

A Prospective Randomized Study Comparing 3D Plates Versus Two Plates for the Treatment of Mandibular Angle Fractures

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Abstract:-

➤ *Background:*

Mandibular fracture treatment is the restoration of anatomical form and function, with particular care to establish the occlusion. Traditionally, this has been achieved by immobilizing the jaws using various wiring techniques. In the past 2 decades, interest has increased for different methods of open reduction and internal fixation (ORIF)

➤ *Aims and Objectives:*

The purpose of this study was to evaluate the clinical outcome of the 3D plate compared to conventional two-plate fixation for stabilization of the mandibular angle fracture.

➤ *Patients and Methods:*

The study, conducted in all adult patients with maxillary and facial fractures, was referred to the Department of Oral and Maxillofacial Surgery, Rama Dental College, Kanpur. The study included 20 patients aged 18-40 years with good or poor angle fractures who were operated with an intra-oral or extra-oral approach. **Group I:** - Includes his 10 patients whose fractures were fixed with three-dimensional titanium plates. **Group II:** - Includes 10 patients with fractures fixed with two conventional titanium miniplates.

➤ *Results:*

Wound healing was satisfactory in all cases in both groups.

- Satisfactory occlusion was achieved in all cases in both groups
- Other parameters such as maximal mouth opening, sensory nerve function, and patient tolerance to plates were comparable.

➤ *Conclusion:*

Three-dimensional plate fixation is comparable to dual miniplate fixation in the fixation of mandibular angle fractures. Both systems provide enough stability for good bone healing, optimal occlusal establishment, and rapid return to normal function.

Keywords:- Mandibular Angle Fracture, 3D Conventional Miniplate, 2 Conventional Miniplate Fixation

I. INTRODUCTION

Today's fast paced, results oriented lifestyle has had a tremendous impact on humanity. The past two decades have witnessed an alarming increase in the number of traffic accidents (road, railway), violence (community or not), sports accidents... very worrying. Maxillofacial trauma is a frequent but important part of these accidents, the severity

of which can vary from simple alveolar/alveolar fracture to severe full-face trauma. Because of the forward projection of the face, the mandible is the bone most commonly associated with traumatic facial fractures. Of the different areas of the mandible that can be fractured, angle is the most common, accounting for about 30% of all mandibular fractures. Anatomically, the angle is defined as a triangular region bounded by the anterior margin of the occlusal muscle at the point of posterior superior attachment to the occlusal muscle (usually distal to the third molar). The marked change in direction of the bone fibers from transverse to longitudinal at the angle of the mandible indicates its weakness compared to other parts of the mandible. Based on the ability to reduce fractures of the medial sphenoid and occlusal muscles, angular fractures can be classified as favorable or unfavorable. Mandibular angle fractures can be treated conservatively or surgically. In conservative treatment, the mandible is immobilized during the healing period by inter-mandibular fixation achieved by dental wire, archwire, cap brace, and gun brace. On the other hand, surgical treatment of mandibular fractures includes exposure of the fracture site inside or outside the mouth and direct bone fusion using a transvaginal wire (Schwenzes 1982), a late screw (Niederdelmann 1982) or a bone plate (Schilli 1975)., Spiessel 1976), Luhr's Vitalli Compression Plates, Dynamic Compression Plates (DCP), Eccentric Dynamic Compression Plates (EDCPs), Regenerating Plates, Single Cortical Incompressible Miniature Plates, Delay Bolts, and Holographic (3D) Plates .

These methods are carried out according to their indications. Sealing is indicated only for favorable fracture forms, whereas for unfavorable fracture forms, surgical management, i.e. ORIF, is the treatment of choice. Based on the study by Champy et al.1,4,30, where they suggested placing the plate on the upper edge, which is the area of traction in the angular area of the mandible, fixing A single 2.0 mm miniplate at the top edge is the most widely used fixation method today. The presence of roughage pellets near the fault line resulted in a reversal of the tension and compression lines that occurred with a tendency to open at the lower edge from where Choi et al recommended the use of 2 miniplates. However, Ellis and walker^{11,19} showed a high complication rate of 28% in 2 mini-plate bone grafts. In their study of bite force after the application of 2D plates placed according to Champy's principle, Gerlach et al. 14 found that after a month of postoperative follow-up, patients were only able to apply 31 % of maximum longitudinal force compared to the control group. . This value increased to 58% after 6 months of follow-up. Another technique used in ORIF for angular fractures is the placement of a single reconstructive plate on the lower margin, which is the method of choice in cases of upper margin bone deficiency secondary to traumatic bone loss. But this approach requires an extraoral incision, which is unacceptable for many patients. Andrew JL Gear (2005) performed a study to compare different treatment modalities used by different surgeons to manage mandibular angle fractures. According to the results, the only miniplate on the upper edge (Champy technique) with or without arch was used by 51% of surgeons; 13% of surgeons use a tension belt on the top edge

and a double-shell screw plate on the bottom edge; double small plate is used by 10% of surgeons while the bottom edge locking screw plate is used by 7% of surgeons.

Along with fastening methods, the field of fastening plate design has also evolved, with three-dimensional (3D) or matrix panels being an addition in recent years. It consists of a straight or curved balance plate fixed along the lateral surface of the mandibular angle. The stability of the 3D panels is said to be comparable to that of the 2.0 mm microplate system, but they were found to be more resistant to out-of-plane motion^{19,22}. Zix et al ²⁴ in 2007 found the 3D plating system useful in immobilizing single jaw angle cracks. Alpar et al²⁵ also concluded their results were similar to Zix et al. Another advantage of the 3D system is the low complication rate (8.2%). The infection rate was 14% if the third molar was retained at the fracture line and 5.2% if the third molar was removed.²⁹ According to research done by Andrew Gear (2005), 3D plate system is used by 6% of surgeons. Jain M et al (2010)³⁰ compared the 3D plate system with conventional 2D fixation system according to Champy's principle and found that Champy's mini tray system is a better and easier fracture fixation method. more easily at the lower jaw angle. They found the 3D system difficult to adapt and unsuitable for use in oblique cracks. Ellis et al (2010)³⁷ performed a study in which they compared the use of MMF with a conventional and rigidly fixed miniplate in the treatment of mandibular angle fractures, in which they concluded that a Conventional miniplate is the easiest to implement and has the least complications. But unlike the above study, the study conducted by Jain M et al., Kumar V et al (2013)³⁶ found that the 3D titanium miniature plates have stable between the original pieces better and with fewer complications than uncompressed titanium shrink plates. The literature is still limited in comparing conventional 2D and 3D miniplates in bite force after ORIF and many other parameters for good rehabilitation of the fractured mandible, namely opening mouth and protrusion. beside. . In the present study, the authors decided to evaluate the same parameters as well as the range of motion between the three study groups, namely the conventional 2D panels and the 4- and 8-hole 3D panels.

II. AIM AND OBJECTIVES

A. Aim:

The main aim of this prospective study is to compare between 3-dimensional titanium mini plates and two-dimensional mini plates in the management of isolated mandibular angle fractures treated by ORIF.

B. Objectives:

The objective of this study was to evaluate the clinical results of 3D plates in mandibular angle fracture fixation compared with conventional two-plate fixation.

C. To Assess the Post Operative:

- Infection.
- Bone union.
- State of occlusion.
- Maximal mouth opening.
- Presence of any paresthesia.
- Hardware failure.

