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A Prospective Randomized Clinical Trial Comparing 3-Dimensional and Standard Miniplate in the Treatment of Mandibular Symphysis & Parasymphysis Fractures

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Abstract

Hippocrates first described the re-approximation of fractured segments with use of circumdental wires and external bandaging. Over the years, the management of trauma has evolved from supportive bandages, splints, circumandibular wiring, extraoral pins, semirigid fixation with transosseous wiring to rigid fixation, and more lately back to semirigid fixation with miniplates (Fonseca & walker 1997) . From the time of Hippocrates, physicians have described many different techniques for treating mandibular fractures, the principle of which has always been precise anatomic reduction and fixation of the bony fragments. Treatment required the jaw to be immobilized for a prolonged period and patient to be on liquid diet. However changing society, and reluctance of many patients to wear intermaxillary fixation for prolonged period forced surgeons to look for different methods which led to development of open reduction and internal fixation (ORIF). Even though these objectives can often be achieved by closed reduction and inter-maxillary fixation (IMF), unfavourable displaced fractures require open reduction and internal fixation.

Keywords: Parasymphysis Fractures, maxillofacial skeleton, tumors

Introduction

In a developing country like India, with increase in urbanisation, rapid influx of high speed automobiles, poor road conditions, road traffic accidents are scaling heights and the incidence of traumatic injuries to the maxillofacial skeleton are increasing alarmingly. The face is the window through which we perceive the world around us and the world noted us. It serves a crucial role in human interaction and injuries to it result in devastating emotional sequelae. The human face constitutes the first contact point in several human interactions, thus injuries and/or mutilation of the facial structures may have a disastrous influence on the affected person (A. Leite Cavalcanti et al 2008)1 . The facial area is one of the most frequently injured parts of the body, and the mandible is one of the most commonly fractured maxillofacial bones. For the past decades, there has been a significant increase in maxillofacial traumas involving mandible. They are mainly caused by vehicular accidents, sport activities, penetrating injuries, physical assault, work-related accident, metabolic diseases or tumors (Lucas Gomes Patrocínio et al 2005)2 . The position, prominence, anatomic configuration, mobility and less bone support of the mandible make it one of the most frequent facial bones to be fractured. The mandibular fracture account for 36% to 54% of all fractures in the maxillofacial region, followed by the maxilla (46%), the zygoma (27%), and the nasal bones (19.5%)(Rafa-Abdelsalam Elgehani et al 2009)3 . Mandible is the 10th most fractured bone in the whole body. They may occur alone or in combination with other facial bone fracture. It plays a major role in the mastication, speech and deglutition. Its fractures result in severe loss of function and disfigurement (Ashfaq Ur Rahim et al 2006)4 . Fractures through the mandible at the level of the Symphysis and or parasymphysis are relatively common and account for approximately 20% of mandibular fractures. These fractures are often associated with a second fracture of the mandible, especially in the subcondylar region (Zachariades N et al 2006)5 . Fractures of the symphyseal region are often associated with the clinical findings of a widened intragonial distance with resultant malocclusion. Fractures of the anterior mandible lack two of the stabilizing factors provided to fractures of the posterior tooth-bearing mandible: the splinting effects of the masseter and internal pterygoid muscles, which form a natural sling, and the interlocking cusps and fossae of bicuspid and molar teeth (Mahmoud E Khalifa et al 2012)6 . Friedrich and associates reported that in patients with mandible fractures, 43% of the patients had an associated injury. Of these patients, head injuries occurred in 39% of patients, head and neck lacerations in 30%, midface fractures in 28%, ocular injuries in 16%, nasal fractures in 12%, and cervical spine fractures in 11%. Other injuries present in this group were extremity trauma in 51%, thoracic trauma in 29%, and abdominal trauma in 14%. 2.6% died of their associated injuries before the mandible fracture could be treated (Donald R Laub Jr et al 2009) 7 . This method is also indicated when IMF is undesirable. There are many situations in which IMF is contra-indicated or relatively contra-indicated. These include the treatment of epileptics, alcoholics and others with drug addiction, those with chronic obstructive airways disease and any condition in which the airway is compromised or potentially compromised. Williams and Cawood have shown that tidal volume may be reduced by up to 40% in patients whose teeth are wired together(JG Williams et al 1990)9 . Cawood has also demonstrated improved mouth opening after Introduction 4 treatment of mandibular fractures with small plate osteosynthesis (Cawood J I 1985)10 . Stable plate osteosynthesis has become an indispensable component of craniomaxillofacial surgery in treatment of fractures and osteotomies of the face(Beal Sp et al 1987) 11. Since the presentation of plate fixation for craniomaxillofacial surgery almost 30 years ago (H W et al 1980) 12, several systems with different charecteristics have been introduced. Spiessl and the AO/ASIF group (Arbeitsgemeinschaft fur Osteosynthese fragen/ Association for the Study of Internal Fixation) introduced the use of rigid plates with 2.7 mm bicortical screws in 1972. This was an adaptation of the experience with internal fixation in long bones with particular modifications for the mandible. The disadvantage with these rigid plates was movement of the fracture fragment while tightening the screws resulting in malocclusion. Also these plates could only be minimally adapted to the fracture fragments and produced more tension on the bone resulting in loosening of screws. . They also require an extraoral approach and are highly technique sensitive. Later a method of stable fixation with mini-plates and 2 mm mono- cortical screws was advocated by Michelet in 1973 for the midface (Michelet Fx et al 1973)29 and was applied to the mandible by Champy in 1978 (Champy M et al 1978) 31 . The requirements of an ideal miniplate for semirigid fixation are that the plates should resist forces depending on the location and be biocompatible and especially easily adaptable , without dislocation of the fragments . The principle of osteosynthesis according to Champy was to restablish the mechanical qualities of the Introduction 5 mandible , hence he advised to use two miniplates in the anterior region. One at the inferior border and second 5mm above the lower plate (Champy M 1978) 31 . Although several materials can be used for manufacture of small plates, generally titanium is used because of its excellent biocompatibility, resistance to corrosion and pliability. Champy’s miniplates require intra oral approach, less technique sensitive and produce consistently good result with regard to occlusion and also avoid the need for IMF.The main advantages of the technique of ORIF include avoiding intermaxillary fixation (IMF) with its hazards to the airway, a more rapid return to normal function with a reduced incidence of weight loss and improved early jaw opening. The conventional rigid fixation technique employs thick compression plate along the lower border of the mandible which negated the forces of torsion and shear, but had the disadvantage of bicortical screws, whereas, the Champy’s osteosynthesis principle produced a natural strain of compression along the lower border of the mandible caused due to mastication. These drawbacks of rigid and semirigid fixation led to the development of three-dimensional (3D) miniplate consisting of two miniplates joined by interconnecting struts. In 1991 , Mostafa Farmand developed the 3 D plates for treating the mandibular fractures .The geometry of 3D plates conceptually allows for stability in three dimensions, and resistance against torque forces while maintaining a low profile and malleability. Unlike compression and reconstruction plates, their stability is not derived from the thickness of the plate but from configuration. In combination with the mono cortical screws fixed to the outer cortex, the rectangular plate forms cuboids, which possesses 3D stability (Farmand 1991) 13 . Introduction 6 The 3D plate doesn't allow for any movement at the superior and inferior borders with manual torsional and bending forces, as opposed to when a single linear plate is applied to the superior border area. When only one linear plate is placed at the superior border, torsional and bending forces usually cause movement along the axis of the plate with buccal-lingual splaying and gap formation at the inferior border, respectively. The basic concept of 3D fixation is that a geometrically closed rectangular plate secured with bone screws creates stability in three dimensions. The stability is gained over a defined surface area and is achieved by its configuration and not by thickness or length (Farmand 1995)14 . The newly introduced 3D plating system provides definite advantages over conventional miniplates. The 3D plating system uses fewer plates and screws as compared to conventional miniplates to stabilize the bone fragments. In case of conventional miniplates, two plates are recommended in symphysis and parasymphysis region, while only one 3D plate is necessary. Thus it uses lesser foreign material, reduces the operation time and overall cost of the treatment (Farmand 1993) 15 . Only a few studies have previously reported clinical experiences with these plates in the treatment of mandibular fractures. The aim of this study is to compare 3-Dimensional versus 2-Dimensional Titanium miniplates for open reduction & fixation of mandibular symphysis & parasymphysis fracture.

