

Comparison of Clinical Efficacy of Screw-retained Arch Bar vs Conventional Erich's Arch Bar in Maxillomandibular Fixation: A Randomized Clinical Trial

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ABSTRACT

Aim: This study aimed to compare the clinical outcomes of a conventional Erich's arch bar vs a modified screw-retained arch bar in maxillomandibular fixation of mandibular fracture.

Materials and methods: This parallel-arm randomized control trial included patients from the outpatient clinic with single favorable mandibular fractures that are indicated for closed reduction. They were subjected to maxillomandibular fixation using conventional Erich's arch bars in the control group and modified screw-retained arch bars in the study group. The outcome measures included operating time, glove perforations, postoperative pain, oral hygiene, fixation stability, occlusion, and mucosal coverage.

Results: A total of 20 patients (12 males and 8 females) with a 1:1 allocation ratio were included. There was a significant statistical difference regarding operation time and number of glove perforations in favor of group B as $p < 0.001$, $p = 0.007$, respectively. There was a significant statistical difference regarding pain after 1 day ($p < 0.001$), 1 week ($p < 0.001$) in favor of group B, and at 4 weeks ($p = 0.015$), and 6 weeks ($p = 0.002$) in favor of group A. Regarding oral hygiene at 1 week ($p = 0.021$) and at 6 weeks ($p < 0.001$), there was a significant statistical difference in favor of group B. Regarding mucosal coverage at 6 weeks, there was a significant statistical difference in favor of group A ($p = 0.005$).

Conclusion: The modified screw-retained arch bar can be considered an alternative to conventional arch bar as it provided less application time and better operator safety. It also showed better patient satisfaction regarding pain and oral hygiene.

Clinical significance: Maxillomandibular fixation with the conventional technique was modified to screw-retained arch bar which is less time-consuming and provides better patient and operator satisfaction.

Keywords: Arch bars, Closed reduction, Erich's arch bars, Mandibular fracture, Maxillomandibular fixation, Randomized clinical trial, Screw-retained arch bars.

The Journal of Contemporary Dental Practice (2023): 10.5005/jp-journals-10024-3613

INTRODUCTION

Maxillofacial injuries occur in a significant proportion of trauma patients.¹ Research that focuses on the presentation and treatment of maxillofacial injuries is important for improving patient care and determining the consequences for patients' health.² When selecting a treatment approach, it is important to consider factors such as disruption of occlusion, the presence of teeth, the patient's masticatory system, the patient's adaptation, and the deviation of the mandible.³ Reduction techniques in maxillofacial fractures can be classified according to the visual access to the fracture site into open reduction and closed reduction. Closed reduction permits manipulation of the fracture segments without direct visual access, taking advantage of dental occlusion.⁴

Maxillomandibular fixation (MMF) has been proven to be the cornerstone of maxillofacial reconstruction.⁵ Erich's arch bar with interdental wiring is the traditional MMF technique, and its ability to attain excellent occlusion reproducibility is well established in the literature.⁶ Although arch bars come relatively with low cost, the wires secured around the teeth for arch bar fixation may cause extrusion of the teeth with subsequent loss of their vitality, also wiring around teeth cervical portions may lead to ischemic necrosis to the related gingival tissue.⁷ In addition, wire manipulation increases the risk of needle stick injury and glove puncture for the surgeon or assistants.^{8,9}

Alternative techniques have been developed recently to avoid these obstacles, such as the modified screw-retained arch

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How to cite this article: Elhadidi MH, Awad S, Elsheikh HAE, *et al.* Comparison of Clinical Efficacy of Screw-retained Arch Bar vs Conventional Erich's Arch Bar in Maxillomandibular Fixation: A Randomized Clinical Trial. *J Contemp Dent Pract* 2023;24(12):928-935.

