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The Adjunct Therapeutic Effect of Lasers with Medication in the Management of Orofacial Pain: Double Blind Randomized Controlled Trial

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Abstract

Objective: This study aimed to evaluate the efficacy of laser therapy in conjunction with a pharmaceutical approach to alleviate myofascial pain dysfunction syndrome. ***Background data:*** A few clinical studies have evaluated the analgesic effect of laser therapy on orofacial pain, most of which reported controversial results. Myofascial pain dysfunction syndrome (MPDS), trigeminal neuralgia, and atypical facial pain are the most common facial pain. ***Methods:*** A double-blind randomized controlled trial was designed to evaluate the therapeutic effect of GaAs laser (peak power 10 W; pulse frequency 3000 Hz; average power 0.012 W; wavelength 980 nm; irradiation duration 300 sec; and dose 12.73 J/cm^2) on the management of common orofacial pain. The laser group ($n=30$) received 10 sessions of treatment with GaAs laser. The control group ($n=30$) was treated identically with sham laser. All patients received the appropriate pharmaceutical treatment as well. Visual analog scale (VAS) was recorded for all patients at baseline, and immediately, 2, and 4 months after the final treatment session. The qualitative variables among the groups were compared using the χ^2 test. ***Results:*** Both groups demonstrated a significant reduction in pain with the progression of time ($p<0.05$). The difference between the two groups was not significant ($p>0.05$). Whereas laser therapy in the present study failed to show any significance over the control group, the role of covariates such as radiation parameters (wave length, dose) should not be overlooked. ***Conclusions:*** We found no significant level of efficacy for the GaAs laser in the management of common orofacial pain. Further studies are suggested to evaluate the efficacy of other types of lasers with different parameters in the management of orofacial pains.

Introduction

ACCORDING TO THE MOST RECENT DEFINITION presented by the International Association for the Study of Pain, pain is described as an unpleasant feeling and an emotional experience accompanied by potential destruction of the tissue.[1]

The most common forms of orofacial pains that are evaluated in this article are trigeminal neuralgia (TN), atypical facial pain (AFP), and myofascial pain dysfunction (MPD). TN is characterized by spontaneous episodes of severe unilateral, electric shock-like pain followed by episodes of remission as a result of an otherwise normal stimulus.[1–3]

According to the definition of the International Headache Society (IHS), any pain that does not present the characteristics of orofacial pain and does not fall into any of the diagnostic groups is referred to as atypical facial pain (atypical odontalgia).[4]

MPD is a pain with muscular origin which occurs as a result of excessive load and hyperactivity of the muscle. MPD is characterized by localized vague pain with certain trigger points in the muscles, tendons, and muscle fasciae.[1]

Each type of pain requires a specific treatment approach. The pharmaceutical approach has been regarded as the most common method, but it may cause many side effects. These side effects may present as a variety of symptoms including drowsiness, nausea, vomiting,[1,5] headache, and xerostomia – the most common ones; various types of blood dyscrasias;[1,6] adverse effect on heart, liver, and various hematopoietic cells;[1,7] erythema multiform; and Stevens Johnson syndrome.[8]

These adverse effects have encouraged researchers to seek alternative therapeutic approaches either alone or in conjunction with medications, to reduce the dose and duration of drug consumption. Acupuncture, meditation, relaxation,

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and laser therapy are among these methods that have been considered more frequently over the past years.

The effects of laser therapy on these common types of orofacial pain have been recently evaluated by a few researchers.

The analgesic effect of laser is through the reduction of histamines, acetylcholine, bradykinin, and prostaglandins,[9] as well as an increase in increase in serotonin, acetylcholine esterase, lymphatic drainage, adenosine triphosphate (ATP), aerobic metabolism, pain threshold, beta endorphins, and enkephalins.[10,11] It also acts through balancing the activity of adrenaline and noradrenalin and causes a reduction in the P substance produced in the dorsal horn of the spinal cord. It induces a reduction in the arteriolar smooth muscle spasm and regulates the blood flow.[12–14]

To the best of our knowledge, only a few acceptable clinical studies evaluated the analgesic effect of laser therapy on orofacial pain, most of which reported controversial results. Here, we mention the most similar clinical trial studies whose results are different or the same as the results of this study.

