



A Prospective Randomized Study on Comparison of 2.0mm Non-Locking Titanium Plates versus Locking Titanium Plates (1.8mm and 2.3mm) System for Mandibular Fracture

Authors

**N. Kiran Kumar¹, N. V. V. Satya Bhushan², B.Kiran Kumar³, A. Sudheer⁴,
S. Prameela⁵, Amrita Patnaik⁶**

¹Professor and Head, Department of Dentistry, Rajiv Gandhi Institute of Medical sciences, Ongole
Email: drnamineni@gmail.com, Phone: 9989807499

²Professor and Head, Department of Oral and Maxillofacial Surgery, GITAM Dental College and Hospital,
Visakhapatnam

Email: dr.satyabhushan@gmail.com, Phone: 09652412606

³Private Practitioner, Kakinada

Email: drkirankumar@gmail.com, Phone: 09247212357

^{4,5,6}Post Graduate student, Department of Oral and Maxillofacial Surgery, GITAM Dental College and
Hospital, Visakhapatnam

Corresponding Author

Dr Adigarla Sudheer

Post Graduate student, Department of Oral and Maxillofacial Surgery, GITAM Dental College and Hospital,
Visakhapatnam.

Email: sudheeradigarla50@gmail.com, Phone: 09912600962, 9491673676

Abstract

Purpose: To comparing the efficacy of noncompression, malleable, thin 2.0 mm titanium non locking miniplates (group A) with 2.3 mm and 1.8mm(upper and lower border) titanium locking miniplates (group B) in the treatment of mandibular fractures.

Materials and Methods: A prospective randomized study analyzing 20 patients with undisplaced or minimally displaced mandibular fractures having insignificant medical history. The data was randomly collected from the patients visiting the Department of Oral and Maxillo- Facial Surgery, Gitam dental college and hospital. The cases were randomly selected for open reduction and internal fixation with 2.0 mm titanium non locking miniplate (10 cases) group A and group B (10 cases) with 1.8mm and 2.3 mm titanium locking plates with respective screws.

Results: Statistical analysis was done using Mann-Whitney U test and Wilcoxon matched pairs test. The results done with Mann-Whitney U test suggested that the comparison of performance with both locking and non locking plates was not found to be statistically significant (p-value <0.05)

Conclusion: Locking plate design comes from the same idea of better fixation and stability. We compared the latest technique of locking plate design with the conventional miniplates and found no statistical significance, by which we can infer that even though there is theoretical advantage for this design practically it does not give better outcome.

Keywords: Titanium miniplates, Non locking miniplates, Locking miniplates, Mandibular fractures.

Introduction

In the era of increasing urbanization in our country, the rapid influx of high speed automobiles and poor road conditions which are contributing to the increase in the incidence of maxillofacial injuries alarmingly. Mandibular fractures accounts for 36-70% of all maxillofacial trauma¹, as the mandible is the only mobile facial bone, with various functions such as mastication, phonation and respiration. Hence the treatment of mandibular fractures is important both functionally and cosmetically.

The philosophies and literature in treating mandibular fractures have been dated back to the era of Egyptians and Romans which was mostly in the form of immobilization and have since then been in a state of evolution especially in the 19th century with the advent of general anesthesia and concepts of AO plating resulted in compression plating which is replaced by miniplates².

Champy's ideal lines of osteosynthesis with monocortical mini plates system is the time tested and considered gold standard in the management of mandibular fractures. Transoral placements of miniplates have gained popularity in the last decade. But the quest to improve stability along the fracture fragments has been the need of the hour because of the increased incidence of high speed road traffic accidents which does not involve normal fracture pattern and in which chances of crush injuries are high, requiring better stability. Conventional screw plating system engages only the bone and may lead to reduced stability by the way of screw loosening which is enhanced by bony pathologies and age.

To overcome this problem newer innovation like locking plates have been developed in which the screws engage both the bone and the plate thus increasing the stability of screws which in turn increases the stability of fracture segments. This has encouraged us to compare monocortical locking miniplate system with monocortical non-locking miniplate system in the treatment of mandibular fractures.

Aims and objectives of the study

This study was aimed at comparing the efficacy of noncompression, malleable, thin 2.0 mm titanium non locking miniplates(group A) with 2.3 mm and 1.8mm(upper and lower border) titanium locking miniplates(group B) in the treatment of mandibular fractures. Twenty patients were randomly selected for this study from the patients who reported to the department of oral and maxillofacial surgery after sustaining mandibular fractures. They were prospectively evaluated for 3 months based on clinical and radiological parameters.