AIMS AND OBJECTIVES:

The aim of the prospective clinical study is to compare the efficacy of Standard miniplate and 3D titanium plate in the open reduction and fixation of the parasymphysis and symphysis fractures by taking certain clinical and radiographic parameters of success into consideration. All the cases will be evaluated for post operative incidence of Pain, Infection, Paresthesia, Segmental mobility, Occlusion, Radiographic reduction.

MATERIALS AND METHODS:

This is a randomized prospective study conducted on patients visiting the out Patient Department of Oral and Maxillofacial Surgery, Regional Dental College, Guwahati with diagnosis of mandibular fractures during the period of 1st april2013 to 1st april 2015. Informed consent was taken. All the cases underwent open reduction and internal fixation either under LA/GA. Details of individual cases were maintained in the proforma. A randomized clinical trial was conducted in which patients satisfying the inclusion criteria as listed below, were randomly assigned into two groups by the coin flip method . Group A 15 patients received 2.0 mm Titanium 3D miniplates. Group B 15 patients received 2.0 mm Titanium standard miniplates.

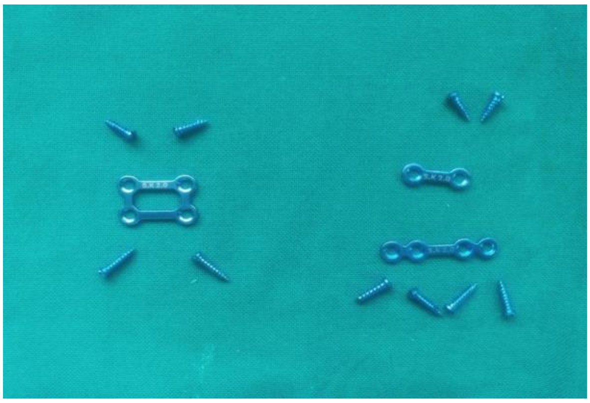


Fig. 1: (On the left – One 4 hole 3 D Titanium plate with four screws 2*6mm and 2* 8 mm and One 2 hole and 4 hole plate with two screws of 2* 6 mm and four screws 2*8mm)

4 holed rectangular Titanium 3 D plate, Titanium 4 holed miniplate and 2 holed miniplate with gap having a thickness of 2.0mm, were used in this study. Monocortical screws (2 mm x 6 mm) and (2 mm x 8 mm) were used. A total of 30 cases of mandibular fractures were selected and analyzed for the study. Both male and female patients between the age 18-60 yrs classified under ASA 1 were included in the study.

Patients with mandibular fractures involving symphysis or parasymphysis fractures and other accompanying angle or condylar fractures which does not require open reduction, patients available for regular periodic review and patients with fractures with or without displacement requiring open reduction were included in the study. Patients with Communited fractures, Infection of the fracture site on initial presentation, Fracture resulting from gun shot wounds, Immunocompromised medical status and Patients with ASA -2 and ASA -3 were excluded from the study. All the armamentarium used in the study can be categorized as follows. Material for mandibular osteosynthesis are Osteosynthesis (Plating) kit, 2mm titanium miniplates and screws, Drapes were used. Open reduction and internal fixation (ORIF) for the symphysis and parasymphysis fractures required, 2 titanium miniplates of 2mm thickness ,one 4 hole with gap and another 2 hole with gap were used for osteosynthesis.6 screws ,4 of them of 8mm length and 2 of them 6mm length were used. ORIF was done as per the champy's ideal lines of osteosynthesis.

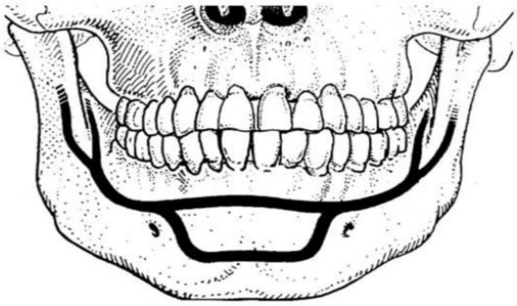


Fig. 2 Champy's lines of Osteosynthesis

2% Lignocaine injection with 1:80,000 adrenaline, 2ml and 5 ml disposable syringes with 26 G needle, Cheek retractor, Mouth prop no.1-4, Mouth mirror and probe, College tweezers, Macindoe's toothed and non toothed forceps, Bard parker blade no.15 with handle, Moltz no 9 periosteal elevator, Howarth periosteal elevator, Tongue depressor, Langenback's retractor, Metal suction tip no.1-4, Surgical physiodispenser and micromotor system and a straight handpiece, Burs-straight fissures-

702/703, Titanium Miniplates and monocortical screws, 3 D Titanium plate, Screw holder and screw driver, Plate bender, Bone holding forcep, Wire twister, wire cutter and 26 Guaze wire, Erich's arch bars, Suture material-3-0 mersilk with3/8 circle round body needle, Suture cutting scissor and needle holder are used for the study.

