

The “at-home LLLT” in temporo-mandibular disorders pain control: a pilot study

Fornaini C ¹, Pelosi A ¹, Queirolo V ¹, Vescovi P ¹ and Merigo E ¹

1: Department of Biomedical, Biotechnological and Translational Sciences (S.Bi.Bi.T.), University of Parma, Italy

Objectives: The Temporomandibular Disorders (TMD) are a set of dysfunctional patterns concerning the temporomandibular joints (TMJ) and the masticatory muscles; its main symptom is pain, probably caused by inflammatory changes in the synovial membrane, alterations in the bone marrow of the mandibular condyle and impingement and compression.

The aim of this preliminary study was to investigate the effectiveness in the TMD pain reduction of a new laser device recently proposed by the commerce that, due to its reduced dimensions and to be a class I laser according to the ANSI classification, may be used at home by the patient himself.

Material and methods: Twenty-four patients with TMD were randomly selected: the inclusion criteria for the sample was the diagnosis of mono- or bi-lateral TMD, with acute pain restricted to the joint area, associated with the absence of any muscle tenderness during palpation.

The patients were randomly assigned to two groups:

Group 1 (12 patients): patients receiving real LLLT (experimental group).

Group 2 (12 patients): patients receiving inactive laser (placebo group).

The treatment was performed once a day for two weeks with an 808 nm diode laser by the patient himself with irradiation of the cutaneous zone corresponding to the TMJ for 15 minutes each side.

Each patient was instructed to express its pain in a visual analogue scale (VAS) making a perpendicular line between the two extremes representing the felt pain level.

Statistical analysis was realized with GraphPad Instat Software, where $P < 0.05$ was considered significant and $P < 0.01$ very significant.

Results: The patient's pain evaluation was expressed in the two study groups before the treatment, 1 week and two weeks after the treatment.

The differences between the two groups result extremely significant with $p < 0.0001$ for the comparison of VAS value after 1 and 2 weeks.

Conclusion: This study, even if it may be considered such a pilot study, investigated a new way to control the pain in the temporomandibular diseases by an at home self administered laser device.

Results are encouraging but they will have to be confirmed by greater studies.

Introduction

Temporomandibular joint is one of the most fascinating and complex synovial systems in the body. It is the area in which the mandible articulates with the cranium ¹). The masticatory system is extremely complex,

which comprises primarily of bones, muscles, ligaments, and teeth, all of which are responsible for activities like mastication, speech, and deglutition. All these movements are regulated by an intricate neurological controlling mechanism, which is important for the system to function normally and efficiently. Lack of such harmony may lead to disruptive muscle behaviour or structural damage to any of the components ²). The function of the TMJ is unique, in that the condyle both rotates within the fossa and anteriorly translates along the articular eminence. Because of the ability of the condyle to translate, the mandible can have a much

Addressee for Correspondence:

Carlo Fornaini
MD DDS MSc
Sezione di Odontostomatologia
Dipartimento di Scienze Biomediche, Biotecnologiche e
Traslazionali Via Gramsci, 14
43126 Parma
Tel: 0039 0521033641
email: carlo@fornainident.it

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higher maximal incisal opening than would be possible with rotation alone.

The Temporomandibular Disorders (TMD) are a set of dysfunctional patterns concerning the temporomandibular joints (TMJ) and the masticatory muscles with frequent involvement of other structures of various body districts with the result of making complicated the classification and the diagnostic processes³⁻⁶; the average age of the patients is 35.6 and the majority of patients are in the group of years ranging from 26 to 40; the gender proportion is generally about 8 to 2 in favour of the female⁷. Diseases related to the TMJ concern about a 1/3 of the general population⁸.

The etiology of pain in TMD patients has not been clearly understood.

Occlusal disharmony and psychological distress are the two hypotheses which have dominated the literature. The psychological hypothesis proposes that the disorder evolves as a consequence of psychological distress that is usually due to the individual's stressful environment. The psychological distress in turn leads to parafunctional habits (tooth clenching and grinding) that result in muscle pain⁹.

There are several possible sources of TMJ pain, such as inflammatory changes in the synovial membrane including fluid resulting in joint effusion¹⁰⁻¹⁴, alterations in the bone marrow of the mandibular condyle¹⁵ and impingement and compression¹⁶.

