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ORIGINAL ARTICLE

A randomized clinical trial comparing the efficacy of low-level laser therapy (LLLT) and laser acupuncture therapy (LAT) in patients with temporomandibular disorders

Azamsadat Madani [1] · Farzaneh Ahrari [1] · Amir Fallahrastegar [1] · Naeemeh Daghestani [2]

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Abstract

This study compared the efficacy of low-level laser therapy (LLLT) versus laser acupuncture therapy (LAT) in patients with temporomandibular disorders (TMDs). In this randomized, double-blind clinical trial, 45 TMD patients were randomly divided into three groups. In group 1 (LLLT), a GaAlAs laser was applied on painful masticatory muscles and TMJs (810 nm, 200 mW, 30 s per point, Gaussian beam, spot size 0.28 cm^2, 21 J/cm^2) two times a week for 5 weeks. In group 2 (LAT), the laser was emitted bilaterally on acupuncture points (ST6, ST7, LI4) with the same settings as the LLLT group. Group 3 (placebo) underwent treatment with sham laser. The patients were evaluated before treatment (T1), after 5 (T2) and 10 (T3) laser applications, and 1 month later (T4). The mandibular range of motion as well as pain intensity in masticatory system was recorded at each interval. There was no significant difference in mouth opening between the groups ($p > 0.05$), but the amount of lateral excursive and protrusive movements was significantly greater in LLLT and LAT groups than the placebo group at some intervals ($p < 0.05$). The overall pain intensity and pain degree at masticatory muscles (except temporal muscle) and TMJs were significantly lower in both experimental groups than the placebo group at most intervals after therapy ($p < 0.05$). Both LLLT and LAT were effective in reducing pain and increasing excursive and protrusive mandibular motion in TMD patients. LAT could be suggested as a suitable alternative to LLLT, as it provided effective results while taking less chair time.

Keywords Low-level laser therapy · Low-intensity laser therapy · Temporomandibular dysfunction · Temporomandibular disorder · Temporomandibular joint · Laser acupuncture · TMD · LLLT · Photobiomodulation

Introduction

Temporomandibular disorder (TMD) is a prevalent condition that affects orofacial muscles, temporomandibular joints (TMJs), or both. TMD is the most common reason of non-dental pain in orofacial area and is more frequent in young and middle-aged females [1]. The epidemiological studies revealed that about 40–75% of the population show at least one sign of TMD, whereas only a few percent of them ask for treatment [2]. The etiology of TMD is multifactorial and therefore diverse treatment modalities have been suggested and applied to cure this condition. Since the definitive treatment of TMD is seldom attained, most clinicians rely on maintaining therapies to alleviate the signs and symptoms of affected patients. Both medical therapy (generally with the use of NSAIDs) and physical therapy (using thermal therapy, acupuncture, transcutaneous electrical neural stimulation, ultrasound therapy, and low-intensity laser therapy) have been used as supplementary methods to control pain and recover the function of the masticatory system in TMD patients. Due to the deleterious effects of NSAIDs, the interest to physical therapy has been increased nowadays to the extent that the American Academy of Craniomandibular Disorders has considered physical therapy as a main treatment modality for TMD management [3].

Low-level laser therapy (LLLT) is a novel, noninvasive, and cost-effective approach in the field of physiotherapy. Because of its unique properties, low-power laser irradiation

✉ Farzaneh Ahrari
Farzaneh.Ahrari@gmail.com; AhrariF@mums.ac.ir

✉ Naeemeh Daghestani
Naeeme28@yahoo.com

1 Dental Research Center, Mashhad University of Medical Sciences, Mashhad, Iran

2 Resident of Pediatric Dentistry, School of Dentistry, Mashhad University of Medical Sciences, Mashhad, Iran

can alter cellular metabolism (bio-stimulating effect), reduce pain (analgesic effect), improve the wound healing procedure (regenerative/reparative effect), reduce edema, and accelerate the inflammation process (anti-inflammatory effect). LLLT has been employed as a treatment modality for a variety of conditions in medicine and dentistry including musculoskeletal pain syndrome, soft tissue injuries and ulcerations, dentin hypersensitivity, and attenuating the complications of surgical procedures [4–11].

Needle acupuncture is a treatment modality based on traditional Chinese medicine, in which small needles made from stainless steel are inserted into special points of the body to improve health or reduce pain in other parts of the body. Despite its proven effects in curing numerous diseases, acupuncture is associated with some disadvantages that reduce its acceptability and popularity among patients, such as aggressive nature of needle insertion and difficult application in some parts of the body such as points around the perineum or genitals [12]. Recently, laser acupuncture therapy (LAT) has been proposed as an alternative to conventional acupuncture therapy to eliminate the need for needle insertion. In this way, low-intensity laser light is employed for stimulating the traditional acupuncture points, and so the procedure is simple, non-aggressive, painless, and inherently safer than needle acupuncture therapy [12–14].

Previous studies reported controversial results regarding the efficacy of LLLT in reducing signs and symptoms of TMD patients. Although most studies reported positive results [15–17], there are also studies that indicated no significant superiority for LLLT over placebo administration concerning TMD symptoms [18–20]. There are also few studies, mainly case series, regarding the outcomes of LAT in managing temporomandibular dysfunction [12, 21, 22]. According to the authors' knowledge, the effectiveness of LLLT versus LAT in treatment of patients with TMD has not been compared in previous studies. Furthermore, in approximately all laser acupuncture studies, laser beam has been emitted not only on acupuncture points but also on the local Ashi point (the point of most tenderness). No study investigated the pure effect of laser irradiation on acupuncture points specifically defined for relieving pain in orofacial area.

This randomized double-blind clinical trial aimed to compare the efficacy of LLLT versus LAT (without irradiation on Ashi points) on pain intensity and mandibular range of motion in TMD-affected patients.

Subjects and methods

The sample of this randomized double-blind clinical trial consisted of 45 TMD-affected patients who referred to the Occlusion and TMD Department of Mashhad Dental School, Mashhad University of Medical Sciences, Mashhad, Iran, during the period from January 2017 to February 2018. The inclusion criteria were limited mouth opening or function and the presence of pain in masticatory muscles and/or TMJs, either in clenching or in jaw movements (TMD muscular disturbance (class Ia, Ib) or arthralgia (class IIIa), according to Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD)). The exclusion criteria involved patients who had major systemic disorders, and those who received analgesic or anti-depressants over the last 2 weeks, as well as patients who had any bony abnormalities of the jaws such as arthropathy of the TMJ or rheumatoid arthritis. Patients with psychological illness, those who received any form of treatment for TMD within the last month, and pregnant and feeding women were also excluded from the sample. The protocol of the study was reviewed and approved by the Ethics committee of Mashhad University of Medical Sciences (IR. Mums.sd.REC.1394.191) and was recorded in Iranian Registry of Clinical Trials with IRCT number IRCT2017010131770N1. The procedure was explained in detail for all the patients and signed consents were taken before the study commencement.

