DOI: 10.4274/*tftr*.57.06

Masticatory Muscle Pain and Low-Level Laser Therapy: A Double-Blind and Placebo-Controlled Study

Çiğneme Kası Ağrısı ve Düşük-Doz Lazer Tedavisi: Çift-Kör ve Plasebo Kontrollü Çalışma

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Summary

Objective: This study was designed to evaluate the efficacy of low-level laser therapy (LLLT) in patients with chronic orofacial pain of muscular origin.
Materials and Methods: A sample of 40 patients with temporomandibular disorders (TMD) of muscular origin was randomly divided on the basis of the treatment applied: laser group versus placebo group. A continuous low-intensity semiconductor laser device with an output of 300 mW, emitting radiation with a wavelength of 820 nm and having energy density of 8 J/cm^2 was used. Laser irradiation was applied to the muscles of mastication every other day for three weeks for a total of ten sessions. Mandibular mobility was examined, masticatory muscles tenderness was assessed, pressure pain threshold (PPT) values and visual analog scale (VAS) scores were obtained.
Results: A repeated measurement one-way ANOVA demonstrated significant differences between the laser and placebo groups. In the laser group, there was a statically significant reduction in PPT values and in the number of muscles with pain on palpation ($p<0.05$). Mandibular movements improved significantly ($p<0.05$) The placebo group demonstrated slight improvement, but it was not statistically significant.
Conclusion: This particular type of LLLT can be an alternative modality in the treatment of TMD in cases of myogenic origin. *Turk J Phys Med Rehab 2011;57:31-7.*
Key Words: Low-level laser, pressure pain threshold, temporomandibular disorders, pain

Özet

Amaç: Bu çalışmanın amacı kronik kas kaynaklı orofasyal ağrılı hastalarda düşük-doz lazer tedavisinin (DDLT) etkinliğini araştırmaktır.
Gereç ve Yöntem: Kassal temporomandibular rahatsızlığı olan 40 hasta uygulanan tedavi seçeneğine göre rastgele iki gruba ayrıldı; lazer grubu ve plasebo grubu. 300 mW güç ile 820 nm dalga boyunda 8 J/cm^2 enerji üreten düşük doz lazer aleti çalışmada kullanıldı. Lazer uygulaması çiğneme kaslarına her iki günde bir üç hafta boyunca toplam on seans olacak şekilde gerçekleştirildi. Mandibuler hareket incelendi, çiğneme kasları hassasiyeti değerlendirildi, basınç ağrı eşiği ve VAS skorları elde edildi.
Bulgular: Tekrarlanan tek-yönlü ANOVA analizi lazer ve plasebo grupları arasında istatistiksel anlamlı sonuçlar ortaya çıkardı. Lazer grubunda basınç ağrı eşiği değerlerinde ve palpasyonda ağrılı kas sayısında istatistiksel olarak anlamlı seviyede ($p<0,05$) azalma gözlendi. Mandibuler hareketler anlamlı derecede iyileşti ($p<0,05$). Plasebo grubunda istatistiksel olarak anlamlı olmayan hafif iyileşme gözlendi.
Sonuç: Belirtilen özellikte düşük-doz lazer kassal temporomandibular rahatsızlıklarda alternatif bir tedavi metodu olabilir. *Türk Fiz Tıp Rehab Derg 2011;57:31-7.*
Anahtar Kelimeler: Düşük doz lazer, basınç ağrı eşiği, temporomandibular rahatsızlıklar, ağrı

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Introduction

The American Academy of Orofacial Pain describes temporomandibular disorders (TMD) as a collective term embracing a number of clinical problems related to masticatory muscles and temporomandibular joint (TMJ) associated structures, or both of them (1). The treatment should be based on possible underlying etiological factors, signs and symptoms of the disorder. Although TMD has been a subject of study for a long time, many controversies still remain regarding its etiology and treatment. Early etiological concepts revolved mostly around theories of occlusal disharmonies, and the treatment was based on the model of ideal biomechanics of TMJ (2). In recent years due to the results of clinical researches, theories on the etiology of TMD have switched from the field of occlusion to field of neurophysiologic science (3-7); this has led to changes in therapeutic approaches. Complex, conservative treatments rather than aggressive and irreversible ones such as complex occlusal therapies and surgeries are preferred to relieve symptoms, diminish pain and reestablish function (2,8).