D. Method of Collection of Data :

➤ Source of data:

The study was conducted on patients who underwent facial trauma due road traffic accident ,assault etc. in the department of oral and maxillofacial surgery in Rama dental college, hospital and research center, Kanpur, between March 2021 – March 2022.

20 Patients in age group between 18 to 40 years with favourable or unfavourable mandibular angle fracture to operated via intra oral or extra oral approach included in this study.

Patients randomly assigned, into two equal groups according to the type of plating system in fracture fixation.

- Group I:- Included 10 patients in which fractures were fixed with three dimensional Titanium plates.
- Group II :- Included 10 patients in which fractures were fixed with two conventional Titanium miniplates.

➤ Sample size: 20 subjects

➤ Investigations:

Routine blood investigation, Chest X ray, ECG, RFT, LFT, Orthopantomogram (OPG). Analysis of Data:

The results will be then statistically analyzed.

➤ Inclusion Criteria:

- Displaced and undisplaced mandibular angle fractures.
- Mandibular unilateral angle fracture with or without associated fracture of facial skeleton.

E. Exclusion Criteria

- Severely Comminuted fractures.
- Bilateral mandibular angle fracture.
- Medically compromised patients.
- Age <18 years.
- Infected fractures.
- Patients who are not willing for follow up.

F. Surgical Technique:

➤ Extra-Oral Approach-

Pre-operative arch bars were placed after oral prophylaxis. The patients were operated under general anaesthesia via naso-tracheal intubation. The site of surgery was painted with 7.5% Povidone Iodine solution, spirit and 5% Povidone Iodine solution followed by isolation with sterile drapes. The skin was marked and 2% lignocaine with 1:80,000 adrenaline was used to infiltrate the incision site. An incision parallel to the inferior border of the mandible was given 1.5 to 2cm below the mandible (Risdon's approach). The skin and subcutaneous tissues to the level of platysma were incised and retracted to expose the superficial layer of deep cervical fascia, which was then dissected to reveal the pterygomasseteric sling. The pterygomasseteric sling was incised at the inferior border of the mandible and the sharp end of the periosteal elevator was used to strip the masseter muscle which was then retracted to expose the fracture site. Once adequate exposure is achieved, debridement of the fracture site was done followed by copious irrigation with 0.9% normal saline. The fracture fragments were reduced to their anatomical position and IMF was done. The conventional miniplate was fixed along the external oblique ridge while the 3D-plates were placed on the lateral surface of mandible in such a way that the horizontal cross bars were perpendicular to the fracture line and vertical cross bars were parallel to it. 2 x 6 mm or 2 x 8 mm screws were used to secure 3D plates (4 holes and 8 holes) to the reduced bone segments. IMF was removed to evaluate the occlusion and was reapplied and maintained for 7 days in all patients. Once hemostasis was achieved, incision was closed in layers using 3-0 vicryl suture. To close the skin incision 3-0 ethelone suture was used. Adhesive pressure bandages were applied extra orally over the angle of the mandible. Antibiotics and analgesics were prescribed postoperatively for a duration of 5 days. Patients were advised to consume only soft diet for 30 days and maintain oral hygiene using 0.2% Chlorhexidine mouthwash. IMF was removed after 7 days to check for study parameters i.e Infection, bone union, state of occlusion, maximal mouth opening, presence of any paresthesia, hardware failure. The surgical site was also examined for any sign of infection at any post operative stage.

➤ Intra-Oral Approach-

Pre-operative arch bars were placed after oral prophylaxis. The patients were operated under general anaesthesia via naso-tracheal intubation. The site of surgery was painted with 5% Povidone Iodine solution followed by isolation with sterile drapes. Site was infiltrated with 2% lignocaine with 1:80,000 adrenaline. A vestibular incision was given in the angle region and the proximal portion of the incision was carried along the external oblique ridge only as high as the mandibular occlusal plane. The mucoperiosteal flap was raised and the fracture site was exposed. The anterior surface of the ramus was then exposed by stripping the buccinator and temporalis tendon with a notched, angled retractor and periosteal elevator thereby exposing the fracture fragments. Once adequate exposure of fracture fragments is achieved, debridement and curettage was done if

required which was followed by copious irrigation with 0.9% normal saline. The fracture fragments were reduced to their anatomical position and IMF was done. The conventional miniplate was fixed along the external oblique ridge while the 3D-plates were placed on the lateral surface of mandible in such a way that the horizontal cross bars were perpendicular to the fracture line and vertical cross bars were parallel to it. 2 x 6 mm or 2 x 8 mm screws were used to secure 3D plates (4 holes and 8 holes) to the reduced bone segments. IMF was removed to evaluate the occlusion and was reapplied and maintained for 7 days in all patients. Once hemostasis was achieved, incision was closed in layers using 3-0 vicryl suture. Adhesive pressure bandage were applied extra orally over the angle of the mandible. Antibiotics and analgesics were prescribed postoperatively for a duration of 5 days. Patients were advised to consume only soft diet for 30 days and maintain oral hygiene using 0.2% Chlorhexidine mouthwash. IMF was removed after 7 days to check for study parameters i.e Infection, bone union, state of occlusion, maximal mouth opening, presence of any paresthesia, hardware failure. The surgical site was also examined for any sign of infection at any post operative stage.

Intra operative photographs were taken during surgery.

H. Group -A (2-Plating system)

All 20 Patients were followed up after 1 week post operative, 1st and 3rd post operative months, to assess the post operative :

- Infection.
- Bone union.
- State of occlusion.
- Maximal mouth opening.
- Presence of any paresthesia. Hardware failure

G. Evaluation Criteria

- Infections— Infection—It is considered an infection if pus is present. patient is assessed as present/absence.
- Bone union—Based on radiographic evaluation and comparison of OPG taken in postoperative followups
- State of occlusion — Based on physical examination. It is assessed as intact/deranged
- Maximal mouth opening—Based on clinical examination. It was evaluated using scale inter-incisally
- Presence of any paresthesia —Based on information obtained from the patient and clinically by performing prick pain. Patient is assessed as present/absence
- Hardware failure—Based on clinical and radiographical assessment of plate fractures and loose screws. Patient is assessed as present/absence.