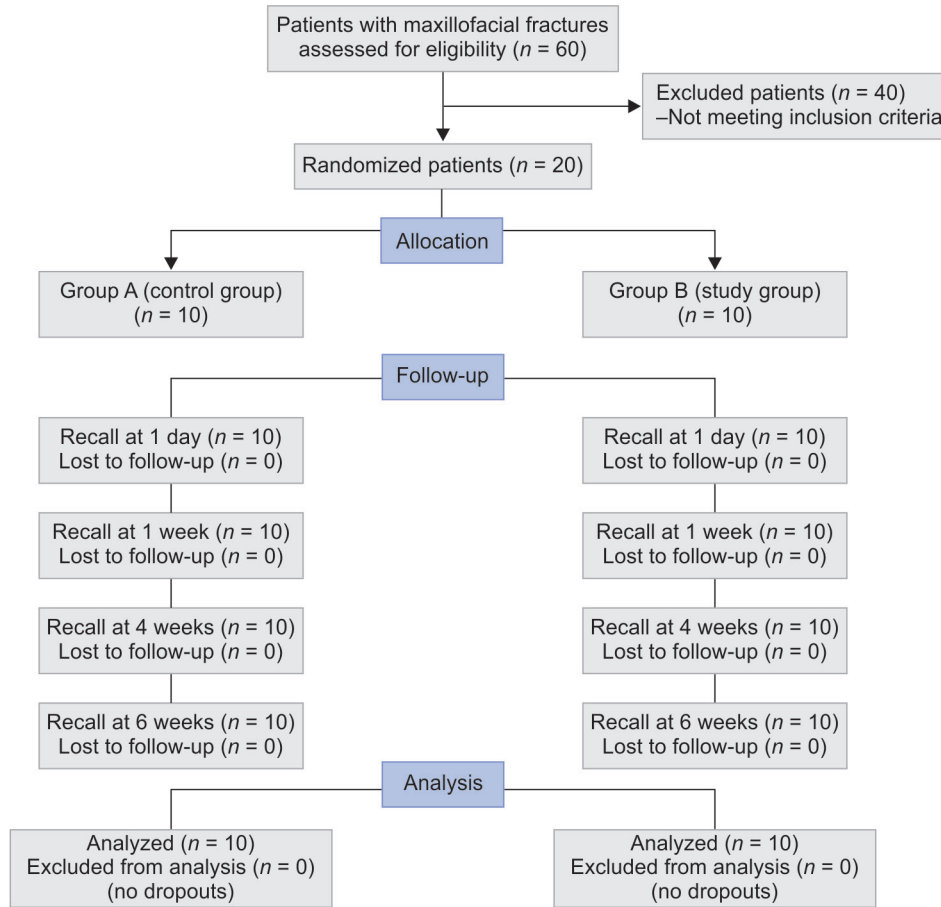
Source of support: Nil

Conflict of interest: None

Patient consent statement: The authors have obtained a written informed consent signed by each patient before the surgical procedure. All patients had the right to withdraw from the study at any time.

bar (mSRAB) on which wires or elastics may be fixed for MMF.⁸⁻¹⁰ Conventional Erich's arch bar (CEAB) has been modified recently by perforating the spaces between the winglets and fastening the arch bar using 1 mm diameter screws to create mSRAB.¹¹ Modified screw-retained arch bar has many advantages as it causes minimal trauma to the periodontium with decreased wire prick injury and glove puncture as suggested by literature.⁷

Flowchart 1: Flowchart representation of groups distribution



The purpose of this study was to evaluate and assess the clinical efficacy of the mSRAB compared to the CEAB. The hypothesis was that there was no significant difference between mSRAB and CEAB in terms of operating time, number of glove perforations, postoperative pain, oral hygiene, MMF stability, occlusion, mucosal coverage, and teeth vitality.

MATERIALS AND METHODS

Patient Selection and Study Design

To achieve the purpose of research, a parallel arm, randomized controlled trial with an equal allocation ratio of 1:1 was planned, designed, and implemented. Patients were selected from the outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Mansoura University from January 2022 to January 2023 (Flowchart 1).

Sample Size Design

The sample size was based on the difference between CEAB and mSRAB retrieved from the previous research using G*Power software for Windows (version 3.1.9.2). A total sample size of 20 patients was decided based on an effect size of 1.4 using a two-tailed test, α error = 0.05, and power = 80%. To achieve an allocation ratio of 1:1, it was considered 10 patients in each group.

Eligibility Criteria

Inclusion Criteria

- The patients' ages ranged from 18 to 50.
- Patients who came within 1 week of the initial trauma with single favorable mandibular fracture that was indicated for closed reduction, including the angle, body, parasymphysis, or symphysis fractures.
- Healthy patients without any systemic condition that would preclude the surgical operations.

