ORIGINAL PAPER

Efficacy of associated therapy in the treatment of temporomandibular disorders

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Abstract:

The purpose of this clinical study was to assess the efficacy of low-level laser therapy (LLLT) as mono- and associated therapy, in temporomandibular disorders (TMDs).

In the randomized controlled clinical trial 123 patients with TMDs, pain in masticatory musculature and limited opening of the oral cavity were included. The patients were divided in 3 groups, the group of patients treated with LLLT as monotherapy (42), the group of patients treated with nonsteroidal anti-inflammatory and centrally acting muscle relaxant medication (40), and the group of patients which benefited by LLLT as associated therapy (41 patients, LLLT and medication). The parameters represented by the reductions in pain and the improvement of mouth-opening were assessed in 8 monitoring sessions. The intensity of pain was evaluated on the visual-analogue scale (VAS), ranging from 0 to 10, and the maximal opening capacity of oral cavity was measured in mm, by ruler, in the morning of the monitoring sessions.

According to the obtained results, the optimal modality with highest success rate is represented by the associated method, where the reductions in pain and the improvement of mouth-opening were significantly increased - in the third group, in comparison with the second and the first group of patients.

Based on the results, associated therapy in the treatment of TMDs should be considered as an alternative method to other monotherapies.

Keywords: painful TMDs, LLLT as mono- and associated therapy, pain reduction in masticatory musculature, improvement of mouth-opening

Introduction

Orofacial pain is manifested in the face or oral cavity area, and includes the disorders of TMJ [1]. Between 5-12% of adult people in the United States [2], 33% of the adult Chinese population in Hong Kong [3], and 33.3% of 2005 individuals in Italy [4], experience pain associated with disorders of the TMJ. The usual symptoms of myogenic temporomandibular disorders (TMDs) are represented by the facial pain, earaches or ringing of the ears, dull, chronic headaches, jaw locking, clicking or popping sounds in the jaw joint, a bite that feels uncomfortable or "off", neck, shoulder and back pain, and swelling on the side of the face [5-7]. The classical treatment used were injections, physical therapy, splints, anti-inflammatory medications (that could have side effects when used over long periods of time), to which have been added self-management strategies, laser therapies and interventions based on cognitive behavioral approaches [8-10].

At present, a conservative treatment approach prevails over surgery, given it is less aggressive and usually results in satisfactory clinical outcomes in mild-moderate temporomandibular disorder (TMDs).

Nocturnal grinding is a detrimental motor activity, a self-destructive parafunction, characterized by „the consequences of a normal function used in abnormal condition". Differential diagnosis in nocturnal or day-grinding patients is realized according to the frequency of phenomenon, the destruction degree, the social discomfort and the manifested symptomatology. The morbid clinical entity of nocturnal-grinding is characterized by the existence of occlusal and TMJ disharmony determined by premature contact areas and by occlusal interferences, strong chaotic contractions of elevator muscles

of mandible, accentuated interdentally friction, etc. [11-13].

Inflammation is a complex, neurotropic, vascular and metabolic self-defense reaction, induced by the penetration of pathogen agents or of own degradation products into the healthy tissues of an organism and has some commune mechanisms with infections and allergies.

According to the therapeutic utilization, the anti-inflammatory medications are divided into four categories: anti-inflammatory with immediate effect, basic anti-rheumatic medication, anti-inflammatory and other adjuvant. All these therapeutical means have the purpose to suppress the infection, eluding the pain, functional improvement and maintenance of T.M.J. The treatment of TMJ disorders is a long-term treatment, motif which can determine the apparition of adverse effects/intolerances and drugs interactions [14-17].

