Original Research
Stomatology

The analgesic effect of photobiomodulation therapy (830 nm) on the masticatory muscles: a randomized, double-blind study

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Abstract: This study assesses the efficacy of photobiomodulation therapy (830 nm) for myalgia treatment of masticatory muscles. Sixty patients with muscular myalgia were selected and randomly allocated into 2 groups (n=30): Group A comprised patients given a placebo (control), and Group B consisted of those undergoing photobiomodulation therapy (PBMT). PBMT and placebo were applied bilaterally to specific points on the masseter and temporal muscles. Referred pain elicited by palpation and maximum mouth opening were measured before (EV1) and after (EV2) the treatments. The data were analyzed using statistical tests, considering a significance level of 5%. No significant differences in range were observed for active or passive mouth opening ($p \geq 0.05$). Comparing the final outcomes (EV1-EV2) of both treatments, statistical significance was verified for total pain in the right masseter muscle ($p = 0.001$) and total pain ($p = 0.005$). In EV2, significant differences in pain reported with palpation were found between Groups A and B for the following: left posterior temporal muscle ($p = 0.025$), left superior masseter muscle ($p = 0.036$), inferior masseter muscle ($p = 0.021$), total pain (left side) ($p = 0.009$), total masseter muscle (left side) ($p = 0.014$), total temporal (left side) ($p = 0.024$), and total pain ($p = 0.035$). We concluded that PBMT (830 nm) reduces pain in algic points, but does not influence the extent of mouth opening in patients with myalgia.

Keywords: Temporomandibular Joint Disorders; Laser Therapy; Orofacial Pain.

Introduction

Temporomandibular disorder (TMD) is a term that comprises various signs and symptoms, including those of the masticatory muscles, temporomandibular joint (TMJ), and associated structures. The most common symptom is pain, which is generally localized to the masticatory muscles, pre-auricular area, and TMJ. Among patient complaints, the most frequent symptoms are maxillary pain, earache, headache, and facial pain.[1]

Pain is considered the basis for every diagnosis and therapeutic approach.[2] Muscular sensitivity is an important clinical sign that is

present in most patients with orofacial pain, affecting up to 88.7% of them.[3]

The preferable criteria for evaluating TMD patients under any therapy are muscular and articular palpation and range of mouth opening.[4,5,6] Muscular sensitivity is evaluated using the palpation exam, manually[7] or with a measuring instrument,[8] such as an algometer, which records the exact value of pressure that is applied to an area.[9] During a clinical evaluation, the amount of pain experienced must be assessed. The visual analog scale (VAS) is typically used to determine and document the level of pain; however, it is difficult to determine a patient's pain, because this experience is subjective.[10]

Dworkin and LeResche (1992) introduced the Research Diagnostic Criteria (RDC/TMD), which have been widely used,[5,11,12] providing researchers and clinicians with a standardized system to examine, diagnose, and classify the most common subtypes of TMD.[5] Diagnoses based on the RDC/TMD are divided into 3 groups: I) muscular diagnosis; II) disc displacement; and III) arthralgia, arthritis, and arthrosis.

TMD treatment is guided by the signs and symptoms reported by the patient. Therapeutic modalities consist of the use of analgesics, anti-inflammatory agents, muscle relaxants, cryotherapy, heat therapy, transcutaneous electrical nerve stimulation (TENS), ultrasonography, acupuncture, massage, exercise, photobiomodulation therapy, and interocclusal splints. Noninvasive techniques are suitable and preferable for TMD treatments.[13]

The multifactorial etiology of TMD prescribes that the clinician begin treatment by relieving pain symptoms. Photobiomodulation therapy (PBMT) with lasers emitting in the infrared spectrum (IS) has been used to treat the deep structures of tissues such as the TMJ, as well as articular and muscular disorders.[14,15]

The photobiomodulating effects of PBMT are related to the proliferation of macrophages, lymphocytes, endothelial cells, and fibroblasts.[16] Laboratory[17] and clinical trials[18,19,20] have demonstrated its analgesic and anti-inflammatory effects.

