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Original Research

Evaluation of efficacy of self-tapping IMF screws over ERICH'S arch bar in establishing intermaxillary fixation in the treatment of mandibular fracture: An original research

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ABSTRACT:

Aim: The aim and objectives of the study were to evaluate the efficacy of self-tapping IMF screws over Erich's arch bar in establishing intermaxillary fixation in the treatment of mandibular fracture using various parameters. Methodology: Twenty patients who reported to the Department of Oral and Maxillofacial Surgery, Yenepoya Dental College, Mangalore with mandibular fractures and required intermaxillary fixation as a part of treatment plan followd by open reduction and internal fixation under GA were selected for this study. They were randomly divided into 2 groups of 10 patients each, that is Group A and Group B. Group A included patients who received intermaxillary fixation with Erich arch bars. Group B includes patients who received intermaxillary fixation with IMF Screws. The patients were followed up intraoperatively postoperatively for assessing the efficacy of the procedure by evaluating the time taken for the procedure, pain intensity, oral hygiene status, vitality, and glove perforation. **Results:** The mean time taken for IMF using IMF screw was around twenty minutes as compared to around 80 minutes with Erich's arch bars. Post-operative pain was assessed and inter-group comparison (IMF screws and Arch Bar) was done and statistically significant lower mean rank values were observed for IMF screws. Oral hygiene status was assessed and compared on the 7th day and 15th day. The oral hygiene status values among group A were higher as compared to the group B on the 7th day. The mean number of glove perforations was significantly more in Group A as compared to Group B.There were no incidence of iatrogenic injury to tooth roots. Conclusion: The use of self-tapping IMF screws for intermaxillary fixation is a valid alternative to conventional Erich's arch bars in the treatment of mandibular fractures. Iatrogenic injury to dental roots is the most important problem to this procedure, which can be minimized by careful radiographic evaluation and treatment planning Key words: Inter maxillary fixation (IMF), Arch bar, Self-tapping Intermaxillary fixation screws

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INTRODUCTION

Among the facial skeletal injuries, mandibular fractures are the most commonly occurring ones which might be following interpersonal violence, road traffic accidents, industrial mishap or any others. Since the time of Hippocrates various surgeons and physicians have reported and described several techniques for treating mandibular fractures.¹ All the documented treatment modalities for mandibular fracture treatment is based on the principle of repositioning and immobilization of bony fragments of the mandible.² The key to uneventful healing is proper anatomical reduction and fixation of fractured

mandibular segments following trauma.³The term fracture is defined as a break in the structural natural bone continuity, for which mainly two treatment modalities are advocated – Closed reduction or Open reduction and internal Fixation. For both type of treatment inter-maxillary fixation is the most crucial and prime step for maintaining and establishment of proper inter-relationship of the occlusal table.⁴ Though the principles involved in the treatment protocol of mandibular fractures keeps changing from time to time, the main goal or aim of the reestablishment of masticatory function and the occlusal balance remained the same throughout history. The most commonly employed methods of inter-maxillary fixation are by using eyelets wire and Erich arch bar. Though they were effective, they had setbacks during usage like compromised oral hygiene, trauma to the periodontium, poor periodontal support, penetrating injury to the surgeon and increased surgical time both in placement and removal .8 Inter-maxillary fixation screws were developed as an alternative for Erich arch bar in 1989.⁹ Literature have documented many advantages of Inter-maxillary fixation screws like relatively inexpensive, ease of handling, gingival health maintenance, reduced risk of needle stick injuries operating time.^{10,11} Scientific and decreased documentation regarding the complications related to inter-maxillary fixation screws have been reported as screw loosening before completion of the intermaxillary fixation period, fracture of the screw on insertion, iatrogenic damage to dental roots, incisive canal, and soft tissue coverage of screws.^{12,13}Arthur G and Berardo N in 1989 introduced the self-tapping inter-maxillary screws and the same was modified by Jones DC in 1999.9,11 The Capstan shaped head design as documented by Jones DC employed a threaded titanium screw of 2 mm diameter and 10 -16 mm length which enables the wires and elastics to directed away from the gingival soft tissues and also has added advantages of easy insertion, reduced operating time and reduced risk of needle stick injuries.¹⁴ There are several studies documented in the literature that have evaluated the efficacy of selftapping inter-maxillary screws, however fewer studies have compared the self-tapping inter-maxillary screws and Erich arch bar.¹⁵ Hence, a study was designed to do a comparative evaluation of titanium self-tapping inter-maxillary fixation screws and Erich arch bar for inter-maxillary fixation for the treatment of mandibular fracture in terms of various soft and hard tissue parameters (Operative time, pain intensity, glove perforation, oral hygiene status and tooth vitality).