The roles of electro-physical modalities and surgery in the management of TMD have not been fully elucidated¹⁷. Initial conservative therapy is based on 3 general approaches: patient education, pharmacologic therapy, and physical therapy. However, patients with chronic TMD usually need a multidisciplinary approach involving a team of therapists, including a dentist, psychologist, physical therapist, and even a chronic pain physician¹⁸.

Among the therapeutic procedures, low-level laser therapy (LLLT) has recently been proposed to reduce pain intensity and improve maximal mouth opening (MMO) in both acute and chronic TMD patients who had received no previous TMD treatment (e.g., surgical treatment, occlusal splint, or LLLT)¹⁹. A systematic review reported that LLLT is probably more effective for the treatment of TMJ disorders, and less effective for the treatment of masticatory muscle disorders²⁰.

The analgesic effect of LLLT acts at different levels and by different mechanisms. Some explanations of this effect are: it increases beta-endorphin level in spinal liquor, increases urinary excretion of glucocorticoids, which is a beta-endorphin synthesis inhibitor,

increases the pain threshold under pressure through a complex electrolytic nerve fibre blocking mechanism, decreases histamine and acetylcholine release, reduces bradykinin synthesis, increases ATP production, improves local microcirculation, increases lymphatic flow thus reducing oedema^{21, 22}.

The aim of this preliminary study is to investigate the effectiveness in the TMD pain reduction of a new laser device recently proposed by the commerce that, due to its reduced dimensions and to be a class I laser according the ANSI classification, may be used at home by the patient himself.

In fact, one of the problems related to the LLLT is represented by the necessity, for the patients, to go to the therapist twice/three times weekly for treatments of some minutes. The appearing in the market of new LLLT appliances, cheaper, smaller and able to be used at home by the patients themselves might represent a solution to this problem, giving the possibility to the patients to receive LLLT treatment also daily avoiding the risk of overpower, due to this device has only a power setting.

Material and methods

Patients

Twenty-four patients with TMD were randomly selected, informed about their participation to the study and instructed about the modalities of the test; all of them gave their consensus to participate to the protocol.

The inclusion criteria for the sample was the diagnosis of mono- or bi-lateral TMD, with acute pain restricted to the joint area, associated with the absence of any muscle tenderness during palpation.

The age of the patients ranged from 17 to 64 and among the 24 patients, 5 were of male and 19 of female gender.

The patients were randomly assigned to two groups:

Group 1 (12 patients): patients receiving real LLLT (experimental group).

Group 2 (12 patients): patients receiving inactive laser (placebo group).

The treatment was performed once a day for two weeks with an 808 nm Ga-Al-As (Gallium-Aluminium-Arsenide) diode laser and it consisted in a "at-home treatment" performed by the patient himself by irradiation of the cutaneous zone corresponding to the TMJ for 15 minutes each side. Before starting the treatment, all the patients were instructed by the same operator about the procedures: to clean the area before the irradiation with absorbent cotton socket with physiologic

solution and to gently apply the device in contact with the skin; in fact the beam source, in this way, is maintained at a constant distance of 20 mm irradiating an area of 4.5 cm². It was not necessary, for the patients, to wear protective glasses, due to fact that the appliance used is classified as class I device by the American National Standard Institute (**Fig.1**).

The laser apparatus was developed by the manufacturer in two identical devices: one for the active laser and one for the inactive placebo laser, the second one marked with a "P" letter. The lasers presented a green visible guide light and only for the group 1 emitted also in the IR; the patients did not know to which group they were assigned (**Fig.2**).

A visual analogue scale (VAS) allows the quantification of pain intensity. This scale consists of a straight line measuring 10 cm in length, with 'absence of pain' written on the left end side and 'worst pain ever felt' written on the right end side. Each patient was instructed to make a perpendicular line between the two extremes representing the felt pain level ²³).

Device

In this study it was used the B-Cure Laser (Israel). It is a Class I safety little device (173 g of weight) emitting in the IR spectrum (808 nm). A green aiming beam is provided to show the irradiation area corresponding to 4.5 cm².



Figure 1: Laser application on the TMD.

The Peak Power is 250 mW, given in micro-pulses with a Pulse frequency of 15 kHz, for a Peak Energy per minute of 14.4 Joules.

Statistical analysis

To analyse the behaviour of the two groups, GraphPad Instat Software was used, where $P < 0.05$ was considered significant and $P < 0.01$ very significant.

