Low intensity laser therapy in the treatment of temporomandibular disorders: a double-blind study

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SUMMARY This study aimed to evaluate the effectiveness of low intensity laser therapy (LILT) in 30 patients presenting temporomandibular joint (TMJ) pain and mandibular dysfunction in a random and double-blind research design. The sample, divided into experimental group (1) and placebo group (2), was submitted to the treatment with infrared laser (780 nm, 30 mW, 10 s, 6.3 J/cm²) at three TMJ points. The treatment was evaluated throughout six sessions and 15, 30 and 60 days after the end of the therapy, through visual analogue scale (VAS), range of mandibular movements and TMJ pressure pain threshold. The results showed a reduction in VAS (p < 0.001) and through the ANOVA with repeated measures it was observed that the groups did not present statistically significant differences (P = 0.2060), as the averages of the evaluation times (P = 0.3955) and the interaction groups evaluation times (P = 0.3024), considering the MVO. The same occurred for RLE (P = 0.2988, P = 0.1762 and P = 0.7970), LLE (P = 0.3265, P = 0.4143 and P = 0.0696), PPTD (P = 0.1558, P = 0.4695 and P = 0.0737) and PPTE (P = 0.2376, P = 0.3203 and P = 0.0624). For PE, there were not statistically significant differences for groups (P = 0.7017) and the interaction groups evaluation times (P = 0.6678), even so in both groups the PE varied with time (P = 0.0069).

KEYWORDS: low intensity laser therapy, laser therapy, temporomandibular joint, temporomandibular disorder, treatment

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Introduction

Temporomandibular disorders (TMD) is a collective term embracing a number of clinical problems that involve the masticatory musculature, the temporomandibular joint (TMJ) and associated structures, or both. TMD have been identified as a major cause of non-dental pain in the orofacial region and are considered to be a sub-classification of musculoskeletal disorders (1, 2).

The TMD aetiology is related to an association of predisposing factors that increase the risk of TMD, initiating factors that cause the onset of TMD, and perpetuating factors that interfere with healing or enhance TMD progression. The most frequent presenting symptom is pain, usually located in the mastication muscles, the pre-auricular area or TMJ and aggravated by chewing or other jaw function. Patients frequently have limited or asymmetric mandibular movements and TMJ sounds (3–5).

The treatment must be based on a correct diagnosis, established from information on possible aetiologic factors, signs and symptoms of each patient. The clinical protocol for TMD patients varies according to the level of damage of muscle and TMJ structures, clinical symptoms and duration of the problem. Thus, the treatment must initiate with therapy to relieve the symptoms, diminish pain, restore function and enable the patient to resume his/her daily activities (3–5).

As in other musculoskeletal conditions, the signs and symptoms can be transitory and self-limiting, without serious long-term effects. Little is known about which
signs and symptoms will progress toward more serious conditions in the natural course of the TMD. Therefore, early aggressive and irreversible treatments, such as complex occlusal therapies and surgeries should be avoided. Conservative and reversible treatments, such as behaviour modification, physical therapy, medications and oral devices are indicated for the initial care of TMD. Physical agents for TMD treatment include electrotherapy, ultrasound, acupuncture and laser. The efficacy of these treatment modalities could diminish the demand for surgeries or medicine use (6–11).

According to some authors, laser is a treatment modality that is becoming widely known. LILT, a term created by Oshiro and Calderhead in 1988, means 'Low Intensity Laser Therapy' and has been investigated and used clinically for about 20 years. Its basic effects are bio-stimulative, regenerative, analgesic and anti-inflammatory. It also seems to act on the immune, circulatory and haematological systems. In addition, LILT appears to have a virustatic and bacteriostatic effect.

The analgesic effect of LILT acts at different levels and by different mechanisms. Some explanations of this effect are: it increases beta-endorphin level in spinal liquor, increases urinary excretion of glucocorticoids, which is a beta-endorphin synthesis inhibitor, increases the pain threshold under pressure through a complex electrolytic nerve fibre blocking mechanism, decreases histamine and acetylcholine release, reduces bradykinin synthesis, increases ATP production, improves local microcirculation, increases lymphatic flow thus reducing oedema (11,12).

