Evaluation of the effect of MLS® Laser Therapy and Ora-Guard™ splint in the treatment of temporomandibular joint disease

J. Rosswag[1], S. Rosswag[1], S. Janke[2], U. Janke[2]
[1]Private Practice, Hauptstraße 42, 68259 Mannheim, Germany
[2]Private Practice, Rodigallee 250, 22043 Hamburg, Germany

ABSTRACT

Temporomandibular joint disorders (TMD) comprise all the conditions that are affecting the temporomandibular system, composed of the temporomandibular joint (TMJ) and the associated neuromuscular system. These conditions may range from TMJ pain, to headache, neck pain up to tinnitus and are often associated to bruxism and clenching. The aim of this study is to evaluate the effect of MLS® Laser Therapy combined with Ora-Guard™ splint for the conservative treatment of TMD.

The study involved 40 patients which were divided into 2 groups: 1 – Ora-Guard™ splint alone; 2 – Ora-Guard™ + MLS® Laser Therapy.

At the first visit, patients were clinically evaluated and Electromyography (EMG) testing was performed. Pain was evaluated using Visual Analogue Scale (VAS) scale at days 1st, 3rd, 5th and 21st.

The results demonstrated that all the patients improved in terms of pain. Stronger improvement was reported for group 2, when both Ora-Guard™ splint and MLS® Laser Therapy were applied. No undesired effects have been reported in the study.

The combination of Ora-Guard™ splint and MLS® Laser Therapy represents a well-tolerated conservative approach able to alleviate TMD pain and improve joint Range of Motion (ROM) and mouth opening. This combined approach should be considered a valuable tool in the multimodal clinical management of TMD patients.

INTRODUCTION

Temporomandibular joint disorders (TMD) are conditions related to the temporomandibular joint and the associated stomatognathic system. The temporomandibular joint (TMJ) comprises the bilateral articulation with condyles of the mandible with the glenoid fossa of the inferior border of the temporal bone, separated by the meniscus or interarticular disc [1]. The stomatognathic system includes teeth, jaw and associated neuromuscular tissues. TMD have multifactorial origin [2], which may include occlusal problems, joint laxity, prolonged micro-trauma, joint overuse/arthrosis, parafunctional habits, psychological factors, stress, etc.

Clinical signs of TMD include pain and tenderness in the masticatory muscles or TMJ, clicking or crepitation of the TMJ during condylar movement, limitation on mandibular movement, noise from temporomandibular joint, vertigo and chin, neck and head pain are also common [3,4]. Tinnitus can also be originated by cervical spine or TMJ disorders [5,6]. Pain is commonly reported at the following muscles: masseter, temporalis, trapezius (cervical spine), sternocleidomastoid. TMD is the most relevant cause of non-dental pain in the orofacial region, negatively affecting quality of life [7,8].

These conditions may also affect the function of the TMJ system, such as mastication, swallowing and speech [9,10].

The prevalence of TMDs in the general population varies from 7% to 10% and 79.5% of patients with TMDs are women [11]. Limitation of mouth opening occurs in 21.3% of patients, while muscle pain affects 30.7%, and headaches are reported in 46.7% of the cases [11].

The goal of TMD treatment is to reduce pain associated to these conditions in order to improve mouth function and opening, neck range of motion and general patient quality of life.

Multiple conservative approaches are

currently used to treat this class of diseases, such as therapeutic exercise, manual therapy, behavioural exercise, soft diet, analgesic drugs and physiotherapy [12]. When those approaches fail, surgical intervention, including arthrocentesis, disc repositioning, or discectomy for patients with resistant internal derangement [12] can be an option. The use of splint is a common conservative approach which is used in the clinical management of TMD [13]. It is useful to stabilize the anatomy and to protect the teeth which are commonly damaged by bruxism and clenching [14]. Ora-Guard™ is a splint specifically 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 Ora-Guard™ allows rotation of the lower jaw down and forward to help relieve pressure on the TMJ.

MLS® Laser Therapy is a valuable treatment able to reduce inflammation [15], alleviate pain, decrease swelling and overall promote tissue healing [16, 17]. Moreover, therapy is safe, non-invasive and well-accepted by the patient. Recent studies have confirmed the efficacy of this therapy in the treatment of a variety of osteoarticular and neuromuscular conditions [18-21]. Preliminary experience on TMD clinical cases treated with MLS® Laser Therapy was recently reported [22,23].