Low-level lasers (LLL) have been used in the treatment of temporomandibular disorders to alleviate pain and in the reestablishment of normal mandibular function (9,10). Theories about the mechanism of action have been proposed (11). LLL have been found to have analgesic, myorelaxant, tissue healing and biostimulatory effects (9,12,13). Several clinical studies have suggested LLL for TMD of articular origin and for myofascial pain syndrome (11,13-16). The interest in this therapy is probably due to its ease of application, shorter treatment duration, less contraindications and low cost (17-19). However, some other studies such as those done by Emshoff et al. (20), Venancio et al. (21), Conti (22), Hansen and Thoroe (23) revealed no beneficial effect of LLL.

To date, the results regarding the efficacy of LLL on muscle pain are inconclusive. The protocols used in clinical studies vary in power intensity, exposure times and location of laser application. The most common wavelength in therapeutic use is probably 810-830 nm (22,24-26). However, different wavelengths: 632.8 nm neon-hellium laser (20), 660 nm (9), 780 nm (11,21), 904 nm (15), 830 to 904 nm soft laser (10) were also used and reported to be effective in managing TMD. There is insufficient evidence on the effective dose of low-intensity laser employed in the treatment of TMD of muscular origin. Therefore, the aim of this study was to investigate the efficacy of LLL with 820 nm, 3 J/cm2, 300 mW output power in the treatment of TMD of muscular origin. We expected that this type of LLL reduce muscle pain and improve mandibular movements better than placebo.

Materials and Methods

Subjects

This study was performed at Istanbul University, Faculty of Dentistry Department of Maxillofacial Prosthodontics. The study population was selected consecutively among the patients requesting orofacial pain treatment over a period of eight months. Between March 2009 and December 2009, 482 TMD patients were examined. Of the total 482 TMD patients, 165 fulfilled the inclusion criteria, 84 accepted to participate in the study, but only 40 of them (24 female, 16 male, with a mean age of 43.7±1.8 years) who were gender and age-matched were included in the study. The patients were randomized to laser and placebo groups with the help of a computer program. In the laser group (n=20, 12 female and 8 male), the patients' age ranged from 22 to 59 (mean age 42.2±3.4) years and in the placebo group (n=20, 12 female-8 male) from 28 to 56 (mean age 42.8±2.1) years. The Ethics Committee of Istanbul University, Istanbul Faculty of Medicine approved the protocol. Written informed consent was obtained from each subject after a full explanation of the study.

The first examination was assigned to evaluate whether the subjects fulfilled the inclusion criteriae. The inclusion criteria were: 1) presence of signs and symptoms of TMD of myogenic origin according to the Research Diagnostic Criteriae for Temporomandibular Disorder (RDC/TMD) (27); 2) orofacial pain lasting for more than 6 months; 3) age between 18 and 60 years. Exclusion criteriae were: 1) disk displacements (disk displacement with reduction, disk displacement without reduction, with limited opening and disk displacement without reduction, without limited opening) and arthralgia, arthritis, arthrosis; 2) general inflammatory connective tissue diseases (e.g. rheumatoid arthritis); 3) psychiatric disorders; 4) tumors; 5) heart diseases, pacemakers; 7) pregnancy; 8) symptoms which could be referred to other disorders of the orofacial region (such as toothache, neuralgia, migraine); 9) any medication use or treatment for TMD within the last six months; 10) very high baseline pain intensity; 11) local skin infections over the masseter muscle, temporalis and/or sternocleidomastoid muscle.

The patients were asked not to take any analgesics or to have any pain treatments, starting one week before and during the study. We expressly pointed out that the patients should avoid using steroids during the treatment, as steroids block the effect of LLL treatment (28).

Study Design

The study was designed as a randomized, placebo-controlled double-blind clinical trial. The scientific recommendations of the World Association for Laser Therapy (WALT) for conducting randomized trials were applied to this research (www.walt.nu). The patients did not know whether they were assigned to laser or placebo group. The equipment used for the placebo group was the same as in laser group. However, in the placebo group, the laser device was only switched-on, not programmed. Assessment of the participants was conducted by an independent investigator who was unaware of the study.