Patient assignment and blinding

The patients were randomly divided into three groups of 15 according to a random numbers table with a random block size of 3. The details of the allocated groups were written on cards contained in sequentially numbered, opaque, and sealed envelopes. These cards were prepared by an independent person who was not involved in the study protocol. Once the participant completed the TMJ examination and was eligible for laser therapy, the allocation assignment was revealed by opening the envelope by this independent person.

Laser treatment was carried out by a single, trained and experienced operator. For ensuring double-blind design of the study, neither the patient nor the subject who evaluated the outcomes was aware of the group assignment.

The clinical procedure

In all groups, the painful points were determined at each assessment interval. Bilateral muscles including masseter (origin, body, and insertion), temporal (anterior, middle, posterior), tendon of temporal, and insertion of internal pterygoid as well as temporomandibular joints (TMJs) at rest and function were palpated and the painful points were recorded in the patient's folder. TMD treatment was performed in Department of Laser of Mashhad Dental School. The participants underwent the following treatments:

Group 1 (low-level laser therapy (LLLT)): The patients in this group received treatment with a low power gallium aluminum arsenide (GaAlAs) diode laser (DD2, Thor, England), applied on painful points. A schematic representation of the points of laser application has been provided elsewhere [9]. The laser apparatus emitted a wavelength of 810 nm (Gaussian beam profile) and was employed in contact and continuous-wave mode with the output power of 200 mW. The probe was held perpendicularly with light pressure for 30 s per point, giving 6 J of energy with energy density (dose) of 21 J/cm^2 to each painful area (surface area of the probe aperture 0.28 cm^2). Laser therapy was performed on posterior and superior of the mandibular condyles, and inside the external acoustic meatus, and also on tender muscle points defined during examination. The laser was applied two times a week for 5 weeks.

Group 2 (laser acupuncture therapy (LAT)): In this group, the 810-nm diode laser was emitted bilaterally on acupuncture points traditionally used in Chinese medicine for relieving facial and neck pain. These points were ST6 (Fig. 1a), ST7 (Fig. 1a), and LI4 (Fig. 1b), as used by previous investigators [12, 22]. The local Ashi point was not irradiated in this study. Stomach 6 or ST6 is located right in the middle of upper and lower jaws. To define this point, the patient was asked to clench his/her back teeth. ST6 was where the muscle in front of his/her earlobe protrudes out. Large intestine 4 or LI4 is located on the highest point of the fleshy joining between the index and thumb fingers when they are stretched outwards. ST7 or Xiaguan (English translation: Below the Joint) is located on the face, anterior to the ear, in the depression between the zygomatic arch and the condyloid process of the mandible. To determine this point, the lower border of the zygomatic arch was palpated towards the ear. ST7 was located in a clearly palpable depression just before the temporomandibular joint and at the posterior border of the masseter muscle. The laser probe and settings were the same as those in the LLLT group (200 mW, CW, 30 s per point, 6 J, spot size 0.28 cm^2, energy density 21 J/cm^2) and the treatment was performed two times per week for 10 sessions.

Group 3 (placebo): The patients in the placebo group received treatment similar to that performed in the LLLT group, but the laser was off and no light was delivered.

Both the patient and the operator wore protective goggles during treatment. The patients in all groups were asked not to resort to self-medication during the study period. Any patient who did not improve during treatment was referred to receive another treatment modality for TMJ dysfunction, if tended.

Patient assessment

The patients were evaluated before treatment (T1), after 5 laser applications (T2), at the end of treatment (T3), and 1 month after the last application (T4). At each assessment interval, the amount of mouth opening and the range of protrusive and lateral excursive movements of the jaw were measured and recorded. To measure mouth opening, the patient was asked to open the mouth at both “maximum pain-free” and “maximum possible” conditions. The vertical interincisal distance was then measured with a digital caliper and recorded in millimeters in patient’s folder. The right and left lateral jaw movement was measured in millimeters by detecting the horizontal distance between the midpoints of the upper and lower central incisors.

The degree of overall pain at rest condition as well as pain degree at tender points was recorded at each assessment interval. To define pain intensity, the masticatory muscles including masseter muscle (origin, body, insertion), temporal muscle (anterior, middle, posterior), tendon of temporal muscle, and insertion of internal pterygoid muscle and also temporomandibular joints (TMJs) at rest and function were palpated bilaterally with firm and constant pressure (about 1 kg for external muscles and about 0.5 kg for intra-oral muscles). A visual analogue scale (VAS) was used for measuring pain intensity upon palpation. This scale consisted of a 10-cm horizontal line with 0 (the left side) indicating no pain and 10 (the right side) indicating the most severe pain. The patients were asked to mark the degree of perceived pain on the scale.

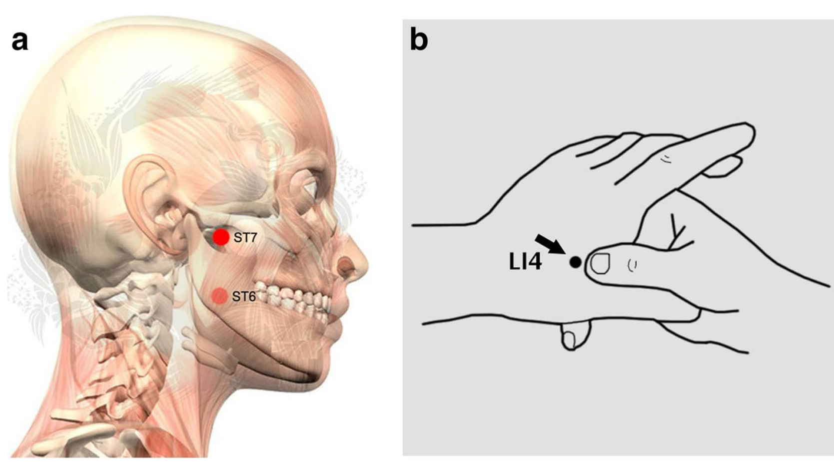

Fig. 1 Acupuncture points irradiated in this study. **a** ST6 and ST7. **b** LI4

Table 1 The age (mean ± standard deviation), sex (number %), and the duration of symptoms (mean ± standard deviation) from the onset of disease (background) in the low-level laser therapy (LLLT), laser acupuncture therapy (LAT), and placebo groups

