Rehabilitative Medicine

Efficacy of red and infrared lasers in treatment of temporomandibular disorders — a double-blind, randomized, parallel clinical trial

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Aim: Low-level laser therapy has still not been well established, and it is important to define a standardized protocol for the treatment of temporomandibular disorders (TMDs) using low level laser. There is no consensus on controlled clinical trials concerning the best option for laser therapy with regard to wavelength. The aim of this study was to evaluate the efficacy of red and infrared laser therapy in patients with TMD, using a randomized parallel-group double-blind trial.

Methodology: Each hemiface of 19 subjects was randomized to receive intervention, in a total of 116 sensitive points. Pain was measured at baseline and time intervals of 24 hours, 30 days, 90 days, and 180 days after treatment. Irradiation of 4 J/cm^2 in the temporomandibular joints and 8 J/cm^2 in the muscles was used in three sessions.

Results: Both treatments had statistically significant results ($P<0.001$); there was statistical difference between them at 180 days in favor of the infrared laser ($P=0.039$). There was improvement in 24 hours, which extended up to 180 days in both groups.

Conclusion: Both lasers are effective in the treatment and remission of TMD symptoms.

Keywords: Laser, Temporomandibular disorders, Quality of life, Orofacial pain

Introduction

According to the American Academy of Orofacial Pain, temporomandibular disorder (TMD) is defined as a collective term that comprises a large number of clinical problems, which affect the masticatory muscles, the temporomandibular joint (TMJ) and associated structures. TMJ disorders are divided mainly into joint and muscle disorders, and their diagnosis is important in the treatment plan and prognosis.[1]

Non-surgical treatments for TMDs generally consist of medications, physical therapy and laser photobiostimulation.[2] Low laser therapy is defined as energy density lower than 500 mW/cm^2.[3] There are no side effects or contraindications related to this power, which can also be called low-level laser therapy (LLLT), provided that this therapy is correctly administered.[4] Therapeutic lasers range from the visible (red) to invisible (infrared) light, close to the electromagnetic radiation spectrum. The most commonly used wavelengths are those between 600 and 1000 nm. They are relatively poorly absorbed and are therefore transmitted through the skin and mucous membranes.[5]

Depending on the wavelength, laser therapy has different effects on the irradiated tissues. The red wavelength has lower activity in nerve tissue, and greater effectiveness in more pigmented tissues such as the vascular type.[6] Infrared laser has greater depth of penetration and greater affinity for non-pigmented tissues such as nerves, providing a photoelectric effect on irradiated cells, increasing the membrane potential and thus reducing nerve impulse conduction.[7,8]

LLLT therapy has still not been well established, and it is important to define a standardized protocol for the treatment of TMD using low-level laser. There

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is no consensus in the literature on controlled clinical trials concerning the best option for laser therapy with regard to wavelength.[2,9–11] There are few clinical trials that have used appropriate methodology and standardized treatment protocols. The aim of the present study was to evaluate and compare the efficacy of red and infrared laser therapy in relieving pain and improving the quality of life of TMD patients.

Methods

Subjects

This randomized and double-blind clinical trial was approved by the Ethics Committee on Human Research (Protocol 092/10) of Federal University of Jequitinhonha and Mucuri Valleys in accordance with Declaration of Helsinki of 1975, revised in 2008. The participants signed a term of Free and Informed Consent before the study.

The sample size was based on a previous study by Conti,[9] who considered a sample of 20 patients adequate to conduct a similar randomized trial.

Participants were selected among patients referred to the dentistry clinic of the Federal University of Jequitinhonha and Mucuri Valleys, from September 2010 to November 2010. The inclusion criteria were: systemic health; TMD diagnosed by the Research Diagnostic Criteria for Temporomandibular Disorders questionnaire (RDC);[12] patients presenting trigger points within pain score $\geqslant 5$ on palpation according to a numerical scale. The exclusion criteria were: participants who made frequent use of analgesics, non-steroidal anti-inflammatory drugs and antidepressants; had previously undergone TMD treatment, or suffered facial trauma.

