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Research Article

The Effect of Intraoral Electrical High-Frequency Neuromodulation on Pain Perception Following Repair of Maxillofacial Trauma

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Introduction

Pain is a negative side effects associated with maxillofacial trauma. Fractures of the maxilla and mandible involving the dentition often require the use of intermaxillary fixation. Historically, this has been accomplished with the use of Erich arch bars and circumdental wires. The recent introduction of bone borne screw retained arch bars have led to a stronger construct for stabilization of the occlusion without reliance of a metal wire interface with the teeth. However, the use of these arch bars requires insertion of a self-drilling monocortical screw into the alveolus apical to the roots of the associated teeth and many times through unattached mucosa. The screw head is designed to sit a few millimeters above the gingival tissue in an attempt to prevent overgrowth of the soft tissue over the screw head or arch bar construct. It is common for patients to present postoperatively with gingival or mucosal irritation. This irritation can be quite painful for the patient and is usually managed with saline rinses, topical anesthetics and non-opioid analgesic. Unfortunately, in some cases, the pain requires opioid analgesic or even early removal of the arch bar appliance. Concomitant conditions such as fractured or abscessed teeth are noted during the postoperative phase while healing from the initial trauma. Many of these patients do not have access to immediate dental care or have practitioners that are hesitant to treat the acute concomitant conditions while in the initial healing phase of maxillofacial trauma.

High-frequency neuromodulation via the Dental Pain Eraser is now available as a non-invasive and nonpharmacologic solution for oral pain management for clinicians to use at chairside and for patients to use at home. Neuromodulation has been in use since the 1960s for the management of craniofacial pain and today is a standard of care in spinal implant management of neurological disorders. The introduction of the Dental Pain Eraser is applying this sound and validated technology to the management of the neural response in the oral cavity.

This device is the world's first pen-shaped, portable electronic dental anesthesia solution that uses patented Advanced PulseWave™ neuromodulation technology to send gentle, subsensory electric pulses to calm the nerves in the mouth and block both soft and hard tissue pain. When the Dental Pain Eraser's metal prongs are applied to a sensitive tooth or a sensitive gum tissue area, the pain will begin disappearing in seconds, with pain relief lasting for up to 48 hours. Overall, the Dental Pain Eraser has proven to alleviate pain for a broad spectrum of dental treatments and oral disorders to target wherever the patient feels pain, including hygiene/periodontics, extractions, surgery, implants, orthodontics as well as canker sores, TMJ/TMD, and sensitivity.

The purpose of this study is to evaluate the response of intraoral transcutaneous electrical nerve stimulation for the use of postoperative mucosal or tooth pain following repair of maxillofacial trauma. The authors have hypothesized that the patient's pain perception will decrease after use of the Dental Pain Eraser. The specific aims of the study were to 1) measure and compare the pain scale upon initial presentation of the postoperative problem to the pain scale after office use of the Dental Pain Eraser; 2) measure the use of additional opioid analgesics required to provide comfort after use of the Dental Pain Eraser.

Materials and Methods

To address the research purpose, the investigator designed and implemented a respective cohort study. The study sample was composed of patients who presented to TriStar Skyline Medical Center in Nashville Tennessee. The study population comprised patients who underwent repair of maxillofacial trauma and presented postoperatively complaining of severe mucosal or tooth pain following placement of bone borne arch bars. Subjects were excluded if they were pregnant, had a history of seizures, cardiac arrhythmias or pacemaker treatment.

The portable, electrical neuromodulation device used in this study, the Dental Pain Eraser, was designed for one button operation, with one output for a safe and stable range of stimulation. It delivers a reversible, non-invasive, biphasic, symmetrical pulse with a maximal alternating current of 10 kHz 10 mA, in accordance with the amplitudes and waveforms tested in various other dental applications. The device was applied to each patient for 2 minutes along the associated area of mucosal pain. The patient was asked to rate the intensity of pain after utilizing whole numbers from 0-10. The patient was then instructed to use non-opioid, over-the-counter pain medication as needed.

