Low Intensity Laser Therapy in Temporomandibular Disorder: a Phase II Double-Blind Study

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ABSTRACT: The purpose of this study was to evaluate the analgesic effect of Low Intensity Laser Therapy (LILT) and its influence on masticatory efficiency in patients with temporomandibular dysfunction (TMD). This study was performed using a random, placebo-controlled, and double-blind research design. Fourteen patients were selected and divided into two groups (active and placebo). Infrared laser (780 nm, 70 mw, 60s, 105J/cm²) was applied precisely and continuously into five points of the temporomandibular joint (TMJ) area: lateral point (LP), superior point (SP), anterior point (AP), posterior point (PP), and posterior-inferior point (PIP) of the condylar position. This was performed twice per week, for a total of eight sessions. To ensure a double-blind study, two identical probes supplied by the manufacturer were used: one for the active laser and one for the inactive placebo laser. They were marked with different letters (A and B) by a clinician who did not perform the applications. A Visual Analogue Scale (VAS) and a colorimetric capsule method were employed. Data were obtained three times: before treatment (Ev1), shortly after the eighth session (Ev2), and 30 days after the first application (Ev3). Statistical tests revealed significant differences at one percent (1%) likelihood, which implies that superiority of the active group offered considerable TMJ pain improvement. Both groups presented similar masticatory behavior, and no statistical differences were found. With regard to the evaluation session, Ev2 presented the lowest symptoms and highest masticatory efficiency throughout therapy. Therefore, low intensity laser application is effective in reducing TMD symptoms, and has influence over masticatory efficiency [Ev2 (0.2423) and Ev3 (0.2043), observed in the interaction Evaluations x Probes for effective dosage].

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emporomandibular dysfunction (TMD) is considered a subcategory of musculoskeletal disorders. It is recognized as the major cause of nondental orofacial pain.¹ TMD is a collective term that comprises a number of clinical problems involving masticatory musculature, the temporomandibular joint (TMJ) and its associated structures, or both. Pain is the most common feature; usually in masticatory muscles, in the pre-auricular area of the TMJ, and resulting from aggravation during mastication in joint function. Hence, TMD patients usually have limited or asymmetric mandibular movements in addition to experiencing joint sounds.² Some TMD signs and symptoms pose strong influences over basic mouth functions, such as feeding and phonation, resulting in substantial functional limitation. Approximately half the patients from a clinic treating orofacial pain presented difficulties chewing food. Additionally, about one-third of the patients reported problems eating and feelings of depression or dissatisfaction with life.³

Treatment should be based upon precise diagnosis, establishment of information regarding possible etiological factors, signs, and symptoms of each patient. Treatment should begin with therapies designed to relieve symptoms, reduce pain, recover functions, and enable patients to resume their daily activities.² Therefore, as in other musculoskeletal conditions, TMD signs and symptoms can be transitory and self-limiting. Little is known about which sign or symptom is to become severe throughout the dysfunction's natural course. However, early aggressive and irreversible treatments, such as complex occlusal therapies and surgeries, should be avoided.⁴

Most current TMD treatments are conservative.⁵ Although different studies have reported symptom improvement with early physiotherapy, controlled comparative studies are scarce, and there exist problematic issues in terms of treatment standardization.⁶ Light amplification by stimulated emission of radiation (laser) is one of the most recent treatment modalities in the field of physiotherapy. Low Intensity Laser Therapy (LILT) is suggested to have biostimulating and analgesic effects through direct irradiation without causing thermal response.7 It has been studied in several musculoskeletal pain syndromes and contradictory results have been reported. Few studies have investigated the efficacy of laser therapy in TMD.8 Due to utilization of different types, frequencies, and duration of laser radiation in various patient groups, the results could not have been standardized.

The purpose of this study was to evaluate the analgesic effect of LILT and its influence on masticatory efficiency in patients with temporomandibular dysfunctions.

