

Is Healing Outcome of 2 Weeks Intermaxillary Fixation Different From That of 4 to 6 Weeks Intermaxillary Fixation in the Treatment of Mandibular Fractures?

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Purpose: This study was undertaken to compare the healing outcome of a short period (2 weeks) of intermaxillary fixation (IMF) with conventional (4-6 weeks) IMF in the management of fractures of the mandibular tooth-bearing area.

Materials and Methods: This was a randomized controlled study conducted at the Lagos University Teaching Hospital, Lagos, Nigeria, between November 2007 and January 2009. Subjects with minimally displaced mandibular fractures in the tooth-bearing area were randomly allocated into 2 treatment groups: IMF for 2 weeks (study group) or IMF for 4 to 6 weeks (control group). For the purpose of study analysis, the primary predictor variable was the treatment (IMF for 2 weeks vs IMF for 4-6 weeks). Other predictor variables were the age and gender of subjects. The primary healing outcome was considered either satisfactory or unsatisfactory. The following outcome variables that described the healing process were also compared in the 2 groups: healing time, postoperative infection, paresthesia, and maximal interincisal opening. Loss of body weight and oral hygiene status at the end of treatment were compared in the 2 groups. A value of $P < .05$ was considered significant.

Results: Satisfactory healing was observed in all cases in both groups. However, satisfactory healing was observed earlier (5.4 ± 0.9 weeks) in the control group than in patients with the short IMF period (7.2 ± 0.9 weeks) ($P < .001$). Malocclusion that was amenable to selective grinding was the only complication seen in both groups ($n = 2$ in study group and $n = 1$ in control group) ($P = .492$). Subjects in the control group lost more weight after treatment than those in the study group ($P < .001$). The recovery of interincisal mouth opening was also better in the study group than in the control group ($P < .001$). The study group had better oral hygiene than the control group at the end of treatment.

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Conclusions: The healing outcome was comparable in both groups. However, the healing time was significantly longer in the group with the short IMF period. The recovery of maximal mouth opening, oral hygiene status, and loss of weight body in the study group were significantly better than those in the control group. This study suggests that a short period (2 weeks) of IMF in the management of minimally displaced mandibular fractures of the tooth-bearing area in young adults is a suitable alternative to the conventional method in terms of the healing outcome.

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The management of fractures to the maxillofacial complex remains a challenge for oral and maxillofacial surgeons, demanding both skill and a high level of expertise.¹⁻³ To adequately treat fractures of the mandible, surgeons must understand the anatomy and biomechanics of the mandible.³ Generally, mandibular fractures are treated by either closed reduction with intermaxillary fixation (IMF) or open reduction and rigid internal fixation (ORIF) with osteosynthetic plates and screws.⁴ For the closed reduction technique, patients with IMF are restricted to a semisolid diet associated with weight loss and have a longer hospital stay, and their return to work is often delayed, thus causing an economic disadvantage.⁵

ORIF is used frequently to treat mandibular fractures. However, ORIF has not become popular in most developing countries because the full complement of equipment and materials required for rigid internal fixation is not readily available in various parts of these countries, such as Nigeria, and where available, the cost of treatment is usually quite high.⁶ Consequently, most of the patients with mandibular fractures requiring open reduction are treated with IMF alone or in combination with intraosseous wire. Attempts have been made through research to minimize the drawbacks of IMF so that it can be used effectively, especially in developing countries. In this regard, suggested options available to the surgeon have included immobilization of the patient's jaw for a short period of 2 weeks, followed by splinting of the lower jaw with an arch bar or acrylic splint, or restriction of the patient to a soft diet.⁷⁻⁹ Research studies in this direction are few in the literature.⁹ Research in this area will be particularly beneficial in these environments where the conventional method of IMF is still widely practiced. Therefore, this study evaluated the healing outcome with a short period of IMF in the management of fractures of the mandibular tooth-bearing area and compared it with the conventional method of IMF.

The purpose of this study was to compare the healing outcome of a short period (2 weeks) of IMF with conventional (4-6 weeks) IMF. We hypothesized that there would be no difference in the healing outcome between the 2 treatment methods.

