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ORIGINAL ARTICLE

Efficacy of Low-Level Laser Therapy in Management of Temporomandibular Joint Pain: A Double Blind and Placebo Controlled Trial

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Abstract

Background Stomatognathic system is an interaction of the muscles of mastication, dentition, neural component, and temporomandibular joint. Any dysfunction in this system may lead to temporomandibular disorders (TMDs). Various non-surgical modalities have been employed for treating TMDs.

Aim and objectives The aim of the study was to objectively evaluate the effects of low-level laser therapy (LLLT) in treatment of patients with TMDs.

Materials and Methods Sixty individuals diagnosed with TMDs were divided randomly into two groups (Group I—placebo and Group II -LLLT). A series of 20 sessions of LLLT applied both in closed mouth and maximum mouth opening position were given over a period of 08 weeks. Assessment was done in terms of improvement in mouth opening, pain, clicking, and deviation of mandible. The data collected were analyzed statistically.

Results The results showed improvement in the pain reduction, improvement in the maximum mouth opening, reduction in deviation, and clicking in both groups but better treatment outcome in the low-level laser group.

Conclusion Though conservative measures improved the symptoms in TMD but LLLT has shown better results in comparison with the placebo group. Being non-surgical can be employed in combination with other modes for effectively treating such disorders. Keywords: Pain, Dysfunction, Temporomandibular joint disorders (TMDs), Low-level laser therapy (LLLT).

Keywords Pain · Dysfunction · Mouth opening · Temporomandibular joint disorders · Low-level laser therapy

Introduction

Temporomandibular disorders (TMDs) are a collective term that includes disorders of the temporomandibular joint (TMJ), and of the masticatory muscles and their associated structures, characterized by pain, joint sounds, and restricted mandibular movement [1, 2]. TMD has a multifactorial etiology, including the presence of parafunctional habits, trauma stress, as well as emotional, systemic, hereditary, and occlusal factors [2]. The etiology is related to an association of predisposing factors that increase the risk of TMD, initiating factors that cause the onset of TMD, and perpetuating factors that interference with healing or enhance TMD progression [3]. TMD is considered the most common cause of pain of nondental origin in the orofacial region and contains a varied group of disorders with common symptoms of psychophysiological orofacial pain, masticatory dysfunction, or both. Signs and symptoms of this dysfunction are present in approximately 86% of the population, most frequently in women in the 30 years old age group [4]. Over the decades TMDs have been managed by non-surgical and surgical methods. Non-

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surgical management is always started with until the patients are refractory. Non-surgical management includes pharmacologic therapy, psychological counseling, use of occlusal splints, and heat therapies [5].

Lasers have been used extensively in the field of medicine and dentistry since its development by Maiman in 1960 [6]. Endre Mester in the late 1960s pioneered the biostimulatory effect of low-level laser, who demonstrated an increase in collagen synthesis in skin wounds [7]. Low-level lasers do not liberate heat or destruct the fibers, and they are named so because their density is lower than 0.5w/cm^2. Some advantages of low-level laser therapy (LLLT) are stimulating biological system and improving cellular metabolism in the injured cells, having anti-irritant effect, improving blood circulation, increasing pain tolerance based on changes in the potential of embryonic layer, adjusting the immune system, increasing intracellular metabolism, speeding up scar recovery and indolence [8]. Due to its easy application, limited treatment time, and minimum contraindications, its analgesic, anti-inflammatory, and regenerative effects, this study has been carried out to evaluate the efficacy of LLLT in the management of TMDs.

Material and Methods

The study was a randomized controlled clinical trial with interventional design and parallel arm design. Patients reporting with pain in the TMJ region were included in the study. All these patients had history of initial treatment in the form of self-care, physiotherapy, occlusal splint therapy which had failed to obtain pain relief. All the study participants were informed about the details of the procedure and a written consent was obtained from them in the language they comprehend the best. The study was approved by the Institutional ethical committee and obtained clearance. A total of 60 patients were selected and divided into two groups of 30 each using the systematic random sampling method with table of random numbers as per Consort 2010 guidelines as shown in Table 1. Sample size was calculated based on the previous studies which performed a similar clinical trial and using the formula for one tailed hypothesis testing, for the hypothesis H_0: $\pi_{1-} \pi_{2} = 0$ against H_1: $\pi_{1-} \pi_2 > 0$ with the following specifications; with $\alpha = 0.05\%$ (5%) and β, Power = 80% (0.80) [9].