Materials and Methods

Patient Selection

Fourteen (14) patients presenting TMD symptoms were selected at the Temporomandibular Disorder Center of the School of Dentistry, University of São Paulo. All patients presented natural dentition, did not wear any removable dentures, or did not have any periodontal problems. Participants answered a questionnaire used by this institution. Sample selection was determined after standardized and complete clinical examination, based upon the criteria set forth by the American Academy of Orofacial Pain.² This included patient's history, masticatory and cervical muscle palpation, palpation of lateral and posterior aspects of the temporomandibular joint, joint noise auscultation, and panoramic radiograph. Inclusion criterion for the sample was diagnosis of TMD

with pain in the joint area, associated or not with muscle tenderness. The sample included those with capsulitis, synovitis, retrodiscitis, and painful disk displacement with reduction. Patients were informed about the therapy and signed a written consent form approved by the Ethics Committee of the School of Dentistry, University of São Paulo (Process #2005.1.700.58.0). Exclusion criteria were: chronic use of analgesic, anti-inflammatory and/or psychotropic medication, occlusal splint, or other treatment for pain control. Before participating in this study, selected patients had either been waiting for treatment at least six months, were chronic patients (IASP-Subcommittee on Taxonomy, 1986),9 or were without any form of professional care. The patients were randomly divided into two groups: the Active Group (received the effective dosage) and the Placebo Group (received the placebo application). Upon completion of the study, researchers committed to treating those patients belonging to the placebo group.

Laser Device

The apparatus used was the GaAlAs Twin Laser (MM Optics, São Carlos – SP, Brazil), which operates with a continuous laser beam (780 nm wavelength; 70 mW power output). For placebo treatment, the manufacturer supplied a probe, which does not emit radiation, but contains a sonorous mechanism for application time. The power output used was 70 mW for 60 seconds, resulting in a dose of 105J/cm2. According to the safety instructions, all individuals close to the laser beam wore protective glasses.¹⁰

Laser Application

Applications were accomplished in continuous mode and in contact with the skin at five points located within the TMJ area: lateral point (LP), superior point (SP), anterior point (AP), posterior point (PP), posterior-inferior point (PIP) of the condylar position (**Figure 1**). This was done on both right and left sides, twice per week for four weeks, totaling eight sessions. During applications, the probe was covered with PVC film, and clinicians wore individual safety equipment.

Double-Blind Study

For this double-blind study, two identical probes supplied by the manufacturer were used: one for the active laser and one for the inactive placebo laser. They were marked with different letters (A and B) by a clinician who did not perform the applications. During the entire study, neither the clinician nor the patient knew whether the probe was active or inactive. Probes were identified at the end of applications and evaluations.

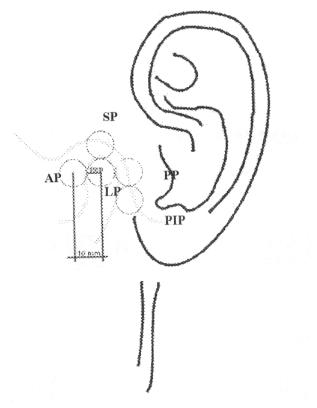


Figure 1

Points of laser application. LP: lateral point; SP: superior point; AP: anterior point; PP: posterior point; PIP: posterior-inferior point of the condylar position.

Colorimetric Method

Rectangular PVC capsules (50 mm x 35 mm; JP-Pharmaceutical Laboratory - Ribeirão Preto) were used for evaluating masticatory efficiency. The capsules were composed of fuchsin based granules (one mm diameter; **Table 1**) and had their smash resistance determined in a universal testing machine (EMIC Equipments and Trial Systems Ltd, São José dos Pinhais, PR, Brazil) equipped with a load cell of 20Kgf to measure tension force until breakage.¹¹

Before the tests, patients remained comfortably seated in a dental chair chewing sugarless gum (Trident, Cadbury-Adams USA) for four minutes. Patients were then asked to chew on a capsule for 20 seconds, and after five minutes, this procedure was repeated with another capsule. The content of each chewed capsule was dissolved in five ml of water, by continuously mixing the solution for 30 seconds. The solution was then filtered and centrifuged in order to remove the casing as well as the grains that had not been triturated. A UV visible spectrophotometer (Beckman DU – 70, Beckman Coulter, Inc. Fullerton, CA) was used to measure absorbance values of the

l able 1				
Granule Composition				
Granule components	Weight			
Lactose	20.60g			
Microcrystalline cellulose	36.85g			
Starch	17.10g			
Sucrose	17.10g			
Hydrogenated oils	8.05g			
Basic fuschin	0.16g			
Water	60ml			
Covering substance				
Eudragit E 100 at 5% in acetone	50ml			

fuchs solution released while patients chewed the capsules dissolved in an aqueous medium.