		LLLT	LAT	Placebo	Significance
Age		32 ± 12.9	43 ± 16.2	35 ± 3.4	$p = 0.22$
Sex	Female	10 (67)	9 (60)	13 (87)	$p = 0.06$
	Male	5 (33)	6 (40)	2 (13)	
Background (months)		14.7 ± 20.6	15.4 ± 30.1	14.7 ± 23.7	$p = 0.87$

Statistical analysis

Each of the right and left painful points of the patients was considered separately in the statistical analysis. Because of the non-parametric nature of the data, between-group comparisons in jaw motion and pain intensity were performed using the Kruskal-Wallis test. When a significant difference was noted, pairwise comparisons were made by Mann-Whitney *U* test. The statistical analysis was performed using Statistical Package for Social Sciences (SPSS version 16.0; SPSS Inc., Chicago, Il) and p value < 0.05 was considered statistically significant.

Results

Thirty-three females and 12 males with age range of 15 to 71 years (mean age 38 ± 15.3 years) participated in this study. The duration of symptoms from the onset of disease ranged from 1 to 120 months. All the participants completed the study period. Table 1 presents the demographic data including age, sex, and the duration of symptoms from the onset of disease in the sample. The study groups were well matched in baseline characteristics at enrollment (Table 1).

Active range of motion

Table 2 indicates the measurements of mandibular movement in the study groups before the commencement of treatment (T1), after the fifth (T2) and tenth (T3) sessions of therapy, and 1 month after the last laser application (T4). There were no significant differences either in maximum pain-free mouth opening or in maximum possible mouth opening between the study groups at any of the assessment intervals ($p > 0.05$; Table 2).

Table 2 Values of mandibular movements (mm) in the study groups at different assessment intervals

		LLLT	LAT	Placebo	Significance
Maximum pain-free mouth opening	T1	29.2 ± 7.09	33.4 ± 7.22	29.7 ± 11.83	$p = 0.17$
	T2	35.3 ± 6.79	35.07 ± 7.64	32.2 ± 9.55	$p = 0.26$
	T3	38.5 ± 8.49	35.3 ± 8.59	32.6 ± 10.79	$p = 0.06$
	T4	39.5 ± 10.21	37.5 ± 8.47	34.0 ± 8.35	$p = 0.10$
Maximum possible mouth opening	T1	34.6 ± 9.78	39.2 ± 7.18	33.1 ± 12.80	$p = 0.06$
	T2	40.8 ± 7.97	40.4 ± 8.27	36.5 ± 10.7	$p = 0.14$
	T3	41.57 ± 8.21	40.82 ± 8.97	38.6 ± 7.72	$p = 0.39$
	T4	42.3 ± 9.24	42.0 ± 8.85	38.4 ± 8.22	$p = 0.23$
Right laterality	T1	8.11 ± 2.07	7.7 ± 2.58	7.3 ± 2.53	$p = 0.33$
	T2	8.14 ± 2.08	8.4 ± 2.03	6.8 ± 2.30	$p = 0.05$
	T3	9.03 ± 1.99	8.9 ± 1.83	7.2 ± 1.58	$p = 0.004$
	T4	8.73 ± 1.94	8.3 ± 1.70	7.0 ± 1.80	$p = 0.15$
Left laterality	T1	8.02 ± 1.46	7.7 ± 3.34	6.25 ± 2.5	$p = 0.18$
	T2	8.42 ± 1.22	8.6 ± 2.15	6.3 ± 1.81	$p = 0.004$
	T3	8.47 ± 1.39	9.4 ± 2.10	6.9 ± 1.75	$p = 0.007$
	T4	9.01 ± 1.56	9.64 ± 2.27	6.3 ± 1.64	$p = 0.001$
Protrusion	T1	5.8 ± 2.64	5.6 ± 1.97	4.9 ± 3.17	$p = 0.38$
	T2	6.3 ± 2.76	6.4 ± 1.61	5.1 ± 3.28	$p = 0.06$
	T3	6.6 ± 3.00	7.1 ± 1.86	4.4 ± 2.97	$p = 0.001$
	T4	6.5 ± 3.02	7.7 ± 0.95	5.3 ± 2.08	$p < 0.001$

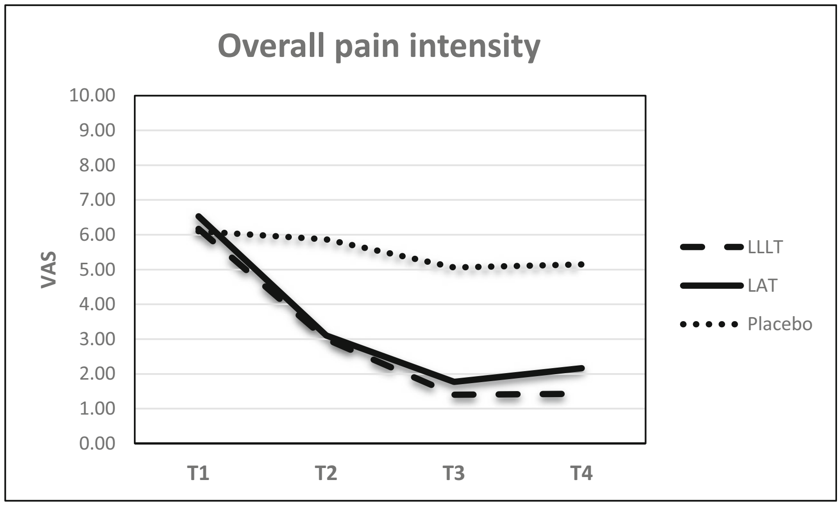

Fig. 2 The overall pain intensity at rest condition in the study groups over the period of the experiment. The Mann-Whitney *U* test demonstrated significantly greater pain intensity in the placebo group than LLLT and LAT groups at T2, T3, and T4 time points ($p < 0.05$)

The mean of right and left lateral excursive movements is presented in Table 2. The statistical analysis revealed no significant difference in right laterality among the groups at T1, T2, and T4 ($p > 0.05$), but the right lateral excursion was significantly greater in LLLT and LAT groups than the placebo subjects at T3 time point ($p < 0.05$). Regarding left laterality, no significant between-group difference was noted at T1 ($p > 0.05$), whereas the left lateral excursion was significantly higher in LLLT than the placebo group at T2 and T4 time points ($p < 0.05$), and in LAT than the placebo group at T2, T3, and T4 intervals ($p < 0.05$).

