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ORIGINAL ARTICLES

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

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Objectives: The Temporo-Mandibular Disorders (TMD) are a set of dysfunctional patterns concerning the temporo-mandibular 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 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 temporo-mandibular diseases by an at home self administered laser device.
Results are encouraging but they will have to be confirmed by greater studies.

Introduction

Temporo-mandibular 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

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

The Temporo-Mandibular Disorders (TMD) are a set of dysfunctional patterns concerning the temporo-mandibular 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 processes [3-6]; 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 female [7]. Diseases related to the TMJ concern about a 1/3 of the general population [8].

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 pain [9].

There are several possible sources of TMJ pain, such as inflammatory changes in the synovial membrane including fluid resulting in joint effusion [10-14], alterations in the bone marrow of the mandibular condyle [15] and impingement and compression [16].

The roles of electro-physical modalities and surgery in the management of TMD have not been fully elucidated [17]. 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 physician [18].

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 disorders [20].

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 gluco-corticoids, 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 cm^2. 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 cm^2.

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

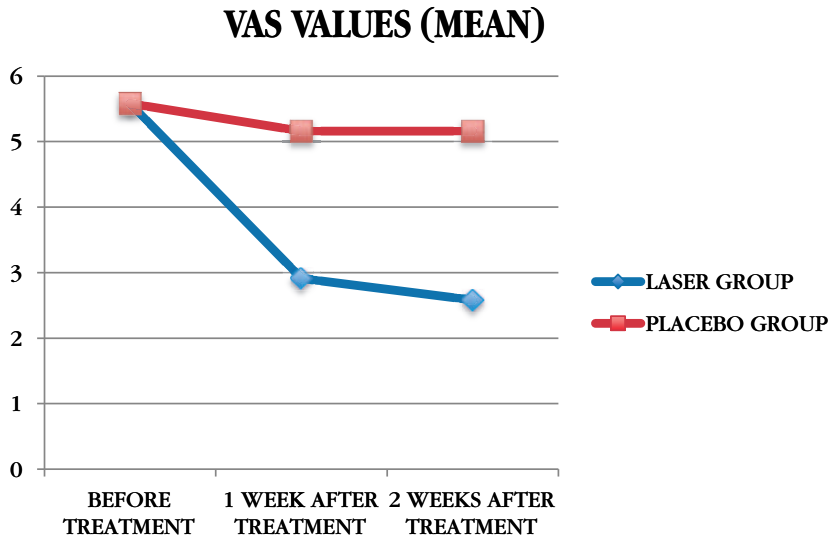

Figure 3: Results of the patients pain evaluation (means of VAS values) in the two study groups before, 1 week after and two weeks after treatment.

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/cm^2 [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 temporo-mandibular diseases by a at home self administered laser device.

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

References

1: Okeson JP. *Management of Temporomandibular Disorders and Occlusion.* 5th edition. St. Louis, Mo, USA: Mosby; 2003.

2: McNeill C. Management of temporomandibular disorders: concepts and controversies. J Prosthet Dent. 1997;77(5):510–522.

3: McNeill C, Mohl ND, Rugh JD, Tanaka TT. Temporomandibular disorders: diagnosis, management, education, and research. J Am Dent Assoc. 1990;120:253,255,257.

4: Mohl ND, Attanasio R. The Third Educational Conference to Develop the Curriculum in Temporomandibular Disorders and Orofacial Pain: introduction. J Orofac Pain. 2002;16:173–175.

5: List T, Walhund K, Wenneberg B, Dworkin SF. TMD in children and adolescents: prevalence of pain, gender differences, and perceived treatment need. Journal Of Orofacial Pain Winter. 1999

6: Al Ani MZ, Davies SJ, Sloan P, Glenny AM. Stabilization splint therapy for TM pain dysfunction syndrome. The Cochrana Database of Systematic Rewiews. 2004

7: Di Paolo C, Costanzo GD, Panti F, Rampello A, Falisi G, Pilloni A, Cascone P, Iannetti G. Epidemiological analysis on 2375 patients with TMJ disorders: basic statistical aspects. Ann Stomatol (Roma). 2013 Mar 20;4(1):161-169.

8: Poirier F, Blanchereau C, Francfort E, Kolev T. Prise en charge chirurgicale de l'articulation temporomandibulaire : à propos de 94 cas. Rev Stomatol Chir Maxillofac. 2006;107:436–440.

