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Evaluation of the efficacy of a new low-level laser therapy home protocol in the treatment of temporomandibular joint disorder-related pain: A randomized, double-blind, placebo-controlled clinical trial

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ABSTRACT

Objective: This study analyzed a home, low-level laser therapy (LLLT) protocol to manage temporomandibular joint disorders (TMJDs)-related pain.

Methods: Ninety TMJD patients (12M, 78F) between 18 and 73 years were randomly subdivided into three groups. Study group (SG) received 1-week home protocol LLLT by B-cure Dental Pro: 808 nm, 5 J/min, 250 mW, 15 KHz for 8′, 40 J each, over pain area, twice daily. Placebo group (PG) followed the same protocol using sham devices. Drugs group (DG) received conventional drugs. Pain was evaluated by visual analog scale (VAS) before and after therapy.

Results: Statistical analysisshowed that treatment was effective ($F(2,83) = 4.882$; $p = .010$). Bonferroni post-hoc analysis indicated a lower pain decrease in PG. SG registered a 34-point decrease per patient, while in PG and DG, the reduction was 25.6 and 35.3, respectively.

Conclusion: The study supports the efficacy of home LLLT management of TMJD related pain.

KEYWORDS
Temporomandibular disorders; laser therapy; photobiomodulation; pain management; laser; low-level laser therapy

Introduction

The temporomandibular joint (TMJ) is essential for most of the functions of the oral and maxillofacial region, playing a crucial role in the chewing function through complex movements. It plays a key role in swallowing and speaking, along with all other rhinopharyngeal structures.

Regarding its kinetics, the TMJ can perform symmetrical movements (opening, closure, protrusion, retrusion) and asymmetrical movements (mainly laterality and chewing).

Two systems ensure these functions: the tissues surrounding the synovial cavity, which binds tightly the disc to the head of the condyle and the articular disc, which divides the TMJ into two cavities, permitting the movement of the condyles into the glenoid fossa of the temporal bone and allowing flow and complex range of motion. Thus, it is not considered a true meniscus [1].

The chewing muscles permit the movements of the mouth. Some of them, such as the pterygoids, masseter and temporal, insert directly into the jaw; other muscles (those responsible for chewing) indirectly guide its movement. During these movements, the posterior and lateral cervical musculature stabilizes the head and neck so that the chewing process may influence the whole posture [2].

From a neurophysiological point of view, many receptors provide, by a feedback mechanism, the fine and harmonic mandibular movements. Psychological stress may influence the stretch reflex and modulate a muscular response of the entire apparatus, leading to parafunctions, such as clenching and bruxism [3].

The joint capsule responds to pressure or chemical stimuli that, in case of inflammation, may lead to high concentrations of substances that may generate pain [4]. Disorders of the TMJ (TMJDs) are defined by the American Association of Orofacial Pain (AAOP) as follows: a collective term that includes a variety of pathological conditions involving the masticatory muscles, TMJ articulation, and the structures associated with them [5].

The diagnosis of TMJDs is based on several symptoms and leads to three different categories of sub

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classification: inflammatory diseases, intra-capsular disorders, and osteoarthritis [6].

Another classification schematically divides the TMJDs into intra-and extracapsular disorders, these latter corresponding to the myofascial disorders [6].

Sixty to 70% of the population have one sign or symptom attributable to TMJDs, while about 20% to 30% of people develop a TMJ problem. The incidence is higher in females aged between 30 and 40 years, although, the age range is increasing up to 50 years and over [7,8]. Three symptoms characterize the pathology: pain, joint sounds (clicks or pops), and mouth opening reduction.

The diagnosis of TMJDs is made when there are at least two of these signs/symptoms. The diagnostic procedure of TMJDs should be based first on patients' medical history, followed by the clinical examination of the head and neck region.

The medical history should not be restricted solely to the head and neck region, but a complete medical record is mandatory. This reveals whether the patient has one or more general conditions usually linked to the pathology. Laboratory tests are recommended to reveal any medical condition that could be the cause of the dysfunction [9].

Often, the clinical examinations of many patients do not show localized pain, but a more complex symptomatology, including headache, cervical pain, atypical facial pain, tinnitus, and head and neck muscles hypersensitivity [6,10,11].