Materials and Methods

STUDY DESIGN/SAMPLE

To address our research purpose, we designed and implemented a randomized controlled study. The study population was composed of all subjects presenting to the Department of Oral and Maxillofacial Surgery, Lagos University Teaching Hospital, Lagos, Nigeria, for evaluation and management of mandibular fractures between November 2007 and January 2009. Approval for the study was obtained from the Health Research Ethics Committee of the institution. Written informed consent was obtained from each participant before enrollment into the study.

To be included in the study, subjects had to fulfill the following criteria:

- Dentate subjects aged between 20 and 40 years with a fracture in the tooth-bearing area of the mandible
- A minimally displaced mandibular fracture in which the displaced fracture was not more than 3 to 4 mm between the occlusal/incisal surfaces of the teeth of the fractured segments
- Subjects with teeth on either side of the fracture
- Subjects with 1 or 2 fracture lines
- Absence of infection at the fracture site at presentation

Subjects were excluded from the study for the following conditions:

- Subjects with gunshot-related fractures
- Subjects with systemic diseases that compromise healing
- Subjects who abused alcohol and were cigarette smokers

Selected subjects with mandibular fractures were diagnosed both clinically and radiographically and were randomly allocated into 2 groups: 2-week period of IMF (study group) and conventional IMF (4-6 weeks) (control group). Reduction and fixation of mandibular fractures were carried out with subjects under local anesthesia and sedation. The time be-

tween injury and treatment (intervention time) was recorded for each group.

STUDY VARIABLES

For the purpose of study analysis, the primary predictor variable was the treatment (IMF for 2 weeks vs IMF for 4-6 weeks). Other predictor variables were the age and gender of subjects. The primary healing outcome was considered either satisfactory or unsatisfactory. "Satisfactory" was defined as adequate bone union in the absence of pain and mobility of the fracture segments at the end of the treatment period.

The following outcome variables that described the healing process were also compared in the 2 groups: healing time, postoperative infection, and maximal interincisal opening. In addition, loss of body weight and oral hygiene status at the end of treatment were compared in the 2 groups.

OPERATIVE MANAGEMENT

Control Group

In the control group, the mandibular fractures were reduced and then the teeth on the main fragments were ligated with 0.45-mm soft stainless steel wire to a stainless steel half-round German arch bar, which was bent to conform to the dental arch. A similar arch bar and ligature wires were also placed on the maxillary teeth. Intermaxillary wires were placed to immobilize the upper and lower jaws. At the end of the fourth week of immobilization, the tie wires were removed for clinical assessment of adequate bone union, which was based on the absence of pain and mobility of the fracture segments. The intermaxillary wires were replaced if the clinical union was inadequate, and this was repeated weekly until satisfactory bone union was achieved.

Study Group

Subjects in the study group were treated in a similar way but had the tie wires removed at the end of 2 weeks of immobilization, and the arch bars and ligature wires were retained until satisfactory bone union was achieved. Patients were then instructed to follow a soft diet and were equally instructed to avoid chewing hard food. No clinical assessment was carried out until the end of the fourth week. This was repeated weekly until satisfactory bone union was achieved. After satisfactory bone union was achieved, the arch bars and ligatures were removed.

Subjects in the 2 groups were given amoxicillin syrup (Beecham, London, UK), 500 mg every 8 hours for 5 days postoperatively. They were also given paracetamol syrup, 1,000 mg (1 tablespoon) every 4 hours for 5 days postoperatively. In addition, they were instructed to use 0.2% chlorhexidine gluconate

mouthwash 3 times daily until the arch bars were removed.

ASSESSMENT OF TREATMENT OUTCOME

End of Treatment

For the purpose of this study, the "end of treatment" refers to the time when satisfactory bone union was confirmed (healing time) and arch bars and ligatures were removed. Subjects in both groups were also assessed for the following at the end of treatment and weekly for 3 consecutive visits:

1. The presence of infection was assessed by the presence or absence of erythema of the adjacent gingiva, swelling, and pus discharge.
2. Paresthesia was assessed subjectively and objectively by the patient's verbal affirmation of abnormal lip sensation and pinprick test of the affected lip, respectively.¹⁰
3. Malocclusion was assessed by use of the incisors' and molars' relationship.