Evaluations

Evaluations were based on pain level using the Visual Analogue Scale (VAS) immediately after direct manual palpation of the condyle lateral pole (LP) in the pre-auricular region (PA), and of the external auditive duct (EA) on both sides (right-R and left-L). All patients were requested to indicate their level of pain according to a scale rating from 0 to 10 (0 indicates absence of pain; 10 indicates presence of intense pain).

When capsules are chewed, constituent grains are fractured and fuchsin is released due to the energy used. Therefore, masticatory efficiency is observed through absorbance values of the fuchsin solution dissolved in an aqueous medium. The UV visible spectrophotometer (Backman DU – 70) allows for obtaining coloration intensity values in nanometers (nm).¹¹

Three evaluations were performed: Ev1- before treatment; Ev2- immediately after the eighth application; and Ev3- 30 days after the last application. All procedures were performed by the same clinician who had been previously instructed in calibration of the manual palpation to provide reliable pain measurement under these conditions.¹² Data obtained were submitted to statistical analysis (ANOVA, Tukey, and Kruskall Wallis tests).

Results

Original data obtained for the VAS are shown in **Table 2**.

The experimental design was submitted to statistical analysis (software GMC 7.0) using Analysis of Variance and Tukey test, which indicate the statistical significance for a determined factor and judges the differences among

	y		ebo Doses in T			
Probes	E. A	Placebo	F 0	E 4	Active	
Evaluation x palpations	Ev 1	Ev 2	Ev 3	Ev 1	Ev 2	Ev 3
LPR	0	2	4	2	0	1
	2 7	0	0	2	1	2
		2 2	3 2	0	3 2	0
	5	2 5	2 7	2		2 2
	6 3	5 2	5	3 0	1 2	23
	8	8	7	0	0	0
DAD	_	0	-	0	0	
PAR	5	6	7	2 2	0	1
	5	2	5		0	3
	7	3	4	0	0	4
	4	3	2 7	3 2	3	3
	7	5 3	6		1 6	1
	4 6	7	5	6 0	0	4 1
EAR	7	8	7	2	0	0
	5	5	8	2	0	0
	8	2	5	3	0	4
	6	4	3	1	1	2
	9	3	7	0	0	2
	6	3	6	8	0	6
	6	7	0	1	1	1
LPL	0	5	2	2	0	2
	3	0	0	4	0	4
	7	2	3	6	0	3
	5	2	2	1	1	1
	3	5	5	0	0	1
	3	2	7	0	2	3
	8	7	9	1	0	0
PAL	2	7	5	2	1	2
	7	3	4	1	0	0
	7	2	4	0	4	0
	6	2	2	1	0	0
	5	5	5	2	1	2
	5	3	6	3	6	6
	6	8	6	1	0	0
EAL	5	8	5	3	0	1
	3	5	7	3	Ő	0
	8	3	3	0	Ő	0
	7	3	3	1	0	1
	2	3	4	1	1	2
	6	4	6	0	5	5

LP: lateral pole of the condyle; PA: pre-auricular region; EA: external auditive duct; R: right; L: left