The presence of these symptoms may worsen the quality of life of patients, interfering with their emotional and social lives [12].

The etiology of the TMJDs remains controversial. They are now considered multifactorial diseases that include postural abnormalities, occlusal parafunctions, and psychological factors, which act synergistically in the onset and course of the disease [13,14,15].

The elimination of risk factors, the diagnosis, and early treatment of TMJDs are fundamental for a correct approach to the disease. The early detection of clinical aspects may facilitate the diagnosis, allowing the realization of the best treatment to quickly enhance the patients' general conditions.

Due to the wide variety of clinical manifestations related to the pathology, its treatment is multidisciplinary, involving different practitioners and therapeutic methods, such as drug therapy, occlusal splints, surgical therapy, acupuncture, transcutaneous electrical nerve stimulation (TENS), ultrasound, massages, psychological support and, recently, low-level laser therapy (LLLT) [16–18].

The main goal of many treatments is to reduce muscle hyperactivity, leading to muscle relaxation, restoration of the normal activity of the articulation and entire region, and reducing pain, spasm, and edema in the meantime.

Drug therapy is the conventional method for managing the pain associated with this pathology, and several drug combinations have been proposed over the years to reduce both pain and muscle tenderness.

The most frequently adopted drug protocol involves the use of anti-inflammatories, which reduce inflammation and pain, and myorelaxants (indicated or both central and peripheral action), which induce relaxation of the muscles, centrally blocking the pain cycle process [19–21].

LLLT was introduced in the early 1960s as a tool to reduce pain and inflammation through bio-modulative action over the tissues. Its application in TMJDs has recently gained overwhelming interest. Photobiomodulation has a biological action that provokes a cascade of biochemical and cellular processes in cells and tissues, which accelerate the healing of targeted tissues [22,23].

According to Karu [24], LLLT consists of a non-thermal treatment that can promote cellular and tissue modifications induced by different metabolic processes, such as greater activity of both the mitochondria and Na^+/K^+ pump, increased vascularization, and fibroblast growth. These changes result in enhanced healing processes and pain reduction. Various authors in recent years demonstrated the therapeutic properties of LLLT in tissue reparation, edema, and inflammation reduction, as well as analgesia in acute and chronic pain [25–27].

One of the main criticisms of LLLT is the necessity to perform multiple applications that require the frequent presence of patients in the dental chair, creating problems for both patients and practitioners.

The aim of this study was to assess the efficacy of a new home LLLT protocol in the management and reduction of TMJD-related pain.

Materials and methods

Trial design, research strategy, and inclusion criteria

A randomized, double-blind, placebo-controlled clinical study was conducted to evaluate the efficacy of a new home protocol of LLLT in the reduction of pain in patients affected by TMJDs.

Participants

Patients' enrollment was performed following the CONSORT (Consolidated Standards of Reporting Trials) criteria (Figure 1); 100 females and males with



Figure 1. Low-level laser therapy (LLLT) application over the pain area.

mono- or bilateral TMJDs were assessed from eligibility. Ten were excluded [not matching the inclusion criteria (n = 6), refusing to participate (n = 3), or for other reasons (n = 1)]. Ninety patients were finally enrolled in the study.

Of the 90 patients, 78 were female, and 12 were male. Therefore, 86.6% of the patients were female, and 13.3% were male. The inclusion criteria to be enrolled in the study were: the presence of pain in the joint area and/or radiating to the face, jaw, or neck for at least six months; reduced mouth opening or jaw locks; painful clicking, popping or grating when opening or closing the mouth; occlusal changes; no muscle tenderness at palpation; and no drug consumption for at least three weeks before treatment.

The disorder was diagnosed by clinical and radiological examinations and according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) Axis I and Axis II [28]. These criteria are the most widely used diagnostic protocols to diagnose TMJDs.

This classification system is based on the biopsychosocial model of pain that includes a physical assessment axis I, which uses reliable and well-operationalized diagnostic criteria, and axis II, which assesses the psychosocial status and disability related to pain. The intent is to provide both the physical status and to identify other important patient characteristics that might influence the expression and tolerance to pain. In fact, the longer the pain persists, the greater the potential for the appearance and amplification of cognitive, psychosocial, and behavioral factors, resulting in higher sensitivity to pain, a greater likelihood of more persistent pain, and reduced possibility of successful treatments [28].

