



Infrequency of Tooth Root Damage with Transgingival Screws

Introducing SMARTLock Hybrid MMF

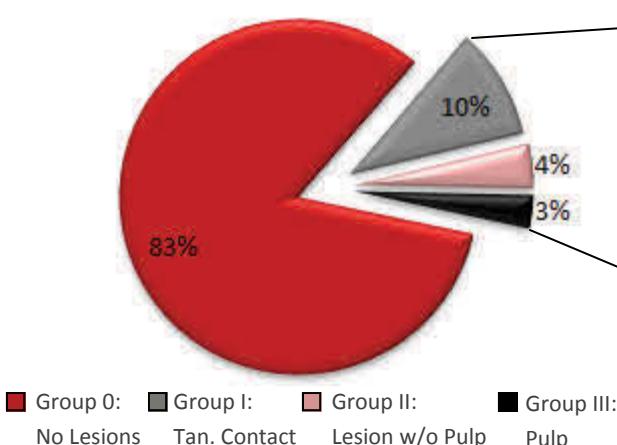
A revolutionary, patented product designed to combine the strength and rigidity of arch bars with the safety and efficiency of MMF screws. With nine potential points of fixation along the plate, posterior fixation and vector control are enhanced when compared to traditional MMF screws. The self-drilling, locking technology of the screws allows for purchase into both the bone and the plate for additional stability. The plate and screw combination omits the need for interdental wiring that is required with arch bars, and thereby reduces the chance of wire stick injuries for health care providers. It is removed under local anesthesia in the office setting, thereby eliminating non-reimbursable OR based removals.

Potential Tooth Root Damage

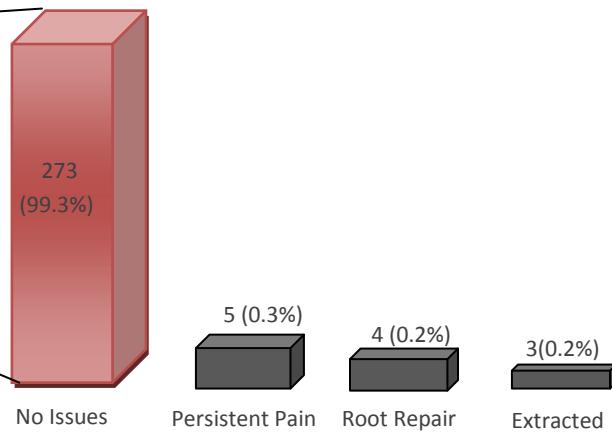
A safe and effective method of maxillomandibular fixation is necessary during surgeries related to reconstructive orthognathic and facial trauma surgery. The SMARTLock Hybrid MMF System utilizes 2.0 x 6mm and 2.0 x 8mm self drilling screws that are inserted transgingivally. One possible concern is the potential for root damage caused by the insertion of the self-drilling screws into the interradicular space. An analysis of a recent study shows that the risk of contacting a tooth root is extremely low with minimal impact on the healing process of the teeth¹. The retrospective study looked at 521 patients that received maxillomandibular fixation with transgingival osteosynthesis screws. 1663 screws were inserted and classified according to the level of contact to the dental root. Group 0 had no lesions of the dental root, where Group I had tangential contact. Group II were lesions without contact with the dental pulp, and Group III were lesions involving the dental pulp. 1378 (82.9%) screws were assigned to Group 0. Group I contained 175 (10.6%) screws. 59 (3.6%) screws were assigned to Group II and 51 (3.1%) screws to Group III. Overall, 285 teeth (17.3%) had radiologically proven lesions by the screws. Post-operative follow-ups were performed on average 10.3 months post-surgery and before the screws were removed. Overall, 5 teeth (0.3%) were persistently painful, 4 teeth (0.2%) had to be root filled and root resected, and 3 teeth (0.2%) were extracted due to apical or peridiapicular inflammation. All extracted and root filled/resected teeth were categorized into Group III¹.

A separate report shows that dental-root damage heals without any incident. Regenerated cementum, periodontal ligaments and alveolar bone were observed. Only pulpal invasion or the presence of inflammatory infiltrate caused wound healing problems². Out of the 51 screws with radiologically proven contact to the dental pulp, 3 teeth had to be extracted and 4 teeth had to be root treated. Furthermore, the study showed that dental pulp is not necessarily affected even if the screw makes contact with the pulp. Without dental pulp involvement, the defects heal without incident. Overall, only 0.7% of the evaluated screw insertion areas caused problems¹. The SMARTLock Hybrid MMF System combines the safety and efficiency of transgingival screws with the strength and rigidity of arch bars with its innovative arch bar plate and self-drilling locking screws.

Level of Contact to the Dental Root (1663 screws)



Complications With Teeth in Contact With Screws



9410-400-396 Rev. None

US Pat. 8,118,850

1. M Schulte-Geers et al. Root trauma and tooth loss through the application of pre-drilled transgingival fixation screws. Journal of Craniomaxillofacial Surgery, Volume 40, Issue 7, Pages e214-e217, 2012
2. M Hembree et al. Effects of intentional damage of the roots and surrounding structures with miniscrew implants. American Journal of Orthodontics and Dentofacial Orthopaedics, Volume 135, Issue 3, Pages 280-281, 2009

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.