Viora's Proprietary Multi-frequency RF Solution for TMD-related Myofascial Pain

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INTRODUCTION

The Temporomandibular Disorder (TMD) consists of several clinical problems that involve the masticatory muscles, the temporomandibular joint (TMJ) and the related structures and as such it is considered a musculo-skeletal disorder. TMD is also the main cause of pain of non-dental origin in the oro-facial region including head, face and related zones [1]. Hence, due to the great complexity of this condition it presents a great challenge for health professionals. This complexity is evident in various aspects, including accurate diagnostic methods, treatment, associated comorbidities and the socioeconomic impact they entail. TMD cases are even more complex when the pathology becomes chronic or persistent [2].

In addition to surgical procedures [3] and trigger-point needling (dry or wet) analgesic effect [4] physical therapy utilizing thermal packs, vapocoolants, and transcutaneous electrical nerve stimulation have been widely used for TMD patients [5]. A recent national survey in the United Kingdom [6] showed that 72% of respondents considered physical therapy to be an effective treatment option for TMD, with jaw exercise (79%), ultrasound (52%), manual therapy (48%), acupuncture (41%), and laser therapy (15%) as the most effective modalities for managing TMD.

According to the World Confederation for Physical Therapy, physical therapy is a healthcare profession aimed at reducing pain and it is the most important discipline to restore and improve movement that has been threatened by injuries, disorders, aging, or environmental factors [7], making the "pain relief" an important pillar in the management of patients with TMD [8].

Recently, both vacuum-assisted and vacuum-free radiofrequency (RF)-based devices have been reported to be used in pain relief management in different body areas [9, 10, 11]. The RF heating of deep tissue helps to reduce edema (swelling), increase blood flow, and relieve pain and muscle spasm. This accelerates the inflammatory processes and mobilizes contracted fibrous tissue. The Vacuum-assisted RF devices in addition to RF deep heating provide a massage effect that affects muscle tone and causes general relaxation. The increased blood flow provides a washout of metabolites and increased muscle temperature makes the sore muscles more compliant [12]. In addition, massage stimulates cutaneous receptors [13], potentially causing local lateral inhibition of pain feedback in the spinal cord. The stretch of and force applied to the muscle fibers from the different massage techniques also activate Ia afferents and Golgi tendon organs [14]. The activation of these larger rapidly conducting nerve fibers could partially block the smaller, slower conducting nerve fibers from detecting pain [15]. Thus, the gate control theory [16] may partly explain the acute reduction in soreness from of the vacuum treatment. In addition, massage also increases lymphatic drainage and squeezes out metabolic waste products and pain mediators such as histamines and bradykinins [13]. In addition, the vacuum-assisted lymphatic drainage promotes blood flow from superficial veins into deep veins. The improved blood flow and prevention of venous stasis reduce edema and helps compensate for impaired venous return.

The aim of this study was to assess the feasibility for Viora's Proprietary CORE™ Technology based on vacuum-assisted multi-Frequency RF energy for pain relief of TMD patients.

MATERIALS AND METHODS

The study was conducted from March 2018 to July 2019 at two dental medical centers in USA, one in Colorado Springs, Colorado and the other in Houston, Texas. The study was performed on 30 patients (55% female and 45% male), age range 23-73 years (average 40 years) with self-reported TMJ-related pain. The inclusion criteria were: 1 ambulatory, age greater than 18; 2. have a clinical diagnosis of temporomandibular joint related pain. The exclusion criteria were related to radiofrequency and vacuum-assisted technology: 1. No systemic/ autoimmune/ endocrine disorders; 2. no pacemaker, or other conditions that could be affected by radiofrequency discharge beams; 3. have no prosthetic joint replacement or placement of any metallic surgical device in the treated area; 4. no interarticular steroid injection in the past three months; 5. Not currently taking any constant dose of nonsteroidal anti-inflammatory or narcotic analgesic drugs; and 6. Be engaged in no other therapeutic modality during the period of the study.

PATIENT ASSESMENT

The patients' assessment included information aimed to assess the pain source in the TMJ area:

1. Patient Medical History
2. Patient Primary Complaint
3. History of trauma: ***Yes / No***
4. History of clicking/popping: ***Yes / No***
5. History of pain from clenching: ***Yes / No***
6. History of pain from opening: ***Yes / No***
7. History of pain from chewing: ***Yes / No***

In addition, the patients' assessment included "Objective Findings":

1. Assessment/Diagnosis: Myalgia/ Myositis/ Myospasm/ Retrodiscitis
2. Selection of areas sore to palpation or movement: Masseter/ Temporalis/ Medial Pterygoid/ Sternocleidomastoid/ Trapezius/ Lateral Pterygoid / TMJ **(Figure 1)**
3. Deviation while opening Left / Right
4. Indication of popping or crepitus: Opening/ Closing/ Both Opening & Closing / Left / Right / Both Sides
5. Occlusal classification: I/ II/ III/ Deep bite/ Open bite/ Cross bite/ Bruxism/Attrition
6. Pre- and post-operative inter-incisal edge distance in millimeters **(Figure 2)**
7. Pre- and post-operative "Pain Assessment" on 0-10 Visual Analogue Scale (VAS) during mouth opening, clenched & seated condyle, excursive movements