Materials and Methods

Source of Data

This is a prospective randomized study analyzing 20 patients with undisplaced or minimally displaced mandibular fractures having insignificant medical history. The data was randomly collected from the patients visiting the Department of Oral and Maxillo- Facial Surgery, Gitam dental college and hospital. The cases were randomly selected for open reduction and internal fixation with 2.0 mm titanium non locking miniplate (10 cases) group A and group B (10 cases) with 1.8mm and 2.3 mm titanium locking plates with respective screws.

Inclusion Criteria

Undisplaced or minimally displaced fractures of the mandible requiring open reduction and internal fixation in any one of the following region: Symphysis, Parasymphysis, Body or angle region, Unilateral condylar fractures.

Exclusion Criteria

Fractures infected prior to treatment, bilateral condylar fractures and comminuted fractures with pan facial trauma were excluded from the study. Patients with compromised medical condition were also excluded.

Procedure

After the routine clinical and radiological examination protocol the fracture site is exposed by intraoral approach with osteosynthesis using locking or non locking miniplates without

maxillomandibular fixation. The patients were evaluated for the location, type and number of fractures, presence of tooth in fracture line, time elapsed between the presentation of the patient after trauma, complications during surgery, pre and postsurgical occlusal relationship, adequacy of reduction on post operative radiograph and any post surgical complications requiring a secondary surgical intervention. All cases were treated by intra oral approach. First the site was prepared with 10% BETADINE solution and then infiltrated with 2% lignocaine with 1:80,000 adrenaline. The lip was retracted and an intra oral vestibular incision was given extending to approximately about two teeth on each side of the fracture line. The mucoperiosteal flap was then raised and fracture site exposed. In the angle region the proximal portion of the incision should be carried along the external oblique ridge only as high as the mandibular occlusal plane. Extending the incision higher predisposes the buccal pad of fat to prolapse onto the surgical field. The anterior surface of the ramus can then be exposed by stripping the buccinator and temporal tendon with a notched, periosteal elevator and angled retractor thereby exposing the fracture fragments. The plate was adapted approximately to the underlying bone and fracture fragments reduced in non locking group and plate adaptation is not considered in locking group, occlusion secured with intermaxillary fixation and 2 x 6 mm screws were then used to secure the fracture in non locking titanium plate system. In the locking titanium plates system 1.8mm plate was placed in the upper border of the fracture and 2.3 mm plate in the lower border of the fracture and if single plate is used (angle) 2.3 mm plate with 6 mm screws are used. Care was taken to center the drill hole in the center of the plate perpendicular to the bone surface with the help of drill guide in case of locking plate system. The intraoral site was closed in layers after achieving adequate hemostasis with vicryl 3-0 sutures and adhesive pressure bandage given extra orally over skin surface. Antibiotics and analgesics were administered for 7 days

following surgery. The patients were followed up for a period of 3 months in a time interval of 1 week, 1 month and 3 months.

Patients were prospectively evaluated for the following findings: 1) patient age, sex and etiology of fracture 2) location of fracture site 3) displacement of the fracture 4) soft tissue injury 5) Paresthesia 6) occlusion 7) mouth opening 8) infection 9) fate of teeth in the line of fracture 10) adequacy of reduction radiographically.

Observations and Results

Comparing the efficacy of noncompression, malleable, thin 2.0mm titanium non locking miniplates (group A) with 2.3 mm and 1.8mm (upper and lower border) titanium locking miniplates (group B) in the treatment of mandibular fractures. They were prospectively evaluated for 3 months based on clinical and radiological parameters.

Etiology and demographics of mandibular fractures

This study revealed that out of 20 patients, the main cause of trauma was road traffic accidents (RTA) in the form of motor vehicle accidents in 11 patients (55%), fall in 5 patients (25%) and other 4 patients (20%) sustained injury due to interpersonal violence (assault). When considering the gender of the patients, mandibular fractures occurred in 18 male (90%) and 2 female (10%) patients. The age of the patients who were studied varied from 18 years to 53 years old, with a mean age of 30.6 years and standard deviation of 10.23 years.

Pre- Operative Clinical Evaluation

The main parameters considered for pre operative clinical evaluation were signs of displacement, soft tissue injury, edema, paresthesia, occlusion, step deformity and inability to open the mouth.

