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ORIGINAL ARTICLE

Photobiomodulation Therapy for Myofascial Pain in Temporomandibular Joint Dysfunction: A Double-Blinded Randomized Clinical Trial

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Abstract
Aims Temporomandibular disorder (TMD) is a complex process that affects the temporomandibular joint (TMJ). The multifactorial process is of unknown etiology and has many manifestations and thus many management options. Photobiomodulation therapy has been suggested for management of TMD, despite the lack of understanding of its exact mechanism. The aim of this study is to examine the effectiveness of photobiomodulation in the treatment of myofascial type TMD.
Methods Patients with unilateral TMJ and masticatory muscles pain during function were recruited and divided into two groups: a control group that received a sham laser treatment every 48 h for 10 days and a test group that received the same frequency of treatment to deliver a dose of 257 J per treatment and a total dose of 1285 J for the entire treatment. Pain was assessed using the visual analog scale (VAS).
Results There was a significant difference in VAS scores between the test and control groups with the test group scoring lower.
Conclusion Photobiomodulation therapy proved to be an effective short-term therapeutic modality for myofascial TMD pain. It is non-invasive, easy to apply with no systemic side effects. Its long-term effect and its effect on different subtypes of TMD need further investigation.

Keywords Low-level light therapy · Temporomandibular joint · Temporomandibular joint disorders · Photomodulation therapy · Laser therapy

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Introduction

Temporomandibular disorder (TMD) is a multifactorial complex process that affects the temporomandibular joint (TMJ) and its associated structures. It has different definitions in the literature. Its symptoms include facial pain, otalgia, TMJ pain, clicking, crepitus, dental wearing, neck pain, restriction in the mandibular range of motion, and/or headaches. Myofascial pain is a common manifestation of TMD. In 1992, the research diagnostic criteria for TMD (RDC/TMD) were established to create a common language for the diagnosis and management of TMD. This has recently evolved to the diagnostic criteria for TMD (DC/TMD) tool which has gained popularity in research and clinical settings [1].

The exact etiology and pathophysiology leading to the development of TMD remain unknown. The suggested risk factors include repetitive trauma to the joint, malocclusion, bruxism, psychiatric diseases, and stress [2]. Diagnosis is mainly based on history data and findings from clinical examination. Imaging may be beneficial in detecting pathology within the TMJ. The best imaging modality for assessment of the osseous structures of the TMJ is computed tomography (CT) or cone beam CT (CBCT), and the best imaging modality for assessment of the intra-articular structures of the TMJ is magnetic resonance imaging (MRI) [3].

TMD therapy typically starts with a variety of non-surgical therapeutic modalities. This includes splint therapy, heat application, occlusal equilibration, anti-inflammatory medications, muscle relaxants, arthrocentesis, and Botulinum toxin injections. Recently, photobiomodulation therapy, previously known as low-level laser therapy (LLLT), has been suggested to be beneficial in TMD therapy [4]. The exact mechanism for its therapeutic effect remains controversial. It has been suggested that the laser has an anti-inflammatory effect by inhibiting the cyclooxygenase pathway and reducing prostaglandin E2 formation [5, 6]. This study was designed to examine the effectiveness of photobiomodulation in the treatment of myofascial-type TMD.

Materials and Methods

This prospective double-blinded clinical trial commenced after ethical approval from the local ethical committees was obtained. Patients were recruited from the outpatient dental clinics of two Oral and Maxillofacial Surgery Department at two different institutions. A signed informed written consent was obtained after explanation of the study protocol. The inclusion criteria included unilateral TMJ and masticatory muscles pain during function of a magnitude of at least 3 on the visual analog scale (VAS) and the absence of any other medical conditions. The exclusion criteria included a history of trauma, collagen and vascular diseases, degenerative or arthritic changes, internal derangement, and any known psychological problems.

