ABSTRACT

BACKGROUND AND OBJECTIVES: Most widely used treatment modality for temporomandibular disorders is the occlusal splint. Low-level laser therapy has been used as therapeutic agent, however as isolated treatment. So, this study aimed at evaluating the effect of the association of low-level laser therapy and occlusal splint to treat temporomandibular disorders.

METHODS: Participated in the study 25 selected patients according to the Research Diagnostic Criteria for Temporomandibular Disorders protocol. Control group (CG) was made up of 12 asymptomatic volunteers. Two groups were randomly formed: “splint-laser” (SLG), being treated with occlusal splint and associated low-level laser therapy; “splint” (SG), treated with occlusal splint only. Jaw movements, pain at palpation and self-perception of signs and symptoms were investigated before and after treatment.

RESULTS: There has been significant decrease in pain at palpation and reported pain according to self-perception of signs and symptoms for both groups, however more significant for SLG. There has been increased amplitude of jaw movements with significant difference after treatment for both groups.

CONCLUSION: The association of low-level laser therapy and occlusal splint to treat temporomandibular disorders has promoted more marked pain decrease as compared to occlusal splint alone. Placebo effect should not be discarded and should be tested in future studies.

Keywords: Low-level laser therapy, Occlusal splints, Temporomandibular joint disorders.

INTRODUCTION

Both acute and chronic pain are still a major reason for seeking for medical and dental treatment and are a major challenge for professionals dealing with orofacial pain (OFP). Temporomandibular disorders (TMD) are among most common OFP. TMD may be understood as a set of clinical changes involving the stomatognathic system, where pain is the primary reason for seeking for treatment. It is classified as musculoskeletal pain, OFP subtype especially characterized by spontaneous pain in orofacial muscles and/or...
or temporomandibular joints (TMJ) which worsens during stomatognathic functions. Currently, its etiology involves predisposing, perpetuating and worsening factors which should be taken into consideration in the diagnosis to establish a treatment approach which is in general multidisciplinary, according to the needs of each case.

Occlusal splint is the most common modality to treat TMD, with positive results widely shown in the literature, both for aspects related to painful sensitivity and those related to biomechanics and neuromuscular system.

Low-level laser (LLL) has been used as alternative therapy for pain relief in muscle and joint TMD presentations for inducing analgesic, anti-inflammatory and biomodulator effect of physiologic cell functions. Studies have shown that LLL is efficient as therapeutic agent for decreasing pain and increasing jaw movement amplitude. In light of the above, this study aimed at evaluating the effect of the association of low-level laser therapy with the use of Functional Anatomic Research Center (FARC) occlusal splint, on pain perceived by TMD patients, as compared to the use of occlusal splint alone.

METHODS

This study was developed in the Faculdade de Odontologia de Ribeirão Preto, Universidade de São Paulo, and volunteers have signed the Free and Informed Consent Term (FICT).

Thirty subjects were selected in a tertiary clinic for TMD patients, of whom 25 have participated in the study till the end, in a total convenience sample of 20 females and 5 males, for having been carried out in compliance with the demand of assistance of the above-mentioned service. Inclusion criteria were TMD diagnosis according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD). Subjects lacking teeth preventing the installation of the occlusal splint, those with central or peripheral neurologic disorders, history of head and neck tumors or trauma, presence of systemic inflammatory diseases and use of analgesics in the last month, and submitted to TMD treatment or others related to the stomatognathic system up to one year before were excluded. Systemic inflammatory diseases and use of analgesics for less than one month were controlled.

Control group (CG) was made up of 12 asymptomatic volunteers paired by age and gender to TMD subjects. To every subject diagnosed with TMD, one of the following treatments was consecutively directed, forming two groups: 1) Splint group (SG): 15 subjects (12 females and 3 males) being treated with occlusal splint alone manufactured and adjusted by a dentist; 2) Splint-laser group (LSG): 10 subjects (8 females and 2 males) being treated with low level laser therapy together with occlusal splint manufactured and adjusted by a dentist. This group has lost patients before treatment completion who were not included in results analyses: 2 by withdrawal and 3 for being unable to come twice a week to comply with the laser application protocol.