Group-1: Placebo group where no laser was applied.

Group-2: Patients who received LLLT.

The inclusion and exclusion criteria were:

Inclusion Criteria

(1) Patients willing to participate in the study.

(2) The presence of TMJ pain during function, absence of a specific clinical TMJ disorder condition defined according to the Clinical Diagnostic Criteria for TMDs [10].

Exclusion Criteria

(1) Patients with a myalgia, collagen vascular disease, or a history of trauma and previous surgery to joint.

Independent single investigator from the Dept of Physiotherapy was used to apply the laser therapy, who was not aware of the outcome of the study. The patients, research therapist as well as investigators were unaware of which type of treatment was applied during the sessions and subsequent follow-ups during the study.

Methodology

Sixty patients selected were divided into two groups of 30 each. The LASER was applied by a blind investigator.

Group-1 the placebo group received laser mimicking LLLT (It was not fired).

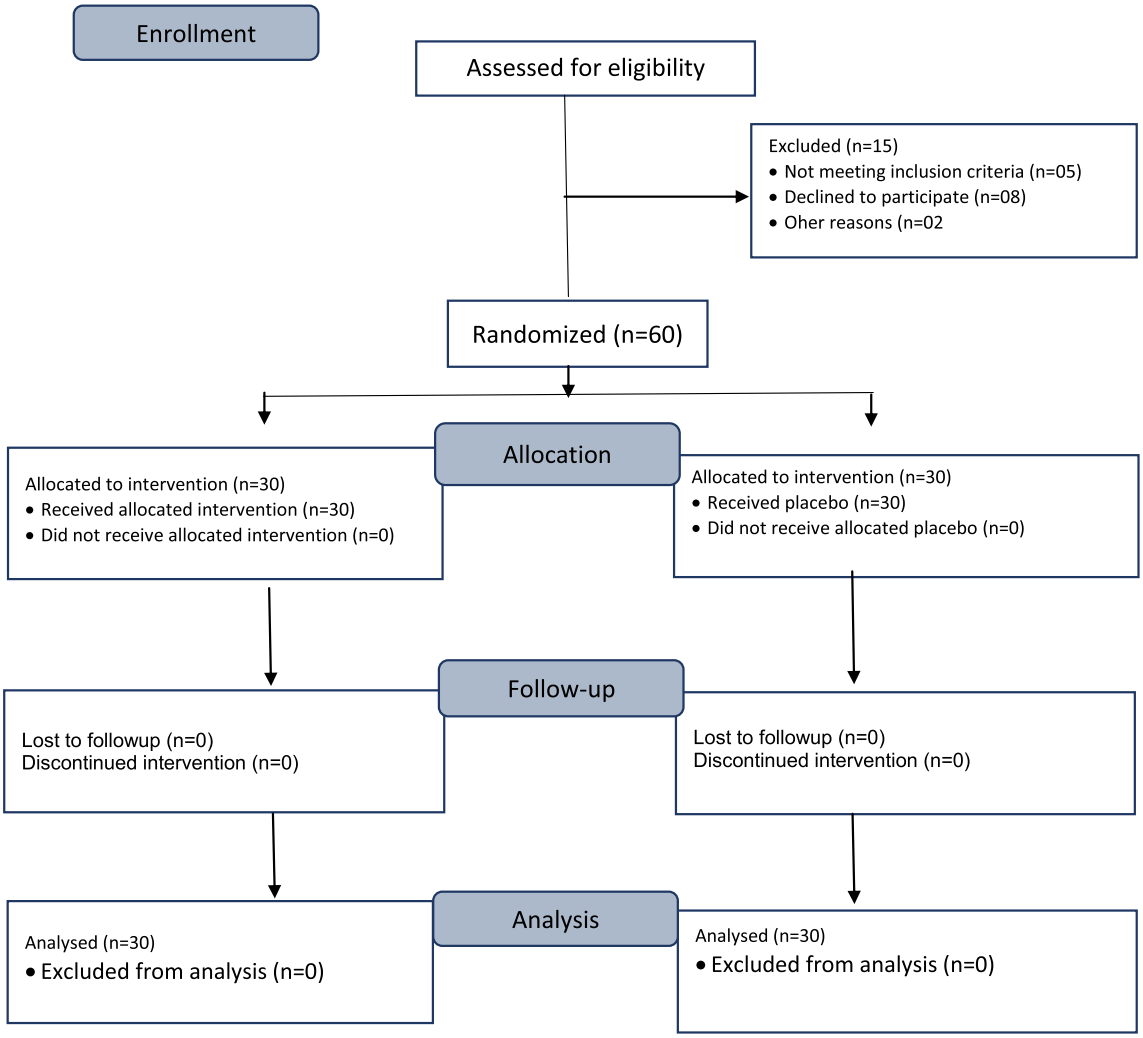
Group-2 the patients received LLLT.