Comparison of the amount of protrusive movement showed a significant difference between groups at T3 and T4 time points ($p < 0.05$). Pairwise comparisons revealed that at both T3 and T4, the protrusive jaw movement was significantly greater in LLLT and LAT groups than the placebo application ($p < 0.05$; Table 2).

Pain intensity variables

The Kruskal-Wallis test demonstrated no significant between-group difference in VAS scores at T1 interval for any of the pain intensity variables. Figure 2 indicates the overall pain intensity at rest condition in the study groups over the period of the experiment. The average pain score was 6.1–6.5 in three groups before treatment and reduced to 1.40 (LLLT group), 1.77 (LAT group), and 5.06 (placebo group) after 10 sessions of therapy. The statistical analysis revealed significant differences between groups at T2, T3, and T4 intervals ($p < 0.05$; Fig. 2).

Figures 3, 4, and 5 illustrate VAS scores in the origin, body, and insertion of masseter muscle in the study groups over the experiment. Significant differences were observed between groups at T2 (body, insertion), T3 (origin, body, insertion), and T4 (body, insertion) intervals ($p < 0.05$; Figs. 3, 4, and 5).

Figures 6, 7, and 8 indicate pain degree at the anterior, middle, and posterior parts of temporal muscle. There was no significant difference between groups for any of these variables at any of the assessment intervals ($p > 0.05$; Figs. 6, 7, and 8).

The degree of pain at the tendon of temporal muscle is illustrated in Fig. 9. The statistical analysis revealed significant differences between groups at T2, T3, and T4 intervals ($p < 0.05$; Fig. 9).

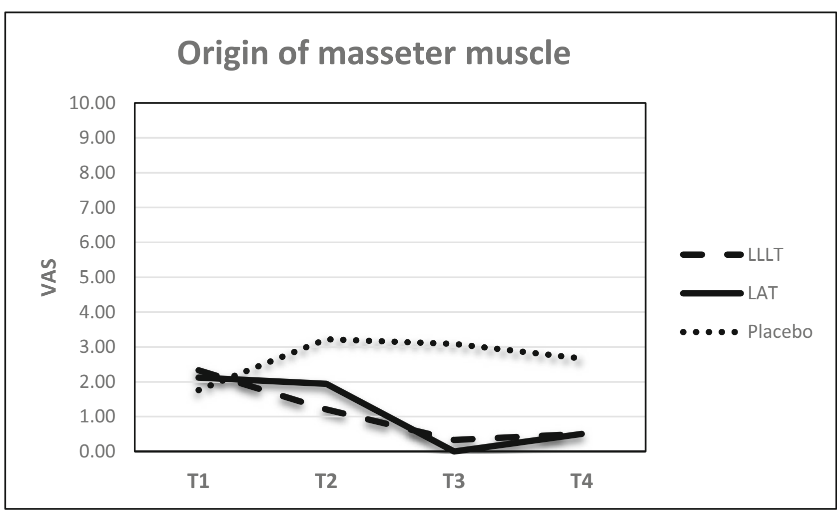

Fig. 3 The measurements of pain intensity at the origin of masseter muscle in the study groups over the period of the experiment. Pain intensity was significantly greater in the placebo group compared with LLLT and LAT groups at T3 time point ($p < 0.05$)

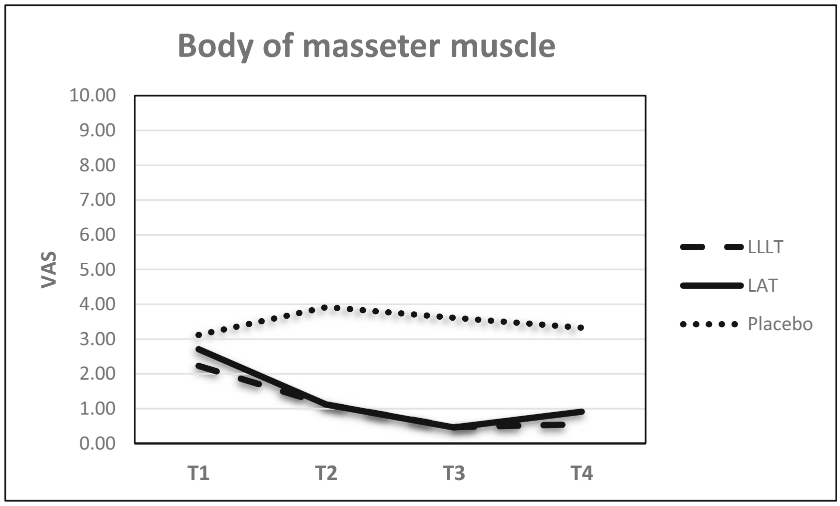

Fig. 4 The measurements of pain intensity at the body of masseter muscle in the study groups over the period of the experiment. Pain intensity was significantly greater in the placebo group compared with LLLT and LAT groups at T2, T3, and T4 time points ($p < 0.05$)

Figure 10 indicates pain degree at the insertion of internal pterygoid muscle over the study period. Significant differences were observed between groups at T3 and T4 time points ($p < 0.05$; Fig. 10).

Figures 11 and 12 illustrate VAS scores of the TMJ at rest and function in the study groups. There were significant differences between groups at T2, T3, and T4 time points for VAS scores of TMJ at rest ($p < 0.05$; Fig. 11) and at function ($p < 0.05$; Fig. 12).

Discussion

The present study compared the effectiveness of laser acupuncture therapy (LAT) and low-level laser therapy (LLLT) in improving mandibular range of motion and intensity of pain perceived at rest and during palpation of masticatory muscles in subjects suffering from TMD. A low-power GaAlAs diode laser was employed for irradiating tender points in the LLLT group and three acupuncture points in the LAT group (ST7, ST6, and LI4). The acupuncture points irradiated in this study are believed to control pain in face and neck area. In contrast to most of the previous studies [12, 21, 22], the Ashi point (the point of most tenderness) was not irradiated in this study in order to assess the net effect of laser irradiation on acupuncture points traditionally defined for relieving pain in orofacial area. The overall outcomes of this study revealed that both LLLT and LAT caused a remarkable decrease in painful symptoms after 5 (T2) and 10 (T3) applications, with a negligible reversal between the end of laser therapy and 1 month later (T4). The placebo patients experienced a lower degree of pain relief over the experiment.