Preoperative Radiological Evaluation

Distribution of fracture site as per the radiographic findings

In this study, total 30 fractures occurred in 20 patients. The distribution of fractures according to site of involvement showed that 19 fractures

occurred at parasymphysis region, 8 at subcondylar region, 2 at angle region and 1 fracture at the body of the mandible. The distribution of 30 fracture shows that 11 fractures (36.6%) occurred at left parasymphysis region, 8 fractures (26.6%) at right parasymphysis region, 4 fracture (13.3%) at left subcondylar region, 4 fractures (13.3%) at right subcondylar region, 1 fracture (0.03%) at right angle of the mandible, 1 fracture (0.03%) at left angle of the mandible and 1 fracture (0.03%) at left body of the mandible.

Post Operative Clinical Evaluation

The main parameters considered for post operative clinical evaluation were signs of infection, mobility of the fracture fragments and paresthesia. All these cases were evaluated at 1 week, 1 month and 3rd month postoperatively.

Signs of infection

As a standard protocol, all the fractures were treated by intraoral approach via vestibular degloving incision. All patients were post operatively evaluated at 1 week, 1 month and 3rd month for the incidence of infection. One patient presented with pus formation and discharging sinus extra orally in locking group, for which the reason is identified to be a mobile tooth in the line of fracture which was firm during fracture reduction and fixation. This tooth was extracted post operatively. All other fracture sites healed uneventfully. There were no signs of infection in all other 19 patients.

Assessment of neurosensory deficit (paresthesia)

Assessment of the involved nerve was done at 1 month and 3 months postoperatively by subjective and objective testing. Hypoesthesia / paresthesia of mucosa in the mental region or lower lip were observed in 17 patients (9 in group A and 8 in group B) preoperatively, in 6 patients (3 in group A and 3 in group B) post operatively at 1 month and none of them at 3rd month. All sensitivity alterations were noted through objective testing and were more frequently related with fracture of the parasymphyseal region.

Incidence of malunion and nonunion

Postoperative evaluation of all the 20 patients for 3 months revealed that there was no case of fibrous union, malunion or non union detected clinically. Healing was satisfactory in all the 20 patients (100%). Plate removal was not required in any of the case. All subcondylar fractures were given intermaxillary fixation for 2-3 weeks.

Post Operative Radiographic Evaluation

Immediate post operative radiograph showed precise anatomic reduction and alignment of the fractured segments in all the patients. At the end of 1st month, the anatomic reduction of the treated fracture was evident without any signs of step defect or gap formation at the two fractured ends. The blending of margins and trabecular bone formation was indistinguishable.

At the end of 3rd month, the anatomic reduction achieved is still evident. Other finding showed that 19 patients had good amount of blending of margins and patient had less amount of blending of margins. All the patients showed gradual increase in blending of margins from 1st to 3rd month. No post-operative radiograph showed hardware impingement over the inferior alveolar nerve.

The results at one month post operative suggested that 90 % of patients healed without complication while 10 % patients had complication in the form of infection in locking plate group which was secondary to mobile tooth present in the line of fracture associated with periodontitis which was firm during plate fixation and was extracted later. It was not related to the hardware or technique used for fracture reduction. The results at 3rd month showed complete union without any complications in both locking and non locking group.

Statistical analysis was done using Mann-Whitney U test and Wilcoxon matched pairs test. The results done with Mann-Whitney U test suggested that the comparison of performance with both locking and non locking plates was not found to be statistically significant (p-value <0.05) shown in Table 1, 2 and 3.

Table 1: Comparison of locking and non-locking groups with respect to different parameters(pre-operatively) at baseline by Mann-Whitney U test.