Nineteen patients, 15 women and 4 men, aged 21–55 years old (mean age: 35 years), were enrolled in this study. In these patients, there were 116 sensitive points that were divided into two sides — left and right, and each side received an intervention. The sensitive points were palpated, according to the RDC: (1) in TMJ (posterior ligament and lateral pole); (2) extra-oral muscles (temporalis, masseter, posterior mandibular region, and submandibular region); and (3) intra-oral muscles (area of the lateral pterygoid and temporal tendon). The patients were also palpated in the cervical muscles (suboccipital, sternocleiodomastoid, and trapezius).

Randomization, allocation, concealment, and masking

Restricted randomization was performed by an independent researcher blinded to the patients. Two opaque envelopes were assigned to each patient, one for the type of treatment to be performed (red or infrared laser), and the other indicating the side that would receive the intervention (left or right hemiface). Lottery drawing was used to take a paper out of each envelope, showing the type of intervention and the corresponding hemiface. The treatment to be performed was revealed immediately before laser applications.

The researcher kept track of interventions by means of a form on which to write the points and the corresponding interventions. The researcher who made the assessments at baseline and follow-up did not have access to the above-mentioned form until the end of the study. The interventions were performed by the same operator, who did not participate in the assessment.

The patient was blinded to the device used (Clean Line Easy Laser), which has two independent tips, one for each type of wavelength: 660 nm (red laser) and 795 nm (infrared laser). This was masked, as the patient wore glasses with black lenses and a mask, which prevented the patient from seeing the red light emitted by the laser. All measurements were recorded by a blinded, trained, and calibrated examiner (ODF).

Treatment and assessments

The sensitive points were detected by palpation and mapped according to the RDC and recorded on the appropriate form (Fig. 1).[13] These painful points received laser applications in accordance with the manufacturer's instructions. The device used was the Clean Line Easy Laser — Low Level Laser Treatment. The laser was applied (8 J/cm^2) on the pain points of the muscle, with an interval of 48 hours between applications. In the joints with sensitivity, a dose of 4 J/cm^2 laser was applied with an interval of 48 hours between applications. Three therapy sessions were conducted according to the controlled trial protocol used by Conti.[9]

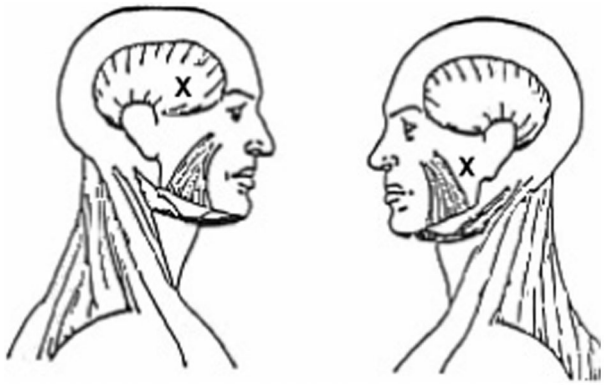

Figure 1 Draw the laser application. Peters and Gross (1995),[13] modified.

Biosafety standards for infection control and waste disposal were implemented in all therapy sessions. Laser was applied in accordance with the manufacturer's recommendations, as regards both the dosimetry applied and protection from radiation with the use of glasses by the operator and patient.

The first assessment was considered baseline. All subsequent assessments were made by the same operator and recorded on appropriate forms. The patients were assessed at time intervals of 24 hours and 30 days (short-term assessment), 90 days (medium-term), and 180 days (long-term) after the last intervention. In all assessments, the patients were asked questions about the treatment: better, same, or worse in comparison with the initial condition.

The amount of pain was assessed by palpation in the mapped points. A numerical rating scale was used to record the pain related to the stimuli, with a pain score from 0 (no pain) to 10 (extreme pain).

The quality of life was measured using the Oral Health Impact Profile (OHIP-14) instrument.[14] The OHIP-14 is a disease specific measure of people's perception as regards the social impact of dental disease on their welfare. The participants answered the questionnaire about the interference in their quality of life before the treatment and 6 months after undergoing treatment.

Statistical analysis

Statistical analysis was performed using the software program SPSS® for Windows® (SPSS, Inc., Chicago, IL, USA), version 20.0. Exploratory data analysis provided frequencies, means, and standard deviations. The confidence interval for all tests was 95%. The assessment of normality of data was performed using the Kolmogorov–Smirnov test. The Mann–Whitney test was used for comparisons between groups, and the Wilcoxon test to compare the same group. In this study, it was decided to analyze "per protocol," i.e. the data of only those participants who adhered to the study, and completed all procedures through to the end were included in the analysis.

