Abstract

Aims and Objective: The objective of this study was to assess the effectiveness of low-level laser therapy (LLLT)/low intensity laser therapy (LILT) in the management of temporomandibular joint (TMJ) pain in a random and double-blind research design. Materials and Methods: TMJ pain patients, randomly assigned into two groups: Group 1 (n = 20) and Group 2 (n = 20), received 2–3 treatments per week for 8 sessions of active LILT with diode laser (gallium aluminium arsenide, 810 nm, 0.1 W). Measures of TMJ pain during function were evaluated at baseline, after completion of 8 sessions of laser treatment, and 30 days after the final laser therapy. Results: At the final treatment point, within-group, pain reduction was observed in both active LLLT and placebo groups at day 0 (P = 0.000), 8th session (P = 0.000), and 1 month (P = 0.001). Between the groups, there is no significant difference at day 0 (P = 0.214), 8th session (P = 0.806), and 1 month (P = 0.230). Significant increased mouth opening was observed in both Group 1 and Group 2 (P = 0.006 and P = 0.021, respectively) after treatment. However, no significant difference was found between the two groups (P = 0.330). Furthermore, significant improvement in clicking was recorded before and after treatment both in Group 1 (P = 0.000) and Group 2 (P = 0.001). Conclusion: The study suggests that LLLT is not better than placebo at reducing TMJ pain during function. It may be assumed that a more tailored application of LLLT should be developed to take into account the multifactorial aspect of the disorder.

Keywords: Low-intensity laser therapy, low-level laser therapy, temporomandibular disorder

Introduction

Temporomandibular disorder (TMD) is the collective term that describes a number of clinical problems involving the masticatory musculature, the temporomandibular joint (TMJ), or both. The prevalence of TMD in the general population is high (40% to 60%).

Epidemiological studies reveal that up to 75% of the adult populations have at least one sign of TMJ dysfunction, approximately 30% have more than one symptom, while only 3%–7% of the population admitted for advice or care.[1]

A range of symptoms may be linked to TMD; pain predominantly in the chewing muscles and/or jaw joint is the most common symptom.[2]

TMDs fall into three main categories. Myofascial pain is the most common form of TMD. It is characterized by discomfort or pain in the masticatory muscles and sometimes also in the neck and shoulder muscles. The second category is the internal derangement of the joint associated with a dislocated jaw or displaced disc and an injury to the condyle. Degenerative joint disease is another category, including osteoarthritis or rheumatoid arthritis in the jaw joint.[1]

The initial management of TMD includes supportive patient education, pharmacologic pain control, and physical therapy, i.e., moist heat, ultrasound, and transcutaneous electrical nerve stimulation.[2]

Low-level laser therapy (LLLT) also known as low-intensity laser therapy (LILT) seems to be in accordance with TMDs treatment philosophy because it represents a noninvasive, reversible therapy without any known side effects. LLLT uses electromagnetic radiation, which is having a single wavelength (red or infrared). It can...
be used as treatment for several pathologies such as wound healing, pain conditions, and inflammatory situations.[2]

In a systemic review of literature, it was concluded that LLLT significantly reduces pain and improves health status in chronic joint disorders including osteoarthritis of the knee, cervical spine, lumbar spine, and TMJ disorders.[3]

LILT has little evidence for its effectiveness in the management of TMDs and it has been widely used in the treatment of musculoskeletal disorders. Contradictory results have been reported in several recent studies on efficacy of lasers in TMD.[4-6]

The aims and objective of this study were to assess the effectiveness of LILT in the management of symptoms of TMDs.

Materials and Methods

This study was conducted in the Department of Oral Medicine and Radiology, Coorg Institute of Dental Sciences, Virajpet, Karnataka, between September 2012 and August 2014.

Source of data

The study and control population was drawn from outpatients visiting the Department of Oral Medicine and Radiology, Coorg Institute of Dental sciences, Virajpet, Karnataka.

Method of collection of data

A total of forty patients, in the age group of 18–40 years, were included and clinical examination was performed using research diagnostic criteria (RDC)/TMD criteria. A detailed review protocol was specified before conducting the review. Patients who have been diagnosed with TMD according to RDC/TMD Axis-I were included in the study.

Inclusion criteria

1. Outpatients attending the Department of Oral Medicine and Radiology who volunteered for the study
2. Patients in the age group of 18–40 years
3. Patients who have been diagnosed as per RDC/TMD Axis I criteria.

