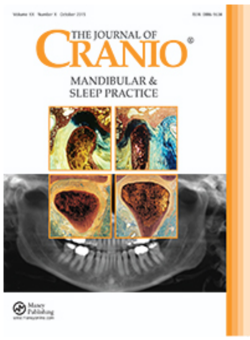

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A comparison trial between three treatment modalities for the management of myofascial pain of jaw muscles: A preliminary study

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ABSTRACT

Objectives: To compare three treatment modalities for the management of myofascial pain of jaw muscles.

Methods: Thirty (N = 30) patients with low pain-related impairment were randomly assigned to receive laser therapy (LST), oral appliance therapy (OA), or counseling (CSL). Visual Analog Scale (VAS) pain levels and the Muscular Index (MI) of the Craniomandibular Index were the outcome variables, which were assessed at baseline, at three weeks, three months, and six months.

Results: At six months, improvement in the MI was maintained both in the LST (p = .025) and OA groups (p < .001). As for VAS values, positive changes were still shown for LST (p = .001), and were also shown for the OA (p = .002) and CSL groups (p = .048).

Conclusions: Despite differences in the short-term effectiveness of LST and OA, with respect to CSL alone, all three treatment groups improved at six months. This suggests that active treatments should be directed to maximize the positive changes in the short-term period.

KEYWORDS
Temporomandibular disorders; lasertherapy; oral appliance; counseling; clinical trial

Introduction

Temporomandibular disorders (TMD) are a heterogeneous group of conditions affecting the temporomandibular joints (TMJ), jaw muscles, and the related structures [1]. They have a multifactorial etiology, and the presence of at least one TMD sign or symptom (e.g. muscle or joint pain, joint sounds, limited jaw motion) is quite common in the general population, with an estimated prevalence of up to 75% over a lifetime [2]. The onset of symptoms is around the age of 25–30 years for joint sounds and/or pain, and over the age of 50 for TMJ arthrosis, with a higher prevalence in females [3,4].

The presence of psychosocial impairment is a challenging condition, since it affects the prognosis negatively in subjects with chronic pain [5,6]. On the other hand, TMD subjects with low pain-related impairment have a favorable natural course [7,8]. A multidisciplinary approach, possibly involving experts in chronic pain management, is required for complex patients, while individuals without a severe psychosocial impairment have a good prognosis with conservative care (e.g. oral appliances, physiotherapy, drugs, counseling, and cognitive-behavioral approaches) [9]. Based on this, irreversible therapies modifying dental occlusion are strongly discouraged, and patients' management should be based on pain medicine strategies [10].

Within this framework, the literature offers very few clinical trials comparing the effectiveness of different conservative treatment approaches [11]. In particular, laser therapy can be adopted in the field of TMD pain management as a possible additional option in the armamentarium of caregivers. Until now, data on its effectiveness are inconsistent among the different studies, possibly due to the unspecific address of TMD conditions [12–14]. Such observation contrasts with the available information on the use of laser therapy to manage similar pain conditions affecting other musculoskeletal districts, thus supporting the need to refine current knowledge, especially as far as the comparison with other treatments is concerned.

Based on these premises, this manuscript presents findings from a randomized trial comparing the effectiveness of multi-wave locked system (MLS®) (Mphi D®, ASA Laser, Vicenza, Italy) laser therapy (LST) with the referenced

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conservative treatments (e.g. oral appliances (OA) or counseling-based cognitive-behavioral treatment (CSL)) for the management of muscle pain in TMD patients with low psychosocial impairment.

Materials and methods

All procedures performed in this study involving human participants were in accordance with the ethical standards of the University of Padova and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Thirty (N = 30) consecutive female patients with a Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) diagnosis of myofascial pain (mean age 35.3 ± 9.4 yrs) and with a low pain-related impairment based on the Graded Chronic Pain Scale (i.e. GCPS grade I or II – low) were recruited and randomly assigned to receive either laser therapy (LST), oral appliance therapy (OA), or counseling (CSL), according to a block randomization sequence. Subjects with systemic diseases and/or history of trauma were excluded from the study.

The study design provided that VAS pain levels, measured on a 10-mm scale with "absence of pain" and "worst pain in my life" as the extremes, as well as the Muscular Index (MI) of the Craniomandibular Index, which measures pain associated with bilateral digital palpation of selected intraoral and extraoral masticatory muscles at a total of 20 sites [15], were adopted as outcome variables.