A standard proforma was used to collect necessary information regarding each case. A detailed history was ascertained and entered in the proforma. A detailed previous history was recorded. Past history of taking any drugs, antibiotics and any history of previous hospitalization, associated illness and habits and diet were recorded in detail. Any significant family history was also recorded. General examinations was carried out in detail considering features suggestive of anemia and jaundice, examination of other systems and of the part concerned were done in detail. Inspection and palpation of the soft tissues followed by a detailed examination of the underlying hard tissue was done.Presence of edema, ecchymosis and hematoma, Presence of extra oral and intra oral wounds, Jaw opening, Tenderness at the fracture site, Step deformity, Teeth in the line of fracture, Presence of infection was observed. Preoperative, intraoperative and postoperative records were maintained of all thecases. Routine blood investigations were done pre operatively in all patients. Hb, TC, DC,ESR, RBS, Blood Urea, Serum Creatinine, CT, BT etc. Radiographs like Panoramic Radiograph (OPG), Chest X ray(PA view), CT Scan(mandible) was taken. Preoperative and postoperative radiographs were taken to evaluate the fractures.

The patients with uncomplicated mandibular symphysis or parasymphysis fractures undergoing open reduction and internal fixation were prepared according to the standard protocol and then shifted to the major or minor O.T based on the type of anesthesia given (G.A/L.A).

The surgical sites was scrubbed with Savlon (Chlorhexidine Gluconate 1.5% + Cetrimide 3%) then painted with betadine (povidone iodine 5%) and draped in the usual standard procedure. Disinfection of the oral cavity with saline and betadine (Povidine Iodine 5%) was done. The oral mucosa, submucosa, and facial muscle are highly vascularised and hence a submucosal injection of a vasoconstrictor (Lignocaine with 1: 80,000 adrenaline) reduced the amount of hemorrhage during incision and dissection. Then a curvilinear vestibular incision about 3- 5mm apical to the mucogingival junction, extending anteriorly out into the lip, was given in the mucosa of the anterior mandible to expose the underlying mentalis muscle. The incision was continued in theunderlying mentalis muscle deep and obliquely to the bone. The mucoperiosteal flap was raised carefully, keeping the mental neurovascular bundle intact. The scalpel was directed perpendicular to bone when incising above the mentalforamen to prevent incision of the mental nerve. The mentalis muscle was stripped from the mandible in a subperiosteal plane. Retraction of the labial tissues was facilitated by stripping them off the inferior borderof the symphysis. Subperiosteal dissection of the mandibular body is relatively simplecompared to that of the symphysis because there are fewer Sharpey's fibers inserting into the bone. Controlled dissection and reflection of the mental neurovascular bundle facilitate retraction of the soft tissue away from the mandible. The periosteum istotally freed circumferentially around the mental foramen and nerve. Retracting the facial tissues laterally will gently tense the mental nerve. Using a scalpel, the stretched periosteum was incised longitudinally, paralleling the nerve fibers , in two or three locations. The sharp end of a periosteal elevator teases the periosteum away from the mental foramen and nerve. Any remaining periosteal attachments are dissected free with sharp scissors. This stripping allowed mobilization on the branchesof the mental nerve, facilitating facial retraction and augmenting exposure of the mandible. The fracture was then reduced after establishment of the ideal occlusion with the help of intraoperative intermaxillary fixation. For Group 1, One 4 hole 3 D plate made of Titanium alloy was adapted in the midsymphysis and Parasymphysis region and secured with two 8.0-mm monocortical screws for the inferior border and 6.0 mm mono cortical screws for the superior border. For Group 2, Two 2.0-mm miniplate made of titanium alloy were adapted along Champy's lines of ideal osteosynthesis in the parasymphysis and midsymphysis and secured with four 8.0-mm monocortical screws for the inferior border and 6.0 mm monocortical screws for the superior border. Care was taken to place these screws lateral to the roots and superior to the neurovascular bundle. Intermaxillary fixation was removed soon after the fixation. The surgical site was irrigated with copious saline and betadine followed by a single layer closure with 3-0 mersilk. The muscle and the mucosal layers thus, were closed on a same level. A pressure dressing, such as elastic tape, was used following the mandibular buccal vestibular approach to prevent hematoma and to maintain the position of the repositioned facial muscles which was removed after 24 hrs.

Postoperatively, patients were not put on maxillomandibular fixation and early function was advised. All patients were prescribed chlorhexidine mouthwash (qid) along with regular antibiotic protocol. All patients were kept on the following regime postoperatively-Injection Ceftriaxone Sulbactum 1.5 gm iv/bid/5 days, Injection Amikacin 500mg iv/bid/5 days, Injection Diclofenac Sodium 2cc/im/bid/3 days, Injection Pantoprazole 40 mg/iv/bid/5 days, Chlorhexidene mouthwash QID/15 days,Capsule becosule OD/15 days.

Post operative IMF was not applied to any patient,so as to ensure early function. Prophylactic antibiotics and mouth washes with povidine iodine was prescribed for atleast five days post operatively and a soft diet was advised for a minimum of 2 week . Stitches were removed on the 7th post operative day. The treated patients were prospectively followed and examined for the post operative complications such as Pain, Infection, Paresthesia, Fracture reduction, Segmental mobility, Occlusion, Radiographic reduction.