A CT (computed tomography) and MRI (magnetic resonance imaging) of the TMJ were requested to complete the diagnosis.

All the patients signed an informed consent document to participate in the study. The study received approval from the Ethical Committee of Sapienza University of Rome (# 4389) and was registered on the International public register for clinical trials, Clinicaltrials.gov (ID #NCT03119324).

Sample size and randomization: sequence generation

Ninety TMJD patients, 78 female (86.6%) and 12 male (13.3%), aged between 18 and 73 years, were randomly subdivided into 3 groups: a study group (SG), a placebo group (PG), and a drugs group (DG), according to a computer-generated series. The web Research Randomizer® free resource for researchers was used for randomization.

The SG consisted of 30 patients, of whom 26 were females (86.6%), and 4 were males (13.3%). The SG patients (n = 30) received LLLT through the B-cure Dental Pro low-level laser device, provided by Biocare Enterprise Limited (Good Energies, Haifa, Israel). This medical device emits a low-level laser beam with a wavelength of 808 nm; each application was performed at 5 J/min, 250 mW and 15 KHz for 8 m, for a total of 40J each, directly over the pain area (Figure 2). The treatment had to be performed twice a day for seven consecutive days.

A laser therapy expert examiner performed the first application at the Department of Dental Sciences and Maxillo-Facial Surgery of Sapienza, University of Rome. This first application was used as an instruction to the patients so they could perform the successive applications by themselves at home. The same examiner explained clearly to each patient how to use and safely store the devices. After the instruction, each patient performed the remaining applications at home.

The PG consisted of 30 patients, of whom 27 were females (90%) and 3 were males (10%). The PG patients (n = 30) received the same instructions and followed the same protocol as the SG patients but