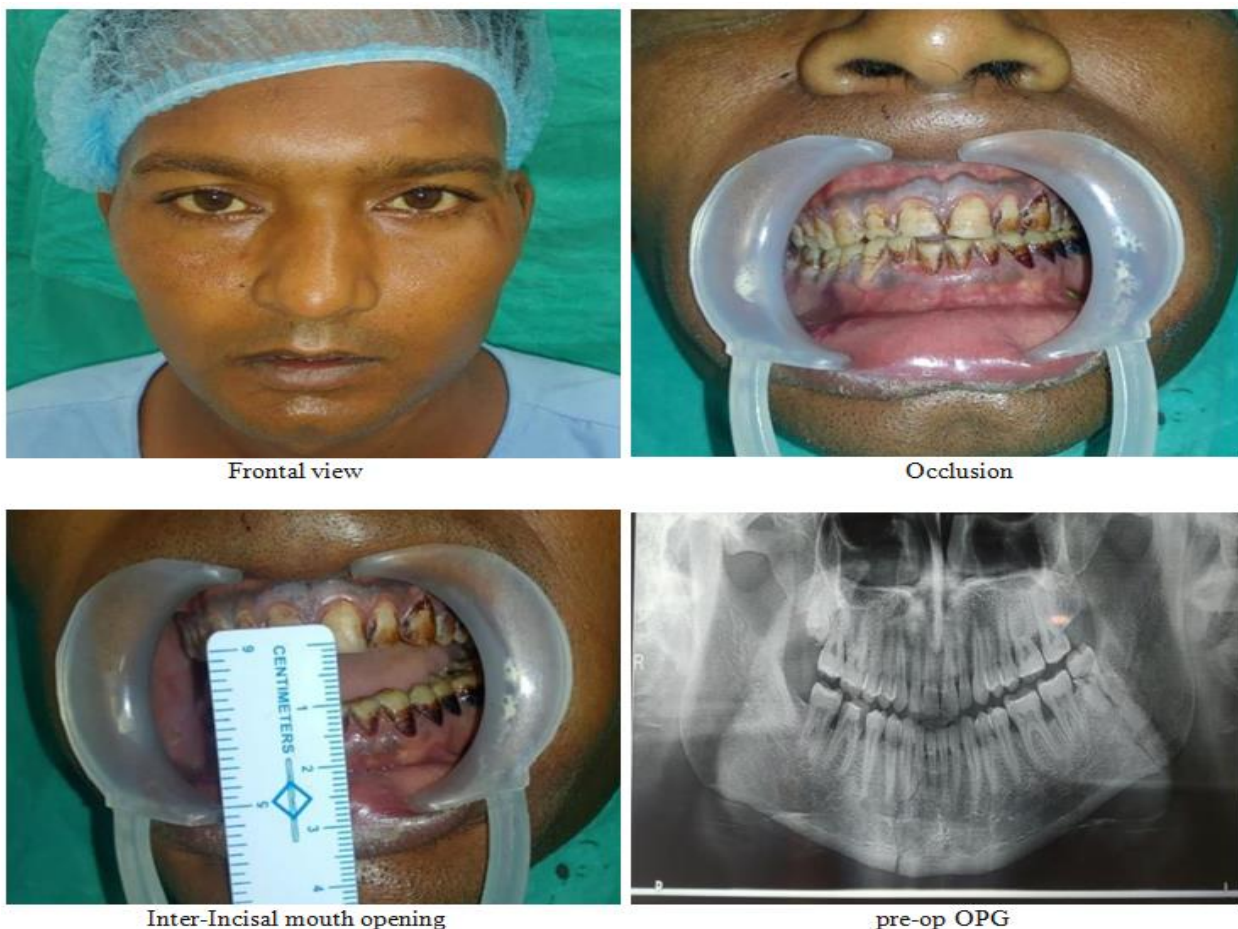


Fig 1 Pre-Operative

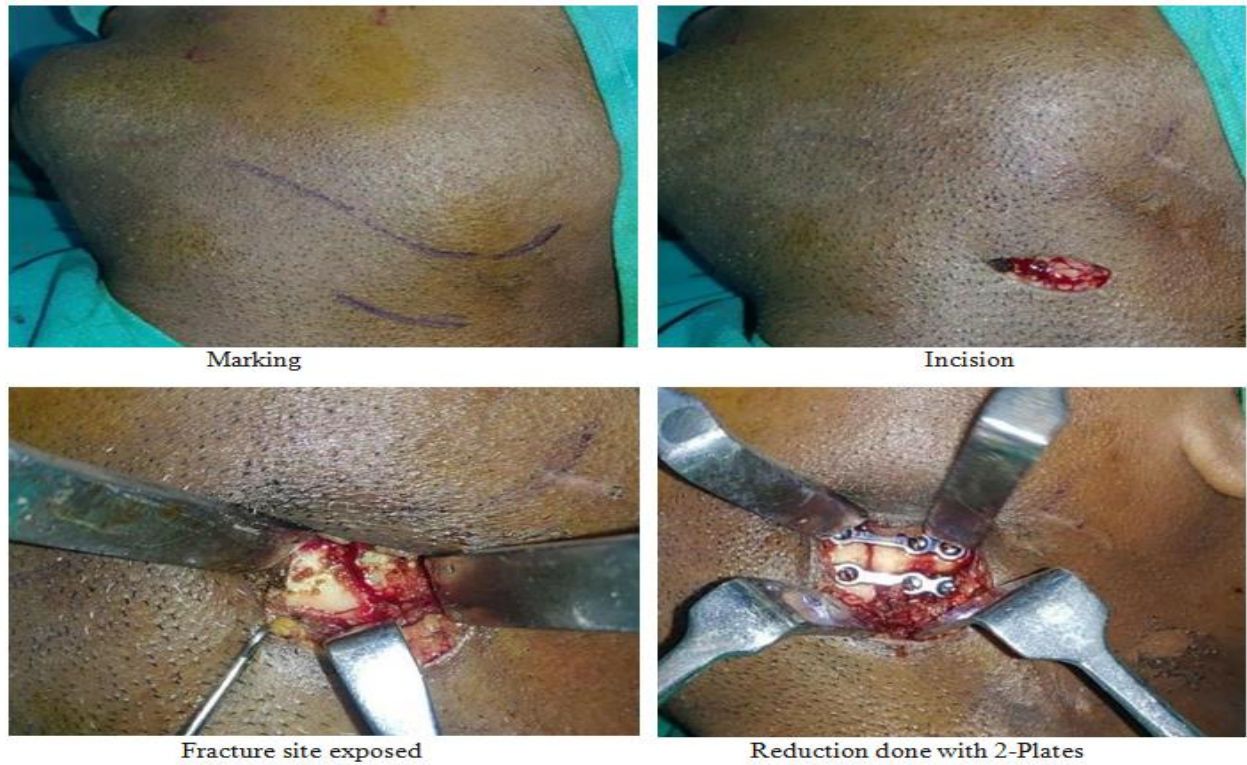
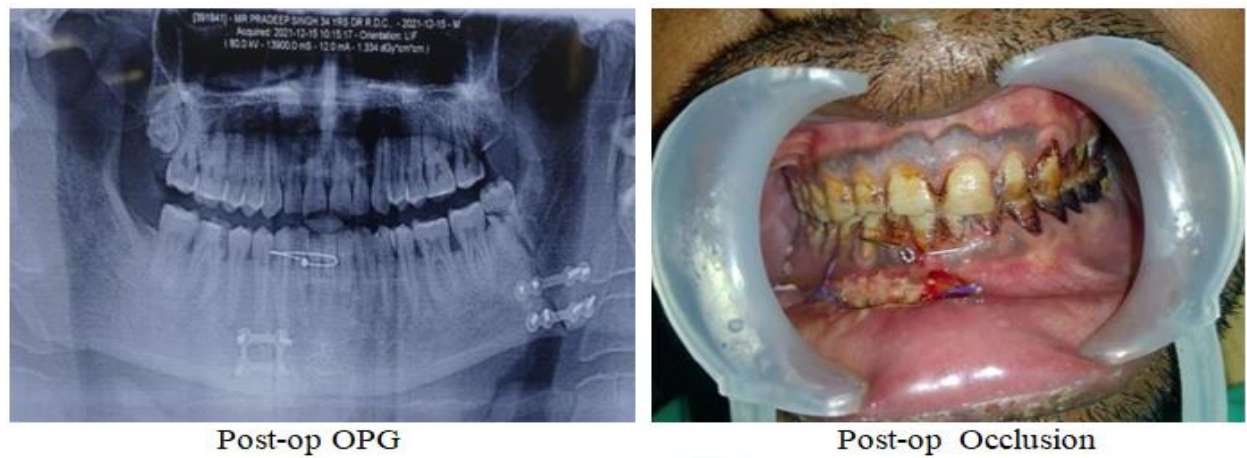