Subjects were evaluated sitting on dental chair, in a room with adequate lighting, by a dentist (different from the professional in charge of the treatments), before (A1) and after (A2) treatments. Major complaint and the presence of oral parafunctional habits were investigated. Evaluation was based on RDC/TMD Axis I. Jaw movement amplitude was measured with digital caliper rule (Mitutoyo, Co., Ltd., Suzhou, China). Pain at palpation was investigated based on the same protocol, adding trapezius (upper portion) and sternocleidomastoid (medial portion) muscles, routinely investigated in this service, and pain intensity was indicated by subjects in a numerical scale from zero to 10, where zero is no pain and 10 the worst imaginable pain. The choice of pain at palpation rather than pain at pressure threshold (PPT) was done due to its relation with pain intensity perception which we tried to investigate.

To investigate subjects’ perception of their signs and symptoms, they have answered the “Protocol to determine TMD signs and symptoms for Multiprofessional centers (ProTM-DMulti)”. The first part is made up of questions admitting just positive and negative answers. The second part indicates how much each sign or symptom is severe in different daily situations, such as at emergence, chewing, speaking and at rest, using a numeric scale from zero to 10 where zero is total lack of sign or symptom and 10 most possible severity. Sum of scores attributed to each sign/symptom in the four investigated situations may vary from zero to 40, indicating higher severity as sum increases.

Occlusal splint: groups SG and SLG received occlusion splint model FARC, developed by the University of Milan, following the biomechanical model proposed by Ferrario & Sforza (acrílico resin splint with 2 mm thickness and contacts of second premolar to second permanent molar, without anterior static or dynamic contacts). Usage orientation has followed the protocol of the University of Milan: daily and nightly in the first two weeks and then nightly for three more weeks, with previously proven positive results.

Low-level laser therapy (LLL): SLG patients were treated with LLL three times a week during the five weeks of treatment with the occlusal splint (total of 10 sessions). Equipment was THERA LASER (DMC, LTDA - São Carlos, São Paulo - Brazil), which emits radiation obtained as from stimulation of a semiconductor diode formed by Gallium-Aluminum Arsenide (AsGaAI) with wavelength of 830 nm, in continuous emission. Protocol was the same as previously tested: infrared laser, with wavelength of 780 nm, fixed power of 70 mW and doses of 105 J/cm². Photostim time was 60 seconds per painful point.

Each session involved laser application in five predetermined TMJ points and on the point of more severe pain of predetermined sites of masseter and anterior temporal muscles, as described: upper point of lateral pole of the jaw head; posterior point of lateral pole of the jaw head; point at the level of outer ear (external acoustic meatus), region
crossed by the auriculotemporal nerve; masseter muscle (3 most painful points identified by digital palpation being one at the origin, one at the body and one at muscle insertion); anterior temporal muscle (one most painful point, identified by digital palpation). Application modality on muscles and joint region was punctual and with direct contact of radiation emission tip with skin to prevent reflection phenomenon.9-12,14.

Biosafety: used laser belongs to Class 3b according to ANSI classification, needing preventive care during its application, with the use of goggles for dentists and patients, and the compliance with official safety standards of the International Standard CEI IEC 825-1. Application sites were cleaned with 70°GL alcohol.

This study was approved by the Ethics Committee for Research with human beings (CAAE 0080.0.138.000-10).

Statistical analysis
Initial evaluation data (A1) and evaluation after five weeks of treatment with occlusal splint (A2) were considered for data analysis, both for SG and SLG. Control group was evaluated only once. For measurement interval data, of reason or ordinals presenting normal distribution, such as jaw movement data, ProTMDMulti and pain at palpation parametric tests were used. ANOVA test was used to compare among groups (CG x SG x SLG). T test for independent samples was used to compare differences between evaluations (A1-A2) of experimental groups (SG x SLG). This analysis was carried out to know the real gain of each group. For intragroup data analysis (A1 x A2), t test for paired samples was used.

