

# **A Novel Technology for Maxillomandibular Fixation: Universal SMARTLock Hybrid MMF**

## **INTRODUCTION**

Maxillomandibular Fixation (MMF) is a critical step in the management of facial trauma and reconstruction. This is done to ensure the interrelationship of surfaces of dental occlusion, which is necessary in the reduction of traumatic or surgically induced fragments of the mandible and maxilla. MMF is used both intraoperatively to aid in Open Reduction Internal Fixation (ORIF) or in the conservative post-operative management of closed reduction of fractures. Currently, the most widely applied technique for MMF is the use of Erich Arch Bars (EABs). While considered the “gold standard” in the treatment of facial trauma, the application comes with significant drawbacks as presented in the literature.

First, application times associated with the placement of EABs have been reported to take over 90 minutes (1, 2). This is a significant time spend for the surgeon and hospital that presents an opportunity for reduction. Not only is the application of EABs a time consuming process, but the secondary procedures in the operating room associated with removal also present a non-reimbursable cost to the facility.

Next, the risk of disease transmission via blood-borne pathogens through wire sticks is also significant (3). The rate of wire sticks due to the placement of EABs in craniofacial trauma is listed between 23-27% while the removal process is also associated with the potential to put the clinician at risk (3, 4). Aside from the actual wire sticks, the risk of glove tears related to sharps involved in EAB placement during

oral and maxillofacial surgery has been reported at 54%, which increases the potential for cross-contamination to health care workers with solid sharps (5, 6).

Also, complications with dentition or soft-tissue may arise due to the interdental wiring of EABs. Post-operative fixation with EABs has been associated with aspects of decreased oral health such plaque, gingival damage, and general pain and discomfort for the patient (1, 4).

Finally, the use of EABs lacks versatility as it is not a viable option for the edentulous patient (7). An alternative technique such as the use of MMF screws is a commonly used option. While providing benefits of speed, safety, and versatility, common drawbacks related to MMF screws include soft-tissue overgrowth of the screw heads which can compromise the interface with wire loops or elastics and a high rate of screw loosening or displacement over time which can compromise the stability of the maxillomandibular closure (8, 9, 10).

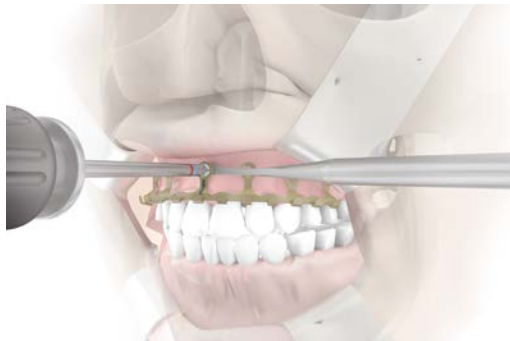
## **SYSTEM OVERVIEW**

The Universal SMARTLock Hybrid MMF System combines the technique concepts of both EABs and MMF screws to ensure dental occlusion. The system contains a 9-hole titanium MMF plate, 6mm and 8mm self-drilling 2.0 titanium locking screws, and instrumentation dedicated to the bending, cutting, and placement of the construct.

The system is FDA 510k approved (#K122313) and indicated for the treatment of mandibular and maxillary fractures in adults and adolescents (12+ years old) in whom permanent teeth have erupted. It is intended to be used for temporary stabilization of maxillary and mandibular fractures in order to maintain proper occlusion during fracture healing. The Universal SMARTLock Hybrid MMF System also eliminates the need for interdental wiring and offers versatile placement options for a number of craniofacial surgical applications.



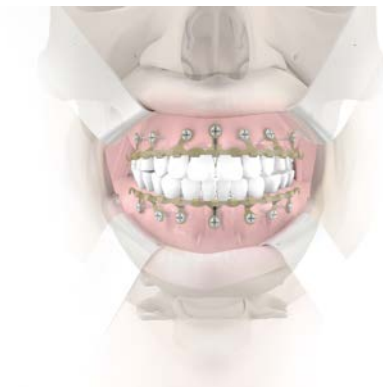
**Figure 1.** Plate sizing utilizing the plate cutter



