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# Efficacy of Low-Level Laser, Hard Occlusal Appliance and Conventional Pharmacotherapy in the Management of Myofascial Pain Dysfunction Syndrome; A Preliminary Study



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# Introduction

Temporomandibular disorders (TMDs) are the major etiology of non-dental pain in the orofacial region,<sup>1</sup> with a prevalence of 40 to 60% in the community, involving more frequently women than men.<sup>2</sup> One of the most common types of TMDs is the myofascial pain dysfunction syndrome (MPDS), characterized by pain and tenderness

Abstract

**Introduction:** Myofascial pain dysfunction syndrome (MPDS) is a common temporomandibular joint disorder. Due to its multifactorial etiology, treatment usually involves more than one modality to obtain complementary results. The purpose of this study was to compare the combined effect of a low-level laser, a hard occlusal appliance, and conventional pharmacotherapy with pharmacotherapy only in the management of patients with MPDS.

**Methods:** In this study, 15 patients with MPDS were diagnosed and randomly assigned to 3 groups (n=5). Subjects in Group 1 were treated with pharmacotherapy (PT); Group 2 received the diode laser (940 nm gallium arsenide) every other day for a total of 10 sessions, plus pharmacotherapy (PTL) and Group 3 were given hard occlusal splint 12 h/day for 4 weeks, plus pharmacotherapy (PTO). The intensity of pain was measured using the visual analog scale (VAS) prior to the treatment, 2 and 4 weeks after the onset of treatment and 2 weeks later. The maximum painless mouth opening and pain intensity at muscle palpation were also recorded. Comparisons were made between the groups via repeated measure analysis of variance (ANOVA) (P<0.05).

**Results:** Pain relief in the subjective VAS was observed in both laser and appliance groups in the third and fourth examination sessions (P<0.05). No statistically significant reduction in pain was noted using pharmacotherapy only. The maximum painless mouth opening and muscle tenderness were not significantly different between the 3 groups (P>0.05).

**Conclusion:** Both the laser and the occlusal appliance combined with pharmacotherapy proved to be effective for pain reduction in patients with MPDS. All groups, however, failed to result in a significant improvement in the maximum mouth opening or tenderness in masticatory muscles. **Keywords:** Myofascial pain dysfunction syndrome; Laser therapy, Low-level; Occlusal splint.

in one or more of the masticatory muscles during functional activities of the jaw and frequently associated with a limitation in the mouth opening.<sup>3</sup> Even though the condition is considered one of the most common causes of chronic pain in the orofacial region, it is not well understood.<sup>4-6</sup> Psychological disorders, especially distress and anxiety and occlusal interferences have shown to play

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a part in its etiology.7

Due to the rather unclear etiopathogenesis and the multifactorial origin of MPDS, clinicians mostly propose a multidisciplinary approach to manage the condition, including physical as well as psychological therapy.8 Conservative physical therapy plays a prominent role in the treatment of TMDs through a wide range of techniques, including manual therapy (for example, joint mobilization/manipulations and soft-tissue mobilization), therapeutic exercise, electrotherapy (for example, low-level laser therapy (LLLT), transcutaneous electrical nerve stimulation, therapeutic ultrasound, and shortwave), dry needling, and acupuncture.<sup>8,9</sup> Other modalities include pharmaceutical therapy, occlusal splints, and biofeedback.10-17

Since pain is typically the reason for the patients with TMDs to seek medical care, pharmacological therapy is most often indicated as the first line of treatment.<sup>10</sup> A wide variety of drugs ranging from short-term treatment with non-steroidal anti-inflammatory drugs and muscle relaxants to the long-term administration of antidepressants for less well-characterized pain have been used.<sup>10,11</sup> Although several medications are typically prescribed, many lack evidence for this specific pathology and are rather empirical.<sup>12</sup>

Occlusal splint therapy is chosen for the treatment of pain and dysfunction in the orofacial region for several reasons. It is relatively simple, noninvasive and reversible. Moreover, a high degree of patients' acceptance has been reported, especially with the soft splints.<sup>13,14</sup>