Subjects were also assessed for oral hygiene status at the end of treatment with the method described by Greene and Vermillion.¹¹ The body weight was checked with a weighing scale and recorded at the end of treatment weekly, for 3 successive visits. The interincisal distance was measured with a Vernier caliper.

The degree of mouth opening in the 2 groups was measured and compared. The subjects in the 2 groups were monitored over a period of 3 weeks at the end of treatment for the degree of mouth opening. At the end of each week, the degree of mouth opening in the 2 groups was compared.

Data analysis was performed with the Statistics Package for Social Sciences (SPSS) for Windows, version 15.0 (SPSS, Chicago, IL). Descriptive statistics and tests of significance were used as appropriate. The critical level of significance was set at $P < .05$.

Results

The study included 43 subjects who sustained a total of 68 fractures. The mean age (\pm SD) of the subjects was 28.4 ± 4.9 years (range, 20-40 years). There were 21 patients with 32 fractures in the study group and 22 patients with 36 fractures in the control group. Most cases of mandibular fracture in both groups were due to road traffic crashes, followed by assaults, sports, and industrial accidents (Table 1). The site distribution of fractures was similar in both groups, with the body of the mandible being the most frequently fractured site, followed by the angle (Table 1). The intervention time ranged between 1 and 10

Table 1. STUDY VARIABLES VERSUS PRIMARY PREDICTOR VARIABLE

Variable	Control Group (4-6 wk of IMF)		Study Group (2 wk of IMF)		P Value
	Male	Female	Male	Female	
No. of patients	18	4	16	5	.21
Age (mean \pm SD) (yr)	28.2 \pm 5.0		27.8 \pm 7.2		.42
Cause					
Road traffic crash	14		13		
Other	8		8		.9
Total	22		21		
Site of fracture					
Body	18		18		
Angle	9		6		.9
Symphysis	7		5		
Parasymphysis	2		3		
Total	36		32		
Intervention time (mean \pm SD) (d)	5.1 \pm 2.9		5.8 \pm 3.4		.49

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days, with a mean (\pm SD) of 5.5 \pm 3.2 days. Only a small number of patients (16.3%) were treated within 24 hours of injury. The mean intervention time of the control and study groups was 5.1 \pm 2.9 days and 5.8 \pm 3.4 days, respectively ($P = .49$). The 2 groups were not significantly different in terms of age, gender distribution, etiology, site of fracture, and intervention time (Table 1).

A satisfactory healing outcome was observed in all cases in both groups. Table 2 compares the outcome variables in both the study and control groups. The mean healing time in the control and study groups was 5.4 \pm 0.9 weeks and 7.2 \pm 0.9 weeks, respectively ($P = .001$). No case of infection, nonunion, malunion, or paresthesia was recorded in the 2 groups. The only complication recorded was minor occlusal discrepancy. This complication was recorded in 3 cases: 2 in the study group and 1 in the control group ($P = .492$). Subjects in the control and study groups lost a median body weight of 4.2 kg and

0.2 kg, respectively (Table 2), at the end of treatment ($P < .001$). Assessment of oral hygiene at the end of treatment (Table 2) showed that 100% of patients in the study group had good oral hygiene, whereas only 68.2% of patients in the control group had good oral hygiene ($P = .005$).

Table 3 shows the multiple regression analysis of the effect of treatment method and intervention time on healing time. Intervention time and treatment methods were independent variables that significantly affected the healing time.

Table 4 shows the statistical analysis of the mean interincisal distance in the 2 groups using multivariate analysis of variance. The result shows that the mean interincisal distance in the study group is significantly higher than that in the control group over a period of time. This occurred throughout the periods of observation. It was observed that the maximal mouth opening improved immediately after treatment (22.3 \pm 7.9 mm in control group and 42.7 \pm 9.4 mm in study group) to the third week after treatment (39.4 \pm 8.6 mm in control group and 48.7 \pm 7.9 mm in study group) in both groups (Table 4).

