

Locking Versus Non-Locking Miniplates in the Treatment of Mandibular Fractures in Above 35 Years Age Patients

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ABSTRACT

Objective: To compare the frequency of short term post-operative infection of locking plates versus non-locking plate in mandibular fractures in patients above 35 years of age.

Methodology: A randomized controlled study was conducted at the Department of Oral and Maxillofacial Surgery, Pakistan Institute of Medical Sciences, Islamabad from January 2018 to January 2019, involving a 100 patients (50 patients in each group). On the basis of history, clinical features, orthopantomogram (OPG) and intraoperative findings, the diagnosis of mandibular fractures was established. Group A patients were treated with reduction and fixation of fracture with locking miniplates and miniscrews following Champy's principle of osteosynthesis. Whereas in group B patients, fractures were reduced and fixed with non-locking miniplates and miniscrews following Champy's principle of osteosynthesis.

Results: Effect modifiers such as age, gender, and type of fracture were controlled by stratification. A post-stratification chi-square test was applied. The 1 patient that had infection in group A had an age range 50- 65 years (53 years) (P value: 0.197) while the 2 patients that had infection in group B were younger in age range of 35-50 years (36 years and 38 years) (P value: 0.322). The 1 patient who had infection in group A was female (P value: 0.043) while the 2 patients of group B who had infection were also females (P value: 0.027). In group A, only 1 patient had infection at the para-symphysis of mandible according to site (P value: 0.494). In group B, 1 patient had infection at para-symphysis of mandible and 1 at the body of the mandible site (P value: 0.599). The results were not statistically significant in terms of infection by the end of 3rd week.

Conclusion: The study concludes that insignificant post-operative infection rates while managing mandibular fractures either by locking plates or non-locking plates.

Keywords: Locking plate, non-locking plate, mandibular fractures, open reduction, infection.

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Introduction

Since ancient times, different techniques have been proposed by physicians for managing mandibular fractures, using the principle of reduction and immobilization of the bony fragments.^{1,2} The treatment of

mandibular fractures has progressed from splinting, closed reduction with intermaxillary fixation, circummandibular wiring, extra oral pins and open reduction with transosseous wires to open reduction and internal fixation (ORIF) with bone plating.^{3,4} Closed reduction does not inflict trauma to the vascular bed and

is cost effective for the patient. However, it involves a period of prolonged immobilization of the jaws and is associated with nutritional problems and delayed return of function. Open reduction and internal fixation instead permits visualization and anatomical reduction of fractured bone segments under direct vision and re-establishing of the patient's preinjury occlusion.⁵ There is, however, a greater chance of potential foreign body infections with this approach since its introduction with stainless steel but it is lesser with the more biocompatible titanium.⁵

Many different plating systems have been used for the management of mandible fractures including micro-plates, mini-plates (1.3-2 mm thickness), locking mini-plates, reconstruction plates, compression plates, THORP system, fracture plates, non-locking and locking plates.^{6,7,8}

The non-locking miniplate system attains stability when head of the screw press the non-locking plate to the bone, compromising the local cortical blood supply. This compromised blood supply theoretically decreases bone healing, while increasing the chance of complications like infection, bone resorption, and secondary loss of reduction.⁹ A study done by Haugh inferred that the amount of plate adaptation affected the mechanical performance of the non-locking systems.¹⁰ Non-locking system may be insufficient in attaining fixation in osteopenic or osteoporotic bone as these bones may not be able to withstand the shear forces created by advancing screw threads.¹¹