In all the groups, the patients were asked for pain at the operated site on 1st review (post-op 1st day), 2nd review (post-op 7th day) & 3rd review post-op 15 day and 4th review(6th week).It was recorded using the scoring system i.e., None- (0), Mild -(1), Moderate -(2), & Severe- (3) (Richard H. Gracely,1990)[117]. Infection was recorded in YES/NO ,as per following observations-Purulent discharge from the surgical or fracture site, increased facial swelling beyond 7thpost operative day, fistula formation at the surgical or fracture site with evidence of drainage, fever associated with local evidence of infection (swelling, erythema ortenderness) (Tuovinen V et al 1994)[51]. Sensory disturbances was evaluated in the patients.Patients were asked about the presence of subjective sensation or hyperesthesia in the mental region and about the difference in the nature of sensation when compared withthe non injured side and with the skin of the cheek. Sensory testing was performed using light touch with cotton wool and sharp or blunt differentiation with a sharp dental probe on the skin of the chin and the lower lip. Finally the response was recorded in YES/NO (Tateyuki Iizuka et al 1991)[42.] Intraoperative assessment of fracture reduction was assessed by placing an appropriate gauze stainless steel wire between the fracture fragments and classified as gap and no gap (Sehgal et al 2014)[96]. Intra-operative and post-operative assessment for stability of occlusion was assessed on the 1st, 7th, 30th, 90th post operative day according to the following criteria: Satisfactory - No gap between upper and lower first molars, Mildly deranged - Gap of 1 - 2mm between upper and lower first molars, Deranged - Gap more than 2 mm between upper and lower first molars,(Sehgal et al 2014)[96]**.** Mobility of fractured segments was assessed by digital palpation with index finger of both hands on the 1st, 7th , 30th, 90th post operative day according to the following criteria: Stable- no movement of fragments, Unstable- movement present, need for intermaxillary fixation (Sehgal et al 2014)[96]. The following radiographic parameters were evaluated using an orthopantomogram (OPG). Pre-operative evaluation of displacement of fracture fragments: Undisplaced, Displaced (<5 mm), Severely displaced (>5 mm) (Sehgal et al 2014)[96].

Radiological assessment was done by digital orthopantomograph (OPG). Post- operative radiograph

was taken as early as possible after the surgical procedure and 3 months post operatively.
They were assessed using the following criteria:
Score 3:Radiological evidence of precise anatomic reduction in the fracturesite.
Score 2: Reduced fractures that were slightly displaced but had a satisfactoryocclusion.
Score 1: Poorly reduced fractures that required a second operation to correct pooralignment and unacceptable occlusion (Malhotra et al 2011)[93].

STATISTICAL ANALYSIS:

The clinical and laboratory data were collected and analyzed statistically Arithmetic mean, Standard deviation, One Way ANOVA, Student's unpaired t test.

RESULT AND OBSERVATIONS:

Thirty patients with isolated symphysis or parasymphysis fracture were enrolled in both the groups, with 15 patients in each group. Out of these 6(20%) were in the Symphysis region , 16(53.33%) in the Left Parasymphysis region and 8(26.66%) in the Right Parasymphysis region(Table 1) . Twenty six patients were treated under Local Anaesthesia and four patients were treated under General anaesthesia. All statistical analysis was done using SAS 9.3 software. Patients were divided into five age groups :- 10-20, 21–30, 31–40 , 41–50 and 51- 60 years. In the present study most common age group of patients who underwent surgery were between 21 and 30 years (50 %), followed by 31 and 40 years (23.33%), 41 and 50 years (20%) and (3.33%) for both 10-20 age groups and 51-60 age groups(Table 2, Graph 1). Number of male patients was higher (93.33 %) than the number of female patients (6.67 %) (Table 3, Graph 2) Mean duration of procedure for group A was 43 min and for group B 51 min (Table 4) In our study, pre-operatively, in Group I, undisplaced and displaced fracture fragments were noted in 6 patients (40%) and 9 patients (60%), respectively. In Group II, undisplaced and displaced fracture fragments were noted in 3 patients (20%) and 12 patients (80%), respectively(Table 6) Preoperative occlusion was found to be deranged in 9 patients in group A and 12 patients in group B . In group A four patients and in group B five patients had gap after reduction of fracture fragments (intraoperatively) while there was no gap in eleven patients in group A and ten patients in group B (Table 8 , Graph 4). Postoperative pain was measured using VAS Scale (0–10), where score of 0 was given for no pain, score of 1–4 was considered mild pain, score of 5–7 was considered moderate pain and score of 8–10 was considered severe pain. At 1st week follow-up, there were 5 patients with mild pain and 6 patients were with moderate pain in group A and 8 patients with mild pain and 5 patients with moderate pain in group B respectively. Six patients had no pain in both group A and B (Table 5, Graph 3) The mobility of fracture fragments was checked by digital palpation i.e. placing the index finger of one hand on proximal fragment intraorally and the thumb of same hand on the posterior border of ramus extraorally of one hand and the index finger of the other hand on the distal fragment intraorally and thumb of same hand on the inferior border of mandible of other hand. Applying alternative pressure assessed the stability. In this study, mobility of fragments was present in 7 patients (46%) in Group I and in 9 patients (60%) in Group II, intra-operatively, before reductionStability of fracture fragments was evaluated manually at intervals of immediate post op 7th day, 30th day and 3 months, which was satisfactory (Table 10, Graph 5). Occlusion was checked post operatively at immediate post op 7th day, 30th day and 3 months intervals and all patients showed satisfactory centric occlusion in all follow up reviews (Table 9, Graph 6) Post operative infection was observed in 6.67 %(two) patients (Table 7, Graph 7). Pus discharge was noted from the sutured area, through which fractured site was exposed. But it was resolved with 7 days of antibiotics with i.v. Ceftriaxone sulbactum and Metronidazole. None of the patients complained of difficulty in opening of mouth or difficulty in eating in the long term follow-up. No patient reported parasthesia or anaesthesia of mental nerve (Table 4). Radiological evaluation (Table 11) did not show any statistically significant difference in reduction between the 2 groups. In all cases, radiographs revealed proper approximation of fracture fragments with good bone healing. Implant failure i.e., breakage of plate or screws was not observed in any of the patients of group A and group B at different follow-up.