Photobiostimulation with therapeutical laser is the use of low-energy laser light on tissues, to achieve a clinical effect. Biostimulation has been used clinically for pain reduction, wound healing and aid in physical therapy for temporomandibular joint disorders. The basic mechanism for biostimulation occurs at molecular level. Laser light penetrates through tissue and strikes a chromophore (photosensitive molecule), which is situated in mitochondria. Mitochondrial cytochromes are responsible for converting adenosine diphosphate (ADP) to adenosine triphosphate (ATP), thus supplying energy to the cell and driving cellular metabolism. The ability of laser light to affect target molecules is dependent on the absorption spectra of biomolecules and tissue optics. With inflammation, the normal resting potential of nerve fibers is decreased, leading to hypersensitivity. Returning the resting potential to normal could decrease pain transmission. This area of biostimulation is clinically important in pain reduction. Biostimulation is also effective in increasing metabolism and cell replication in fibroblasts and endothelial cells [18-22].

Epic 10 diode lasers can be used too for temporary relief of minor pain, including pain associated with TMJ or other temporomandibular disorders, by providing a therapeutic and non-invasive way in treating pain. Using a special handpiece attachment, the Epic 10 laser is transformed in a device capable to reduce and manage oral and maxillofacial pain. Technical specifications of Epic 10 diode lasers are: laser classification IV (4); InGaAsP semi-conductor diode; 940 nm wavelength; 10 W peak power. The presentation mode of Epic 10 diode laser, of the handpiece and the method of use for the device in our study can be observed in figure 1 [23,24].

The pain therapy procedure with Epic 10 laser is the process by which tissue temperature is elevated for the temporary relief of minor pain, the temporary increase in local blood circulation, and the temporary relaxation of muscle. Affected muscles and/or joints have to be exposed to an adequate level of therapeutic energy over a short period of time, to provide effective therapeutic effects [26].

A B C

Figure 1. The presentation mode of Epic 10 diode laser (A), of deep tissue handpiece (B), and using method (C) [24, 25]

The visual analogue scale (VAS) is one-dimensional psychometric response scale, which can be used for measuring the pain intensity in adult populations. VAS helps to assess the subjective pain intensity of the patient (before, during, and after the

treatment), in questionnaires. VAS scale was noted between "no pain" (score of 0) and "pain as bad as it could be" (score of 10) (as none, mild, moderate, or severe). VAS scale has the advantage of easy and quick use, reduced time required to fill in the questionnaire, and of the low cost [27-29]. The VAS scale inserted in the questionnaire used in this study had the aspect presented in figure 2.

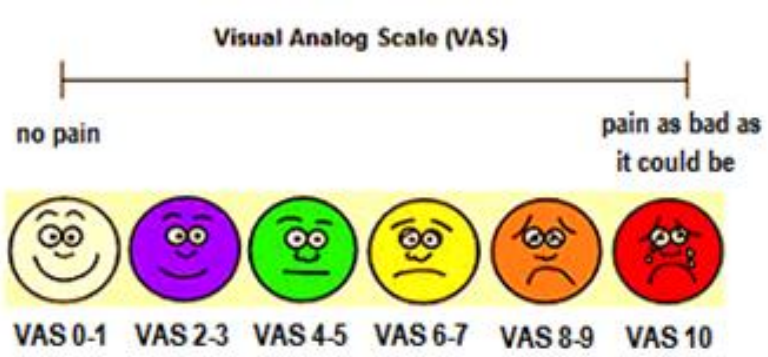


Fig. 2. The aspect of VAS inserted in the used questionnaire of study

The purpose of this study was to assess the effectiveness of low-level laser therapy (LLLT) as mono- and associated therapy, in temporomandibular disorders (TMDs).

Materials and method

The study was performed according to ethical principles and good clinical practice.

All participants signed written informed consent prior to the beginning of this study.