RESULTS

Only one subject had isolated muscle TMD. Others had association with joint dysfunctions. When asked about major complaints leading them to look for treatment, the following reports were given: headaches (60%), facial pain (52%), TMJ pain (20%) and noises (16%), dental wear (12%), earache (8%) and neck ache (4%). Noxious oral habits were reported: headaches (60%), facial pain (52%), TMJ complaints leading them to look for treatment, the following

| Table 1. Mean and standard deviation of jaw opening, right laterality, left laterality and protrusion movements for control group and splint and splint-laser groups, both with temporomandibular disorders, before and after proposed treatments |
|-----------------|-------|-----|-------|-----|-------|-------|-------|-------|
|                 | CG    | SLG | SG    | SLG |
|                 | Mean  | SD  | Mean  | SD  | Mean  | SD  | Mean  | SD  |
| Opening         | 56.38 | 5.65| 43.59 | 6.43| 53.17 | 6.17| 47.13 | 6.16|
| Right laterality| 8.35  | 1.75| 6.03  | 2.22| 9.84  | 1.67| 7.76  | 1.91|
| Left laterality | 8.55  | 1.17| 6.62  | 2.52| 10.85 | 1.55| 8.13  | 2.76|
| Protrusion (mm) | 7.76  | 1.63| 7.29  | 1.16| 9.98  | 1.68| 6.17  | 2.49|

CG = control group; SLG = splint-laser; SG = splint group; A1 = before treatment; A2 = after treatment.
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Masseter, anterior temporal, supra-hyoid, sternocleidomastoid (medial portion), trapezius (upper portion) and TMJ (p<0.01); and for SG there has been difference for masseter, anterior temporal, TMJ and right (p<0.01) and left (p<0.05) sternocleidomastoid muscles (medial portion).

Comparative analyses of “A1-A2” subtraction (Student t – independent data) between experimental groups have shown difference only in right masseter palpation, with lower scores attributed by SLG. Table 2 shows mean values and standard deviation of scores attributed by subjects to pain at palpation. According to ProTMDMulti part I questionnaire data, absolute frequency of TMD signs and symptoms for each group in initial and final evaluation were obtained, and decreased number of reports were observed in the final phase for both groups. These data are shown in table 3.

According to ProTMDMulti part II questionnaire data, severity of each sign or symptom was determined by the sum of scores attributed to the four questioned situations (emergency, chewing, speaking, at rest). Scores varied from zero to 40, being that the higher the value the more severe the TMD. Table 4 shows mean scores attributed to signs and symptoms evaluated by ProTMDMulti in each group, in the two evaluation moments (A1 and A2).

Comparison between groups (ANOVA) has shown that in the initial evaluation there has been significant difference only between experimental groups and control group for muscle pain, TMJ pain and noise, dental sensitivity (p<0.01) and neck pain (p<0.05). SLG was different from CG also in aural plenitude (p<0.05). SG and SLG were not different at experiment onset (p>0.05), however at final evaluation SLG was not different from CG (p>0.05), but was different from SG for muscle pain, TMJ pain (p<0.01), neck pain and dental sensitivity (p<0.05) and this group was different from CG with regard to the same initial symptom (p<0.05).

In comparing A1 and A2 (Student t – paired data), SLG had significant difference for seven evaluated symptoms with ProTMDMulti: muscle pain, TMJ pain and noises, neck pain, dental sensitivity (p<0.01), tinnitus and aural plenitude (p<0.05). For SG there has been significant improvement in four reported symptoms: TMJ pain and noise (p<0.01), dental sensitivity and aural plenitude (p<0.05).

Comparative analyses of “A1 – A2” subtraction (Student t – independent data) have shown difference between experimental groups (p<0.05) for muscle pain, TMJ pain, neck pain, muscle fatigue, TMJ noises, head pain, ear pain, tinnitus, aural plenitude.

Table 2. Mean, standard deviation and comparison (Student t for paired data) of scores attributed by subjects to pain at palpation, for control group, splint-laser group and splint group, before and after proposed treatments