Table 1: Site of mandibular fracture

Site	**Total**
Symphysis	6 (20%)
Left Parasymphysis	16(53.33%)
Right Paraysmphysis	8(26.66%)

Table 2: Age wise distribution of patients

Age	**Frequency**	**Percent(%)**
10-20	1	3.33
21-30	15	50.00
31-40	7	23.33
41-50	6	20.00
51-60	1	3.33

Table 3: Gender wise distribution of patients

Sex	**Frequency**	**Percent**
Female	2	6.67
Male	28	93.33

Table 4: Comparison of clinical and radiographic parameters

Clinical/radiographic parameter	Group A (15)	Group B (15)
Duration of operation (minutes)	43 min	51 min
Infection	2	0
Paresthesia	0	0
Unsatisfactory radiographic reduction	0	0
Deranged post-operative occlusion	0	0
Mobility between fracture fragments	0	0

Table 5: Pain evaluation (one week post operatively)

Group	No pain	Mild pain(1-4)	Moderate pain (5-7)	Severe pain (8-10)
A	4	5	6	0
B	2	8	5	0
Total	6	13	11	0

Table 6: Comparison between both the groups with respect to Displacement of Fracture Fragments (Pre-operative)

	Undisplaced	Displaced	Severely displaced
Group1	6	9	0

Group2	3	12	0
Total	9	21	0

Table 7: Infection rate of both the groups compared at (1st,7th ,30th ,90th post opintervals)

Table of Group by Infection		1st visit		7th day		30th day			90th day	
		Infection	Total	Infection	Total	Infection		Total	Infection	Total
Group		Nil		Nil		Nil	Present		Nil	
1	Frequency	15	15	15	15	13	2	15	15	15
	Percent	100	100	100	100	86.66	13.34	100	100	100
2	Frequency	15	15	15	15	15	0	15	15	15
	Percent	100	100	100	100	100	0	100	100	100
Total	Frequency	30	30	30	30	28	2	30	30	30
	Percent	100	100	100	100	93.33	6.67	100	100	100
P-value						0.48				

Among both the groups with respect to infection at all time intervals was found to bestatistically not significant i.e. on 1st,7th,30thand 90th post operative days.
(Chi square test : P>0.05)

Table 8: Comparison between both the groups with respect to Reduction ofFracture Fragments (Intra-operative).

	Gap	No gap
Group A	4	11
Group B	5	10
Total	9	21

Table 9: Occlusal stability

		Visit=1st			Visit=7th			Visit=30th		Visit=90th	
Table of Group by occlusion											
		Occlusion		Total	occlusion		Total	occlusion	Total	occlusion	Total
Group		1	2		1	2		2		2	
1	Frequency	6	9	15	6	9	15	15	15	15	15
	Percent	40	60	100	40	60	100	100	100	100	100
2	Frequency	4	11	15	1	14	15	15	15	15	15
	Percent	26.66	73.34	100	6.66	93.3	100	100	100	100	100

						4					
Total	Frequency	10	20	30	7	23	30	30	30	30	30
	Percent	33.33	66.67	100	23.33	76.67	100	100	100	100	100
P Value				0.438			0.03				

Among both the groups with respect to occlusal stability at all time intervals was found to be statistically not significant i.e. on 1st, but it was found to be significant onthe 7th day .On 30thand 90th post operative days, P- value could not be calculated(Chi square test : P>0.005)

Table 10: Fracture stability

Table of Group by Stability of fracture		Visit=1st		7th visit		30thVisit		90th Visit	
		Stability of Fracture	Total	Stability of fracture	Total	Stability of fracture	Total	Stability of fracture	Total
Group		1		1		1		1	
1	Frequency	15	15	15	15	15	15	15	15
	Percent	100	100	100	100	100	100	100	100
2	Frequency	15	15	15	15	15	15	15	15
	Percent	100	100	100	100	100	100	100	100
Total	Frequency	30	30	30	30	30	30	30	30
	Percent	100	100	100	100	100	100	100	100

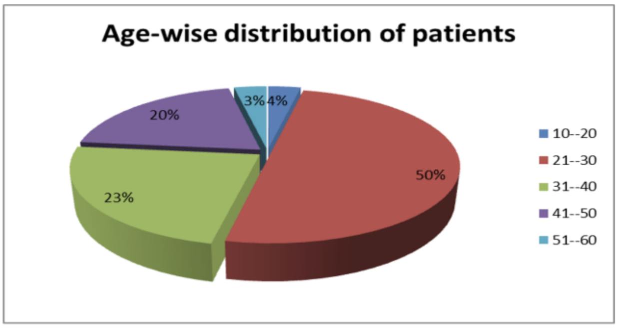
Among both the groups with respect to fracture stability at all time intervals i.e. on 1st,7th,30thand 90th post operative days, P value could not be calculated as no difference was noted in two groups . (Chi square test : P>0.05)

Table 11: Radiographic reduction score

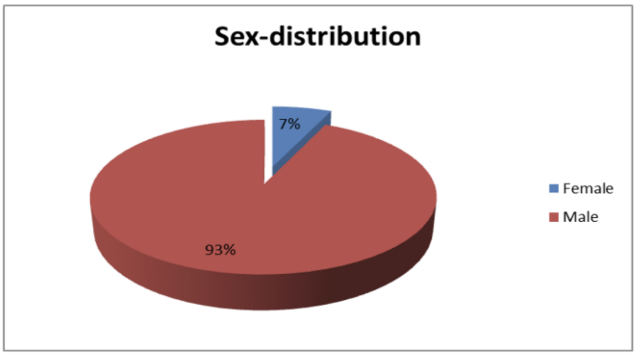
Table of Group by Radiographic reduction score					
		Radiographic reduction score			**Total**
		1	**2**	**3**	
Group		2	27	1	30
1	**Frequency**				
	Percent	3.33	45.00	1.67	50.00
2	**Frequency**	0	27	3	30
	Percent	0.00	45.00	5.00	50.00
Total	**Frequency**	2	54	4	60

	Percent	3.33	90.00	6.67	100.00
P value	0.2231				

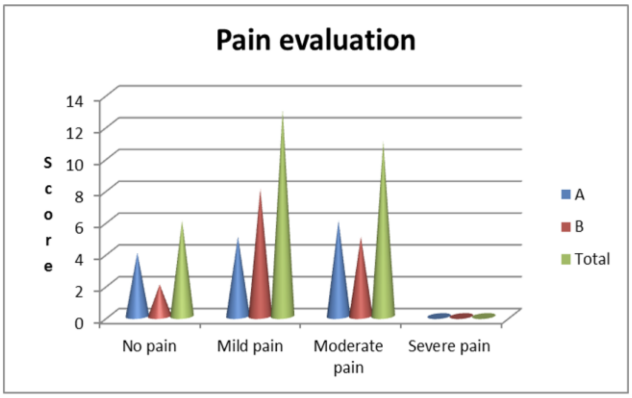
Among both the groups with respect to radiographic reduction score at all time intervals was found to be statistically not significant i.e. on 1st and 90th post operative days. (Chi square test : P>0.05)