Fig 2 Intra-Operative



Post-op OPG

Post-op Occlusion



Post-op mouth opening

Fig 3 Immediate Post Operative

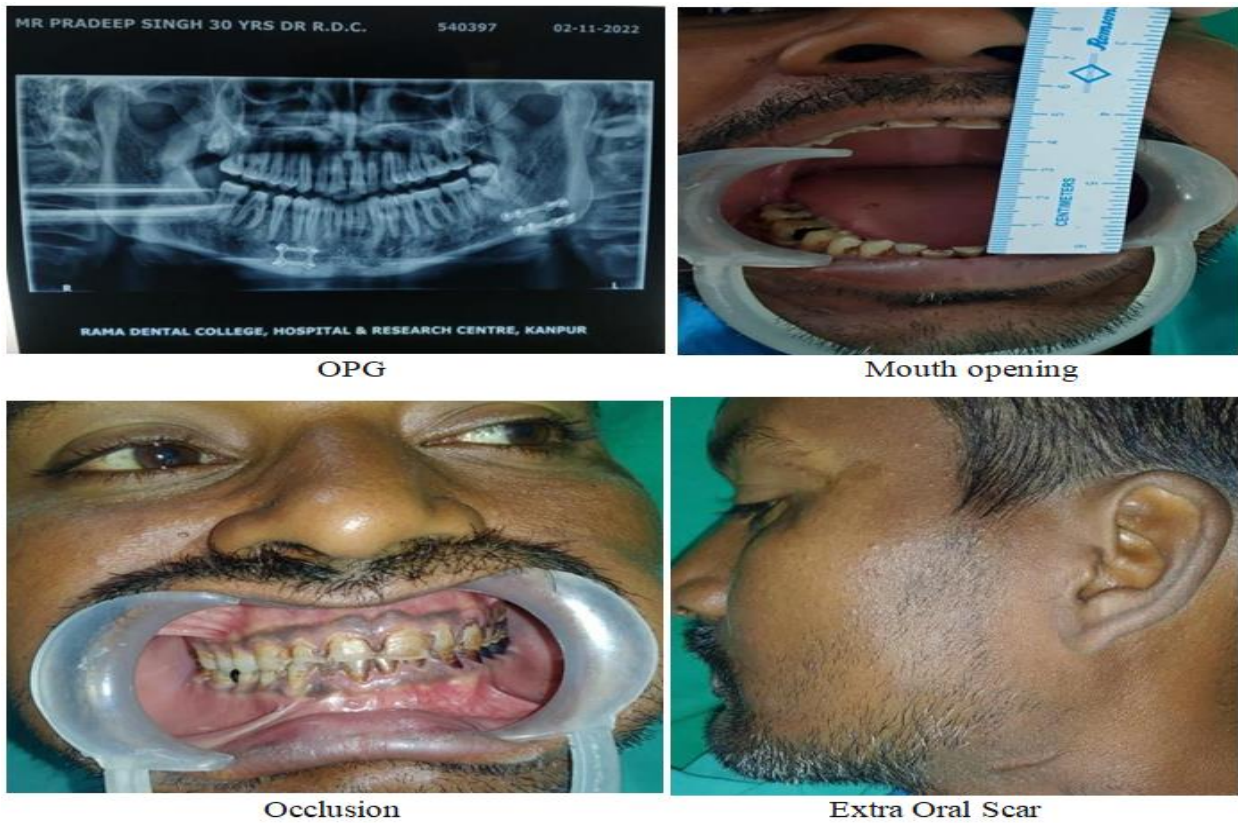


Fig 4 3rd Month Follow up

I Group-B 3D -Plate Fixation System



Fig 5 Pre Operative



Fig 6 Intra Operative

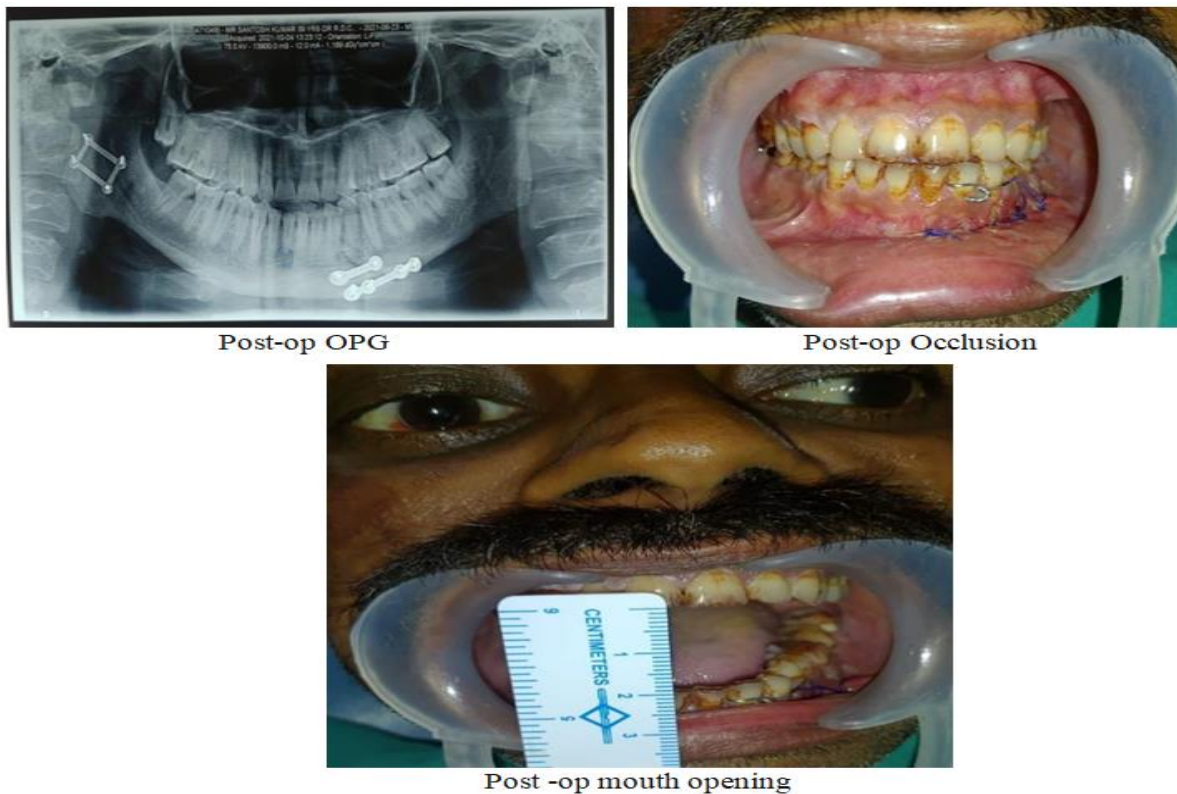


Fig 7 Immediate Post Operative

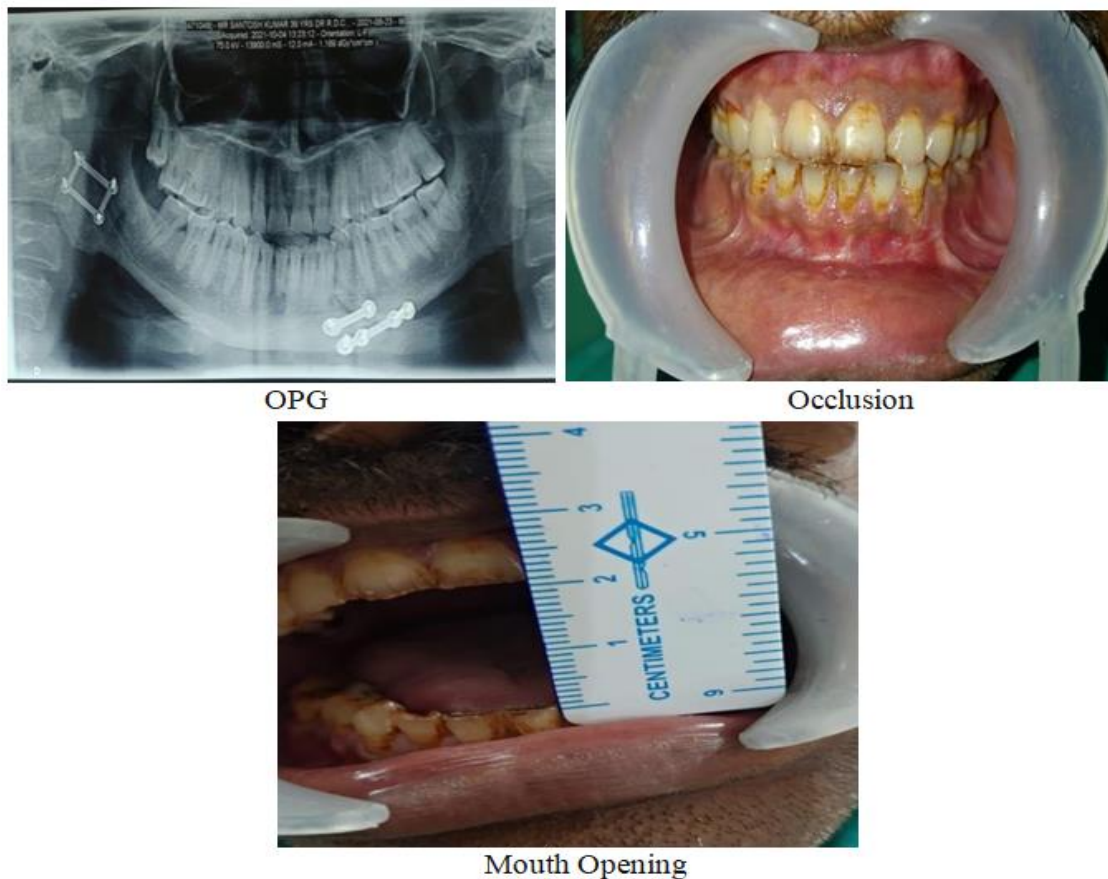


Fig 8 3rd Month Follow up

III. RESULTS

Table 1 Intergroup Comparison of Mouth Opening

Timeline	Group	Mean	Std. Deviation	SEM	P value
Pre- operative	2 Plate	17.3000	6.60051	2.08726	0.25
	3D Plate	20.8000	6.64664	2.10185	
Day 7	2 Plate	18.0000	6.81502	2.15510	0.73
	3D Plate	17.1000	4.70106	1.48661	
1 month	2 Plate	24.1000	6.78970	2.14709	0.47
	3D Plate	22.0000	5.94418	1.87972	
3 months	2 Plate	31.2000	7.14609	2.25979	0.25
	3D Plate	27.5000	6.77003	2.14087	

Test: Independent samples t test

➤ *Inference:*

There is no significant difference in Mouth opening between the groups at all the timepoints of the study.

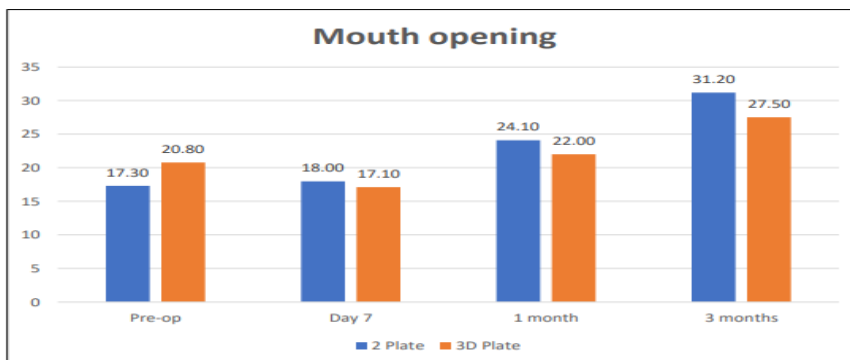