This randomized controlled clinical trial initially enrolled 155 patients. We excluded patients who were admitted as emergency patients and were in acute pain and dysfunction that required other forms of treatment, and thereafter those who were unable to cooperate within the studied requirements. The patients were selected after a detailed anamnesis and all patients presented painful cranio-mandibular dysfunctional syndrome and nocturnal bruxism. Also, the included 123 patients presented TMDs, pain in masseter and temporalis masticatory musculature and limited opening of the oral cavity. The participating dentists attended a training day to ensure consistency of examination and treatments. The patients were monitored during the period of 2012-2018 in the Dental Clinics of the Dental Medicine Faculties.

The inclusion criteria of patients were: an age range of 41-60 years, pain and muscle fatigue in the TMJ area and in the masseter and temporal masticatory muscles, reduced opening of the oral cavity under 35 mm, no sensibility/ adverse effects/intolerances at anti-inflammatory drugs/medication, no allergic reactions, any other adverse reaction to anti-inflammatory medication, and without other acute or chronic, general or dental diseases (e.g. gastritis, digestive ulcer, gastro-intestinal hemorrhages, liver- and renal disturbances, etc.) in personal antecedents. The mean (±SD) of selected patients' age was 50.5 ± 9.5 years.

Prior to the start of therapy, professional oral hygiene was performed in all the patients.

The 123 eligible patients were randomized in three groups:

- First group of patients (L group, n = 42, 24 females and 18 males) benefited from a series of 4 sessions LLLT as monotherapy, once every 2 days, with the Epic 10 laser device. Treatment takes 10 minutes for each site (left and right), to provide relief from disagreeable TMJ symptoms. The deep tissue handpiece with attached protective cover was used at the 30 mm spot size. Laser parameters was selected for pain therapy program. LLL treatment was performed by placing the handpiece with protective cover in the treated area, by using the red laser beam as reference for center of

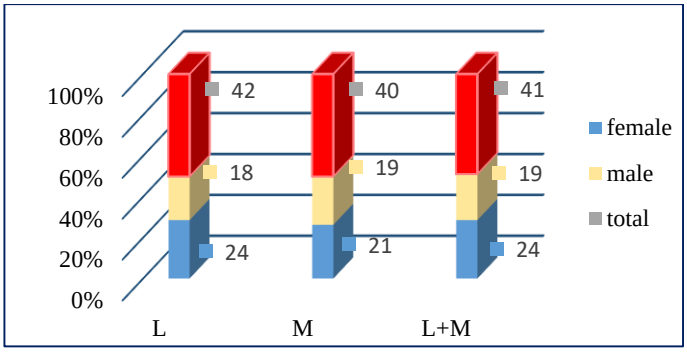
the treatment location to position the handpiece, and by checking periodically the patients comfort during the use of the Epic 10 laser device. The eyes of patient and clinician were protected with colored in green plastic glasses, and the laser fascicle irradiated the skin surface. We seated the laser screen to the recommended initial power settings for therapeutic effect (at 4.0 W delivered over 10 minutes = 600 seconds of continuous treatment = CW). The patient response was monitored in order to adjust the needed power and/or distance for the patient comfort. Power frequency was 50-60 Hz magnetic field and 3 A/m in continuous level.

- The patients of second group (M group, n=40, 21 females and 19 males), were treated for 8 days with nonsteroidal local anti-inflammatory gel (by massaging 3 times a day with Fastum gel in the masseter and temporal muscles area) and centrally relaxant medication for muscles (2 tablets of Clorzoxazon of 250 mg 2 times a day, so 500 mg x 2 times a day).
- Third group of patients (L+M group, n=41, 24 females and 19 males), benefited from associated therapy, LLLT (4 irradiation sessions) and the previously mentioned medication (nonsteroidal local anti-inflammatory gel Fastum gel) and centrally relaxant medication for muscles (Clorzoxazon tablets).

The distribution of the patients in groups, after gender and the used therapy, is presented in graph 1.

Graph 1.

