




Effects of different photobiomodulation dosimetries on temporomandibular dysfunction: a randomized, double-blind, placebo-controlled clinical trial

Rosana Mengue Maggi Borges¹ · Daniela Steffen Cardoso¹ · Bianca Chuaste Flores¹ · Raquel Dimer da Luz¹ · Catiuci Roberta Machado² · Guilherme Pessoa Cerveira³ · Rodrigo Boff Daitx³ · Marcelo Baptista Dohnert³ 

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Abstract

Changes involving temporomandibular joint, masticatory musculature, and associated structures characterize temporomandibular dysfunction (TMD). The analgesic and anti-inflammatory effect produced by photobiomodulation has contributed to pain relief and functional improvement. However, the parameters to be used have not yet been well established. The aim of this study is to compare the efficacy of three different photobiomodulation dosimetries in the treatment of patients with TMD. A randomized, double-blind, placebo-controlled clinical trial with 44 subjects divided into the groups 8 J/cm² ($n = 11$), 60 J/cm² ($n = 11$), 105 J/cm² ($n = 11$), and control ($n = 11$). Pain, symptom severity, and joint mobility were evaluated before and after a ten-session protocol of photobiomodulation with AlGaAs laser (830 nm), at a power density of 30 mW/cm². The mouth opening increased in the 8-J/cm² group from 10.49 ± 4.68 to 15.40 ± 6.43 degrees, and in the right protrusion from 9.80 ± 4.2 to 12.56 ± 5.40 degrees after the intervention protocol ($p < 0.05$). All groups significantly decreased pain ($p < 0.05$). 830-nm laser photobiomodulation was effective in reducing TMD pain and symptoms at all doses tested. Only the doses of 8 J/cm² were effective regarding maximal opening and protrusion of the mandible.

Keywords Lasers · Physical therapy modalities · Low-level light therapy · Temporomandibular joint disorders · Temporomandibular joint dysfunction syndrome

Introduction

Temporomandibular dysfunction (TMD) is the term used to characterize a set of abnormalities involving temporomandibular joint (TMJ), masticatory muscles, and associated structures [1–3]. The proper functioning and normal range of TMJ movements are extremely important for the performance of vital functions such as chewing, swallowing, sucking, breathing, and speech [4].

When there is an imbalance in this system, a wide range of clinical problems arise. These musculoskeletal disorders develop very characteristic signs and symptoms, the main one being muscle and/or joint pain, which implies the limitation of mandibular movements [5, 6]. In addition to these, other symptoms commonly appear, which may or may not be concomitant, such as cephalgia, cervical pain, joint noise, muscle fatigue, dizziness, hearing loss, and tinnitus [1, 5].

The causes for the onset of TMD are associated with multiple factors, including the presence of parafunctional habits, occlusal factors, inadequate postures, local traumas, and biopsychosocial aspects such as stress, anxiety, or depression [1, 3, 4, 7, 8].

Laser photobiomodulation has become a popular option in the treatment of musculoskeletal syndromes due to its analgesic, anti-inflammatory, and regenerative action [1, 9, 10]. Moreover, this therapy has the great advantage of being of low cost and non-invasive [3, 11].