Results

Among the patients assessed for eligibility ($n=23$), one did not reach the minimum score for pain, and three dropped out before randomization. All patients ($n=19$) presented chronic myofascial pain. In the follow-up, two patients were lost: one forgot to get the last intervention, and another did not receive the laser therapy. A total of 116 sensitive points were allocated to this study. There were 15 articular points and 46 muscle points treated with red laser, and 10 articular points and 45 muscle points treated with infrared laser (Fig. 2). The treated areas included 51 intraoral muscle points, 46 extraoral muscle points, and 25 sensitive joints.

There were no statistical differences ($P>0.05$) between the groups at baseline, 24 hours, 30 days, and 90 days. At 180 days, there was significant difference between the red and the infrared group ($P=0.039$) (Table 1). In the intragroup analysis, both showed similar results of improvement at the time intervals of 24 hours, 30, 90, and 180 days when compared with the baseline values ($P<0.05$). The improvement made within 24 hours lasted 180 days. The mean of the pain score regarding the red and infrared laser is shown in Fig. 3.

Total OHIP-14 scores varied from 2.00 to 37.00 points with a median of 22.00 at baseline, and from 0.00 to 38.00 points (median=14.00) at 6 months ($P=0.01$).

In the self-assessment at the end of treatment, 13 (76.5%) patients reported that there was an improvement; 1 (5.9%) noted a worse condition; and 3 (17.6%) subjects stated that there was no difference (Table 2).

Discussion

According to several studies,[9,11,15,16] there is a prevalence of female subjects (90%) and an average age of 35 years in patients with TMD, which is similar to the present study. This may be due to the fact women are more concerned about their health than men.

Laser phototherapy is a non-invasive treatment modality that has been widely used in the management of many different diseases, among them myoarticular disorders. It is often used in the clinical practice of physical therapy for pain relief and tissue regeneration, and this technique has been certified as beneficial in the treatment of TMD. The therapy produces anti-inflammatory and analgesic effects, and modulates cellular activity, as has been proven in several studies.[2,15,17–19]

In a randomized and controlled clinical study,[20] the combination of two diode lasers has been studied in the treatment of TMD versus placebo, with statistically significant improvement in immediate post-treatment evaluation, which was maintained for up to 1 month. Because lasers interact in different ways in biological tissues, it is believed that when the lasers of different wavelengths are used, they would show different results.[21] This could be noted in the present study, in which the results showed that infrared lasers were more effective than the red laser in achieving remission of painful symptoms and providing

