The Use of Screw Retained Hybrid Arch Bar for Maxillomandibular Fixation in the Treatment of Mandibular Fractures: A Comparative Study

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Introduction: The use of screw-retained hybrid arch bars (HABs) is a relatively recent development in the treatment of mandibular fractures. The purpose of this study is to compare the clinical outcome between HAB and the conventional Erich arch bar (EAB) in the closed treatment of mandibular fractures. Materials and Methods: This study included 18 patients who were treated for mandibular fractures with maxillomandibular fixation (MMF), patients were randomly assigned into a control group (n = 10) in which EAB was used and study group (n = 8) in which HAB was used. The outcome variables were time required for application and removal, gingival inflammation scores, postoperative complications, and incidence of wire-stick injury or gloves perforation. The groups were compared using unpaired t-test, Mann–Whitney test, Chi-square test, or Fisher test. The differences were considered significant at P < 0.05. Results: The mean application time was significantly more in EAB than HAB (61.6 ± 11.4 vs. 41.6 ± 6 min, respectively). The mean time of removal for EAB was significantly less than HAB (11.1 ± 2 vs. 14.2 ± 3 min, respectively). There was nonsignificant difference in gingival inflammation between the groups. No major complications were recorded. Screw loosening and mucosal overgrowth were recorded in 12.5% and 31.2% of the screws, respectively, in HAB group. The incidence of gloves tear in EAB group was 70%. Discussion: HAB can be used as an alternative to EAB for MMF in patients with mandibular fracture, it requires less time for application and provides more safety for the surgeons.

Keywords: Erich arch bar, hybrid arch bar, mandibular fractures, maxillomandibular fixation, postoperative complications

Introduction

Mandibular fractures remain the most common facial fractures encountered. The treatment of mandibular fractures can be accomplished with either closed treatment or open reduction–internal fixation (ORIF). Maxillomandibular fixation (MMF) can be defined as any method used to secure the maxilla and mandible to each other into the appropriate dental occlusion. It is a standard component of the treatment of mandibular fracture where it is required for closed treatment and for most of ORIF cases. The three main principles of MMF are to establish occlusion, provide stability, and immobilize the jaws.[1]

Several techniques have been described for MMF including but not limited to arch bars, interdental eyelet wiring, bonded brackets, embrasure wires, Ernst ligatures, and external pin fixation. However, the placement of Erich arch bars (EABs) fixated to the dentition with circumdental stainless steel wires has been the standard practice for MMF for or during the repair of mandibular fractures for many decades.[2] Most of these techniques are limited in the setting of poor dentition or in patients who are partially edentulous, in addition of being time-consuming, and are associated with risks of mucosal, dental, and needlestick injuries.[3,4]

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Bone-supported devices such as intermaxillary fixation screws have been described, but its use may be limited to minimally displaced and favorable fractures as they do not exert a tension band effect. The development of new materials and technology along with the surgeon’s desire to use products that reduce operating time, increase safety, and still have good surgical outcomes has created an alternative, which was the use of titanium arch bars fitted with eyelets for self-drilling locking screw fixation directly to the maxilla and mandible. This device, hybrid arch bar (HAB), combines features of arch bars and bone-supported devices, potentially yielding the advantages of both. Potential advantages include applicability in cases of poor dentition or in partially edentulous patients, tension band effect, less time required for device application, and decreased risk of wire-stick injuries. However, possible disadvantages include tooth root or mucosal injury, screw loosening, and hardware failure.

There are few studies that compare HAB with conventional arch bars in treatment of mandibular fractures; therefore, the aims of the study were to compare the clinical outcome between conventional EAB and screw-retained HAB in the closed treatment of mandibular fractures in terms of the time required for application and removal, gingival inflammation scores, the postoperative complications, and incidence of wire-stick injury or gloves perforation. The hypothesis is that there are no significant differences in the investigated variables between the two types of arch bars.

**Materials and Methods**

**Study design**

To address the aims of this study, a prospective randomized controlled clinical study was designed and conducted, the study was guided by the Consolidated Standards for Reporting Trials statement. It included patients who have sustained isolated mandibular fractures and were treated at the department of oral and maxillofacial surgery during the period from January 2019 to August 2020.