METHODOLOGY INCLUSION CRITERIA

Patients with mandibular fracture not associated with dentoalveolar fracture, The age group of 18 to 60 years, Patients with vital teeth in the area of screw placement, Patients who are willing to participate in the study

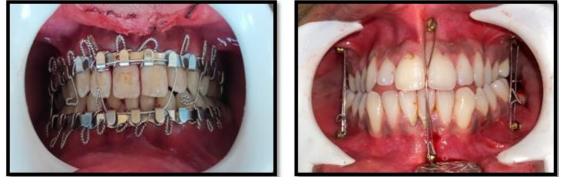
EXCLUSION CRITERIA

Patients with comminute fracture, Severely displaced fracture, Presence of systemic conditions like bronchial asthma, mental retardation, psychiatric abnormalities or seizure, Edentulous patients, Patients with overcrowded teeth, Patients with any pathological fracture of the mandible

INTERVENTION PROCEDURE

The patients from the OPD of Oral and Maxillofacial Surgery who were diagnosed with a fracture of the mandible and indicated for intermaxillary fixation were included in this study. A detailed case history was taken with a clinical examination.Pre-treatment OPG or CT was obtained.Local anaesthesia containing 2% lignocaine with 1:80,000 epinephrine was administered locally.In one group of patients [group A], for IMF, Erich's arch bar was placed using the standard method. In patients with complete dentition, it can be extended on both sides to the second molar and in the case of a deficient number of teeth, third molars can also be included. To secure the arch bar to the teeth and to achieve intermaxillary fixation 26-gauge wires were used(Picture.1). In the other group of patients (group B), IMF was achieved by using titanium self-tapping IMF screws of 2.0mm diameter and 8mm length. The screws were placed at the level of mucogingival junction. The most preferred site for placement is between the two central incisors and between premolar and molar.Intermaxillary fixation was achieved by using 26 gauge wires .A postoperative orthopantomogram was used to evaluate screw placement.All patients were on chlorhexidine mouthwash for 15 days.All the patients were advised to have a liquid diet till the completion of treatment.(Picture 2). The patients were followed up on day 3, day 7, and day 15 to evaluate the efficacy of the procedure.

Picture 1- Intermaxillary fixation using Erich's archbar &Picture 2- Intermaxillary fixation using self tapping IMF screws.

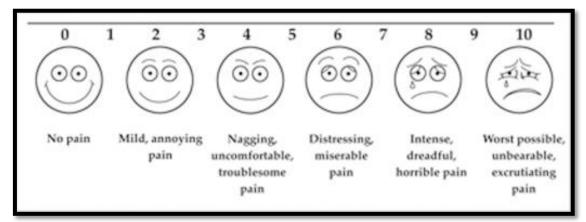


CLINICAL ASSESSMENT

The following parameters were taken into consideration for the assessment of the procedure: Time taken to place the arch bar and self-tapping IMF screws: Was evaluated by recording the time

via stopwatch from the start of the placement till the completion of the procedure.