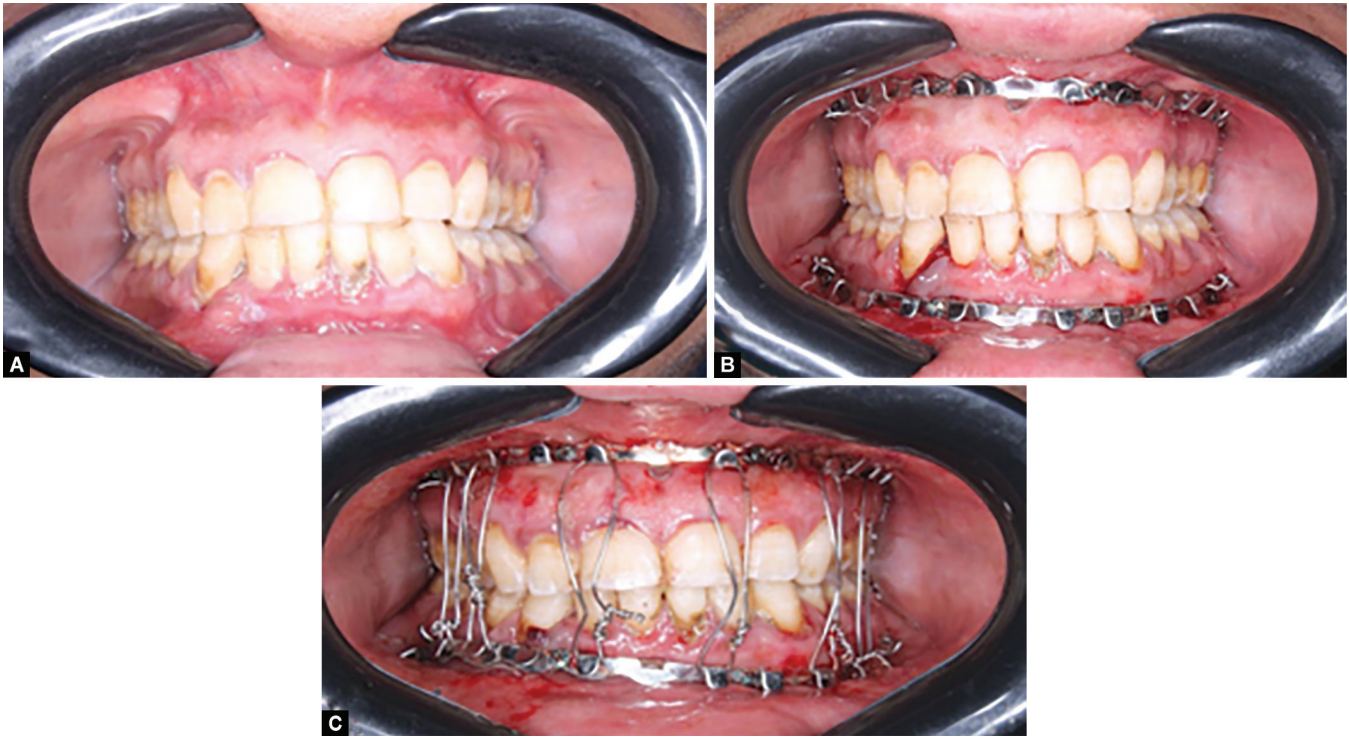
Exclusion Criteria

- Fractured edentulous jaws.
- Patients with primary and mixed dentition.
- Patients with unfavorable, comminuted, infected, or pathologic fractures.
- Patients indicated for open reduction and internal fixation (ORIF).
- Patients with missing one or more maxillary or mandibular first molar.

Grouping

The patients in this trial were split into two groups:

1. Group A (control group): in which CEAB was used for MMF.
2. Group B (study group): in which mSRAB was used for MMF.



Figs 1A to C: (A) Preoperative photograph showing dental occlusion; (B) Intraoperative photograph showing mSRAB; (C) Immediate postoperative photograph showing MMF with mSRAB

Randomization

Microsoft Excel spreadsheet was used to produce a sequence of random numbers and generate random allocations using a tool called "RAND," that effectively randomly allocated the study participants.

Blinding

In this trial, the patients were blinded to which MMF technique group they were assigned. The surgeon and the evaluator were essentially aware of the MMF technique. Opaque, numbered, and sealed envelopes were used to conceal the corresponding allocation for each patient. The allocation concealment technique was performed by one of the department's senior residents, who was not involved in the study and was not aware of any relevant treatment protocols to avoid selection bias. The surgeon opened the envelope right before surgery. Also, the statistician was unaware of treatments and groups.

Maxillomandibular Fixation Technique

Preoperative Procedures

- Clinical examinations and emergency management were performed (Fig. 1A).
- A panoramic radiograph was made (Fig. 2A).
- Full medical and dental histories were acquired.
- Study casts were constructed for arch bar modification.
- Patients were instructed to rinse their mouth with 0.1% chlorhexidine gluconate (Listermix Plus mouthwash, SIGMA, Egypt) for 1 minute before starting the surgical procedure.