Despite the scant evidence on the biomodulating effects of PBMT, and the lack of protocols on its use for TMD,[20,21,22] several reviews have encouraged its application as an alternative to analgesia and a resource to improve mandibular biomechanics.[23]

This clinical study was performed to determine the effects of PBMT (830 nm) regarding analgesia of the masticatory muscles.

Materials and Methods

Ethical aspects

The study protocol was approved by the research ethics committee of the School of Dentistry, University of São Paulo (Protocol # 317.627).

Sample characteristics

Prior to the outset of the study, patients were examined using the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD).[23] The inclusion criteria consisted of patients of both genders, minimum age of 18 years, and myalgia of the temporalis and masseter muscles after initial examination and independent of the final diagnosis of TMD. The exclusion criteria were patients with neurological issues and those using interocclusal splints or any other concurrent treatment for TMD. Individuals who had been using medications that could have influenced pain sensations for at least 7 days before the start of the trial were also excluded.

Patients were selected consecutively over 6 months, and those who met the inclusion criteria were informed about the nature of the research; subjects who agreed to participate were requested to sign an informed consent form.

Sixty participants were selected and allocated randomly[1] into two groups: Group A consisted of volunteers who were administered placebo, and Group B comprised those who underwent PBMT. The treatment was given on the same day of the selection.

Pain evaluation during muscular palpation and measurement of maximum mouth opening

Two examiners oversaw the clinical procedures. Examiner 1 was responsible for muscular palpation, mouth opening measurements, and pain evaluation

1 Randomization was done with a computer program (www.randomization.com).

using the VAS, before and immediately after each treatment (placebo or PBMT), and was blinded to the treatment for each volunteer. Examiner 2 applied the treatments (placebo or PBMT) to the volunteers.

RDC/TMD analysis

The participants were evaluated using the RDC/TMD, with regard to type of temporomandibular disorder, myalgia, or arthralgia. They were examined for any sign of disc displacement, such as closed locking, clicking sounds, and crepitation. The history of the disorder was evaluated, including parafunctional habits, bruxism, and trauma.

Muscular palpation was performed at 2 sites: the temporal muscle (anterior, medium, and posterior) and the superficial masseter muscle (superior and inferior). The palpation was bilateral; thus, the pain could be reported on the right or left side of the face or both. A pressure algometer (Power Dial, Wagner Instruments, Greenwich, USA) was used, and 1 kg/cm^2/s of force was applied. The measurements were made by Examiner 1 in the same area where the PBMT was applied.

Evaluations were conducted with the participants seated in a chair, with their torso straight and feet on the ground parallel to the Frankfort horizontal plane. The examiner positioned the algometer on the predefined area and applied gradual pressure. The participant had to classify his pain according to each point, as follows: no pain or just pressure (0), light pain (1), moderate pain (2), or severe pain (3). Pain scores for each point were summed, for a maximum of 30 points (15 for each side).

The participant underwent the admeasurement of general pain after the palpation using the VAS, according to which he scored the amount of pain on an unnumbered 10-cm line, ranging from the extremes of "no pain" to "worst possible pain."

Mandibular movement was measured (in mm) during active and passive mouth opening. Active mouth opening was verified without the assistance of the examiner and comprised the interincisal distance and the vertical trespass. If a participant had open bite malocclusion, the extent of open bite (mm) was discounted from the measurement. All measurements were taken with a digital caliper (Mitutoyo Sul America Ltda., São Paulo, Brazil). Passive mouth opening was measured in the same manner as active mouth opening, except that the examiner interfered with the mouth opening process.

Photobiomodulation therapy

A Thera Lase® (DMC Equipamentos Ltda, São Carlos, Brazil) infrared laser (830 nm) was used for the irradiation at the following settings: power: 100 mW, energy density: 100 J/cm^2, exposure: 28 seconds at each irradiation point, and energy: 2.8 J per point. Five irradiation points were considered on each side of the face (temporal muscle: anterior, medium, and posterior; and superficial masseter muscle: superior and inferior), as shown in Figure 1, based on the methodology used by Ahrari et al. (2014) [24], totaling the 14 J of energy applied to the tissue. The spot size of the laser beam was 0.028 cm^2. The output power was measured using a power meter (Molectron PM600, Coherent, Santa Clara, USA) before and after irradiation of each volunteer.