Parameters		locking	%	Non-locking	%	total	%
Displacement	Un-displaced	1	10.00	2	20.00	3	15.00
	displaced	9	90.00	8	80.00	17	85.00
	Z=0.3780, P=0.7055						
Soft tissue injury	Negative	4	40.00	5	50.00	9	45.00
	positive	6	60.00	5	50.00	11	0.00
	Z=0.3780, p=0.7055						
Oedema	Negative	0	0.00	1	10.00	1	5.00
	positive	10	100.00	9	90.00	19	95.00
	Z=0.3780, p=0.7055						
Paresthesia	Negative	2	20.00	1	10.00	3	15.00
	positive	8	80.00	9	90.00	17	85.00
	Z=0.3780, p=0.7055						
Occlusion	Normal	1	10.00	0	0.00	1	5.00
	damaged	9	90.00	10	100.00	19	95.00
	Z=0.3780, p=0.7055						
Sleep deformity	Negative	1	10.00	1	10.00	2	10.00
	positive	9	90.00	9	90.00	18	90.00
	Z=0.0000, P=1.0000						
In ability to open the mouth	Negative	1	10.00	2	20.00	3	15.00
	positive	9	90.00	8	80.00	17	85.00
	Z=0.3780, p=0.7055						
	total	10	100.00	10	100.00	20	100.00

Table 2: Comparison of locking and non-locking groups with respect to different parameters at one month by Mann-Whitney U test

Parameters		locking	%	Non-locking	%	total	%
Infection	Positive	1	10.00	0	0.00	1	5.00
	Negative	9	90.00	10	100.00	19	95.00
	Z=0.3780, p=0.7055						
Mobility of fracture fragments	Positive	0	0.00	0	0.00	0	0.00
	Negative	10	100.00	10	100.00	20	100.00
	Z=0.0000, p=1.0000						
Occlusion	Achieved	10	100.00	10	100.00	20	100.00
	Non-achieved	0	0.00	0	0.00	0	0.00
	Z=0.0000, p=1.0000						
paresthesia	Negative	7	70.00	7	70.00	14	70.00
	Positive	3	30.00	3	30.00	6	30.00
	Z=0.0000, p=1.0000						
	Total	10	100	10	100	20	100

Table 3: Comparison of locking and non-locking groups with respect to different parameters at 3rd month by Mann-Whitney U test

Parameters		Locking	%	Non-locking	%	total	%
Infection	Positive	0	0.00	0	0.00	0	0.00
	Negative	10	100.00	10	100.00	20	100.0
	Z=0.0000, p=1.0000						
Mobility of fracture fragments	Positive	0	0.00	0	0.00	0	0.00
	Negative	10	100.00	10	100.00	20	100.0
	Z=0.0000, p=1.0000						
Occlusion	Achieved	10	100.00	10	100.00	20	100.0
	Non-achieved	0	0.00	0	0.00	0	0.00
	Z=0.0000, p=1.0000						
Paresthesia	Positive	0	0.00	0	0.00	0	0.00
	Negative	10	100.00	10	100.00	20	100.0
	Z=0.0000, p=1.0000						
	Total	10	100	10	100	20	100

Discussion

In a developing country like India, exposure to trauma due to various reasons is increasing day by day. The incidences of injuries to the facial skeleton have alarmingly increased due to the rapid emergence of many high speed automobiles and gradual increase in incidences of interpersonal violence^{1, 6, 11}. Amongst all the bones of the facial skeleton, the zygoma and the mandible are highly susceptible to traumatic injuries¹¹. Disfigurement of the face becomes a serious cause of concern making the surgical treatment of fractured facial skeleton an essential part to restore the function and aesthetics.

The treatment of the facial fractures have evolved over a period of time from methods like splinting and bandaging which resemble the closed reduction of recent times. With the introduction to open reduction and rigid internal fixation over the past 30 years and its increasing popularity has brought numerous advances in the management of fractures of the mandible².

The organized research done by AO group has recommended open osteosynthesis for maxilla-facial region; the original management objectives were the most important advantages of this technique. They were found to be the 1) early, active, pain free mobilization of the jaws 2) avoidance of IMF 3) safe and secured airways without tracheostomies particularly in polytrauma patients. 4) shorter periods of hospitalization. These were at first represented as the fundamentals of good internal fixation¹⁰. However, with increased understanding of the importance of soft tissues, the biomechanics of fixation and the fracture healing, resulted in certain conceptual changes in the management of fracture mandible.

The rigid fixation with dynamic compression osteosynthesis is an alternative method for the treatment of mandibular fractures without maxillomandibular fixation. This leads to rapid wound healing without callus formation. However, the main disadvantages associated with this technique were (1) wide extra oral incision causing risk of damage to marginal mandibular

branch of facial nerve and post operative scar formation, (2) bicortical screw engagement (3) bulky nature of the plates causing sensitivity, (4) uneven compression by the plate which may lead to necrosis of bone (5) not applicable in comminuted fractures and (6) requirement of second surgery for plate removal⁵.

