Combined use of Armourbite and MLS® in temporomandibular disorders, craniofacial pain and neuromuscular dysbalance.

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ABSTRACT

Temporomandibular disorder (TMD) is a nonspecific diagnosis that includes a group of conditions involving the muscles of mastication and/or the temporomandibular joint (TMJ). TMD comprises a wide range of clinical symptoms, such as headache, facial and jaw pain, neck pain or movement limitation, etc. and severely impact on patient quality of life.

The incidence of the TMD in the general population is widespread and many people suffer to a greater or lesser degree from these disorders.

Current conservative gold standard treatment is represented by occlusal splints, but recently other therapeutic approaches are being used, among which laser therapy is giving interesting results.

The aim of this study is to report on four cases in which the combination of MLS® laser treatment and the Armourbite splint was used to relieve TMD symptoms. In order to provide some early comments on the comparison with the results obtained with splint alone, 2 patients with similar characteristics and treated only with Armourbite have been included in this report as well.

In the studied patients, the MLS® laser therapy together with Armourbite splint represented an effective and fast treatment for TMD and in most cases the treatment was able of reestablishing the neuromuscular functions. Clinical studies are needed to confirm these preliminary observations and determine the most appropriate treatment parameters.

INTRODUCTION

The temporomandibular disorders (TMD) represent a range of clinical disorders involving the masticatory muscles, the temporomandibular joint and associated structures. Symptoms associated to TMD include: headaches; facial pain; jaw pain; sore, chipped, broken, or worn teeth, clicking or popping in the jaw, and limited jaw movement. In addition to pain symptoms, signs are frequently found joint sounds such as clicks or crackle and limitation or deviation of mandibular opening. Some patients may experience all of the reported symptoms, while other will report only a few of those problems. The area of the face where the temporomandibular joint (TMJ) is located is a complex of bones, including the teeth, muscles, and nerves. Because of this, TMJ conditions affect many areas of the body, from the top of the head in migraine-like headaches to numbness or tingling in the arms and pain in the neck or shoulders.

Data released by the American Academy of Orofacial Pain (AAOP) estimate that 75% of the population in the United States has presented signs and/or symptoms of TMD. These conditions are present in the very young population, increase with age to eventually decrease after age 50. The highest prevalence in the population is between 20 and 40 years of age. Globally, epidemiological studies have shown that approximately 10% of the population is affected, and 30-year-old women are the population segment most likely to be affected by TMD [1, 2].

It is known widely in the literature that, in most of the cases, TMD are due to a multifactorial etiology and the competition of multiple risk factors. The multifactorial etiology of the disorder requires a multidisciplinary treatment approach with a team that is responsible for the management of patients with problems of the stomatognathic system. Among the factors that can lead to TMD, the main one are trauma (i.e. car accident, sport injury), improper occlusion, joint inflammation, grinding or clenching of teeth, neuromuscular imbalance, diseases such as rheumatoid arthritis or degenerative osteoarthritis and sleep disorders.

The variety of disorders collected under the name of TMD makes diagnosis and treatment challenging. An accurate diagnosis is critical for successful treatment. Real-time objective physiologic data such as electromyography represent a useful
The therapy of the TMD is essentially based on conservative approaches and reversible, including counseling and the realization of occlusal splints constitute the reference standard, together with any drug therapy support. Splints are designed to fit over the teeth. They prevent the upper and lower teeth from coming together, based on the fact that the role of occlusion in the etiology of TMD has been widely documented in the dental literature [3].

Armourbite is a splint designed with the aim of creating an optimal spacing of the jaw by placing space between molars, preventing teeth from clenching. The specific design of Armourbite allows rotation of the lower jaw down and forward to help relieve pressure on the TMJ.

Recently, some studies have been addressing the use of alternative treatments, such as transcutaneous electrical nerve stimulation (TENS), ultrasound, trigger point injections and acupuncture. Laser therapy has also been considered for the treatment of TMD [4-6], based on the fact that its main effects, such as healing promotion, analgesic and anti-inflammatory effects, can play an important role in reducing signs and symptoms associated with TMD.

Given the multifactorial origin of TMD, the ideal treatment should include synergic strategies, targeting the different aspects of the condition in order to provide the patient with the most successful treatment.

In this light, the objective of this study was to report the preliminary experience on a random sample of 4 patients in which the combination of MLS® laser treatment and the Armourbite splint was used to relief TMD symptoms. In order to provide some early comments on the comparison with the results obtained with splint alone, 2 patients with similar characteristics and treated only with Armourbite have been included in this report.