The placebo treatment was given by placing a metallic film over the beam's output. This simulated PBMT (placebo) was applied to the same 5 points bilaterally as the actual PBMT.

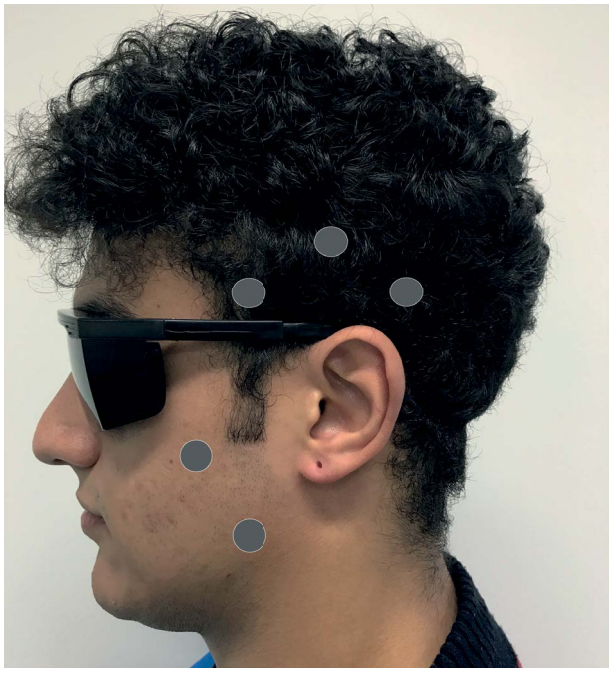

Figure 1. Anatomical sites for PBMT application

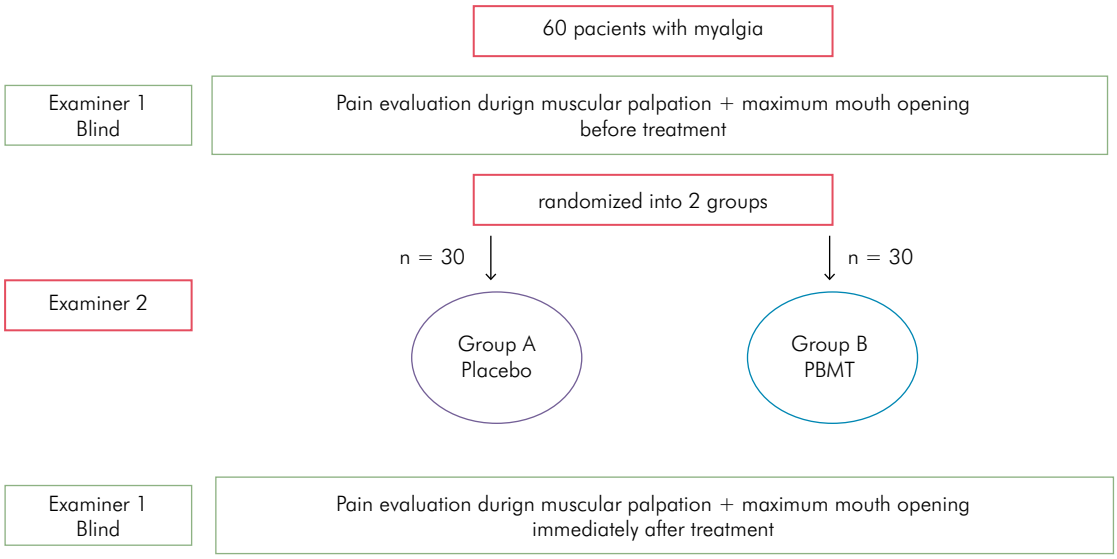

Figure 2. Study design

Evaluation period

The PBMT was applied to each participant in a single day, and the pain evaluation and measurements were made immediately after the PBMT or placebo application, as shown in Figure 2.

Statistical analysis

Summary measures were used to describe the sample, such as frequency and percentage (qualitative variables) and average double/standard deviation and median/interquartile range (quantitative variables).