The inclusion criteria for the study were patients ≥18 years of age presenting with one or more mandibular fractures indicated for closed treatment, involving the condyle, ramus, angle, body, parasympysis, or symphysis, within 1 week of the original trauma.

The exclusion criteria were mandibular fractures in children and patients with comminuted, infected, or pathological fractures, fractures of edentulous mandible, or fractures indicated for ORIF. The patients were randomly assigned using Microsoft Excel (2016) into two groups: in the control group, MMF was achieved using EAB secured with circumdental wires, whereas in the study group, MMF was achieved by placement of titanium HAB (Stryker SMARTLock MMF plate) secured by self-drilling locking screw fixation to the mandible and maxilla.

The study was conducted in accordance with the ethical standards of the Helsinki Declaration of 1975, as revised in 2000 and was approved by the Research Ethics Committee of the Scientific Council of Maxillofacial Surgery on January 3, 2019 (#580) and each patient signed informed consent to participate in the study.

Prior to the surgical procedure, the patients were informed about the nature of the procedure and the possible complications that may arise. All the patients were treated by closed reduction and MMF under general or local anaesthesia by the same operator and assistants. For the patients in control group, EAB was adapted to the buccal surfaces of the teeth from first molar to first molar in both maxillary and mandibular arches and secured using prestretched (0.5 mm) gauge stainless steel wire [Figure 1]. In the study group, the HAB was contoured and its length adjusted to fit both the maxillary and mandibular arches. The arch bar was secured using 2-mm × 6-mm and/or 2-mm × 8-mm locking screws inserted into the center of the arch bar hole, while the assistant positioned the spacer instrument between the mucosa and the metal rim of the hole, this elevated the metal rim away from the mucosa to avoid gingival compression. The screws were placed at 90° angles to the bone. The screw holes were adjusted with the plate bender to orient the screws between the roots of the teeth [Figure 2]. For each arch bar, four screws were placed at least one screw for each side of the fracture line, with a total of eight screws for each patient. MMF was secured by gauge (0.5 mm) stainless steel tie wires. When a satisfactory occlusion was difficult to achieve, elastics were applied until the desired occlusion was obtained, then the wire was applied. The time of application and removal of arch bars for both study groups was recorded in minutes.

Antibiotics and analgesics were prescribed for all the patients postoperatively. All the patients were followed up on a weekly basis; during the follow-up, all the complications were recorded and managed accordingly. For all the patients in HAB group, the vitality of the teeth adjacent to the screw insertion sites was assessed by using highly vapourised ethyl chloride aerosol (IP Frees, Germany) 1 week after the treatment. During the follow-up period, any loosened screw was replaced by another one placed in the adjacent hole under local anaesthesia. Postoperative panoramic radiograph was taken immediately after treatment and after 6 weeks postoperatively. The MMF was removed after 6 weeks under local anaesthesia.

**Study variables**

The predictor variables in this study were the use of HAB system or EAB in MMF. The outcome variables were the time necessary for device application and removal recorded in minutes, the oral hygiene scores during the follow-up periods which were recorded using gingival index presented by Loe and Silness, which were recorded as 0 for normal, 1 for mild, 2 for moderate, and 3 for severe, in addition to the complications encountered which included: the incidence of wire-stick injury and perforations in the gloves of the operator or assistant identified by water inflation method, the incidence of tooth mobility or root injury evaluated by panoramic radiograph and vitality test for the involved teeth, and the incidence of mucosal overgrowth, hardware complications such as screw or wire loosening and screw breakage, and the late complications of malunion, delayed, or nonunion.
Statistical analysis
The statistical analysis was performed using GraphPad Prism version 6 for Windows (GraphPad Software, La Jolla, CA, USA). For the descriptive analysis, percentages or the mean ± standard deviation were recorded. All numerical variables were analyzed statistically using the Shapiro–Wilk normality test, unpaired t-test, and Mann–Whitney test. For categorical variables, Chi-square test or Fisher’s exact test were used. The differences were considered significant at $P < 0.05$.

