

To Analyze the Effectiveness of Low-Level Laser Therapy and Sham Laser in Patients with Temporomandibular Disorder

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Running Title: Syed et al Effectiveness of LLLT and Sham Laser in TMD

Abstract: *Background:* Temporomandibular joint disorder (TMD) is a collective term, characterized by symptoms involving muscles of mastication, Temporomandibular joint (TMJ), and orofacial structures resulting from a dysfunction of the somatogenic system. Low-Level Laser Therapy (LLLT) is based on photo-biostimulation which involves the use of visible red and near-infrared light to stimulate and improve healing as well as reducing pain. This study aims to find out the efficacy of LLLT in patients with TMD and also to find out the efficacy of sham laser therapy in patients with TMD. *Methodology:* Thirty patients from OPD of Nanded Rural Dental College and research center were included in the study based on the selection criteria. They were randomly divided into group A (treated with LLLT) and group B (treated with sham laser therapy). The parameters selected were the wavelength of 632.8 nm, maximum output of 1 Mw with energy density 1.3J/cm². VAS and AROM of TMJ were used as the outcome measure taken before and after the end of 2 weeks of treatment. *Results:* There was a statistically significant difference in VAS, mouth opening, and mandibular protrusion and retrusion between LLLT and sham laser therapy groups post-treatment. *Conclusion:* LLLT is a better treatment module for patients with TMD

Keywords: Low-Level Laser Therapy, Sham Laser Therapy, Temporomandibular disorder

1. Introduction

Temporomandibular joint disorder (TMD) is a collective term, characterized by symptoms involving muscles of mastication, Temporomandibular joint (TMJ), and orofacial structures resulting from a dysfunction of the somatogenic system¹. It is one of the most common causes of musculoskeletal pain (second after low back pain) found in all age groups and more often in women². This disorder has a multifactorial etiology which is explained by the bio-psycho-social model.

The anatomical structure of the TMJ is unique. It is a synovial joint formed by the mandibular condyle inferiorly and the articular eminence of the temporal bone superiorly but the articulating surfaces are covered by fibrocartilage and not hyaline cartilage, with an interposed articular disk. The fibrocartilage disk divides the joint into the upper and lower joint cavity³. The motions of the TMJ are mandibular depression (mouth opening), mandibular elevation (mouth closing) mandibular protrusion (jutting the chin forward), mandibular retrusion (sliding the teeth backward), lateral deviation of the mandible (sliding the teeth to either side)³. Most of the patients of TMD complain of pain, which could be of myofascial origin, arthralgia, or degenerative joint disease⁴. Disorders of the TMJ can be efficiently treated by the combined efforts of the Physical therapist and dentist.

The most common subtypes of TMDs include pain-related disorders, such as myofascial pain and arthralgia, and disorders associated with the TMJ, primarily internal derangements and degenerative joint disease. Besides, the bio-psycho-social perspective recognizes the importance of

assessing the impact of chronic pain on the person, including psychologic disabilities, such as depression, as well as psychosocial dysfunction, such as inability to perform activities of daily living, susceptibility to medication abuse, and frequency of treatment-seeking. These are significant components of the clinical presentation of many chronic pain conditions, including TMDs.

Various physical therapy interventions such as exercise programs, electrical modalities, and manual therapy techniques have been used in the treatment of TMJ disorders. One such modality is low-level laser therapy (LLLT) which gained popularity especially since the invention of diode lasers. This modality works on the principle of photo-bio-stimulation in which the incident electromagnetic energy is converted into ATP, causing an enhanced cellular activity and increased microcirculation, all of which promote tissue healing⁵.

2. Materials and Methods

This study was conducted at the out patient department of Nanded Physiotherapy College & Research Centre, Nanded. Ethical clearance was obtained from the institutional ethics committee. The already diagnosed patients with TMD's referred from the out patient department of Nanded Rural Dental College & Research Centre, Nanded was the population for the study. Out of which, those who gave the consent to participate were considered to be included in the study based on the inclusion and exclusion criteria. Both male and female subjects were allowed to participate in the study.

The sample size was 30 divided into two groups.

Research Design: Experimental Study Design

2.1 Materials

- Laser equipment with HE-NEON having a wavelength of 632.8 nm.
- Protective goggles.
- Couch and Pillow
- Millimeter scale
- Pencil
- Visual analog scale (Printed on Paper)

Outcome Measures: Visual Analog Scale (VAS) and Range of motion (ROM) of TMJ.

