

EVALUATION OF BONE SUPPORTED SMART LOCK HYBRID ARCH BAR VERSUS ERICH ARCH BAR FOR THE TREATMENT OF MANDIBULAR FRACTURES: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Objectives: The purpose of this study was to compare IMF involving placement of titanium arch bars applied using screw fixation (smart lock hybrid arch bar) with Erich arch bars secured with circum-dental wires to the maxilla and mandible in the treatment of mandibular fractures.

Methods: This study was conducted on thirty six patients with mandibular fractures. The patients were divided randomly into two groups. MMF was performed to all cases either treated with CR or with ORIF. In group (A) All patients had MMF using Smart Lock Hybrid arch bar (titanium arch bars fitted with eyelets by self-drilling locking screw) fixation to the maxilla and mandible. While in group (B) Patients had MMF using Erich arch bars. The clinical evaluation included assessment of gingival health via GI, number of gloves penetration for the operator and assistant, time consumed for application and removal of the device, complications during surgery, as well as, determination of patient satisfaction via questionnaires (HADS, UW-QOL v4 and VAS) and cost.

Results: Smart Lock Hybrid arch bar group showed significant lower gingival index after arch bar removal and lower glove penetration than Erich arch bar group. Group A showed shorter time for application or removal of the arch bar than Group B. In group A, patients showed complications such as gingival growth over the eyelets of arch bar and screws, mucosal tears and screw looseness. One case in group A needed endodontic treatment for the lower first molar as a result of root injury. Group A showed better patient satisfaction score than those of group B .The Smart Lock Hybrid arch bar was higher cost than Erich arch bar.

Conclusion: Smart Lock Hybrid arch bar was a perfect choice as an alternative to the traditional Erich arch bar for treatment of mandibular fractures. Smart Lock Hybrid arch bars offer a lot of advantages over traditional Erich arch bars and circumdental wires, including shorter placement and removal times, and greater margin of safety for the operating surgeon and assistant (fewer glove tears and penetrations). It also showed better satisfaction and higher cost.

KEYWORDS: Mandibular fracture, closed reduction, ORIF, Erich arch bar Smatr Lock Hybrid arch bar, Stryker arch bar.

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INTRODUCTION

Mandibular fracture is one of the most common fractures in the maxillofacial region because of its location and anatomy. The cause of mandibular fractures varies based on lifestyle, cultural background, socioeconomic status and different geographic zones.⁽¹⁾ Mandibular fractures can lead to significant problems in function and esthetics if they are not well treated. Although treatment of mandibular fractures is challenging, the treatment aims simply to restore normal function (mastication, occlusion and speech) and esthetics through proper reduction of the fractured parts. Proper reduction is achieved through perfect dental occlusion through intermaxillary fixation (IMF).⁽²⁾

Treatment of mandibular fractures could be classified into closed reduction (CR) or open reduction (ORIF). This depends on multiple factors such as: location of fracture, classification of the fracture (simple / compound or comminuted), amount of displacement of the fractured segments and presence or absence of contraindications for closed reduction (vomiting, respiratory disorders, pregnancy and mental disorders). The MMF could be achieved through different methods such as Erich arch bar, bridle wires, ivy loops and IMF screws.

MMF has an essential role in the treatment of mandibular fractures. In closed reduction, it is considered the main method of treatment. The patient is put on 4-6 weeks of mandibular immobilization through MMF to get a proper bone healing.⁽³⁾ This is usually accompanied by a lot of problems such as patient inconvenience, bad nutrition, weight loss, social and work difficulties. As regarding the open reduction, no MMF is needed which facilitates good nutrition and better acceptance from the patient. Even though the rigid internal fixation has become the standard method in treatment of simple and complex facial fractures, intraoperative temporary intermaxillary fixation (IMF) or postoperative wire or elastic placement has traditionally been achieved with the use of Erich arch bars⁽⁴⁾