In order to evaluate appropriately the patient neuromuscular dysbalance, the electromyograph BTS TMJOINT was used.

**MATERIALS AND METHODS**

A group of patients coming from Dr Janke’s and Dr Rosswag’s practice have considered in this report. The material and methods applied had the following common aspects.

The inclusion criteria were: age ≥18 and <75 years, presence of a retained TMJ opening, presence of parafunctions (clenching and bruxism), cervical spondylosis, neuromuscular dysbalance of the elevator muscles of the jaw (masseter and temporalis) evaluated with BTS TMJoint (BTS Bioengineering, Italy).

Patients wearing pacemakers, pregnant, subjects with severe comorbidities (such as hypertension, diabetes mellitus, cardiac rhythm), subjects with severe respiratory disease (COPD), outcomes of major traumatic diseases, subjects with chronic encephalopathy and cerebral disorders (i.e. Parkinson’s disease, epilepsy) and severe postural conditions (such as congenital torticollis, asymmetry of the lower limbs) were excluded from the study.

At the first visit, clinical evaluation was performed, myofascial pain type was indicated (i.e. masseter/temporal muscle hypertonia, cervicalgia, trapezius muscle hypertonia, sternocleidomastoid muscle hypertonia, TMJ pain or others), trigger points and irradiation areas were recorded by the dentist and the presence of edema, cervical arthrosis, muscle contracture, wound, trigger points, bruxism/clenching and/or other specific conditions was reported. Additionally, the patient was asked to estimate the number of pain events during the day and during the week.

At the same visit, electromyograph (BTS TMJoint, BTS Bioengineering, Italy) was used to provide a gnathological examination of dental occlusion by recording electromyographic activity of the masseters and temporalis (left and right).

At each therapy session, the following assessments were performed:

- pain evaluation using the VAS scale (pre and post therapy)
- muscle contracture
- cervical spine range of motion (left and right)

Additionally, reactions, side effects and further notes were recorded.

The Armourbite group patients were treated with splint only (Armourbite Mouthpiece, BiteTech, UK).

The Armourbite and MLS® group received MLS® Laser Therapy (Mphi D, ASA S.r.l., Italy). MLS® laser is a class IV NIR laser with two synchronized sources (laser diodes). These emit at different wavelengths, peak power and emission mode. The first one is a pulsed 905 nm laser diode with 25 W peak optical power. The pulse frequency may be varied in the range 1-2000 Hz, thus varying the average power delivered to the tissue. The second laser diode (808 nm) may operate in continuous (power 1.1 W) or pulsed mode (repetition rate 1-2000 Hz, 550mW mean optical power, with a 50% duty ratio independently of the repetition rate). The two laser beams are emitted synchronously and the propagation axes are coincident. The treatment was carried out by treating the patient with a holistic approach consisting in the treatment of muscle contracture and trigger points. The following operating parameters were applied according to the static and dynamic protocol. Static protocol for TMJ treatment includes treatment of the condyle and masseter area (Energy delivered= 47J) and also of trigger points on the sternocleidomastoid (SCM), if present (Energy delivered=3J...
During dynamic protocols, MLS® treatment over paravertebral area from C3 to C7 bilaterally and the upper trapezius (Energy delivered= 41J). If present, trigger points on the upper trapezius area and on SCM area are treated (Energy delivered=3J for point).

During dynamic protocols, MLS® treatment is performed in scanning mode on areas where muscles are in motion. TMJ treatment is performed during depression/elevation movements and mandibular lateral excursion. Cervical area treatment involves the application during cervico-cranial rotation, and extension/ flexion and lateral flexion movements. For dynamic trigger point treatment, the patient has to actively extend the belly of the muscle, with the help on the operator, and in this condition the supraspinatus muscle trigger points must be specifically treated.

RESULTS
Six individuals have been included in this case report. Two patients received Armourbite treatment and four patients received Armourbite together with MLS® treatment.