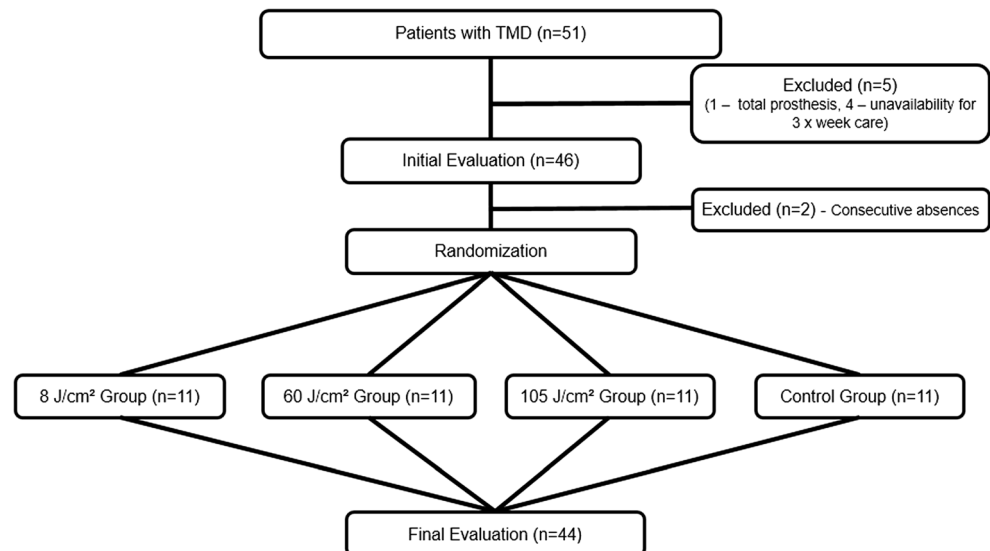
✉ Marcelo Baptista Dohnert
mdohnert@hotmail.com

¹ Physiotherapy Course, Lutheran University of Brazil, Parque do Balonismo, 1900, Torres, RS, Brazil

² Physiotherapist, Torres, Brazil

³ Lutheran University of Brazil, Torres, RS, Brazil

Fig. 1 Study flow chart



Several studies have demonstrated the efficacy of laser in the treatment of TMD, mainly related to the immediate relief of pain after application and recovery of function [2, 5, 7, 10–13]. Notwithstanding, the lack of consensus on which dosimetry to use is evident, and there are controversies in the results between studies that used different parameters [1, 5, 7, 14].

In view of the above, this study aims to compare the efficacy of three different photobiomodulation dosimetries in the treatment of patients with temporomandibular dysfunction.

Material and methods

This is a pilot study. The study was approved by the Ethics Committee of the Lutheran University of Brazil, under number 2011-175H. Participants who met the eligibility criteria were informed about the procedures and signed the Free and Informed Consent Form. The study was registered in the Brazilian Clinical Trials Registry (REBEC) under the number RBR- 4WT6FW.

We used the statistical software EPI-INFO® to calculate the sample size. After reviewing the literature, we observed a TMD prevalence varying from 18 to 22% on the adult population. Knowing that the municipal population is around 35,000, and using a study power of 80%, a 95% confidence interval, an effect power of 10, and a prevalence of 22%, we reached the estimated number of 11 subjects for each study group.

Forty-four subjects of both sexes with a clinical diagnosis of TMD participated in the study. They were referred by dental surgeons from the public and private services of the municipality of Três Cachoeiras/RS.

Subjects with medication to control pain, with contraindications for laser therapy, such as suspicion of infections and/or tumors, and patients using orthodontic appliance or total dental prosthesis were excluded.

The subjects were randomized by an independent researcher through a list of random numbers, assigned into 8, 60, and 105 J/cm² group, and placebo group.

The evaluations were performed at two different time points, initially and soon after the end of the treatment

Table 1 Anatomical points used for the angular analysis of the movement

Movement	Image plan	Anatomical points	Measured angle
Opening	Lateral	Condyle of the mandible and angle of the mandible	Condyle of the mandible × mental protrusion × orthogonal axis “X”
Lateralization	Frontal	1 cm below the anatomical process of the anterior nasal spine and mental protuberance	Nasal spine × mental protrusion × orthogonal axis “X”
Mandibular protrusion	Lateral	Anterior nasal spine line and mental protrusion	Anterior nasal spine × protuberance × orthogonal plane “Y”
Mandibular retraction	Lateral	Anterior nasal spine line and mental protrusion	Anterior nasal spine × protuberance × orthogonal plane “Y”

protocol. Data collection was performed by a collaborating researcher, previously trained with the evaluation instruments and not knowledgeable of the group to which the subject belonged (Fig. 1).