Parametric and nonparametric tests were performed, depending on the normality of the data, verified by the Anderson-Darling test. Quantitative variables were analyzed by the two-tailed *t* test for normally distributed variables or the Mann-Whitney test, otherwise. Fisher's exact test was performed to analyze the qualitative variables of the entire sample, as well as the placebo and laser groups. The data were analyzed using R 3.1.2. (R Team, 2012, URL http://www.R-project.org/), and the significance level was set at 5%.

Results

A total of 60 volunteers were selected for the study, 90% of whom were women. The mean age was 38.8 (± 14.2) years, ranging from 18 to 76 years. The mean age for women was 38.9 years, versus 45.8 years for men.

According to the RDC/TMD, 51 (85%) of the 60 volunteers, presented with myalgia and arthralgia, whereas 9 (15%) presented with only myalgia. Of all the volunteers, 48.33% (29/60) reported closed locking, 91.67% (55/60) related clicking sounds in the TMJ, and 30% (18/30) noted crepitus during palpation and mouth opening. All the volunteers reported a parafunctional history, such as bruxism, and 14 (23.33%) reported suffering trauma to the face. Headache was reported by 90% (54/60) of the volunteers, and 90% presented with stress or anxiety. The sample characteristics are listed in Table 1.

Pain evaluation during muscular palpation

Table 2 shows a descriptive analysis of the pain evaluations of Groups A and B. In the first evaluation (EV1), only the score for the right superior masseter differed from the other measurements, all of which were not significantly different. In the final evaluation (EV2), significant improvements in pain were observed between Groups A and B with regard to the following: left posterior temporal muscle ($p = 0.025$), left superior masseter muscle ($p=0.036$), inferior masseter muscle ($p = 0.021$), total pain (left side) ($p = 0.009$), total masseter muscle (left side) ($p = 0.014$), total temporal (left side) ($p = 0.024$), and total pain ($p = 0.035$).

Table 3 compares the final outcomes (EV1-EV2) of both treatments, showing significance difference

Table 1. Description of the qualitative variables of the total sample, placebo and PBMT groups.

Variable	Category	Total sample (n = 60)	Placebo group (n = 30)	PBMT group (n = 30)	Fisher test
		n (%)	n (%)	n (%)	p-value
Gender	Female	54 (90)	26 (86.67)	28 (93.33)	0.671
	Male	6 (10)	2 (3.33)	4 (6.67)	
Closed locking	No	31 (51.67)	15 (50)	16 (53.33)	1
	Yes	29 (48.33)	15 (50)	14 (46.67)	
Clicking	No	5 (8.33)	1 (3.33)	4 (13.33)	0.353
	Yes	55 (91.67)	29 (96.67)	26 (86.67)	
Bruxism	No	0 (0)	0 (0)	0 (0)	
	Yes	60 (100)	30 (100)	30 (100)	
Trauma	No	46 (76.67)	24 (80)	22 (73.33)	0.761
	Yes	14 (23.33)	6 (20)	8 (26.67)	
Headache	No	6 (10)	2 (6.67)	4 (13.33)	0.671
	Yes	54 (90)	28 (93.33)	26 (86.67)	
Diagnosis	Myalgia	9 (15)	4 (13.33)	5 (16.67)	1
	Myalgia + arthralgia	51 (85)	26 (86.67)	25 (83.33)	
Clicking	No	30 (50)	13 (43.33)	17 (56.67)	0.439
	Yes	30 (50)	17 (56.67)	13 (43.33)	
Crepitation	No	42 (70)	21 (70)	21 (70)	1
	Yes	18 (30)	9 (30)	9 (30)	

for total pain in the right masseter muscle (p = 0.001) and total pain (0.005). There were no significant differences in pain measurements based on VAS scores, as shown in Table 4.

Maximum MOUTH OPENING

The average active mouth opening after the first evaluation in Group A (placebo) was 44.87 mm, versus 45.17 mm in Group B (PBMT). After the treatment, Group A had an average mouth opening of 45 mm, compared with 46.43 mm for Group B. However, the differences between the groups in each evaluation were not significant.