Oz's group provided laser therapy twice a week (10 weeks) for myofascial pain. They used diode laser (820 nm, 3 J/cm^2, 300 mW).[15] Shirani and colleagues applied two different doses of diode laser (660 nm, 6.2 J/cm^2 and 890 nm, 1 J/cm^2). The laser was irradiated twice a week for 3 weeks and they concluded that the low-level laser therapy (LLLT) group displayed significantly lower pain exhibited on the VAS than did the control group treated with placebo.[12]

This study targets the effects of laser therapy on AFP, MPD, and TN, and aimed to evaluate the effect of laser therapy alone or in conjunction with pharmaceutical approaches in the management of orofacial pain. It is clear that the mechanisms of the analgesic effect of laser do not relate to the cause of pain. They trigger the perception of pain at higher levels (dorsal horn of the spinal cord) and the local and central mediators of cause and also of continuing pain.[10] Therefore, designing heterogonous groups with different causes of pain can not impact the methodology of this research.

Methods

This was a randomized clinical trial with a control and case group. A power calculation was performed, and the sample size was deemed 28 based on the visual analogue scale (VAS) obtained from the previous studies, first degree error (0.05), and the study power (80%). However, 30 patients were recruited for further certainty. The patients were chosen among those referred to the Oral and Maxillofacial Department of the Dental School and the Neurology Clinic in Imam Reza Health Center, affiliated to Shiraz University of Medical Sciences, Shiraz, Southern Iran, between September 2009 and December 2011.

Patients meeting the diagnostic criteria presented by the IHS and those with a history of orofacial pain who had failed to respond to medication therapy previously, were deemed eligible for the study. Pregnancy and history of recovery following drug administration led to the exclusion of the patients.

Ninety patients were evaluated for inclusion criteria, 30 of them were excluded, and the remainder (60 patients) were divided into two groups (30 patients in each group) using block randomization. The block number was 10 and the size of each block was 6. Twenty possible permutations of treatments were listed and then a randomization code was generated for the order in which to select each block. The randomization was performed by a methodologist, while one investigator was in charge of the diagnosis and recruitment and the other one was in charge of providing the treatment.

The proposed intervention was LLLT (980 nm, 3000 Hz and 12.73 J/cm^2) offered in 10 sessions (3 sessions per week). The type of laser applied was diode GaAs laser (DLT 101, Behsaz Gostar, Iran) with MOD II (980 nm, 3000 Hz, pulse duration 400 ns, average power 0.012 W) pulse mode and maximum power of 10 W. The probe diameter was 0.6 mm; therefore, beam spot size at irradiation target (πr^2) was 0.2826 (cm^2). The device has two preset modes. The mode that leads to the optimum radiation dose of 12.73 J/cm^2 in combination with proper frequency and wave length was MOD II. According to the device properties and the limitations of applying laser for a long duration in a session, and also wide research on the optimum dose for reducing this kinds of pain, the actual dose of 12.73 J/cm^2 was chosen. (Irradiance at target was 0.042 [W/cm^2] and radiant energy per irradiation site was 3.6 J.) The application technique was stationary contact.

Prior to irradiation, the desired dose was set and confirmed by a dosimeter device installed on the laser instrument. The laser was then irradiated for 5 min on each trigger point so that the total irradiated area for each patient was productive of the beam spot size at irradiation target and number of trigger points. In the absence of a trigger point, the laser was irradiated on several foci along the line of pain.

All the patients in both groups had initially provided written informed consent, and also both groups received the appropriate pain control medication as the first line of treatment.

Patients with AFP received tricyclic antidepressants and those with myofascial pain dysfunction (MPD) syndrome were prescribed anxiolytics and muscle relaxants. Carbamazepine was prescribed for patients with TN.[1,16]

The patients in the laser group were subjected to LLLT in conjunction with the medications, and the control group received sham laser treatment in addition to medication. VAS was used to quantify the level of pain among the patients at baseline, the mean VAS of each treatment session, and VAS at 2 and 4 months after the final session.VAS is a scale between 0 and 10 that explains the severity of the pain. It can be a simple written scale. The numbers from 0 to 10 were written in ascending order. When the patient reported no pain, 0 was chosen, and 10 showed the greatest degree of pain. The position of the numbers and the instructions to the patients helped the illiterate to show the degree of pain.