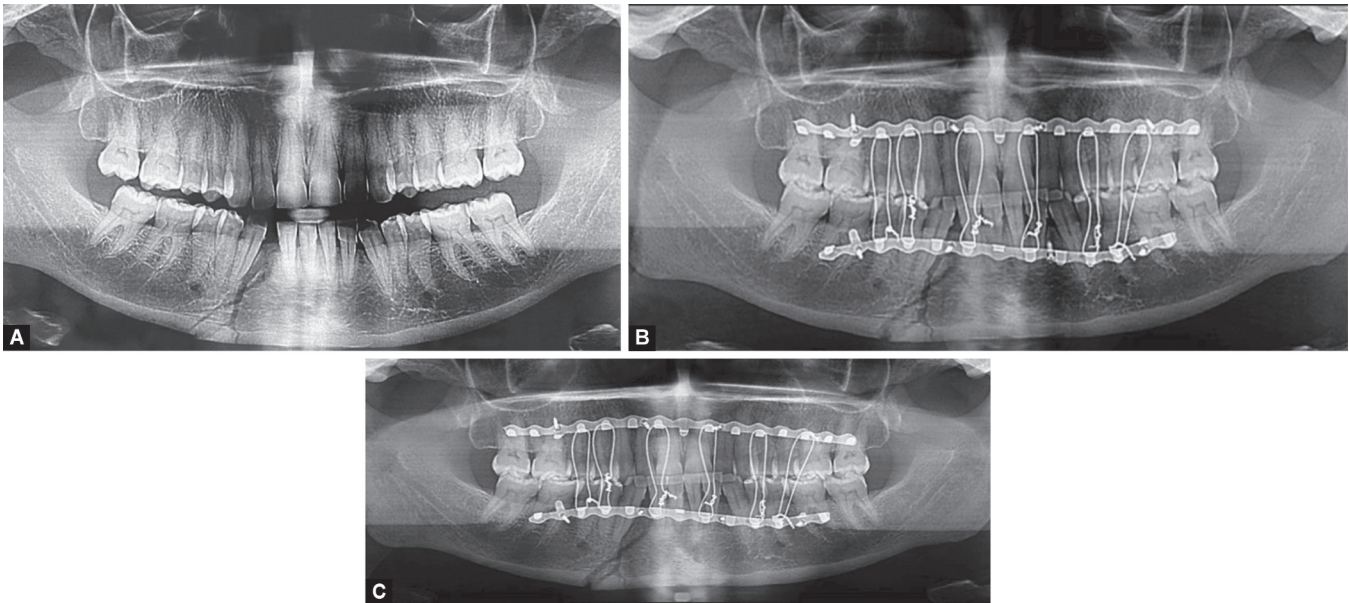
Surgical Procedure

All operations were done in an outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Mansoura

University by a single surgeon under 4% articaine local anesthesia (Septanest with adrenaline 1:100,000; Septadont, Saint Maur des Fosses, France). The local anesthesia techniques utilized were bilateral maxillary nerve block in the maxilla and bilateral inferior alveolar nerve block, bilateral lingual nerve block and bilateral long buccal nerve block in the mandible. The number of cartridges used was 4–5 in respect to the maximum recommended dose to each patient following the FDA guidelines.

In Group A: Patients received conventional Erich's arch bar (DENTAURUM GmbH & Co. KG. 31, 75228 Ispringen, Germany), which was cut to a suitable length distally. A 26 gauge wire (DENTAURUM GmbH & Co. KG. 31, 75228 Ispringen, Germany) was utilized for arch bar fixation.¹² Then MMF was achieved using wires on the hooks of the arch bar.¹³ The duration of the surgery was recorded in minutes.

In Group B: Using a No. 701 bur fitted to a high-speed handpiece, a conventional arch bar was adjusted on cast to make perforations opposite the interdental bone in the gaps between the winglets or under the winglets by bending it occlusally to avoid root injuries (two holes anterior and two holes posterior). The arch bar was modified to fit the vestibular surface of the maxilla and mandible, at the depth of mucobuccal fold. After reduction of occlusion, the screws (ANTON HIPPI, Annastraße 25/1,78567 Fridingen an der Donau, Germany) were fixed to the bone with the screwdriver (ANTON HIPPI, Annastraße 25/1,78567 Fridingen an der Donau, Germany) at 90° angles to the bone. For each arch bar, four screws were placed, two anteriorly and two posteriorly, for a total of eight screws for each patient (Fig. 1B). Self-tapping self-drilling fixation screws with 1.5 mm in diameter and 7 mm in length were used. It was not essential to tighten the screw very much, just enough to achieve arch bar stabilization before applying wires for MMF (Fig. 1C). The duration of the surgery was recorded in minutes.