Later anatomical and biomechanical studies done by Champy et al³ had proved that under physiological strain there were forces of tension produced along the alveolar border and forces of compression along the lower border of the mandible. The traction strains were found to be injurious and had to be neutralized. At the level of body of the mandible these forces were found to produce moments of flexion predominantly, which are found to be strongest towards the angle and weakest in the premolar region. In the anterior part of the mandible in front of canines, these forces produced predominantly torsional moments that increase in strength towards the midline. Therefore the principles of osteosynthesis were modified according to the mechanical qualities of the mandible, taking into account the anatomical variations in the mandible. This supports the fact that monocortical fixation alone is sufficient in the mandibular fractures as the osteosynthesis by plates and screws on the outer cortical plate is solid enough to support the strains developed by the masticatory muscles. Champy et al³ also recommended that the compression of the fragments was no longer advisable because there existed a natural strain of compression along the lower border of mandible due to the masticatory forces. Based on these observations, Champy et al³ suggested the *ideal lines of osteosynthesis*. According to this, by placing the plate at the most biomechanically favorable site the thickness of the plate can be kept to a minimum with the consequent advantage of increased malleability of the plates.

Hence miniplates have replaced compression plates for bone fixation in the maxillomandibular region as they are: 1) small and easy adaptable plates 2) mono cortical application 3) intra oral

approach 4) functional stability 5) bio mechanical favorability 6) no need for second surgery 7) less skin sensitivity⁵. Initial biomaterials available for mini plates were vitallium (cobalt based alloy) later the more successful material stainless steel was used. The current decade has seen another material called as titanium which has superior mechanical properties than other materials used till date. The advent of titanium soon replaced stainless steel allowing surgeons to use smaller mini plates (less than 1 mm) for rigid internal fixation of fracture mandible^{8,16}.

But the mini plates also have some inherent disadvantages mainly due to their design¹³. They are 1) conventional bone plate/screw systems require precise adaptation of the plate to the underlying bone, without this intimate contact, tightening of the screws will draw the bone segments toward the plate, resulting in alterations in the position of the osseous segments and the occlusal relationship 2) in conventional bone plate/screw systems stability of the fracture segments is achieved by the friction between the bone and the screw interface only. If the screw is placed along the fracture line there may be absence of bone present around the screw leading to screw loosening. This may lead to inflammatory response and subsequent chances of infection 3) Bony pathologies with altered bone architecture are relatively contraindicated for internal rigid fixation in long bones^{4,9} and it is relatively difficult in mandible¹² as the bone quality to be engaged during plating is not suitable for fixation.

To overcome these disadvantages a new type of plating system was developed which has a locking system in between screw and the plate also called as locking screw/ plate system. These plates achieve stability by locking the screw onto the plate and have been shown to enhance fixation stability, as the screws are unlikely to loosen from the plate. This means that, even if the screw is inserted into the fracture line, loosening of the screw will not occur. The possible advantage to this property of the locking plate/screw system

decreased incidence of inflammatory complications from loosening of hardware¹³. Here the screw, plate and the bone act as a single functional unit acting as a mini *internal fixator*, which transmits the functional forces to the bone there by dissipating the forces. In the case of conventional mini plates there may be concentration of functional forces around the screw and bone interface leading to possible release of inflammatory response and subsequent bone resorption around the screws leading to screw loosening¹². Another unique and probable theoretical advantage to the locking plate/screw system is that it becomes unnecessary for the plate to have intimate contact with the underlying bone making plate adaptation easier leading to lesser alterations in the alignment of the segments and changes in the occlusal relationship upon screw tightening¹⁵. It is observed that the degree of plate adaptation affected the mechanical behavior of nonlocking plates but did not affect the locking plate/screw system¹⁵. The third advantage in the locking plate/screw system is that they do not disrupt the underlying cortical bone perfusion as much as the conventional plates which compress the undersurface of the bone plate to the cortical bone. It is also proposed that this system provides greater stability than does the standard conventional miniplate¹³ and also in bony pathologies like osteoporosis and other age related bony changes locking plate system provides better stability across fracture segments^{7,9}. The only exception is that one should use a drill guide to “center” the drill hole within the center of bone plate to facilitate proper screw locking to the plate. The screws, plate and bone form a solid framework with higher stability than the traditional miniplate system. The locking plate/screw system has demonstrated higher stability across a fracture/osteotomy gap compared with the conventional non locking 2.0 mm miniplate in in-vitro studies¹². The current study was undertaken to compare the outcome and results of the treatment of 20 undisplaced or minimally displaced mandibular fractures with

thin 2.0 mm non locking titanium miniplates of less than 1mm thickness (0.9mm) (group A) and 1.8 and 2.3mm locking plates of 1mm thickness (upper and lower border) (group B) fixed with 6 mm self-threading monocortical screws in both the groups. All the cases were selected randomly were treated accordingly. Similar kind of titanium miniplates was used by Marisa Gabrielli et al¹¹.