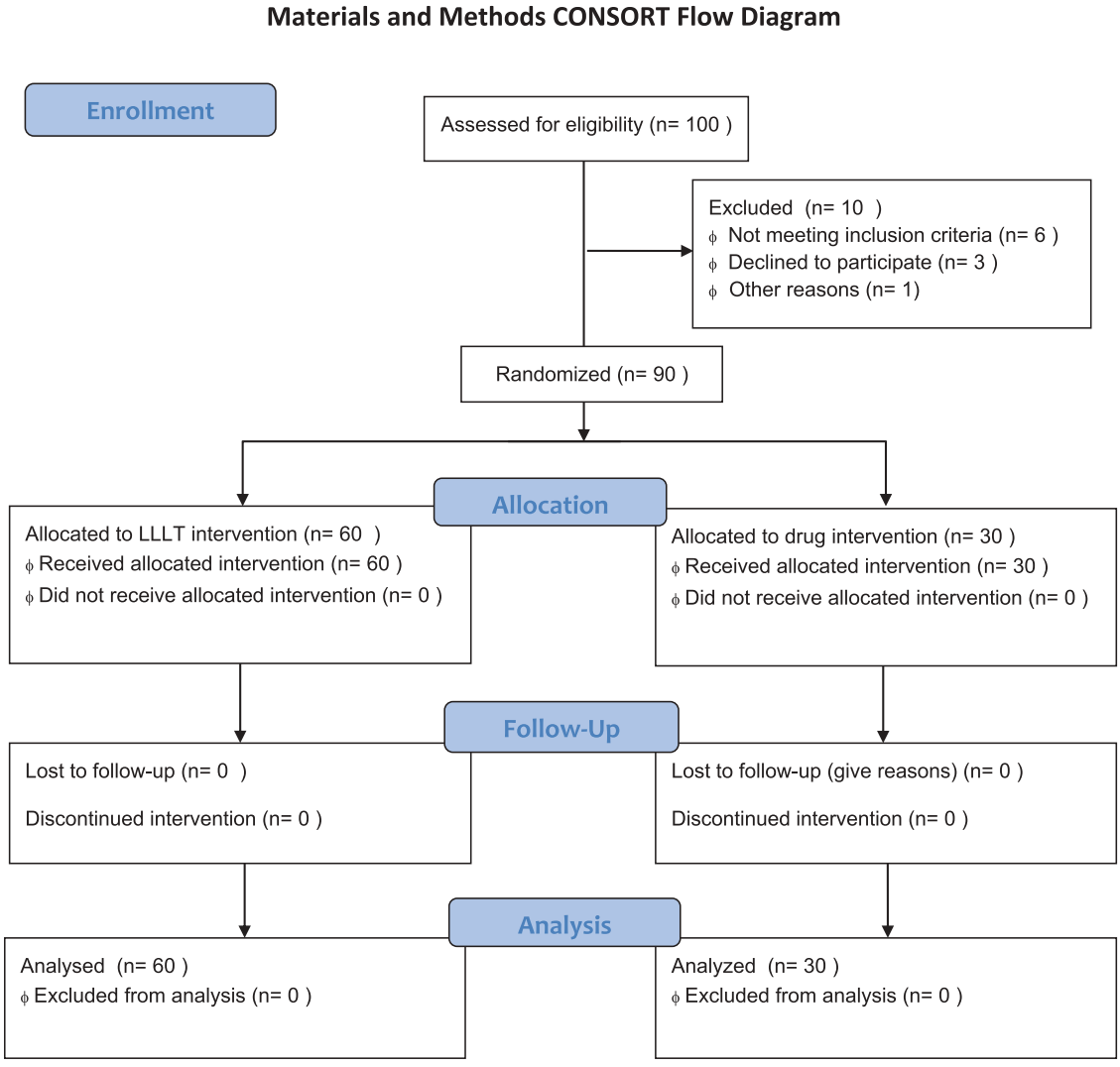


Figure 2. Consort flow diagram.

received a sham laser device manufactured also by Biocare Enterprise Limited (Good Energies, Haifa, Israel) with the same exterior characteristics of the effective device, including the guide beam and the working sound, but devoid of the therapeutic diode source.

In both groups, SG and PG, neither the patients nor the examiner knew whether the device was effective or not.

The DG consisted of 30 patients, of whom 25 were females (83.3%), and 5 were males (16.6%).

These patients (n = 30) received the conventional drug therapy protocol usually applied in the department, comprising two non-consecutive cycles of five days of nimesulide (100 mg a day), interspersed with one 5-day cycle of cyclobenzaprine hydrochloride (10 mg a day).

A pain evaluation was registered by the same blinded examiner immediately before (T0) and at the end of the treatments (T1).

Pain evaluation was performed by the visual analog scale (VAS). This scale is based on a request of the examiner to the patient to indicate the level of pain sensation on a 100 mm scale; it was successfully adopted, due to its good reliability and accuracy in many similar clinical trials [27]. After the treatment, all the patients received conventional therapy for the resolution of the TMJDs.

Results

An analysis of variance (One-Way ANOVA) was performed to compare the mean pain decrease in SG, DG, and PG patients between T0 and T1. Results indicated that the effect of the treatment was significant ($F(2,83) = 4.882$; $p = .010$). Post-hoc analysis (Bonferroni test) showed that the mean decrease in pain in the PG group was significantly lower than both SG ($p < .05$) and DG ($p < .05$). No

difference was found between the SG and DG groups (p = 1.000) (Table 5).

In the SG, a pain reduction between T0 to T1, of a mean of 34 VAS points per patient was registered. Additionally, in the PG, a mean pain decrease of 25.6 points was found. Finally, in the DG, a mean reduction of pain of 35.3 points was noted per patient. This preliminary evaluation showed that LLLT and drug therapy have almost the same efficacy in the treatment of pain related to TMJDs (Table 4).

Statistical evaluation

Aim of the study and queries

The study had two main objectives. The first was to evaluate whether the LLLT could be efficient in the reduction of pain in TMJD patients. The second aim was to evaluate the LLLT efficacy in comparison with the conventional pharmacological therapy and the possible presence of a placebo effect related to the LLLT application.

For the statistical evaluation, only 86 of 90 patients were included. Four patients (one each for the Study and Drug Groups and two for the Placebo Group) were excluded from the analyses because their data were not considered reliable; this may be due to the self-evaluation, not in line with the standards applied in the study.

Participants

A total of 86 patients, 74 females (86%) and 12 males (14%) were recruited to serve as participants. In the sample, the average age was 42.55 ± 14.84 (range 19–73 years old) (Table 1).