Table 2. COMPARISON OF VARIABLES THAT DESCRIBE HEALING PROCESS BETWEEN GROUPS

Outcome Variable	Control (4-6 wk of IMF)	Study (2 wk of IMF)	P Value
Mean healing time (wk)	5.4 \pm 0.9	7.2 \pm 0.9	.001
Complications	1	2	.492
Median body weight loss (kg)	4.2 \pm 2.25*	0.2 \pm 3.0000*	.001
% with good oral hygiene	68.2	100	.005

*Interquartile range.

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Discussion

In our unit 4 weeks is the standard duration of IMF, and, sometimes, this is extended to 6 weeks when no adequate healing is observed at the end of the fourth week. This study set out to compare the healing outcome of a short period (2 weeks) of IMF with conventional (4-6 weeks) IMF. We hypothesized that there would be no difference in the healing outcome between the 2 treatment methods. A statistically significant difference in the healing time was found between the 2 groups. Regression analysis also

Table 3. MULTIPLE REGRESSION ANALYSIS RELATING HEALING TIME TO BOTH INTERVENTION TIME AND TREATMENT

Model	Coefficient	SE	<i>t</i>	<i>P</i> Value	Fcal	<i>R</i> ²
Intercept	3.068	0.439	6.995	<.001	29.156	0.593
Intervention time	0.105	0.041	2.572	.014		
Treatment	1.756	0.256	6.872	<.001		

NOTE. The fitted model was found to be significant at .05 (Fcal = 29.156, *df* = 2, *df*₂ = 40) with an *R*² value of 0.0593.

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showed that treatment method was an independent variable that significantly affected the healing time. Fracture healing in the study group was delayed for about 2 weeks relative to the control. The plausible reason for delayed healing in the study group might be because of expected micromovement across the fracture line after a short period of IMF. Furthermore, the functional loading across the fracture line might have exceeded the physiological loading limit (2,000 microstrain)¹² and reflect the fact that the arch bar does not provide rigid fixation. This physiological loading limit is considered necessary for osteoblastic differentiation and callus remodeling.¹² Andreasen et al¹³ also reported that some degree of micromovement accelerates fracture healing. However, functional loading greater than 2,000 microstrains will delay osteoblastic differentiation and bone matrix formation. The excess interfragmentary motion will encourage the formation of a cartilaginous callus to stabilize the fracture site, and this is gradually replaced by new bone through endochondral ossification. Thus, the soft callus initially formed at the repaired site is very weak and less resistant to movement, and it might require adequate protection in the form of bracing or rigid internal fixation.^{9,12}

Table 4. STATISTICAL ANALYSIS OF MEAN INTERINCISAL DISTANCE IN TREATMENT GROUP USING MULTIVARIATE ANALYSIS OF VARIANCE

Time	Mean Interincisal Distance (cm)	Fcal	P Value
Control group (4-6 wk of IMF)			
Immediate	22.2727 ± 7.9852	23.894	<.001
First week	25.000 ± 8.0312		
Second week	32.3809 ± 8.3814		
Third week	39.4081 ± 8.6336		
Study group (2 wk of IMF)			
Immediate	42.7143 ± 9.4294	23.894	<.001
First week	42.7273 ± 10.6600		
Second week	45.3636 ± 9.5745		
Third week	48.7143 ± 7.912		

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Therefore the premature release of IMF is often feared because it may contribute to fibrous union.^{9,14} However, it has been reported that the most critical period of fracture healing is during the first 2 weeks in which inflammation and revascularization occur.¹⁵ Therefore this might be justified because this critical period has passed before release of the tie wires in the study group. Early release of IMF would also encourage slight functional stress across the fractured line; this will, however, enhance vascular and lymphatic circulation in the tissues and possibly accelerate consolidation.¹⁶

Only 7% of the subjects had malocclusion after treatment of mandibular fractures, and this was amenable to minor occlusal grinding. Al-Belasy⁹ reported a 13.3% malocclusion rate in his study. The presence of postsurgical malocclusion depends on the number of fractures and degree of displacement, the reduction that can be achieved, the kind of immobilization, and the time of immobilization.^{9,17} The low complication rate in this study may be attributed to the fact that only minimally displaced mandibular fractures were selected. Furthermore, one would have expected the number of subjects with malocclusion to be greater in the study group because of the early release of IMF; this, however, was not the case. This could be because the arch bar was still in place to maintain the fractured segments in position.