The visual analogue scale (VAS) was used for measuring pain. The Anamnestic Questionnaire of Fonseca et al. [15], which allows classification as without TMD, mild TMD, moderate TMD, and severe TMD, quantified symptom severity.

TMJ mobility was assessed through computerized biophotogrammetry. Thirteen millimeters of spherical surface markers were used in the glabella and 1 cm below the anatomical process of the anterior nasal spine, in the mental protuberance, body, and portion of the condylar process of the mandible. These points were used to guide joint angle measurements, quantified through the program Corel Draw X7® (Table 1).

The images were taken by a 12.1-megapixel digital camera (brand Canon® Power Shot sx40 SH) with auto-zoom. The camera-object distance was fixed at 1.60 m and leveled on a tripod 1 m above the ground. The images were obtained simultaneously in the anterior frontal, right, and left lateral planes. Movements of maximal mouth opening and occlusion, right and left lateralization of the mandible, and mandibular protrusion and retraction were recorded.

The photobiomodulation intervention protocol was performed three times a week, totaling ten sessions, with three levels of energy density. The equipment used was a low-level aluminum gallium arsenide (AlGaAs) laser (brand Ibramed®, model Laserpulse Diamond Line) previously calibrated, with a wavelength of 830 nm, power of 30 mW/cm², and contact area of 0.01160 cm² (Table 2). The placebo group received the



Fig. 2 Application of photobiomodulation points

application of laser therapy with the equipment turned on, but with zero intensity for 15 s at each point. In all groups, photobiomodulation was performed punctually and in contact with the surface, perpendicular to the skin, bilaterally. Four application points were used for each temporomandibular joint. The application points were in the preauricular region and in the external acoustic meatus (Fig. 2).

The SPSS (Statistical Package for the Social Sciences) software, version 22.0, was used to analyze the results. Initially, a descriptive analysis of the variables, expressed as absolute number, mean, and standard deviation was performed. The study groups were statistically analyzed by the Student's *t* test for parametric intragroup analyses. ANOVA was used for intergroup analyses, followed by the Tukey post hoc test. For those data that did not present a normal distribution, the Wilcoxon test was used for intragroup analysis and the Kruskal-Wallis test for analysis between

Table 2 Parameters used in different groups of photobiomodulation

	Energy density of 8 J/cm ² per point	Energy density of 60 J/cm ² per point	Energy density of 105 J/cm ² per point
Wavelength (nm)	830	830	830
Radiation energy per point (J)	0.96	7.2	12.64
Power equipment (mW)	30	30	30
Mode of emission	Continuous	Continuous	Continuous
Spot size (cm ²)	0.11600	0.11600	0.11600
Power density (W/cm ²)	2.59	2.59	2.59
Total irradiated points	Eight (four for each side)	Eight (four for each side)	Eight (four for each side)
Frequency of irradiation	3× week/10 sessions	3× week/10 sessions	3× week/10 sessions
Total irradiation time per point (sec)	32	240	420
Total energy density per session (J/cm ²)	64	480	840
Total radiation energy per session (J)	7.68	57.6	101.12
Total irradiation time per session (sec)	266	1920	3360
Total irradiation time in 10 sessions (sec)	2586	19,200	33,600

Sec seconds

Table 3 Characterization of the initial study sample ($n = 44$)