In this study, little improvement was observed in pain-free mouth opening and maximum possible mouth opening in all groups, with no significant between-group differences at any of the assessment intervals. This indicates that neither LLLT nor LAT with the parameters of this trial were effective modalities for improving mouth opening in TMD patients. The right and left lateral excursion was significantly greater in LAT and LLLT groups than the placebo group at some points after treatment. The protrusive jaw movement was also significantly greater in LAT and LLLT groups compared with the

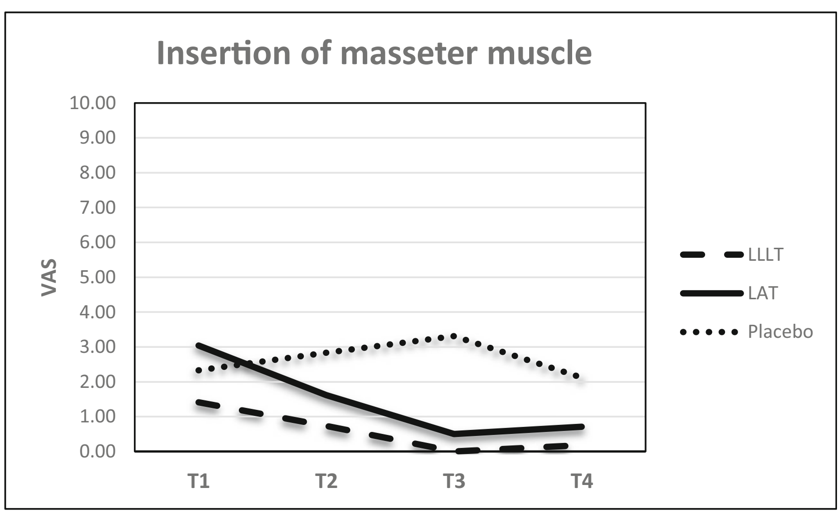

Fig. 5 The measurements of pain intensity at the insertion of masseter muscle in the study groups over the period of the experiment. Pain degree was significantly greater in placebo than the LLLT group at T2, T3, and T4 intervals, and was significantly greater in placebo than the LAT group at T3 interval ($p < 0.05$)

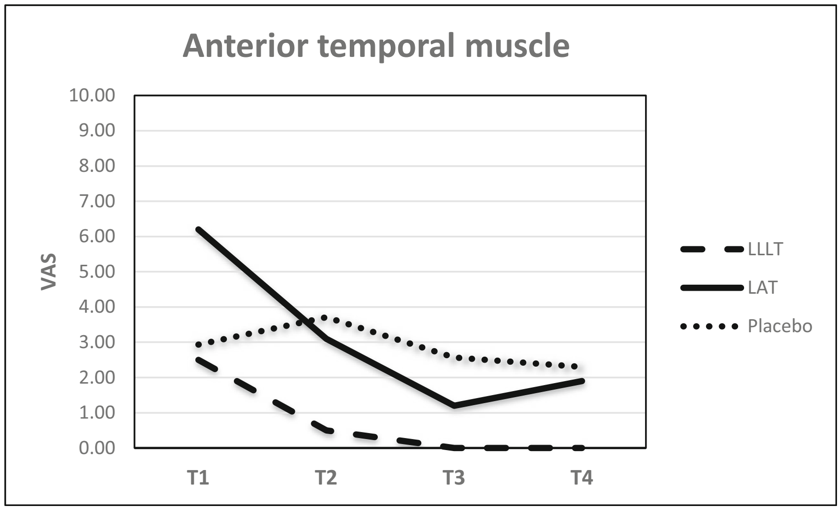

Fig. 6 The measurements of pain intensity at the anterior temporal muscle in the study groups over the period of the experiment. The difference between groups was not significant at any of the assessment intervals ($p > 0.05$)

placebo application at T3 and T4 time points. These results indicate the effectiveness of LAT and LLLT in promoting excursive and protrusive jaw movements in TMD patients. In agreement with the findings of this study, several studies reported no significant difference between LLLT and placebo groups for maximum mouth opening ability in TMD patients [9, 19, 23]. Hotta et al. [21] and Huang et al. [12] reported no significant increase in measurements of mandibular movements after laser acupuncture of TMD patients. In contrast, Cetiner et al. [15] found a significant improvement in maximal mouth opening in myogenic TMD patients who underwent LLLT as compared with the placebo group.

Comparison of the VAS scores verified the effectiveness of laser therapy in reducing overall pain intensity perceived by TMD patients. The measurements of pain intensity showed 77% reduction in the LLLT group and 73% reduction in the LAT group after 10 laser applications, whereas the average pain relief in the placebo group was only 17% over that period. Although pain still existed in laser groups at the end of the experiment, but it was less intensive and could be tolerated by most patients. The statistical analysis revealed that pain degree was significantly lower in LLLT and LAT groups than the placebo group at T2, T3, and T4 time points, indicating that laser therapy is an effective treatment modality for reducing pain of TMD patients.

The different parts of the masseter muscle (origin, body, and insertion) were treated in this study. The body of the masseter muscle showed an excellent response to both LLLT and LAT, so that VAS scores were significantly lower in the experimental groups than the placebo group from the fifth session after therapy (T2) to the end of the experiment (T3 and T4). The difference in VAS scores at the origin of masseter muscle was only significant at T3 interval between the placebo and the experimental groups. When considering pain degree at the insertion of masseter muscle, the results of LLLT were somewhat better than LAT, because patients in the LLLT group experienced significantly lower pain than those in the placebo group at T2, T3, and T4 intervals, whereas the participants in the LAT group perceived significantly lower pain degree than those in the placebo administration just at T3 time