LLLT has recently been put under the spotlight because it's safe, non-invasive, easy to use, fast, and aseptic and has few contraindications.<sup>15</sup> It is almost well tolerated at any age. The basic effects of LLLT are biostimulative, regenerative, analgesic, and anti-inflammatory.<sup>16</sup> In a randomized clinical trial, LLLT for the treatment of patients with a myogenous temporomandibular joint disorder produced a significant improvement in the pain level and mouth opening.17 Lasers in conjunction with pharmaceutical therapy for Trigeminal Neuralgia were shown to be effective in reducing the dosage of pharmacotherapy and hence their side effects.<sup>18</sup> Literature reviews usually indicate that LLLT is effective in reducing pain in TMDs mostly through its anti-inflammatory effects.15,16,19 However, a systematic review in 2012 concluded no definitive results could be drawn on the efficacy of LLLT in the treatment of TMDs except that it was probably more effective in the treatment of TMJ disorders and less effective in masticatory muscle disorders.<sup>20</sup> Therefore, the relative clinical efficacy of LLLT in the treatment of TMD is controversial and sufficient evidence is lacking regarding its benefits in MPDS.<sup>21</sup> Beside the widely variable parameters, comparisons have often been made between traditional pharmacotherapy and new treatment modalities such as the laser, rather than combined effects. It is believed that combining various types of treatments in TMDs could result in not only a better treatment outcome but also a reduction in the dosage and duration of pharmacotherapy and therefore their side effects.<sup>8,9,15</sup> The purpose of this study was to compare the efficacy of pharmaceutical therapy only with its use in combination with the laser and the occlusal appliance in the treatment of MPDS.

# **Materials and Methods**

In this study, the cases were selected from the patients referring to the Pain Department of Tehran University of Medical Sciences, Dental School, International Campus from October to December 2016. Our patients were selected according to the standardized examination/ diagnosis procedure based upon the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TDM).<sup>1</sup>

The inclusion criteria were age between 18 to 65 years, no history of orthodontic treatment and the presence of all teeth in the oral cavity.<sup>22</sup> Admission criteria included a diagnosis of MPDS based on at least two of the following<sup>23</sup>:

- Pain during mastication and functional and parafunctional movements.
- Pain in the ear, jaw, preauricular area and the temporal region
- A complaint of pain at the site of either masseter temporalis, medial pterygoid or lateral pterygoid muscles
- A complaint of pain during the mouth opening or at the maximum mouth opening

The exclusion criteria were pregnancy, history of pharmacotherapy for MPDS in the past two weeks and any kind of systemic diseases.<sup>22</sup>

Fifteen patients with MPDS (n = 5) participated in this preliminary study. The purpose of the study was described to each participant and informed consent was obtained prior to the onset of the treatment. These patients were interviewed and evaluated by an oral medicine specialist. Their medical history and a panoramic radiograph were taken to rule out disorders from dental and joint origins and then their related data were registered. In the first examination session, the pain level and jaw movements were recorded. The primary examination included locating the exact site of pain, the assessment of pain severity, and the tenderness of the muscles of mastication (masseter, temporalis, medial and lateral pterygoid) using the visual analog scale (VAS). The VAS ranged from 0-10; 10 indicated the most severe pain imaginable, while 0 indicated no pain. The maximum painless mouth opening was also measured using a ruler. All patients received necessary instructions for home care, quitting parafunctional habits, behavioral therapy, and relaxation exercises, and examinations were repeated 2 weeks after. The patients were then divided into 3 groups using block randomization for intervention. The treatment in all groups started at the same time and was performed by an

oral medicine specialist. For the third group, the entire clinical procedure for occlusal appliance therapy was performed by a prosthodontist and the laboratory works were done by an expert prosthetic technician.