Sampling Technique:

The sampling technique used in this study was simple random sampling and the total sample size was 30 subjects. The subjects were randomly allocated into 2 groups as follows:

- Group A – 15 subjects LLLT group
- Group B - 15 subjects sham laser therapy group

Inclusion Criteria

- Age above 18 yrs.
- Pain at rest or opening or closing of the jaw.
- Decreased mouth opening or closing.
- Uncomfortable bite.
- Muscle tenderness (at masseter, temporal muscles)
- The subjects, who can understand VAS and ROM.
- Bilateral and unilateral TMJ pain.

Exclusion Criteria

- Skin infection.
- Congenital Abnormality of TMJ.
- Recent trauma or surgery or any other form of treatment for TMJ pain.
- Patients having tumors in the maxillofacial regions.
- Patients who are not able to understand VAS and ROM.
- Patients who are not willing to participate in the study.

Methods of Data Collection

All the following parameters were assessed before and after treatment. The pre-treatment findings were considered as the baseline values, which were compared with post-treatment findings.

- The pain level was assessed by Visual Analog Scale (VAS).
- TMJ range of motion was assessed by the millimeter scale.
- The mandibular depression and elevation were measured by placing a millimeter-scale between upper and lower incisors and asking the patient to open and close their mouth as wide as possible.
- Mandibular protrusion and retrusion were measured by placing a millimeter-scale between upper and lower incisors and asking patients to move the jaw forward and backward.

- Lateral deviations were measured by placing a millimeter-scale between upper and lower incisors and asking patients to move their jaw laterally.

3. Procedure

Prior informed consent was obtained from all the subjects participating in the study. Clearance was obtained from the institutional ethics committee. The researchers explained the procedure to the participants. A brief explanation of the process was given to prepare the subjects after obtaining informed consent.

- Group A with bilateral TMJ (n=7) pain, right side TMJ (n=5), and left side TMJ (n=3) was given Low-Level laser Therapy.
- Group B with bilateral TMJ (n=5) pain, right side TMJ (n=5), and left side TMJ (n=5) was given sham laser therapy.

Low-level laser therapy treatment procedure:

The participants were placed in a side-lying position with the affected side facing upwards. They were given protective goggles to wear during the treatment. The laser therapy machine was switched on and the parameters (a continuous frequency with the wavelength of 632.8 nm, maximum output of 1 Mw with energy density 1.3 J/cm²) were selected for the treatment by probe Method. The probe of the laser therapy device was kept close to the painful TMJ side and the laser therapy application was given for 10 minutes. The treatment was continued for 2 weeks

The patients were assessed using the VAS (Visual Analog Scale) and millimeter-scale (ROM of TMJ) at the beginning and the end of 2 weeks.

The sham laser therapy procedure:

The participants were placed in a side-lying position with the affected side facing upwards. They were given protective goggles to wear during the treatment. With the laser therapy machine switched off the probe was placed close to the TMJ on the affected side for 10 minutes. The treatment was continued for 2 weeks.

The patients were assessed using VAS (Visual Analog Scale) and millimeter-scale (ROM of TMJ) in the beginning and at the end of 2 weeks.

4. Results

Data was analyzed using the statistical package SPSS 2017. The results were presented for groups were expressed as "mean ± SD". The effectiveness of LLLT and sham laser therapy in patients with TMD was analyzed using paired 't' test. For independent samples i.e. effects of LLLT with sham laser therapy, an unpaired 't' test is used. The 'p' values less than 0.05 were considered as significant and 'p' values less than 0.01 as highly significant.

Table 1: Efficacy of Low-Level Laser Therapy (LLLT) in patients with TMJ disorder (Mean ± SD)

	Pre	Post	95 % C.I. of difference	t-value	p-value
VAS	7.13 ± 0.83	1.53 ± 0.91	5.015 – 6.185	20.546	P<0.0001
Mouth Opening	22.07 ± 6.70	41.07 ± 5.65	15.48 – 22.52	11.57	P<0.0001
Mandibular Protrusion and Retrusion	2.53 ± 0.74	7.20 ± 0.67	4.266– 5.067	24.973	P<0.0001

Degree of freedom =14

Table 2: Efficacy of efficacy of sham laser therapy in patients with TMJ disorder (Mean ± SD)

	Pre	Post	95 % C.I. of difference	t-value	p-value
VAS	6.87 ± 0.99	2.93 ± 1.16	3.256 – 4.611	12.458	P<0.0001
Mouth Opening	21.33 ± 7.09	33.87 ± 3.94	9.813 – 15.254	9.883	P<0.0001
Mandibular Protrusion And Retrusion	2.33± 0.89	6.07± 0.88	3.161– 4.305	14.00	P<0.0001