Fig 9 Mouth Opening

Table 2 Intergroup Comparison of Qualitative Variables

		2 Plate system		3D Plate		P value
		N	%	N	%	
Occlusion -Pre	Deranged (Open-Bite)	6	60.0	4	40.0	0.371
	Intact	4	40.0	6	60.0	
Occlusion -Post	Intact	10	100.0	10	100.0	1.0
Paraesthesia- day 7	No paraesthesia	9	90.0	10	100.0	0.30
	Paraesthesia	1	10.0	0	0	
Paraesthesia- 1month	No paraesthesia	9	90.0	10	100.0	0.30
	Paraesthesia	1	10.0	0	0	
Paraesthesia- 3months	No paraesthesia	10	100.0	10	100.0	1.0
Bone union – Day 7	Evidence of fracture line	10	100.0	10	100.0	1.0
Bone union – 1month	Evidence of fracture line	10	100.0	10	100.0	1.0
Bone union – 3months	No evidence of fractureline	10	100.0	10	100.0	1.0
Hardware failure	No abnormality detected	10	100.0	10	100.0	1.0
Infection	No abnormality detected	10	100.0	10	100.0	1.0

Test: Chi-square test

There is no significant difference between distribution of Occlusion, Paraesthesia or Bone union observed between the groups.

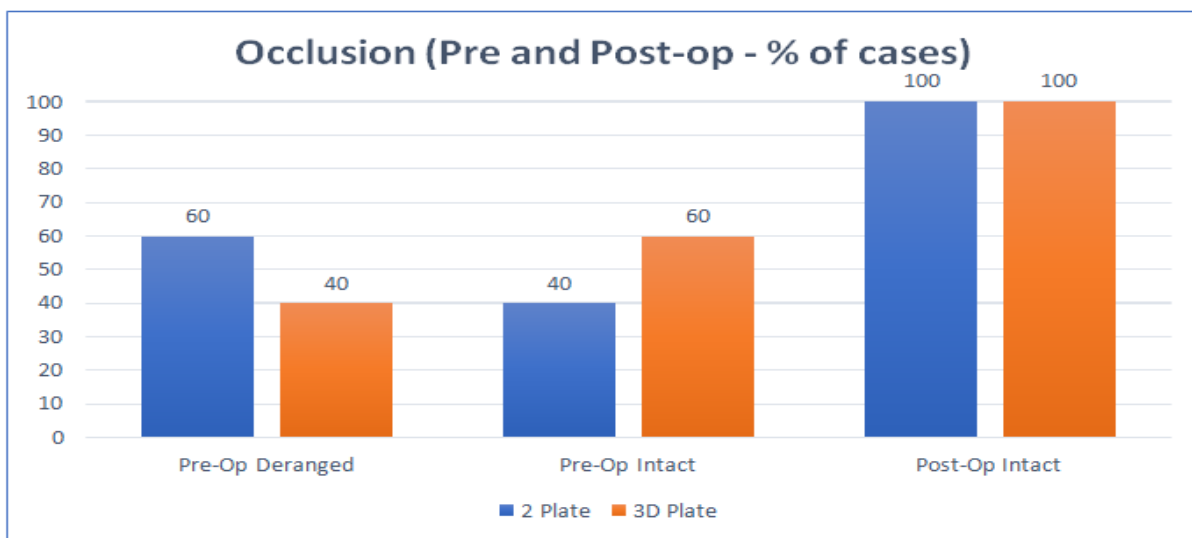


Fig 10 Occlusion (Pre and Post-op-% of Cases)