Results

Patient 1, 24-year-old male treated for repair of bilateral mandible fracture back in August of 2023, did not return for removal of his arch bars presenting in April of 2024 complaining of gingival pain in the upper right premolar region, examination showed patient had vertical fracture of tooth 5. His pain scale was 9/10, he was treated with the Dental Pain Eraser for 2 minutes along the facial aspect and 2 minutes on the palatal aspect, pain scale was 1/10, patient did not require any postoperative narcotics, patient was seen 72 hours later for arch bar removal and removal of tooth 5 (Figures 1-3).

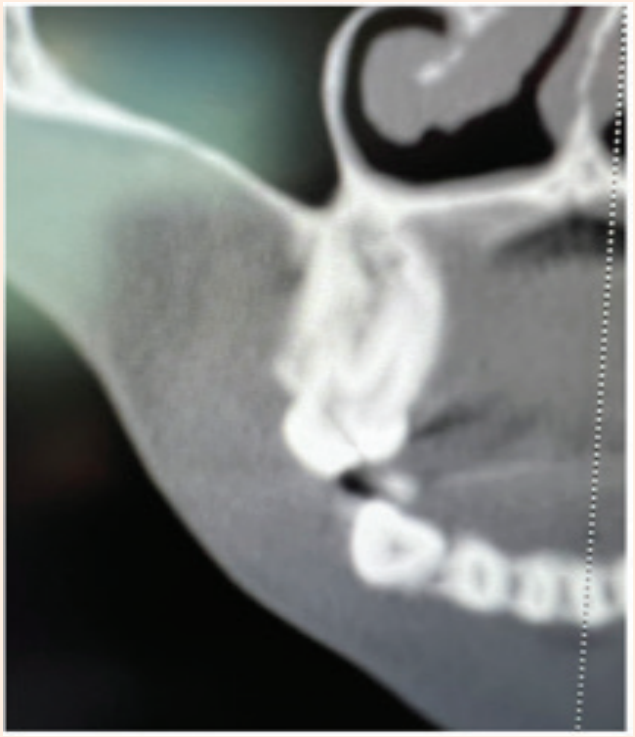

Figure 1: CT showing Vertical Fracture Tooth #5.

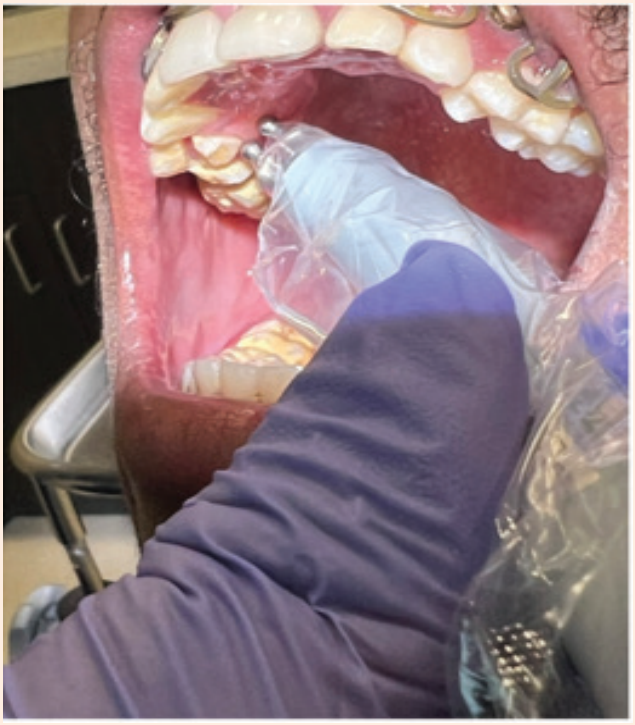

Figure 2: Application of Dental Pain Eraser along the palatal aspect of fractured tooth #5.

Figure 3: Application of Dental Pain Eraser along the palatal aspect of fractured tooth #5.