Degree of freedom =14

Table 3: Comparison of effects of LLLT with sham laser therapy in patients with TMD at pre-test (Mean ± SD)

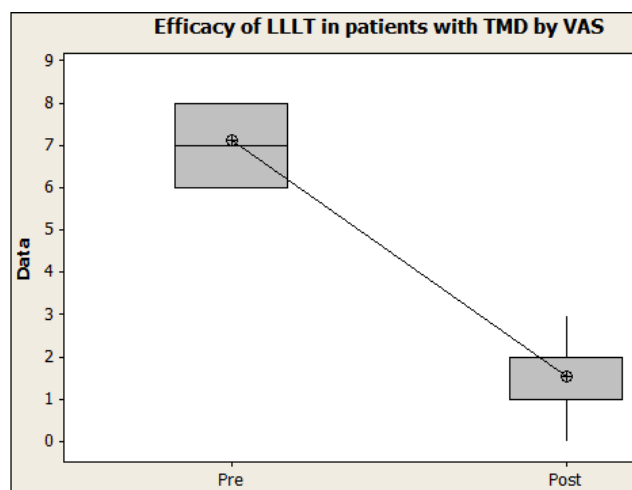
	Low-Level Laser Therapy	Sham Laser Therapy	T	p-value
VAS	7.13 ± 0.83	6.87 ± 0.99	0.797	P>0.05
Mouth Opening	22.07 ± 6.70	21.33±7.09	0.290	P>0.05
Mandibular Protrusion and Retrusion	2.53 ± 0.74	2.33±0.89	0.664	P>0.05

Degree of freedom =28

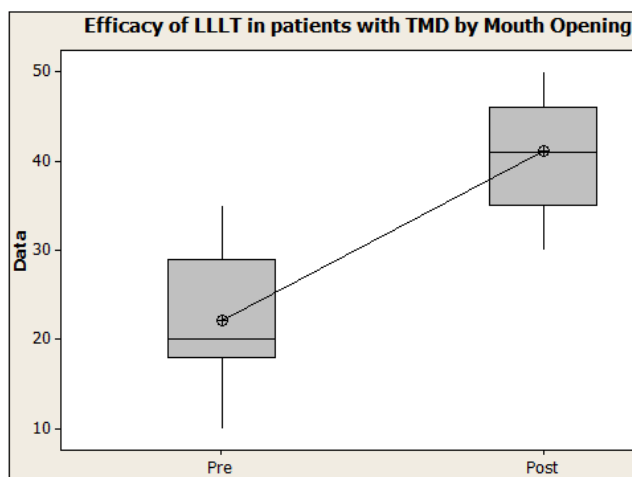
Table 4: Comparison of effects of LLLT with sham laser therapy in patients with TMD at post-test (Mean ± SD)

	Low Level Laser Therapy	Sham Laser Therapy	t	p-value
VAS	1.53 ± 0.92	2.93 ± 1.16	3.664	P<0.001
Mouth Opening	41.07 ± 5.65	33.87 ± 3.94	4.047	P<0.0004
Mandibular Protrusion and Retrusion	2.53 ± 0.74	2.33 ± 0.89	3.945	P<0.0005

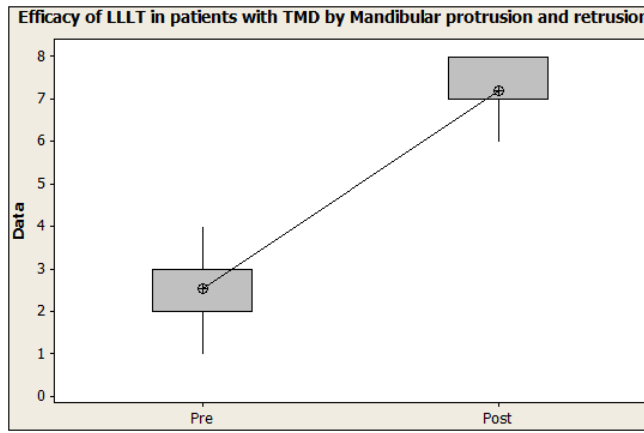
Degree of freedom =28



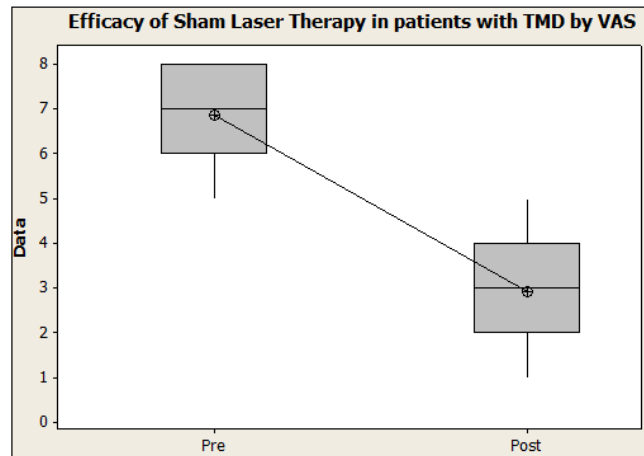
Graph 1: VAS Scores Pre & Post LLLT Treatment