**Figure 2.** Insertion of the first screw utilizing the plate spacer



**Figure 3.** Screw hole manipulation utilizing the plate bender



**Figure 4.** Universal SMARTLock Hybrid MMF construct

## **EARLY PRODUCT SURVEILLANCE (11)**

User feedback of the system was recorded from the first 33 cases with Oral Surgery, Plastic Surgery, and Otolaryngology Departments at 25 facilities across the United States and Germany. The median placement time for the system was identified as 16 minutes and 11 seconds (IQR of 15:00 to 21:14). Ninety four percent of respondents considered the Hybrid MMF construct to be as strong or stronger as their traditional MMF technique and were satisfied or very satisfied with the overall use and function of the plates and screws. Eighty eight percent of users were satisfied or very satisfied with the ease of screw insertion, 97% percent of respondents were satisfied or very satisfied with the ease of plate contouring, while 100% were satisfied or very satisfied with the ease of plate cutting. Finally, 94% of the surgeon replies stated the technique was either quicker or much quicker in regards to the speed of fixation compared to their normally used technique.

In a general survey of the initial users, the potential benefits of the system include:

1. Speed of placement
2. Construct strength
3. User safety and/or the avoidance of wire sticks
4. Ease of application
5. No or less wires needed to produce maxillomandibular fixation
6. Versatility for use in maxillomandibular fixation applications
7. An alternative technique of maxillomandibular fixation for the inexperienced surgeon



**Figure 5.** Intra-operative application of SMARTLock Hybrid MMF construct



**Figure 6.** Post-operative panoramic x-ray of SMARTLock Hybrid MMF

## **COST ANALYSIS**

In a challenging economic time throughout the health care environment, cost savings strategies can be implemented without compromising the quality of care to the patient. Implantable medical devices that are fast and efficient to use present an opportunity to decrease procedure time for the surgeon/staff as well as the subsequent operating room (OR) time for the institution. The Universal SMARTLock Hybrid MMF System is designed to offer a safe and effective treatment in the management of maxillofacial trauma that potentially presents such a cost saving strategy.

Based on the initial EPS case data, placement of the SMARTLock Hybrid MMF System takes place in roughly 16 minutes. Given published reports of an average of 90 minutes for the alternative technique (Erich Arch Bars) and an average OR cost of \$62/min in the United States (12), the time savings to the hospital can consist of 74 minutes and an overall cost savings of roughly \$4588 per case involving maxillomandibular fixation.

## **SAFETY ANALYSIS**

The risk of sharps injuries is a current epidemic in the health care environment, which creates a huge economic burden to the system. The Centers for Disease Control has reported an annual rising of these events with the risk being higher for surgeons compared to other health care workers (3). The injuries can also be associated with bloodborne infections such as HIV, Hepatitis B (HBV), and Hepatitis C (HCV) (3). The financial costs associated per sharps injury was reported as high as \$672 per event (13). These costs were associated to hospital visits, lab charges for testing, and treatment (13). It did not include other cost burdens such as missed time from work or the psychological burden on the subject (13).

The risk of such disease transmission has been shown to be higher for oral and maxillofacial surgery where the seroprevalence of HCV in oral surgeons is reported at almost 10-fold higher than other surgical workers (3). A reason for the high incidence in oral surgery has to do with the circumstance and emergent nature of their case volume; notably, the standard

utilization of MMF techniques in the management and care of facial trauma (3). The application of EABs consists of extended time using sharps via interdental wiring and other instrumentation. In this setting, the reported rate of sharps injury is listed between 23-27% of procedures (3, 4).

The Universal SMARTLock Hybrid MMF system removes the need for interdental wiring and subsequent added risk of sharps injuries in the management and care of facial trauma. Therefore, this novel technology offers the potential benefit to not only the surgeon user, but also the health care institution that is responsible for the safety of their employees.

## **DISCUSSION**

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The Universal SMARTLock Hybrid MMF System is a novel and impactful technology in the field of maxillofacial surgery. In our experience through the first 15 cases with the system, this product provides an efficient surgical alternative to current MMF techniques by allowing a quicker and user-friendly application.

The malleability as well as the number and spacing of the holes on the plate were considered adequate. When placed in concert with the plate bender for screw hole adjustment and the in situ plate cutter, it was very straightforward process with a minimal learning curve for use. In practice, a minimum of 3 screws were used per arch and placement tended to be in every other hole of the plate. In the event of an edentulous space, a screw was also placed superior to that position as well. A screw

was placed first in the midline of the plate and then bent laterally toward the posterior anatomy. It was also common to have a second surgeon or assistant pin the arch bar just anterior to the screw hole in order to prevent unwanted spacing or gaping within the system. Upon engagement of the screw to the bone, there were no issues with blade to screw retention or insertion.