Although Erich arch bar provides an effective and versatile means of maxillomandibular fixation either IMF or MMF, its use is not without consequences. Teeth are subjected to treatment forces which could result in their mobility or even avulsion. Other consequences include: damage to the gingiva (injury to inter dental papilla) and high risk of penetrating injury to the surgeon because of gloves puncture by wires during application and removal of the Erich arch bar. Another disadvantage is the long time taken for the application and removal of the arch bar.⁽⁵⁾

All these complications led to the rise of the Smart Lock Hybrid arch bar to overcome such problems. The smart lock hybrid arch bar is a titanium arch bar with eyelets supported to bone via fixation by self drilling screws⁽⁶⁾. This arch bar combines the advantages of bone supported devices as the speed and simplicity of application and the advantages of having an arch bar. The Smart Lock Hybrid MMF System from Stryker is a newer approach for maxillomandibular fixation. It was designed to maximize the advantages of having an arch bar, with its flexibility, ability to serve as tension band, speed and simplicity of application similarly afforded by the IMF screws and all advantages of bone supported MMF, and to decreased operating room time. The system consists of the SMART Lock Hybrid MMF arch bar, which is made of commercially pure titanium.⁽⁶⁾ The plate consists of an arch bar segment and nine screw hole segments that project from the arch bars. This plate is secured with monocortical titanium alloy screws placed through the oral mucosa into the supporting bone in a fashion similar to maxillomandibular fixation screws. These screws are 2.0 mm in diameter and come in lengths of 6 and 8 mm. The system also includes a screwdriver, plate cutter, plate bender, and screw spacer. The spacer is used to hold the plate away from the oral mucosa until the screws lock into the plate. The purpose of this study was to compare IMF involving placement of Smart Lock Hybrid arch bar with Erich arch bars

to the maxilla and mandible in the treatment of mandibular fractures.⁽⁶⁻⁹⁾

MATERIALS AND METHODS

Thirty-six patients with mandibular fractures (condylar, sub-condylar, ramus, angle, body, parasymphysis, and symphysis) were selected from the outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Cairo University.

Eligibility criteria

The patients were selected according to the following criteria:

Inclusion criteria

1. Age range was from 18:60 years old.
2. Patients with mandibular fracture (condylar, sub-condylar, ramus, angle, body and parasymphysis and symphysis) indicated for IMF.
3. Patients free from any systemic diseases.

Exclusion criteria

1. Patients with comminuted mandibular fracture.
2. Patients with fractures other than mandibular fractures.
3. Patients with gunshot wounds.
4. Completely edentulous patients.
5. Patients with absolute or relative contraindications to IMF (e.g. pregnant females, mental disorders).

Study design

This study is a randomized clinical trial. Mandibular fracture treatment (open reduction/closed reduction) was performed to all patients. Patients were randomly assigned into two equal groups: group (A) and group (B) according to the website (<http://www.random.org>). Each group was formed of eighteen patients:

Group (A)

All patients had MMF (closed reduction /open reduction) using Smart Lock hybrid Arch Bar (Manufactured by **Stryker Germany**) these are titanium arch bars which were fixed to the maxilla and mandible through eyelets and self-drilling locking screws.

Group (B)

Patients had MMF (closed reduction / open reduction) using Erich arch bars secured with 24-gauge round stainless steel circum-dental wires placed around premolars and molars.

Preoperative preparation

The patients were free from any major systemic diseases. Clinical examination was done. Panoramic radiograph was used.. In cases treated with ORIF under G.A., complete blood count (CBC), blood glucose level, coagulation profile (PT, PTT, and INR), urine analysis, ECG, chest x-ray, BUN, creatinine and liver function tests were performed.