According to studies conducted on mandibular fractures it was seen that Locking plating system shows certain "conceptual" advantages over contemporary systems.¹² Locking system, which was introduced in year 2000, claims that precise plate adaptation is unessential.¹³ The concept of locking plates was that not only the screws locks to the bone but the plates as well, an achievement of double threaded screw. One thread will lock the bone; another will engage a threaded area of the bone plate, which transforms it into a mini-internal fixator.¹⁴ As internal fixator locking plates do not depend on frictional force between the locking plate and bone to attain stability, local cortical blood supply under the plate is preserved.¹⁵ Screws are less likely to unlock from the plate due to the threading mechanism linked in locking screw/plate systems. This, as a result, leads to a reduced chance of inflammation due to loosening of the hardware.¹⁴ Locking plates transform shear stress to

compressive stress at the screw bone interface, making them a good alternative in osteopenic or osteoporotic bone.⁹

Numerous studies done previously have shown insignificant short-term complication rates between fixation via locking and non-locking system except in terms of infection, paresthesia and reducing the need and duration of IMF.^{9,13} Amjad Ali et al found 100 percent post-operative infection free healing in both locking and non-locking plates⁹, while Ajay Verma et al found 13.6 percent infection in non-locking plates and 4.7% in locking plates.¹⁶ Statistically insignificant results were perhaps due to not limiting the age range to osteopenic age changes in bone or at the age when the mandible mostly depends on its periosteal blood supply. Insignificant complication rates were also questioned in terms of the wide age range of patients in a meta-analysis done in 2014.¹³

The rationale for this study was to resolve the disparity in literature comparing locking to non-locking plates; thereby highlighting the choice of treatment with regard to postoperative complications and therefore aiding in better definitive management of patients.

Methodology

This was a randomized control trial that was conducted in Department of Oral and Maxillofacial surgery, Pakistan Institute of Medical Sciences, Islamabad from 10th January 2018 to 9th January 2019. A simple consecutive non-probability sampling technique was used. Sample size was calculated by using WHO sample size calculator with Level of significance: 5%, Power of test: 80%, anticipated population proportion P1: 0⁹, anticipated population proportion P2: 136¹⁶ resulting in sample size of 42 in each group. We took 100 patients, divided into two group, i.e. 50 patients in each group.

Age limit of 35 to 65 years and patients having isolated symphysis, para-symphysis and/or body of mandible fracture were included criteria. Patients having infected wounds, comminuted fractures, gunshot injury or bone defects, Patients not fit for general anesthesia and associated other facial fractures were excluded from the study.

Permission from hospital ethical committee was obtained. Informed consent was taken from patients. Patients were admitted in Oral and Maxillofacial Surgery Department of Pakistan Institute of Medical Sciences Islamabad. For

the collection of information and observations, a predesigned proformas were filled. This form included biographic data, clinical findings and follow-up details.

Diagnosis of mandibular fractures were established on the basis of history, clinical features, orthopantomogram and per operative findings. All patients were operated by a single team of surgeons under general anesthesia. Lottery method was used to randomly allocate the patients into group A and B. Pre-op baseline investigations and general anesthesia fitness was taken prior to surgery. In group A patient's reduction and fixation of fracture were done with locking miniplates and miniscrews following Champy's principle of osteosynthesis using gingivo-buccal sulcus incision. Whereas in group B fractures were reduced and fixed with non-locking miniplates and miniscrews following Champy's principle of osteosynthesis using gingivo-buccal sulcus incision.

All the patients were given Injection Amoxicillin/clavulanic acid 1.2g, Infusion Metronidazole 500mg i/v and inj. dicloran 75 mg i/m pre-operatively and were continued postoperatively for 3 days. Patients were discharged on third postoperative day if deemed fit for discharge with oral medications mentioned above. Patients were advised to use soft diet and maintain strict oral hygiene and were followed-up for 3 weeks postoperatively at intervals of 1st, 2nd, 3rd weeks after surgery. Infection was assessed up till the end of 3rd post-operative week.