The age distribution of the 90 patients enrolled in the clinical study was as follows: 18 patients between 20 and 30 years old with TMJD; 29 patients between 30 and 40 years old; 19 patients aged between 40 and 50 years old; 17 patients in the group between 50 and 60 years old; and 7 patients in the group between 60 and 70 years old. Seventy-eight of the 90 selected patients were females (86.6%), and 12 were males (13.3%). There were no significant differences in gender distribution between groups (χ^2 = .506; p = .776) (Table 2). No significant differences were found between SG, PG, and DG patients in terms of age (F (2.83) = 1.647; p = .199) (Table 3). Additionally, no significant difference was found between groups with regard to the pain level registered, respectively, at T0 and at T1 (Table 6).

Table 1. Age distribution in the sample.

	Mean age	Standard deviation	F(1.83)	Significance
Females	42.40	14.679	.056	.813
Males	43.50	16.457		
Total	42.55	14.842		

The F is the Fisher value for group significance. Being >.5 it demonstrated that there were not significant age differences in M/F groups.

Table 2. Gender distribution in the three groups.

		Group			
		SG	PG	DG	Total
Gender	Females	25	25	24	74
	Males	4	3	5	12
Total		29	28	29	86

SG: Study group; PG: Placebo group; DG: Drugs group.

Table 3. Age distribution in the three groups.

	N	Mean	Standard deviation
SG	29	39.04	15.286
PG	28	46.18	16.207
DG	29	42.45	12.520
Total	85	42.55	14.842

N: Number of subjects; SG: Study group; PG: Placebo group; DG: Drugs group.

Table 4. Mean VAS reduction between T0 and T1 in the three groups.

	N	Mean	Standard deviation
SG	29	35.17	22.139
PG	28	22.14	16.635
DG	29	36.55	18.181
Total	86	31.40	20.010

VAS: Visual analog scale; T0: Immediately before treatment; T1: After treatment; *N*: Number of subjects; SG: Study group; PG: Placebo group; DG: Drugs group.

Table 5. Bonferroni test shows that the values in PG were lower than both SG and DG.

(I) Group	(J) Group	Means difference (I-J)	Standard error	Significance
SG	PG	13.030*	5.075	.036
	DG	−1.379	5.030	1.000
PG	SG	−13.030*	5.075	.036
	DG	−14.409*	5.075	.017
DG	SG	1.379	5.030	1.000
	PG	14.409*	5.075	.017

SG: Study group; PG: Placebo group; DG: Drugs group.

Table 6. No significant differences in the pain level, respectively, at T0 and T1 in the three groups.

Group		T0	T1
SG	Mean	65.52	30.34
	N	29	29
	Standard deviation	17.441	20.439
PG	Mean	58.57	36.43
	N	28	28
	Standard deviation	15.567	21.294
DG	Mean	74.48	37.59
	N	29	29
	Standard deviation	13.252	23.092
Total	Mean	66.28	34.77
	N	86	86
	Standard deviation	16.666	21.624

T0: Immediately before treatment; T1: After treatment; *N*: Number of subjects; SG: Study group; PG: Placebo group; DG: Drugs group.

According to the results obtained, it is possible to answer positively to the main query of the study, since the pain reduction obtained in the SG was significant. Concerning the answers to the two secondary queries, it is possible to affirm that the efficacy of the laser treatment is very promising, being at the same level of the one registered in the DG, while it is not possible to exclude completely, through the results of this study, a relevant placebo component. This result is, in general, also reported in other similar studies focused on pain evaluation, and its definitive clarification will be obtained with studies with larger cohorts of patients and with multiple and more complex analyses for pain evaluation.

Discussion

Several studies have analyzed the application of LLLT in the management of pain associated with TMJDs, but the real innovation that characterizes this trial is the opportunity to perform a new protocol at home. Its introduction in the management of pain related to this disorder would be very helpful because it could be an effective alternative to traditional LLLT treatments, which usually consist of multiple laser applications in the dental chair that are not well accepted by either patients or clinicians.

In this study, to achieve a highly precise determination of the efficacy of this protocol, only patients suffering from facial pain associated with TMJDs for at least six months were enrolled. Patients with pain that could be related to other conditions, such as sinus or ear infections, various types of headaches, and neurological pain, were excluded from the study.