All patients were initially managed with conservative treatment for 2 weeks. This consisted of oral non-steroidal anti-inflammatory drugs (Diclofenac sodium 50 mg daily), muscle relaxant (Chlorzoxazone 500 mg twice a day), and heat applications to the pre-auricular and masseteric region bilaterally for 10 min, 3 times a day. They were then randomly allocated to a control and test groups using a coin toss. For the control group, a sham laser was used without notifying the patient or the treating therapist. The statistician was blinded by assigning each patient a unique computer digital number. For the test group, a diode laser was applied using the Ezlase 940 device (Biolase Technology, Inc. California, USA). A 7 W laser beam with a 2.8 cm^2 spot size emitting radiation continuously at a wavelength of 940 nm was applied by the therapist extraorally and at a 2 cm distance from the skin to 5 points at the temporal (center of Temporalis muscle), zygomatic (origin of Masseter muscle), angle of the mandible (insertion of Masseter muscle), pre-auricular, and mastoid areas. Parameters of the laser treatment are outlined in Table 1. Each application lasted 2 min (24 s per application point) so that each patient received approximately 300 J of energy per treatment as per the following equation:

$$\text{Joules} = (\text{Watts/laser wand diameter}) \times \text{duration of each treatment session in seconds}$$

Baseline VAS pain scores were recorded for all participants. The patients were instructed to record a mean value of pain during function over a 48 h period between each treatment session. Statistical analysis was conducted using IBM SPSS software version 22 (SPSS Inc, Chicago, IL, USA). Simple descriptive statistics were used to define the characteristics of the study variables through a form of counts and percentages for the categorical and nominal variables while continuous variables were presented by means and standard deviations. Independent *t* test and one-way ANOVA were used in comparing two group means and more than two groups, respectively. Paired-Samples *t* test was used to assess the change of the study variable relative to time. Statistical significance was set at a p value < 0.05.

Results

Initially, 214 patients diagnosed with unilateral myofascial pain TMD according to DC/TMD were included in the trial. Twelve patients failed to complete the protocol and were excluded. The remaining patients were assigned to the test group ($N = 108$) and to the control group ($N = 94$). There was no significant difference in age and gender

Table 1 Parameters of the photobiomodulation therapy

Irradiance or power density	7 W/2.8 cm^2
Dose	300 J/cm^2
Duration of each treatment session	120 s
Frequency of treatment	Every 48 h for 10 days
Cumulative dose	1500 J

Table 2 Age and gender distribution for test and control groups

Variable		Test group (N = 108)			Control group (N = 94)			
Gender		49 M: 59 F			43 M: 51 F			
	min	max	Mean	SD	min	max	Mean	SD
Age	19	58	34.3	10.5	18	58	33.3	10.7

SD standard deviation, *VAS* visual analog scale

distribution between the two groups (Table 2). In addition, there was no significant difference between the baseline VAS scores for the two groups (Table 3). Then, two-way ANOVA was used to compare the measures in the control group with that of the test group and there was a significant differences within the measures as demonstrated in Table 4. Hence, post hoc testing was done to determine the significant pairs. Test group VAS values were significantly different from the control group, with a p value equal to 0.01. Table 5 summarizes the possible differences within and between the days of the two groups. Most show significant differences at alpha 0.05.

Discussion

Patients with TMD remain a challenge for the medical professionals involved in managing them. This is due to the vague pathophysiology, the unknown etiology, and the variability in symptoms. Moreover, there is a variety of therapeutic options but with low levels of predictability. This resulted in favoring non-invasive therapeutic modalities with minimal side effects. Photomodulation therapy has recently gained popularity due to its non-invasive nature, ease of application, and lack of systemic side effects. In our study, we found a statistically significant difference in pain reduction between the test and control groups with the test group scoring lower pain.

Khalighi et al. [7] compared the effect photobiomodulation to Naproxen in a clinical trial and found that photobiomodulation was more effective in pain reduction and improving mouth opening. Chen et al. [8] conducted a meta-analysis of 14 randomized clinical trials and concluded that photobiomodulation therapy significantly improved function in TMD patients but had limited efficacy in pain reduction. However, their meta-analysis was limited by the lack of details related to the dose and total energy density in multiple studies. There was also a high degree of variability in the frequency and total number of laser treatments. Carrasco et al. [9] and Mazzetto et al. [10] used photomodulation therapy twice a week for 8 sessions, while Venancio et al. [11] recommended 6 sessions only with a similar frequency. Furthermore, there is no consensus on the application points of the laser. We applied the laser wand to pre-established points for all the patients. Others have recommended applying the laser wand to areas with pain only [9, 12, 13]. Limitations of this study include lack of long-term follow-up to assess the duration of the therapeutic effect of photomodulation therapy on myofascial TMD pain. Photobiomodulation therapy proved to be an effective short-term therapeutic modality for myofascial TMD pain. It is non-invasive, easy to apply with no