Method of assessment

1-Gingival index (GI):⁽¹⁰⁾

GI was calculated before and after applying the arch bar to assess the gingival health of the patient. It scores the marginal and interproximal tissues separately on the basis of 0 to 3.0 for Normal gingiva, 1 for Mild inflammation (slight change in color and slight edema but no bleeding on probing), 2 for Moderate inflammation (redness, edema and glazing, bleeding on probing) and 3 for Severe inflammation (marked redness and edema, ulceration with tendency to spontaneous bleeding).

The bleeding was assessed by probing gently along the wall of soft tissue of the gingival sulcus. The scores of the four areas of the tooth were summed and divided by four to give the GI for the

tooth. The GI of the individual was obtained by adding the values of each tooth and dividing by the number of teeth examined. The selected teeth assessed were upper right first molar, upper left lateral incisor, upper left first premolar, lower left first molar, lower right lateral incisor and lower right first premolar. The score of the GI of the individual was documented as following: from 0.1 to 1.0 for mild inflammation, from 1.1 to 2.0 for moderate inflammation and from 2.1 to 3.0 signifies severe inflammation.

2-Gloves penetration

Number of gloves penetrations (operators' and assistants' gloves puncture) for both groups were documented during the application and removal of the arch bar. The operator and the assistant wore double gloves.

3-Time

Time consumed for application and removal of the arch bar (Smart Lock Hybrid / Erich) was documented during the procedure in minutes.

4-Patient satisfaction ⁽¹¹⁾

Patient satisfaction was recorded through questionnaires (HADS, UW-QOL v4 and VAS). Patient satisfaction questionnaire was a self-complete questionnaire. The three questionnaires were combined as one document, as follows :

The Hospital Anxiety Depression scale (HADS) ⁽¹²⁾

This questionnaire contained questions related to subscales of anxiety and depression. It was a 14-item scale developed for patients with physical illness. Seven items assessed the anxiety and seven items assessed the depression. Each item scored from 0 (best) to 3 (worst). Anxiety and depression were scored separately, so that the range of scores for each varied from 0 (best) to 21 (worst).

A modified University of Washington Quality of Life questionnaire (UW-QOL) ⁽¹³⁾

This used nine items to record the outcome in patients with head and neck cancer. We did modifications to suit patients with head and neck trauma. The eight items used in this study were: pain, activity, recreation, employment, speech, swallowing, disfigurement and chewing. The item related to shoulder function was omitted for the purposes of this study. Each domain was scored, with 100 denoting no functional problem and 0 the worst outcome.

VAS

Patient acceptance of hardware tolerability (pain duo to impingement of hardware on soft tissue) was graded by visual analog scale (VAS) as good, fair, and poor. ⁽¹⁴⁾

5- Cost

The groups (A, B) were sub divided each one into two subgroups. One for patients treated by ORIF and the other for who treated by closed reduction. Group (A I): ORIF + Smart Lock Hybrid arch bar while, group (B I): ORIF + Erich arch bar. Group (A II): closed reduction + Smart Lock Hybrid arch bar, and Group (B II): closed reduction + Erich arch bar.

The cost for **group (A I) and (B I)** were calculated as the market value of arch bar and (wires / 10 screws) used in fixation + (cost of OR room per I min. in Cairo University educational dental hospital x time consumed for arch bar application), while the cost for **group (A II) and (B II)** were calculated regardless the time consumed for application.

Surgical Procedure

All cases were operated by the same operator and assistant under local or general anesthesia. Cases were treated either by closed or open reduction. Cases who treated by closed reduction were done under L.A., while those who treated by ORIF were

done under G.A. The arch bar was contoured and adapted. The length of the arch bar was adjusted with the cutter.