The VAS score was recorded by a third person who was not involved in the treatment procedures. The operators were blind to the results of their treatments, recorded as VAS, whereas the patients were blind to the all procedures. The data analyst was blind to the intervention groups as well.

The qualitative variables among the groups were compared using the χ^2 test. To evaluate the normal distribution of the quantitative variables, the one sample Kolmogorov–Smirnov test was used, and to assess the pattern of pain

Table 1. Distribution of Patients with Respect to Type of Pain and Sex (Number and Percentage)

Type of pain	*Male*	*Female*
MPDS ($n=20$, 33.3%)		
Laser ($n=8$)	1 (12.5%)	7 (87.5%)
Control ($n=12$)	2 (16.6%)	10 (83.3%)
Trigeminal neuralgia ($n=26$, 43.3%)		
Laser ($n=12$)	4 (33.3%)	8 (66.6%)
Control ($n=14$)	5 (35.7%)	9 (64.2%)
Atypical facial pain ($n=14$, 23.3%)		
Laser ($n=10$)	4 (40%)	6 (60%)
Control ($n=4$)	1 (25%)	3 (75%)

MPDS, myofascial pain dysfunction syndrome.

variation from the baseline up to 4 months post-treatment, the repeated measurement ANOVA test followed by Mauchly's sphericity test were applied to validate the results. Finally, a sensitivity analysis was performed to confirm the accuracy of the findings.

This clinical trial has been registered in Iranian Registry of Clinical Trials (IRCT) and code IRCT201201018585N1 has been allocated to it. The ethics committee of Vice Chancellor of Research Affairs, Shiraz University of Medical Sciences of Iran confirmed this study and received ethics code 90-5886.

Results

A total of 60 patients (73.33% females and 26.66% males) with mean age of 47.22 years (females: 45.43, and males: 54 years) participated in this study (Table 1). Each group consisted of 30 patients. Seven patients in each group withdrew from the postoperative evaluations and were excluded from analyses (one patient [3.3%] immediately after the final session and 6 [20%] on the 2- to 4-month follow up visits). CONSORT 2010 flow diagram (Fig. 1) explains the steps of trial.[17] Those who dropped out were similar in all aspects except for the type of pain (Table 2).

The two groups failed to present any significant differences in terms of the type of pain ($p=0.172$) (Table 3).

Table 4 and Fig. 1 represent the mean VAS scores and the pain variation pattern among the study groups. The repeated measures ANOVA revealed a significant difference in the level of pain within each study group at baseline and immediately after the final treatment session, with a descending pattern ($p<0.0001$). The pain level, however, increased significantly among both groups after 2–4 months, compared with the immediate post-treatment levels ($p<0.0001$) (Table 4).

The laser group presented lower levels of pain at the three intervals than did the control group; however, the difference was not significant ($p<0.726$).

Both groups presented similar patterns in the level of pain, with no marked difference in the rate of the variations