Variable	Group				<i>p</i> value
	8 J/cm ² ($n = 11$)	60 J/cm ² ($n = 11$)	105 J/cm ² ($n = 11$)	Placebo ($n = 11$)	
Age, years ($n \pm sd$) ^a	35.82 ± 13.77	27.73 ± 9.75	34.82 ± 15.28	29.45 ± 12.45	0.42
Gender, M/F ^b	0/11	1/10	2/9	1/10	0.53
Skin color, n (%) ^b					0.55
White	10 (90.9)	11 (100)	11 (100)	10 (90.9)	
Black	1 (9.1)	0 (0)	0 (0)	1 (9.1)	
Time of pain, months ($n \pm sd$) ^a	38.59 ± 75.75	14.00 ± 21.65	14.00 ± 91.60	7.55 ± 6.56	0.42
Occupation, ($n \pm sd$) ^b					0.39
Diarist	2 (18.2)	0 (0)	0 (0)	0 (0)	
Housewife	2 (18.2)	2 (18.2)	2 (18.2)	0 (0)	
Student	1 (9.1)	2 (18.2)	2 (18.2)	5 (45.5)	
Vendor	0 (0)	2 (18.2)	0 (0)	0 (0)	
Other	6 (55.5)	5 (45.4)	7 (63.6)	6 (55.5)	
Affected TMJ, n (%) ^b					0.82
Right	1 (9.1)	2 (18.2)	1 (9.1)	1 (9.1)	
Left	1 (9.1)	1 (9.1)	0 (0)	0 (0)	
Bilateral	9 (81.8)	8 (72.7)	10 (90.9)	10 (90.9)	

^a One-way ANOVA

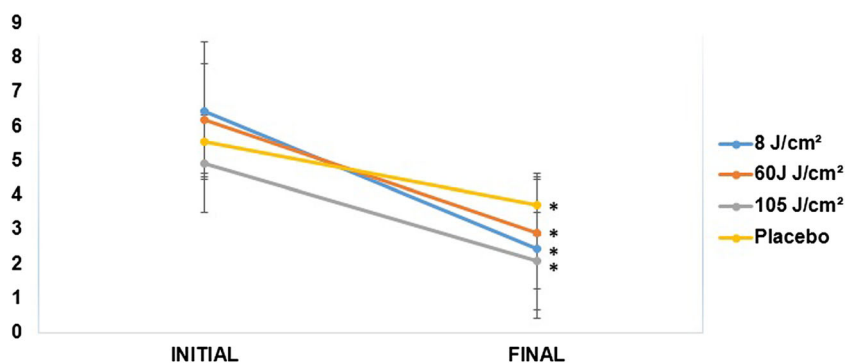
^b Chi-square test

groups. The level of significance established for the statistical test is $p < 0.05$.

Results and discussion

Forty-four subjects participated in the study, of which 90.9% were female. The age was 31.9 ± 12.9 years (ranging from 15 to 59 years). 95.4% were white. The mean time of pain was 77.2 ± 68.7 months. Temporomandibular dysfunction was bilateral in 65.9% of the subjects. The groups were homogeneous regarding age, gender, time of pain, occupation, and affected TMJ (Table 3). The prevalence of the female sex observed in this study corroborates the literature, since it has been described that women present greater TMD symptomatology than men [16–18].

Fig. 3 Results of the initial and final Fonseca questionnaire in the different study groups. [#] $p < 0.05$ relative to the initial evaluation of the same group. Student's *t* test (mean and standard deviation)



All intervention groups, including the placebo group, demonstrated a significant reduction of pain in the VAS from pre- to post-intervention, with no differences between groups. In the 8-J/cm² group, the initial average was 6.45 ± 2.50 , decreasing to 1.88 ± 1.64 in the final evaluation ($p = 0.001$). In the 60 J/cm² group, the initial pain score was 6.11 ± 2.22 , decreasing to 2.70 ± 2.00 ($p = 0.001$). In the 105 J/cm² group, the initial pain level was 4.91 ± 1.51 , decreasing to 2.09 ± 1.97 at the end of the study ($p = 0.001$). Finally, in the placebo group, the initial VAS value was 5.55 ± 2.06 , decreasing to 3.70 ± 2.11 at the end of the study ($p = 0.01$).