In *group (A)* A self drilling screw was first inserted in the middle hole. Then the arch bar was fixed using five (2.0- / 6-8 mm long) self-drilling screws in each jaw while positioning the spacer instrument between the mucosa and the metal rim of the arch bar hole. Eyelets were selected and bended to be located between the expected courses of roots of teeth, while in *group (B)* Erich arch bars were secured in place using 24-gauge round stainless steel circum-dental wires placed around teeth. For both groups the hooks of the arch bar were used as anchor points to apply the stainless steel wires between the mandible and maxilla. (fig.1A,1B,1C)

The patients were recalled for follow up one week post-operatively to check arch bar and MMF in cases of closed reduction and to evaluate wound healing, removal of suture in case of ORIF. Then weekly till 4-6 weeks to evaluate arch bar stability and wire or elastics loosening and to assess potential post-operative complications and local healing of surgical wounds, occlusion and to control potential problems from arch bar placement (pain and any other symptoms). At the end of 4-6 weeks the arch bars were removed. Every patient was recalled after 1 month. Panoramic radiograph was performed to all patients immediately post-operative.

RESULTS

This study was conducted on thirty-six patients with mandibular fracture (condylar, sub-condylar, ramus, angle, body, parasymphysis and symphysis). The age range of the patients was from 18 to 60 years old. The age mean was 29.1 with (SD 10.5) in Group A, while the age mean was (33 ± 14.9) . The gender was 13 male and 5 female in Group A, while 9 male and 9 female in group B.

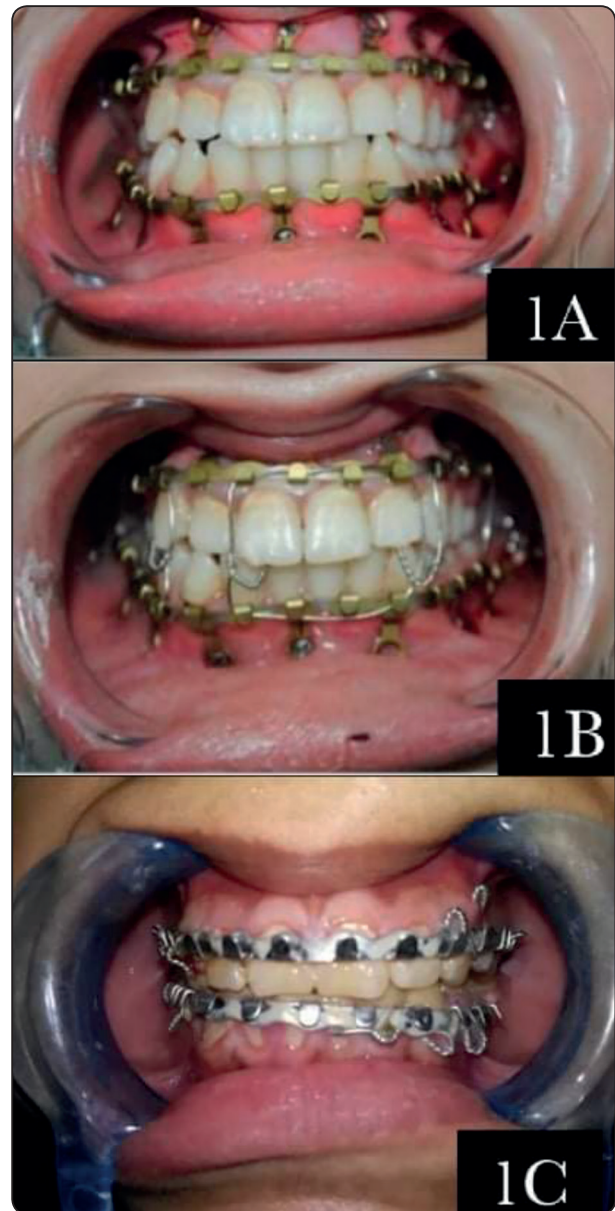


Fig. (1) Smart Lock Hybrid and erich arch bar (1A) A clinical photograph showing smart lock hybrid arch bar fixated with self drilling screws. (1B): showing MMF for closed reduction by Smart Lock Hybrid arch bar after application for closed Reduction. (1C): A clinical photograph showing Erich arch bar

Number of gloves' penetration

No gloves' penetration were found in Group A either during application or removal. While in Group B number of gloves' penetration ranged from 7 to 18 during application and 2-7 on removal. So

during application or on removal of arch bar; group A showed lower statistically significant difference number of gloves' penetration than Group B.