Case #1 - Patient treated with Armourbite
Female patient, 57 years old presenting headache and back, neck and shoulder pain and reported sleeping problems. At clinical evaluation, hip height and leg length differences were observed. Myofascial painful points were located at the masseter/temporal and trapezius muscles. Muscle contracture, trigger points and bruxism/clenching were also present. The patient reported more than 10 hours/day of pain events and a weekly occurrence of pain events of 5 or more days. The patient received Armourbite + MLS® treatment and was followed up for 3 months. The treatment involved a first phase with the use of Armourbite Mouthguard alone, the second phase involved the MLS® treatment which comprised 5 sessions over 3 months: from 1 to 4, using the static program, while session #5 was carried out with the dynamic protocol. The static and dynamic programs involve the use of the following parameters:
- Frequency:350 Hz; Intensity: 50%; Time: 3’;
- Frequency:700 Hz; Intensity: 50%; Time: 2’ 30’’;
- For Trigger points: Frequency:10 Hz; Intensity: 25%; Time:25’’;

Energy dose for each trigger point is 1 J/cm². Energy dose for each area for static program is in the range 0.8 - 2,5 J/cm². Energy dose for each area for dynamic program is <0.5 J/cm².

Energy for Health [17]

Case #2 – Patient treated with Armourbite
Male patient, 36 years old presenting neck problems. Myofascial painful points were located at the trapezius muscle, on the left and right side. The patient reported pain events during the time with a duration between 5 and 10 hours/day and a weekly occurrence of pain events between 1 and 3 times. The patient received Armourbite treatment and was observed for 4 days. In this period, VAS score related to neck pain immediately improved of 7 points, from 8 to 1.

Case #3 - Patient treated with Armourbite+MLS®
Female patient, 25 years old presenting headache, sleeping and hip/leg pain and reported sleeping problems. Myofascial painful points were located at the left side of trapezius muscle, on the left and right side. The patient reported more than 10 hours/day of pain events and a weekly occurrence of pain events of 5 or more days. The patient received Armourbite + MLS® treatment and was followed up for 3 months.

Energy dose for each area for dynamic program is <0.5 J/cm².

Case #4 – Patient treated with Armourbite+MLS®
Female patient, 56 years old presenting headache, sleeping and hip/leg pain and reported sleeping problems. Myofascial painful points were located at masseter/temporal, sternocleidomastoid and trapezius muscle, additionally, cervicalgia was reported. Muscle contracture, trigger points and bruxism/ clenching were also present. The patient reported more than 10 hours/day of pain events and a weekly occurrence of pain events of 5 or more days. The patient received Armourbite + MLS® treatment and was followed up for 3 months.

The treatment involved a first phase with the use of Armourbite Mouthguard alone, the second phase involved the MLS® treatment which comprised 5 sessions over 3 months: from 1 to 4, using the static program, while session #5 was carried out with the dynamic protocol. The static and dynamic programs involve the use of the following parameters:
- Frequency:350 Hz; Intensity: 50%; Time: 3’;
- Frequency:700 Hz; Intensity: 50%; Time: 2’ 30’’;
- For Trigger points: Frequency:10 Hz; Intensity: 25%; Time:25’’;

Energy dose for each trigger point is 1 J/cm². Energy dose for each area for static program is in the range 0.8 - 2,5 J/cm². Energy dose for each area for dynamic program is <0.5 J/cm².

The VAS score immediately improved of 7 points from 8 to 1. Trigger point pain also improved from 8 to 3 on the third day.

Energy for Health [17]

Female patient, 56 years old presenting headache, sleeping and hip/leg pain and reported sleeping problems. Myofascial painful points were located at masseter/temporal, sternocleidomastoid and trapezius muscle, additionally, cervicalgia was reported. Muscle contracture, trigger points and bruxism/ clenching were also present. The patient reported more than 10 hours/day of pain events and a weekly occurrence of pain events of 5 or more days. The patient received Armourbite + MLS® treatment and was followed up for 3 months.

The treatment involved a first phase with the use of Armourbite Mouthguard alone, the second phase involved the MLS® treatment which comprised 5 sessions over 3 months: from 1 to 4, using the static program, while session #5 was carried out with the dynamic protocol. The static and dynamic programs involve the use of the following parameters:
- Frequency:350 Hz; Intensity: 50%; Time: 3’;
- Frequency:700 Hz; Intensity: 50%; Time: 2’ 30’’;
- For Trigger points: Frequency:10 Hz; Intensity: 25%; Time:25’’;

Energy dose for each trigger point is 1 J/cm². Energy dose for each area for static program is in the range 0.8 - 2,5 J/cm². Energy dose for each area for dynamic program is <0.5 J/cm².

The VAS score immediately improved of 7 points from 8 to 1. Trigger point pain also improved from 8 to 3 on the third day.