Patients who received analgesic therapy within two to three weeks before the start of treatment, patients who received long-lasting analgesics or NSAIDs for systemic diseases, such as rheumatoid arthritis, patients who had already received previous therapies for TMJD-related pain (both conventional or laser treatments), pregnant women, and patients affected by epilepsy, coagulative disorders and/or connective tissue diseases, were all excluded from the trial.

The VAS pain evaluation system was selected because of the many advantages it offers, compared with other pain evaluation methods.

The potential benefits of LLLT have been demonstrated in many medical applications and include tissue healing, reduction of inflammation, and pain control.

The general advantages that are linked to LLLT are well documented in various studies in the literature. It is well known that LLLT substitutes for the administration of conventional drugs that are characterized by adverse side effects affecting the stomach, bowels, kidneys or liver, and adverse skin reactions [29,30].

LLLT is the application of a low-power laser light to stimulate cell responses (photobiostimulation) to achieve cellular beneficial effects [22,23]. Da Cunha et al. [31] demonstrated that LLLT could inhibit the synthesis of cyclooxygenase (COX–2), thus hindering the transformation of arachidonic acid to prostaglandins (PGE2, PGF2α), and thromboxane. Thus, analgesia occurs after the decrease in the synthesis of those precursors. Low-level laser light penetrates the tendons or joint capsule, decreasing the prostaglandin (PGE2) level in vivo and, subsequently, inflammation.

Other studies have demonstrated the effectiveness of the application of lasers at many sites of the human organism for the treatment of various musculoskeletal injuries and degenerative diseases [32].

Many studies conducted on the head and neck region have indicated that LLLT is a reliable, safe, and modern approach for the treatment of various oral and dental disorders [33].

The laser photochemical action starts at low-power fluencies (0.001 J/cm^2 -10 J/cm^2), with long exposure times, and wavelengths included in the so-called "therapeutic window," ranging from the visible red to near-infrared (650–1300 nm) that are poorly absorbed by the main constituents of the organism and have, in the meantime, a good penetrating potentiality.

LLLT acts through two different mechanisms: the first is based on the interaction between photons and specific chromophores within the cells, and the second results from the biochemical changes derived from the enhanced cell vitality.

Several studies have shown that, similar to a common drug, the biostimulative effects of LLLT are dose-dependent, with poor or no effects for low dosages and adverse up to inhibitory effects when the therapeutic dose is exceeded.

The analgesic action of lasers can be attributed to at least two main mechanisms: the first is the capability of LLLT irradiation to block the late discharges in the response of the caudal neurons that are evoked by excitatory inputs from C-fibers, although it does not suppress the early discharges evoked by inputs from A delta-fibers. This indicates that low-power laser irradiation inhibits the excitation of unmyelinated fibers, without affecting fine myelinated ones. Additionally, low-power laser irradiation has a suppressive effect on injured tissue by blocking the depolarization of C-fiber afferents, as shown by Wakabayashi [34].

The second mechanism is attributable to the induction of a higher release of endorphins [35], nitric oxide [36], bradykinin, and serotonin, both at the central and peripheral levels, with a relative increase in the central thresholds of pain [37].

According to Montesinos, instead, LLLT increases the sole production of endorphins [38]. Many authors believe that the analgesic mechanism of LLLT is due to an increase in the beta-endorphin content in the central nervous system, thus increasing the pain threshold [31,39].

Venancio et al. [39] considered that LLLT could increase the discharge of glucocorticoid, a synthetic inhibitor of endorphin, thus generating an analgesic effect.

Da Cunha et al. [31] demonstrated that local irradiation of LLLT could stimulate microcirculation of peripheral nerve tissues to block pain transmission, thus achieving an analgesic effect.

Many studies emphasized that LLLT improves the generation of adenosine triphosphate in the mitochondria. This reaction provides the energy for local metabolism and inhibits the release of endogenous pain-producing substances, such as histamine acetylcholine and bradykinin, decreasing the synthesis of pain factors [39,40].

According to other authors, the low-power laser radiation enhances the production of ATP, leading to activation of the $Ca^{2+,}$ pump and intracytoplasmic calcium accumulation, which induces cell growth and proliferation.