The laser used was Helium–neon LASER available in the Dept of physiotherapy (Fig. 1). The probe was placed directly on the skin perpendicularly at the center of the upper joint space, approximately 1 cm in front of the tragus (Fig. 2). The laser beam was delivered through a handheld single laser probe. Each session, consisted of 2 min at both the closed mouth and maximum mouth opening position. Each patient received series of 20 treatments. Each series lasted 8 weeks, and patients were treated 2–3 times a week as per indication. Evaluation of TMJ pain during function was accomplished by patient self-assessment using a visual analog scale (VAS) as per Fig. 3 patients registered the mean pain perceived on chewing or eating hard foods in the preceding 7 days. Maximum interincisal mouth opening, mandibular movements in various excursions and deviation on opening or closing (figs. 4, 5, 6, 7). The data were obtained at baseline (week 0) and follow-up (weeks 2, 4, and 8 after the first laser therapy). Data obtained were analyzed statistically. All the patients who were still symptomatic were treated by conservative means that is mouth opening exercises and diet modification as well.

Results

Of the 60 patients included in the study, it comprised of 38 females and 22 males with age ranging from 25 to 54 with mean age of 38.4. Gender distribution was similar in both

Table 1 Consort diagram



groups with no significance statistically (p value > 0.05) as shown in Table 2.

The statistical analysis of various variables was carried out. Various parameters included VAS, maximum mouth opening, and lateral movements. Readings were noted at week 0, week 2, week 4, and week 8. The statistical analysis included comparative evaluation between the groups and within each group.

The comparative analysis of the degree of pain based on VAS among both groups showed that there was statistically significant improvement in the degree of pain in both the groups at week 2, week 4, and week 8 as shown by p value < 0.05, but as compared to group 1, group 2 showed better improvement in the degree of pain as indicated by higher mean values as shown in Table 3.

The maximum mouth opening in Group I improved from a mean of 24.03 mm at week 2 to mean of 25.73 mm at week 8, whereas Group II showed mean value of degree of mouth opening of 29.10 mm at week 2 to mean value of 35.36 at week 8. The improvement in the degree of mouth opening was statistically significant in both groups (p value < 0.05), but it was higher in Group II as shown in Table 4.

The degree of lateral movement improved from 3.73 mm to 8.86 mm in Group II over a period of 08 weeks in comparison with improvement from 3.8 mm to 4.6 mm in Group I. Group II showed a statistically significant results (p value < 0.05), as shown in Table 5.

Further the statistical analysis was carried out within each group to know the changes in each of the group. In group 1, i.e., the non-LASER group, there was improvement in the degree of pain from week 0 to week 2 and week 0 to week 4 but it was not statistically significant (p value < 0.05). However, there was statistically

