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Assessment of bite force– A comparative evaluation between three dimensional locking plate versus conventional miniplates in the treatment of mandibular fractures – A prospective clinical study
Subject: Surgery

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ABSTRACT:
Aim and objectives: The aim of this study is to assess the efficacy of 2.0 mm three dimensional (3D) titanium locking plate system and to compare it with 2.0 mm conventional titanium plating system in mandibular fractures. **Materials and Methods:** Among 20 patients, 10 patients were treated with open reduction and internal fixation using 2.0 mm three dimensional locking titanium plates in group I and 10 patients were treated using 2.0 mm conventional titanium miniplates in group II. The patients were assessed at periodic intervals for 6 months postoperatively. The patients were evaluated for bite force, stability, operating time and segment approximation. Chi-square test was applied to compare the results within the group and Mann Whitney U test were used to compare more than two systems. **Results:** The bite force was superior in the study group than the control group and it was statistically significant with higher value after first month. The fracture site stability was reliable in all the cases. The operating time was higher for control group than the study group and it was statistically significant. Though the result between the groups were statistically insignificant for segment approximation, there was a slight increase in the study group on comparing with control group. **Conclusion:** Based on this study, the clinical outcome of 3D titanium locking plate system showed statistically significant advantages of improved bite force and lesser operating time than the titanium conventional miniplate system, there are few advantages and disadvantages in both 3D locking and conventional miniplates. An identical study with a large sample size could give a definitive result.

Keywords: 3D Locking plate and screw system, Conventional mini plates, Mandibular fractures, Open reduction internal fixation (ORIF).

I. INTRODUCTION:

The management of maxillofacial trauma has evolved significantly over the centuries. The ultimate achievement for any fixation technique is to ensure a stable, harmonious occlusion and optimum post-operative masticatory function.[1] The evolution of mandibular fracture fixation mainly includes two approaches. Spiessl et al proposed rigid stabilization and Champy et al proposed semi-rigid fixation.[2] Conventional bone plate/screw systems require precise adaptation of plate to the underlying bone which is not required in case of locking plate/screw as the screws are tightened, they lock to the plate thus stabilizing segments. Also the latter provides greater amount of stability across the fracture/ osteotomy.[2]

Farmand and Dupoirieux in 1992 introduced the concept of three dimensional (3D) miniplates which is quadrangular in shape that has a geometrically stable configuration for support. It creates 3D stability of fractured and osteotomized bony segment. In 3D plates, the transverse bars were at right angles to fracture line and vertical

ones were parallel to it.[3] The 3D plating system uses fewer plates and screws as compared to conventional miniplates to stabilize bone fragments in symphysis and parasymphysis regions thereby using lesser foreign material, decreasing operation time and reducing overall cost of treatment.[2] Three-dimensional plating system gives 3D stability to the fractured segments during healing. On the other hand, Locking system does not allow screw loosening and alteration in bone alignment or occlusal discrepancies on screw tightening. Thus Three-dimensional locking plates have been designed to solve the disadvantages of the both the systems and also to combine the advantages of both systems in the management of mandibular fractures.[2]

Comparing the efficacy of 3D locking plate system with conventional miniplating system with bite force as one of the criterion only have limited studies when concerned with literature review. Considering the above background, a study was conducted to compare and evaluate 2.0 mm 3D titanium locking plates and 2.0 mm conventional titanium plates in the treatment of mandibular fractures.

II. MATERIALS AND METHODOLOGY:

The patients who reported to the department of Oral and Maxillofacial Surgery at CSI College of Dental Sciences and Research, Madurai for the treatment of mandibular fracture were selected in this prospective comparative clinical study. Prior approval and ethical clearance was obtained from the Institutional ethical committee (CSICDSR/IEC/0182/2021). All the subjects participated in this study were explained about the nature of the study and a written informed consent was obtained from all the participants.