Pain Intensity: Was evaluated by a 10 level Visual Analogue Scale (VAS) with the patient placing a mark on the scale to indicate an intensity range from no pain '0' to severe/unbearable pain '10'. This will be recorded in patients with self-tapping IMF screws and Erich's arch bar on the 2nd day, 3rd day, 7th day, 15th day.



Glove Perforation: Was assessed by using the water inflation method. Noted as present or absent.

Oral Hygiene Status was checked on the 7th and 15th day as good, fair or poor.

STATISTICAL ANALYSIS

The collected data was entered in Microsoft Excel Software by the examiner. The entered data were exported to SPPS Software for statistical analysis. Statistical tests were done using SPSS 21.0 (Statistical package for social sciences; IBM Standard Statistics. 2012).Mean, deviation. Frequencies and Percentage distribution were obtained from the data using Descriptive statistics. Intergroup comparison was done using Analysis of Variance (ANOVA).Pair-wise intergroup comparison was done using Analysis of Variance (ANOVA) after adjusting for multiple comparisons using Bonferonni Correction (Post-hoc analysis).Pair-wise intra-group comparison was assessed using General Linear Model for Repeated Measures / Repeated measures ANOVA (RMA) after adjusted for multiple comparisons using Bonferonni Correction. Intergroup comparison was done using Kruskal Wallis Test. Intra-group comparison Friedman Test. Pair-wise intra-group comparison was assessed using Wilcoxon Signed Ranks Test. The level of significance was set at p < 0.05.

RESULT

After conducting Normality Test using Shapiro-Wilk's test of the obtained research data, it was decided to use Parametric tests – Independent-t-Test for Inter-group comparison and ANOVA (Analysis of Variance) Test for intra-group overall comparison followed by Post-hoc analysis using Repeated Measures ANOVA (RMA) Test after adjusted for multiple comparisons using Bonferonni Correction for the normally distributed data (Homogeneous Distribution); and for the not-normally distributed data (Heterogeneous Distribution) it was decided to use Parametric tests – Mann-Whitney Test for intergroup comparison and Wilcoxon Signed Ranks Test for intra-group comparison.

		Ν	Mean	Standard Deviation	p-value	
Time	Arch Bar	10	1.1060	0.55961	0.001*	
Time	IMF Screws	10	0.2020	0.03676	0.001	
p-value based on Independent Samples Test						
* = Statistically Significant (p < 0.05)						

The time comparison (**Table 1**) shows that IMF screws (0.20 ± 0.03 hours) require statistically significant (p < 0.001) lower time as compared to arch bar (1.10 ± 0.55 hours). This comparison was done using Independent-t-Test.

 Table 2: Inter-group Comparison of postoperative pain intensity among Arch bar and IMF screws

		Ν	Mean Rank	p-value
PPI Day2	Arch Bar	10	13.20	0.043*
	IMF Screws	10	7.80	0.045
PPI Day3	Arch Bar	10	14.15	0.004^{*}

	IMF Screws	10	6.85			
PPI Day7	Arch Bar	10	13.25	0.035*		
PPI Day/	IMF Screws	10	7.75			
	Arch Bar	10	13.40	0.029*		
PPI Day15	IMF Screws	0.029				
p-value based on Mann-Whitney Test						
* = Statistically Significant (p < 0.05)						

Post-operative pain was assessed and inter-group comparison (IMF screws and Arch Bar) was done on the 2^{nd} day, 3^{rd} day, 7^{th} day and 15^{th} day using the Mann-Whitney test (**Table 2; Graph 1**). Statistically significant lower mean rank values were observed for IMF screws at 2^{nd} day (p = 0.043), 3^{rd} day (p = 0.004), 7^{th} day (p = 0.035) and (p = 0.029).

Graph 1: Intergroup	comparison of	f postoperative	pain intensity
or up in the more broup	eon par son of	postoperative	Pullin more and



Table 3: Inter-group Frequency Distribution Of glove perforation

		Frequency	Percentage
Arch Bar GP	Present	6	60.0
Arcii Dar Gr	Absent	4	40.0
IMF Screws GP	Present	2	20.0
INIT SCREWS GP	Absent	8	80.0

Glove perforation was seen among 60% in the Arch bar group which was higher as compared to 20% in the IMF screw group and it was statistically insignificant (p = 0.143) when compared using the Mann-Whitney test (**Table 3**).