Discussion

The high frequency of women among the TMD participants in our study is supported by the literature, reporting that 90% are female.[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,25] There are many factors that contribute to the development of TMD, according to Okeson[1] and Leeuw,[26] primarily: occlusion conditions, trauma, emotional distress, and parafunctional habits (clenching and bruxism). Stress symptoms are associated with the development of TMD, and the manifestation of pain could be the chief cause of TMD [27,28], as observed in our sample.

The prevalence of muscular disorders associated with arthralgia was higher than that of muscular disorders alone, in contrast with Wiese et al.,[11] who reported higher rates of muscular disorders without arthralgia among TMD patients. The decision not to irradiate the temporomandibular joint was based on reports from the literature and the inclusion criteria, which determined that the patient's pain should originate in the muscle and not necessarily descend from the TMJ.

The average period of pain prior to PBMT intervention exceeded 6 months; thus, our sample was defined as having chronic pain, considering that the transition from acute to chronic pain was baselined in 6 months.[1] Patients with acute manifestations of pain tend to report greater improvement than those with chronic disorders.[11] In our evaluation, there was

Table 2. Description of pain levels for EV1 and EV2, for both groups (A and B), and multiple comparison tests

Evaluation	Variable	Group A (n = 30)		Group B (n = 30)		Test	p-value
		Average (SD)	Median (IR)	Average (SD)	Median (IR)		
EV 1	Temporal muscle (right)						
	Anterior	1.13 (0.97)	1 (2)	1.2 (1.21)	1 (2)	Mann-Whitney	0.932
	Medial	1.33 (0.96)	2 (1.75)	1.13 (1.04)	1 (2)		0.453
	Posterior	1.03 (0.85)	1 (2)	0.93 (1.01)	0.5 (2)		0.61
	Total	3.5 (2.47)	3 (4.75)	3.27 (2.78)	3.5 (4.75)		0.682
	Temporal muscle (left)						
	Anterior	1.13 (1.14)	1 (2)	0.93 (1.11)	0.5 (2)	Mann-Whitney	0.466
	Medial	1.03 (1.03)	1 (1.75)	0.77 (1.01)	0 (1.75)		0.245
	Posterior	1.2 (1.06)	1 (2)	0.73 (1.01)	0 (1.75)		0.068
	Total	3.37 (2.88)	3 (4.75)	2.43 (2.61)	2 (4)		0.186
	Masseter muscle (right)						
	Superior	1.53 (0.94)	1.5 (1)	2.03 (0.96)	2 (1)	Mann-Whitney	0.036
	Inferior	1.7 (1.02)	2 (1.75)	1.9 (1.06)	2 (2)		0.424
	Total	3.23 (1.81)	3 (2)	3.93 (1.82)	4 (2.75)		0.117
	Masseter muscle (left)						
	Superior	1.87 (1.04)	2 (2)	1.53 (0.94)	2 (1)	Mann-Whitney	0.171
	Inferior	1.93 (0.98)	2 (1)	1.77 (1.04)	2 (1.75)		0.531
	Total	3.8 (1.81)	4 (2)	3.3 (1.84)	4 (3)		0.309
	Total pain						
	Right side	6.77 (3.9)	7 (6.75)	7.2 (3.37)	7 (4.75)	t-test	0.647
	Left side	7.17 (4.19)	7.5 (4.75)	5.73 (3.95)	5 (6)		0.178
	Both sides	13.93 (6.88)	13.5 (10.75)	12.93 (6.27)	11 (9.75)	Mann-Whitney	0.667
	Mouth opening						
	Active	44.87 (6.89)	45 (8.25)	45.17 (4.93)	45.5 (7.5)	t-test	0.847
	Passive	47.93 (7.25)	49.5 (8.25)	49.03 (4.8)	50 (6.75)		0.492
EV2	Temporal muscle (right)						
	Anterior	1.3 (1.06)	1 (2)	1.13 (1.01)	1 (2)	Mann-Whitney	0.538
	Medial	1.03 (1)	1 (2)	0.8 (0.92)	0.5 (1.75)		0.364
	Posterior	1.03 (0.85)	1 (2)	0.73 (0.78)	1 (1)		0.173
	Total	3.37 (2.65)	3.5 (4.75)	2.67 (2.28)	2 (3.75)		0.347
	Temporal muscle (left)						
	Anterior	0.93 (0.98)	1 (2)	0.6 (0.89)	0 (1)	Mann-Whitney	0.146
	Medial	1.03 (0.96)	1 (2)	0.63 (0.93)	0 (1)		0.074
	Posterior	1.23 (0.9)	1 (1)	0.7 (0.88)	0 (1.75)		0.025
	Total	3.2 (2.27)	3 (4)	1.93 (2.43)	0.5 (3.75)		0.024
	Masseter muscle (right)						
	Superior	1.43 (0.9)	1 (1)	1.2 (0.89)	1 (1.75)	Mann-Whitney	0.409
	Inferior	1.6 (1.07)	1.5 (1.75)	1.4 (1.04)	1 (1)		0.486
	Total	3.03 (1.81)	3 (2)	2.6 (1.75)	2.5 (2.75)	t-test	0.35
	Masseter muscle (left)						
	Superior	1.57 (1.01)	2 (1)	1.03 (0.89)	1 (2)	Mann-Whitney	0.036
	Inferior	1.93 (0.83)	2 (1.75)	1.3 (1.12)	1 (2)		0.021
	Total	3.5 (1.57)	3 (2)	2.33 (1.84)	2 (3)		0.014
	Total pain						
	Right side	6.4 (3.93)	6 (5.75)	5.23 (3.46)	4 (4)	t-test	0.227
	Left side	6.7 (3.34)	7 (5.75)	4.27 (4.02)	3 (6)	Mann-Whitney	0.009
	Both sides	13.1 (6.64)	13.5 (10)	9.5 (6.44)	8 (7)		0.035
	Mouth opening						
	Active	45 (7.49)	44 (10)	46.43 (4.9)	46 (7)	t-test	0.385
	Passive	48.2 (8)	47.5 (9.75)	50.37 (4.69)	50 (5)		0.207