Thermographic studies have shown that LLLT can indirectly cause a temporary rise in tissue temperature, due to an increase in local blood flow [41]. Furthermore, the intensity of the electric field derived from polarized light changes the conformation of the double lipid layer of cell membranes using electron polarization of the lipids' electrical dipoles. One of the consequences of this effect is the modification of the surface charge of cell membranes and processes associated with the membranes themselves, such as the production of energy, immunological processes, and enzymatic reactions [42].

The reaction of LLLT wavelengths with hemoglobin seems to be another key process underlying the laser-induced biostimulation. The result of the action of the laser on the cells is to greatly accelerate the rehabilitation, reduction, and resolution of inflammation and swelling, significantly decrease pain, increase the repair process, and stimulate the immune system [43]. It has been suggested by some authors that lasers would stimulate the entire body immune system with a systemic effect. The use of therapeutic lasers has recently gained increasing acceptance in all fields of dentistry, especially for conditions such as TMJDs, which require analgesia and inflammation reduction.

Generally, patients respond well to LLLT; it is tolerated at all ages, it is painless, sterile, convenient and, among other things, it often has a positive psychological effect.

If well applied, LLLT is free of adverse side effects, and no pathological or negative effects on the human body have been reported in the literature.

Some authors have suggested that LLLT can be used as monotherapy or as a complementary approach to other therapeutic procedures for pain derived from TMJDs [44].

However, there is an ongoing scientific debate on the therapeutic value of LLLT, as evidenced from the conflicting results reported in the literature. According to different reviews by Bjordal et al. [22] and Maia et al. [45], LLLT seemed to be effective in reducing pain from chronic joint disorders. The hypothesis that LLLT acts through a dose-specific anti-inflammatory effect in the irradiated joint capsule is a potential explanation of its positive results.

The greatest criticism related to LLLT in TMJDs concerns the proper dose, as evidenced by many studies [45].

According to some authors, this lack of consensus created many controversial results and differed from the widest acceptance of laser protocols for many clinical conditions [46].

Recently, Rodrigues et al. [47] suggested a protocol based on six sessions of LLLT (three times per week for two weeks) with laser GaAs at 904 nm, 0.6 W, 60 s, and 4 J/cm^2. They registered pain intensity, the number of tender points, joint sounds, and active range of motion before and immediately after each session and after one week, two weeks, and one, three, and six months; in their series, all the patients reported significant enhancement of the symptoms and mouth-opening capability.

Sayed et al. [46] proposed the application of a GaAlAs diode laser (780 nm; with a spot size of 0.04 cm^2) in the contact mode. In their study, they matched two different protocols: in patients presenting with myofascial pain, they proposed a protocol based on the application of the laser at 10 mW, 5 J/cm^2, 2 s, and 0.2 J per point; however, for patients affected by TMJDs, they used the following parameters: 70 mW, 105 J/cm^2, 60 s on five points, and 4.2 J per point. Two sessions of LLLT per week were carried out in four consecutive weeks, with eight sessions. The reduction in pain intensity was statistically relevant in both groups.

Chen et al. [48] achieved positive results with six sessions of LLLT (three times per week for two weeks) with laser GaAs (904 nm, 0.6 W, 60 s, 4 J/cm^2). Pain intensity, the number of tender points, joint sounds, and active range of motion were assessed before and immediately after each session and after one week, two weeks, and one, three, and six months.

In a systematic review, Chang et al. [49] evaluated the efficacy of LLLT in patients affected by TMJDs. Their results indicated that LLLT was not better than placebo in reducing chronic TMD pain. However, LLLT provided significantly better functional outcomes in terms of maximum mouth opening, maximum

passive vertical opening, protrusive excursion, and right lateral excursion.

De Cunha et al. [31] indicated that an 830 nm diode laser could penetrate the soft tissue to a depth of 1 to 5 cm; thus, it was suitable for the treatment of TMJ-related pain.

Cetiner et al. [50] performed a study with LLLT characterized by a wavelength of 830 nm and dosage of 7 J/cm^2, with results showing that this wavelength is suitable for treating TMJ pain.

Mazzetto et al. [51] suggested that a laser with a wavelength of 780 nm is also appropriate for the treatment of TMJ pain because, even if this wavelength is more superficial, it provides sufficient tissue penetration and causes no thermal effect or dysmetabolic response in tissues.