Table 4: Inter-group Frequency Distribution of oral hygiene index

		Frequency	Percentage
	Good	2	20.0
Arch Bar OHS Day 7	Fair	4	40.0
	Poor	4	40.0
Anch Don OHS Dor 15	Good	5	50.0
Arch Bar OHS Day 15	Fair	5	50.0
	Good	2	20.0
IMF OHS Day 7	Fair	6	60.0
	Poor	2	20.0
	Good	4	40.0
IMF OHS Day 15	Fair	5	50.0
	Poor	1	10.0

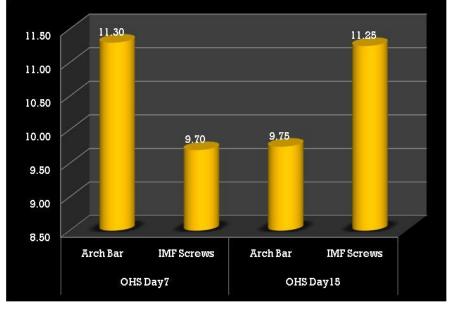
se comparison or or ar n	ygiciic status					
	Sum of Ranks	p-value				
Arch Bar OHS Day 7	28.00	0.008^{*}				
Arch Bar OHS Day 15	28.00	0.008				
IMF OHS Day 7	6.00	0.083				
IMF OHS Day 15	0.00	0.085				
p-value based on Wilcoxon Signed Ranks Test						
* = Statistically Significant ($p < 0.05$)						

Table 5: Intra-group Pair-wise Comparison of oral hygiene status

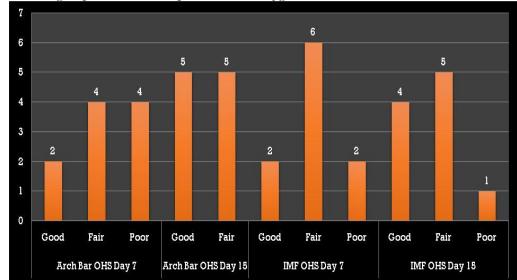
Oral hygiene status was assessed and compared among archbar group on the 7th day and 15th day. The oral hygiene status values among the Arch bar group were higher as compared to the IMF screw group on the 7th day; more participants had fair (40%) and poor (40%) oral hygiene scores (**Table 4, Graph 2**) as compared with IMF screw Group. Among the Arch bar group on the 15th day (**Table 4, Graph 2**), the oral health status improved (50% Good & 50% Fair).

All the above-mentioned comparisons done using Mann-Whitney Test were statistically insignificant. Intra-group pair-wise comparison done using Wilcoxon Signed Ranks Test between 7th day and 15th day for Arch group showed statistically significant difference (**Table 5, Graph 3**); whereas the statistically insignificant difference was observed between 7th day and 15th day among IMF screw group

Graph 2-: Inter-group Frequency Distribution of oral hygiene index



Graph 3-: Intra-group Pair-wise Comparison of oral hygiene status



incra group comparison of pain among Arch bar group.						
	Ν	Mean	Standard Deviation	p-value		
Arch Bar PPI Day 2	10	4.7000	0.82327			
Arch Bar PPI Day 3	10	3.8000	0.63246	$< 0.001^{*}$		
Arch Bar PPI Day 7	10	2.1000	0.31623	< 0.001		
Arch Bar PPI Day 15	10	1.4000	0.51640			
p-value based on ANOVA (Analysis of Variance) Test						
* = Stati	stical	ly Signi	ficant (p < 0.05)			

Table 6(a): Overall intra group comparison of pain among Arch bar group.