Laser Exposure

A continuous low-intensity semiconductor (Doris Diode Laser, CTL 1106 MX, Warsaw, Poland) was used for laser irradiation. This device generates continuous radiation with regulated power. The single-probe laser device applies a laser diode generating infrared radiation of 820 nm wavelength. The beam diameter of the device is 6 mm and the probe has an angle of 45°. The energy intensity given

to each muscle point was adjusted to be 8 J/cm^2 by applying 300 mW output power for 10 seconds. LLL treatment was applied precisely and continuously into five points: three points of the masseter muscle (superior point, middle point, inferior point), one point of the temporalis (anterior point) and one point of the sternocleidomastoid muscle (superior SCM). Laser was in direct contact with the skin surface. The patients were exposed to active laser and sham application every other day for three weeks, for a total of ten sessions. The output of the laser device was tested before and after the study.

Procedure

The patients were evaluated two times: half an hour before the first session and half an hour after the last session of the assigned therapy. Each patient was assessed according to the following parameters: 1) functional examination; 2) pressure pain threshold (PPT) measurement, 3) visual analog scale (VAS). All examinations were performed by the same clinician who was an experienced prosthodontist trained in the treatment of craniomandibular disorders and was calibrated in using Research Diagnostic Criteria for Temporomandibular Disorder (RDC/TMD) as the gold standard. The clinician was unaware of the study.

1) Functional Examination: The functional examination was based on the RDC/TMD (27). The suggested translation of the RDC/TMD by the International RDC-TMD Consortium was used in this study. The masticatory muscle tenderness were assessed on both sides by bilateral palpation. The mobility of the mandible was measured with a plastic millimeter ruler on opening, lateral excursions and protrusion. The alterations in the opening pathway were also evaluated. The patients were asked to report any pain during muscle palpations and mandibular movements and the answers were recorded according to the verbal scale. The degree of pain under palpation was rated as 0-no pain; 1-mild pain; 2-moderate pain; 3-severe pain.

2) Pressure Pain Threshold (PPT) Examination: A dial algometer (Wagner Pain Test™ Model FPK Algometer, Wagner Instruments, Post Office Box 1217, Greenwich, CT 06836-1217) was used to measure the PPT on the masticator muscles. The compressions were performed via 1 cm^2 rubber tip. The PPT were obtained with the aid of an algometer by applying pressure to three points in the masseter (superior point, middle point, inferior point), three points in the temporalis (anterior point, middle point, posterior point) and one in the sternocleidomastoid muscle (superior SCM) before and after the treatment. The examiner was calibrated in pressure measurements with algometer before the study. The measurements were performed on both sides. Before the procedure was begun, a few test measurements were performed on the patients' lower arms. The patients were instructed to state immediately when the pressure feeling turned into pain feeling and the pressure was then stopped. After a rest of 30 seconds, the next measurement was performed. PPT was recorded as kg/cm^2.

3) Visual Analog Scale (VAS): In this study, the subjective report of pain was evaluated using VAS before the treatment was begun, at the end of the first week, at the end of the second week and after the assigned therapy. Pain intensity was recorded in mm on a 100 mm VAS.

Statistical Analysis

Under the assumption of a difference of one standard deviation with respect to the primary end point between the groups, an alpha level of 5 % and power goal of 80%, twenty patients per group were necessary. For all statistical tests, NCSS 2007 and PASS 2008 Statistical & Power Analysis Software (NCSS, Kaysville, Utah, USA) were used. All variables were analyzed descriptively. Descriptive statistical methods (mean, standard deviation and frequency) were applied. For the comparison of quantitative data, student t-tests were performed for between-group comparisons of parameters showing a normal distribution. The Mann-Whitney U test was performed for between-group comparisons of parameters showing a non-normal distribution. For the comparative evaluation of parameters showing normal distributions within the group, the paired-samples t-test were used. The results were analyzed at a 95% confidence interval, and the significance level was set at $p<0.05$.