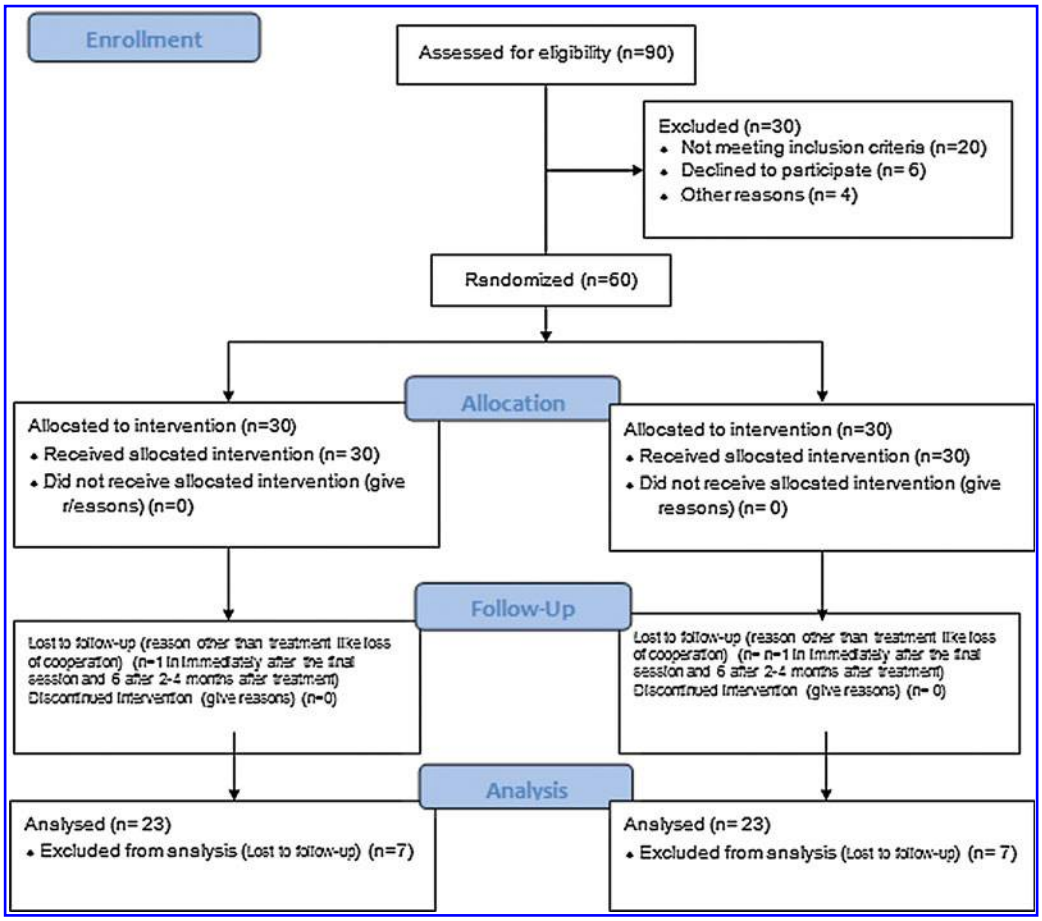

FIG. 1. CONSORT 2012 flow diagram.

Table 2. Distribution of Withdrawals Throughout the Experiment Among Each Pain Category

Study population (n = *60*)	*Lost to follow-up* (n = *14*)	
	Immediately after the final session (n = *2*)	*After 2–4 months post-treatment* (n = *12*)
Laser group ($n=30$)		
MPDS ($n=8$)		2 (25%)
TN ($n=12$)	1 (8.3%)	2 (16.7%)
AFP ($n=10$)		2 (20%)
Control group ($n=30$)		
MPDS ($n=12$)		3 (25%)
TN ($n=14$)		2 (14.3%)
AFP ($n=4$)	1 (25%)	1 (25%)

MPDS, myofascial pain dysfunction; TN, trigeminal neuralgia; AFP, atypical facial pain.

($p<0.498$), which indicates the absence of interaction between the evaluation time and the respective groups.

For sensitivity analysis, the highest VAS score was considered for each patient before providing them with any treatments as a substitute for the missing data. The statistical analysis was then performed and similar patterns of variation in the pain level were observed among both groups (initial decrease and subsequent increase) ($p<0.0001$). In terms of the average VAS score, the laser group showed an overall lower pain level; however, the differences were not significant between the two groups at the time intervals mentioned ($p=0.824$). Furthermore, this research failed to identify any marked differences in the rate of variation of the pain level between the two study groups ($p=0.534$).

For the second stage of the sensitivity analysis, the mean VAS score obtained from all the patients in the same group with the same type of pain and for the same time interval substituted for the missing data. The statistical analysis revealed similar results in terms of the pattern of pain level variation. The laser group displayed a slightly higher level of pain reduction; however, the difference was not significant ($p=0.614$). The pain level variation rate also failed to show any marked difference between the two study groups ($p=0.276$) (Fig. 2).

This study attempts to provide an effective approach to orofacial pain treatment, with minimum adverse effects.