Figs 2A to C: (A) Preoperative panoramic radiograph showing parasymphyseal fracture line; (B) Immediate postoperative panoramic radiograph showing fracture line and MMF using mSRAB; (C) Panoramic radiograph showing fracture line and MMF using mSRAB at 6 weeks

Postoperative Instructions

- Patients were instructed to have a soft diet.
- Postoperative antibiotics and analgesics were prescribed.
- Patients were instructed to use mouthwash 0.1% chlorhexidine gluconate (Listermix Plus mouthwash, SIGMA, Egypt) for 1 minute, three times per day.
- The MMF duration was 6 weeks in both groups.
 - In group A, conventional Erich arch bars and stainless-steel wiring were removed after 6 weeks postoperatively.
 - In group B, MMF screws were retrieved after 6 weeks postoperatively in the outpatient clinic under local anesthesia.

Follow-up

- All the patients were followed-up at 1 day, 1 week, 4 weeks, and 6 weeks postoperatively.
- A postoperative panoramic radiograph was taken immediately (Fig. 2B) and 6 weeks postoperatively (Fig. 2C).
- During the period of follow-up, the secondary outcome variables were recorded.

Data Collection

The data regarding outcome measures were collected immediately, 1 day, 1 week, 4 weeks, and 6 weeks postoperatively, as follows.

Duration of the Surgery

The time required for the surgical procedure in minutes from the beginning of surgical procedure till MMF achievement was assessed intraoperatively.

Number of Wire Pricks and Glove Perforations

The number of wire pricks and glove perforations was identified by the water inflation method. Gloves were tested by insufflating the glove with approximately 500 mL of tap water. Each glove was twisted and closed at the cuff end with gentle pressure applied to the palm and individual fingers. All punctures' evaluation was

done by the same examiner. The number of punctures per glove was tabulated and analyzed.¹⁴

Postoperative Pain

Assessment was done 1 day, 1 week, 4 weeks, and 6 weeks postoperatively. It was performed using a numeric rating scale (NRS) in which participants rated their pain on a scale from 0 to 10. The 11-point numeric scale varies from “no pain” (representing the lowest possible level of pain) to “pain as severe as you can imagine” (representing the highest level of pain).¹⁵

Oral Hygiene

Oral hygiene was assessed 1 week postoperatively and at 6 weeks using the Oral Hygiene Index-Simplified (OHI-S). The OHI-S values from 0 to 6. The OHI-S score was good between 0 and 1.2, medium between 1.3 and 3, and poor between 3.1 and 6.¹⁶

Occlusion

In both groups, preoperative occlusion and occlusion at time of MMF removal were evaluated according to the Angle classification of malocclusions:

- Class I molar relationship: The buccal groove of the mandibular first molar and the mesiobuccal cusp of the maxillary first molar occluding in line.
- Class II molar relationship: The mesiobuccal cusp of the maxillary first molar occluding anterior to the buccal groove of the mandibular first molar.
- Class III molar relationship: The mesiobuccal cusp of the maxillary first molar occluding posterior to the buccal groove of the mandibular first molar.¹⁷

Maxillomandibular Fixation Stability

Maxillomandibular fixation stability was evaluated at the time of MMF removal for both groups. The stability of the MMF was recorded as adequate if there was no or minimal micromovement in the stabilized arch bar. It was recorded as inadequate if there

Table 1: Mann–Whitney *U* test showing the results of NRS in both groups at 1 day, 1 week, 4 weeks, and 6 weeks postoperatively

Variables	Group A (Medians ± SD)	Group B (Medians ± SD)	95% confidence interval of differences		p-value
			Lower	Upper	
NRS at 1 day	5 ± 0.994	2 ± 0.623	1	5	< 0.001*
NRS at 1 week	2.5 ± 0.823	0 ± 0.675	0	2	< 0.001*
NRS at 4 weeks	2 ± 1.299	3 ± 0.789	2	3	0.015*
NRS at 6 weeks	2 ± 0.949	3.5 ± 0.966	0	5	0.002*

Statistical significance was set at $p < 0.05$

was severe micromovement or loosening in the stabilized arch bar, which may cause inadequate fixation.^{18–20}

Mucosal Coverage

Complete, partial, and absence of mucosal coverage was recorded in patients at time of arch bar removal.

Teeth Vitality

Eight fixed teeth were tested in each arch, which were in close relation to the screws in the study group (central incisors, lateral incisors, second premolars, and first molars). They were tested preoperatively and after 6 weeks for vitality loss using an electric pulp tester.