The hypothesis tested in the study were as follows:

$$H_0: \mu_{before} - \mu_{after} = 0 \qquad H_1: \mu_{before} - \mu_{after} < 0$$

$$\text{Test statistics was } t = \frac{(\bar{X}_{before} - \bar{X}_{before}) - (\mu_{before} - \mu_{before})}{\sqrt{\frac{S^2_{before}}{n_{before}} + \frac{S^2_{after}}{n_{after}}}}$$

Table 1. Demographic features of the study population.

		Laser Group	Placebo Group	P
		Mean±SD	Mean±SD	
Age (years)		42.2±3.4	42.8±1.2	0.142$^+$
Education (years)		8.65±6.20	9.50±2.89	0.480$^+$
Pain duration (months)		10.5±2.7	11.0±3.1	0.289$^+$
Gender		n	n	
	Female	12	12	1.000^{++}
	Male	8	8	
Marital Status	Married	10	9	0.752^{++}
	Single	10	11	

$^+$P values were assessed by student t-test.
$^{++}$P values were assessed by chi-square test.

Results

The current study included forty patients with TMD of muscular origin (24 female, 16 male, with a mean age of 43.7±1.8 years). The demographic features of the study participants and groups are shown in Table 1. We did not identify any statistically significant differences between the laser and control groups with regard to age, gender, education or marital status. Mandibular movements and associated pain, tenderness upon palpation in masticatory muscles and PPTs were assessed in both groups. There was a statically significant increase in PPT of the examined muscles in the laser group, but no statistical significance in the placebo group (Table 2). The masseter muscle demonstrated the most severe muscle pain in both groups. As shown in Table 3, in the laser group, there was a significant decrease in pain at palpation after laser exposure and the number of muscles without any pain on palpation increased significantly. However, in the placebo group, pain severity decreased slightly, but it was not statistically significant (Table 3). The laser group demonstrated statistically significant improvements in vertical movements, lateral excursions and protrusions (Table 4).

The mean difference, standard deviation and p values of VAS before and after the treatment in both groups are given in Table 5. A statistically significant difference in VAS was not identified between the two groups before treatment (p>0.05), but it was observed that there was a significant drop in VAS after LLL treatment (Table 5).

None of the patients reported adverse effects related to laser application during or after the treatment period.

Discussion

The present study was designed to investigate the clinical effect of a specific type of LLL treatment (820 nm, 3 J/cm^2, 300 mW output power) involving direct application on the painful masticator muscles. Patients who received laser application did benefit from the therapy. Significant improvements were obtained in the tested parameters in the active laser group contrary to the placebo group.

Attempt was made to identify the apparent effectiveness of LLL in TMJ disorders, but there is insufficient evidence either for or against the use of LLL treatment. LLL treatment has often been applied in different types of pain conditions. Simunovic et al. (29) reported that patients treated with LLL recovered more rapidly and demonstrated more pain relief compared to untreated patients. The mechanisms underlying significant analgesia on muscles after laser exposure is not exactly known, but rely upon the chances in cell level

Table 2. Comparison of PPT (kg/cm^2) values. Prasure pain throrhold.

		Laser Group	**Plasebo Group**
		Mean±SD (kg/cm^2)	Mean±SD (kg/cm^2)
TA	Before treatment	18.47±4.08	18.52±4.73
	After treatment	30.55±6.68	18.87±4.17
	++p	0.027532*	0.27757 **
TM	Before treatment	19.70±3.07	14.45±3.29
	After treatment	34.02±4.34	15.17±4.93
	++p	0.02022 *	0.52936 **
TP	Before treatment	14.50±5.72	15.80±5.23
	After treatment	32.87±4.48	19.82±4.97
	++p	0.00274 *	0.26742 **
MS	Before treatment	21.37±6.72	21.87±7.34
	After treatment	34.87±5.21	28.60±6.11
	++p	0.00956 *	0.55225 **
MM	Before treatment	23.30±3.31	22.15±5.19
	After treatment	33.62±5.31	23.57±3.22
	++p	0.00303 *	0.94166 **
MI	Before treatment	21.80±5.53	26,65±6.32
	After treatment	32.55±5.64	28.25±5.13
	++p	0.00062 *	0.70732 **
SCM	Before treatment	15.80±5,93	26.65±6.32
	After treatment	22.55±5.64	24.25±5.13
	++p	0.00061 *	0.95113 **

Student t test was used.