A literature review conducted by Aparicio et al. demonstrated a placebo effect of photobiomodulation on pain in 40% of the reviewed studies [1]. The authors believe that TMD patients are susceptible to placebo effects because of the psychological component involved, and that the desire

to feel better seems to influence physiological processes, thus achieving a favorable outcome [1]. Likewise, Shukla and Muthusekar, in their systematic review, found that of the 13 selected studies, seven demonstrated superiority of laser therapy over the placebo effect, while the other six did not demonstrate significant differences between the intervention and placebo groups in relation to pain [19]. Magri et al. verified the efficacy of laser therapy on pain intensity by VAS in 61 women with myofascial pain, using, as a therapy, a laser with 780-nm wavelength, continuous

emission mode, energy density of 5 J/cm² at three points in the masseter muscle, and 7.5 J/cm² at three other points in the anterior temporalis muscle, totaling eight sessions [20]. There was a reduction in pain in both groups, with no differences between the laser therapy and the placebo group [20]. Unlike these results, Mazzeto et al. evaluated the pain symptoms and mandibular movements of 40 patients with TMD, using parameters similar to those in this study (AlGaAs laser, 830 nm, continuous mode at five points around TMJ, power of 40 mW, and energy density

Table 4 Results of initial and final joint mobility in each study group (*n* = 44)

Variable	Group				<i>p</i> value
	8 J/cm ² (<i>n</i> = 11)	60 J/cm ² (<i>n</i> = 11)	105 J/cm ² (<i>n</i> = 11)	Placebo (<i>n</i> = 11)	
Right opening, degrees					
Initial	10.49 ± 4.68	15.01 ± 5.65	17.63 ± 4.84	16.56 ± 5.96	0.02 ^{bc}
Final	15.40 ± 6.43	17.91 ± 6.97	16.28 ± 6.82	16.02 ± 6.85	0.86
<i>p</i> value	0.01	0.13	0.39	0.65	
Left opening, degrees					
Initial	10.81 ± 5.46	13.46 ± 7.00	17.09 ± 6.51	15.76 ± 5.26	0.05 ^b
Final	15.93 ± 7.77	16.06 ± 9.55	15.38 ± 7.78	15.44 ± 6.70	0.99
<i>p</i> value	0.03	0.25	0.07	0.77	
Right lateralization, degrees					
Initial	6.23 ± 3.19	6.38 ± 4.36	8.04 ± 4.16	7.24 ± 3.56	0.60
Final	7.28 ± 3.32	7.79 ± 4.58	10.63 ± 4.80	8.17 ± 4.67	0.25
<i>p</i> value	0.39	0.23	0.11	0.75	
Left lateralization, degrees					
Initial	6.93 ± 3.96	6.73 ± 4.01	8.78 ± 3.77	7.24 ± 3.56	0.59
Final	8.46 ± 5.24	7.35 ± 4.23	9.90 ± 7.08	8.93 ± 2.36	0.70
<i>p</i> value	0.26	0.50	0.43	0.09	
Right protrusion, degrees					
Initial	9.80 ± 4.24	10.38 ± 5.24	10.42 ± 4.26	12.09 ± 4.99	0.74
Final	12.56 ± 5.40	11.05 ± 4.88	10.77 ± 5.21	11.66 ± 5.79	0.88
<i>p</i> value	0.05	0.58	0.85	0.97	
Left protrusion, degrees					
Initial	13.02 ± 6.76	11.51 ± 6.98	9.42 ± 4.53	8.64 ± 3.78	0.32
Final	12.49 ± 5.40	11.04 ± 6.90	8.99 ± 4.56	10.95 ± 2.88	0.54
<i>p</i> value	0.99	0.68	0.76	0.17	
Right retraction, degrees					
Initial	10.76 ± 7.44	4.34 ± 3.48	3.31 ± 2.06	5.29 ± 3.67	0.02 ^{ac}
Final	9.16 ± 5.80	7.15 ± 5.33	6.21 ± 3.67	6.88 ± 4.58	0.35
<i>p</i> value	0.70	0.19	0.22	0.64	
Left retraction, degrees					
Initial	10.19 ± 5.80	3.62 ± 2.79	4.91 ± 4.98	5.59 ± 5.44	0.09
Final	7.59 ± 5.06	6.17 ± 4.76	5.72 ± 2.75	6.9 ± 3.42	0.82
<i>p</i> value	0.71	0.09	0.92	0.79	

One-way ANOVA

^a *p* < 0.05 comparing the 8-J/cm² group with the 60-J/cm² group

^b *p* < 0.05 comparing the 8-J/cm² group with the 105-J/cm² group

^c *p* < 0.05 comparing the 8-J/cm² group with the placebo group

of 5 J/cm² per point) [21]. Significant improvements in painful symptoms were observed by VAS only in the group receiving photobiomodulation, whereas the placebo group did not present significant results [21].