Statistical Analysis

The collected data were tabulated and analyzed using IBM-SPSS software (IBM Corp., released 2019). IBM SPSS Statistics for Windows, Version 26.0 (Armonk, NY: IBM Corp.).

All numerical variables were analyzed statistically using the Shapiro–Wilk normality test followed by independent *t* test (for normally distributed variables), Mann–Whitney *U* test (for non-normally distributed variables), and Chi-squared test (for nominal variables). The differences were considered significant at a $p < 0.05$.

RESULTS

Demographic Data

A total of 20 patients (12 males and 8 females) were randomly allocated to either of the two groups. The mean age of patients in group A was 34 ± 9.9 years and ranged (from 20 to 50) while in group B was 33.9 ± 12.5 years and ranged (from 19 to 55). Comparing the two groups, there were no significant statistical differences regarding age and gender as $p = 0.98$ and $p = 1.000$, respectively.

Clinical Evaluation

Duration of the Surgery

The average working time for group A was 34.3 ± 3.6 minutes, while in group B, it was 19.5 ± 3.1 minutes. Comparing the two groups, there was a high significant statistical difference in favor of group B as $p < 0.001$.

Number of Gloves Perforation

Comparing the number of gloves perforation between both groups, there was a high significant statistical difference in favor of group B. The mean and standard deviation in group A and group B were (2.2 ± 0.79 and 0.1 ± 0.32 , respectively), $p = 0.007$.

Pain (NRS)

Comparing NRS after 1 day and 1 week, there was a statistically significant difference in favor of group B as $p < 0.001$ and $p < 0.001$, respectively, on 95% confidence interval of difference. On the contrary, comparing NRS at 4 and 6 weeks, there was a statistically significant difference in favor of group A as $p = 0.015$, $p = 0.002$, respectively, on 95% confidence interval of difference (Table 1).

Oral Hygiene

On the first postoperative week, the oral hygiene status was good in 10% ($n = 1$) of patients, medium in 50% ($n = 5$) of patients, and poor in 40% ($n = 4$) of patients of group A. On the other hand, in group B the oral hygiene was good in 60% ($n = 6$) of patients, and medium in 40% ($n = 4$) of patients.

At the time of removal of MMF, the oral hygiene status was poor in 100% ($n = 10$) of patients of group A. On the other hand, in group B the oral hygiene was good in 60% ($n = 6$) of patients, medium in 30% ($n = 3$) of patients, and poor in 10% ($n = 1$) of patients.

Comparing oral hygiene at 1 week between group A and group B, there was a high significant difference in favor of group B as $p = 0.02$. Also, comparing oral hygiene of the two groups at 6 weeks revealed a high significant difference in favor of group B as $p < 0.001$. (Fig. 3)

MMF Stability at MMF Removal

Comparing the MMF stability, between modified CEAB and mSRAB at the time of removal. In group A, the stability was acceptable in 90% ($n = 9$) of the patients. In group B, it was acceptable in 80% ($n = 8$) of the patients. There was no significant statistical difference between the two groups as $p = 0.531$.

Occlusion

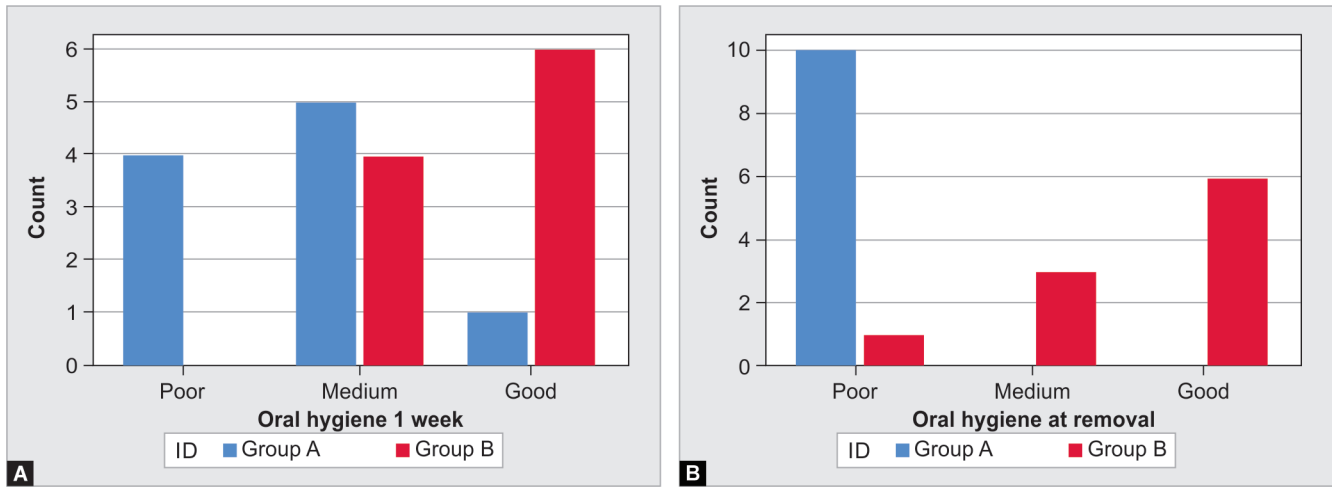
Comparing patients' preoperative occlusion and occlusion at 6 weeks in both groups, there was no significant statistical difference as p -values were ($p = 1$) for both.