The selection of each type of laser should be based on the security, commercial availability and directions for use to control pain, which includes the treatment techniques, methods of application and selection of laser device.

More recently, many clinical trials have been conducted in order to achieve a consensus about the exact power intensity, exposures times, and location of laser application. However, in many cases, the protocols used in these studies do not follow accepted scientific standards for clinical research and have little credibility because of lack of detailing of the methodology. According to Gam et al. (13), there is no scientific evidence to show that laser light can penetrate deeper structures and the 23 studies they analysed lead them to conclude that LILT is not effective in musculoskeletal syndromes.

It should be pointed out that there is considerable diversity in the results reported, depending on parameters and methodology used. Double-blind studies are more appropriate when a new therapeutic modality is being tested, because the placebo effect seems to be very strong, especially in chronic patients.

The greatest advantage of continuing to test laser devices for TMD management is its non-invasive and less harmful characteristics. The aim of this study was to test a new laser device in a double-blind placebo trial and to evaluate the effect of LILT on relieving pain and improving function in arthrogenic TMD patients.

Materials and methods

Experimental subjects

A sample consisting of 30 consecutive subjects was selected on a voluntary basis from patients who presented for diagnosis and treatment of TMD in the Occlusion and Temporomandibular Disorders Clinic at a Dentistry School. Sample selection was based on a standardized and complete clinical examination, based on the criteria of American Academy of Orofacial Pain (3), including patient’s history, masticatory and cervical muscle palpation, palpation of lateral and posterior aspects of the TMJ, measurements of the active and passive range of motion, joint noises auscultation and panoramic radiograph. The inclusion criterion for the sample was the diagnosis of TMD, with pain restricted to the joint area, associated with the absence of any muscle tenderness during palpation. The sample included those with capsulitis/synovitis, and painful disk displacements with reduction. It was very difficult to selected patients with these diagnoses exclusively, with absence of any palpation tenderness of masticatory muscles. The sample of 30 subjects was obtained after examination of 250 patients.

Before participating of this study the selected patients had been waiting for treatment for at least 6 months, without any form of professional care. Patients presenting psychiatric disorders, heart diseases, epilepsy, pregnancy, rheumatoid arthritis, degenerative joint diseases, tumours and subjects with pacemakers were not included in this study.

The free informed consent form was obtained from each patient prior to participation in this study, according to Code of Ethics.
Treatment protocol

After initial evaluation and diagnosis, the patients were randomly assigned to two groups:

Group 1: patients receiving real LILT (experimental).
Group 2: patients receiving inactive laser (placebo).

The treatment was performed twice a week, for three consecutive weeks, with a 780 nm Ga–Al–As (Gallium–Aluminium–Arsenide) diode laser (Twin Laser)*. Given the uncertainty of which laser dose would be the most effective, the protocol suggested by researches of Department of Optical and Photonic, Physics Institute, University of São Paulo State (USP), São Carlos, SP, Brazil was employed. For experimental group, LILT was performed with an output of 30 mW, a time of 10 s and $6 \times 3 \text{J cm}^{-2}$ at three points in each TMJ, as shown in Fig. 1 (a) the posterior aspect of the joint with the mouth open to treat the posterior articular branches of the auriculo-temporal nerve; (b) the area anterior to condyle in the sigmoid notch with the mouth closed, which gives the patient a short rest, and is the area of insertion of the lateral pterygoid muscle into the condylar neck and disc; (c) the joint interface with the mouth open (16). For the placebo group, the laser device was adjusted for the same time and applied to the same points, but without power. Protective goggles were worn by patients and clinician during applications.

At the beginning of the experimental period, the patients were advised about resting the joints, following a soft diet and conscious relaxation of the masticatory muscles.

Double-blind control

The laser apparatus was developed by the manufacturer with two identical probes: one for the active laser and one for the inactive placebo laser, marked with different colours. The colours were hidden and the probes were designated A and B by a clinician who did not perform the applications. The two probes presented a red visible guide light and the integrated output power measuring device of the apparatus was disabled. Thus, the treating clinician did not know which were the active and the inactive probe during the entire experiment, and the patients did not know to which group they were assigned.

