounding tissues with retractors to prevent injury while drilling which in itself adds on the total time required for fixation of 3 D non locking miniplates compared to 3 D locking miniplates. The overall surgical ease of fixation was more in group B compared to group A with only limitation being surgical accessibility.

The art of surgery demands that we evaluate the risk and benefits of each treatment modality and apply appropriately for each patient. As treatment options expand, it remains imperative that we consider the anatomic, physiologic and biomechanical factors associated with managing these injuries. From the advent of osteosynthesis in

maxillofacial surgery, different systems have been designed to overcome the shortcomings of existing devices. After completed our study results suggests that 3 D locking plate/ screw system have more promising results compared with the 3 D non locking mini plate/ screw system. Further studies with a larger sample size eliminating confounding factors are required to ascertain the clinical benefits of the theoretical advantages of this system; over that of Non Locking 3D miniplates.

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