A randomized prospective comparison of maxillomandibular fixation (MMF) techniques: "SMARTLock" hybrid MMF versus MMF screws

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Objective. The aim of this study was to assess the efficacy of the "SMARTLock" hybrid system and determine whether it results in fewer intraoperative and postoperative complications compared with placement of intermaxillary fixation (IMF) screws in trauma patients.
Study Design. This prospective study, which was approved by the institutional review board, compared the results of MMF in mandibular fractures by using the Stryker "SMARTLock" hybrid system versus traditional IMF screws. Patients were recruited and assigned randomly to either group. The 2 groups were compared for placement time, intraoperative complications, loosening of hardware, postoperative complications, and time to device removal.
Results. We enrolled 32 patients in the study, with 13 patients randomized to the group receiving hybrid MMF (HMMF) with the SMARTLock system and 19 to the group of patients receiving MMF with traditional IMF screws. The mean application time for HMMF was 25.92 minutes compared with 18.28 minutes for IMF screws. After removal, the HMMF was associated with gingival overgrowth and gingival edema.
Conclusions. This is the first study to compare HMMF with MMF with the use of IMF screws. Hybrid arch bars do require more manipulation for ideal placement compared with individually placed bone screws to achieve ideal MMF. Compared with IMF screws, the hybrid device was associated with gingival edema and overgrowth, but there was decreased incidence of loosening in the postoperative period. (Oral Surg Oral Med Oral Pathol Oral Radiol 2020;130:640–644)

Maxillomandibular fixation (MMF) is a critical step in the management of facial trauma and maxillofacial surgery to correct and maintain the dental occlusion during healing of bone. MMF is used both intraoperatively to aid in open reduction internal fixation (ORIF) or in closed reduction for stabilization of fractures. Historically, the most widely applied technique for MMF is the use of Erich arch bars (EABs). Although considered by many as the "gold standard" in the treatment of facial trauma, the application of EABs comes with significant drawbacks, as reported in the literature; these include time for fixation, safety risks to the surgeon/user because of wire stick injuries, and compromised general oral health of the patient.[1-4]

MMF screws are now commonly used as an alternative method of MMF. Although this method provides some benefits, such as speed, safety, and versatility, common drawbacks related to MMF screws include damage to the tooth roots and soft tissue overgrowth on the screw heads. This can compromise the interface with wire loops or elastics and can make eventual removal more challenging. Furthermore, there are reports of a high rate of loosening or displacement of screws (29%) over time, which can compromise the stability of the MMF and the eventual healing of the fracture.[5-8]

The Universal SMARTLock hybrid MMF (HMMF) system (Stryker Corporation, Kalamazoo, MI) was designed to combine the mechanical strength and benefits of EAB fixation with the speed and safety of MMF screws. The locking plate and screw design aims to ensure stable and more rigid MMF throughout fracture healing.

This study will compare the safety and efficacy of the SMARTLock HMMF system with that of MMF screws for the management of mandibular trauma.

The following were the primary objectives of our study:

1. To determine the rates of hardware failure (screw breakage, loosening, and pull out) with the HMMF system compared with MMF screws.
2. To determine the average time of implant placement and removal with the HMMF system compared with MMF screws.

Statement of Clinical Significance

The design of the Universal SMARTLock Hybrid maxillomandibular fixation (MMF) locking plate and screw aims to ensure stable and more rigid MMF throughout fracture healing. This study will compare the safety and efficacy of the hybrid MMF with the safety and efficacy of MMF screws for the management of mandibular trauma.

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Received for publication Mar 6, 2020; returned for revision Jun 27, 2020; accepted for publication Jul 23, 2020.

2212-4403/$-see front matter
https://doi.org/10.1016/j.oooo.2020.07.015

3. To determine the rate of tooth root damage with the use of the HMMF System compared to MMF screws.
4. To determine the rate of soft tissue complications related to HMMF compared with MMF screws.

MATERIALS AND METHODS

The study was designed as a prospective randomized controlled trial and was conducted at a Level 1 trauma center designated as a primary adult resource center.

Our control group included patients treated with MMF screws, and our test group included patients treated with the SMARTLock HMMF system. In total, 32 patients were included in the study, with 19 patients in the HMMF treatment arm and 13 patients in the control group.

Patients with mandible fractures requiring intraoperative and postoperative MMF were enrolled in the study. Both isolated and concomitant fractures of the mandible were included. The study was conducted in a prospective randomized manner comparing 2 treatment arms: MMF utilizing the SMARTLock HMMF system and the standard MMF technique using only fixation screws. Fixation screws were placed in regions of the tooth-bearing segments that would ensure stability of the occlusal relationship. Self-drilling locking screws were used with the SMARTLock HMMF device and the MMF screw technique. All screws were 2 mm wide and either 6 mm or 8 mm long. The number of screws used was dependent on the required clinical stability.

On average, the number of screws used for the SMARTLock HMMF device was 9.9 versus 5.7 screws needed for the MMF group.