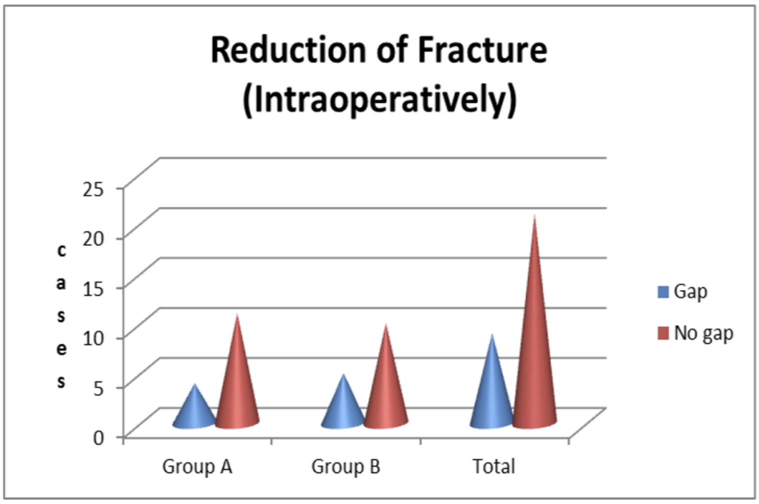
Graph 1. Age wise distribution of patients



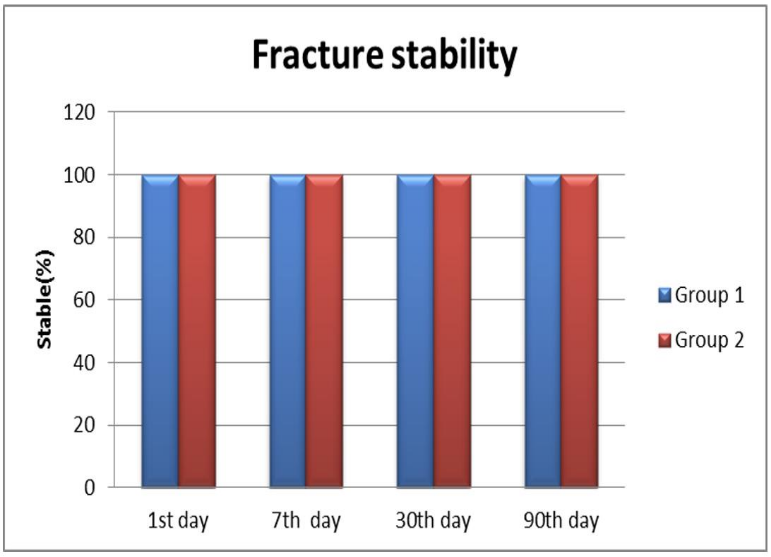
Graph 2: Gender wise distribution of patients



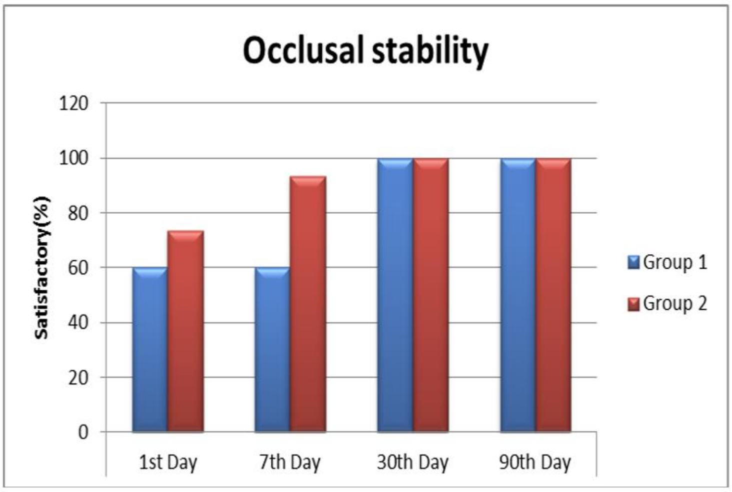
Graph 3. Pain evaluation



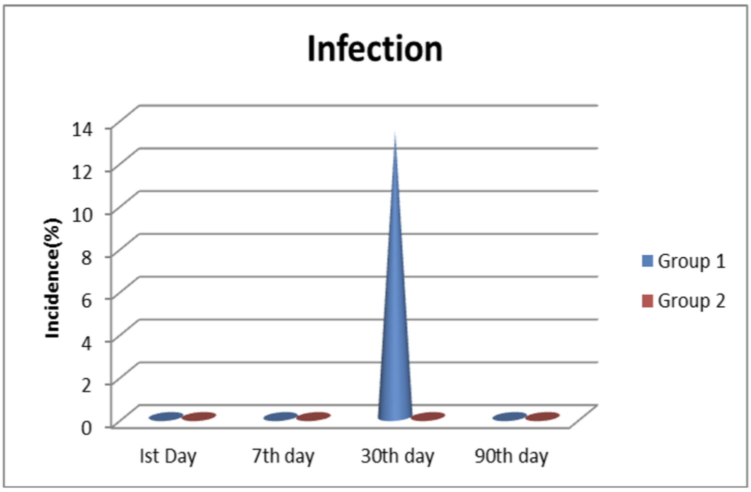
Graph 4: Intraoperative Fracture reduction



Graph 5. Fracture stability of patients (1st day , 7th day . 30th day. 90th day postoperative intervals)



Graph 6: Occlusal stability of patients (1st day , 7th day . 30th day. 90th day postoperative intervals)



Graph 7: Infection rate of patients (1st day , 7th day . 30th day. 90th day post opintervals)

DISCUSSION:

Very few studies in the literature have compared standard miniplate to 3D plate in treatment of a particular site of mandible. A preliminary report in their biomechanical experiment by Feledy et al114 ,found better bending stability and more resistance to out-of-plane movement in the 3D plating system. The use of 3D miniplates in mandibular fracture has not yet become established. Only a few follow-up series are presented in the literature, with few studies (Farmand 1993, Guimond et al 2005) 13 ,72 emphasizing the hardware related advantages over conventional miniplates and reconstruction plates. In the present study, 3D miniplates and 2D miniplates were compared in 30 patients who were randomly divided into two groups. The most common age group of patients who underwent surgery were between 21 and 30 years (50 %), followed by 31 and 40 years (23.33%), 41 and 50 years (20%) and (3.33%) for both 10-20 age groups and 51-60 age group with a mean age of 32.16 ± 18.84 years . Mean age of the patients in other studies were as follows: 28.6 years in the study of Guimond et al. 72, 26 years in Bui et al. 84 and 33.9 years in the study of Zix et al 83 . This could be attributed to greater physical activity and self-mobility seen in this group. This is consistent with findings of previously published work. (Ellis 1992) 46 . The incidence of trauma group above the >50 years is less in our study because up to that age the physical activities become very less. In line with the global picture the male populations are predominantly affected by maxillofacial trauma. This group makes up the most active group in society, and they tend to be more involved in maxillo-facial trauma. Therefore, it is not surprising that males out number females in this study (Gabrielli et al) 70 .

The causes of fracture have extremely variable incidence. In the present study, the decreasing order of frequency found was: road traffic accidents, falls, interpersonal violence, sports related injuries. Road traffic accidents was the most common etiology of fracture as was also observed in other studies by Parmar et al106 , Jain et al 86 . The explanation given for this is that a large proportion of the population uses a motorcycle and other vehicles on a daily basis. High speed, imprudence, use of open helmets or no use of helmets can explain the high number of fractures secondary to road traffic accidents. Moreover, improvements in infrastructure have not kept up with the surge in traffic, and as a result, motorbikes & other vehicles have found a niche as a form of public transport. The main cause of this difference is that safety rules are less compiled by car drivers and motorcycle riders in developing countries compared with the developed countries. However, in some other studies of 3-D plating system, the common etiology of fracture was interpersonal violence as reported by Guimond et al. 72 , Bui et al. 84 , and Zix et al 83 study. In this study the most common site of fracture were 6 patients (20%) in the Symphysis region , 16(53.33%) in the Left Parasymphysis region and 8(26.66%) in the Right Parasymphysis region. This was compatible with the results of the studies conducted by (Vetter et al. 1991, Subhasraj et al., 2006) 111,107 . Fridrich and associates, (1985)109 showed that when fractures due to automobile accidents were considered, the condylar region was the most common site. When motorcycle accidents were considered, the symphysis was affected most often. When assault was considered, the angle demonstrated the highest incidence of fracture.

In our study, pre-operatively, in Group I, undisplaced and displaced fracture fragments were noted in 6 patients (40%) and 9 patients (60%), respectively. In Group II, undisplaced and displaced fracture fragments were noted in 3 patients (20%) and 12 patients (80%), respectively. van den Bergh et al. reported that out of a total of 280 fractures, 66 fractures (23.57%) were severely displaced (>5 mm) and 129 (46.07%) were displaced (<5 mm) Van Den Bergh et al 2012.[108]

There wasn't any statistically significant difference between Group I and Group II with respect to infection rates at follow up visits .The incidence of infection for Group I was 2 cases at 1 month follow up and incidence of infection for Group II was nil after 4 weeks .With the use of open reduction and internal fixation, the reported incidence of infection ranged from 3% to 32%. It has been claimed that mobility of fractured segments is a causative factor in post-operative infections. Because infection is the most common complication in mandibular fractures, the improvement of plate stability might be a way to minimize this problem. The infection rate in group 1 was 6.67% at the third follow-up probably due to the patients poor oral hygiene , whereas in other studies, the infection rates were: 5.4% in the study of Guimond et al. 72, 0% in Zix et al. 83 , 8.2% in Bui et al. 84 , 10% in Jain et al. 86, and 6.6% in Parmar et al. 106 . Paresthesia of mental nerve was 0% in this study and is similar to that reported by Jain et al.86 and Parmar et al. 106 , whereas in other studies like those of Guimond et al. 72 and Zix et al. 83 , it was considerably high, i.e. 60% and 25%, respectively. When these results were compared to those of Feller et al. 71 on miniplate fixation using Champy's principle, it was found that paresthesia rate was 6% in that study. Similar study by Moreno et al. on Champy's principle showed paresthesia rate of 2.2%. Study by Moreno et al. 115 using 2.7-mm AO plate for mandibular fracture fixation had paresthesia rate of 3.1%. Incidence of low paresthesia in our study is due to the use of monocortical plate as compared to other types of plating system in which chances of inferior alveolar nerve injury are more due to bicortical screws. The average time period for adaptation and fixation of three dimensional plates was found to be less. These findings concur with that of Hughes112 who evaluated three dimensional plates against lag screw technique for treatment of fractures of the anterior mandible . Wittenberg79 also reported about the advantage of rapid reduced time for transoral application of three-dimensional titanium miniplates in the treatment of mandibular angle fractures. Because of the smaller size and thinner profile of the miniplates, they are less likely to be palpable, As the horizontal crossbars of the three dimensional titanium miniplates are placed perpendicular to the fracture line, and the vertical cross bars parallel, Periosteal stripping is minimal, when compared to other conventional miniplate osteosynthesis technique. They may decrease the degree of stress shielding seen following rigid fixation. Finally, because the screws are monocortical, the plates may be placed in the areas of mandible adjacent to tooth roots with minimal risk of dental injury. The rationale of using monocortical plate in mandibular fracture is that osteosynthesis by the plate screwed on the outer cortical plate is solid enough to support the strain developed by the masticatory muscles. In this study, malocclusion was not observed in any case and was similar to the studies by Bui et al 84 and Jain et al 86. However, malocclusion recorded was 6% in a study by Sebastian Sauerbier (2010) 115 in which 2-mm locking plating system was used, 4.4% in a study by Moreno et al. 116 which was based on Champy's principle, and 2.7% in a study by Moreno et al. using