## Group 1: Pharmacotherapy

The patients in this group received muscle relaxant, 500 mg methocarbamol (Amin Chemical & Pharmaceutical Co., Tehran, Iran) 3 times a day, a non-steroidal antiinflammatory drug, 250 mg naproxen (Pars Darou Co., Tehran, Iran) twice a day, and benzodiazepine, 1 mg (one-fourth of a tablet) clonazepam (Sobhan Darou Co., Tehran, Iran) once a day for a period of 2 weeks.<sup>10-12,23</sup>

## Group 2: Low-level Diode Laser Along With Pharmacotherapy

The patients in this group received pharmacotherapy and also underwent laser irradiation. Pharmacotherapy was prescribed in the same way as the first group. Laser therapy was performed using the low-level gallium arsenide diode laser (Biolase, USA) at a 940 nm wavelength with 0.2 W output power and 2 J energy.

Laser calibration was done before use and the laser probe was disinfected with alcohol before each treatment. The laser in a non-contact mode was irradiated on the involved muscle for 10 seconds with an energy density of 2.5 J/cm<sup>2</sup> (ED =  $10/0.785 \times 0.2$  cm<sup>2</sup> =2/0.8 =2.5 J/cm<sup>2</sup>). Treatment sessions were scheduled 3 days a week (every other day) for a total of 10 sessions.<sup>12</sup> The probe was held perpendicular to the targeted muscle. The masticatory muscles were evaluated bilaterally with firm and constant pressure to define painful areas. For each painful masticatory muscle, the laser light was delivered to the tender points diagnosed at the start of the treatment.

# Group 3: Occlusal appliance plus pharmacotherapy

The patients in this group received both pharmacotherapy and the occlusal appliance. Pharmacotherapy was performed in the same way as the first group. For the fabrication of occlusal appliances, a full arch alginate impression (Zhermack, Germany) free of bubbles and voids was taken from both jaws using prefabricated stock trays. Centric relation was recorded via silicone bite registration paste (Futar D, Kettenbach GmbH & Co., Germany) and the impressions were poured immediately. A stone cast was then obtained in less than 20 minutes, trimmed to the depth of a vestibule and mounted on a semi-adjustable articulator (Mani, Tehran, Iran). For all the patients, a hard maxillary occlusal appliance was fabricated. Undercuts in the maxillary arch were blocked out, and the appliance developed in wax. The waxed appliance was then invested and processed with heatcured acrylic resin (Acropars, Iran). Final adjustments for fit and contacts were made intraorally.<sup>21</sup> The occlusal appliances were delivered to the patients and they were instructed to use them for a minimum of 8 hours a day for 1 month.

Parameters were measured prior to the treatment, 2 and 4 weeks after the onset of the treatment and 2 weeks later. The efficacy of the treatment in terms of change in the severity of pain was assessed using the VAS. The maximum painless mouth opening was also measured as the functional index.

The functional examination was based on RDC/TDM, and pressure pain values were obtained with the VAS. The data were analyzed using SPSS version 25. The qualitative variables among the groups were compared using the repeated measures ANOVA (P < 0.05). As the interaction between the time of examination and study groups became significant, one-way ANOVA with a post hoc test (Dunnett's T3) was used to compare the VAS at different examination time in each group.

## Results

All participants completed the study. They included 11 females and 4 males in the age range of 26-63 years, distributed randomly among the 3 groups. The mean age of the patients in the study groups was 52, 56.40, and 40.80 respectively.

## Pain Severity

No significant changes were noted in pain severity based on the VAS score in any groups between the first and second sessions. In the third and fourth sessions, the mean pain scores in the pharmacotherapy plus the laser group and the pharmacotherapy plus the occlusal appliance group were significantly lower than those in the pharmacotherapy only group. No significant differences in pain severity reduction were noted between the pharmacotherapy plus the laser group and the pharmacotherapy plus the laser group and the pharmacotherapy plus the occlusal appliance group (P > 0.05) (Table 2).

# Maximum Painless Mouth Opening

The mean maximum painless mouth opening in the first session was not significantly different among the study groups (Figure 1). Likewise, changes the in maximum mouth opening were not significant in any of the groups after the completion of treatment sessions.