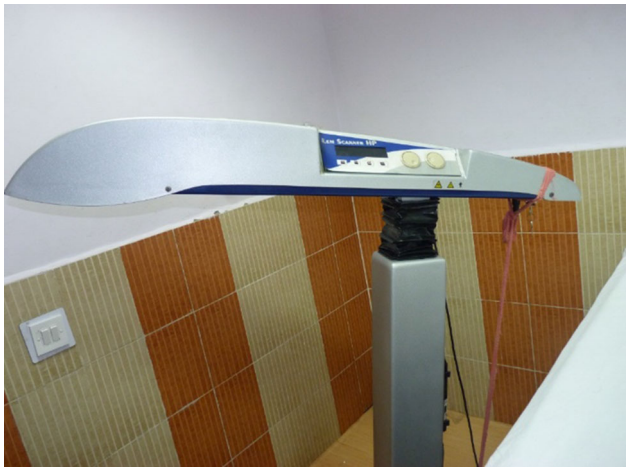


Fig. 1 Helium–neon laser

Fig. 2 Positioning of the laser

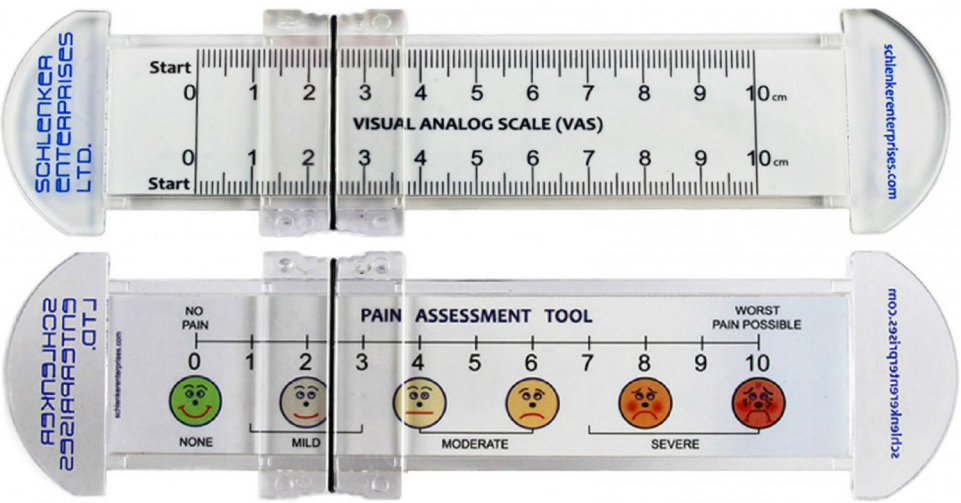
Fig. 4 Recording of pre-op maximum interincisal mouth opening

significant improvement in the degree of pain from week 0 to week 8. In Group 2, i.e., the LASER group, there was statistically highly significant improvement in the degree of pain from week 0 to week 2, week 0 to week 4, and week 0 to week 8 (p value < 0.0001), thus showing better results in the LASER group (Tables 6, 7, 8).

The statistical analysis for the degree of mouth opening within group 1 as well as group 2 showed significant improvement in the values at week 0–week 2, week 0–week 4, and week 0–week 8.

The statistical analysis for the degree of lateral movement within Group 1 showed that the improvement from week 0 to week 2 was not statistically significant (p value > 0.5). But there was statistically significant improvement at week 4 and week 8 from the baseline at week 0 (p value < 0.05). In group 2 the improvement was

Fig. 3 VAS for pain



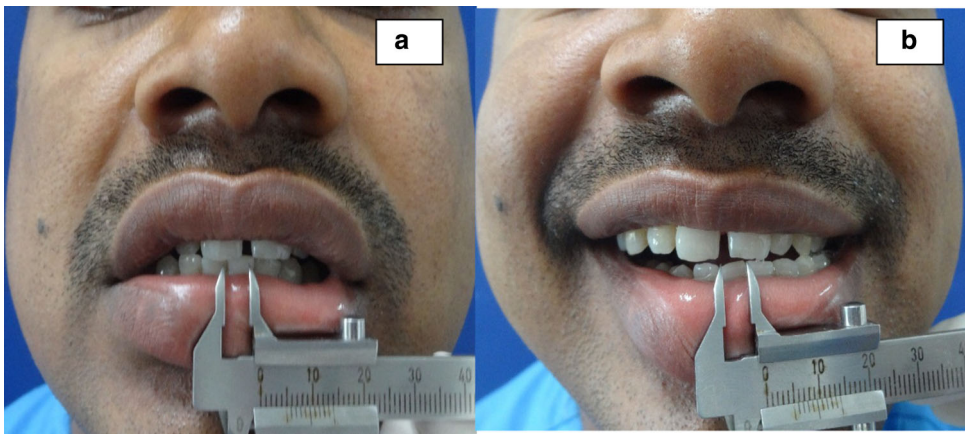


Fig. 5 **a** and **b** Pre-op recording of lateral movements toward right and left side

Fig. 6 Recording of post-op maximum interincisal mouth opening

statistically highly significant at all intervals week 0–week 2, week 0–week 4, and week 0–week 8 (p value < 0.05).