Patients of the LST group underwent nine laser applications on the painful muscles over a three-week period; patients undergoing OA treatment wore a flat occlusal appliance covering the maxillary teeth at night for three weeks, and then with intermittent use for the following two months; patients of the CSL group received advice on the symptoms and how to try self-managing them, with one reinforcement session per week over three weeks. Outcome variables were assessed at baseline, at three weeks, three months, and six months by the same clinical practitioner, who was blind to the treatment approach the patients were undergoing.

Patients of the LST group received treatment with a MLS® device, which provides two synchronized emissions of 808 and 905 nm wavelength. The 808 nm source emits in continuous or frequenced mode (power 1.1 W), while the 905 nm source is pulsed, with a 25 W peak optical power and frequency ranging from 1 to 2000 Hz. LST with the Mphi Device is based on standardized parameters for the application of pulses, with a frequency of 10–700 Hz, a total energy of 100–200 J, an application time of 6–10 min, and a power of 25–100%. All LST applications were performed by the same trained physical medicine therapist.

Patients of the OA group received treatment with a flat occlusal appliance covering all superior teeth, made of transparent heat-polymerized rigid acrylic resin and without clasps for extra retention. They received instructions to wear it during the nighttime and were asked to call for help/advice in case they were not able to wear the appliance because of discomfort on the teeth. The device was built by increasing the original vertical dimension of occlusion of 3 mm and was calibrated *in situ* by the same trained TMD practitioner. A symmetric distribution of occlusal contacts on the appliance was the target for a clinical OA calibration, and it was verified at all follow-up assessments.

Patients of the CSL group received educational information about the anatomy and physiology of normal and pathological TMJ and were taught self-care strategies to control parafunctions and to manage pain. Patients were also reassured about the etiology and good prognosis of TMD. Information about the improvement of sleep and correct body posture, the importance of dietary habits, the execution of a home exercise program focusing on habit-reversal techniques as well as about easily available pain control techniques (e.g. thermotherapy and massage in the painful area) were also given. A leaflet with all this information was given to the patients in an attempt to help them remember all the advice. All counseling sessions were performed by the same trained TMD practitioner, who was different from the OA provider.

A third TMD practitioner, blind to the patients' group assignment, assessed outcome variables at baseline and during follow up appointments.

All patients gave their consent to receive the proposed treatment approach, and the study was approved by the University of Padova's institutional review board (IRB).

Analysis of variance (ANOVA) for repeated measures was performed to assess within-group changes over time in the outcome variables, based on the study hypothesis that all three treatments are effective in reducing pain levels and muscular impairment in patients with myofascial pain of jaw muscles with low psychosocial impairment.

Results

Only one patient belonging to the OA group dropped out of the study, due to family problems. At baseline, after randomization, groups were matched for age and sex, and there were no differences as far as the outcome variables were concerned.

ANOVA for repeated measures showed that the LST and OA groups achieved significant improvements in the MI after the three-week period (LST, p = .038; OA, p = .008) (Table 1), while VAS values decreased

Table 1. Changes over time in Muscular Index values with the three treatment protocols.

	LST	OA	CSL
T0 (baseline)	0.50	0.43	0.34
T1 (3 weeks)	0.30*	0.27*	0.31
T2 (3 months)	0.38	0.26*	0.37
T3 (6 months)	0.38*	0.25*	0.33

Note: LST, laser therapy; OA, oral appliance therapy; CSL, counseling.
*Indicates significance at $p < 0.05$.

Table 2. Changes over time in VAS pain levels with the three treatment protocols.

	LST	OA	CSL
T0 (baseline)	4.6	4.2	5.0
T1 (3 weeks)	3.3*	3.2	3.8
T2 (3 months)	4.2	2.4*	3.5*
T3 (6 months)	3.3*	3.0*	4.1

Note: VAS, Visual analog scale; LST, laser therapy; OA, oral appliance therapy; CSL, counseling.
*Indicates significance at $p < 0.05$.

significantly only in the LST group ($p = .018$) (Table 2). At six months, improvement in the MI was maintained both in the LST ($p = .025$) and OA groups ($p < .001$). As for VAS values, positive changes were still shown for LST ($p = .001$) and were also shown for the OA ($p = .002$) and CSL groups ($p = .048$).

Discussion

This investigation compared the effectiveness of laser therapy with two reference options for the management of myofascial pain of jaw muscles: oral appliances and counseling.