Inclusion Criteria include fracture requiring open reduction and internal fixation in the various regions of mandible, 16 – 60 years old patient of both gender. Exclusion Criteria include preoperative infection at the site of fracture, comminuted fracture, untreated fracture more than 2 weeks, decreased mandibular vertical height between root apex of teeth and lower border of mandible.

The patients were categorized into two groups. Study group: Odd numbers (n=10) were included in which the fixation was done with 2.0 mm titanium 3D locking plate and 2x10mm titanium locking screws. Control group: Even numbers (n=10) were included in which the fixation was done with 2.0 mm titanium conventional plate and 2x10mm titanium conventional screws. If the patient had fracture at two different sites of mandible then both the sites were included in the same group.

All patients included in the study underwent clinical examination including case history, radiological investigations, surgical profile as per protocol. All the cases were performed under strict aseptic protocol. Under nasotracheal intubation, general anesthesia was administered. After preparation and draping of surgical site, local anesthesia with adrenaline (1:2,00,000) was administered along the surgical site. A standard vestibular incision was given or through existing extraoral laceration, the fracture site was exposed, anatomically reduced and maximal intercuspation was achieved. MMF was done to stabilize the occlusion. Operating time was measured in minutes after achieving anatomical reduction till the placement of last screw. In the study group 2.0 mm titanium 3D 4 hole locking plate was placed in an ideal position on either side of fracture site and the 2 x10mm titanium locking screws were tightened to engage both the bone and the plate. In the control group, a standardised protocol was followed for miniplate fixation as per champy's principle using 2.0mm titanium conventional 4 hole with gap plate and fixed with 2x10mm titanium conventional screws. MMF was released and occlusion was checked. Surgical site was irrigated with betadine, saline and primary closure was done. All the patients were extubated uneventfully. Post operative antibiotics and analgesics were administered. Patients were advised to rinse the mouth with 0.12% Chlorohexidine mouth rinse and to maintain proper oral hygiene.

The patients were reviewed on the first post-operative day to evaluate post operative pain, bleeding from surgical site, inflammation and stability. An immediate post-operative digital orthopantomogram was taken at this stage to evaluate segment approximation. All the patients were recalled after 1 week to evaluate the bite force, soft tissue healing, evidence of paresthesia and the skin sutures were removed. In case of paresthesia, Capsule Renerve Plus was prescribed for 15-30 days O.D. Bite Force was measured using Customised flexiforce sensor device. Stability (Fragment rigidity) was analyzed by passive occlusion and bimanual palpation. Bite force measurement and stability were assessed at first month, third month and sixth month postoperatively. Digital Orthopantamogram was taken at third month, sixth month postoperatively for evaluating segment approximation.

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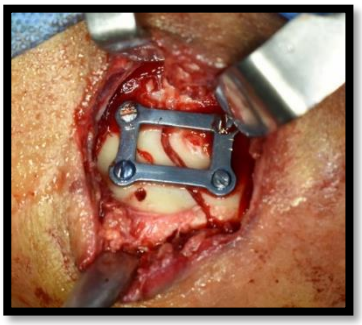
THREE DIMENSIONAL TITANIUM LOCKING PLATE SYSTEM

Pre Operative Orthopantamogram



3D plate fixation

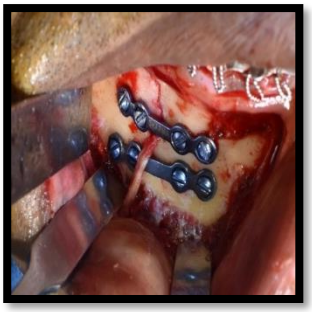
Bite force

Immediate Post Operative Orthopantamogram

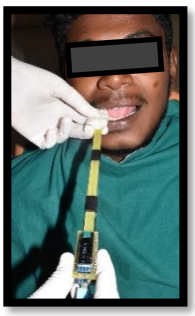
VI month Post Operative Orthopantamogram

CONVENTIONAL TITANIUM MINIPLATING SYSTEM

Pre Operative Orthopantamogram



Conventional plate fixation



Bite force

Immediate Post Operative Orthopantamogram

VI month Post Operative Orthopantamogram

III. STATISTICAL ANALYSIS:

The statistical analysis was performed using "statistical package for social sciences"

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("SPSS", version 26) software package ("IBM corporation, Armonk, USA"). Intergroup comparison for "bite force" (affected and unaffected side) recorded at four different time periods: one week, one month, three months and six months was performed using "Mann Whitney U test". Intergroup comparison for "segment approximation" (affected and unaffected side) observed at three different time periods: after one day, three months and four months was performed using "chi square test".