Results
A total of twenty patients with mandibular fractures who met the inclusion criteria were initially enrolled in this study with equal assignment into the two groups, two patients assigned to the study group were lost to follow-up and the remaining 18 patients consisted of 6 females and 12 males. The basic steps for enrolment of the subjects and progress through the phases of this study for both groups are illustrated in Figure 3.

Table 1 demonstrates the differences in age, gender, and sites of fracture between the two groups. Statistically, there were no significant differences between the two groups, so none of these factors acted as a confounding factor that may affect the outcome of this study.

The differences in outcome variables between the two groups are shown in Table 2. Tooth mobility was noted only in one tooth (lower second premolar) in the control group that was not related to the fracture line. No hardware failure was recorded in both groups and all the patients presented with acceptable arch bar stability during follow-up period.

With respect to the complications associated with HAB system (study group), mucosal overgrowth [Figure 4] was
This study showed that the HAB takes a significantly longer duration for removal than the EAB. Chao and Hulsen also found that the HAB required a longer duration for removal than EAB (10 vs. 8 min); however, the difference in time between the two groups was not significant statistically.[8] The longer duration of HAB removal in this study is mostly attributed to the presence of mucosal growth over the screws.

The data obtained from the present study demonstrated that there was no significant difference in gingival index scores between the two groups, although higher scores of gingival inflammation were recorded in the EAB group, this is in line with King and Christensen[2] who, in their comparative study, showed that there was no significant difference in the gingival appearance between EAB and HAB groups at the end of treatment period. On the other hand, Mario et al. demonstrated, in their study for clinical evaluation of HAB on 19 patients, that the oral hygiene based on simplified debris index was maintained or improved in about (79%) of the patients during MMF period.[17] We suggest that the maintenance of oral hygiene is highly dependent on the oral hygiene measures taken by the patients during the MMF period, also on the oral health condition before the treatment regardless of the type of arch bar used.

This study recorded a relatively high incidence of mucosal overgrowth (31.2%) associated with the HAB which is in line with Kendrick et al.[1] who demonstrated that the most common complication associated with this system was mucosal overgrowth, which was reported in 37% of the patients. Overgrowth of the mucosa prolonged the duration required for removal of the arch bar, however, it did not cause any unwanted clinical effect. The proper use of the screw spacer instrument will reduce the chance of mucosal migration over the screw.

Another complication associated with the HAB that was noted in the current study was the screw loosening which was also reported in a previous study in 17% of the patients.[11] However, there was no significant effect of screw loosening on the overall stability of the devices throughout the follow-up period.

In this study, no instances of iatrogenic dental root injury were recorded. This finding is consistent with a previous study demonstrating that although contact between screw and root does occur with transalveolar screws, the possibility of clinically major damage is low.[8] Dental root damage can be avoided by proper analysis of the preoperative panoramic radiograph to plan placement of the screws and by adjustment of the screw holes between the roots.

In this study, no wire-stick injury for the operator or assistants was reported despite the higher incidence of glove tear that was recorded during the placement of EAB. In contrast, the application of HAB was not associated with any incident of glove tear. The risk of infection transmission is high during wiring procedures, as they are contaminated by blood and saliva. It has been reported that, during the application of EAB, the incidence of

| Variable | Control | Study | P |
|----------|---------|-------|---|
| Age/years, mean±SD | 28.20±7.86 | 27.75±8.63 | 0.9094* |
| Gender/patients (%) | | | |
| Male | 7 (70) | 5 (62.5) | 1.0000† |
| Female | 3 (30) | 3 (37.5) | |
| Sites of fracture (%) | | | |
| Condyle | 1 (10) | 1 (12.5) | 0.7687‡ |
| Angle | 3 (30) | 1 (12.5) | |
| Body | 3 (30) | 2 (25) | |
| Parasympysis | 3 (30) | 4 (50) | |

*Unpaired t-test, †Fisher’s exact test, ‡Chi-square. SD=Standard deviation

**DISCUSSION**

Mandibular fractures are one of the most common types of maxillofacial trauma, it occurs in 37% to 67% of the patients with facial injury.[14-16] The essential steps for successful treatment of mandibular fracture include reduction, fixation, and immobilization. The screw-retained HAB represents the most recent development in the MMF techniques.[1] The purpose of this study was to evaluate the clinical outcome and complications of the HAB in the treatment of mandibular fracture, in comparison with traditional EAB.