Many factors are considered responsible for the incidence of maxillofacial trauma. Ellis et al⁶ showed that the assaults to be the first cause for fractures followed by motor vehicle accidents and falls, another study done by Jose -Moreno et al¹⁴ encountered 43.1% fractures due to road traffic accidents and 35.8% due to assaults. Marisa Gabrielli et al¹¹ also concluded the same findings. Our study showed road traffic accidents in 11 patients (55%) as the main cause of mandibular fractures followed by accidental fall in 5 patients (25%) and assault in 4 patients (20%).

Out of the 20 patients who were evaluated, 9 patients (45%) had multiple mandibular fractures; the concomitant fracture site involved being the subcondylar fracture in 8 patients and one angle fracture. Amongst the 20 patients studied, 16 patients had complete set of dentition and 4 patients were partially edentulous. Similar ratio was seen in study done by Verma A, et al¹. 20 patients showed 30 fracture sites, out of which 11 fractures (36.6%) occurred at left parasymphysis region, 8 fractures (26.6%) at right parasymphysis region, 4 fracture (13.3%) at left subcondylar region, 4 fractures (13.3%) at right subcondylar region, 1 fracture (0.03%) at right angle of the mandible, 1 fracture (0.03%) at left angle of the mandible and 1 fracture (0.03%) at left body of the mandible. These are comparable with the figures proposed by Jose Moreno et al¹⁴ who encountered 39.2% fractures at parasymphyseal region.

The main parameters considered and seen for pre operative clinical evaluation were signs of displacement (85%), soft tissue injury (55%), edema (95%), paresthesia (85%), deranged occlusion (95%), step deformity (90%) and

inability to open the mouth (85%). Radiographic evaluation was done with panoramic and posteroanterior mandibular radiographs.

Parameters considered for post operative clinical evaluation were signs of infection, mobility of the fracture fragments, occlusal disturbances and paresthesia. All are evaluated at 1 week, 1 month and 3rd month postoperatively. Radiographic evaluation was done at 1st and 3rd months.

Condylar region is the most susceptible area for fracture in the mandible, with condylar fractures ranging from 36-42% as stated by Rudolf et al⁷. In our study of 20 patients, mandibular fractures were detected at 30 sites, out of which 8 (26%) were condylar fractures. They were given intermaxillary fixation for 2-3 weeks. After 3rd month post operative follow-up, radiographically it was confirmed that none of the patient developed condylar resorption.

The complications observed in this preliminary study of 20 patients (both locking and non locking) were minimal, we have conducted Wilcoxon matched pairs test which showed 100% success rate in both the plating systems. Jose Moreno et al¹⁴ concluded that the occurrence of complications in mandibular fractures is fundamentally related to the direction, degree, magnitude of the force and severity of the fracture rather than to the type of fixation used.

The results are compared with Mann-Whitney U test which suggested that the comparison of performance of both locking and non locking groups were found to be statistically insignificant with a p-value <0.05, showing similar complication rates in both the groups. This study suggests that there is only theoretical advantage of locking plates over conventional non locking mini plates in the fracture fixation of minimally displaced or undisplaced fractures of the mandible. This is in accordance with Edward Ellis III and John Graham¹³

Conclusion

In order to achieve better fixation, increased stability and early return to function while treating

minimally displaced or undisplaced mandibular fractures various techniques and biomaterials have evolved in the past.

The present study on locking plate design comes from the same idea of better fixation and stability. We compared the latest technique of locking plate design with the conventional miniplates and found no statistical significance, by which we can infer that even though there is theoretical advantage for this design practically it does not give better outcome.

As we did not encounter any cases with bony pathologies during our study course, we recommend further studies for fixation of fractures in more number of patients with the locking plate design in geriatric and patients with bony pathologies.

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