IV. RESULTS:

On evaluating the gender distribution among groups, 80% males and 20% females were involved in case group and 80% males and 20% females were involved in control group. Thus males were more commonly affected by trauma than females as shown in table 1. On evaluating the age distribution in group I and II, most of the patients fall under the category of 16-60 years (Mean age = 28.95 ± 10.45) as shown in table 2.

Table 1: Distribution among groups according to gender

	Group 1	Group 2	Total
Male	8	8	16
Female	2	2	4

Table 2: Age distribution among groups

	Group I	Group II
Mean age group	33±11.5	24.9±9.4

In both the groups, road traffic accident (RTA) (75%) was the most common etiologic factor for fracture of mandible. In the group I, 7 (70%) out of 10 mandibular fractures were due to RTA, 2 (20%) were due to self fall and 1 (10%) was due to sports injury. In the group II, 8 (80%) out of 10 were RTA cases and remaining 2 (20%) cases were due to self fall as shown in table 3. In this study, Parasymphysis, angle of mandible and condylar fracture region were equally seen. Parasymphysis fractures mostly associated with condyle fracture and in some cases along with other anatomical sites as shown in table 4.

Table 3: Distribution of patients according to etiology

	Road traffic accident (RTA)	**Assault**	**Self-fall**	**Sports injury**	**Total**
Group 1	7	0	2	1	10
Group 2	8	0	2	0	10

Table 4: Distribution of fracture site among the group

	Symphysis	**Para symphysis**	**Mandibular body**	**Mandiblular angle**	**Condyle or sub condyle**	**Total**
Group I	1	7	0	6	2	16
Group II	2	4	4	2	7	19

Although higher bite force was observed in affected side for case group after: one week (46.60±16.51), one month (259±63.48), three months (515±89.97) and six months (661.90±90.6), in comparison with control group [one week (54.50±13.79), one month (174.30±42.19), three months (497.5±81.65) and six months (596.8±70.58)], statistically significant difference was observed only after one month (p=0.004) and after six months (p=0.043).The bite force was observed to be greater on the unaffected side for study group at all the assessed time periods: one week (167.2±45.34), one month (383.5±91.42), three months (768.5±78.65) and six months (771.8±79.38), in comparison with control group [one week (161.4±25.58), one month (365.4±50.05), three months (700.4±111.07) and six months (711.6±110.71)], the differences were not statistically significant as shown in table 5.

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Table 5: Intergroup comparison for bite force performed using Mann Whitney U test

	Group	N	Mean	Std. Deviation	Std. Error Mean	P value
Bite force Affected one week	Case group	10	46.60	16.514	5.222	0.280
	Control group	10	54.50	13.786	4.360	
Bite force Unaffected one week	Case group	10	167.20	45.340	14.338	1.000
	Control group	10	161.40	25.579	8.089	
Bite force Affected one month	Case group	10	259.00	63.477	20.073	0.004*
	Control group	10	174.30	42.188	13.341	
Bite force Unaffected one month	Case group	10	383.50	91.419	28.909	0.481
	Control group	10	365.40	50.045	15.826	
Bite force Affected three months	Case group	10	515.00	89.970	28.451	0.052
	Control group	10	497.50	81.650	25.820	
Bite force Unaffected three months	Case group	10	768.50	78.646	24.870	0.914
	Control group	10	700.40	111.072	35.124	
Bite force Affected six months	Case group	10	661.90	90.602	28.651	0.043*
	Control group	10	596.80	70.578	22.319	
Bite force Unaffected six months	Case group	10	771.80	79.383	25.103	0.035*
	Control group	10	711.60	110.714	35.011	

*p<0.05 is statistically significant
**p<0.001 is statistically highly significant

In both group I and group II, the fracture site stability and rigidity was evaluated manually by checking the segment mobility across the fracture site. It was stable in both groups. The operating time was reported to be higher for control group (28.25±4.45) when compared with study group (19.9±2.53) and the observed difference was statistically significant(p=0.038) as shown in table 6.