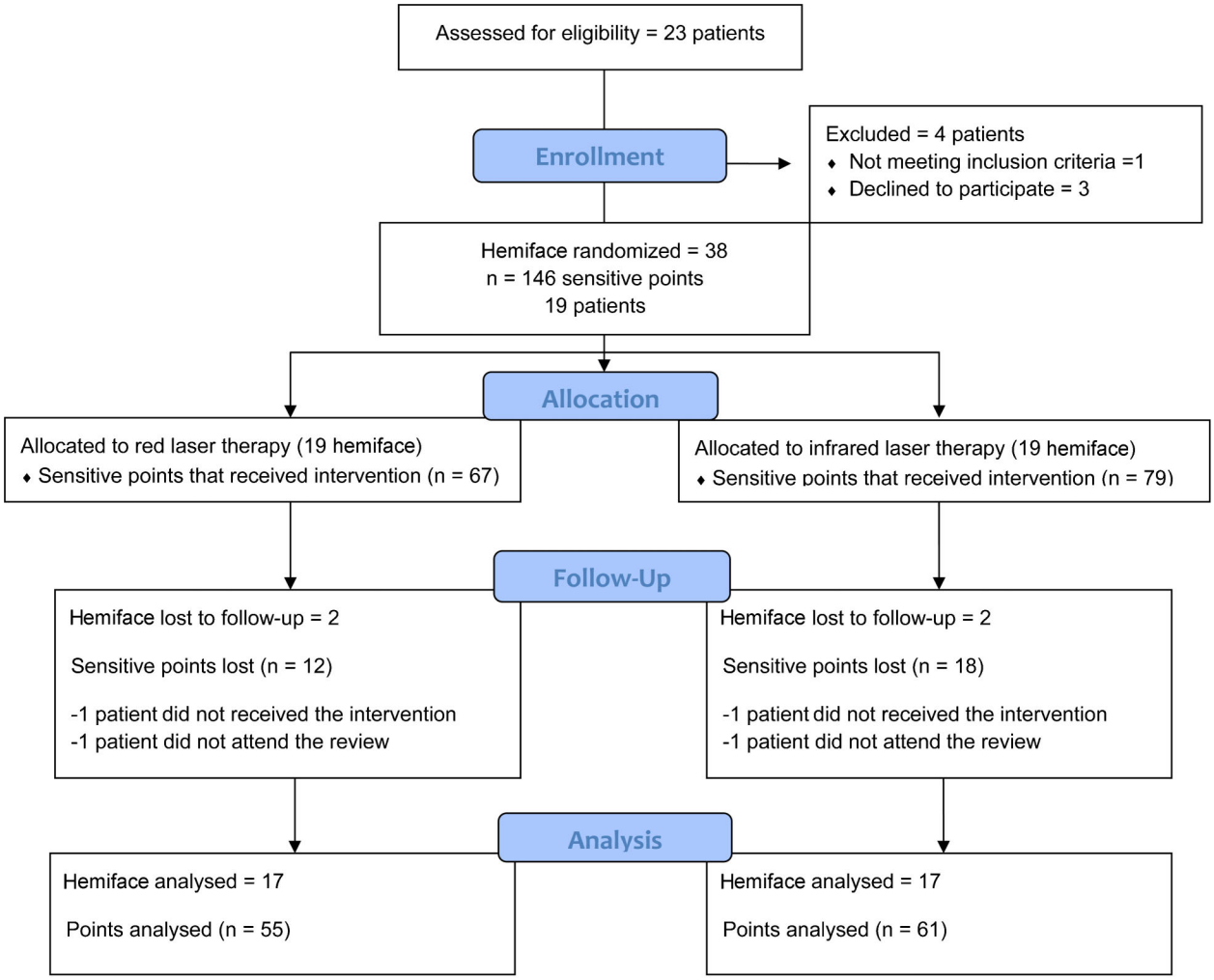

Figure 2 Flowchart of the participants.

Table 1 Mean (standard deviation) of scores obtained by the palpation of the sensitive points

		Assessment	Mean (SD)	*P**	*P***
Laser	Red	Baseline	7.38 (1.7)	Baseline × 24 hours <0.001	
		24 hours	5.04 (2.4)	Baseline × 30 days <0.001	
		30 days	4.76 (2.8)	Baseline × 90 days <0.001	
		90 days	4.84 (2.9)	Baseline × 180 days <0.001	
		180 days	4.95 (2.9)	24 hours × 30 days 0.346	
				24 hours × 90 days 0.499	
				24 hours × 180 days 0.386	
				30 days × 90 days 0.756	
				30 days × 180 days 0.585	
				90 days × 180 days 0.978	Baseline 0.121
	Infrared	Baseline	6.91 (1.6)	Baseline × 24 hours <0.001	24 hours 0.471
		24 hours	4.65 (2.5)	Baseline × 30 days <0.001	30 days 0.230
		30 days	4.20 (2.4)	Baseline × 90 days <0.001	90 days 0.334
		90 days	4.44 (2.5)	Baseline × 180 days <0.001	180 days 0.039
		180 days	3.73 (2.6)	24 hours × 30 days 0.079	
				24 hours × 90 days 0.160	
				24 hours × 180 days 0.005	
				30 days × 90 days 0.281	
				30 days × 180 days 0.051	
				90 days × 180 days 0.022	

Note: *Wilcoxon test.
**Mann–Whitnney test.

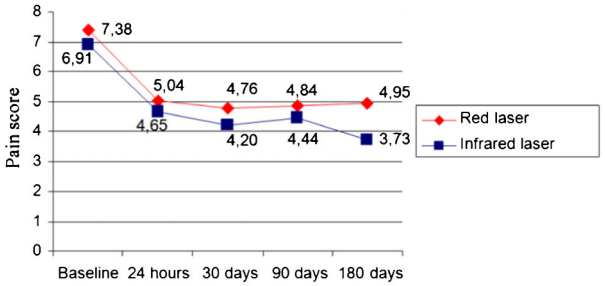

Figure 3 Mean of the pain score according to the time evaluation.