# Muscle Tenderness

Four main masticatory muscles were examined for muscle tenderness: masseter, temporalis, medial, and lateral pterygoids. In the first session, the highest and lowest muscular involvement was noted in the masseter and temporalis respectively (Figure 2).

VAS score analysis revealed no changes in tenderness in any of the 4 muscles during the treatment sessions between the study groups (Figure 3).

# Discussion

The effectiveness of pharmacotherapy only versus the combined LLLT and pharmacotherapy and the occlusal

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Table 1. Descriptive statistics of the Pain Score (VAS), Including Minimum, Maximum, Mean, and Standard Deviation Values of Different Study Groups at Different Examination Sessions

Study Group	Examination Session	Minimum	Maximum	Mean	Standard Deviation
РТО	1	8	9	8.40	.548
	2	4	8	5.00	1.732
	3	2	4	2.60	.894
	4	1	4	2.40	1.342
PTL	1	6	10	8.00	1.581
	2	3	7	5.40	1.517
	3	3	5	4.20	1.095
	4	2	6	3.80	1.483
РТ	1	6	10	8.00	1.581
	2	5	8	6.00	1.225
	3	4	7	5.20	1.095
	4	4	7	5.20	1.095

Note: PTO, Pharmacotherapy +occlusal appliance; PTL, pharmacotherapy + Laser; PT, Pharmacotherapy only.

appliance plus pharmacotherapy in the treatment of the patients with MPDS was investigated in this study, using the parameters of pain intensity, the maximum painless mouth opening, and muscle tenderness.

Eleven females and 4 males who met our inclusion criteria participated in the study. The higher prevalence of females was actually in line with most epidemiologic studies around TMDs<sup>24,25</sup> and is mostly attributed to hormonal and bio-behavioral factors, a higher demand for treatment among females, and their higher proneness to psychological disorders.<sup>26</sup> The mean age of the patients in the study groups was 52, 56.40 and 40.80 respectively, confirming that it is primarily a condition of young and middle-aged adults rather than children or the elderly.<sup>27</sup>

The highest prevalence of muscle involvement was noted in masseter and the lowest in temporalis. The same pattern of involvement was seen by Michelotti et al who assessed the additional value of a home physical therapy regimen versus patient education only for the treatment of myofascial pain of the jaw muscles.<sup>28</sup> Kato et al<sup>29</sup> and Oz et al,<sup>30</sup> assessing the efficacy of LLLT in the management of TMDs, reported the involvement of masseter and temporalis in all patients. In a study by Fouda et al, masseter and temporalis were the most commonly involved muscles.<sup>31</sup> In the studies by Mortazavi et al<sup>32</sup> and Darbandi et al,<sup>33</sup> investigating TMJ disorders and MPDS, medial pterygoid was observed to be the most commonly involved muscle.

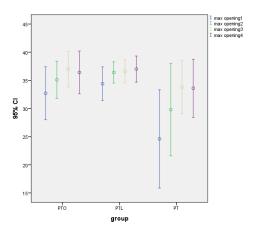


Figure 1. The Error Bar of the Mean Maximum Painless Mouth Opening and 95% Confidence Interval in the Study Groups.

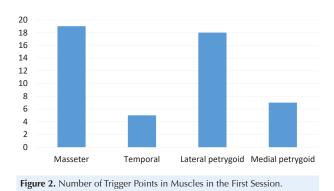


Table 2. The Comparison of the Pain Score Between the 3 Groups at Different Sessions

Examination Sessions	Study Groups		P-value
	PTL	PT	0.928
1		PTO	0.928
	PTO	PT	1.00
	PTL	РТО	0.971
2		PT	0.662
	PTO	PT	0.866
	PTL	PT	0.043
3		PTO	0.097
	PTO	PT	0.010
	PTL	PT	0.032
4		PTO	0.373
	PTO	PT	0.020

Note: PTO, Pharmacotherapy +occlusal appliance; PTL, pharmacotherapy + Laser; PT, Pharmacotherapy only.