SD: standard deviation; IR: interquartile range.

Table 3. Pain level differences between the first and second evaluations for PBMT and placebo treatments.

Variable	Placebo (n = 30)		PBMT (n = 30)		Test	p-value
	Average (SD)	Median (IR)	Average (SD)	Median (IR)		
Right side						
Masseter	0.2 (1.45)	0 (1)	1.33 (1.24)	1 (1)		0.001
Temporal	0.13 (2)	0 (2)	0.6 (1.83)	0.5 (2.75)	Mann-Whitney	0.291
Total	0.37 (2.75)	0 (3)	1.97 (2.03)	2 (2.75)		0.01
Left side						
Masseter	0.3 (1.42)	0 (1)	0.97 (1.45)	0.5 (2)		0.179
Temporal	0.17 (1.82)	0 (1.75)	0.5 (1.46)	0 (1.75)	Mann-Whitney	0.166
Total	0.47 (2.7)	0 (2)	1.47 (2.05)	2 (3)		0.032
			Both sides			
Total pain	0.83 (3.37)	0 (5)	3.43 (3.46)	3.5 (4)	t-test	0.005

Table 4. Values for quantitative pain analysis using VAS score, before and after placebo and PBMT treatment.

VAS score	Control group (n = 30)	PBMT (n = 30)	Test	p-value
	Mean (SD)	Mean (SD)		
Before treatment	7.29 (1.34)	7.17 (1.18)	t-test	0.722
After treatment	6.09 (2.29)	6.02 (1.66)	t-test	0.898

no difference between the groups with regard to chronic or acute pain, based on the average period of pain reported by both groups.