Table 3 T test results for testing significant difference between baseline VAS scores for test and control groups

Samples	Test value	*df*	p value
Test baseline versus control baseline	− 0.471	197.89	0.638
Male test baseline versus male control baseline	− 1.003	89.19	0.318
Female test baseline versus female control baseline	0.212	103.04	0.832

df degrees of freedom

Table 4 Two-way ANOVA results for testing VAS score differences between test and control groups with regards to the photobiomodulation therapy, day of treatment and the combination of the two elements

	df	Sum Sq	Mean Sq	F value	p value
Photobiomodulation therapy	1	556.1	556.1	1002.07	$\approx 2 \times 10^{-16}$[a]
Day of therapy	4	862.7	215.7	388.62	$\approx 2 \times 10^{-16}$[a]
Combination of therapy and day	4	113.5	28.4	51.15	$\approx 2 \times 10^{-16}$[a]
Residuals	1000	555.0	0.6		

df degrees of freedom

[a]Significantly different at alpha = 0.05

Table 5 Summary results for Tukey HSD post hoc test for determining significant pairs

Pairs	*p* value
Between groups	
Test versus control	≈ 0.00[b]
Test 2nd day versus control 2nd day	0.001[b]
Test 2nd day versus control 4th day	0.952
Test 2nd day versus control 6th day	0.001[b]
Test 2nd day versus control 8th day	0.001[b]
Test 2nd day versus control 10th day	0.001[b]
Test 4th day versus control 2nd day	0.001[b]
Test 4th day versus control 4th day	0.001[b]
Test 4th day versus control 6th day	0.001[b]
Test 4th day versus control 8th day	0.277
Test 4th day versus control 10th day	0.821
Test 6th day versus control 2nd day	0.001[b]
Test 6th day versus control 4th day	0.001[b]
Test 6th day versus control 6th day	0.001[b]
Test 6th day versus control 8th day	0.001[b]
Test 6th day versus control 10th day	0.001[b]
Test 8th day versus control 2nd day	0.001[b]
Test 8th day versus control 4th day	0.001[b]
Test 8th day versus control 6th day	0.001[b]
Test 8th day versus control 8th day	0.001[b]
Test 8th day versus control 10th day	0.001[b]
Test 10th day versus control 2nd day	0.001[b]
Test 10th day versus control 4th day	0.001[b]
Test 10th day versus control 6th day	0.001[b]
Test 10th day versus control 8th day	0.001[b]
Test 10th day versus control 10th day	0.001[b]
Between days	
2nd 4th	≈ 0.001[b]
2nd versus 6th	≈ 0.001[b]
2nd versus 8th	≈ 0.001[b]
2nd versus 10th	≈ 0.001[b]
4th versus 6th	≈ 0.001[b]
4th versus 8th	≈ 0.001[b]
4th versus 10th	≈ 0.001[b]
6th versus 8th	≈ 0.001[b]
6th versus 10th	≈ 0.001[b]
8th versus 10th	8.00×10^{-7}[b]
Within groups	
Test 2nd day versus Test 4th day	0.001[b]
Test 2nd day versus Test 6th day	0.001[b]
Test 2nd day versus Test 8th day	0.001[b]
Test 2nd day versus Test 10th day	0.001[b]
Control 2nd day versus control 4th day	0.001[b]
Control 2nd day versus control 6th day	0.001[b]
Control 2nd day versus control 8th day	0.001[b]
Control 2nd day versus control 10th day	0.001[b]
Test 4th day versus Test 6th day	0.001[b]
Test 4th day versus Test 8th day	0.001[b]
Test 4th day versus Test 10th day	0.001[b]
Control 4th day versus control 6th day	0.001[b]
Control 4th day versus control 8th day	0.001[b]
Control 4th day versus control 10th day	0.001[b]
Test 6th day versus Test 8th day	0.001[b]
Test 6th day versus Test 10th day	0.001[b]
Control 6th day versus control 8th day	0.070
Control 6th day versus control 10th day	0.004[b]
Test 8th day versus Test 10th day	0.001[b]
Control 8th day versus control 10th	0.998

[b]Significant at alpha = 0.05

systemic side effects. Its long-term effect and its effect on different subtypes of TMD need further investigation.

Compliance with Ethical Standards

Conflict of interest All authors declare no conflict of interest.

Ethical Standard All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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