The plate spacer is a useful tool to engage the locking mechanism of the plate and screw construct. This helped to avoid the creation of torque on the plate or additional pressure on the adjacent soft tissue. Given the lack of requirement for interdental wiring, the interdental gingiva, papilla, and periodontal health were unaffected throughout these procedures in which the SMARTLock Hybrid MMF was used. The strength and rigidity of the construct was perceived as being similar to arch bars. And unlike the use of MMF screws which tend to loosen or completely disengage over time, the SMARTLock Hybrid MMF system is designed to have multiple fixation vectors joined in a locking plate construct. Subsequently, MMF screw loosening can compromise the potential length of proper MMF for the patient. Another benefit compared to MMF screws is the post-operative patient compliance. It is common for soft tissue to engulf standard MMF screws that are placed higher in the vestibule. The SMARTLock Hybrid MMF is placed along the mucogingival junction, which helps reduce this phenomenon. Given this placement, the arches lie appropriately over the dentition to allow access for easier placement of guiding elastics to the construct.

The potential safety benefit of the Hybrid MMF System is a significant advantage to the user as well. The system offers a safe and stable alternative to traditional arch bar

placement where wire sticks and/or glove tears are always a paramount concern. The time savings in this user's hands is also significant compared to alternative techniques; namely, the placement of arch bars. While initial cases took up to 20 minutes for placement with the Universal Hybrid MMF System, subsequent cases after the initial learning curve of the product resulted in placement times of as low as 10 minutes.

The versatility of the system also provides an advantage to the clinician. It has been used for intraoperative MMF as well as for a period as long as 6 weeks post-operatively with great surgeon satisfaction during traumatic cases. Both wires and guiding elastics were easily placed in a variety of vectors given the need and situation, providing vast potential for MMF in craniomaxillofacial surgery.

In summary, the Universal SMARTLock Hybrid MMF system is a novel concept that provides a valuable tool in the arsenal of the maxillofacial surgeon. The aforementioned benefits in relation to ease of use, user safety and versatility, and advantages over the current standards of care have been an important evolution in this surgeon's practice.

## References

1. Rai A et al. Are maxillomandibular fixation screws a better option than erich arch bars in achieving maxillomandibular fixation? A randomized clinical study. *Journal of Oral and Maxillofacial Surgery*. 69: 3015, 2011.
2. Gaujac C et al. Comparative analysis of 2 techniques of double gloving protection during arch bar placement for intermaxillary fixation. *Journal of Oral and Maxillofacial Surgery*. 65: 1922, 2007.
3. Bali R et al. Incidence of patterns of needlestick injuries during intermaxillary fixation. *British Journal of Oral and Maxillofacial Surgery*. 49: 221, 2011.
4. Ayoub AF and Rowson J. Comparative assessment of two methods used for interdental immobilization. *Journal of Craniomaxillofacial Surgery*. 31: 159, 2003
5. Kuroyanagi N et al. Risk of surgical glove perforation in oral and maxillofacial surgery. *International Journal of Oral and Maxillofacial Surgery*. 41:1014, 2012.
6. Pigadas N et al. A randomized controlled trial on cross-infection control in maxillofacial trauma surgery: a comparison of intermaxillary fixation techniques. *International Journal of Oral and Maxillofacial Surgery*. 37: 716, 2008.
7. Vartanian AJ and Alvi A. Bone-screw mandible fixation: an intra-operative alternative to arch bars. *Otolaryngology Head and Neck Surgery*. 123: 718, 2000.
8. Ansari K et al. A comparison of anterior vs. posterior isolated mandible fractures treated with intermaxillary fixation screws. *Archives of Facial Plastic Surgery*. 13(4): 266, 2011.
9. Cornelius CP and Ehrenfeld M. The use of MMF screws: surgical technique, indications, contraindications, and common problems in review of the literature. *Craniomaxillofacial Trauma and Reconstruction*. 3(2): 55, 2010.
10. Hashemi HM and Parhiz A. Complications using intermaxillary fixation screws. *Journal of Oral and Maxillofacial Surgery*. 69: 1411, 2011.
11. Early Product Surveillance Report on file with Stryker Craniomaxillofacial
12. Macario. What does one minute of operating room time cost? *Journal of Clinical Anesthesia*. 22: 233, 2010.
13. Jagger J et al. Direct cost follow-up for percutaneous and mucocutaneous exposures to at-risk body fluids: Data from two hospitals. *Advances in Exposure Prevention*. 3:1, 1998.

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