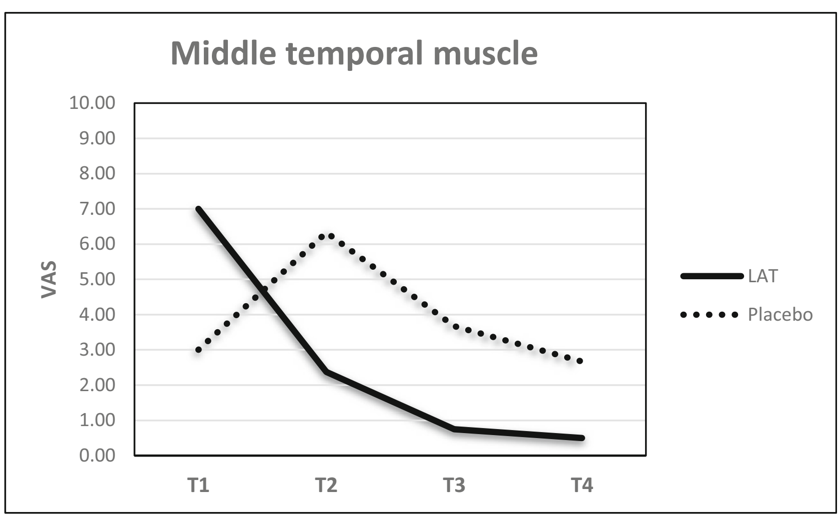

Fig. 7 The measurements of pain intensity at the middle temporal muscle in the study groups over the period of the experiment. No patient in the LLLT group perceived pain at this point. The difference between groups was not significant at any of the assessment intervals ($p > 0.05$)

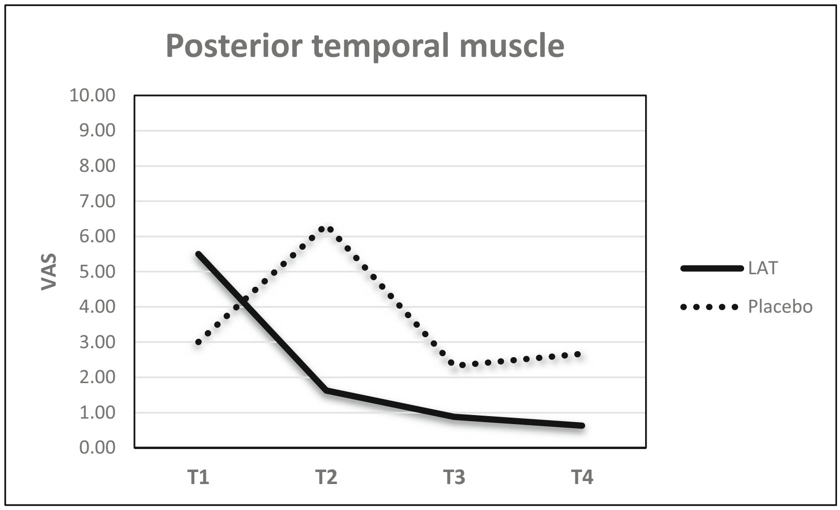

Fig. 8 The measurements of pain intensity at the posterior temporal muscle in the study groups over the period of the experiment. No patient in the LLLT group perceived pain at this point. The difference between groups was not significant at any of the assessment intervals ($p > 0.05$)

point. Therefore, the reduction in pain intensity may be more remarkable when applying laser beam at the insertion of masseter muscle, as compared with laser acupuncture points.

The degree of pain at the anterior, middle, and posterior parts of temporal muscle decreased over the experiment in all groups. Although LLLT and LAT groups showed lower VAS scores than the placebo group after treatment, the difference between groups was small and not statistically significant. This may be related to the low number of patients who perceived pain in the temporal muscle. The tendon of temporal muscle showed an excellent response to both LLLT and LAT, so that pain intensity was significantly lower in LLLT than the placebo group at T3 and T4 intervals, and was significantly lower in LAT than the placebo group at T2, T3, and T4 time points. The insertion of internal pterygoid muscle also showed a favorable response to treatment. At the end of laser therapy (T3) and 1 month later (T4), patients in both LLLT and LAT groups perceived significantly lower VAS scores at the insertion of internal pterygoid muscle, as compared with those in the placebo administration.

Pain intensity at TMJ was assessed at both rest and function in the present study. Laser radiation in the LLLT group was performed on three points located at the posterior and superior parts of the mandibular condyles and inside the external auditory meatus. The three acupuncture points irradiated in this study are believed to influence the whole orofacial area, and therefore no extra irradiation on TMJ was performed in the LAT group. The outcomes of this study revealed that both LLLT and LAT were effective modalities in reducing the intensity of TMJ pain, but LLLT performed somewhat better than LAT. The VAS scores were significantly lower in LLLT than the placebo group at both rest and function from T2 to T4 time points whereas, the difference between LAT and placebo groups was only significant at T2 for TMJ pain at rest, and at T3 for TMJ pain at function.

LLLT involves the application of light usually from a low-power laser to a pathologic lesion to induce photochemical instead of thermal reactions. The therapeutic effects of low-level lasers have been described through several mechanisms including bio-simulative, regenerative, analgesic, anti-

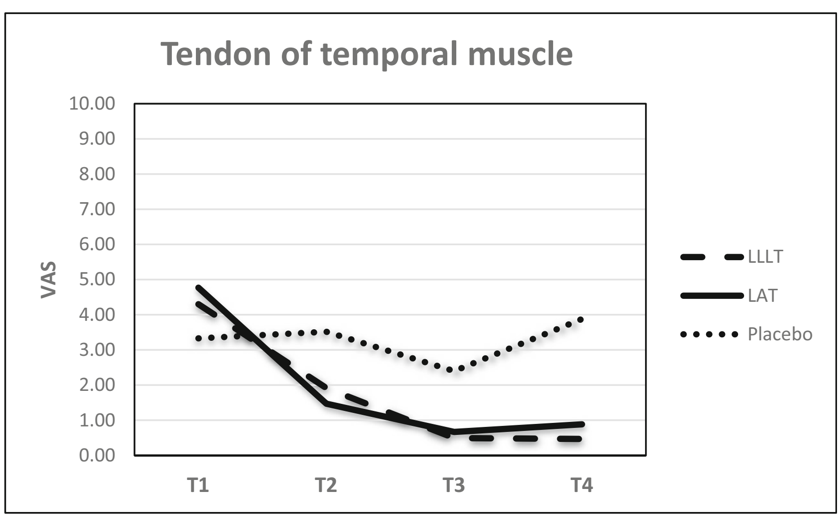

Fig. 9 The measurements of pain intensity at the tendon of temporal muscle in the study groups over the period of the experiment. Pain degree was significantly greater in placebo than the LLLT group at T3 and T4 intervals, and was significantly greater in the placebo group than the LAT group at T2, T3, and T4 time points ($p < 0.05$)