Data was recorded in a predesigned proforma and was interpreted for short term post-operative infection in both groups. To limit confounding factors and bias in the study, results and exclusion criteria were followed strictly. The data was entered and analyzed using the statistical program SPSS version 23. Descriptive statistics like mean ± standard deviation was calculated for quantitative variables like age. Frequency/percentage was calculated for categorical variables like type of fracture and outcome of infection or not. Infection was compared by chi square test. Between two groups effect modifiers like age, gender, type of fracture was controlled by stratification P- value ≤ 0.05 was considered significant.

Results

A sum of 100 patients fulfilling the inclusion criteria, having mandibular fractures were included in the study. Out of which, 50 patients randomly were allocated group A and the other 50 to group B. The patients were aged

from 35 years to 65 years with a mean of 47.34 years (SD± 8.211). Patients aged from 35-50 were grouped as group 1 and 50-65 were grouped as group 2. Group 1 had 65 and group 2 had 35 patients. In this study majority were males 75% (n=75) whereas females constituted 25% (n=25). Overall type of fracture wise distribution was 30%(n=30) symphysis of mandible, 40% (n=40) had para-symphysis fracture and 30% (n=30) had body of mandible fracture. Overall only 3% (n=3) patients had infection at the end of 3 weeks follow up period (Table I). Infection at the end of 3rd week follow up was compared between the two groups by applying chi-square. Group wise distribution of infection showed 1 patient of group A to have infection while 2 patients of group B had infection at the end of 3 weeks follow up period (P value: 0.558) (Table II).

Effect modifiers such as age gender and type of fracture were controlled by stratification. Post stratification chi-square test was applied. The 1 patient that had infection in group A had an age range 50- 65 years (53 years) (P

Table I: Descriptive statistics

Variable	Characteristics	N	%
Age	Group 1	65	65.0
	Group 2	35	35.0
Gender	Male	75	75.0
	Female	25	25.0
	Total	100	100.0
Type of fracture	Symphysis	30	30.0
	Para-symphysis	40	40.0
	Body of mandible	30	30.0
	Total	100	100.0
Infection at the end of 3 rd week	No	97	97.0
	Yes	3	3.0
	Total	100	100.0

Table II: Infection at the end of 3rd week compared in group A and B.

	Assessment of infection at the end of 3 rd week		Total	P. Value
	No	Yes		
Group A (ORIF with 2.0 mm locking plates)	49	1	50	0.558
Group B (ORIF with 2.0 mm non-locking plates)	48	2	50	
Total	97	3	100	

value: 0.197) while 2 patients had infection in group B were younger in age range of 35-50 years (36 years and 38 years) (P value: 0.322) (Table III). The 1 patient which had infection in group A was female (P value: 0.043) while the 2 patients of group B who had infection were also females (P value: 0.027) (Table IV). In group A, only 1 patient had infection at para-symphysis of mandible according to site (P value: 0.494) In group B, 1 patient had infection at para-symphysis of mandible and 1 at body of mandible site (P value: 0.599) (Table V).

Table III: Effect of age on infection rate

Assessment of infection at the end of 3 rd week	Patient's Age in group A		Total	P. Value
	35-50 years	50-65 years		
	No	31		
Yes	0	1	1	
Total	31	19	50	
Assessment of infection at the end of 3 rd week	Patient's Age in group B		Total	P. Value
	35-50 years	50-65 years		
	No	32		
Yes	2	0	2	
Total	34	16	50	

Table IV: Effect of gender on infection rate

Assessment of infection at the end of 3 rd week	Patient's sex in group A		Total	P. Value
	Male	Female		
	No	40		
Yes	0	1	1	
Total	40	10	50	
Assessment of infection at the end of 3 rd week	Patient's sex in group B		Total	P. Value
	Male	Female		
	No	35		
Yes	0	2	2	
Total	35	15	50	

Table V: Effect of fracture type on infection rate.