Overall intra-group comparison (**Table 6a**) of postoperative pain among Arch bar group over the period done using ANOVA (Analysis of Variance) test showed statistically significant difference (p < 0.001) across the period from 2nd day to 15th day; with pain values gradually decreasing over the period till 15th day of assessment

Table 6(b): Individual pair-wise comparison of postoperative pain among Arch bar group.

		Mean Difference	p-value		
	Arch Bar PPI Day 3	0.900	0.023^{*}		
Arch Bar PPI Day 2	Arch Bar PPI Day 7	2.600	< 0.001*		
	Arch Bar PPI Day 15	3.300	< 0.001*		
Arch Bar PPI Day 3	Arch Bar PPI Day 7	1.700	< 0.001*		
ATCII Dal FFT Day 5	Arch Bar PPI Day 15	2.400	< 0.001*		
Arch Bar PPI Day 7	Arch Bar PPI Day 15	0.700	0.057		
p-value based on Post-hoc analysis using Repeated Measures ANOVA (RMA)					
Test after adjusted for multiple comparisons using Bonferonni Correction					
* = S	statistically Significant (p	0 < 0.05)			

Individual pair-wise comparison of Arch bar group (**Table 6b**) shows that there was actual statistically significant difference when comparison was done on the following days -2^{nd} day and 3^{rd} day (p = 0.023), 2^{nd} day and 7^{th} day (p = < 0.001), 2^{nd} and 15^{th} day (p = < 0.001), 3^{rd} and 7^{th} day (p = < 0.001), 3^{rd} and 15^{th} day (p = 0.<001). There was no statistically significant difference when 7^{th} day and 15^{th} day pain values were assessed (p = 0.057).

Table 7(a): Overall intra group comparison of post operative pain among IMF screw group.

	Ν	Mean	Standard Deviation	p-value	
IMF PPI Day 2	10	3.5000	1.35401		
IMF PPI Day 3	10	2.4000	0.96609	0.006^{*}	
IMF PPI Day 7	10	1.5000	0.52705	0.000	
IMF PPI Day 15	10	0.7000	0.48305		
p-value based on ANOVA (Analysis of Variance) Test					
* = S	tatisti	cally Sig	nificant (p < 0.05)		

Overall intra-group comparison (**Table 7a**) of postoperative pain among IMF screw group over the period done using ANOVA (Analysis of Variance) test showed statistically significant difference (p = 0.006) across the period from 2nd day to 15th day; with pain values gradually decreasing over the period till 15th day of assessment.

Table 7(b): Individual	pair-wise comp	arison of p	postoperative	pain among IM	F screw group.

		Mean Difference	p-value
IMF PPI Day 2	IMF PPI Day 3	1.100	0.040^{*}
	IMF PPI Day 7	2.000	0.001^{*}
	IMF PPI Day 15	2.800	0.001^{*}
IMF PPI Day 3	IMF PPI Day 7	0.900	0.023*
	IMF PPI Day 15	1.700	0.004^{*}
IMF PPI Day 7	IMF PPI Day 15	0.800	0.019*
p-value based on Post-hoc analysis using Repeated Measures ANOVA (RMA)			
Test after adjusted for multiple comparisons using Bonferonni Correction			
* = Statistically Significant (p < 0.05)			

Individual pair-wise comparison of IMF screw (**Table 7b**) shows that there was actual statistically significant difference when comparison was done on the following days -2^{nd} day and 3^{rd} day (p = 0.040), 2^{nd} day and 7^{th} day (p = 0.001), 2^{nd} and 15^{th} day (p = 0.001), 3^{rd} and 7^{th} day (p = 0.023), 3^{rd} and 15^{th} day (p = 0.004), 7^{th} and 15^{th} day (p = 0.001).



Graph 4: Comparison of post operative pain between Arch bar and IMF screws.