Mouth opening did not differ significantly before and after PBMT. However, a difference of 1.26 mm could be clinically significant, because changes in mouth opening can translate into a successful index for TMD treatments.[29,30,31,32]

PBMT is a complementary treatment for TMD-related pain, based on its analgesic and anti-inflammatory effects and muscular relaxant properties.[19] PBMT stimulates homeostasis, increasing mitochondrial oxidative phosphorylation, and thus increasing ATP; normalizes the levels of fibrinogen and protein synthesis; enhances the mitotic potential of cells; and intensifies the proliferation and differentiation of fibroblasts and the maturation of granulomatous tissue, with consequent stimulation of epithelization of the skin and other tissues.[14,16]

A rise in the levels of endogenous opioids, a decrease in the membrane permeability of nerve cells, and greater ATP production are effector mechanisms of PBMT. The literature indicates that PBMT influences prostaglandin synthesis by allowing the arachidonic acid to penetrate endothelial tissues, thus leading to vasodilation and allowing anti-inflammatory mechanisms to guide tissue repair. Analgesic and anti-inflammatory effects of PBMT have been demonstrated in experimental and clinical studies [17,18,19,33,34,35,36]. Our findings corroborate other studies [20,21,22] reporting that PBMT reduces TMD-induced pain.

A study by Chow[36] found differences in the effects the infrared laser (IL) compared with the visible red laser (VRL), in which the red photons increased electron voltage and coherence. These characteristics allow the VRL to have a greater interference capacity. However, the IL penetrates deeper into the tissues (3–5 cm) than the visible laser (2–5 cm). The 830nm continuous wave generates a local blockage, leading to diminished peripheral sensitization, causing an anti-inflammatory response affected by cell stimulation, which promotes an inflammatory cascade, the main mechanism of pain relief. This wavelength inhibits and decreases the mitochondrial membrane potential in neurons, leading to a decrease in ATP generation, thus blocking sensorial innervation, and causing pain

reduction immediately after the laser application; it also limits vasodilation and edema.[37]

Shirani et al.[38] and Ahrari et al.[24] performed clinical studies to compare PBMT and placebo. These authors evaluated the effectiveness of both treatments in reducing myofascial pain (using VAS scores) and increasing mouth opening. They concluded that PBMT significantly decreases the pain level and improves mouth opening measurements in patients with TMDs. Their findings are consistent with our results, in which PBMT was efficient in lowering pain; however, we saw no significant improvement in mouth opening.

Venâncio et al.,[15] Emshoff et al.,[39] Cunha et al.,[40] and Venezian et al.[33] conducted randomized clinical studies on PBMT. These authors evaluated pain and mouth opening, and concluded that pain decreased after therapy versus placebo, but that there were no differences between the active and the placebo PBMT therapies. These trials were long-term studies, ranging from 2 to 8 weeks, with therapy sessions held 2 to 3 times a week, in contrast with our program, which administered therapy in 1 single session. Moreover, it is difficult to compare these studies, due to the various designs and therapeutic protocols.

Maia et al.,[41] Aparicio et al.,[42] and Chang et al.[43] published meta-analyses of the clinical effects of PBMT on patients with TMD-related pain. Most of the authors concluded that the experimental groups (PBMT) reported less pain after TMJ palpation. Aparicio et al.,[42] however, confirmed that there is still no scientific evidence regarding the benefits of PBMT for TMDs.

Our study concluded that TMD-related pain and muscular sensitivity warranted using PBMT to mitigate these symptoms, and indicates it as an important coadjuvant resource to deal with this pathology. Studies on this new therapy have reported that it was able to reduce pain in patients with TMD.[15,20,21,22]

Our results showed a tendency toward greater mouth opening in both groups, supporting those by McNeely et al.[44]

The concurrent use of several therapeutic approaches, however, could be a more suitable modality of treatment, especially considering that TMD is a multifactorial pathology. In this regard, PBMT is an important noninvasive tool for immediate pain relief, greater mobility, and lower anxiety levels, that may contribute positively to the recovery of a patient's daily activities.

Conclusion

The photobiomodulation therapy (830 nm) acted effectively on the analgesia of the masticatory muscles in the participants with TMD, based on muscular palpation, but was not effective regarding the criteria for mouth opening range. Further research is needed to evaluate the long-term effects of PBMT (830nm) on the treatment of patients with chronic pain from temporomandibular disorders.

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