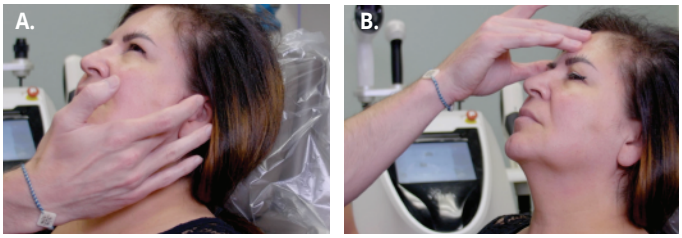

Figure 1 Patient assessment technique (palpation of muscles of mastication and TMJ)

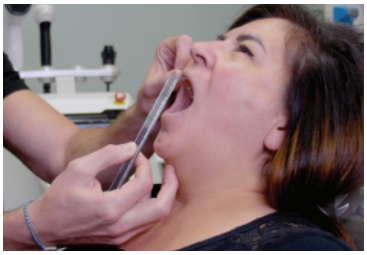

Figure 2
Patient assessment of pre- and post-operative interincisal edge distance

TREATMENT PROTOCOL

The treatment was performed with a V-Series device (Viora Inc, New York, NY, USA) with vacuum-assisted multi-polar RF handpiece, the V-FORM handpiece over the facial and neck areas **(Figure 3)** and bi-polar RF contact cooling handpiece, the V-ST over the frontalis or temporalis areas (where relevant, **Figure 4**). Both V-FORM and V-ST handpieces are based on Viora's proprietary CORE™ Technology which enables practitioners to work with 3 operational modes (Mode I, II and III) based on three RF frequencies, 0.8, 1.7 and 2.45 MHz, respectively, and an additional operational mode IV which includes all three RF frequencies together [17].

Figure 3
TMD treatment with V-FORM handpiece

Figure 4
TMD treatment with V-ST handpiece

The patients received RF-based treatment with target temperature between 39-42° C held for 6 minutes with the V-FORM handpiece per each involved muscle and / or joint) using Mode I (RF frequency of 0.8 MHz). While using the V-ST handpiece, the treatment was performed by covering each involved area with 6 passes (frontalis or temporalis).

Patients with acute pain received 1-2 treatments with 4 days intervals while patients with chronic pain received up to 4 treatments.

RESULTS

Among 30 treated patients, 50% diagnosed with Myalgia & Retrodiscitis, 38% with Myalgia and 13% with Myalgia & Myositis & Myospasm.

80% of patients were classified as Class 1 on "Occlusal classification", 13% as Bruxism/Attrition and 7% as Class 2.

55% of these patients reported on TMJ related trauma, 55% reported on history of clicking and popping, 91% reported on history of pain on clenching, 91% on history on pain on opening and 73% reported on history of pain from chewing.

64% of the recruited patients were with acute pain, of which 71% received a single session and the rest, 29%, two sessions. The remaining 36% of the patients diagnosed with chronic pain, of which half received three sessions and another half, four sessions.

The initial pain level of the patients ranged from 1 to 9, with an average pain level of 6.4 on the VAS scale, which reduced in average by ***33%*** after a single treatment to an average pain level of 4.3 on the VAS scale. The pain level reduction after each treatment ranged from 0 (in 12%) up to 6 points change with an average 2 points change after single treatment. However, ***patients that received 2 treatments reported pain reduction by an average 3.6 points,*** compared to their initial pain level evaluation and ***patients that received more than 3 treatments reported an average pain reduction by 4.6 points.***

The inter-incisal edge distance increased from 0 mm (in 23%) up to 24 mm, after single treatment, with an ***average edge distance increase of 9.1 mm.*** Patients that received ***more than 2 sessions, showed an increase in the inter-incisal edge distance from 7 up to 30 mm, with an average increase of 14.2 mm.***

DISCUSSION AND CONCLUSION

In this first reported vacuum-assisted RF based treatment for TMD, we found 100% treatment response. All recruited patients showed at least one type of improvement, either in the pain level reduction, either in the inter-incisal edge distance increase, or both. The pain reduction was gradual and accumulative with the time, with an average 2 point reduction after first treatment, 3.6 points reduction after second treatment and 4.6 points after third and fourth treatments, contributing to a total 52% improvement in pain sensation.

The 23% of patients that did not show any clinical outcomes in the inter-incisal edge distance after the first treatment did show an increase in the following treatment by an average increase of 10 mm.

Although TMD is a multifactorial pathology, regardless of its source, the aim of physiotherapy in the treatment of TMD is to relieve pain, reduce muscle spasm, improve joint mobility and restore functions. The derived results from this pilot study indicate that vacuum-assisted bi-polar RF treatment can be considered as part of the physiotherapy of the TMD patients.

Viora's TMD treatments aimed mainly at relief of the patient's function and quality of life due to impaired mobility, joint sounds and head & neck pain. Moreover, since the treatment provides an immediate relief in pain level and improvement in mouth opening, the non-invasive, pain-free Viora treatment may provide the dental practitioner an additional tool to perform general dental procedures that are not related to TMD since the patient can tolerate the following dental procedure.

Although physiotherapy may be used as the sole treatment, it may be combined with occlusal splint therapy and pharmacological management. The combination approach has been reported to result in more rapid symptom relief, decreased treatment time and overall superior therapeutic outcome [18]. With correct tendency adapting multimodal and multidisciplinary approach [2] to improve clinical outcomes of TMD treatment, Viora's CORE™ Technology integration can play an important role in the biopsychosocial model where active and adaptive type treatments are fundamental.

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