(SD: Standard deviation, 95 % confidence interval, * p <0.05 statistically significant, ** p≥0.05 statistically non-significant)

(TA:temporalis anterior, TM:temporalis middle, TP: temporalis posterior, MS: masseter superior, MM: masseter middle, MI: masseter inferior, SCM: sternocleidomasteideous)

with increased adenosine triphosphate (ATP) production by mitochondria (30), increase in the electrical potential of the mitochondria membrane (31) and increased serotonin and endorphins (32,33). Furthermore, local blood circulation is reported to be increased, too (34,35). Successful treatment results were reported for LLL treatment in TMD of arthrogenic origin (36,37). However, there are contradictory reports that LLL treatment is ineffective in the treatment of TMJ capsulitis/synovitis and painful disk displacement with reduction (21). The same controversy is valid for the effect of LLL treatment in muscle pain, too. Many clinical studies reported favoring results of LLL in the treatment of muscle pain (9,10,15,25,38). The promising results of this clinical study support the findings published in the literature that LLL treatment is better than placebo in myogenic cases. The null hypothesis that the muscle tenderness does not increase, mandibular mobility and pain intensity will not change when patients are exposed to LLL is

Table 3. The results of muscle palpations. It demonstrates the percentage of the pain intensity of the examined muscles before and after real laser exposure and placebo laser application.

Muscle	Treatment	Pain	Laser group	Plasebo group
			n (%)	n (%)
Temporalis anterior	Before	No pain	8 (40)	9 (45)
		Mild	5 (25)	5 (25)
		Moderate	4 (20)	4 (20)
		Severe	3 (15)	2 (10)
	After	No pain	13 (65)	10 (50)
		Mild	7 (35)	10 (50)
Temporalis middle	Before	No pain	12 (60)	12 (60)
		Mild	5 (25)	5 (25)
		Moderate	2 (10)	2 (10)
		Severe	2 (10)	1 (5)
	After	No pain	18 (90)	12 (60)
		Mild	2 (10)	8 (40)
Temporalis posterior	Before	No pain	15 (75)	15 (75)
		Mild	1 (5)	1 (5)
		Moderate	3 (15)	30 (15)
		Severe	1 (5)	10 (5)
	After	No pain	19 (95)	16 (80)
		Mild	1 (5)	4 (20)
Masseter (superior)	Before	No pain	1 (5)	1 (5)
		Mild	7 (35)	7 (35)
		Moderate	6 (30)	6 (30)
		Severe	7 (35)	6 (30)
	After	No pain	13 (65)	2 (10)
		Mild	5 (25)	8 (40)
		Moderate	2 (10)	10 (50)
Masseter (middle)	Before	No pain	1 (5)	2 (10)
		Mild	9 (45)	9 (45)
		Moderate	2 (10)	4 (20)
		Severe	8 (40)	5 (25)
	After	No pain	16 (80)	4 (20)
		Mild	4 (20)	16 (80)
Masseter (inferior)	Before	No pain	1 (5)	7 (35)
		Mild	7 (35)	7 (35)
		Moderate	7 (35)	5 (25)
		Severe	5 (25)	1 (5)
	After	No pain	10 (50)	10 (50)
		Mild	10 (50)	10 (50)

rejected. In this study, objective and subjective parameters were used to evaluate the effect of LLL in patients with myofascial pain. The PPTs increased significantly and other clinical measures showed improvement and, muscle pain on palpation decreased significantly after the treatment. VAS evaluation revealed similar results.

There are many reasons explaining why the effect of LLL varies in the treatment of TMD of arthrogenic and myogenic origin. Methodological differences in patient selection and LLL treatment parameters (wavelength, power output, energy intensity and exposure duration) may affect the results. The effect of a therapy can only be identified through a well-designed clinical study. Beckerman et al. (38) conducted a criteria-based meta-analysis to assess the efficacy of laser therapy. For this purpose, the authors included only the randomized clinical trials (RCTs) in the analysis, as RCTs are the best study designs for obtaining a reliable evaluation of the treatment effects and conclusions can only be drawn from the best methodological studies. In this meta-analysis, it was concluded that the studies with positive outcome had generally a higher methodological quality. Another important point in clinical evaluation of a therapy effect in chronic pain is the blinding of the researcher. The blinding of the researcher about the type of the therapy as well as the unawareness of the patients regarding the type of treatment they receive (placebo and/or active) avoid the interference in the results. The present study aimed to investigate the effect of LLL treatment in TMD of myogenic origin. The study was designed as a randomized, double-blind, placebo-controlled study; neither the patients nor the observer was aware of the assigned therapy (active or placebo).