Patient 2, 27-year-old male treated for anterior maxillary and mandibular alveolar fractures requiring closed reduction and intermaxillary fixation presents for irritation and ulceration of the lower lip in the area of a vestibular laceration that was repaired, his pain scale was 8/10, he was treated with Dental Pain Eraser for 2 minutes along the lower lip mucosa in the area of the ulcerations for 2 minutes, pain scale was 1/10 patient did not require any postoperative narcotics, the irritating wire was repositioned, the patient underwent arch bar removal 4 weeks later.

Patient 3, 28-year-old male treated for left mandibular fracture presenting with gingival pain in the area of tooth number 22 due to the mucosal tissue starting to grow over the arch bar appliance, pain scale is 8/10, patient was treated with Dental Pain Eraser for 2 minutes along the mucosal tissue. His pain scale dropped to 2/10, patient did not require postoperative narcotics, pain relief lasted for 72 hours, residual discomfort was treated with non-opioid over-the-counter analgesic, until the arch bars were removed 2 weeks later Figure 4.

Figure 4: Application of Dental Pain Eraser along the facial aspect of wave plate arch bar.

Patient 4, 67-year-old male treated for mandible fracture presenting with gingival pain in anterior mandibular vestibule near the fixation screws of the arch bar, pain scale is 7/10, patient was treated with Dental Pain Eraser for 2 minutes along the mucosal tissue pain scale dropped to 2/10, patient did not require postoperative narcotics, pain relief lasted for 24 hours, arch bars were removed the following day.

Patient 5, is a 29-year-old female treated for mandibular fracture presenting with gingival pain along with poor dentition near the fixation screws of the arch bar, pain scale is 8/10, patient was treated with Dental Pain Eraser for 2 minutes along the mucosal tissue. The pain scale dropped to 2/10, patient did not require postoperative narcotics, pain relief lasted for 72 hours, residual discomfort was treated with non-opioid over-the-counter analgesic, until the arch bars were removed 1 week later.

Discussion

Clinical studies have assessed the positive effects of TENS treatment on adult and pediatric patients. It has been shown that children prefer TENS treatment over the use of local anesthesia [1-3]. It was noted that there was no difference in pain reduction between TENS and 2% lidocaine during extraction, cavity preparation or pulpal therapy of deciduous teeth in 180 pediatric patients. Adult patients reported a significant reduction in periodontal pain after 24 and 36 hours during orthodontic separator placement.

Biomedical engineering research on neuromodulation devices such as the Dental Pain Eraser, has tested specific amplitudes, frequencies and delivery types with the goal of blocking nerve depolarization, therefore reducing both the initial neuropeptide response and feedback loop. Neuromodulation for craniofacial pain is well established. It has been successfully used for treatment of cluster headaches, occipital and trigeminal neuralgia. Pain reduction and cessation of opioid medication use has been shown with a 10-kHz stimulation without compromising tactile sensitivity or motor activity [4].

Neuromodulation with the Dental Pain Eraser has been validated to significantly reduce pain in the oral cavity, with broad application for many oral pain issues. Case in point, orthodontic discomfort is a primary concern for patients and the Dental Pain Eraser was shown to improve comfort for wire adjustments, detailing or insertion of fixed appliances or aligners [5]. In a recent blinded university study [6] conducted on pre-needle application in the pediatric population, neuromodulation significantly reduced pain and anxiety versus other modalities like Biolase laser and placebo.

This retrospective pilot study showed that the Dental Pain Eraser, a portable neuromodulation unit is effective in reducing dental and intraoral mucosal pain following the repair of maxillofacial trauma. The five patients presented with an average of 8/10 pain scale and after 2 minutes of treatment their pain was less than 2/10. None of the patients required narcotic opioid pain medication following the treatment with the Dental Pain Eraser.

Conclusion

The result of this pilot study shows that the high-frequency neuromodulation produced by the Dental Pain Eraser reduced mucosal pain following bone borne arch bar placement for the treatment of maxillofacial trauma and eliminated the use of narcotic pain medication in the postoperative period when patients present for mucosal pain and irritation from the appliance or from a fractured tooth. Future investigations may include post-surgical pain, ulcerations from pathologic conditions and reduction of pain from acute injury prior to repair.

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