Table 2 Age and sex distribution

Group	N	Mean	Std. deviation	T	df	p value
1	30	38.2667	8.39513	− 0.616	58	0.540
2	30	39.6333	8.77883	− 0.616	57.885	0.540

Discussion

Photobiotherapy is an old method which has been used from years for treatment. This dates back to when sunlight radiations were being used, but because normal light has the natural properties of releasing and distributing in all directions, it is unable to penetrate enough living tissues, thus limiting its role only for biologic stimulation in limited dermal treatments. Laser, on the other hand, can be easily localized due to its property of monochromaticity and directionality and the power of penetration helps to accelerate tissue growth and development via cellular stimulation without the use of any drug [11].

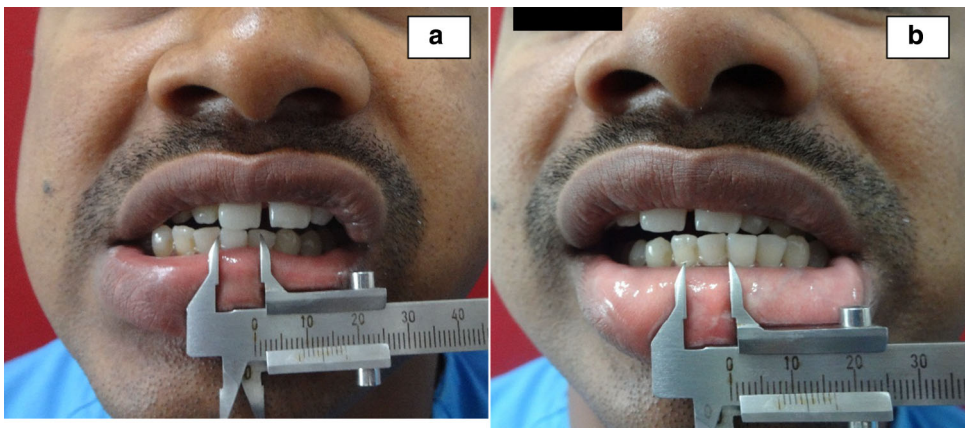


Fig. 7 **a** and **b** Post-op recording of lateral movements toward right and left side

Table 3 Degree of pain based on VAS

	Group	*N*	Mean	Std. deviation	Std. error mean	*t*	df	*p* value
Degree of pain week 0	1	30	8.6000	0.81368	0.14856	0.154	58	0.878
	2	30	8.5667	0.85836	0.15671	0.154	57.835	0.878
Degree of pain week 2	1	30	7.5000	0.93772	0.17120	3.218	58	0.002
	2	30	6.7333	0.90719	0.16563	3.218	57.937	0.002
Degree of pain week 4	1	30	6.4667	0.81931	0.14958	7.068	58	0.000
	2	30	5.0000	0.78784	0.14384	7.068	57.911	0.000
Degree of pain week 8	1	30	5.2000	0.76112	0.13896	8.537	58	0.000
	2	30	3.2333	1.00630	0.18372	8.537	53.999	0.000

Table 4 Degree of mouth opening

	Group	*N*	Mean	Std. deviation	Std. error mean	*t*	df	*p* value
Mouth opening week 0	1	30	23.6333	3.38845	0.61864	0.044	58	0.965
	2	30	23.6000	2.44385	0.44618	0.044	52.745	0.965
Mouth opening week 2	1	30	24.0333	3.40874	0.62235	− 6.531	58	0.000
	2	30	29.1000	2.53731	0.46325	− 6.531	53.588	0.000
Mouth opening week 4	1	30	24.9667	3.13471	0.57232	− 10.752	58	0.000
	2	30	32.8000	2.46912	0.45080	− 10.752	54.983	0.000
Mouth opening week 8	1	30	25.7333	3.01643	0.55072	− 14.522	58	0.000
	2	30	35.3667	2.02541	0.36979	− 14.522	50.732	0.000