The chief complaint of the patients in the present study was pain. Pain levels of the subjects at baseline and throughout the study were evaluated with VAS in order to determine the change over time. In clinical trials designed to investigate the efficacy of pain treatments, the primary analysis involves reduction in pain intensity (39). For chronic pain, most measures of treatment response involve patient-reported outcomes for which the patient is the most important judge of whether changes are important or not (40-42). Evaluation of pain is difficult, because it is not controlled in the clinical research and it is a complex procedure requiring the assessment of biological, structural, functional as well as emotional pain experience. Recent chronic pain studies recommend evaluation of pain through subjective report and these should be the primary measures. In the clinical recordings, objective evaluation of pain in the masticatory muscles should be performed with a quantitative method, such as PPT which enhances the clinical assessment of pain, standardizes the outcomes and makes comparisons possible. In the present study, the objective functional measures based on the RDC/TMD and PPT values were obtained with the aid of an algometer in both groups and the patient-reported pain intensity was evaluated with VAS at different time points. PPT values supported the VAS results and demonstrated that LLL is effective in pain release; it does not act like placebo treatment.

There is a large discrepancy of the wavelength used in trials investigating the efficacy for muscle disorders. Different wavelengths: 632.8 nm neon-hellium laser (20), 660 nm (9), 780 nm (11,21), 810 nm (43), 904 nm (15), 830 to 904 nm soft laser (10) were used and reported to be effective in managing TMD. In the present study, we used a dose (820 nm) that was within the interval recommended for deep tissues. It is well known that energy density is also important in the therapeutic effect of LLLs. In some of the clinical studies that reported negative results, inadequate power or energy densities were used (20-22). According to Tuner and Hode (17), 6-10 J is suitable for myogenic conditions. Therefore, in the present study, 8 J/cm^2 was applied per point over muscle.

Table 4. Mandibular movements. Each line demonstrates the statistical analysis of a mandibular movement after LLL treatmant and placebo application.

	Laser Group		Plasebo Group	
	Mean Difference±SD (mm)	**p**	**Mean Difference±SD (mm)**	**p**
OP	18.3±4.60	0.00317*	3.28±0.75	0.34084**
MUO	19.9±2.94	0.00865*	4.32±078	0.26096**
MAO	10.4±5.09	0.05259*	5.22±0.74	0.26551**
LLE	5.9±1.20	0.00071*	0.89±0.19	0.05401**
RLE	6.05±1.50	0.02265*	0.83±0.86	0.08266**
P	5.35±1.38	0.00036*	1.23±0.97	0.53079**

Student t test was used.

(SD: Standard deviation, 95 % confidence interval, * p<0 .05 statistically significant, ** p≥0.05 statistically non-significant)

(UOP: unassisted opening without pressure, MUO: maximum unassisted opening, MAO: maximum assisted opening, LLE: left lateral excursion, RLE: right lateral excursion, P:protrusion)

Table 5. Visual Analog scale scores according to groups.

	Before Treatment	First week	Second week	After Treatment
	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Laser group	60.05±10.42	56.05±5.2	41.24±11.81	30.05±7.14*
Plasebo group	53.31±8.79	52.80±12.49	50.05±11.56	49.75±9.54**

*Mann-Whitney for differences before /first week/second week/after treatment
* p<0.05, statistically significant ** p≥0.05 - not statistically significant

There is only limited scientific evidence for the effectiveness of LLL in the treatment of TMD. The present study examined the effect of specific dose of LLL on pain release and mandibular function and found out that active laser treatment is superior to sham application. However, the present study investigated the short-term effects. Additional research should be conducted in order to investigate the long-term effects of LLL in the treatment of TMD.

This study was supported by Research Fund of Istanbul University (Project Number: UDP-4090/16072009) and presented (as oral presentation) in 33rd Annual Congress of European Prosthodontic Association 2009, Innsbruck.

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