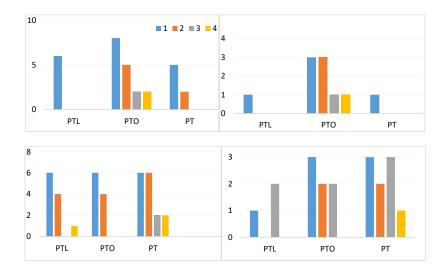


Figure 3. Changes in the Tenderness of Masticatory Muscles; Masseter (A), Temporalis (B), Lateral Pterygoid (C), and Medial Pterygoid (D).

The use of the low-level laser has been suggested for the treatment of different myofascial and skeletal pain syndromes such as MPDS due to its anti-inflammatory and analgesic properties. It decreases muscle tension and regulates cellular activities.<sup>24,26,34,35</sup> In our study, the laser at a 940 nm wavelength was irradiated and it resulted in a significant reduction in pain in all the patients. The positive outcome of LLLT was demonstrated in previous studies by Salmos-Brito et al,<sup>36</sup> Ahrari et al,<sup>17</sup> Mazzetto et al,<sup>37</sup> Shirani et al,<sup>38</sup> Ebrahimi et al,<sup>18</sup> Azizi et al,<sup>22</sup> and Khalighi et al,<sup>39</sup> who all found a significant reduction in pain intensity of TMD patients with LLLT. Khalighi et al assessed the efficacy of 810 nm galliumaluminum-arsenide diode source laser therapy versus pharmacotherapy in improving MPDS in 40 patients. The patients in the laser group received a placebo drug and the patients in the naproxen group received a placebo laser. The maximum mouth opening also increased significantly in the laser group from the eighth session compared to those receiving 500 mg of naproxen.<sup>39</sup> Our study, however, failed to demonstrate any significant improvement in the mean maximum painless mouth opening between the study groups. That might somehow be attributed to the differences in laser parameters, treatment sessions, and a longer follow-up period which was 2 months after completing the treatment in their study and only 2 weeks in ours. Perhaps if we had continued to monitor the patients, we could have noticed pain reduction in their maximum painless mouth opening as well. Öz et al compared the efficacy of LLLT and the occlusal splint in patients with MPDS and reported similar results to ours. Pain and muscle tenderness were reduced, and the maximum mouth opening improved in both groups of the laser and the splint with no superiority between the two groups.30

The findings of this study are in contrast to Emshoff

et al<sup>21</sup> and da Cunha et al,<sup>40</sup> who reported a significant reduction in pain intensity in both laser and placebo groups, suggesting that improvement was mostly due to the placebo effect of laser administration. However, the two studies focused on the efficacy of treatment in TMJ pain during function, and not MPDS.<sup>21,40</sup> Our results were also in contrast to Katsoulis et al who reported a superior efficacy in the placebo group; however, they used the laser with a lower wavelength compared with our study (690 nm).<sup>41</sup> Altan et al performed a study over 53 patients with cervical myofascial pain syndrome to investigate the effect of GaAs laser therapy. They used a frequency of 1000 Hz for 2 minutes over each trigger points in trapezius muscle bilaterally once a day for 10 days during a period of 2 weeks and failed to show the superiority of the tested modality. However, using the same laser at a 940 nm wavelength for 10 seconds, we encountered a great improvement in the laser plus pharmacotherapy group compared to pharmacotherapy only. The difference in results may come from differences in laser parameters including wavelength, frequency, output, and dosage as well as the number of subjects and the location of pain. Moreover, the control group in their study received no treatment except for the instructions on daily isometric exercises and stretching.42

We recorded the pain level and jaw movements on the first visit. All the patients then received the necessary instructions for home care, quitting parafunctional habits, behavioral therapy, and relaxation exercises. Examinations were repeated 2 weeks after. The pain score (VAS) decreased not for more than 1 unit in all the patients, which indicated that the afore-mentioned initial treatments were not effective enough and other modalities were required.<sup>28</sup> Since it was unethical to deprive the patients of the conventional treatment in one group to assess the efficacy of anther modality,