The radiation dosage is determined by the irradiation time and treatment course. The key to effective treatment is the adequacy of the dosage delivered to the tissue.

Moreover, the pain through LLLT is reduced not only immediately after the treatment but, as Venancio et al. [39,52] found in their study, the activity of the TMJ was increased significantly, and the pain was relieved at the two-month follow-up.

Da Cunha and Venancio [31,39] explained that irradiation with a low-level laser could hyperstimulate the proprioceptive receptors in joint capsules, changing the secondary afferent signals, with relaxing action of masticatory muscles and reduction of damage to the TMJ.

Many other wavelengths have been used for the treatment of TMJDs – 632.8 nm helium-neon (He–Ne) laser [53], 670 nm [54], 690 nm [55], 780 nm [39], 830 nm [49,56], 890 nm [23], wavelengths of 830 nm to 904 nm [56], and 904 nm [56], with excellent results.

Carvalho et al. [57] proposed to use a combination of different wavelengths: 660 nm and/or 780 nm, 790 nm or 830 nm, arguing that the association of red and infrared laser light could be effective in pain reduction on TMDs.

Shirani et al. [23] also reported that the combination of two wavelengths, 660 nm (InGaAIP visible red light) and 890 nm (infrared laser), were proven to be effective treatments for pain reduction in patients with myofascial pain dysfunction syndrome.

Additionally, Brosseau et al. [58] reported in their study that there was no statistical difference between the 632 nm and 820 nm wavelengths. However, there is a trend for improved outcome with 632 nm compared with 820 nm for pain, although the confidence limits overlap.

However, most of the aforementioned studies showed that an efficient analgesic effect is achieved with wavelengths ranging between 830 nm and 780 nm.

Many authors have emphasized the role of the fluencies adopted in LLLT-induced analgesia [39,49,52].

However, even in this case, a clear consensus is lacking. In particular, De Medeiros et al. [54] recommend an applied energy density of 2 J/cm^2, Venancio et al. [39] suggested 6.3 J/cm^2, while Fickácková et al. [52] proposed a dosage of 10 or 15 J/cm^2. Similar dosages were also proposed by Carvalho et al. [57] (1-2 J/cm^2), Çetiner et al. [50] (7 J/cm^2), Nuñez et al. [53] (3 J/cm^2), and Kato et al. [56] (4 J/cm^2).

It is evident that more studies are needed to resolve the issues concerning the proper dosages and protocols, as well as the repeated presence of patients in the dental chair. In this study, the positive results achieved using 808 nm and 8 J/cm^2 are in agreement with those of previous studies. In no case was the worsening of pain recorded. The study supports the considerations that LLLT can be a safe and sure treatment for TMJD-related pain without negative side effects.

Moreover, the positive outcome of this home protocol confirmed by the substantial equivalence of pain reduction registered in SG and DG opens an interesting alternative to the repeated applications in the dental chair.

The advantage becomes even greater, considering that the efficacy of the pain reduction obtained by the LLLT usually lasts longer (up to one month) than the one achieved by conventional drug therapy that ends with the conclusion of treatment, as demonstrated by Bjordal et al. [22].

In some cases of SG patients, an early increase of pain was registered, but this result was probably due to an initial local hyperemia, very common during low-level laser treatments; however, after a few hours, the pain was reduced quickly to the definitive values. This finding totally agrees with the results by Marini et al. [59].

Attention should be given to the high values of pain reduction obtained in PG. These results are often registered in similar studies concerning LLLT. Enwemeka [60] suggests that the results obtained by placebo lasers should be interpreted with caution. In fact, irradiation with sham devices should not be considered as ineffective, as one would expect. The author reported a good healing process of ulcerative lesions treated with placebo lasers, with only the pointer light turned on, almost comparable to those treated with effective lasers. This effect could be referred to the attainment by the pointer light of a threshold value sufficient to stimulate, even if poorly, a tissue response. To correctly understand these values, the total amount of energy released by the pointer should be determined to correctly evaluate the obtained results.

Conclusion

The results of the current study confirm the hypothesis that LLLT is effective in reducing TMJD-related pain, highlighting that this new at-home protocol is easy to use and provides positive results.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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