Testing criteria

Each patient was evaluated according to the following parameters:

1. Subjective pain reporting: 0–10 cm visual analogue scale (VAS: 0, no pain; 10, pain as bad as could be).
2. Pressure pain threshold of TMJ (PPT), measured in kgf using an electronic algometer (model DDK 20)† (17). The 12 mm diameter plain and circular active tip of the algometer was placed perpendicularly to the lateral pole of TMJ, supporting the patient’s head with the hand on the opposite side to that it was receiving the pressure, thus preventing the displacement. The patient remained with teeth in contact and the device was applied exerting pressure gradually, until the patient notified the operator of the beginning of the painful sensation in the place. The operator, then, immediately removed the tip of the device that automatically registered in the viewfinder the value for the pressure supported by the patient. The PPT was measured separately for right and left TMJ (PPTD and PPTE). Five patients of group 1 and five of group 2 presented unilateral TMJ pain symptoms, so the PPT was calculated for 25 joints of each group.
3. Mandibular dysfunction: painless maximum vertical opening (MVO), right (RLE) and left lateral excursion.
(LLE), and protrusion excursion (PE), measured using an electronic digital caliper with resolution of 0.01 mm and accuracy of 0.03 mm.

Each patient was evaluated immediately before the first, third and fifth treatment sessions, and at the follow-up appointments after 15, 30 and 60 days of the end of treatment, to investigate effectiveness and cumulative effects.

Statistical data analysis
Initially all the variables were analysed descriptively. For the quantitative variables this analysis was made through the minimum and maximum values, and the calculation of medians, means and standard deviation. For the analysis of the hypothesis of equality between the two groups the non-parametric test of Mann–Whitney was used, when the assumption of normal distribution of the data was rejected. For the comparison of the evaluation times in each one of the groups the non-parametric test of Friedman was used, when the assumption of normal distribution of the data was rejected. To analyse the behaviour of the groups considering the studied conditions, the Analysis of Variance with repeated measures was used, which consisted of the adjustment of a linear multivariate model from which the following hypotheses were tested: $H_{01}$: the average profiles of the groups are parallel, or either, does not exist interaction between the factor group (experimental and placebo) and the factor evaluation time (first session, third session, fifth session, 15, 30 and 60 days); $H_{02}$: the average profiles are coincident, or either, does not exist effect of the factor group. $H_{03}$: the average profiles are parallel to the abscissas axis, or either, it does not have effect of the factor evaluation times. The hypotheses $H_{02}$ and $H_{03}$ were tested when $H_{01}$ was not rejected. The statistics of Wilks, with the approach for $F$-statistics, was used in the test of the hypotheses above. The level of significance used for the tests was 5%.

Results
The sample included 30 patients, whose demographic characteristics and duration of arthrogenous pain are shown in Table 1.

The means, standard deviations and $P$-values for VAS are showed in Table 2 and for the other evaluated parameters in Tables 3 and 4.

Through the non-parametric test of Friedman it was observed that in the experimental group as in the placebo there was significant alteration of the VAS along the evaluation times ($P < 0.001$). In the experimental group, the first session differed significantly from the sessions at 15, 30 and 60 days, the third session differed significantly from the 60 days, and the other comparisons did not present significant difference. In the placebo group, the first session differed significantly from the others, except the fifth session, and the other comparisons did not present significant difference. Through the non-parametric test of Mann–Whitney it was observed that the experimental and placebo groups did not present statistically significant differences in the evaluation times, although there was

<table>
<thead>
<tr>
<th>Table 1. Demographic characteristics and duration of arthrogenous pain</th>
</tr>
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<tbody>
<tr>
<td>Characteristics</td>
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<tr>
<td>----------------------------------</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Male</td>
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<tr>
<td>Mean age (range)</td>
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<td>Mean duration of pain (range)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2. Means, standard deviations (SD) and $P$-values for VAS</th>
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<tbody>
<tr>
<td>Evaluations</td>
</tr>
<tr>
<td>--------------------------------</td>
</tr>
<tr>
<td>Group 1</td>
</tr>
<tr>
<td>Group 2</td>
</tr>
<tr>
<td>Between groups$^{**}$ (P-value)</td>
</tr>
</tbody>
</table>

$^a$Statistically significant differences for both groups (Friedman test).