Table 2 Self-evaluation after treatment

At the end of your treatment, how do you consider the result?	*n*	%
Better	13	76.5
No difference	3	17.6
Worse	1	5.9

immediate improvement, which was maintained for 180 days of the study. There was no statistically significant difference between them regarding the other evaluation time.

In one study, HeNe laser therapy, low power was analyzed in a double-blind and placebo-controlled trial. Twenty treatment sessions were performed on a total of 52 patients diagnosed with TMD, and no statistical difference was found between LLLT and placebo in any of the assessments periods.[16] Psychological factors, such as the desire to feel better, may have influenced the physiological processes, culminating in the desired result without differentiating between the two treatments[20,22] or even the methodological quality of trials, and may have contributed to these results.[23]

LLLT was applied in 74 patients, with the treatment of choice for TMJ being infrared and red laser wavelength for muscle points, applied in 12 sessions. Significant improvement was found after both treatments at the end of the study.[21] This article was an experience report that did not have a standardized application protocol for the intervention; in other words, the dosimetry applied was not the same in all treatment sessions, so caution is needed when considering the results. In the present study, the dosimetry was applied in accordance with the manufacturer's recommendations, and the same protocol was used in three therapy sessions, according to the previous study by Conti.[9]

In an *in vivo* laboratory study[24] that evaluated the analgesic effect of red and infrared laser therapy at time intervals of 5, 20, 25, and 30 minutes accumulated in the tissues of intact mouse footpads, red was found to be the wavelength that showed the best analgesic action. In this study, the performance of neither laser showed any statistically significant differences from the baseline values, with immediate improvement obtained in 24 hours, which remained until 90 days of follow-up.

At 180 days, the infrared laser resulted in a more intense and prolonged analgesic and anti-inflammatory effect, showing the best efficacy in reducing the painful symptomatology compared to the red laser. Low-level laser in the infrared spectrum (with a wavelength of over 700 nm) has better penetration into tissue (between 3 and 5 cm), than red laser (between 600 and 700 nm, penetrating 2–5 mm), in spite of also being absorbed in the more superficial regions.[25]

In a study, in which the subjective evaluation of pain was compared after treatment with lasers using two types of dosimetry and a placebo,[8] the improvement in TMD-related pain was self-reported by 76% of patients with chronic pain treated with infrared LLLT, and by none of the patients treated with the placebo laser. In the present study, when patients were subjected to self-assessment at the end of treatment after 90 days, all patients reported a better clinical condition when compared with their initial state before the intervention. At the 180-day evaluation, 13 patients still considered that their condition was better, and one patient felt worse.

This suggests that laser therapy can be effective for TMD, in spite of the pain relief occurring with spontaneous remission at 6 months, and that the symptoms may begin to return in some patients.[26] Moreover, the pain scale showed a statistically significant difference when comparing the OHIP-14 questionnaire applied before and after interventions.

Some authors attribute the ability of low-intensity laser therapy to assist in the symptomatic treatment of pain, providing the patient with a considerable degree of comfort moments after application. In the study of Venancio *et al.*,[26] the treatment was performed twice a week for 3 consecutive weeks (laser and placebo), and each patient was evaluated immediately before the first, third, and fifth sessions of treatment and at follow-up after 15, 30, and 60 days after treatment. From the first session, statistically significant differences were observed in both groups during the follow-up time intervals, and although the results showed no statistically significant differences between groups (laser and placebo), it is believed that laser therapy is effective for pain reduction.

The relative effectiveness of laser therapy for the treatment of TMDs is still controversial. Some

authors have reported the efficacy of laser treatment to be superior to that of the placebo in a double-blind study,[7,11] while others found no significant differences between laser and placebo for measures of TMJ pain.[9,26] In view of this fact, the outcome in studies of LLLT may depend on the sample of patients,[27–30] treatment procedures, wavelengths, dosimetry of application, and design study.[5,26] According to Vieira *et al.*,[31] larger observation periods could increase the capacity of the study to detect differences between test and placebo groups.

Conclusion

The two types of lasers were effective in the treatment and remission of TMD symptoms. The immediate improvement obtained in 24 hours lasted 180 days, causing a significant impact on the improvement in quality of life. The infrared laser showed better effectiveness at 180-day follow-up.

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