Graphical trend analysis (**Graph 4**) of post-operative pain across all the time points assessed shows that there was a gradual decrease of pain scores for the Arch bar group, whereas for the IMF screw group there was a steady decrease in pain scores across all the time points assessed, which was markedly (**Graph 4**) and statistically (**Table 2**) less as compared to arch bar group. This shows that the IMF screw group was better perceived by the study participants in terms of pain scores assessed as compared to the arch bar group.

DISCUSSION

Mandibular fracture treatment over the decades has evolved in various dimensions, but the principles of it remained the same (Re-establishment of the occlusal table and regaining masticatory functions).¹⁹ The conventional methods of using arch bar wiring and splinting teeth for immobilization have been replaced by newer methods.²⁰ Today many clinician use these newer methods to place intermaxillary fixation in their clinics.From the epidemiological viewpoint, mandibular fractures commonly occur among males. As per the literature, the reasons for the same are falls, road accidents, physical assaults, use of alcohol, sports injuries, and so on.20 The various sites of fracture occurrences are parasymphysis, angle, symphysis, condyle, body, and ramus.²¹ These injuries could be with or without various other facial injuries. The revolution in the management and treatment of mandibular fractures took place with the understanding of lines of osteosynthesis and semi rigid fixation technique.²¹ The concept of miniplate and monocortical screw osteosynthesis was first described and explained by Michelet FX (1973)²² and

the clinical experiences were elaborated by Michelet A $(1973)^{23}$. Both the authors have explained in detail in their respective documented literature. Arthur and Berardo described IMF screw as a reliable modality of treatment of mandible fractures.First-generation IMF screws were simply modified monocortical screws which required drilling of the hole for placement of screws. Then the second-generation screws were used.Which provide improved tactile feedback, limiting thepossibility of root damage. Additionally, because power equipment is not needed, the system can be used outside of the operating room; eg, in the intensive care unit or department. emergency The manufacturer recommends placing screws above the root apices for the maxilla and below for the mandible. However, we found subapical placement led to mucosal overgrowth complicating their removal. In the present study, the time taken for IMF using IMF screws was less with the mean value of 0.20 ± 0.03 hours. Whereas the time taken for achieving IMF using Erichs arch bar was around 1.30 hours with a mean of 1.10 ± 0.55 hours. This could be due to the easy handling of IMF screws and less instrumentation. This observation is in line with the findings of Barodiya A et al $(2017)^{15}$, who reported a mean time of 74.9 minutes for arch bar placement and 16.1 minutes for IMF screw placement. Nandini GD et al (2011)¹⁴found that the average time to place an IMF screw was 8.52 minutes, but the time to place Erich arch bars was 100 minutes.Glove perforation was observed in 60% of the Arch bar group, which was higher than the 20% recorded in the IMF screw group, and was statistically insignificant in the current study.. The majority of glove perforations in