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Table 6: Intergroup comparison of operating time performed using Mann Whitney U test

	Group	N	Mean	Std. Deviation	Std. Error Mean	P value
Operating time	Case group	10	19.900	2.5254	0.7986	0.038*
	Control group	10	28.250	4.4550	1.4088	

*p<0.05 is statistically significant
**p<0.001 is statistically highly significant

The chi square test revealed that there was no statistically significant difference with respect to "segment approximation" observed at three different time periods: after one day (p=0.314), three months (p=0.5) and four months (p=0.5).

V. DISCUSSION:

Maxillofacial surgery has evolved over the years and there has been a paradigm shift from closed reduction to open reduction of fractures with the aim of improving the overall outcome of treatment without compromising the form, function or aesthetics enabling the rapid recovery of the patient.[2] But with the standard miniplates, loosening of screws due to transmission of pressure to the underlying bone led to loss of fracture stability and then fixation failure. Other limitations of standard miniplates include need for precise adaptations and less stability across the fracture site.

Locking plate systems have many advantages over other plating systems. The theoretical advantages of locking system are: 1) less screw loosening 2) greater stability across the fracture site 3) less precision required in plate adaptation 4) presence of less alteration in osseous or occlusal relationship upon screw tightening and no need for a friction lock between plate and bone for stability resulting in decreased pressure transmitted to the underlying bone.[2] The disadvantages of locking plates are that these plates require to 'center' the drill hole with the plate hole to ensure perpendicular placement of the screw. If screws are not placed perpendicular to plate the screw will not engage the threaded plate hole precisely and therefore will not lock. Another disadvantage of locking plate is it is expensive when compared to the conventional plates.[3]

The introduction of 3-dimensional (3D) system has offered certain advantages over other plating systems. Advantages include: (1) close approximation, (2) greater stability across the fracture site (3) less precision required in plate adaptation (4) less alteration in osseous or occlusal relationship upon screw tightening (5) less operating time.[4] Possible limitations of 3D miniplates include excessive implant material due to the extra vertical bars incorporated for countering the torque forces limits its use. The expenditure of these plates are slightly more than the conventional plates. Difficult to adapt at the mental foramen region.[3]

In the present study, 20 patients were evaluated, 10 in study group and 10 in control group with isolated mandibular fracture. Though we included both the genders, the study showed high male predominance 80%, with male to female ratio 4:1. Only healthy adults in the age group of 16 to 60 years with a mean age of 28.95 years were included in the study. These demographic data was correlated with the study which was done by Mohsin Khan et al, Uttar Pradesh, who reported 80% incidence of mandibular fracture in males and mean age of patients was 29.45years.[4]

The present study was conducted in our institution at Madurai, a city in southern part of India with quite high density of population, where the most common etiological factor for mandibular fracture was road traffic accident (77.5%), followed by self-fall (20%). The results were comparable to the study by Pavan Kumar et al, Andhra pradesh, India, who concluded that 85% fractures occurred due to road traffic accidents followed by self fall and interpersonal violence.[5]

In this study, Parasymphysis, angle of mandible, condylar fracture region were equally affected. Parasymphysis fractures were mostly associated with condyle fractures and in some cases along with other anatomical sites.