$^{**}$None statistically significant difference for all sessions (Mann–Whitney test).
In this study, even though they are rarer at the study clinic, patients with only joint pain were selected and there was concern about making a correct clinical evaluation. The evaluation of pain is a subject not totally controlled in the clinical and pain research areas, because it is a complex procedure that involves some concepts and methods, and requires the assessment of biological, structural and functional, as well as the emotional, cognitive and behavioural aspects of the painful experience. All methods present limitations, but the evaluation of pain is important to identify elements involved in its genesis, maintenance or exacerbation and to guide the choice of therapeutic procedures. The most recent publications on TMD recommend the evaluation of pain in the masticatory muscles and TMJ through the subjective report and digital palpation. The use of a device, like the algometer, is an attempt to quantify pain better, through measuring the PPT, standardizing data collection and making their comparison possible.

In the TMD, the TMJ clinical findings are pain and dysfunction, which appears to be due to the pain or an alteration of the disc-condyle relation and can generate limited and irregular movements and joint sounds. The TMJ pain is classified as deep and somatic, of musculo-skeletal type, and can be identified by the fact that there is a relation between pain and masticatory function effort and with gradual increase on digital palpation.

### Table 3. Means and standard deviations (SD) for PPTD, PPTE, MVO, RLE, LLE and PE (mm)

<table>
<thead>
<tr>
<th>Evaluations</th>
<th>First session</th>
<th>Third session</th>
<th>Fifth session</th>
<th>15 days</th>
<th>30 days</th>
<th>60 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPTD Group 1</td>
<td>1.20 (0.47)</td>
<td>1.16 (0.52)</td>
<td>1.30 (0.33)</td>
<td>1.06 (0.35)</td>
<td>0.91 (0.38)</td>
<td>1.07 (0.26)</td>
</tr>
<tr>
<td>PPTD Group 2</td>
<td>1.18 (0.48)</td>
<td>1.22 (0.25)</td>
<td>1.03 (0.17)</td>
<td>1.03 (0.33)</td>
<td>0.95 (0.23)</td>
<td>0.99 (0.34)</td>
</tr>
<tr>
<td>PPTE Group 1</td>
<td>1.08 (0.42)</td>
<td>1.14 (0.47)</td>
<td>1.29 (0.57)</td>
<td>1.00 (0.49)</td>
<td>0.99 (0.47)</td>
<td>0.72 (0.58)</td>
</tr>
<tr>
<td>PPTE Group 2</td>
<td>1.15 (0.48)</td>
<td>0.91 (0.44)</td>
<td>0.83 (0.49)</td>
<td>0.80 (0.40)</td>
<td>0.83 (0.31)</td>
<td>0.85 (0.32)</td>
</tr>
<tr>
<td>MVO Group 1</td>
<td>41.49 (8.70)</td>
<td>40.77 (7.76)</td>
<td>42.72 (7.48)</td>
<td>43.36 (7.82)</td>
<td>42.98 (7.73)</td>
<td>44.09 (8.43)</td>
</tr>
<tr>
<td>MVO Group 2</td>
<td>45.36 (8.77)</td>
<td>44.96 (7.31)</td>
<td>45.65 (5.07)</td>
<td>44.81 (7.74)</td>
<td>43.93 (6.35)</td>
<td>43.96 (5.75)</td>
</tr>
<tr>
<td>RLE Group 1</td>
<td>7.69 (2.86)</td>
<td>7.59 (2.94)</td>
<td>8.60 (2.78)</td>
<td>8.13 (2.87)</td>
<td>8.32 (1.86)</td>
<td>8.78 (1.76)</td>
</tr>
<tr>
<td>RLE Group 2</td>
<td>7.26 (2.85)</td>
<td>6.98 (3.71)</td>
<td>6.41 (2.22)</td>
<td>6.73 (3.13)</td>
<td>7.82 (2.53)</td>
<td>7.39 (2.77)</td>
</tr>
<tr>
<td>LLE Group 1</td>
<td>6.66 (3.02)</td>
<td>6.75 (2.98)</td>
<td>7.69 (3.07)</td>
<td>8.10 (2.83)</td>
<td>7.71 (2.43)</td>
<td>7.54 (2.63)</td>
</tr>
<tr>
<td>LLE Group 2</td>
<td>7.65 (3.32)</td>
<td>8.27 (3.04)</td>
<td>8.25 (3.37)</td>
<td>7.75 (3.64)</td>
<td>7.90 (3.69)</td>
<td>9.53 (3.06)</td>
</tr>
<tr>
<td>PE Group 1</td>
<td>5.81 (2.15)</td>
<td>6.18 (1.93)</td>
<td>6.44 (1.64)</td>
<td>6.23 (1.62)</td>
<td>6.00 (1.43)</td>
<td>5.53 (1.77)</td>
</tr>
<tr>
<td>PE Group 2</td>
<td>4.65 (2.02)</td>
<td>4.43 (2.17)</td>
<td>4.29 (2.00)</td>
<td>4.29 (1.90)</td>
<td>4.40 (1.63)</td>
<td>3.97 (2.01)</td>
</tr>
</tbody>
</table>