Table 5 Degree of lateral movement

	Group	*N*	Mean	Std. deviation	Std. error mean	*t*	df	*p* value
Lateral movement week 0	1	30	3.8000	1.09545	0.20000	0.241	58	0.811
	2	30	3.7333	1.04826	0.19139	0.241	57.888	0.811
Lateral movement week 2	1	30	4.0667	1.22990	0.22455	− 11.551	58	0.000
	2	30	7.3000	.91539	0.16713	− 11.551	53.585	0.000
Lateral movement week 4	1	30	4.4000	1.19193	0.21762	− 14.365	58	0.000
	2	30	7.8667	.57135	0.10431	− 14.365	41.659	0.000
Lateral movement week 8	1	30	4.6000	1.22051	0.22283	− 17.341	58	0.000
	2	30	8.8667	.57135	0.10431	− 17.341	41.128	0.000

LLLT has gained lot of popularity as a method of management of many localized, painful, musculoskeletal conditions. LLLT makes use of the electromagnetic radiation of a single wavelength, usually in the red or infrared regions. LLLT provides treatment for several pathologies, including impaired wound healing, pain conditions, and inflammatory situations [12]. Its basic effects are biostimulative, regenerative, analgesic and anti-inflammatory. It also seems to act on the immune, circulatory, and hematological systems [3]. LLLT may promote analgesic effects via several mechanisms (e.g., increases liberation of endogenous opiates, increases urinary excretion of glucocorticoids, improves local microcirculation, increases lymphatic flow thus reducing edema, decreases permeability of the nerve cell membrane, decreases release of algesic agents in pathological sites, increases ATP production, decreases tissue asphyxia and acceleration of wound healing) [13, 14].

The importance of investigating the actual analgesic efficacy of LLLT lies on the fact that TMD symptoms have

Table 6 Degree of pain

Paired samples test									
		Paired differences					*t*	df	*p* value
		Mean	Std. deviation	Std. error mean	95% Confidence interval of the difference				
					Lower	Upper			
Comparison within Group I									
Pair 1	Degree of pain week 0–Degree of pain week 2	1.10000	0.75886	0.13855	0.81664	1.38336	7.940	29	0.000
Pair 1	Degree of pain week 0–Degree of pain week 4	2.13333	0.81931	0.14958	1.82740	2.43927	14.262	29	0.000
Pair 1	Degree of pain week 0–Degree of pain week 8	3.40000	0.93218	0.17019	3.05192	3.74808	19.977	29	0.000
Comparison within Group II									
Pair 1	Degree of pain week 0–Degree of pain week 2	1.83333	0.69893	0.12761	1.57235	2.09432	14.367	29	0.000
Pair 1	Degree of pain week 0–Degree of pain week 4	3.56667	0.72793	0.13290	3.29485	3.83848	26.837	29	0.000
Pair 1	Degree of pain week 0–Degree of pain week 8	5.33333	1.06134	0.19377	4.93702	5.72964	27.524	29	0.000

Table 7 Degree of mouth opening

Paired samples test									
		Paired differences					*t*	df	*p* value
		Mean	Std. deviation	Std. error mean	95% Confidence interval of the difference				
					Lower	Upper			
Comparison within Group I									
Pair 1	Mouth opening week 0–Mouth opening week 2	− 0.54839	1.26065	0.22642	− 1.01080	− 0.08598	− 2.422	30	0.022
Pair 1	Mouth opening week 0–Mouth opening week 4	− 1.58065	1.92828	0.34633	− 2.28795	− 0.87334	− 4.564	30	0.000
Pair 1	Mouth opening week 0–Mouth opening week 8	− 2.41935	2.41901	0.43447	− 3.30666	− 1.53205	− 5.569	30	0.000
Comparison within the Group II									
Pair 1	Mouth opening week 0–Mouth opening week 2	− 5.50000	1.57020	0.28668	− 6.08632	− 4.91368	− 19.185	29	0.000
Pair 1	Mouth opening week 0–Mouth opening week 4	− 9.20000	1.95466	0.35687	− 9.92988	− 8.47012	− 25.780	29	0.000
Pair 1	Mouth opening week 0–Mouth opening week 8	− 1.17667E1	2.07918	0.37960	− 12.54305	− 10.99029	− 30.997	29	0.000

been treated by a wide array of methods separately, such as interocclusal splint, medication, physical therapy, and transcutaneous electric nerve stimulation; in most cases, however, better outcome is achieved when the therapies are associated, where lasers can be of great value [15]. In view of the above we conducted a study to evaluate the efficacy of LLLT in management of the painful TMJs.