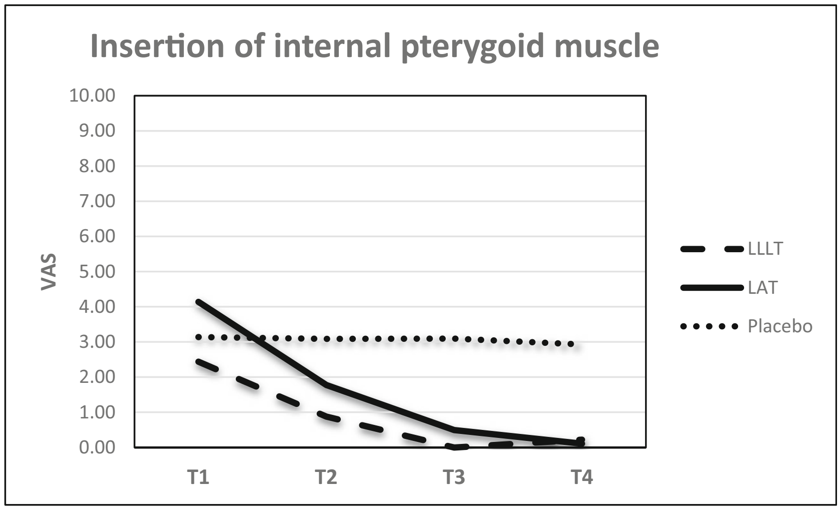

Fig. 10 The measurements of pain intensity at the insertion of internal pterygoid muscle. Pairwise comparisons revealed that pain degree was significantly greater in the placebo group than LLLT and LAT groups at T3 and T4 intervals ($p < 0.05$)

inflammatory, and anti-edematous effects. It has been demonstrated that LLLT improves vasodilatation and blood circulation, stimulates fibroblast function, inhibits the formation of inflammatory mediators such as prostaglandin E2 and cyclooxygenase 2 (COX-2), promotes the production of endogenous opioids, blocks neurotransmission, and increases pain threshold by affecting the cellular membrane potential in the target area [9, 12, 19, 24].

According to the Traditional Chinese Medicine, the acupuncture points on the body are connected through the pathways, which are called meridians. These pathways (meridians) also connect to internal organs in the body. By application of acupuncture needles, pressure, or heat to a point or two separate points on the body, the energy flow called Qi or Chi can be created along the meridians. Qi is thought as one's life force. The improvement in the meridian energy can relieve the symptoms of a variety of medical conditions such a chronic pain and respiratory problems [22]. Other studies indicated that stimulating the acupuncture points can lead to the secretion of endogenous opioids (such as enkephalin and β-endorphin) and block the passage of detrimental pulses and thus reducing painful sensation [12, 25–27]. Laser acupuncture therapy (LAT) is a novel treatment modality that was proposed to reduce the complications of conventional needle acupuncture treatment, which usually occur as a result of lack of knowledge about the related anatomy or not applying aseptic procedures [12, 22]. Although the mechanism of laser acupuncture has not been well understood, it may act on the basics of needle acupuncture, so that the stimulation by needle is achieved by laser beam.

The outcomes of this study are consistent with the results of some previous authors who found that LLLT was a reasonable and noninvasive adjunctive option for management of TMDs [2, 15–17, 28, 29]. Basili et al. [30] demonstrated that LLLT is a valuable tool in decreasing pain perception in acute and chronic temporomandibular joint dysfunction. Several studies reported significant improvement in pain scores of the masticatory muscles following LAT [12, 21, 22, 31]. Recent systematic reviews [32, 33] concluded that despite the weak scientific evidence, acupuncture or laser acupuncture therapy

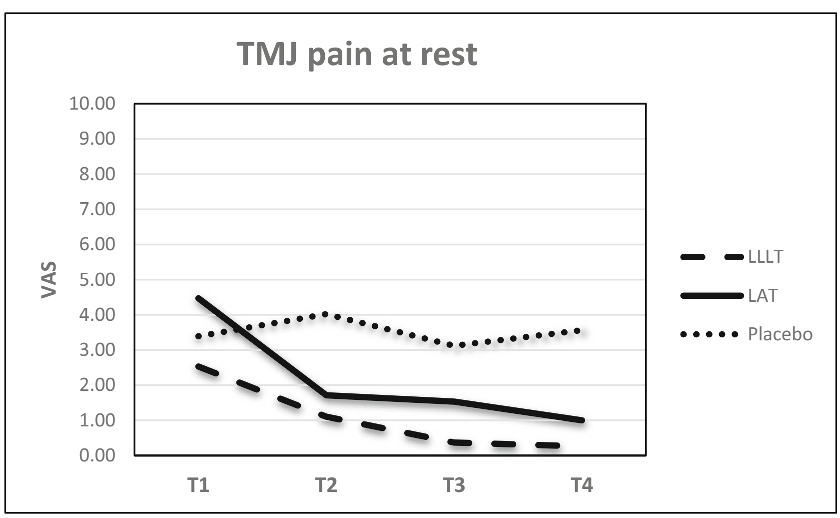

Fig. 11 The measurements of pain intensity in TMJ at rest. Pairwise comparisons revealed that pain intensity was significantly greater in the placebo group than the LLLT group at T2, T3, and T4 intervals, and was significantly greater in placebo than the LAT group at T2 time point ($p < 0.05$)