### Table 4. ANOVA P-values for PPTD, PPTE, MVO, RLE, LLE and PE

<table>
<thead>
<tr>
<th>Variables</th>
<th>Between groups (P-value)</th>
<th>Among evaluation times (P-value)</th>
<th>Groups × evaluation times (P-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPTD</td>
<td>0.1558</td>
<td>0.4695</td>
<td>0.0737</td>
</tr>
<tr>
<td>PPTE</td>
<td>0.2376</td>
<td>0.3203</td>
<td>0.0624</td>
</tr>
<tr>
<td>MVO</td>
<td>0.2060</td>
<td>0.3955</td>
<td>0.3024</td>
</tr>
<tr>
<td>RLE</td>
<td>0.2988</td>
<td>0.1762</td>
<td>0.7970</td>
</tr>
<tr>
<td>LLE</td>
<td>0.3265</td>
<td>0.4143</td>
<td>0.0696</td>
</tr>
<tr>
<td>PE</td>
<td>0.7017</td>
<td>0.0069*</td>
<td>0.6678</td>
</tr>
</tbody>
</table>

*Statistically significant difference.

**Discussion**

In the TMD, the TMJ clinical findings are pain and dysfunction, which appears to be due to the pain or an alteration of the disc-condyle relation and can generate limited and irregular movements and joint sounds. The TMJ pain is classified as deep and somatic, of musculo-skeletal type, and can be identified by the fact that there is a relation between pain and masticatory function effort and with gradual increase on digital palpation.

a tendency to a difference \( P = 0.05 \) between two groups regarding VAS at 60 days (Table 2).

Through the ANOVA with repeated measures it was observed that the groups did not present statistically significant differences \( P = 0.2060 \), as the averages of the evaluation times \( P = 0.3955 \) and the interaction groups × evaluation times \( P = 0.3024 \), considering the MVO. The same occurred for RLE \( P = 0.2988, P = 0.1762 \) and \( P = 0.7970 \), LLE \( P = 0.3265, P = 0.4143 \) and \( P = 0.0696 \), PPTD \( P = 0.1558, P = 0.4695 \) and \( P = 0.0737 \) and PPTE \( P = 0.2376, P = 0.3203 \) and \( P = 0.0624 \). For PE, there were not statistically significant differences for groups \( P = 0.7017 \) and the interaction groups × evaluation times \( P = 0.6678 \), even so in both groups the PE varied with time \( P = 0.0069 \) (Tables 3 and 4).

diagnosis. Cases of mixed problems, with muscle and joint pain could have made the control of variables and the evaluations become more complex.

Another recommendation in the clinical evaluation of pain is the adoption of a double-blind design, because of the influence of the researcher on the opinion of the patients who are being treated. The unfamiliarity of the patient regarding the type of treatment that he/she receives (real or placebo) and the blindness of the researcher about the type of treatment that is offered, avoids interference in the results. The division of the groups in a random drawing also is essential for establishing a well controlled experiment. The random inclusion of each patient in determined group diminishes the possible effect of variables that are difficult to control, such as occlusion, psychological factors and parafunctional habits, on the maintenance of pain. Thus, reliable comparisons were possible, regardless of the severity of TMD symptoms or the type of treatment.

Considering the values found in the visual analogue scale (VAS), they were similar for both groups along the sessions and showed a response of 1 week to laser application, regardless the type of treatment, real or placebo.