The rationale for laser therapy is the possible modulation of cell metabolism and improvement in energy supply with MLS® impulse. In vitro studies showed an increase in Protein Phosphatase 1 (PP1), contractile proteins, and ATP-binding proteins in muscle cells [16]. This effect can help regulate the muscle contraction mechanism and glycogen metabolism. In short, the MLS impulse provides thermal stimuli under the damage threshold; such stimuli induce indirect photomechanic effects that, in turn, lead to minor mechanical stress at cell level. Within the muscle, as well as in all tissues with mechanical functions, such stress favors trophism, homeostasis, and cell differentiation, thus helping cell repair processes. Moreover, an increase in anti-inflammatory protein NLRP10 levels was found in muscle cells exposed to MLS emission [17]. This, along with the purported analgesic action of laser therapy, may explain the decrease in muscle pain levels reported in many investigations on various musculoskeletal districts [18,19]. Thus, to refine findings in the field of TMD pain, laser therapy has been adopted as a test treatment in this study protocol.

Two conservative approaches, e.g. oral appliances and counseling, were adopted as comparisons to assess the relative effectiveness of laser therapy with respect to other reference treatments. The reasons for the adoption of such comparison protocols are twofold. Indeed, the literature is inconsistent as far as the superiority of laser therapy with respect to oral appliances, and the effectiveness of laser therapy versus counseling was never evaluated before [20–22]. In particular, this latter comparison may be viewed as an attempt to assess laser-induced changes with respect to a natural time-related course of symptoms.

Findings suggest that, even with minor differences in the short term period, improvement in pain levels and muscular index achieved with laser therapy is similar to oral appliances and superior to the improvement in subjects who received counseling alone.

These results are open to several interpretations. First, they confirm the study hypothesis that MLS laser therapy is effective for managing muscle pain in TMD patients. The positive outcomes, which are comparable to those achieved with oral appliances, are thus promising in terms of the potential risk-to-benefit ratio. Indeed, while OAs, which are historically considered the reference treatment to provide relief from TMD pain, may have side effects (e.g. worsening of obstructive sleep apnea, progressive dental changes) and/or be poorly tolerated by the patients [23], laser therapy has never been associated with negative side effects.

Second, the superiority of LST and OA protocols, with respect to counseling alone, supports the concept that those treatments are actively helpful. The inclusion of a control group would be needed to show improvement over a no treatment group, since patients with low pain-related impairment have been shown to have a positive course even if untreated. This may indicate that reinforcement of information and self-management strategies is enough to implement the positive evolution of symptoms, but the superior effects of LST and OA treatments with respect to counseling alone in this investigation suggests that they somehow facilitate the symptoms' decrease. Possible mechanisms of action involve the above described purported analgesic and muscle cell repair process for laser therapy as well as the shifts in muscle workloads for oral appliances. Further studies on both topics are needed to re-appraise such hypotheses.

Third, these findings can be useful for refining the design of future investigations. In particular, the adoption of multimodal treatments is fundamental to maximize therapeutic effectiveness by combining the approaches here investigated for a better understanding of their relative role.

Some considerations should also be made to limit generalization of findings. The low sample size might have influenced the study results in terms of likelihood of possible type II error (i.e. false negative findings) as well as in terms of time progression data, which are not consistently significant across the time periods. In particular, it should be remarked that findings concerning the changes over time in patients belonging to the LST and the OA groups showed the most improvement during the first three weeks and an obscillation of values during the remainder of follow up. The former observation suggests that the likelihood of a false negative result is low, but the latter suggests the need for better comprehension of treatment effectiveness mechanisms. Importantly, this study included only subjects with a low psychosocial impairment, while individuals with severe pain-related impact on their psychological and social functioning were excluded. This choice was due to recent observations that axis II findings (e.g. psychosocial assessment) influence treatment outcome, due to the very poor response of individuals with chronic TMD and high pain-related impairment [6]. Such subjects were excluded from this study to maximize the internal validity of findings and avoid the presence of a possible psychosocial confounder, which is unrelated to the effectiveness of treatment approaches under investigation.

Conclusions

Findings of this randomized trial show that all three treatment groups improved at six months. This may support a positive natural course of myofascial pain of jaw muscles in the absence of pain-related impairment. The differences in the short-term effectiveness of LST and OA, with respect to CSL alone, may suggest that active treatments should be directed to maximize the positive changes in the short-term period.

Disclosure statement

M.M. is Director of Research at the ASA Campus Joint Laboratory. The other authors declare they do not have any conflicts of interest.

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