Patients were preinterviewed to determine inclusion/exclusion; informed consent from patients was also obtained. Appropriate imaging and physical examinations were conducted for all potential patients, as determined by the physician both preoperatively and postoperatively. The intended follow-up period was 6 weeks ± 10 days.

The inclusion and exclusion criteria are shown in Tables I and II. Of note, nonreducible or unstable fractures were included in the exclusion criteria. These included cutaneous compound fractures and unfavorable angle fractures. All cases included in the study, including those that required ORIF, were deemed to be clinically stable.

Data were analyzed by using SPSS v.20 (IBM, Armonk, NY). First, an explorative analysis was carried out according to the parameters of comparison. The explorative analysis was followed by Fisher's exact test in the case of qualitative data or the Student *t* test under the assumption of normally distributed data for all quantitative data. In both cases, an alpha of 0.05 was defined as statistically significant.

Table III lists the potential adverse events encountered when the screws were placed for maxillomandibular fixation.

Table I. Inclusion criteria

1	Patients with mandibular fractures requiring 6 weeks of maxillomandibular fixation as determined by the physician
2	Patients who consent and are willing and able to participate in the study

Table II. Exclusion criteria

1	Patients with nonreducible or unstable fractures*
2	Patients in whom damage to unerupted permanent teeth by screw insertion may be anticipated
3	Patients with a severely atrophic mandible and resection/reconstruction of the mandible
4	Patients with active infections
5	Patients with known metal allergies or foreign body sensitivities
6	Noncompliant patients who have mental or neurologic conditions and who represent a higher physical or psychological risk or are unwilling or unable to follow postoperative care instructions
7	Patients with insufficient quality or quantity of bone
8	Patients with unstable physical and/or mental health conditions as deemed by the surgeon
9	Other medical conditions that are typically contraindications for maxillomandibular fixation, such as epilepsy, chronic substance abuse, airway obstruction, or eating disorders
10	Patients younger than 18 years of age
11	Patients unwilling to give consent for enrollment
12	Vulnerable patient populations, as defined by the local institutional review board (prisoners, non−English speaking, pregnant females, etc.)

RESULTS

In total, 32 patients were enrolled and randomized to 2 groups: 19 patients in the HMMF treatment group and 13 patients in the control group.

Almost all patients had presented to the hospital within 48 hours of their injury. Nine (28%) patients presented with no malocclusion, and 23 (72%) presented with malocclusion and either a crossbite or an open bite.

All patients were evaluated with radiography (panoramic radiography, computed tomography [CT], or both). Ten (31%) patients had a condylar fracture in addition to other fractures of their maxillofacial skeleton.

The majority (n = 24; 75%) of patients were treated with closed reduction only, and 8 (25%) were treated with a combination of ORIF and MMF.

Table III. Potential adverse events as a result of screw placement

1	Poor implant fixation and or stability resulting in malunion or nonunion of fractures
2	Implant breakage resulting in malunion or nonunion of fractures
3	Damage to erupted or unerupted tooth roots
4	Pressure necrosis of gingival and/or mucosal injury

Intraoperative complications

Intraoperative complications included glove tears, tooth root impingement, screw loosening, and wire breakage in both groups. There were no "needlestick" injuries from steel wire manipulation. There were more intraoperative complications in the MMF group (n = 14) compared with the HMMF group (n = 8), although this was not statistically significant ($P = .699$).

Gingival edema

Gingival edema was defined as smooth enlargement of the attached gingival mucosa and of the marginal and interproximal gingival tissues as well; 80% of all gingival edema occurred around the HMMF device compared with the MMF device; however, this was not statistically significant ($P = .006$).

Gingival overgrowth

This was defined as abnormal or redundant tissue overgrowth or irregular hypertrophy of the unattached gingiva around the appliance. It occurred more frequently around the HMMF device compared with MMF screw fixation (n = 7 and 1, respectively). This was statistically significant ($P = .004$).

Gingival erythema

This was defined as desquamation, ulceration, or intense redness of tissues, typically accompanying edema; the lesion bled easily when probed and was tender to the touch. Of all the gingival erythema noted, in 88.9% of the cases, it was associated with the HMMF device. This was statistically significant ($P = .001$).

Screw loosening

The MMF group was found to have the highest number of loosened screws (66.7%); however, this was not statistically significant ($P = 1.00$). On average, the number of screws used for the SMARTLock HMMF device was 9.9 versus the 5.7 screws needed for the MMF group.

Wire loosening

There were 4 instances of wire loosening in the MMF group versus the 2 instances in the HMMF group.

Of all the wire loosening noted, 80% was found to be in the MMF group, and only 20% of loosening occurred in the HMMF group. However, this was not a statistically significant finding ($P = .368$).

Implantation time

The average time to perform the fixation was 25.92 minutes in the HMMF group compared with the 18.28 minutes in the screw MMF group. This trended toward statistical significance ($P = .054$).

Tooth root impingement

Root impingement occurred in 1 HMMF subject and 1 MMF subject, but no secondary intervention was required.