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we designed the study with 3 groups and added laser therapy and the occlusal appliance to pharmacotherapy. Combined treatments are often used in a clinical setting. Lasers increase tissue resistance and the use of lasers and occlusal appliances decreases the need for taking too many medications and subsequently decreases the side effects of pharmacotherapy.<sup>42</sup>

The use of the hard occlusal splint in this study caused a significant reduction in the mean pain score compared to pharmacotherapy only. Occlusal splint therapy is chosen for the treatment of pain and dysfunction in the orofacial region for several reasons. In a meta-analysis by Zhang, splints were reported to be effective for the treatment of TMJ disorders and its use was highly recommended.43 Evaluating the clinical performance of different kinds of occlusal splints in the management of myofascial pain, Amin et al reported that soft, hard, and liquid oral splints all resulted in an optimal outcome at the end of 3 months; however, the hard splint proved to be more effective in a shorter period.44 Demirkol et al, in 2015, evaluated the efficacy of the occlusal splint and the low-level laser (Nd:YAG) in TMD patients characterized with myofascial pain versus the placebo. The control group received pharmaceutical therapy. They reported that both the occlusal splint and LLLT were effective in pain reduction, which was similar to our findings. Moreover, they showed that the laser was more effective than the occlusal splint in pain reduction.45

In this study, 250 mg naproxen, 500 mg methocarbamol, and 1 mg clonazepam were prescribed for all the patients over a period of 1 week. Naproxen should be administered every 12 hours for 10 to 14 days and patients might experience constipation, bloating, and stomachache.<sup>46</sup> In a study by Guimaraes et al., naproxen was used in a gel form and no significant differences were noted between the naproxen and placebo groups.<sup>47</sup> In the current study, we systemically prescribed naproxen in the tablets form, which is easier for use by the patients. The combination of drugs has shown to be more effective in the treatment of TMDs. Several studies have shown that patients with TMDs have personal characteristics similar to those of patients with chronic pain, and because of the similar pathophysiology of chronic pain and depression, benzodiazepines such as clonazepam has been added to the pharmacotherapy of patients with MPDS. Michelotti et al assessed the effect of the simultaneous administration of fluoxetine and clonazepam on the treatment of MPDS. This combination of drugs, irrespective of the psychological condition of the patients, resulted in a 90% improvement in pain and no side effect was noted after.28 We also prescribed methocarbamol (muscle relaxant) in addition to the above-mentioned medications for the patients. This pharmaceutical regimen was highly effective for patients and no side effect was reported. It is important that the positive effects of treatment do not disappear over time. Michelotti et al. used a 780 nm laser and showed immediate pain relief after therapy; however, the symptoms returned 30 days after treatment.<sup>28</sup>

In this study, we followed our patients 2 weeks after the treatment and the results remained the same. Although a period of 2 weeks does not seem to be enough for MPDS which has more of a chronic nature, it can be acceptable for a preliminary study. Moreover, the major difference of our study from the above-mentioned ones is its sample size. Had we done the study with a larger sample, we might have ended up with a different result. Considering the conservative nature of laser and occlusal splint therapy, future studies with larger sample groups, longer duration of the interventions, and long-term follow-ups are needed to determine their efficacy in the management of patients with MPDS. The combined effect of other available treatment modalities with LLLT and the possible synergism or interaction between them should also be investigated in future studies.

## Conclusion

In this research, a significant improvement was observed in pain reduction using both the laser and occlusal splints. Therefore, LLLT can be considered as a suitable alternative for conventional treatments of MPDS. However, no significant improvement was noticed in the maximum painless mouth opening or tenderness of the masticatory muscles in any of the groups.

#### **Ethical Considerations**

The ethical protocol was approved by the Ethics Committee of Tehran University of Medical Sciences, Dental School ("IR.TUMS.DENTISTRY.REC.1396.2718")..

#### **Conflict of Interests**

The authors declare no conflict of interest.

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