Discussion

Although the average VAS of the laser group was less than that of control group, the difference was not statistically significant. The results of the present study in terms of the efficacy of laser in pain reduction in comparison with the control group was in line with those of Oz et al., Carrasco et al., Dundar et al., Altan et al., and Hansen et al. [9,10,15,18,19] Fulop and colleagues further conducted a meta-analysis on this subject and confirmed these findings.[20] The notable issue in all these studies was that laser therapy failed to prove to be any more effective than other therapeutic approaches.

Table 3. Distribution of Patients in the Laser and Control Groups with Respect to Type of Pain

	MPDS (n = *20*)	*TN* (n = *26*)	*AFP* (n = *14*)
Laser group ($n=30$)	8 (40%)	12 (46.2%)	10 (71.4%)
Control group ($n=30$)	12 (60%)	14 (53.8%)	4 (28.6%)

MPDS, myofascial pain dysfunction; TN, trigeminal neuralgia; AFP, atypical facial pain.

Table 4. The Mean VAS (±SD) at Baseline, Immediately After the Final Treatment Session, and 2–4 Months Post-Treatment Among the Laser and the Control Group

	VAS		
	Baseline	*Immediately after the final treatment session*	*After 2–4 months*
Laser group	7.7 ± 1.9	2.3 ± 2.3	3.5 ± 2.8
Control group	7.5 ± 2.3	3 ± 3.7	3.8 ± 3.7

VAS, visual analogue scale.

Although studies have more or less reported the radiation parameters of the tested lasers, some have failed to provide information about the density of the applied laser and others have applied densities at the two ends of the spectrum [either too high ($>20\,J/cm^2$) or too low ($<5\,J/cm^2$)]. Very few studies applied a medium level of density; therefore, the researchers set the dose at $12.73\,J/cm^2$.

Carrasco and colleagues applied very high densities of laser ($25, 60, 105\,J/cm^2$) and failed to obtain any significant results.[10] Therefore, based on other reports and the recommended doses for GaAsAl laser,the present study attempted to apply a lower density. The applied density in Oz's study was $3\,J/cm^2$ and in Hansen's study the denstities were 4.7 and $9.4\,J/cm^2$. Considering their results, the researchers of this study preferred to evaluate a higher density.[15,19]

To evaluate the longevity of the efficacy of laser therapy, different studies reported the VAS at different intervals. Carrasco and coworkers evaluated the analgesic efficacy of laser therapy 15 and 30 days after treatment. Dundar performed the evaluations 4 weeks post-treatment, and Altan and colleagues evaluated the VAS on weeks 0, 2, 12, and 14. Despite the differences in the evaluation times, similar results were obtained. [9,10,18]

In terms of the frequency of the sessions, Oz's group provided the treatments twice a week for 10 weeks,[15] Carrasco's protocol was twice a week for 4 weeks,[10] Dundar et al. and Altan et al. irradiated the laser once a day for 15 and 10 consecutive days, respectively,[9,18] and Hansen and colleagues performed eight sessions of treatment over a period of 4 weeks.[19] The analgesic effect after each laser therapy session is said to last for 9–72 h; therefore, in order to avoid the cumulative effect of the sessions, the frequency of the treatment sessions in the present study was set at three times per week. Considering the width of the intervals between each session, and the longevity of the analgesic effect of the laser, appropriate design of the treatment protocol is highly disputable and of significant importance.

Other studies, including those of Shirani et al.,[12] Hakguder et al.,[11] Ceylan et al, [21] and Walker [22] have reported