There was no reported case of infection in this study. This is, however, in contrast to a report from a similar study by Al-Belasy,⁹ who reported 2 patients with infection. Some earlier studies have shown a decreased incidence of infection if compound fractures are treated within 48 hours.^{18,19} Stone et al²⁰ did not find delay in treatment to be a risk factor for the development of infection. However, Prein and Beyer²¹ stated that most mandibular fractures that are not treated within the first 36 hours must be regarded as infected. Absence of infection in our study could be due to the fact that patients were given postoperative antibiotics for 5 days.

Reports from previous studies in the studied environment²²⁻²⁴ on maxillofacial trauma reported that more than 70% of patients received treatment after 24

hours of injury. The result of our study corroborates these findings. Only a small number of subjects (16.3%) were treated within 24 hours of injury. Several reasons have been adduced for delayed treatment in our environment. Poverty is one of the main reasons, and most of the patients who report to the government hospital are from a socioeconomic group that cannot afford the fees even though these have been highly subsidized by the government. Although a health insurance scheme has been introduced in the country, trauma management is not on the list of treatments that are covered by the scheme. These patients and their relatives will have to find other sources for the needed funds, which might take some days. Other causes of delay include ignorance (patients do not know where to report), delayed referral to the appropriate health institution, long distance from the maxillofacial centers, and limited number or unavailability of maxillofacial surgeons in most general hospitals.

The mean healing time in this study was 5.4 weeks and 7.2 weeks in the control and study groups, respectively. This is in contrast to 4.67 weeks and 4.93 weeks, respectively, in the study of Al-Belasy.⁹ This might be attributed to the fact that the mean intervention time was shorter in the study by Al-Belasy (2.15 days) than that in our study (5.5 days).

Regression analysis also shows that intervention time was an independent variable that significantly affected healing time. In clinical studies of healing of mandibular fractures, the effect of intervention time on healing has been a subject of controversy. A recent systematic review of retrospective studies on the effect of early or delayed treatment on healing of mandibular fractures did not find any strong difference in healing time between early treatment and delayed treatment of mandibular fractures.^{25,26} This finding is also supported by recent studies in Nigeria²² and Egypt.²⁷ However, our study suggests that the first 24-hour period might be a critical threshold in healing of minimally displaced mandibular fractures. Thus we encourage clinicians to treat mandibular fractures as early as possible to relieve patients of pain and discomfort and to maximize healing potential.

There was a significant difference in oral hygiene status between the 2 treatment groups at the end of the treatment period. This was not a surprise because the subjects in the study group had resumed normal oral hygiene measures earlier because of the early release of IMF. In addition, the maximal mouth opening ability at the end of treatment and over a period of 3 weeks in the study group was better than that in subjects in the control group. Moreover, mean body weight loss was significantly lower in the study group. Early improvement in oral hygiene status, early recovery

of maximal mouth opening, and reduced mean body weight loss are added advantages of the short period of IMF.

This study shows that the short period of IMF is effective and significantly reduces the potential adverse effects of long-term IMF. The strength of the study lies in being a randomized controlled study. Although the sample size of 43 subjects was an improvement over a similar study by Al-Belasy,⁹ future randomized controlled studies with larger sample sizes are encouraged on the subject matter.

A satisfactory healing outcome was observed in all cases in both groups. However, the healing time was significantly longer in the group with a short IMF period. The recovery of maximal mouth opening, oral hygiene status, and loss of weight body in the study group were also significantly better than those in the control group. This study suggests that a short period of IMF in the management of minimally displaced mandibular fractures of the tooth-bearing area in young adults is a suitable alternative to the conventional method in terms of the healing outcome.

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