The mechanism of action of photobiomodulation is not yet fully understood [22, 23]. It is known that photobiomodulation can influence the synthesis and release of several substances involved in analgesia [24]. The theories report that there is a release of endogenous opioids, increased urinary excretion of glucocorticoids, increased ATP production, stimulation of local microcirculation, and decreased cell hypoxia [1, 21]. Other authors further affirm increased level of beta-endorphins, reduced bradykinin expression, and release of histamine associated with increased lymphatic flow and blood circulation, controlling the inflammation process and inducing muscle relaxation [2, 5]. In addition to Karu, Pyatibrat and Afanasyeva, Freitas and Hamblim also described that the effects of photobiomodulation are mainly due to increased oxidative metabolism in mitochondria [23, 24]. One of the most important chromophores is the enzyme cytochrome c oxidase, which absorbs light in the region close to the infrared spectrum [23, 24]. The main hypothesis is that photons dissociate inhibitory nitric oxide from this enzyme, leading to an increase in electron transport and ATP production [23, 24]. Another hypothesis is the activation of light-sensitive ion channels, which allow calcium to enter the cell, triggering signaling pathways through reactive oxygen species (ROS), cyclic AMP, nitric oxide, and Ca²⁺, leading to activation of transcription factors, which may increase the expression of genes related to protein synthesis, cell migration and proliferation, anti-inflammatory signaling, anti-apoptotic proteins, and antioxidant enzymes [23, 24].

Regarding the severity of TMD symptoms, evaluated through the Fonseca questionnaire, the results found were similar to the pain level responses by VAS. A significant decrease was observed in all groups from pre- to post-intervention, including the placebo group. The 8 J/cm² group had an initial mean score of 80.63 ± 14.25 points, and 31.25 ± 31.36 points ($p = 0.001$) at the end. The 60 J/cm² group showed an initial score of 71.67 ± 12.74 points, and a final score of 31.25 ± 19.22 points ($p = 0.0001$). The values of the 105 J/cm² group decreased from 63.89 ± 19.32 points to 27.22 ± 23.06 points ($p = 0.0001$). The placebo group obtained an initial score of 62.78 ± 26.47 points, and a final score of 34.44 ± 18.78 points ($p = 0.012$) (Fig. 3).

The use of functional questionnaires to assess TMD is poorly described in the literature [2, 15]. The Fonseca questionnaire was developed according to the Helkimo's anamnestic index and is one of the few instruments available in Portuguese to characterize the severity of TMD symptoms [15]. There are still few studies that use these questionnaires or functional scales to compare results before and after photobiomodulation, as was done in this study. They end up

being more used for diagnostic purposes, with the aim of presenting the most prevalent symptoms [16].

In the assessment of temporomandibular joint mobility, evaluated by biophotogrammetry, the subjects in the 8 J/cm² group demonstrated a significantly lower ADM than those of the 105 J/cm² group on both sides, and placebo group on the right side ($p < 0.05$). However, at the end of the study, all groups showed similar results (Table 4).

In the retraction movement on the right side, the initial mean of the 8 J/cm² group was significantly higher than that of the 60 J/cm² and placebo groups ($p < 0.05$) (Table 4).

The 8 J/cm² group was the only one that demonstrated a significant increase in the maximal mouth opening movement bilaterally from pre- to post-intervention ($p < 0.05$) (Fig. 4). Notwithstanding, it is important to observe that the group 8 J/cm² demonstrated, initially, a smaller right and left opening than the other intervention groups. This result was also observed in the protrusion movement on the right side ($p < 0.05$) (Table 4).