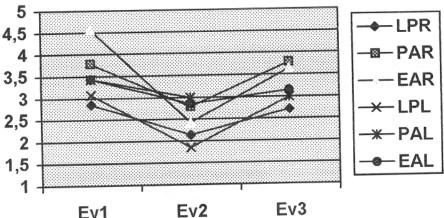
the averages that compose the evaluated factor, respectively. Analysis of Variance revealed significant difference (a=1%) for the variation factor Probes (Pr), and statistical significance at 5% for the factor Evaluations (Ev), as well as for the interaction Probes x Evaluations x Palpation. For the factor Palpation (P) and the interaction between the variation factors Evaluations x Palpation, Probes x Evaluations, and Probes x Palpation, there was no statistical significance. After analysis of results regarding the confrontation of means by Tukey's critical value (0.73459%) it is observed that for the Evaluation factor (independent of sessions, points used, and palpated regions), two groups were formed. The first consisted of Ev2 (2.5119). It is characterized as having fewer painful symptoms and significance at a 5% difference probability level than Ev3 (3.2142) and Ev1 (3.5238). These formed the second group. For the Palpation factor (independent of evaluation sessions and points used) there was no statistical significance among palpated regions. Independent of evaluation sessions and palpated regions, a 1% difference probability was observed for the Probes factor among the studied samples. When an effective dose was applied (average 1.5158) there was improvement in painful symptoms compared to subjects who received placebo (average 4.6507). No statistical significance was found for the interaction Evaluations x Palpation. However, observing Figure 2, it is clear that painful symptoms improved as of the second evaluation.

Average numerical values regarding masticatory efficiency are depicted in **Table 3**. The Kruskal-Wallis parametric test revealed that, for the Probes factor, there was no statistical difference between groups (effective dose, average 0.2153; placebo dose, average 0.1648). Multiple comparisons of the Evaluations factor showed no statistical difference among evaluations (Ev1 = 0.1655; Ev2 = 0.2122; Ev3 = 0.1924). Though there were no statistical differences, Ev2 presented a higher numerical value for coloration measured by the spectrophotometer. Better masticatory efficiency was observed in the interaction Evaluations x Probes for the effective dose in Ev2 (0.2423), followed by Ev3(0.2043). The worst masticatory efficiency behavior was observed when the placebo dose was applied in Ev1(0.1317) (**Figure 3**).

Discussion

At present, TMD remains a complex disorder which is sometimes difficult to define and can be challenging to diagnose and manage. At all times, physical therapy will continue to play an important role in conservative treatment.^{13,14}

Based on the results of experimental studies and therapeutic evaluations, LILT is preferred in the management of TMD through its analgesic, anti-inflammatory and biostimulating effects. Even though the mechanism behind its analgesic effect is not well understood, increased pain threshold through alteration of neuronal stimulation and firing pattern and inhibition of medullary reflexes are thought to be involved.¹⁵ Few studies have been pub-



Evaluations x Palpation

Figure 2

Graph of interaction between evaluations x palpations for symptoms. LP: lateral pole of the condyle; PA: preauricular region; EA: external auditive duct; L: left; R: right.

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Table 3 Averages of Numeric Values for Masticatory Efficiency (nm)					
Probes x evaluations	Placebo	Active			
Ev 1	0.0731	0.0886			
	0.0702	0.1181			
	0.2211	0.1495			
	0.0626	0.1899			
	0.1563	0.1560			
	0.1679	0.2344			
	0.1708	0.4589			
Ev 2	0.1098	0.1355			
	0.0987	0.1448			
	0.3724	0.1811			
	0.0733	0.2146			
	0.2057	0.2004			
	0.1962	0.5293			
	0.2195	0.2908			
Ev 3	0.1195	0.1264			
EVO	0.1283	0.1760			
	0.3305	0.1867			
	0.0609	0.2117			
	0.2086	0.2008			
	0.1929	0.2237			
	0.2238	0.3051			

lished concerning clinical efficacy of laser treatment in TMD.^{4,6,8,15,16} There is still a lack of scientific explanation in the literature for the apparent effectiveness of laser in the treatment of pain. Although some authors present opposite results, other studies demonstrate that the reduction of pain is effective.^{14,17,18} A great variation was observed in terms of type, duration, and frequency of laser employed.¹⁶ The doses used in these studies are different, making comparisons difficult while limiting conclusions. It is still unclear if the effect of laser is dependent upon the wavelength of light, irradiance, or dosage.¹⁹ It has been proposed that infrared laser penetrates deeper than ultraviolet laser and is most effective between the frequency ranges of 700-1000 Hz.¹⁷