our study were unnoticed during the procedure and proved by water test in both the groups (60% in group A and 20% in group B) which is having of clinical importance as it leads to a prolonged breach in the barrier between patient and surgeon with the suction action of perforations resulting in hand contamination which may enter skin abrasions. The lower incidence of glove perforation among group B is due to the very less number of wires used for IMF using the IMF screws as compared to Erich's arch bar and thus decreased the risk of disease transmission and occupational injuries.Cornelius CP and Ehrenfeld M (2010)27, Nandini GD et al (2011)¹⁴, Oureshi AA et al (2016)45, and Pathak P et al (2019)56 revealed reduced glove perforation rates for the IMF screw group and greater glove perforation rates for the Arch bar group in their respective trials. Fernandas AI et al (2021)62 showed fewer iatrogenic oral injuries for inter-maxillary fixation screws and greater glove perforation ratio for Erich arch bars usage in a recent comprehensive review and meta-analysis of the available recorded literature. The results were statistically significant. According to Yashmeet Kaur Sandhu et al (2017)²², the chances of glove perforation and needle stick injury are much more when the procedures are performed under local anesthesia as compared to general anesthesia. Because the patient is fully conscious and aware. Moreover, the full cooperation of the patient is required during the procedure as any inadvertent movement of the patient can enhance the chances of such injuries.Oral hygiene status was assessed and compared on the 7th day and 15th day. The oral hygiene status values among the Arch bar group were higher as compared to the IMF screw group. The mean plaque index value was found to be higher in Group A, i.e., patients treated using Erich arch bars. This implies that, with the use of IMF screws, maintenance of oral hygiene is improved, also the risk of periodontal diseases is significantly reduced. We also noticed better patient compliance with the use of IMF screws than arch bars. In the studies reported by Nandini GD et al (2011)¹⁴ and Trupthi DV et al (2014)³⁵ a similar statistical pattern was documented. Rai et al., in a comparative study also reported moreplaque accumulation in patients treated using Erich arch bars as compared to IMF screws. They found a significant difference between the plaque index values of both the groups and based on this, they concluded that maintenance of oral hygiene is better in patientstreated using MMF screws.Postoperative pain was assessed and inter-group comparison (IMF screws and Arch Bar) was done on the 2nd day, 3rd day, 7th day, and 15th day and statistically significant lower mean rank values were observed for IMF screws on those days. This shows that the IMF screw group was better perceived by the study participants in terms of pain scores assessed as compared to the arch bar group. Barodiya A et al $(2017)^{15}$ and Anslem O et al $(2017)^{25}$ to have reported a similar pain recording in their respective studies. In the recently conducted systematic review and metaanalysis conducted by Jain A and Rai A (2021), ¹⁸; and Jain A et al (2021)¹⁸ reported lower pain intensity for the IMF screw group which was statistically significant, but the level of evidence was not strong enough to be made conclusive. There was no incidence of IMF screw fracture as well as iatrogenic injury to the roots of teeth adjacent to the site of screw insertion in our study.Farr and Whear (2011)17, on the other hand, found an incidence of IMF screw fracture in their investigation. Coletti et al., in their study, advised that the use of self-drilling screws as they have higher tactile feedback during placement. It can prevent root damage as it allows the surgeon to modify the insertion position of the screw in case of high resistance. Despite this, the author encountered root damage during screw placement in 2 (4%) out of 49 patients. Both the teeth were eventually extracted. Hence, proper planning before the insertion of MMF screws is essential. The site for screw placement should be determined after comprehensive radiographic assessment with the use of Orthopantomographs and intraoral periapical radiographs. The three-dimensional relationship of the path of insertion of the screw with the surrounding dental structures should be carefullyassessed to reduce the iatrogenic dental trauma.We observed a complication of partial or complete mucosal coverage at the time of IMF screw removal, which necessitated an incision, while the rest of the screws were removed with the use of topical anesthesia. After removing the screws, all of the screw locations healed normally within a week.In the current study, considering the advantages of IMF screws over the Erich arch bar in terms of s duration of placement, postoperative pain intensity, minimal glove perforations, better oral hygiene status, and tooth vitality makes us to believe that the IMF screws for achieving intermaxillary fixation in the treatment of mandibular fractures have better clinical efficacy.

CONCLUSION

Owing to the benefits of IMF screws over the Erich arch bar in terms of time for surgery, pain intensity, glove perforations, oral hygiene status, and tooth vitality in the presently conducted study, it can be concluded that the IMF screws for the treatment of mandibular fractures have better clinical efficacy. When it comes to fracture care, surgical time is a critical component, which is greatly reduced when IMF screws are used. Patients tolerated the IMF screws' post-operative discomfort better, making them a popular choice for patients with mandibular fractures. Following surgery, the maintenance of oral hygiene is crucial to avoid post-operative infections the same can be better achieved with IMF screws. Minimal needle stick injury during surgical operations makes IMF screws a better option among surgeons. However IMF screw intermaxillary fixation has the disadvantage of screw loosening, partial or complete mucosal coverage which may need to be kept in mind for long term IMF.

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