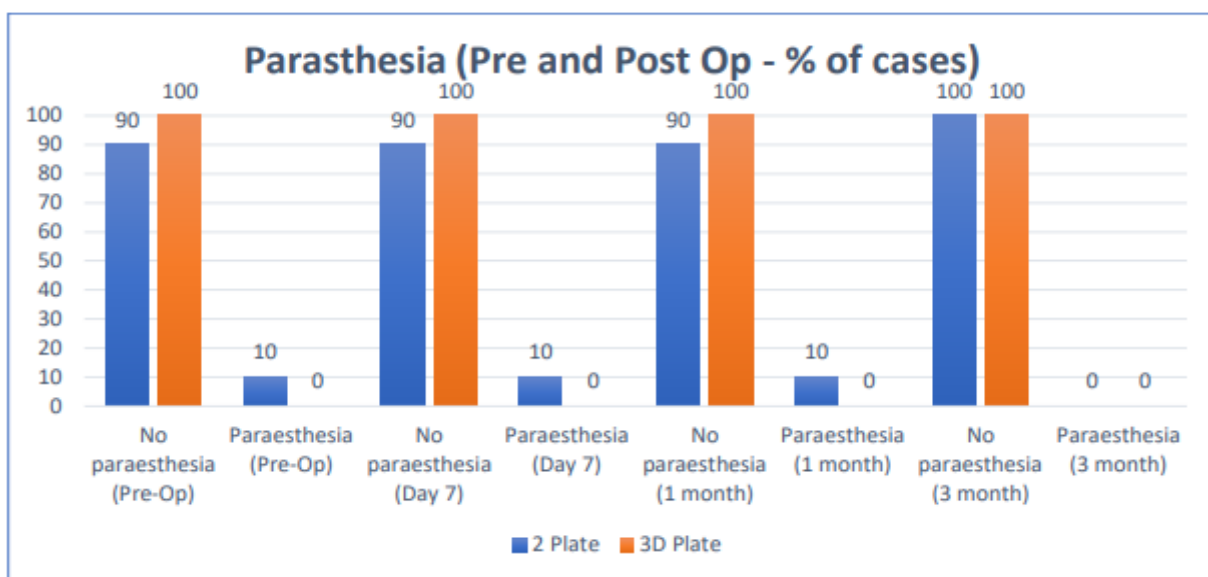


Fig 11 Parasthesia (Pre and Post-op-% of Cases)

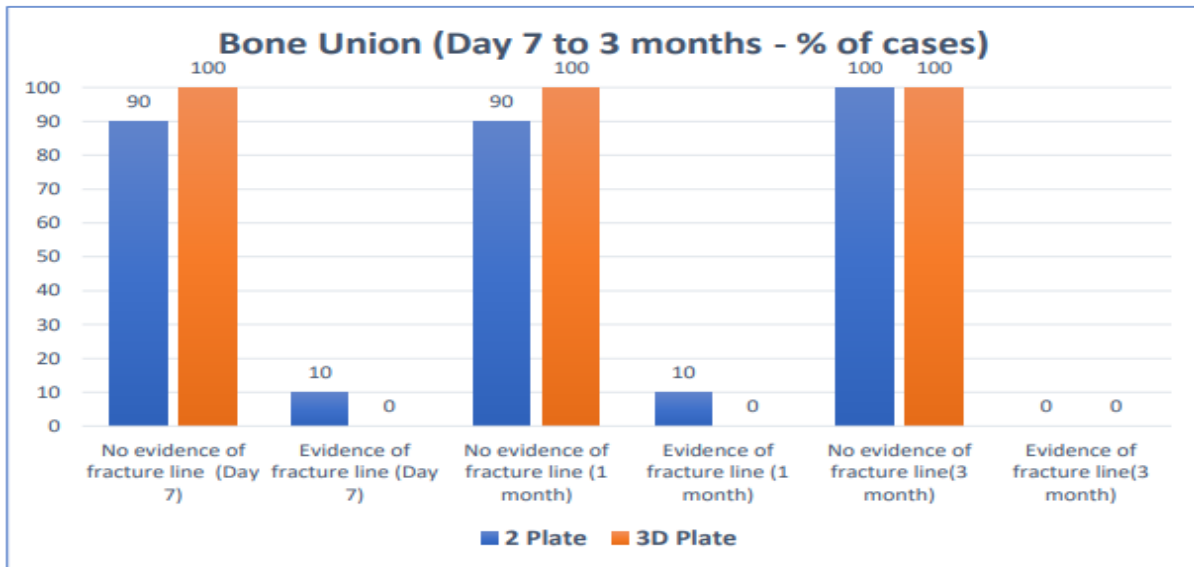


Fig 12 Bone Union (Day 7 to 3 Months - % of Cases)

Table 3 Intragroup Comparison of Mouth Opening in each Group

Group		Mean	Std. Deviation	P value
2 Plate	Pre-op	17.3000	6.60051	0.003
	Day 7	18.0000	6.81502	
	1 month	24.1000	6.78970	
	3 months	31.2000	7.14609	
3D Plate	Pre-op	20.8000	6.64664	0.001
	Day 7	17.1000	4.70106	
	1 month	22.0000	5.94418	
	3 months	27.5000	6.77003	

Test: Repeated Measures ANOVA

There is a significant change (increase) in mouth opening from baseline to 3 months seen separately in both the groups.

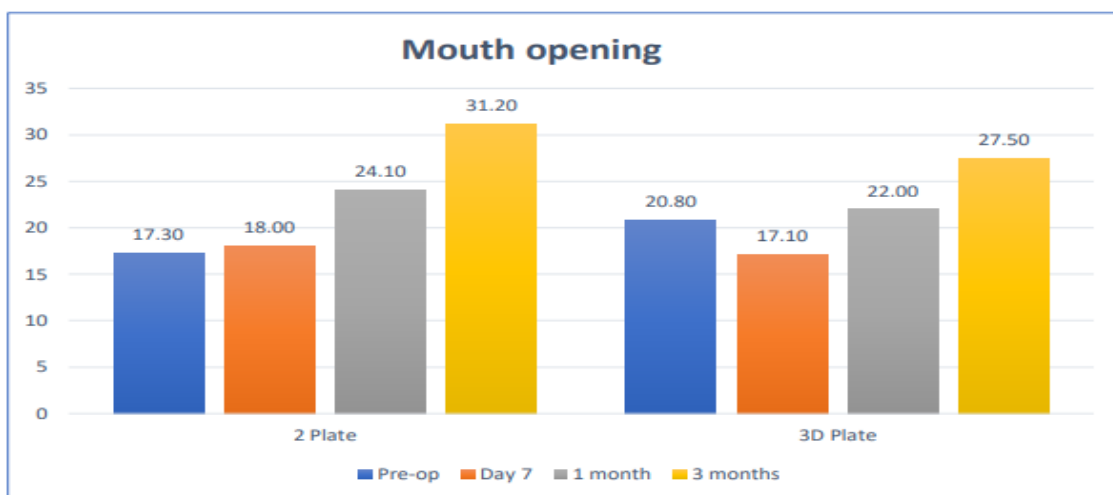


Fig 13 Mouth Opening

Table 4 Intragroup comparison of Qualitative Variables Intragroup Comparison of Occlusion