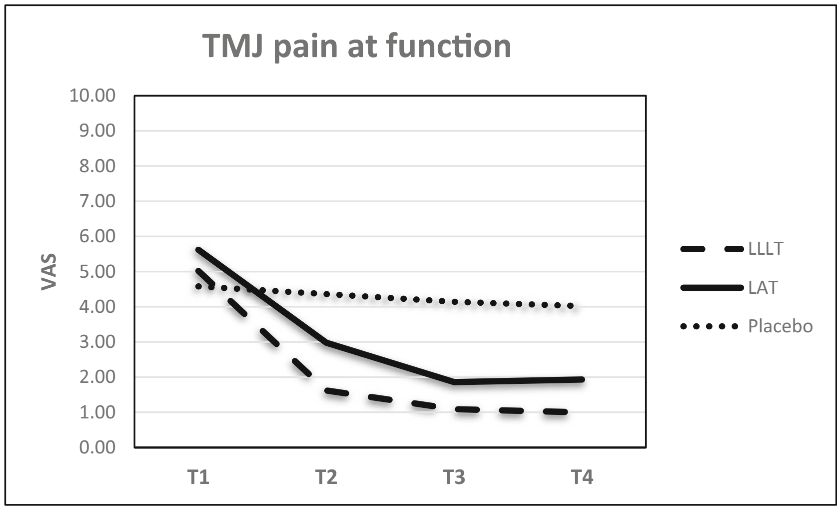

Fig. 12 The measurements of pain intensity in TMJ at function. Pairwise comparisons revealed that pain intensity was significantly greater in the placebo group than the LLLT group at T2, T3, and T4 intervals, and was significantly greater in the placebo group than the LAT group at T3 time point ($p < 0.05$)

appears to attenuate the signs and symptoms of pain in myofascial TMD. In contrast to the findings of this study, several authors demonstrated that LLLT was not superior over sham laser for relieving pain in patients with painful TMD symptoms [18–20]. The studies on the use of LAT for TMD treatment are generally case reports and case series, without a control group. A systematic review and meta-analysis demonstrated that there is limited evidence to support the efficacy of acupuncture as a treatment for TMD symptoms [34]. The differences between the outcomes of this study and those of previous investigations may be related to the different laser wavelengths or parameters selected in these studies.

In laser therapy, the physical parameters should be selected correctly to gain a therapeutic effect. The choice of energy and energy density (J/cm^2, dose or fluence) as well as the number of treatment sessions and the interval between laser applications are important factors for the success of therapy. Although the energy density delivered to the tissue has been considered as the most important parameter in producing biologic effects, but it should be noted that the energy (J) is as important as the dose (J/cm^2), and the dose can easily become high by using a thin probe [19]. In the present study, 6 J of energy was irradiated to tender points or laser acupuncture points with energy density of 21 J/cm^2. Huang et al. [12] employed a much higher light dose (100.5 J/cm^2) for stimulation of acupuncture points, assuming that the higher light dose provides greater stimulation on acupuncture points, and enhances the clinical effect of pain relief. There is a great controversy in literature regarding the suitable energy density for attaining the best therapeutic effect. Borges et al. [35] investigated the effects of different photobiomodulation dosimetries (8 J/cm^2, 60 J/cm^2, and 105 J/cm^2) on temporomandibular dysfunction and found that all doses were effective in reducing TMD pain and symptoms, but maximal opening and protrusion of the mandible increased only in subjects who received the dose of 8 J/cm^2. Although the energy density applied in the current investigation was higher than the therapeutic window suggested by Arndt-Sculz [36], it should be noted that the TMJ and masticatory muscles are located deeply; therefore, some of the emitted energy is absorbed in the skin and interstitial tissues, and only a fraction of the beam is delivered to the target area. Furthermore, the choice of energy irradiated to the target area was suitable (6 J for masticatory muscles and TMJs). The seemingly high energy density observed in this study was mainly related to the small size of the probe aperture, which concentrated the emitted energy at a small surface area.

The placebo effect of laser therapy was not confirmed in the present study. Although a small reduction in pain intensity and some increase in mandibular range of motion occurred in the placebo group over treatment, the LLLT and LAT groups were significantly better than the placebo application for attenuating most signs and symptoms of patients with TMD. The placebo effect of laser therapy has been attributed to treatment with a high-technology device and the close relationship between the patient and laser therapist over several sessions of treatment [19, 37].

The overall findings of this study suggest that both LLLT and LAT could be considered as effective, non-aggressive, and cost-effective physiotherapy modalities to promote pain relief and improve jaw movements. However, the reduction in pain intensity was somewhat better with LLLT than LAT in some areas including the insertion of the masseter muscle and TMJ at both rest and function. On the other hand, LAT involved laser irradiation on three easily identified, extra-oral acupuncture points and the whole treatment lasted for 180 s (both sides), whereas the time spent for LLLT was much higher in patients with severe joint and muscle affliction. Direct laser radiation on points around TMJ may be beneficial in patients with arthralgia to achieve better response when choosing laser acupuncture in TMD management.

The strength of this study is the simultaneous comparison of three modalities including LAT, LLLT, and placebo application in managing TMDs, whereas the low sample size and the short follow-up period should be considered as its limitations. Further, double-blind, randomized controlled trials in a larger patient sample and with long-term follow-up periods are warranted to better elucidate the suitable approach for treatment of patients with TMD. Comparison of various laser parameters in LLLT and LAT modalities should be carried out in future studies to determine the optimal setting and maximize the physiological benefits of laser therapy for TMD treatment.

Conclusion

Under the conditions used in this study:

1- The measurements of mouth opening were not significantly different among the groups over the experiment, but at some points after therapy, the right and left laterality and protrusive jaw movement was significantly greater in LAT and LLLT groups, as compared with the placebo application.
2- The overall pain intensity at rest condition was significantly lower in both LLLT and LAT groups than the placebo group from the fifth session (T2) until the end of therapy (T3) and 1 month later (T4), corroborating the analgesic effect of both modalities in TMD patients.
3- The masticatory muscles including masseter (body, origin, insertion), tendon of temporal, and insertion of internal pterygoid responded well to LLLT and LAT, so that pain intensity in these areas was significantly lower than those in the placebo group at most intervals after therapy. The difference in VAS scores remained significant at 1 month after the last application in both experimental groups, as compared with the placebo administration.
4- The VAS scores in TMJ at both rest and function were significantly lower in LLLT than the placebo group at T2, T3, and T4 intervals, whereas the difference between LAT and placebo groups was only significant at T2 (for TMJ pain at rest) and T3 (for TMJ pain at function). Therefore, LLLT was more effective than LAT for attenuating arthralgia.
5- Both LLLT and LAT proved to be pain-free, non-aggressive, and cost-effective modalities for improving TMD symptoms. Laser acupuncture could be suggested as a suitable alternative to LLLT for patients suffering from TMD, as it provided effective results over a shorter treatment duration.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The protocol of the study was reviewed and approved by the Ethics committee of Mashhad University of Medical Sciences (IR. Mums.sd.REC.1394.191) and was recorded in Iranian Registry of Clinical Trials with IRCT number IRCT2017010131770N1.

Informed consent The procedure was explained in detail for all the patients and signed consent documents were taken before the study commencement.

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