Exclusion criteria

1. Patients with any underlying systemic disease
2. Patients in their pregnancy
3. Patients who are on any form of treatment for TMD in the last 1 month
4. Patients with a recent history of trauma
5. Patients with any other joint disorders, rheumatoid arthritis, etc.

Study procedure

An informed consent was obtained from all the patients willing to be a part of the study. Detailed case history regarding predisposing factors, TMDs, and symptoms related to TMJ such as pain, joint noises, and muscle pain was recorded in designed pro forma. The study was approved by the Ethical Committee of the institution.

Based on the history and clinical findings, clinical diagnosis was given based on RDC/TMD Axis I criteria. The patients were subjected to a screening panoramic radiograph and TMJ radiographic (Panoramic open and closed view) examination to rule out and exclude cases with gross osseous changes of condyles and odontogenic conditions that may be a source of patients’ symptoms. Radiographs had no direct role in the study as RDC was employed for the diagnosis of TMD.

A total of 43 patients who have been diagnosed with TMD as per RDC/TMD Axis I were included in the study, of which three patients did not meet the inclusion criteria because they refused to adhere to the treatment protocol. Forty patients were included and they were randomly assigned to two groups; Group 1 (n = 20) and Group 2 (n = 20).

The patients were instructed to avoid using any analgesic, anti-inflammatory, muscle relaxants, or psychotropic medication during the treatment and evaluation. Patients were instructed to adhere this treatment protocol during the evaluation period.

The treatment was performed with a diode laser (Gallium, Aluminium, Arsenide; PICASSO, USA), noncontact mode, continuous wave, 0.1 W (100 mW), 810 nm, 6 J/cm², 2–3 times a week, for a total of 8 sessions, 60 s/session [Figure 1]. Two identical probes were used (tip of the diameter = 300 µ), one for active laser and one for placebo laser marked A and B by a clinician who did not perform the applications.

During the application, all individuals close to the laser beam were instructed to wear protective eyewear. The clinician who performed the evaluation and the patient was blinded from the study. Calibration of the clinician performing the evaluation was reevaluated by the senior faculty.

Figure 1: Laser unit and probe
Patients were informed that they could withdraw from the treatment at any point of time during the study and they were given an informed choice of other conventional treatment modalities such as medications and occlusal splints. Patients of both the groups were also advised self-care including, soft diet, moist heat application, TMJ exercises during the treatment, such as Rocabado 6 × 6 program, which utilizes six exercises six times per day and isometric exercises: forcefully placing the chin on a closed hand during depression jaw movement (mouth opening) and hindering its elevation (closing) by pressing the inferior incisors with the index and middle fingers.

The laser probe was placed perpendicular, directly on the skin at the center of the upper joint space, approximately 1 cm in front of the tragus and also at the trigger points which is assessed and localized by the patient.

Pain during function and at rest was accomplished by patient self-assessment using a visual analog scale (VAS). The assessment was performed at three different points of time; before treatment, after the final treatment, and 30 days after the final treatment.

Statistical analysis

Descriptive analysis was done to tabulate the demographic data using mean and standard deviation (SD). Significance was set at $P < 0.05$. Independent t-test was performed to analyze the significant difference in mouth opening and VAS score between the two groups. Paired t-test was used to analyze the significant difference in VAS at day 0, 8th session, and after 1 month and to analyze mouth opening and clicking before and after treatment in both Group 1 and 2. The nonparametric tests of Kruskal–Wallis test and post hoc test were performed to determine the number of session where significant improvement in pain reduction was observed both in Group 1 and 2.

All data were analyzed using SPSS software version 20 (IBM company, United States).

Results

Baseline comparisons of demographic data between the laser and the placebo group were made based on age, gender, and baseline VAS score. Descriptive analysis was performed to tabulate the data using mean and SD and independent sample t-test was used to analyze the significant difference between the two groups. It shows that there is no significant difference in the baseline demographics such as age ($P = 0.06$), gender ($P = 0.48$), and VAS score at baseline level ($P = 0.214$) between the two groups shown in Table 1.

Radiographic examination showed no evidence of bony changes in the condyle and TMJ region. Based on the clinical RDC/TMD Axis I, in Group 1, 12 patients (65%) had internal derangement with reduction with myofascial pain, one patient (5%) had only myofascial pain, and the remaining 7 (30%) had internal derangement with reduction [Figure 2]. Whereas in Group 2, 9 patients (45%) had internal derangement with a reduction with myofascial pain, two patients (10%) had myofascial pain, the remaining 9 (45%) patients diagnosed as internal derangement with reduction [Figure 3].