The therapeutic effects of the combination of splinting with Ora-Guard™ with MLS® Laser Therapy in comparison with Ora-Guard™ have been evaluated in a total of 40 patients treated conservatively for TMD, which have been divided into two groups.

MATERIAL AND METHODS

A total of 40 patients seeking for TMD care in Dr. Janke's and Dr. Rosswag's practice have been included in the study. 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 (1 to 5 hours, 5 to 10 hours or more than 10 hours a day) and during the week (1-3, 3-5 or 5-7 events a 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).

Clinical evaluation and electromyographic measurement were performed at days 1st, 3rd, 5th and 21st.

At each therapy session, the following assessments were performed:

- pain evaluation using the VAS scale
- muscle contracture and mouth opening
- cervical spine range of motion (left and right)

Additionally, reactions, side effects and further notes were recorded. The patients were divided into 2 groups: Group 1 – treated with Ora-Guard™ splint, Group 2 – treated with MLS® Laser Therapy and Ora-Guard™ splint.

Group 1 – was treated with oral splint (Ora-Guard™, BiteTech Inc., USA) alone.

Group 2 – was treated with oral splint (Ora-Guard™, BiteTech Inc., USA) and received MLS® Laser Therapy with Mphi D (ASA srl, Italy). Patients in this group received 4 sessions of MLS® Laser Therapy on days 1st, 3rd, 5th and 21st. MLS® Laser Therapy was performed using Mphi D device (ASA Srl, Italy). MLS® Laser is a class IV NIR laser with two synchronized sources (laser diodes). One diode emits at 905 nm with 25 W peak optical power. The pulse frequency can be adjusted in the range 1-2000 Hz. The other diode emits at 808 nm and can operate in two modes: continuous (power 1.1 W) or pulsed (repetition rate 1-2000 Hz, 550mW mean optical power, with a 50% duty ratio independently of the repetition rate). Correspondent laser beams are emitted synchronously with coincident propagation axes. 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: static protocol for TMJ treatment included treatment of the condyle and masseter area (Energy delivered= 47J) and also of trigger points on the sternocleidomastoid (SCM), if present (Energy delivered=3J for point). Static protocol for shoulder and cervical pain included 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 were treated (Energy delivered=3J for point).

RESULTS

A total of 40 patients have been included

in the study, 20 were allocated to Group 1 and 20 were allocated to Group 2. Patients demographics and clinical evaluation are reported in Table 1. Most of the patients were female (69,2%).

Clinical evaluation revealed the presence of multiple symptoms, as it is typical of TMD conditions, ranging from myofascial pain in TMJ and cervical area, to bruxism and clenching. Hypertonia was common in masseter/temporal muscle, sternocleidomastoid muscle and trapezius muscle. TMJ pain was the most common symptom, and was present in 80% of the total patients (75% of patients in group 1 and 85% of patients in group 2, respectively), followed by trapezius and masseter/temporalis hypertonia (both reported in 47,5% of the total patients). Trigger points were also very commonly reported and were present in all the patients in Group 1 and 90% of patients in Group 2. Quite often, head pain and neck pain were reported (45% of total patients and 30% of total patients respectively). The variety of symptoms found was reflecting the clinical conditions that are commonly found in TMD patients.

Pain events data and VAS before and after treatment are reported in Table 2. The VAS values demonstrated that both groups improved in terms of pain. Improvement was reported in 90% of patients in both groups. The group with the most relevant improvement was Group 2, which started from most severe pain and reached the lowest VAS value.

In group 1, pain decrease corresponded to 53,9% and in group 2 to 75,9%.

All patients with limited mouth opening before entering the study recovered normal mouth opening at the end of the treatment.

Regarding range of motion, all patients, regardless of the group showed an improvement after the treatment.