See Table IV for a summary of the results of this study.

DISCUSSION

MMF is an essential tool in the treatment of maxillofacial fractures. Many different MMF methods, such as Ivy-loop wiring, wired arch bars, and so on, have been described in the literature. However, these techniques can extend the operating time and are associated with potential complications.

Table IV. Summary of results

Variable			*P value*
Number	Total	32	
	Control MMF	19 (59.3%)	
	Hybrid MMF	13 (40.6%)	
Gender	Male	26 (81.2%)	
	Female	6 (18.7%)	
Presenting symptoms	No malocclusion	9 (18%)	
	Malocclusion	23 (72%)	
CT findings	Condylar fractures	10 (31.2%)	
	CMF fractures without condylar involvement	22 (68.7%)	
Management	Closed reduction	24 (75%)	
	ORIF and MMF	8 (25%)	
Intraoperative complications related to use of hardware			
	MMF	14/19	P = .699
	Hybrid MMF	8/13	
Gingival edema	Total cases of gingival edema	10	
	MMF	2	P = .006
	Hybrid MMF	8	
Gingival overgrowth	Total cases of gingival overgrowth	8	
	MMF	1	P = .004
	Hybrid MMF	7	
Gingival erythema	Total cases of erythema	9	
	MMF	1	P = .001
	Hybrid MMF	8	
Screw loosening	Total cases	3	
	MMF	2	P = 1
	Hybrid MMF	1	
Wire loosening	Total cases	5	
	MMF	4	P = .368
	Hybrid MMF	1	
Implantation time	MMF	18.28 min	P = .054
	Hybrid MMF	25.92 min	
Tooth root impingement	Total cases	2	
	MMF	1	
	Hybrid MMF	1	

CMF, Cranio-Maxillo-facial; *CT,* computed tomography; *MMF,* maxillomandibular fixation; *ORIF,* open reduction internal fixation.

Fig. 1. Soft tissue overgrowth as a result of inadequate positioning of the hybrid device on the upper arch.

Fig. 2. Similarly, soft tissue overgrowth over several screw holes as the the hybrid device has been positioned too inferiorly in the mandible.

The SMARTLock HMMF system has been a more recent addition to the MMF armamentarium. This bone-borne titanium arch bar eliminates the reliance on teeth for fixation.

In a previous study published by Kendrick et al., the SMARTLock HMMF system has been found to be safe and easy to use, with a cost similar to that of EABs.[9,10]

Our study performed a direct comparison of MMF screws with the SMARTLock HMMF device. We found that use of the HMMF system resulted in more soft tissue overgrowth compared with MMF screws. These findings were similar to those by Kendrick et al., who had compared the HMMF system to EABs, the reported an incidence rate of soft tissue overgrowth as 38%.[9] Nizam and Ziccardi[10] reported a 60% incidence of "mandibular gingival hyperplasia" associated with the SMARTLock HMMF appliance.

Positioning and placement of the HMMF device is critical and does impact the likelihood of soft tissue overgrowth. Placement in the nonattached mucosa beyond the mucogingival junction, either too superior in the maxilla or too inferior in the mandible, results in tissue overgrowth, as shown in Figures 1 and 2. The HMMF arch bar is fixed with locking screws to avoid soft tissue compression as the screw is tightened and for maintaining space between the undersurface of the screw hole of the bar and the mucosa. We found that if this space is not carefully maintained during application of the device, greater soft tissue irritation and overgrowth will result. Therefore, placement position and technique have a major influence on soft tissue outcomes. Lack of attention to screw position in relation to the mucogingival junction, as well as to tissue contact and compression during screw tightening, will likely result in a higher incidence of soft tissue overgrowth. Figures 1 and 2 demonstrate soft tissue overgrowth and irritation occurring as a result of poor positioning and screw tightening during HMMF device placement.

Placement of the HMMF device typically requires many more fixation screws compared with simple MMF screw fixation. The average number of fixation screws placed in our HMMF group was 11 compared with 6 in the MMF screw group. This translated to longer placement time for HMMF, which may result in higher overall cost. Soft tissue overgrowth and the use of more screws in the HMMF system also increase the time required to remove the device.

CONCLUSIONS

The HMMF device has been used to successfully treat uncomplicated mandibular fractures. Our study demonstrated the advantages and disadvantages of the HMMF

system. The lower rate of loosening of the HMMF device during the postoperative period indicates its clear advantage over MMF screws in terms of both fracture stabilization and healing. This system also reduces the need for additional procedures to remedy loose fixation. The disadvantages of the HMMF system compared with MMF screw fixation are the higher incidence of adverse soft tissue response (overgrowth, edema, and erythema) seen in patients receiving HMMF and the fact that placement of the HMMF appliance takes more time compared with MMF screw fixation. However, adverse soft tissue results can be minimized by positioning the fixation screws in the attached mucosa and using the locking screw and spacer to prevent soft tissue contact and compression during screw tightening.

This study had some limitations because of the small number of cases included, so a future study with a higher number of patients would be desirable.

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