Mucosal Coverage

Complete, partial, and absence of mucosal coverage was recorded in patients at time of arch bar removal. Comparing the two groups, there was a significant statistical difference in favor of group A as ($p = 0.005$) (Table 2).

Teeth Vitality

In group B, the vitality was measured to eight teeth in each arch which in close relation to the screws before and after the MMF. There was no statistically significant difference regarding teeth vitality between the two time points as $p = 1$.



Figs 3A and B: Bar chart showing oral hygiene at 1 week and at removal in both groups

Table 2: Chi-square test showing mucosal coverage at time of MMF removal

Variable	Subgroups	Group A	Group B	Total	p-value
Mucosal coverage	No	10 (100%)	3 (30%)	13 (65%)	0.005*
	Partial	0 (0.0%)	6 (60%)	6 (30%)	
	Complete	0 (0.0%)	1 (10%)	1 (5%)	

Values are presented as number (%). Statistical significance was set at $p < 0.05$

DISCUSSION

Maxillofacial fractures can be treated using a variety of methods, including closed reduction and ORIF. Since the First World War, the arch bar has been the cornerstone of treatment for maxillary mandibular fracture.²¹ The mSRAB can be considered a better alternative to CEAB in MMF.⁷

Based on the results of this study, the null hypothesis was rejected as there was a significant statistical difference between group A and group B regarding the duration of the surgery, number of gloves perforated, postoperative pain, and oral hygiene in favor of group B. In addition, there was a significant statistical difference comparing mucosal coverage in both groups, in favor of group A.

Regarding operating time, the present study showed that the mSRAB decreases MMF time significantly. This may be related to the decrease of wires used in mSRAB and to the number and type of screws used in this study. Only four self-tapping, self-drilling screws were used per arch for arch bar stabilization in mSRAB.²² These findings are in line with other studies comparing the two types of arch bars.^{20,22,23}

Chao and Hulsen²² evaluated the clinical outcome of the mSRAB system, they revealed that the operation duration was 42 minutes, which was less than the time required for CEAB application (62 minutes) and this was the same as our results in the present study. Pathak et al.²⁰ revealed that mean time duration was 27.2 minutes for SRAB patients when compared to 82.5 minutes for CEAB patients which was comparable to our study.

Regarding the number of gloves perforation, this study showed a high significant statistical difference in favor of group B as $p = 0.007$. This was in line with a study by Venugopalan et al.⁷ who found that, the surgeons and assistants wire injuries were

18.8% in mSRAB group and 56.3% in CEAB group ($p = 0.0005$). This may be due to the lesser use of stainless-steel wires in mSRAB group which are the main cause of gloves perforation. In contrast to our result, Pathak et al.²⁰ reported that there was no significant statistical difference between mSRAB and CEAB regarding gloves perforation as $p = 0.21$.

Avery and Johnson²⁴ in their prospective study, compared surgical glove perforations acquired during management of mandibular fractures in small plate osteosynthesis and in interdental wiring. They concluded that small plate osteosynthesis is better than interdental wiring in terms of reducing the risk of penetrating injury and intraoperative cross-infection as it offered less glove perforations.

Regarding pain, it was measured by NRS, and it was reported in our study that there was a significant difference comparing both groups at the first postoperative day and first postoperative week as $p < 0.001$ in the two time points. This difference was in favor of group B, and this may be related to that the mSRAB is less traumatic with a fewer number of gingival penetrations resulting in less bleeding chance and less postoperative pain. Kim et al.¹⁹ reported that patients suffered from pain due to gingival injury with sharp wires used for arch bar fixation to the teeth, and the pain may be also attributed to rubber bands or wires used for MMF as it may cause mucosal irritation.