| Palpation | CG Mean SD | A1 Mean SD | SLG Mean SD | A2 Mean SD | SG Mean SD | A1 Mean SD | A2 Mean SD |
|-----------|------------|------------|------------|------------|------------|------------|------------|
| RM        | 1.84 1.86  | 6.9 6.9    | 1.5** 1.5  | 6.06 6.06  | 3.26** 3.26| 2.46 2.46  |
| LM        | 1.46 1.80  | 6.8 6.8    | 2.69 2.69  | 1.6** 1.6  | 2.11 2.11  | 2.83 2.83  | 2.26 2.26  |
| RAT       | 0.84 0.98  | 7 7        | 2.82 2.82  | 1.6** 1.6  | 2.36 2.36  | 6 6         | 2.72 2.72  | 2.8** 2.8**| 2.17 2.17  |
| LAT       | 0.30 0.48  | 4.2 4.2    | 3.79 3.79  | 1.93** 1.93| 2.34 2.34  | 3.4 3.4     | 2.22 2.22  | 1.4** 1.4**| 1.77 1.77  |
| SHR       | 0.46 1.19  | 3.2 3.2    | 3.48 3.48  | 0.1** 0.1  | 0.31 0.31  | 3.53 3.53  | 3.52 3.52  | 1.46 1.46  | 2.50 2.50  |
| SHL       | 0.3 0.85   | 4.5 4.5    | 3.71 3.71  | 0.2** 0.2  | 0.42 0.42  | 3.13 3.13  | 2.69 2.69  | 2.06 2.06  | 2.96 2.96  |
| ECM-R     | 2.46 2.29  | 6 6        | 2.78 2.78  | 2.1** 2.1  | 1.52 1.52  | 5.6 5.6     | 2.35 2.35  | 3.13** 3.13| 2.5 2.5  |
| ECM-L     | 2.32 2.09  | 5.06 5.06  | 2.90 2.90  | 1.7** 1.7  | 1.49 1.49  | 4.3 4.3     | 3.17 3.17  | 3.66* 3.66*| 2.94 2.94  |
| Tr. R     | 2.15 2.11  | 5.4 5.4    | 3.27 3.27  | 2.6** 2.6  | 2.54 2.54  | 4.53 4.53  | 3.40 3.40  | 3.33 3.33  | 2.63 2.63  |
| Tr. L     | 2.23 2.20  | 4.6 4.6    | 3.30 3.30  | 2.6** 2.6  | 2.36 2.36  | 5.88 5.88  | 3.39 3.39  | 4.13 4.13  | 3.11 3.11  |
| ATM-R     | 1.46 1.26  | 7.1 7.1    | 2.59 2.59  | 1.8** 1.8  | 1.54 1.54  | 7.33 7.33  | 2.38 2.38  | 4.06** 4.06| 2.34 2.34  |
| ATM-L     | 1.15 1.46  | 7.4 7.4    | 2.63 2.63  | 1.9** 1.9  | 1.28 1.28  | 6.93 6.93  | 2.49 2.49  | 4** 4**  | 2.77 2.77  |

CG = control group; SLG = splint-laser; SG = splint group; A1 = before treatment; A2 = after treatment; RM = right masseter; LM = left masseter; RAT = right anterior temporal; LAT = left anterior temporal; SHR = supra-hyoid to the right; SHL = supra-hyoid to the left; ECM-R = right sternocleidomastoid; ECM-L = left sternocleidomastoid; Tr. R = right trapezius; Tr. L = left trapezius; ATM-R = right temporomandibular joint; ATM-L = left temporomandibular joint. *significant difference (p<0.05); **significant difference (p<0.01).

Table 3. Absolute frequency of signs and symptoms in the three studied groups, according to answers to ProTMDMulti part I protocol, before and after proposed treatments

| Signs and symptoms | CG | SG | SLG | SLG | A1 | A2 |
|--------------------|----|----|-----|-----|----|----|
| Muscle pain        | 0  | 15 | 10  | 8   | 2  | 2  |
| Muscle fatigue     | 0  | 12 | 9   | 7   | 2  | 2  |
| TMJ pain           | 0  | 15 | 7   | 9   | 2  | 2  |
| TMJ noises         | 0  | 15 | 8   | 8   | 4  | 4  |
| Headache           | 3  | 15 | 9   | 7   | 2  | 2  |
| Earache            | 0  | 9  | 5   | 4   | 0  | 0  |
| Tinnitus           | 1  | 9  | 6   | 6   | 2  | 2  |
| Aural plenitude    | 1  | 12 | 8   | 6   | 1  | 1  |
| Difficulty         | 0  | 10 | 8   | 5   | 1  | 1  |
| Mouth opening      | 0  | 5  | 4   | 2   | 0  | 0  |
| Mouth closing      | 0  | 11 | 7   | 5   | 3  | 3  |
| Chewing            | 0  | 9  | 9   | 5   | 6  | 6  |
| Yawning            | 0  | 6  | 3   | 2   | 0  | 0  |
| Swallowing         | 0  | 7  | 3   | 4   | 0  | 0  |