The cumulative effect of laser could have been responsible for the tendency to reduction of pain observed at 60 days follow-up, being in agreement with the studies of Bezur (18), Conti (19), Gray (20, 21), Pinheiro (22, 23), Simunovic (11, 12) and Walker (24, 25). Although the laser is related to the reduction of the healing time, it is necessary to wait for the tissues to recover. Therefore, the patients were oriented to prevent damages to the region that was being treated and not to abandon the treatment. During the treatment, in the present study, there was no need to use occlusal appliances or drugs to relieve pain.

The PPT did not present statistically significant differences between the two studied groups. These PPT findings contradict the VAS values and can lead to a hypothesis of lack of laser effectiveness and that laser acts like the placebo treatment. These contradictory results possibly occurred because VAS is a complex and subjective evaluation of pain, possibly based in the sensation of how much the pain is disabling the individual, where as the PPT is an objective measure, made in a static state of TMJ.

The power of the placebo effect has been widely demonstrated in the treatment of TMD. A good relationship between professional and patient, associated with the appearance of the high technology of the laser, might explain the VAS reduction for both groups. During treatment, it was observed that patients were very receptive to LILT and the improvement observed during treatment also had a positive psychological effect, which is reflected in the VAS values. Moreover, the self-limiting aspect of the TMD, with periods of remission of symptoms, may partly explain not only the response to treatment of the placebo group, but also the pain reduction for the experimental group observed in the VAS means after 1 week (Fig. 2).

There is still a lack of scientific explanations in literature for the apparent effectiveness of laser in the treatment of pain. Although many authors present opposite results, the majority of the studies (about 85%) demonstrated that the reduction of pain is effective. Kitchen and Partridge (26) showed that a variety of conditions, like rheumatoid arthritis, chronic neuralgias, and muscle pain, can be treated with low intensity laser. Some studies, like those of Simunovic (11,12) and Eckerdal and Bastian (27) presented a reduction of the tissue inflammation or a direct effect on nerve tissues. Other studies, like those of Conti (19), believe in pain relief, but not in physical improvement. The doses used in these studies are different, making comparisons difficult and limiting conclusions. It is still unclear if the effect of laser is dependent upon the wavelength of the light, irradiance or dose (28).
Considering the mandibular dysfunction, none statistically significant difference was found, except for PE, but both groups remained with similar values in all evaluation times. However, Bezuur et al. (18) found an improvement in the mandibular movement for patients with degenerative joint disease and improvement in the MVO for patients with TMJ pain. Heussler et al. (29) had a general improvement in the amplitude of movements in a group of rheumatoid arthritis patients. Palano (30) also observed a significant effect on TMJ clicking and mouth opening, and associated the functional improvement with the reduction in muscle contraction and inflammation. This possibly occurs as a result of the anti-inflammatory effect of the laser, already suggested by Hansen (28). Another plausible explanation for the increase in joint mobility may be the alteration of secondary muscle inhibition that occurs because of the hyperactive sensory receptors within the joint (31–33).

The most recent studies describe its methods, but they do not give a complete description for the choice of the dosage parameters. The use of inadequate power or energy density could cause undesirable effects. The recommendations are primarily based on positive clinical experiences rather than classical placebo-controlled clinical trials. Only a limited number of controlled studies have been performed, especially with chronic painful conditions. The reproduction of studies with longitudinal follow-up is also necessary to confirm the findings of other authors. Certainly, for controlling chronic conditions over a long period, the use of more than one treatment modality is mandatory, as well as clinical follow-up of patients for controlling all the factors involved. Bradley (14–16) and Simunovic (11,12) have emphasized the importance of the duration of the treatment in chronic patients, who generally demand a longer period and the interaction between professionals of various health areas.

Conclusions

After carrying out this research, it is considered that the effect of the low intensity laser therapy in pain, within the possibilities of the methodology used and considering all the difficulties of research with human beings, involving the diagnosis and treatment of painful conditions, was not demonstrated in our study, because it was similar to the placebo effect. The active LILT did not promote improvement for mandibular excursions, as the placebo LILT. Finally, based on the non-invasive aspect of this treatment modality, it is suggest that studies in this area should continue, to define effective fluences or energy doses, as well as the effect of its interaction with other treatment modalities, using a higher number of applications for a longer period of treatment.

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References


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