The results of our random placebo-controlled study, designed to investigate the efficacy of LILT in TMD, are rather promising. A significant improvement in pain parameters was obtained in the active treatment group. In contrast, it was not significantly improved in the placebo group. With regard to the between group comparison, Analysis of Variance revealed a significant difference and, independent of evaluation sessions and palpated regions, a 1% difference probability was observed among the studied samples. However, no statistical differences were found for the parameter masticatory efficiency. LILT was previously demonstrated to improve pain and masticatory functions.^{15,20} In this study, pain relief was obtained, but not physical improvements such as in other studies.^{4,21}

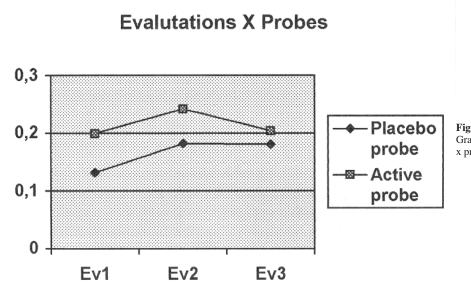


Figure 3 Graph of interaction between evaluations x probes for masticatory efficiency.

LOW INTENSITY LASER THERAPY IN TMD

Few studies have addressed the effects of laser in TMD, yet improvement in pain has been demonstrated in most of them. However, shortcomings such as small number of subjects, lack of a control group and diversity of techniques employed have caused weakness in reliability.16 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.⁴ The power of the placebo effect has been demonstrated in the treatment of TMD. A good relationship between practitioner and patient, associated with the highly technological appearance of the laser, might explain similarities between groups in terms of masticatory efficiency. Moreover, TMJ dysfunction's self-limiting aspect partially explains the response to treatment in the placebo group.⁴ During treatment, there was great receptiveness to the laser as well as effective improvement in symptoms. This caused a positive psychological effect, which reflected on values found for masticatory efficiency in both groups. However, masticatory efficiency did not present statistically significant differences between the two groups studied. These contradict VAS values and can lead to a hypothesis supporting lack of laser effectiveness, suggesting that laser acts as a placebo treatment. Results do not support the hypothesis that symptom improvement leads to better stomatognathic system functioning.^{15,16,20} The reduced sample size and short period of application and patient observation may be reasons for nondifferentiation between groups. Although no significant differences were found for masticatory efficiency in analysis between groups, the greatest mean value was met in Ev2. Better masticatory efficiency was observed in the interaction Evaluations x Probes for effective dosage in Ev2 (0.2423), followed by Ev3 (0.2043), which could be considered a meaningful clinical finding. The cumulative effect of laser^{21,22,23} could have been responsible for the tendency in pain reduction and the improvement of masticatory effectiveness observed in Ev2.22,24 This tendency toward improvement in masticatory efficiency may be related to the reduction in muscular contraction and inflammation²⁵ resulting from the laser's anti-inflammatory effect.¹⁹ It may also be related to the secondary muscular inhibition that occurs due to sensorial hyperactivity of joint receptors.15

Therefore, studies with increased sample size and long-term follow-up should continue in order to determine the exact role of laser therapy in decreasing musculoskeletal pain and, consequently, in increasing masticatory function. Further research should focus on optimal treatment parameters such as frequency and duration with double-blind, random, placebo-controlled trials. Comparing effectiveness of different modalities in TMD deserves further investigation. Certainly, for controlling chronic conditions over a long period, the use of more than one treatment modality is mandatory. Clinical patient follow-up is also necessary to control all factors involved.

Conclusions

Resulting from this study, the effects of LILT on pain were clearly demonstrated. Superior results of the active group over the placebo group are evident. Results do not support our hypothesis that symptom improvement leads to better stomatognathic system functioning, due to similarities between groups and the placebo effect in terms of masticatory efficiency. Finally, the LILT is effective support therapy for treatment of patients with TMD and pain relief. Though there were no statistical differences between groups and between the evaluations, this research showed a low intensity laser application influence over masticatory efficiency (Ev2 = 0.2423), observed in the interaction Evaluations x Probes for effective dosage. Based on the noninvasive aspect of this therapy, further studies should be performed in order to better define effective doses. Also in need of further investigation are the effects of interaction with other support therapies as a way to help improve masticatory efficiency and achieve treatment success in the long term.

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