Occlusion -timeline	items	2 Plate system		3D Plate	
		N	%	N	%
Pre-op	Unsatisfactory (Open-Bite)	6	60.0	4	40.0
	Satisfactory	4	40.0	6	60.0
Post-op	Satisfactory	10	100.0	10	100.0
P value		0.001		0.001	

Test: McNemar’s test (Variant of Chi-square test)

There is a significant change in the distribution of occlusion observed in both the groups separately from pre-op to post-op.

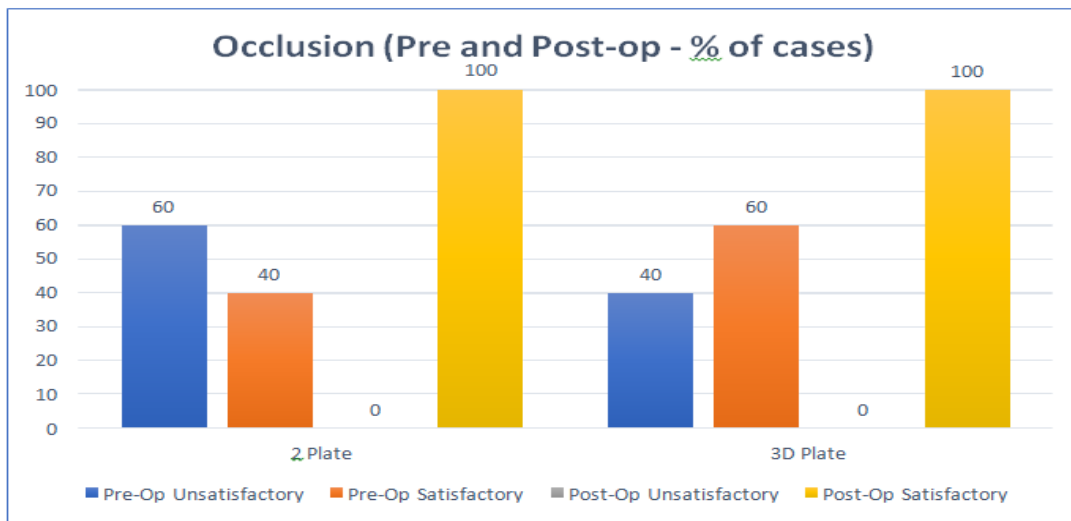


Fig 14 Occlusion (Pre and Post-op-% of Cases)

Table 5 Intragroup Comparison of Paraesthesia

Paraesthesia-timeline	Items	2 Plate system		3D Plate	
		N	%	N	%
Day 7	No paraesthesia	9	90.0	10	100.0
	Paraesthesia	1	10.0	0	0
1 month	No paraesthesia	9	90.0	10	100.0
	Paraesthesia	1	10.0	0	0
3 months	No paraesthesia	10	100.0	10	100.0
P value		0.001		0.001	

Test: McNemar’s test (Variant of Chi-square test)

There is a significant change in the distribution of paraesthesia observed in both the groups separately from Day 7 to 3 months (Significant paraesthesia at baseline to no paraesthesia at 3months)

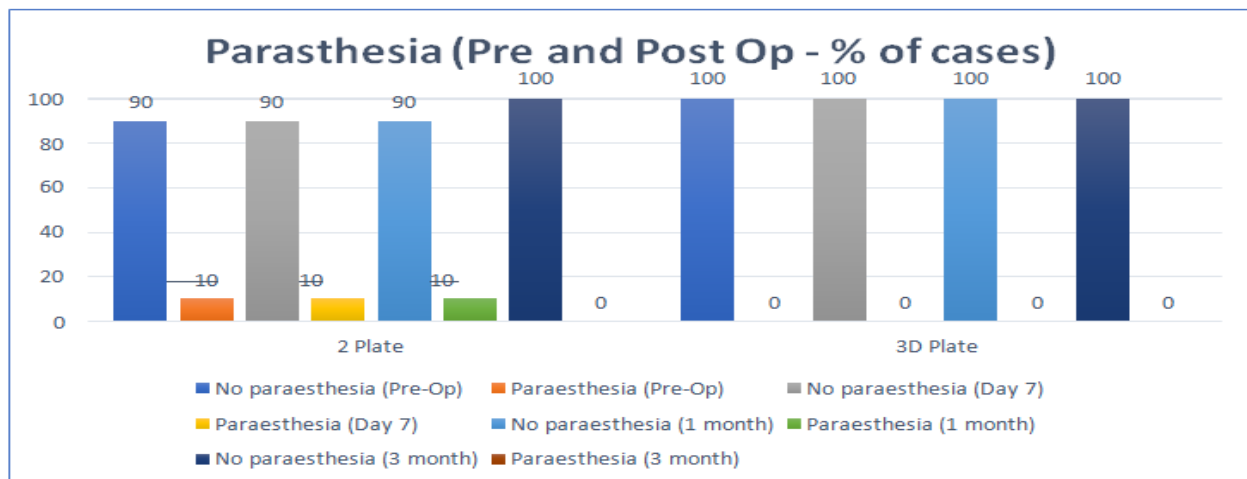


Fig 15 Parasthesia (Pre and Post-op-% of Cases)

Table 6 Intragroup Comparison of Bone Union

Bone union -timeline	Items	2 Plate system		3D Plate	
		N	%	N	%
Day 7	Evidence of fracture line	10	100.0	10	100.0
1 month	Evidence of fracture line	10	100.0	10	100.0
3 months	No evidence of fractureline	10	100.0	10	100.0
P value		0.001		0.001	

Test: McNemar’s test (Variant of Chi-square test for matched pairs design)

There is a significant change in the distribution of Bone union observed in both the groups separately from Day 7 to 3 months (Significant fracture line at baseline to no fracture line at 3months)