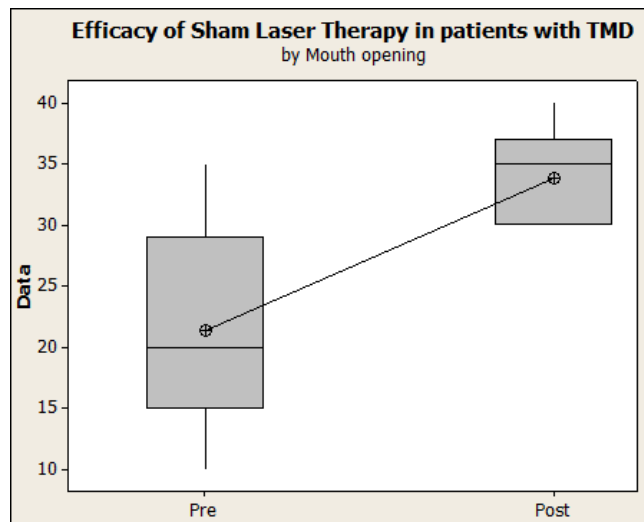
Graph 2: Mouth Opening Scores Pre & Post LLLT Treatment



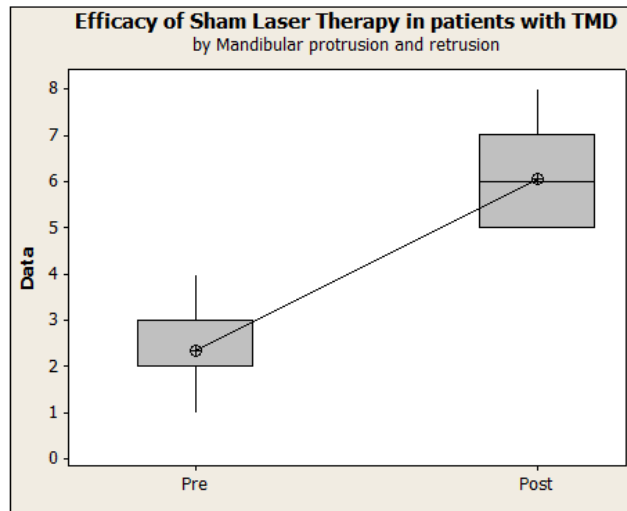
Graph 3: Mandibular Protrusion & Retrusion Pre & Post LLLT Treatment



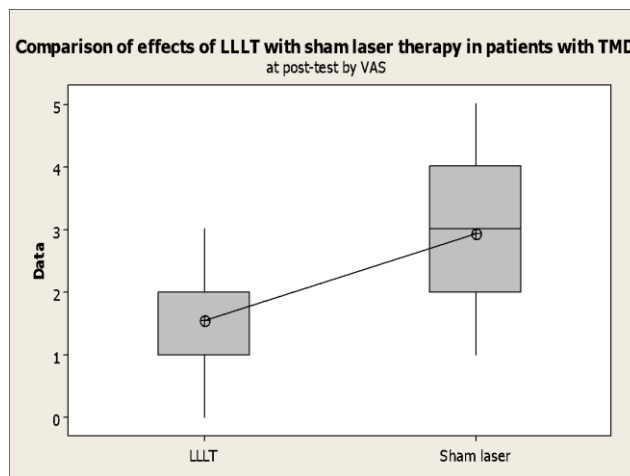
Graph 4: VAS Scores Pre & Post Sham LASER Therapy Treatment



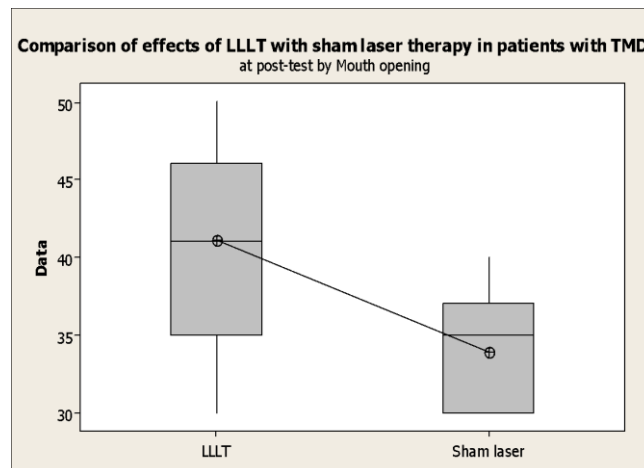
Graph 5: Mouth Opening Pre & Post Sham LASER Therapy Treatment