In our study, we evaluated bite force, stability (fragment rigidity), operating time and segment approximation for all patients at regular interval of time. Maximum bite force is one of the best indicator to know about the functional state of the masticatory system. In this study, Bite force was evaluated between maxillary and mandibular first and second molar on both right and left side using customized flexiforce sensor device. Post operatively the bite force was assessed after a week then after a month followed three months and six

months subsequently in the affected side and unaffected side. Higher bite force was observed in affected side in the study group at all the assessed time periods. One week, one month, three months and six months postoperatively in comparison with control group [one week, one month, three months and six months postoperatively], the differences were statistically significant only after one month and after six months. The bite force was recorded and observed. The result was greater on the unaffected side in the study group at all the assessed time periods: one week, one month, three months and six months in comparison with control group [one week, one month, three months and six months], the differences were not statistically significant. The results were comparable to the study by Bhupendra Harjani et al, Uttar Pradesh in which locking group showed significant increase in bite force at all follow up as compared to nonlocking group.[6]

Stability (Fragment rigidity) was analyzed by passive occlusion and bimanual palpation in both cases and controls. The fracture site stability and rigidity were evaluated manually by checking the segment mobility across the fracture site. It was stable in all cases. One of the main advantage of 3D plates is their improved stability compared with standard miniplates. In this study, Postoperative segmental mobility was not evident in any of our cases, whereas Manoj Jain et al reported 10% segmental mobility in a study series of 20 patients.[7]

The operating time was reported to be higher for control group when compared with study group and the observed difference was statistically significant. Feledy and Hughes in their clinical study stated that the reduced average operating time is due to the easier application of 3D plates. They also commented that because of simultaneous stabilization at both superior and inferior borders 3D plates are a time saving alternative to conventional miniplates. Deepak Yadav et al, concluded that 3D plates fixation had significantly faster fixation time compared to conventional mini plates and was statistically significant.[7]

In our study, Segment Approximation was evaluated using Orthopantamogram. Though the results showed better approximation at the end of third month and sixth month in study group than in control group, the differences were not statistically significant. In a biomechanical comparison study by Alper Alkan et al, they concluded that stability is better with 3-D plating system.[7]

Patients were evaluated preoperatively and postoperatively after surgery for the signs of infection. None of the cases in both the groups showed any signs of postoperative infection, wound dehiscence or plate exposure. Zix et al reported 0% infection rate in their study. In that study it has been stated that fractured segment mobility is a major causative factor in post-operative infections. Therefore the improvement of plate stability might minimize this problem. Guimond et al also stated the low incidence of plate exposure and wound dehiscence with the use of 3D plate in comparison to Champy's miniplate.[7] Occlusion of the patient was evaluated on both preoperative and postoperative period. No significant statistical difference of incidence of malocclusion between the cases and controls. This is consistent with the study done by Pavan Kumar et al in which statistical analysis did not show significant difference of incidence of malocclusion between the two groups.[5] In case of malocclusion cases, Intermaxillary fixation was done. Paresthesia was evident in two cases of group II along the distribution of inferior alveolar nerve. Both of the cases had fracture of body of mandible. Postoperatively patient showed complete return of sensation in 3 months. And also in these two cases, we didnot use 3D locking plate because of the presence of mental nerve in that region. It is one of the major disadvantage of 3D locking plate.

VI. CONCLUSION:

Based on this study, the clinical outcome of 3D titanium locking plate system showed statistically significant advantages of improved bite force and less operating time than the standard titanium miniplate system, there are few advantages and disadvantages with the use of 3D locking miniplates which are highlighted. Even so the merits of 3D locking plates include relatively lesser operating time with higher bite force, a "one-plate- for- all" system i.e. minimizing the number of fixation system, stabilization at both the superior and inferior borders giving three dimensional stability at fracture site, lesser trauma to the periosteum and soft tissues and better stability, it also has certain demerits like excessive implant material due to the extra vertical bars incorporated for countering the torque force and it cannot be used in cases where the fracture line passes through oblique fractures and mental foramen region. In those cases, 3D plates cannot be adapted. Based on the study, we are suggesting that the area of fracture should also be the criteria to decide the type of plating system. Thus a similar study with large sample size could give a definitive result.

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