Catão et al. used an AlGaAs laser with wavelength of 830 nm, power of 40 mW, and dose applied per point of 4 J/cm² in 20 patients with TMD, being applied at five points in each temporomandibular joint [16]. The authors found a significant increase in mouth opening ($p = 0.028$) after treatment [16]. Similarly, Mazzetto et al. also showed a significant improvement in right and left mandibular movements in the group treated with an active dose of AlGaAs laser (830 nm) and energy density of 5 J/cm² per point in five points around the TMJ, when compared to the placebo group [21] (Fig. 5).

Salmos Brito et al. evaluated the effects of 12 photobiomodulation sessions in 58 patients with acute and chronic TMD using an AlGaAs laser at five points around the TMJ, in continuous mode, with a wavelength of 830 nm, beam

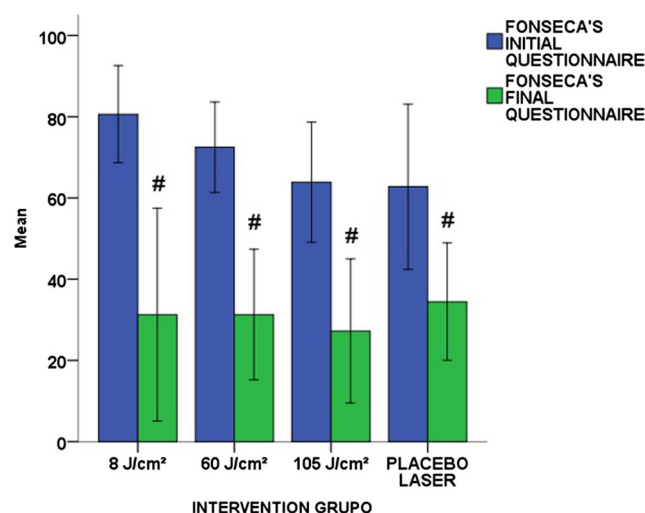


Fig. 4 Results of the initial and final right and left mandibular opening movement in the different study groups. # $p < 0.05$ relative to the initial evaluation of the same group. Student's t test. * $p < 0.05$ relative to the same evaluation of the other group. One-way ANOVA

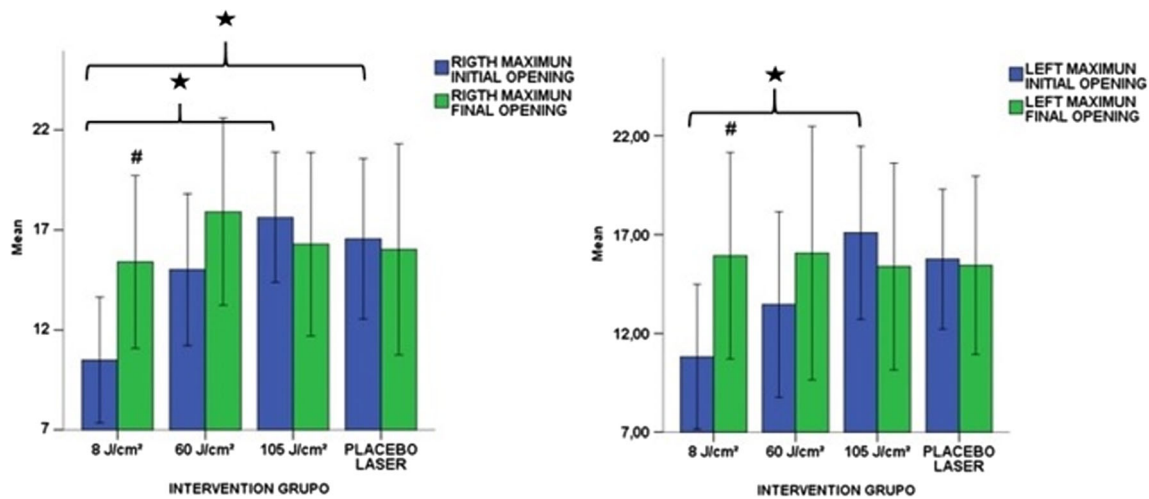


Fig. 5 Results of the initial and final right and left mandibular opening movement in the different study groups. # $p < 0.05$ relative to the initial evaluation of the same group. Student's t test. * $p < 0.05$ relative to the same evaluation of the 8 J/cm² group. One-way ANOVA