No side effects have been reported in the study. Two patients in group 1 and two in group 2 did not show any improvement

Table I

	Group 1	Group 2
Sex (M/F)	9/11	3/16+1 NA
Average age (min-max)	40,25 (24-63)	47,4 (27-68)
TMJ pain	15	17
Masseter/temporal muscolar hypertonia	10	9
Cervicalgy	4	4
Trapezius muscle hypertonia	9	10
Sternocleidomastoid muscle hypertonia	1	6
Other	1 (trigeminal neuralgia)	0
Trigger Point	18	20
Bruxism/Clenching	8	3
Muscle contracture	4	1
Arthrosis	0	1
NA	2	0
Headache	9	7
Neck pain	7	5
Limited ROM	1	3
Limited mouth opening	1	3

Table 2

	Group 1	Group 2
Pain events during the day		
1-5h	12	10
5-10h	5	5
>10h	3	5
Pain events during the week		1=NA
1-3	5	6
3-5	11	7
5-7	4	6
VAS before treatment	8,35	8,7
VAS after treatment	3,85	2,1

and the two of them in group 2 were sent to a neurologist for re-evaluation.

DISCUSSION

TMD is recognised as a multifactorial condition and its treatment is currently based on multiple approaches [4, 24, 25], in line with the fact that under the TMD diagnosis, several symptoms with different origins and characteristics are recognised. This study investigated the potential combination of MLS® Laser Therapy and Ora-Guard™ splint in TMD patients, assessing the clinical results of the combined use in comparison with use of Ora-Guard™ splint alone. The study data confirm that when the double approach is carried out, best results in terms of VAS reduction are achieved. This is specifically true as the group treated with the double approach had higher starting VAS compared to the single approach group and reached lowest VAS value at the end of the evaluation.

The MLS® Laser Therapy protocol that was used in this study was in agreement with the static protocol used in our practices in previously reported clinical cases [23], confirming the safety of the device and the good results in terms of pain management.

Previously, Manfredini et al [22] have evaluated the use of MLS® Laser Therapy, oral appliance and counselling comparing them in the treatment of myofascial pain of jaw muscles, demonstrating that on long term (6 months) all the treatments are effective and that oral appliance and MLS® Laser Therapy should be directed to maximize the positive changes in short term. This is why our study took into account early results up to 21 days, revealing the immediate effect on pain, ROM and mouth opening.

MLS® Laser Therapy demonstrated to have a role in cell metabolism, increasing the levels of serine/threonine protein phosphatase activity as well as the expression of ATP-binding proteins and PP1 protein, which is involved in glycogen metabolism regulation and myosin dephosphorylation [15, 16]. Moreover, it has been reported that MLS® Laser Therapy can control of inflammation, by increasing NLRP10 protein, an inflammasome inhibitor [16]. Since both inflammation and muscle contracture are important factors in the aetiology of TMD pain, these effects, combined with the analgesic effect of the MLS® Laser Therapy, are the base of the action on muscle pain that is reported in many musculoskeletal conditions [19, 26] and are likely to be responsible of the effect seen in the study patients.

The use of Ora-Guard™ was supported by the evidence that splint protects the dental structure, promotes pain relief in the masticatory muscles and TMJ, improves the physiological musculoskeletal relationship in the stomatognathic system. [27-29].

When used together, MLS® Laser Therapy and Ora-Guard™ were associated with good tolerance, confirming the feasibility of combining the two approaches in the clinical practice, in line with the increasing attention that the adoption of multimodal approaches in TMD treatment is getting by dentists and physical therapists. In fact, oral exercise therapy including passive and active movements, stretching and strengthening exercises demonstrated to decrease the signs and symptoms related to TMJ dysfunction since they improve the mouth opening and mandibular movements [30, 31], which, along with pain management, are the main goals of TMD treatment.

Additionally, the treatments are non-invasive and well tolerated by the patients.

It has to be underlined that, in the few patients which were not responding to the treatment, psychological and emotional factors could have played a key role [32, 33], as those aspects are known to strongly influence the outcome of TMD therapy, in terms of poor response [34]. In fact, literature reports that muscle hyperactivity, myospasms or myositis and parafunctional activity are associated with increased level of emotional stress [35].

In conclusion, this study underlines that the combination of MLS® Laser Therapy and Ora-Guard™ is an effective and well tolerated dual strategy for the treatment of TMD patients. Further studies on a larger number of patients will be useful to confirm these findings and identify the criteria to select the type of patients that can benefit most from this approach.

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