Mucosal coverage was not found in group A; while in group B, 30% of cases were found with no mucosal coverage, 60% of cases were found with partial mucosal coverage and 10% was found with full mucosal coverage. There was a significant statistical difference between the two groups regarding mucosal coverage at time of MMF removal as $p = 0.005$. This explains the cause of increased pain in group B at 4 and 6 weeks. As there was a significant statistical

difference in the pain between the two groups at 4 and 6 weeks in favor of group A.

Kendrick et al.²⁵ reported that the most common complication associated with smart lock hybrid maxillomandibular fixation system was mucosal overgrowth, which was noticed in 37% of the cases and this may be related to arch bar fixation adjacent to or within the mobile mucosa.²⁶ Rai et al. proposed adding stainless-steel washer, which keeps the oral mucosa away from the MMF screws and arch bars.²⁷

Regarding the oral hygiene, on the first postoperative week and at the time of MMF removal, there was a significant difference between the two groups in favor of group B as $p = 0.02$ and $p < 0.001$, respectively. This may be related to the presence of less MMF wires in group B which facilitate cleaning the teeth and the gingiva resulting in better oral hygiene. Rothe et al.²⁸ compared CEAB, MMF screws, and mSRAB and reported that maximum hygiene was found in MMF screw group followed by mSRAB group and CEAB group, respectively, which agree with our study.

King and Christensen²³ in their comparative study, showed no significant difference in the gingival health between conventional and modified arch bars. This may be dependent on preoperative oral health condition. Also, the maintenance of oral hygiene is highly dependent on individual oral hygiene measures during the MMF period.

Regarding MMF stability, it was reported that the stability was acceptable in 90% of the patients in group A while in group B, it was acceptable in 80% of the patients. There was no significant statistical difference between the two groups as ($p = 0.531$). In addition, in our study no screw loosening was recorded in group B so there was no significant effect of screw loosening on the overall stability of the devices throughout the follow-up period. In contrast to our results, Hamid and Bede²⁹ reported screw loosening which was also reported by Kendrick et al.²⁵ in 17% of the patients.

Venugopalan et al.⁷ reported that CEAB was less stable than mSRAB and required more device replacement. These findings were parallel to the findings reported by Nandini et al.⁹ who reported that mSRAB provided better stability than CEAB. The possible reason for this could be the adaption of the mSRAB to the vestibular surface of the maxilla and mandible and not to the cervical portion of the teeth also the used bone screws for arch bar stabilization provided better stability of the devices.

Comparing patients' preoperative occlusion and occlusion at 6 weeks in both groups, there was no significant statistical difference and there was no malunion or delayed union reported in our study. This was in line with Hamid and Bede²⁹ who reported that at the end of follow-up period all the patients enrolled in their study had acceptable occlusion.

In group B, teeth vitality was measured preoperative and postoperative resulting in no statistically significant difference in teeth vitality after removal of MMF. This may be related to the use of self-tapping self-drilling screws without the need for drilling that may cause root injury and loss of vitality. Also, it may be related to the precise location and careful fixation of the MMF screws between the roots.²⁹ On the contrary, Coletti et al.³⁰ reported tooth root injury in two patients out of 49 (4%) in their study.

The novelty lies in the modification of the CEAB made chair-side in the outpatient clinic. This modified arch bar presented easier and quicker MMF technique than CEAB with lower cost and better preservation of teeth vitality than ready-made perforated

arch bar. It also demonstrated increased patient satisfaction as it decreased the postoperative pain and allowed them to maintain oral hygiene control. However, there were some limitations or potential implications that the surgeon needed to be aware of to give successful and safe treatment.

The limitations of this study are the small sample size. Moreover, if the patient has osteoporosis or the fracture is significantly comminuted, mSRAB may not be suitable. Future research could further examine the difference between CEAB and mSRAB regarding cost analysis and surgeon satisfaction. In addition, further research can be carried out on a large sample size along with a thorough radiographic evaluation.

CONCLUSION

It was concluded that modified screw-retained arch bar is a better alternative than conventional arch bar as it provided less application time and better operator safety. It also showed better patient satisfaction regarding pain and oral hygiene.

Clinical Significance

Maxillomandibular fixation with the conventional technique was modified to screw-retained arch bar which is less time consuming and provides better patient and operator satisfaction.

Ethical Approval

This study was approved by the Ethical Committee of the Faculty of Dentistry, Mansoura University, following the Declaration of Helsinki, with code number (A03080921). The planned surgical procedures and possible expected risks were explained in brief to all patients. This study was registered on ClinicalTrials.gov. with the reference number (NCT05401994).

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