output power of 40 mW, diameter of 6 mm, point energy density ranging from 1.5 to 2 J/cm², and total energy density for each side of 8 J/cm², applied to patients in the acute, subacute, or chronic phases [11]. There was a significant reduction in pain intensity and improvement in maximal mouth opening after treatment [11]. Among the groups, the acute phase presented better results when compared to the chronic phase [11].

Rohlig et al. reported improvement in mandibular movements after application of ten laser sessions with wavelength of 820 nm, 3 J/cm², and output power of 300 mW at trigger points of masticatory muscles [25]. A total of 40 patients were included, being divided into intervention group and control group [25].

Light parameters and applied doses are fundamental in photobiomodulation [2, 24]. It is known that if the parameters are applied incorrectly, the treatment will probably be ineffective [24]. Knowledge of the potential effects of irradiation parameters, including wavelength, pulse rate, power, energy, and energy density is essential in the treatment of a given condition [26]. Very low or very high doses may not promote significant effects, and, above all, excessive light may lead to unwanted inhibitory effects [27]. At low doses (up to 2 J/cm²), photobiomodulation stimulates proliferation, while at higher doses (16 J/cm² or higher), photobiomodulation is suppressive [25]. Usually, fluences above 80 J/cm² induce apoptosis by activating caspase-3, and mitochondrial permeability transition after high fluence low-power laser irradiation is the main mechanism of mitochondrial injury [24].

Although studies are still unclear as to the definition of the best protocol for photobiomodulation treatment in TMD, there already seems to be a consensus that the use of laser provides benefits when applied and administered correctly [2, 28]. The present study demonstrated positive effects regarding TMD pain and symptoms at the different energy densities used, as

well as in the placebo group. Notwithstanding, only in the 8- J/cm² group there was a significant improvement of joint mobility for mandibular opening and right protrusion, which leads us to believe that this dose may be more efficient in the treatment of TMD. In addition, the application time spent for irradiation of this dose is lower, which optimizes the performance of other therapeutic techniques.

Different wavelengths have been used in the photobiomodulation approach in TMD [4]. However, the most common situation in therapeutic use has been wavelengths in the range of infrared light spectrum, located in the electromagnetic spectrum between 780 and 904 nm, due to its increased penetration [28–30]. The energy density and optical properties of the tissue are also considered essential factors that could influence the treatment of TMD [2]. Nonetheless, to date, studies have not reached a definitive scientific conclusion about the frequency and duration of the sessions to be performed [31]. The number of sessions differs considerably between studies, ranging from a single session to 20 applications [2]. Controversies over the effectiveness of photobiomodulation in TMD are believed to be due to disagreement over which dosimetry to use [31]. Many studies have not reported all the parameters that were used, which makes it difficult to compare their results [8, 10, 16]. Describing the parameters used is essential for this study to become reproducible.

Conclusion

The results of this study did not show effect of photobiomodulation over temporomandibular joint mobility. However, the results demonstrated a significant reduction of TMD pain and symptoms in all the photobiomodulation protocols used, including the placebo group. No significant differences were observed between the different dosimetry protocols

used. The 8-J/cm² group showed a positive effect on the mandible protrusion movements. Therefore, lower fluence doses need smaller exposition time, optimizing the association of other therapeutic approaches in the TMD approach.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The study was approved by the Ethics Committee of the Lutheran University of Brazil, under number 2011-175H.

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