The present study revealed that the HAB required less time for application than traditional EAB, these findings are in line with other recent studies comparing the two types of arch bars.[1,2,6-10] Chao and Hulsen in 2015[8] were the first to evaluate the clinical outcome of the HAB system, they found that the time necessary for its application was 42 min, which was faster than that required for EAB application (62 min), which is similar to our findings in this study.

Glove perforation of the operator and/or assistant was evident in 7 out of ten patients (70%) treated in the control group, whereas no perforation of gloves was recorded in study group patients. No wire-stick injury was recorded in the operator and/or assistant in both groups. At the end of the 6-week follow-up, no late complications were evident and all the patients in both groups showed stable acceptable occlusion.

This study demonstrated that the most recent development in the MMF techniques.

**Table 1: The differences in age, gender, and sites of fracture between the two groups**

| Variable | Control | Study | P |
|----------|---------|-------|---|
| Age/years, mean±SD | 28.20±7.86 | 27.75±8.63 | 0.9094* |
| Gender/patients (%) | | | |
| Male | 7 (70) | 5 (62.5) | 1.0000† |
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| Condyle | 1 (10) | 1 (12.5) | 0.7687‡ |
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| Body | 3 (30) | 2 (25) | |
| Parasympysis | 3 (30) | 4 (50) | |

*Unpaired t-test, †Fisher’s exact test, ‡Chi-square. SD=Standard deviation

**Table 2: The differences in outcome variables between the two groups**

| Variables | Mean±SD | P |
|----------|---------|---|
| Time of application/(min) | 61.60±11.46 | 41.63±6.02 | 0.0004* |
| Time of removal/(min) | 11.10±2.025 | 14.25±3.576 | 0.0311* |
| Gingival index scores | 2.60±0.52 | 2.125±0.64 | 0.1342† |

*Unpaired t-test, †Mann-Whitney test. SD=Standard deviation
wire-stick injury ranges from 37% to as high as 90%.\textsuperscript{18‑23} King and Christensen compared the occurrence of glove tear and finger injuries between two groups, one treated by EAB and the other treated by HAB, they found that the incidence of glove tears and finger injuries was higher in EAB group (0.56/surgery) than that recorded in HAB group (0.11/surgery).\textsuperscript{[2]}

In this study, malunion, delayed, or nonunion were not reported, all the patients enrolled in the study had acceptable occlusion at the end of follow-up period, this is in keeping with Chao and Hulsen\textsuperscript{[9]} who demonstrated that in symphyseal, parasymphseal, and body fractures the HAB functions as a tension band and may be a comparable alternative to the traditional EAB in the treatment of mandibular fractures with respect to the clinical outcome.

Previous studies showed that the HAB system is much more expensive than EAB; however, the overall cost was comparable, this was attributed to the decreased time in the operating room.\textsuperscript{[10,8]} Furthermore, Khlemsky \textit{et al.}\textsuperscript{[24]} revealed that HAB was a cost-minimizing intervention over the EAB except when operating room fees are low. In our study, the treatment was provided in a governmental health institution, and information about the operating room fees and the cost of the EAB, which is the standard MMF device in this institution, could not be verified; therefore, the cost difference between the two types of arch bars was not considered in the study.

It is noteworthy that the results of this study need to be interpreted after considering its main limitation of small sample size, as this study was limited to treatment of patients with simple mandibular fractures that are indicated for closed treatment.

**Conclusion**

This study demonstrated that HAB system can be used as an alternative to the traditional EAB for MMF in patients with mandibular fractures with no major complications associated with its use, it requires less time for application than EAB. It also demonstrated that the use of HAB system significantly reduces the incidence of wire-stick injuries providing better safety for the operators and their assistants. In addition, the impact of HAB system on the gingival tissue seemed to be comparable to that of EAB during the treatment period.

**Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) have/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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**Conflicts of interest**

There are no conflicts of interest.

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