This study used a specific type of LLLT treatment (HeNe, continuous wave, 632.8 nm, 30 mW) involving direct irradiation on painful TMJs, applied 2 to 3 times a week over 8 consecutive weeks. Participants with TMJ pain did benefit throughout the treatment period from the LLLT protocol used in this study. The variable of VAS pain during function improved significantly in both groups, and the active LLLT treatment group failed to show any tendency for greater beneficial changes compared with the placebo group. This finding is most likely related to the placebo effect. In support of our findings, better therapeutic

Table 8 Degree of lateral movement

Paired samples test									
		Paired differences					*t*	df	*P* value
		Mean	Std. deviation	Std. error mean	95% Confidence interval of the difference				
					Lower	Upper			
Comparison within Group I									
Pair 1	Lateral movement week 0–Lateral movement week 2	− 0.35484	1.08162	0.19426	− 0.75158	0.04190	− 1.827	30	0.078
Pair 1	Lateral movement week 0–Lateral movement week 4	− 0.70968	1.18866	0.21349	− 1.14568	− 0.27367	− 3.324	30	0.002
Comparison within Group II									
Pair 1	Lateral movement week 0–Lateral movement week 8	− 0.93548	1.15284	0.20706	− 1.35835	− 0.51262	− 4.518	30	0.000
Pair 1	Lateral movement week 0–Lateral movement week 2	− 3.56667	1.16511	0.21272	− 4.00172	− 3.13161	− 16.767	29	0.000
Pair 1	Lateral movement week 0–Lateral movement week 4	− 4.13333	1.19578	0.21832	− 4.57984	− 3.68682	− 18.933	29	0.000
Pair 1	Lateral movement week 0–Lateral movement week 8	− 5.13333	1.13664	0.20752	− 5.55776	− 4.70890	− 24.736	29	0.000

results of LLLT compared to placebo laser treatment were also described in studies by Bradley et al., Bertolucci and Grey, Kulekcioglu et al., Beckerman et al., Cetiner et al., Sanseverino et al. and Gray et al. [13, 16–21].

Hanssen and Thoroe described no difference between active and placebo laser therapy [22]. In a meta-analysis Gam et al. [23] did not find a better therapeutic effect for active laser therapy than for placebo [23]. Similarly, significant differences between real and placebo laser treatment were not found in a study by Conti [24].

When the amount maximum mouth opening was compared among the groups, there was statistically significant increase in both groups but higher in the Group 2. This was not in agreement with the study by Camila et al. [9]. In the study conducted by them, nonsignificant increase in maximum mouth opening was found in the post-treatment evaluation of the LLLT group and a nonsignificant reduction was found in the placebo group. Their data did support the hypothesis that LLLT increases the range of motion, whereas Ahrari et al. found better results in the laser group than the placebo group regarding pretreatment and post-treatment maximum mouth opening mandibular range of motion [25].

The statistical analysis of the lateral movement showed significant improvement in both the groups with higher mean values in Group 2. Mazzetto et al. found similar results with improved pain and range of mandibular movement compared with placebo [15]. In contrast to our study, Da Cunha et al. and Emshoff found that LLLT was not effective in the treatment of temporomandibular disorders compared with placebo [26, 27].

The use of laser as a modality of TMD treatment presents several advantages, since it induces healing and allows for tissue reorganization [28, 29]. Besides, it provides fast response, is user-friendly, and may be employed for both acute and chronic pain. Kitchen and Partridge also reported that the low-level laser promotes cell alteration and proliferation, phagocytosis, and increased immune response [30]. They also stated that healing occurs by stimulation of macrophages, mast cells degranulation, activation of fibroblasts, alteration of cell membrane, angiogenesis, and photodissociation of oxyhemoglobins.

Conclusion

The present study was conducted at a single center in a comparatively small cohort. To confirm the outcome of the study, a longitudinal study with a larger sample size needs to be carried out to achieve the consistent results. Low-level therapy (LLLT) definitely has a role to play in reducing TMJ pain and improving the range of motion.

In view of the increase in the quantum of the patients with TMDs, LLLT can be made available at the maxillofacial surgical center to enable effective treatment of these patients. LLLT is not an alternative but an effective adjunct for the existing treatment modalities for treating TMDs.

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