Assessment of infection at the end of 3 rd week	Fracture diagnosis in group A			Total	P. Value
	Symphysis of mandible	Para-symphysis of mandible	Body of mandible		
No	14	20	15	49	0.494
Yes	0	1	0	1	
Total	14	21	15	50	
Assessment of infection at the end of 3 rd week	Fracture diagnosis in group B			Total	P. Value
	Symphysis of mandible	Para-symphysis of mandible	Body of mandible		
No	16	18	14	48	0.599
Yes	0	1	1	2	
Total	16	19	15	50	

Discussion

Non-locking miniplate system attains stability by compressing the fixation plate to the bone with the help of tightening the screw, resulting in compromised local cortical blood supply.

Contrary to that, the concept of locking plates was that not only the screws locks to the bone but to the plates as well, an achievement of double threaded screw. One thread will lock the bone; another will engage a threaded area of the bone plate which transforms it into a mini-internal fixator.¹⁴

The study Amjad Ali et al had no infection at the end of 3 months of post op follow up in group A or B. Only one patient reported with infection in the first post-operative month, which was subsequently resolved and the plate was not removed.⁹ A study by Ruchika et al reported transoral wound dehiscence leading to exposure of plate in 2 (8%) of patients who was treated by irrigation and primary closure or by other measures like antibiotic impregnated packing. There was a major complication in 1 (4%) patient with infection at fracture site requiring incision and drainage complemented with antibiotic coverage. The infection regressed after 7 days. In all the cases, adequate reduction and favorable healing was noted in the 1st and 3rd months of the postoperative period. A study by Edward Ellis reported postoperative infection in 6 patients. Most of those patients were treated in the outpatient clinic with transoral incision and drainage, irrigations, and oral antibiotics. However, 1 patient acquired a severe infection thereby requiring admission to the hospital, extraoral incision and drainage under general anesthesia and intravenous antibiotics.¹⁵ In the study by Chad et al there were 6 complications, with a rate of 4.1%. These complications were categorized as minor. Three complications occurred in the

parasymphyseal region, two in the angle and 1 in the body region. Three complications occurred in the locking group and 3 in the standard group, with an equal complication rate of 4.6% and 5.2%, respectively. Most of these were minor infections requiring plate removal, and 1 was a postoperative occlusal discrepancy.¹⁷ In our study, we observed similar findings of 2% (n= 1) infection rate in the locking group and 4% (n=2) in non-locking group resulting in an insignificant p value (0.558) (Table III)

All the effect modifiers controlled had insignificant P values except the gender variable. Infection that was reported was only found in female patients resulting in significant P values in both treatment groups. The 1 patient who had infection in group A in our study, was post-menopausal affecting the bone density, which could be the probable cause of infection in that patient. Osteoporosis in post-menopausal women has nowadays is an established fact leading to an increased risk of post op infections.²⁴ Chlorhexidine has been proven and is now recommended as a mean of oral hygiene in order to reduce post op infection rates. The 1 patient in the non-locking group was mentally handicapped, hindering the daily oral hygiene measures.²⁵ The other patient in the non-locking group had uncontrolled type 1 diabetes, which is thought to be the culprit of infection.²⁶

In spite of the fact that this was a prospective randomized study of which randomization done by lottery method, there were certain limitations; multiple mandibular fractures are one such limitation. Extra fractures may behave as confounding variables and affect the conclusion of the study. Physical or mental barriers to maintaining oral hygiene, as well as systemic conditions that suppress the immune system, may all play a role in the end result of infections. It is suggested that a detailed study controlling all the confounding factors which might be affecting the outcome should be done to evaluate the precise differences between management with locking or non-locking systems.

Conclusion

Our study shows infection rates in mandibular fractures managed by non-locking versus locking plates (4% vs 2% respectively) to be statistically insignificant, but the slightly better results of locking plates warrant their use in special cases. It is still difficult to conclude the specific recommendations for the use of locking plates over non-locking miniplates. Further multicenter research should

be carried out to have clear guidelines in the management of mandibular fractures for optimal patient care and the best interests of the community and healthcare providers.

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