2.7-mm AO plate. All patients had satisfactory occlusion after the 30th post-operative day, which is in accordance with the results of other studies (Thangavelu and Shankar, 2004; Parmar et al., 2007)89,106 Hardware failure in this study was 0% and is similar to the findings of other studies, i.e. 0% by Bui et al. 84 and Jain et al. 86, whereas Zix et al 83 reported a hardware failure of 5.8%. Plate fracture was the most important complication in the study by Zix et al83 . The reason for the hardware failure most likely lies in the reduced interfragmentary cross-sectional bone surface at the fracture site. The maximal mouth opening/interincisal distance after the surgical procedure was satisfactory in all the patients. The mobility of fracture fragments was checked by digital palpation i.e. placing the index finger of one hand on proximal fragment intraorally and the thumb of same hand on the posterior border of ramus extraorally of one hand and the index finger of the other hand on the distal fragment intraorally and thumb of same hand on the inferior border of mandible of other hand. Applying alternative pressure assessed the stability. In this study, mobility of fragments was present in 7 patients (46%) in Group I and in 9 patients (60%) in Group II, intra-operatively, before reduction. In the follow-up period of the study, no mobility of fragments was noted in any patient. This is in accordance with the results reported in literature (Gabrielli et al., 2003; Mittal and Dubbudu, 2012) 70,113 . In a biomechanical comparison study by Alkan et al 87, it was concluded that stability is better with 3-D plating system. In this study, no radiographic evidence of plate fracture was noted in patients in Group I or Group II in the follow-up period post-operatively. This is in accordance with the results reported in published literature (Mittal and Dubbudu, 2012; van den Bergh et al., 2012)113,108 . It is seen that, in this study both 3-D titanium miniplates and standard miniplates were effective in the treatment of mandibular anterior fractures and overall complication rates were lesser. In the symphysis and parasymphysis regions, 3-D plating system uses lesser foreign material, as only one plate and four screws are used as compared to two plates and eight screws in case of conventional miniplates using Champy's principle. This also reduces the operating time and overall cost of the treatment (J Zix et al , Boyd N et al) 83,117 . The use of 3D miniplates in mandibular fracture fixation has not yet become established. In a recently published survey of 104 North American and European AO/ASIF surgeons, only 6% stated that they use this type of plate. Only four studies presenting either biomechanical or preliminary clinical findings with this plate type have been published. Of these, Guimond et al72 and the work group of Feledy114 evaluated their clinical results of the use of curved 2 mm angle strut plates in 37 and 22 patients, respectively. Both these previous studies on the use of the curved 2 mm angle strut plate for angular fracture treatment reported low complication rates and concluded that the 3D plate is a predictable alternative to biomechanical experiment, and found better bending stability and more resistance to out-of-plane movement in the 3D plating system (Guimond et al 2005) 72 . Although results obtained in this study do not show a major difference in clinical outcome between the two-dimensional miniplate system and three-dimensional miniplate system, yet three-dimensional miniplate was found to be better than two dimensional miniplates in terms of ease of surgical technique, and also in terms of cost because of fewer number of plates and screws used in this technique. As per the principle of a 3D plate to treat fractures near the mental foramen, the plate should be placed above the nerve, and, to avoid injury to the dental roots, holes should be drilled monocortically, directing them into the space between the roots. However, three-dimensional miniplates were difficult to adapt in cases where the fracture line was oblique and in close proximity to the mental foramen. The quadrangle geometry of the 3D plate assures a 3-dimensional stability of fracture sites as it offers good resistance against torque forces. A 2.0 mm 3-dimensional titanium miniplate provided sufficient interfragmentary stability in all our patients with a relatively low complication rate and decreased risk of plate fracture, fracture motion and subsequent infection when compared with single 2.0 mm standard titanium miniplates. Low profile and ease of application are other advantages of 3-D miniplates over standard miniplates. Owing to fewer numbers of cases in the present study, the superiority of three dimensional miniplate could not be established statistically. Therefore clinical studies with larger sample size and different fracture sites are recommended.

CONCLUSION:

Thirty patients reporting to the department of oral and maxillofacial surgery at Regional Dental College & Hospital, Guwahati presenting with fractures of Symphysis & Parasymphysis fracture of mandible and requiring open reduction and internal fixation were selected to compare the efficacy between 3 D Plate and Standard Miniplate. 15 fractures were treated using 3 D plate and 15 patients with Standard Miniplates. Postoperatively, patients were not put on maxillomandibular fixation and early function was advised. Post operative infection was observed in 6.67 %(two) patients in patients treated with 3D plate. Pus discharge was noted from the sutured area, through which fractured site was exposed. But it was resolved with 7 days of antibiotics. Patients were able to function postoperatively with reasonable level of success in both the groups. Although results obtained in this study do not show a major difference in clinical outcome between the two-dimensional miniplate system and three dimensional miniplate system. Through this study three dimensional miniplate was found to be better than two dimensional miniplates in terms - a) Of ease of surgical technique, b) Lesser cost because of fewer number of plates and screws used in this technique c) Short Operative Time Conclusion 71 But, three-dimensional miniplates were difficult to adapt in cases where the fracture line was oblique and in close proximity to the mental foramen. However as the number of patients recruited in this study is small, it is recommended that a large number of cases be studied before a statistically valid conclusion can be reached.

Fig. 5a. Pre Operative Photo.

Fig. 5b. Pre Operative OPG

Fig. 5 c. Fracture siteexposed

Fig. 5 d. Fractured site reduced with 33D plate

Fig. 5 e. Post operative OPG

Fig .6 a. Pre Operative photo

Fig .6b. Pre operative OPG

Fig, 6c. Fracture Site Exposed

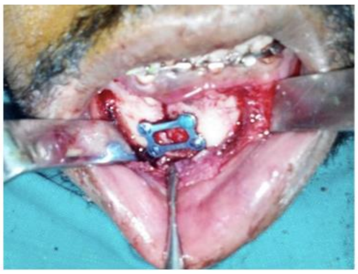


Fig. 6d. Fracture reduced with 3 D plate.

Fig. 6 e. Post op OPG


Fig . 7a. Pre Operative Photo


Fig. 7b. Pre Operative OPG


Fig. 7c. Fracture site exposed


Fig. 7d. Fractured site reduced


Fig. 7 e. Post operative OPG


Fig. 8a. Pre Operative photo


Fig. 8b. Pre operative OPG


Fig. 8c. ORIF done with standard miniplate.


Fig. 8d. wound closed with 3-0 mersilk

Fig. 8e. Post op OPG

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