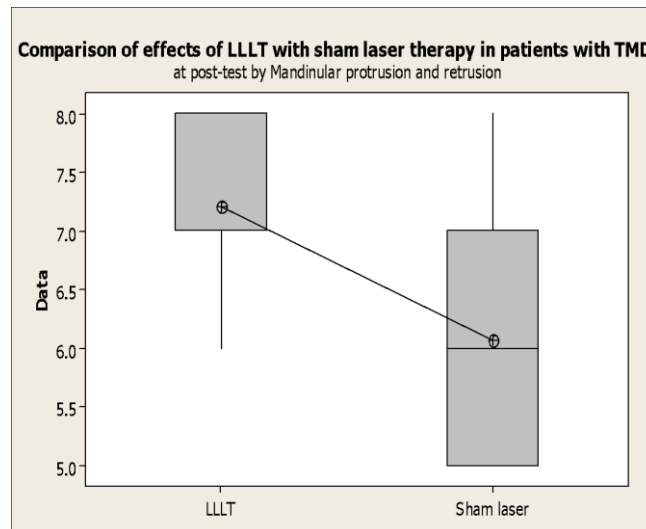
Graph 6: Mandible Protrusion Retrusion Pre & Post Sham LASER Therapy Treatment



Graph 7: VAS Scores comparison of LLLT & Sham LASER Therapy Treatment



Graph 8: Mouth Opening Scores comparison of LLLT & Sham LASER Therapy Treatment



Graph 9: Mandibular Protrusion & Retrusion Scores comparison of LLLT & Sham LASER Therapy Treatment

5. Discussion

This study was conducted to determine the effectiveness of LLLT versus sham laser in patients with TMD. The data analysis and results show that there was a reduction in pain and improvement in ROM in both groups (table 1 and table 2). However further analysis shows that the LLLT group showed greater improvement in the outcome measures compared to sham laser (table 3 and table 4).

There was a significant difference found in VAS between LLLT and sham laser therapy post-treatment which indicates, pain reduction in the LLLT group was more than the sham laser group. Also, there was a statistically significant difference in mouth opening and mandibular protrusion and retrusion between LLLT and sham laser therapy post-treatment thereby indicating that the increase in ROM in the LLLT group was more effective as compared to the sham laser group.

In the majority of the cases of TMD, the pain is primarily of non-dental origin but it is extremely debilitating for the patients as it disrupts the masticatory function⁶. Thus, relief of pain and enhancement of jaw mobility is an essential component in the treatment of TMD. LLLT induces photo-bio-stimulation, in the tissues where it is applied. The near infra-red wavelengths penetrate several millimeters and stimulate healing in the deep-seated tissues. This in turn causes proliferation of macrophages, lymphocytes, endothelial cells, and keratinocytes along with the release of cytokines and growth factors leading to collagen synthesis⁷. It also causes tissue regeneration induces analgesia and has an anti-inflammatory effect in the tissues where it is applied⁸. Though the exact mechanism of analgesia is not well known it is postulated that there is an increase in microcirculation and reduction in the edema caused by enhanced lymphatic flow^{9, 10, 11}. LLLT is a non-thermal form of treatment having the potential to cause alterations in cell metabolism leading to increased mitochondrial activity, the formation of fibroblasts, enhanced sodium-potassium pump which promotes healing¹². The photons are absorbed by the mitochondria stimulating more production of adenosine triphosphate (ATP) and reactive oxygen species¹³. Irradiation using LLLT has also been shown to affect

gene expression thus directly stimulating cell growth and proliferation and indirectly stimulating DNA synthesis, cell remodeling, and migration and also suppresses cell apoptosis¹⁴. These mechanisms explain the physiological basis of the LLLT. However, studies have shown that placebo treatment is effective in a large proportion of patients which explains the outcomes in the sham laser group¹⁵.

6. Conclusion

From this study, we can conclude that LLLT is effective in the treatment of patients with TMD. It causes a reduction in the pain as well as improves the ROM which together enhances functional outcome and allows patients to perform activities of daily living (ADL) effectively.

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