Application and removal time

The application time mean was 22.6 (SD = 2.8) in Group A, while in Group B the application time mean was 53.7 (SD= 8). The removal time mean was 4 (SD = 1.5), while the removal time mean was 13.2 (SD = 3).

Whether during application or removal of the arch bar; group A showed statistically significantly lower difference time than group B (P -value <0.001, Effect size = 5.202) and (P -value <0.001, Effect size = 3.333), respectively.

Gingival Index (GI)

The gingival index range was 0.02 - 2.16 before arch bar application in Group A, while the range was 0.05 – 2.65 in Group B. On the other hand after arch bar application the gingival index range was the same for Group A and turned to be 1 -2.65 in Group B.

A. Comparison between the two groups

Before application of arch bar: there was no statistically significant difference in median GI between the two groups (P -value = 0.310, Effect size = 0.342).

After application of arch bar: group A showed lower statistically significant difference GI than group B (P -value = 0.001, Effect size = 1.276).

B.Changes within each group

In Group A: there was no statistically significant difference GI after application of arch bar (P -value = 0.180, Effect size = 0.318).

While in Group B: there was a statistically significant increase in median GI after application of arch bar (P -value = 0.001, Effect size = 0.750).

Intraoperative and postoperative complications

In group A, patients showed complications such as gingival growth over the eyelets of arch bar and screws, mucosal tears and screw loosening (Fig: 2A,2B). While in group B complications as tooth mobility, bad odor and coated tongue were found. No tooth avulsion happened during treatment of all patients in both groups, although one case in group A needed dental treatment (endodontic treatment) for the lower first molar as a result of root injury during fixation of the arch bar with a self drilling screw. In group A, patients treated with ORIF: In two cases we had to remove the arch bar after the inferior (non-compression) plate was applied to be able to apply the tension plate. There was no statistically significant difference in the complications between the two groups except : In (Group A) Mucosal tear and

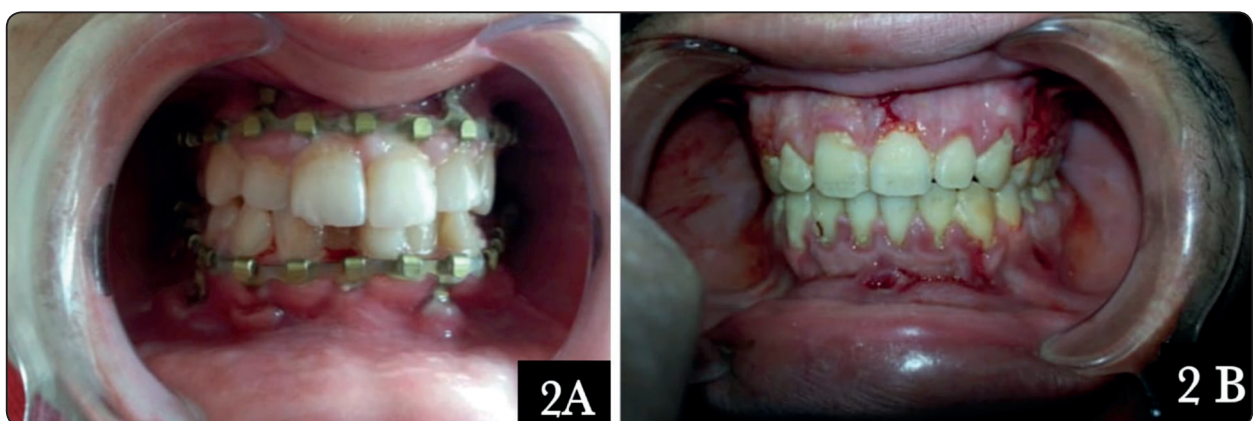


Fig. (2) (2A) clinical photograph showing gingival growth over the eyelets and screws, (2B) : A clinical photograph showing complications of smart lock hybrid arch bar as mucosal tear and soft tissue injury.