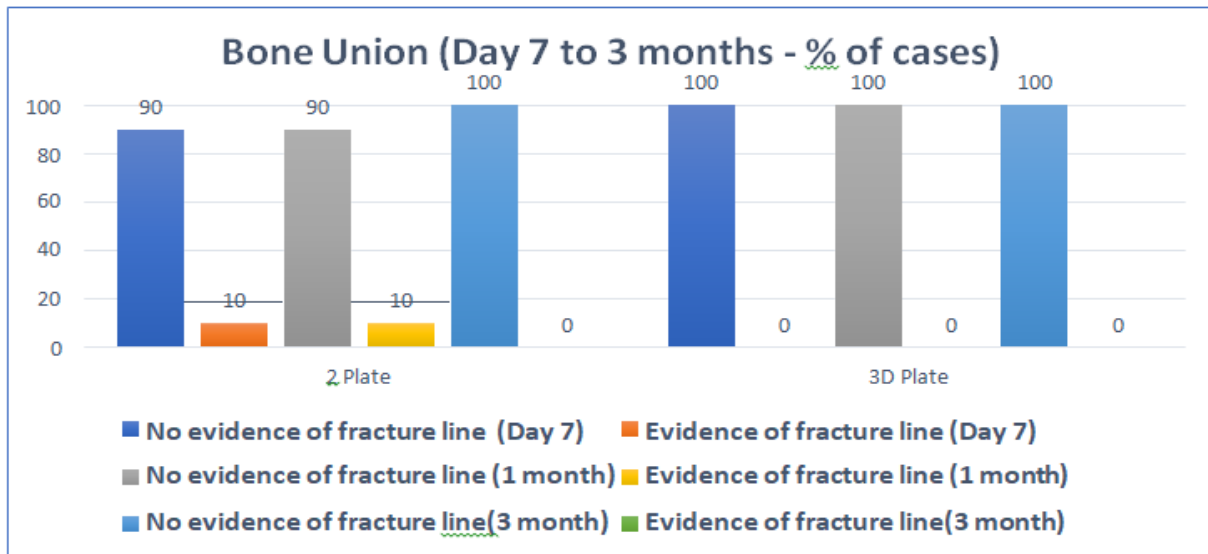


Fig 16 Bone Union (Day 7 to 3 Months - % of Cases)

IV. DISCUSSION

Re-establishing the normal occlusion and masticatory function is the primary objective in the treatment of mandibular fracture. A complete recovery of the masticatory function is thought to have occurred when the patient has achieved a normal mouth opening with normal movements and bite force with no residual pain at the fracture site either during static position or during dynamic activities of the mandible. The management of mandibular fractures have seen a gradual shift from the conventional Inter-maxillary fixation (IMF) techniques to Open Reduction and Internal Fixation (ORIF) during the past few decades. Numerous plating systems have been designed and tested during this time in order to achieve the goal of re- establishment of normal occlusion and masticatory function.

Currently the most widely used osteosynthesis techniques for ORIF of mandible is the monocortical miniplate osteosynthesis which was first introduced by Michelet et al in 1973 and later developed by Champy and Lodde in 1975¹. They introduced monocortical 2D miniplates which were fixed at the “Neutral zones” after surgical exposure and reduction of the fracture sites. According to Champy’s principles, the neutral zone for fixation of miniplate in cases of mandibular angle fracture is the superior border. They recommended placement of a single 2D monocortical miniplate at the superior border of mandibular angle. But studies have shown that this single plate fixation does not provide enough stability due to the tendency of gaping at the lower mandibular margin due to shifting of the line of tension from the upper to lower border when the loading forces are close to the fracture line⁵. Due to this, Spiessl(1989)⁸ recommended placement of two miniplates with one at the external oblique ridge and the second one at the inferior border. Some other recommendations include the use of Lag screws and single reconstruction plate at the inferior border.

In 1992 Farmand and Dupoirieux came up with the concept of three dimensional (3D) plating system. A geometrically closed quadrangular plate secured with bone screws creates stability in three dimensions which is the basic concept of 3D fixation. A better blood supply is ensured to the bone by the large free areas between the plate arms and minimal dissection. The advantages of 3D plates as summarized by Zix et al²⁴ include 1) Ease of operation due to compact design. 2) More resistance to the torquing forces so that thinner plates can be used. 3) Requirement of less screws and plates as compared to conventional miniplates and hence lesser foreign material and lesser cost.

Due to these advantages of the 3D system, this study decided to compare its effectiveness with the conventional 2D miniplate system (2.0 mm). In this study we decided to compare the systems using the following parameters Infection, bone union, state of occlusion, maximal mouth opening, presence of any paresthesia, hardware failure.

In this study we found that mouth opening after 1 week was maximum in Group A (2 plate system) and group B patients (3-D Plate system). A statistically significant difference was found between group A and B during the period of one month postoperatively where there is a significant change (increase) in mouth opening from baseline to 3 months seen separately in both the groups. Similar results found in study conducted by N.H. Al-Tairi et al.(2015)⁴¹ where the preoperative mean maximal mouth opening in patients with 3D plates was 19.62 mm. It further decreased to 17.62 mm at immediate post operatively. The mouth opening measures 27.12 millimeters after one week. All patients resumed adequate mouth opening of (41.12 mm) after 1 month follow up which was further improved at 3rd month and 6th month to 43.25 mm and 43.37 mm respectively.

In our study occlusion was assessed both before and after surgery. Following surgery, the patients in both groups had normal occlusion. The findings were consistent with research by Bui et al.²⁹ and Kumar et al.⁴² in 3D mandibular fracture where the post operative occlusion was found to be intact. Based on these studies, it is clear that both plating systems are relatively likely to achieve good occlusion, as evidenced by our study.

In this study paresthesia of inferior alveolar nerve was found in one patient in group A post operatively during 1st month. However there was no paresthesia reported at 3rd month followup in both groups in our study. A study by Kumar et al.⁴² and Parmar et al who assessed the effectiveness of 3D against conventional (Champy's) miniplate fixation in the treatment of mandibular fractures. The use of 3D miniplates rigid fixation in fractures of the mandible showed similar results. The reduced paresthesia in our study could be attributed to the fact of adoption of monocortical screws in all our subjects of both the groups.

In the present study patients were evaluated pre-operatively and postoperatively after 1 week post operative, 1st and 3rd post operative months after surgery for signs of infection by a single surgeon and there were no case of any infection reported as strict aseptic measures were followed. Similar results were found in study conducted by N.H. Al-Tairi et al.(2015)⁴¹ where they compared 3D plate vs 2 plates in angle of mandible intraorally where 0% of infection found post operatively. However, infections were observed with this observation Guimond et al.⁴³ reported a 5.4% rate with the use of a 3D 2.0-mm curved angle strut plate for mandibular angle fracture.

In this study we assessed for hardware failure and at any follow up period, there was no indication of hardware failure in any subjects in both the groups. None of the patients when assessed had poor fracture segment stability at follow-up period of 1st week post operative, 1st and 3rd post operative months after surgery. Similar results obtained in a study conducted on comparison of 3D and locking plate in mandibular fractures by Sakshi et al.(2017)⁴⁴ where they found no sign of hardware failure.

This study also evaluated the bone union through follow-up radiographs and almost total absence of fracture lines or the presence of continuous anatomical structures around a fracture site which was reduced in width was noted in all our subjects in Group A & B which is classified as good bony union and healing. Same explanation given by T. Kawai et al.(1997)⁴⁵ on study on Radiographic changes during bone healing after mandibular fractures.

V. SUMMARY AND CONCLUSION

The sample size is small on the basis of which it is difficult to comment on the superiority of one group over the other group. Overall results shows There was no significant difference in outcome between the two groups, and both are equally effective in treating angle fractures. 3-

D miniplate fixation is a user-friendly alternative to conventional miniplates in terms of reduced manipulation time and simultaneous top and bottom stabilization with his two plates. In the angular region, a single conventional miniplate fixed using the Champy technique can be easily placed in the oral cavity with less operative time, less surgical trauma, and similar clinical outcomes. The superior design of the 3D plate places the maximum number of screws close to the fracture site, thus improving stability and opening up the opportunity for satisfactory use in treating of displaced Angle fractures.

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