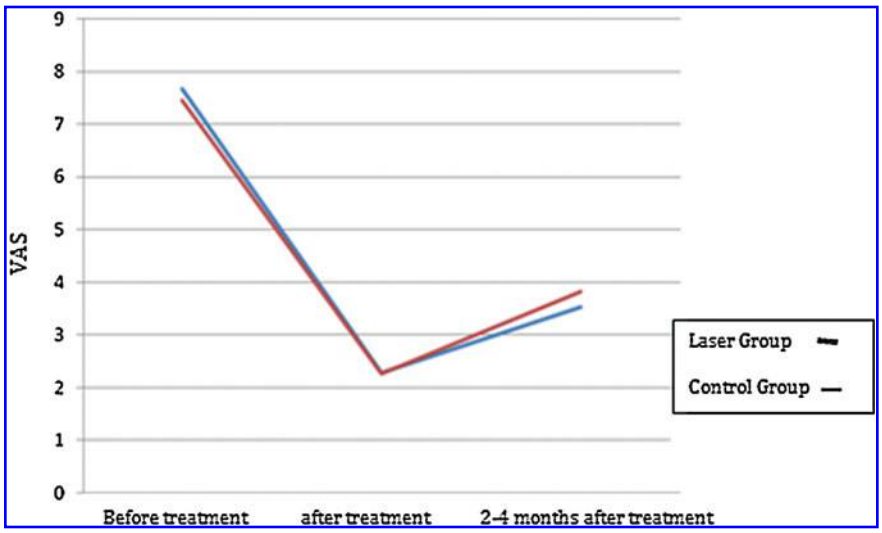

FIG. 2. The mean visual analogue scale (VAS) (±SD) at baseline, immediately after the final treatment session, and 2–4 months post-treatment for the laser and the control groups.

controversial results. They have shown that laser therapy is significantly more effective in pain management than placebo.

Shirani et al. and Hakguder et al. applied GaAsAl laser at 6.2 and 5 J/cm^2, respectively.[11,12] The treatment protocol in Shirani's study was two sessions per week for 3 weeks.[12] The differences between the results of their studies versus this study may be attributed to the different lasers used. Because of the widespread use of GaAsAl laser, the diode laser GaAs was chosen instead.

The wavelength applied in the abovementioned studies (Shirani et al., Hakguder et al., Ceylan et al., and Walker) ranged between 650 and 1000 nm, which presented high penetrating ability (20–40 mm) and was suitable for deep pain.[11,12,21,22]

Yang et al., IIbuldu et al., Pinheiro et al., and Gam et al. conducted controlled clinical studies to evaluate the efficacy of lasers in the management of chronic orofacial pain. They initially prescribed the appropriate pharmaceutical agent for each patient in the laser and control groups, and then irradiated the test laser for the intervention group, and the sham laser for the control group. This helped to minimize bias in the patient's interpretation of the intervention.[23–27]

This study tried to choose the most suitable type of laser, the correct wavelength, and the most beneficial interval between the treatment sections, according to valid references and articles. As laser therapy is not the primary approved treatment for these patients, on an ethical basis, laser therapy can be prescribed only as an adjuvant treatment until it can be proven that laser therapy has the efficacy comparable to the current primary treatments. Medical therapy has no interfering effect on the results because both groups received medication. This study was a double blind clinical trial; therefore, the psychological effects of applying laser for patients were considered for both groups.

It appears that in the studies of the efficacy of lasers as a therapeutic modality, definitive determination of the type of suitable laser, radiation dose, and wavelength may not be practical. The literature fails to provide specific guidelines on the selection of these parameters, and studies base their decisions on the available resources and clinical and experimental experiences.

For example, laser therapy is believed to activate the somatosensory receptors, resulting in a reduction in the regional pain perception and the relaxation of the trigger points. This hypothesis, however, may not be true in the case of deeper trigger points, which may be one of the reasons that this study failed to demonstrate marked difference in pain reduction between the two groups. It is very likely that with the set radiation parameters, deep trigger points remained unaffected, which led to there being controversial results throughout the literature. Therefore, determining the real depth of trigger points can be an important subject that needs to be investigated.

The amount of pain reduction in control group was considerable, and was comparable to that for the laser group. This might show the powerful psychological effect of laser therapy.

According to these findings, laser therapy is not a perfect and independent treatment for myofascial pain; however, further research that is more accurate about real depth of trigger points and the proper dose of radiation is recommended.

Conclusions

The findings of this study failed to present a significant level of efficacy for the GaAs laser in the management of common orofacial pain, including theTN, AFP, and MPD syndrome. Both groups displayed some level of pain reduction. Despite the absence of statistical significance in the efficacy of lasers in the tested setting, the results should be interpreted with caution, and further studies are suggested to evaluate the efficacy of other types of lasers with different parameters in the management of orofacial pains.

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Author Disclosure Statement

No competing financial interests exist.

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