The distribution of the patients in groups, after gender and the used treatment



All patients were monitored to pursue the results. Before VAS evaluations of pain in TMJ area, were assessed the mouth opening variables with a ruler. VAS evaluations were based on the found pain level, after direct extraoral palpation of masseter and temporalis muscles. Both sides of the head were examined separately, to avoid confusion in the patient reactions. The parameters represented by the improvement of mouth-opening and the reductions in pain were assessed before (Ev.1) and after (Ev.2) the first applied treatment, in the third day (after the second session of LLLT = Ev.3), in the fifth day (after the third session of LLLT = Ev.4), in the seventh days (after the fourth session of LLLT = Ev.5), respectively after 3 months (Ev.6), after 6 months (Ev.7) and after 9 months (Ev.8). In total, 8 monitoring sessions were carried out on the effects of applied therapies in the selected patients.

Result and Discussions

In the first part of the assessment, the oral cavity opening (MO) was measured and recorded in all patients of the 3 groups.

In the first group of patients (L) (table 1):

- the highest number of patients presented the MO=24mm in Ev.1 (19.04%), MO=30mm in Ev.2 (19.04%), MO=38mm in Ev.3 (19.04%), MO=44mm in Ev.4 (19.04%), MO=46mm in Ev.5 (19.04%), MO=42mm in Ev.6 (19.04%), MO=40mm in Ev.7 (19.04%), and MO=38mm in Ev.8 (16.66%);
- minimum values of MO increased from Ev.1 (=18mm) to Ev.5 (=33mm), and then decreased in Ev.6 (=30mm), Ev.7 (=26mm) and at Ev.8 (=24mm);
- maximum values of MO increased from Ev.1 (=30mm) to Ev.6 (=54mm), and then decreased in Ev.7 (=48mm) and at Ev.8 (=44mm).

Table 1. Assessment of the opening of oral cavity, in first group (L) of 42 patients (in mm)

MO-mm	Ev. 1	Ev. 2	Ev. 3	Ev. 4	Ev. 5	Ev. 6	Ev. 7	Ev. 8
16	-	-	-	-	-	-	-	-
18	3	-	-	-	-	-	-	-
20	6	2	-	-	-	-	-	-
22	6	3	-	-	-	-	-	-
24	8	4	-	-	-	-	-	1
26	7	6	1	-	-	-	1	3
28	7	6	2	-	-		2	4
30	5	8	3	2	-	1	3	4
32	-	6	4	3	1	1	3	4
34	-	4	4	3	2	2	4	5
36	-	2	6	4	3	2	5	6
38	-	1	8	4	4	3	5	7
40	-	-	7	6	6	4	8	5
42	-	-	4	6	7	8	6	2
44	-	-	2	8	7	7	2	1
46	-	-	1	3	8	6	2	-
48	-	-	-	2	2	5	1	-
50	-	-	-	1	1	1	-	-
52	-	-	-	-	1	1	-	-
54	-	-	-	-	-	-	-	-
56	-	-	-	-	-	-	-	-

In the second group of patients (M) (table 2):

- the highest number of patients presented the MO=24mm in Ev.1 (20%), MO=26mm in Ev.2 (20%), MO=34mm in Ev.3 (17.5%), MO=36mm in Ev.4 (20%), MO=40mm in Ev.5 (17.5%), MO=38mm in Ev.6 (17.5%), MO=36mm in Ev.7 (15%), and MO=34mm in Ev.8 (17.5%);
- minimum values of MO increased from Ev.1 (=18mm) to Ev.5 (=28mm), and then decreased in Ev.6 (=26mm), Ev.7 (=24mm) and at Ev.8 (=22mm);
- maximum values of MO increased from Ev.1 (=30mm) to Ev.5 (=48mm), and then decreased in Ev.6 (=46mm), Ev.7 (=44mm) and at Ev.8 (=42mm).