Results

Table 1 and **Figure 3** show the results of the patients pain evaluation expressed as mean values of VAS and standard deviation (SD) in the two study groups before treatment, 1 week after and two weeks after.

The differences of the two groups result extremely significant with $p < 0.0001$ for the comparison of VAS value after 1 and 2 weeks.

Discussion

In 2004, the World Association of Laser Therapy approved an agreement on the format of clinical studies with LLLT for muscle and joint pain.

Lasers with an infrared wavelength are more suitable because they are absorbed by the deeper layers of the tissue and not by the upper layer. The most commonly used are located in the electromagnetic spectrum from 780 to 904 nm ²⁴).

In a recent study, Kobayashi et al ²⁵) hypothesized that one of the pain relief mechanisms when



Figure 2: Devices used blindly by the patients: treatment device and placebo device.

Table 1: Results of the patients pain evaluation expressed as mean values of VAS and standard deviation (SD).

LASER GROUP	Before treatment	After 1 week	Diff 1w- before	After 2 weeks	Diff 2w-1w
MEAN	5.58	2.92	2.67	2.58	0.33
SD	0.99	0.99	0.88	1.50	1.23
PLACEBO GROUP	Before treatment	After 1 week	Diff 1w- before	After 2 weeks	Diff 2w-1w
MEAN	5.58	5.17	0.42	5.17	0.00
SD	0.99	1.27	0.99	0.94	1.044
P Value	NS	<0.0001	<0.0001	<0.0001	0.4860

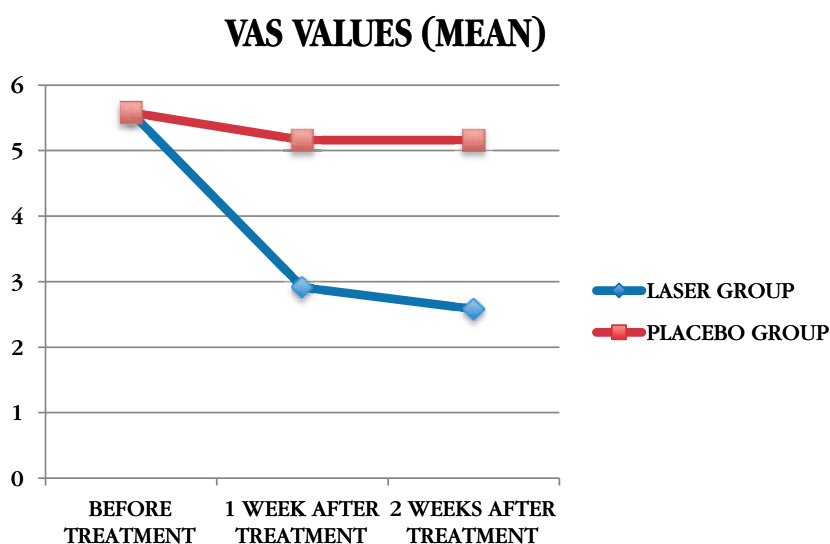


Figure 3: Results of the patients pain evaluation (means of VAS values) in the two study groups before, 1 week after and two weeks after treatment.

using LLLT in the treatment of TMJ disorders is the improved microcirculation in the temporal and masseter muscles. This improved circulation helps to remove noxious deposits associated with hypertension of the tissues. Pain relief is also felt by normalizing the intramuscular pressure on sensory nerve endings. Other studies have demonstrated that LLLT was shown to be effective for those with chronic pain and in those who did not respond to other previous conservative treatments ²⁶.

The main important aspect regarding the LLLT treatment of the TMJ pain concerns the correct parameters to use: in fact the intensity of the laser must not harm the tissue, but can cause biochemical effects on cells, so the laser is also known as the cold laser or soft laser ²⁷.

The output power is normally less than 500 mW

and the therapeutic doses are less than 35 J/cm² ²⁸.

Due the applicable laser dosage follows the Arndt-Schultz rule, which means that photo-bio-modulation only occurs when the dosage reaches the threshold level ²⁹, an effect would be suppressed if the dosage exceeds the threshold.

Conclusion

This study, even if it may be considered such a pilot study due to its limits (number of patients, number of data recorded, subjective evaluations) investigated a new way to control the pain in the temporomandibular diseases by a at home self administered laser device.

Results are encouraging but they will have to be confirmed by more enlarged studies.

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