Energy for Health [17]
**Case #5 – Patient treated with Armourbite + MLS®**

Male patient, 45 years old presenting very limited neck range of motion. The patient reported to be able to sustain only up to 30 min in the sitting position, as after this time both leg numbness occurred. Myofascial painful points were located on the right side at masseter/temporal, TMJ, sternocleidomastoid and trapezius muscle, additionally, cervicalgia was reported. Muscle contracture, trigger points and bruxism/clenching were also present.

The patient reported more than 10 hours/day of pain events and a weekly occurrence of pain events of 5 or more days.

The patient received Armourbite + MLS® treatment and was followed up for 4 weeks.

The treatment involved a first phase with the use of Armourbite Mouthguard alone, the second phase involved the MLS® treatment which comprised 5 sessions over 1 week: from 1 to 4, using the static program, while session #5 was carried out with the dynamic protocol. The static and dynamic programs involve the use of the following parameters:

- Frequency: 350 Hz; Intensity: 50%; Time: 3';
- Frequency: 700 Hz; Intensity: 50%; Time: 2' 30'';
- For Trigger points: Frequency: 10 Hz; Intensity: 25%; Time: 25'';

Energy dose for each trigger point is 1 J/cm². Energy dose for each area for static program is in the range 0.8 – 2.5 J/cm². Energy dose for each area for dynamic program is <0.5 J/cm².

The VAS score improved of 9 points from 7 to 1.

**DISCUSSION**

As a general comment, both the treatments used (splint and laser therapy) were well tolerated by the patients and no adverse effects have been reported.

Armourbite is a splint designed to re-establish the neuromuscular balance in the masticatory system. The impact of the Armourbite treatment can both treat local painful symptoms, and also deeply affect quality of life, such as eliminating headache and sleeping disorders. This is confirmed by the two cases, #1 and #2, which received Armourbite treatment alone.

Laser application is effective in reducing TMD symptoms, especially pain [7], and has influence over masticatory efficiency [8].

Therefore, the combination of Armourbite splint and MLS® laser therapy seems to be a promising and practical approach to address the complex TMD picture.

The combined therapeutic protocol including Armourbite and MLS®, applied in 4 of the reported cases, was easy to follow, very effective and was able to provide results in a limited number of sessions. In particular, it was evidenced that some selected cases can obtain beneficial outcome even in just 3 days of treatment, as happened for case #3.

Therefore, MLS® appeared to be a treatment able to maximize the positive effects of Armourbite: the joint effect of the two strategies is exemplified in case #5, where 50% improvement in range of motion was obtained with the use of Armourbite and then the addition of MLS® treatment allowed for a full range of motion restoration.

In fact, MLS® laser therapy can reduce inflammation, decrease muscle contracture and improve muscle function by inducing the synthesis and/or modulation of proteins involved in the regulation of inflammasome activity, anabolic processes, contraction/relaxation processes [9].

In order to make the most from the treatment of TMD with MLS® laser therapy, a global approach is recommended. This involves not only the local painful point treatment, but includes the all muscle groups and trigger points that are involved in the pathology, directly or indirectly. To maximize the effect of the treatment, static and dynamic procedures have been defined. Generally, the first treatment phase involves the static treatment and the dynamic procedure completes the therapy in the latter sessions i.e. case #4 and case #5. The static treatment aims at decontracting, reducing inflammation and pain. The dynamic protocol adds to these effects the proprioceptive and joint recovery. The combination of the two is especially indicated in high complexity situations, where several painful areas can be identified and the pain symptoms are also associated to other problems, for examples limited ROM and bruxism/clenching (case #4) and also limb numbness (case #5).
problems (case #5).
The reported cases demonstrate the positive outcome in the TMD treatment when the combination of Armourbite splint and MLS® therapy is used, nevertheless, more clinical information are needed to clarify the mechanism of action of this protocol and confirm the clinical significance. A randomized controlled study would be the ideal clinical method to further study the combination of these two approaches in the treatment of TMD and related issues.

Key features for reliable studies are the reporting of allocation, blinding, sequence generation, withdrawals, intention-to-treat analysis, and any other potential source of bias in the study. In addition, there should be use of well-validated standardized outcomes so that the RCTs could be compared with other similar trials [10].

**CONCLUSION**

In the reported cases, the MLS® laser therapy together with Armourbite splint represented a very effective, fast, predictable and successful treatment for TMD and in most cases the treatment was able of reestablishing the neuromuscular functions exceeding the clinical expectations. Additional clinical studies are required to confirm this preliminary experience in the combination of MLS® and Armourbite, to optimize treatment modalities and to identify the patients that can get the most by this therapeutic combination.

**BIBLIOGRAPHY**