GC = control group; GSL = splint-laser; GS = splint group; A1 = before treatment; A2 = after treatment; TMJ = temporomandibular joint.
dental sensitivity and difficulty to swallow, that is, positive evolution of these symptoms was better evaluated by SLG subjects being that remaining symptoms had positive evolution according to perception of both groups, without significant difference (p>0.05).

**DISCUSSION**

TMD is a term used for musculoskeletal facial pain conditions involving several signs and symptoms, being pain the primary motivator for looking for treatment. This way, this study has based its analyses on painful perception of daily situations and on intensity of pain at palpation. Methodology for sample structuring (by convenience) and its size (n) was similar to previous studies which have evaluated the effects of TMD therapy. Being that expectation added to treatment experience is variable according to individuals, but they have been associated to painful TMD in a previous study. In this study, proposed method has not considered a correlation analysis allowing predicting the influence of such habits on TMD symptoms of the studied sample, which may represent a limitation of the study. Clinically, it is up to the professional to analyze this relationship in each case to consider it during diagnosis, treatment plan and prognosis, as factor contributing to the presentation. Jaw mobility restriction is considered a major clinical TMD symptom. Although subjects before treatment had no limitations according to normality patterns, at the end there has been significant increase in movement amplitude for both treated groups, which has also been observed in previous study, being SLG values higher that SG values. This has allowed the reflection that individual amplitude may be larger than the normality pattern and mask an individual movement restriction. And although a significant difference in mouth opening movement between CG and SG after treatment, there has been approximation between values found for treated groups and control group. This indicates the efficiency of both proposed treatments, where further painless jaw movements freedom is needed to recover stomatognathic system functionality. Biomodulator LLL effect might have favored muscle flexibility and pain remission, when offering effects which occlusal splint alone is unable to produce, complementing conventional treatment. Results suggest that the association of LLL to conventional treatment may more efficiently contribute to the handling of cases with jaw mobility difficulties, because its light promotes analgesia and has anti-inflammatory effect on muscles and joints, that is, its action mechanisms are different from those of the occlusal splint, however complementing them. This hypothesis however would have been better tested with the presence of an additional group treated with occlusal splint and laser-placebo (just guide-light) which was not possible due to characteristics of the equipment used. It is known that expectation added to treatment experience

| Table 4. Mean and standard deviation of scores attributed by subjects to signs and symptoms investigated with ProTMDMulti protocol, for control group, splint-laser and splint groups before (A1) and after (A2) proposed treatments. ANOVA for analysis between groups; Student t for paired data for intragroup analysis |
|-----------------|---|---|---|---|---|---|---|---|---|
|                | CG | A1 | SLG | A2 | SG | A1 | SG | A1 | SG |
| Pain (mm)      | 0.8 | 1.7 | 17.7a | 6.8 | 4.3c** | 5.5 | 17.6a | 10.4 | 10e | 7.9 |
| Pain TMJ       | 0  | 0  | 18a  | 7.3 | 3.1c** | 4.5 | 22.3a | 9.5  | 14.7e* | 12.1 |
| Neck pain      | 0.6 | 1.3 | 12.9b | 9.2 | 3.2** | 3.9 | 13.1b | 12.7 | 13.6e | 13.4 |
| Earache        | 0  | 0  | 3.5  | 7.8 | 0.3  | 0.6 | 12.8 | 10.1 | 4.7  | 9.4  |
| Tinnitus       | 2  | 6.3 | 9.8  | 11.5 | 0.7* | 1   | 13.5 | 12.4 | 5.6  | 9.8  |
| Plenitude      | 0.3 | 0.9 | 10.8 | 11.9 | 0.7* | 1.1 | 13.5a | 12.4 | 7.7e* | 10.9 |
| SDent          | 0.5 | 1.3 | 15.3a | 8.7 | 1d** | 1.7 | 15.3a | 12.4 | 9.5e* | 10.6 |
| TMJ noise      | 0.6 | 0.9 | 16.4a | 8.06 | 3.3  | 3.1 | 16.2a | 7.3  | 7.7e* | 7.3  |
| Swallowing     | 0  | 0  | 3.5  | 7.08 | 0.1  | 0.3 | 8.2  | 13.4 | 6.1  | 11.5 |
| Speaking       | 0  | 0  | 8.7  | 13.5 | 0.1  | 0.3 | 7    | 10.8 | 6.3  | 9.5  |