In the third group of patients, with associated therapy (L+M) (table 3):

- the highest number of patients presented the MO=24mm in Ev.1 (19.51%), MO=32mm in Ev.2 (19.51%), MO=40mm in Ev.3 (19.51%), MO=44mm in Ev.4 (21.95%), MO=48mm in Ev.5 (19.51%), MO=46mm in Ev.6 (21.95%), MO=42mm in Ev.7 (19.51%), and MO=40mm in Ev.8 (19.51%);
- minimum values of MO increased from Ev.1 (=18mm) to Ev.5 (=36mm), and then decreased in Ev.6 (=30mm), Ev.7 (=28mm) and at Ev.8 (=26mm);
- maximum values of MO increased from Ev.1 (=30mm) to Ev.5 (=56mm), and then decreased in Ev.6 (=52mm), Ev.7 (=50mm) and at Ev.8 (=48mm).

The mouth opening (MO) in all the patients increased gradually during the therapy till Ev.5, and then decreased until the Ev.8. The yellow color of the boxes in the tables indicates the maximum number of patients.

Table 2. Assessment of the opening of oral cavity, in second group (M) of 40 patients (in mm)

MO-mm	Ev. 1	Ev. 2	Ev. 3	Ev. 4	Ev. 5	Ev. 6	Ev. 7	Ev. 8
16	-	-	-	-	-	-	-	-
18	3	2	-	-	-	-	-	-
20	5	4	-	-	-	-	-	-
22	6	7	1	-	-	-	-	1
24	8	7	1	-	-	-	1	2
26	7	8	4	3	-	1	3	4
28	6	6	5	3	2	2	3	4
30	5	4	6	5	3	3	4	4
32	-	2	6	6	4	4	5	5
34	-	-	7	6	4	4	5	7
36	-	-	4	8	4	5	6	5
38	-	-	3	3	6	7	5	5
40	-	-	2	2	7	6	4	2
42	-	-	1	2	5	5	2	1
44	-	-	-	1	2	2	2	-
46	-	-	-	1	2	1	-	-
48	-	-	-	-	1	-	-	-
50	-	-	-	-	-	-	-	-
52	-	-	-	-	-	-	-	-
54	-	-	-	-	-	-	-	-
56	-	-	-	-	-	-	-	-

Table 3. Assessment of the opening of oral cavity, in third group (L+M) of 41 patients (in mm)

MO-mm	Ev. 1	Ev. 2	Ev. 3	Ev. 4	Ev. 5	Ev. 6	Ev. 7	Ev. 8
16	-	-	-	-	-	-	-	-
18	5	-	-	-	-	-	-	-
20	6	2	-	-	-	-	-	-
22	6	2	-	-	-	-	-	-
24	8	3	-	-	-	-	-	-
26	6	4	-	-	-	-	-	1
28	6	6	-	-	-		1	2
30	4	7	1	-	-	1	2	3
32	-	8	1	1	-	1	3	3
34	-	4	2	1	-	2	3	3
36	-	3	3	2	1	2	3	5
38	-	2	3	2	2	3	5	6
40	-	-	8	4	3	3	7	8
42	-	-	7	7	5	6	8	6
44	-	-	7	9	7	7	5	2
46	-	-	6	7	7	9	2	1
48	-	-	3	5	8	4	1	1
50	-	-	-	2	4	1	1	-
52	-	-	-	1	2	1	-	-
54	-	-	-	-	1	-	-	-
56	-	-	-	-	1	-	-	-

The mouth opening (MO) in all the patients increased gradually during the therapy till Ev.5, and then decreased until the Ev.8. The yellow color of the boxes in the tables indicates the maximum number of patients.

Table 4 presents the reported answers of pain intensity in all three groups of patients, in all eight evaluation sessions, according to the analogical visual scale (VAS) for pain. The reference points used in our study were: VAS 0-1 = no pain; VAS 2-3 = mild pain; VAS 4-5 = moderate pain; VAS 6-7 = severe pain; VAS 8-9 = very severe pain; VAS 10 = the most intense pain possible.