Gingival growth showed statistically significantly higher difference than (Group B), however tooth mobility in (Group A) showed statistically significantly lower difference than (Group B).

Patient satisfaction

VAS

The VAS scores in Group A were 11 good (61.1%), 6 fair (33.1%), 1 poor (5.6%). While in Group B the VAS scores were 4 good (22.2%), 11 fair (61.1%), 3 poor (16.7%). There was a statistically significant difference between VAS for patient satisfaction in the two groups (P -value = 0.049, Effect size = 0.399). Group A showed higher prevalence of good score while Group B showed higher prevalence of poor and fair scores.

HADS Hospital Anxiety and Depression Scale

The HADS results in Group A range for (A component) were 3-10 and for (D component) were 0-12, while in Group B the range were 2-15 for (A component) and 4-19 for D component. Whether for (A) or (D) components of HADS; Group A showed statistically significantly lower difference than Group B (P -value = 0.027, Effect size = 0.788) and (P -value = 0.006, Effect size = 1.025), respectively.

University of Washington Quality of Life Questionnaire (UW-QOL v4)

Questionnaire domains

There was no statistically significant difference between the two groups regarding Pain, Chewing, Speech, Taste and Saliva. Group A showed statistically significantly higher median score than Group B regarding appearance, activity, recreation, swallowing, mood and anxiety

Global questions

There was no statistically significant difference between the two groups regarding QOL compared to a month before trauma (P -value = 0.054, Effect

size = 0.594). Group A showed statistically higher significantly difference than Group B regarding QOL in the past 7 days (P -value = 0.017, Effect size = 0.827) and overall QOL (P -value = 0.017, Effect size 0.848).

Significant problems

There was no statistically significant difference between the two groups regarding pain, appearance, activity, recreation, swallowing, chewing, speech and anxiety. Group A showed statistically significantly lower difference of subjects whom considered mood as a significant problem than Group B (P -value = 0.034, Effect size = 0.354).

Cost

The mean cost for group (AI) was 5997.8 L.E., while the mean cost for group (BI) was 571.9 L.E. Group(AI) showed statistically significantly higher mean cost than Group (BI). Group (AII) showed statistically significantly higher cost than Group (B II). The cost for group (AII) was 5800 L.E, while the cost for group (BII) was 100 L.E.

DISCUSSION

The purpose of this study was to evaluate the placement of Smart Lock Hybrid arch bar system secured with bone-borne self-drilling locking screws and compare it with EABs secured with circum dental stainless steel wires in the treatment of mandibular fractures. The specific aims of the study were to compare: 1) clinical outcomes and the incidence of postoperative complications between the 2 techniques, 2) the time necessary for device application and removal, 3) glove perforation rates, 4) gingival health, 5) patient satisfaction, and 6) cost.

In this study the most common complication associated with the Stryker Smart Lock Hybrid arch bar was overgrowth of the mucosa. Mucosal overgrowth did not have any unwanted effect except for difficulty in removal of the arch bar.

Other complications associated with the Smart Lock hybrid arch bar were screw loosening, tooth root damage. Only one patient required further treatment of a tooth because of injury from screw placement. This was in accordance with the study done by **Kendrick in 2016**.⁽⁶⁾ The low incidence of root damage supports the use of the Smart Lock hybrid arch bar.

In the current study the time of application of Stryker Smart Lock Hybrid arch bar was significantly less that required for application of EABs, this was in acceptance with results of study that were done by **Chao and Hulsen** in 2015⁽¹⁵⁾, **king et al**⁽¹⁶⁾. However both application times were shorter than those in our study which might be due to individual variations in the operators.