9: Scarfe WC, Farman AG. Diagnostic imaging of the temporomandibular joint. In: White SC, Pharoah MJ, editors. *Oral Radiology, Principles and Interpretation.* 6th edition. Noida, India: Elsevier; 2010. pp. 473–478.

10: Haley DP, Schiffman EL, Lindgren BR, Anderson Q, Andreasen K. The relationship between clinical and MRI findings in patients with unilateral temporomandibular joint pain. J Am Dent Assoc 2001;132:476–481.

11: Rudisch A, Innerhofer K, Bertram S, Emshoff R. Magnetic resonance imaging findings of internal derangement and effusion in patients with unilateral temporomandibular joint pain. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2001;92:566–571.

12: Emshoff R, Brandlmaier I, Bertram S, Rudisch A. Risk factors for temporomandibular joint pain in patients with disc displacement without reduction - a magnetic resonance imaging study. J Oral Rehabil 2003;30:537–543.

13: Yano K, Sano T, Okano T. A longitudinal study of magnetic resonance (MR) evidence of temporomandibular joint (TMJ) fluid in patients with TMJ disorders. Cranio 2004;22:64–71.

14: Larheim TA. Role of magnetic resonance imaging in the clinical diagnosis of the temporomandibular joint. Cells Tissues Organs 2005;180:6–21.

15: Emshoff R, Rudisch A. Temporomandibular joint internal derangement and osteoarthrosis: are effusion and bone marrow edema prognostic indicators for arthrocentesis and hydraulic distention?. J Oral Maxillofac Surg 2007;65:66–73.

16: Güler N, Yatmaz PI, Ataoglu H, Emlik D, Uckan S. Temporomandibular internal derangement: correlation of MRI findings with clinical symptoms of pain and joint sounds in patients with bruxing behaviour. Dentomaxillofac Radiol 2003;32:304–310.

17: Emshoff R, Bösch R, Pümpel E, Schöning H, Strobl H (2008) Low-level laser therapy for treatment of temporomandibular joint pain: a double-blind and placebo-controlled trial. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 105: 452–456.

18: Okeson JP (2012) Temporomandibular Disorders in Chapter 5 - Diseases of the Head and Neck. In: Bope ET, Kellerman RD, editors. Conn's Current Therapy 2013, 1st ed., Pennsylvania: Saunders. pp. 320–323.

19: Salmos-Brito JA, De Menezes RF, Teixeira CE, Gonzaga RK, Rodrigues BH, et al. . (2013) Evaluation of low-level laser therapy in patients with acute and chronic temporomandibular disorders. Lasers Med Sci 28: 57–64.

20: Melis M, Di Giosia M, Zawawi KH (2012) Low level laser therapy for the treatment of temporomandibular disorders: a systematic review of the literature. Cranio 30: 304–12.

21: Simunovic Z. Low-level laser therapy with trigger points technique: a clinical study on 243 patients. J Clin Laser Med Surg 1996;14:163–167.

22: Simunovic Z. Pain and practical aspects of its management. In: Laser Medico, ed. Lasers in medicine and dentistry. Basic science and up-to-date clinical application of low energy level laser therapy – LLLT. Rijeka: European Medical Laser Association, 2000; cap. 14: 269–301.

23: Ferreira-Valente MA, Pais-Ribeiro JL, Jensen MP: Validity of four pain intensity-rating scales. Pain 2011, 152:2399-2404.

24: Venancio RA, Camparis CM, Lizarelli RF. Low intensity laser therapy in the treatment of temporomandibular disorders: a double-blind study. J Oral Rehabil. 2005;32:800–807.
25: Kobayashi M, Kubota J. Treatment of temporomandibular joint (TMJ) pain with diode laser therapy. J Laser Therapy 1999; 11.
26: Shiroto C, Ohshiro T. A new standard of Efficacy for Low Level Laser Therapy (LLLT) in Pain Attenuation in Japan (a secondary publication). Laser Ther. 2014 Sep 30;23(3):183-190.
27: Gonçalves RV, Novaes RD, Matta SL, et al. : Comparative study of the effects of gallium-aluminum-arsenide laser photobiomodulation and healing oil on skin wounds in wistar rats: a histomorphometric study. Photomed Laser Surg, 2010, 28: 597–602.
28: Aggarwal A, Keluskar V. Physiotherapy as an adjuvant therapy for treatment of TMJ disorders. Gen Dent, 2012, 60: 119–122.
29: Lubart R, Lavi R, Friedmann H, et al. Photochemistry and photobiology of light absorption by living cells. Photomed Laser Surg, 2006, 24: 179–185.