GC = control group; SLG = splint-laser; SG = splint group; A1 = before treatment; A2 = after treatment; TMJ = temporomandibular joint; SDent = dental sensitivity.

a: significant difference (p<0.01) when comparing control group with SLG and SG groups in phase A1; b: significant difference (p<0.05) when comparing control group with SLG and SG groups in phase A1; c: significant difference (p<0.01) when comparing SLG and SG in phase A2; d: significant difference (p<0.05) when comparing SLG and SG in phase A2; e: significant difference (p<0.05) when comparing CG and SG in phase A2; f: significant difference between A1 and A2 (p<0.05); g: significant difference between A1 and A2 (p<0.01).
induces placebo effect\textsuperscript{18}, which could have been the case with this study, because such effect was shown with LLL in previous studies\textsuperscript{6,11}. Due to the subjectivity of pain, its diagnosis, mostly done by its description, is in general not accurate with regard to different variables, such as individual threshold, perception, emotional aspects and individual discomfort, that is, each individual learns to attribute the term “pain” to their sensations by means of their personal experiences\textsuperscript{4,15}. “ProTMDMulti” protocol was developed, tested and validated to investigate people’s perception of the presentation of their primary complaint\textsuperscript{13}. According to this protocol, it was possible to observe that subjects treated with LLL associated to splint had relief in 7 out of 10 investigated signs and symptoms, versus four in subjects conventionally treated with splint alone. In addition, comparison of subtraction of values found in the two evaluation moments of this study (A1-A2) has shown significant difference (p<0.05) between groups (SG x SLG) for muscle pain, TMJ pain, neck pain, dental sensitivity and difficulty to swallow, being these better evaluated by SLG subjects after treatment. It has also to be considered that subjects’ perception could have been influenced by the placebo effect, not tested in this study, induced by more marked pain decrease expectation in face of a more complete treatment with more frequent professional-patient contact, stimulating brain areas of pain modulating neurotransmitters release\textsuperscript{18}. Palpation of orofacial and cervical muscles was used as diagnostic method for muscle sensitivity changes, as well as to evaluate the effects of proposed treatments. Cervical region evaluation was suggested for often presenting TMD-related disorders\textsuperscript{19,20}. As with the evaluation of signs and symptoms perception, pain at palpation after treatments has also improved for both TMD groups, but more markedly for SLG, especially in sites submitted to LLL. This might be the result of LLL analgesic and anti-inflammatory effects\textsuperscript{6,10,14}, in addition to its placebo effect, thus potentiating the effect of the occlusal splint treatment. Not directly treated cervical muscles (sternocleidomastoid – medial portion – and trapezius – upper portion) had also significant decrease in sensitivity to palpation (Table 2), possibly due to the influence of the orofacial region with which they have relation, or due to the placebo effect\textsuperscript{10,11,14,18-20}. Finally, the association of therapies for TMD, involving occlusal splint and LLL, has shown better effect in decreasing pain and increasing jaw movement amplitude as compared to occlusal splint alone, confirming that it is an easy to apply method, accessible to the clinician and of low cost to patients. However, the necessary availability of time twice a week was one limitation of this study, considering the number of subjects not concluding the treatment. Future studies involving the association of these therapies with larger samples will be necessary to confirm statistical results, which should be considered with care in this study. In addition, controlling aspects which could have influenced results, such as parafunctional habits, LLL placebo effect, specific joint and muscle TMD diagnosis, as well as their randomized distribution in different groups shall help the reliable understanding of the tested association of treatments.

**CONCLUSION**

The protocol of therapies association proposed in this study has shown more positive results as compared to isolated conventional treatment, suggesting that complementary therapy with low-level laser potentiates its effects when simultaneously applied.

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