In our study the mean removal time recorded (4 minutes) for hybrid arch bars was significantly lower than the mean removal time recorded (13.2 minutes) for EABs in according to that found in studies done by **King et al**⁽¹⁶⁾ and **Kendrick et al**⁽⁶⁾ but in contrary with **Chao and Hulsen**⁽¹⁵⁾ who found that there were not significant difference between the removal times for EABs and Smart Lock Hybrid arch bar which might be also due to individual variations in the operators. However our mean removal time in this study was shorter than that found by **Kendrick et al**⁽⁶⁾ probably due to using a screw for every hole in the hybrid arch bar, rather than the 5 screws per arch used in our study.

In study comparing EABs and hybrid arch bars, **Bouloux**⁽¹⁷⁾ in 2018 conducted a randomized controlled trial with total operative time as the primary outcome variable and arch bar application time as the secondary outcome variable. Bouloux found no significant difference in the total operative time between groups but did find a significantly difference in the arch bar application time in favor of Smart Lock Hybrid group in accordance with our study results.

In the current study, we found that high significantly difference in glove penetration during appli-

cation in the EAB group, than in the Smart Lock hybrid arch bar group, similar that was found by **king et al**.⁽¹⁶⁾ This wasn't in acceptance with what found by **Chao and Hulsen**⁽¹⁵⁾ that there is no significantly difference between the two groups however, during the use of EABs, wire sticks were published to occur at a rate from 37% to as high as 90%.⁽⁹⁸⁾

In our study, Group A showed statistically significantly lower median GI than Group B. Before this study there were no published studies recording the changes in the gingiva before and after arch bar application between Smart Lock Hybrid arch bar and EABs using gingival index, however **king et al**⁽¹⁶⁾ documented that there were no difference in overall gingival appearance at the time of device removal, the health of the gingiva surrounding the devices was evaluated and recorded using the following descriptors: poor, fair, good, or excellent. This was converted to a numerical score from 1 to 4, with 1 being "poor". No currently published studies have examined the patient satisfaction with hybrid arch bars. In this study we documented the patient satisfaction with hybrid arch bars and EABs using VAS, HADS and UW-QOLv4. Regarding VAS we found that Smart Lock Hybrid group showed higher prevalence of good score while EABs group showed higher prevalence of poor and fair scores. Whether for (A) or (D) components of HADS; Smart Lock Hybrid group showed significantly lower than EABs group There was no significant difference between the two groups regarding Pain, Chewing, Speech, Taste and Saliva. While Smart Lock Hybrid group showed significantly higher score than EABs group regarding Appearance, Activity, Recreation, Swallowing, Mood and Anxiety.

In our study the comparison between the absolute cost of Erich arch bar and smart lock hybrid arch bar was in favor of Erich arch bar as it was most cost effective than the smart lock hybrid arch bar similar to results of **chao and hulsen**⁽¹⁵⁾ in 2015, **king et al** in 2019.⁽¹⁶⁾

In our study when accounting for cost of OR time consumed for arch bar application the result was in favor of EABs, this was in contrary to the results of **chao and hulsen** ⁽¹⁵⁾ in 2015, **king et al** in 2019 ⁽¹⁶⁾ who found that after adding the OR time cost the result was in favor of hybrid arch bar. That was because the cost of OR minute in our study was severely less in cost than that in other studies.

CONCLUSION

In this study, we concluded that Smart Lock Hybrid Arch bar is more effective than the conventional Erich arch bar in the treatment of mandibular fractures. As it reduces the operating time and the risk of needle stick injuries and provides better patient acceptance, although it is more expensive. We recommend more studies to be done regarding the cost of OR minute in Egypt and further studies evaluating Smart Lock Hybrid arch bar on larger sample size and to use Smart Lock Hybrid arch bar as a tension band.

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