Studying the values of table 4, it is noticeable that the pain intensity reported by the patients was decreased from Ev.1 (from the maximum "severe pain", VAS = 8-9) to Ev.5 (to minimum "no pain", VAS = 0).

On Ev.6, Ev.7 and Ev.8, it is noticeable that a new increase in pain appeared.

We underline that VAS values were the lowest in patients in the third group (L + M), thus patients who received associated therapy, followed by the VAS values of the first group of patients (L). VAS values in the second patient group (M) were higher than in the other two groups, throughout the applied therapies and monitoring sessions.

The yellow color of the boxes in the tables indicates the maximum number of patients.

Table 4. Reported answers of pain intensity according to the Visual Analogue Scale (VAS)

Group	VAS	Ev. 1	Ev. 2	Ev. 3	Ev. 4	Ev. 5	Ev. 6	Ev. 7	Ev. 8
L 42 patients	0-1	-	-	1	11	12	12	10	8
	2-3	-	1	3	17	21	22	15	15
	4-5	2	6	16	12	9	8	16	17
	6-7	15	18	11	2	-	-	1	2
	8-9	20	15	11	-	-	-	-	-
	10	5	2	-	-	-	-	-	-
M 40 patients	0-1	-	-	-	3	6	6	6	4
	2-3	-	-	2	6	9	9	8	7
	4-5	1	1	4	8	11	9	9	8
	6-7	16	16	15	14	9	12	12	12
	8-9	19	20	17	9	5	4	6	9
	10	4	3	2	2	-	-	-	-
L+M 41 patients	0-1	-	3	5	15	17	18	14	8
	2-3	-	7	11	17	15	16	16	16
	4-5	2	6	13	9	9	7	11	15
	6-7	15	14	9	-	-	-	-	2
	8-9	19	1	3	-	-	-	-	-
	10	5	-	-	-	-	-	-	-

According to the obtained results, the optimal modality with highest success rate is represented by the associated therapy, due to the improvement of the mouth-opening that was significant increased, and the pain intensities that were reduced in the patients of third group, in comparison with the patients of first and the second group.

The Epic 10 device in pain therapy determines local heating of treated tissues, which induce a temporary increase of the blood circulation, and temporary relaxation of the contracted muscles. [30].

The researches of Shukla et al [31], demonstrated that LLLT seems to be effective in the pain reducing of TMDs, and the treatment with soft lasers may be an option for the patients which are interested in non-invasive therapy. Leite et al [32] underlined that most studies about LLLT presented pain remission, but the standardization of used parameters (wavelength, output power,

frequency) and defined protocols for the use of LLLT are necessary for an efficient treatment of TMDs. The studies of Melis [33], suggest that the use of LLL in the therapy of TMDs cannot be recommended. Kathuria et al [34], indicates that LLLT should be applied with great attention in the patients with malignancies and coagulation disorders. Eroglu et al [35], consider that extra-oral single-sessions with LLLT effectuated immediately after the extraction of impacted third molar can help patients be less affected by the postoperative trismus and swelling.

Currently, there is no consensus in the literature on the frequency and the number of LLLT sessions. [36].

Conclusions

- LLLT as monotherapy, proves its efficiency in comparison with medication therapy.
- The efficacy of associated therapy was demonstrated, the improving of the oral cavity opening was demonstrated and the time interval for pain disappearance of TMDs was shorter in patients with associated treatment, than in the other patients.
- Associated therapy in the treatment of TMJ disorders should be considered as an alternative method to monotherapies.
- The utilization of LLLT in the treatment of painful TMDs is a facile method, is easily performed, allows the patient increased comfort, and cuts patient's anxiety.
- If proper occlusal equilibration is not performed, regardless of the type of applied treatment, the pain in TMJ and the TMDs reappears.
- The present study did not evaluat the long term effect of applied treatments and there is need to design a study with longer follow-ups. Moreover, controlled double-blind clinical trials and multicenter studies are necessary.

Conflict of interest: None to declare.

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