Mouth opening

Mouth opening was assessed before and after treatment in both Group 1 and 2. In Group 1, mean of mouth opening before and after treatment was 43.05 mm and 45.25 mm, respectively, whereas in Group 2, it was 45.3 mm and 46.65 mm before and after treatment, respectively. Paired t-test was performed to analyze the significant difference. A significant increase in mouth opening was observed both in Group 1 ($P = 0.006$) and Group 2 ($P = 0.021$); however, independent t-test showed no significant difference between the two groups before and after treatment, $P = 0.247$ and $P = 0.330$, respectively [Table 2 and Figure 4].

![Figure 2: Research diagnostic criteria-temporomandibular disorder Axis I criteria in Group 1. IDWR: Internal derangement with reduction, MFP: Myofascial pain](image)

Table 1: Baseline comparison of demographic and standard measures between low-level laser therapy and placebo group

| Variables               | Study groups (mean±SD) | Test      | Test value | $P$  |
|-------------------------|------------------------|-----------|------------|------|
| Age (years)             | Group 1 ($n=20$)       | 30.85±6.31| Independent t-test | 1.892 | 0.06 |
|                         | Group 2 ($n=20$)       | 27.55±4.58|            |      |      |
| Female/male             |                        | 17/3      | Independent t-test | 1.761 | 0.48 |
|                         |                        | 14/6      |            |      |      |
| VAS score level (mm)    |                        | 5.00±1.486| Independent t-test | 1.264 | 0.214|
|                         |                        | 4.35±1.75 |            |      |      |

$P<0.05$ is considered as significant. SD=Standard deviation, VAS=Visual analog scale
Temporomandibular joint clicking

Nineteen patients (95%) had clicking in Group 1 before treatment and of 19 patients, 12 patients showed no clicking after treatment (8th session). In Group 2, 17 (85%) patients presented with TMJ clicking before treatment and out of 17, 10 patients showed no clicking after treatment (8th session). It shows a significant reduction in clicking in both Group 1 ($P = 0.000$) and Group 2 ($P = 0.001$). However, no significant difference was observed between the groups ($P = 0.752$) [Table 3 and Figure 5].

Muscle involvement

In this study, 13 patients (65%) presented with TMJ pain with muscle involvement in Group 1 and 10 patients (50%) in Group 2 [Figure 6].

Visual analog scale analysis

Pain during function was accomplished by patient self-assessment using a VAS score 0–10. The assessment was performed at three different points of time; before treatment (day 0), after the final treatment (8th session), and 30 days after the final treatment.

Descriptive statistics was used to tabulate the data using mean ± SD and the mean VAS score of day 0, 8th session, and at 1 month in Group 1 is 5.0, 1.5, and 0.45, respectively, and in Group 2 is 4.3, 1.35, and 0.95, respectively [Figure 7].

Paired $t$-test was done to analyze the significant difference in VAS scores between day 0, 8th session, and after 1 month in both Group 1 and 2. It shows a significant difference between day 0, 8th session, and after 1 month treatment both in Group 1 and 2 [Tables 4 and 5] and Group 1 shows

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**Table 2: Mouth opening in Group 1 and 2 before and after treatment**

| Group            | Mean±SD      | Test       | Test value | $P$  |
|------------------|--------------|------------|------------|------|
| Group 1          |              |            |            |      |
| Before treatment | 43.05±6.329  | Paired $t$-test | 3.118 | 0.006|
| After treatment  | 45.25±4.447  |            |            |      |
| Group 2          |              |            |            |      |
| Before treatment | 45.30±5.768  | Paired $t$-test | 2.526 | 0.021|
| After treatment  | 46.65±4.522  |            |            |      |
| Between Group 1 and Group 2 | |            |            |      |
| Before treatment | Independent $t$-test | 1.175 | 0.247|
| After treatment  | Independent $t$-test | 0.987 | 0.330|

SD=Standard deviation
### Table 3: Temporomandibular joint clicking in both Group 1 and Group 2 before and after treatment

| Group           | Percentage With clicking | Mean±SD | Test     | Test value | df  | P   |
|-----------------|--------------------------|---------|----------|------------|-----|-----|
| Group 1         |                          |         |          |            |     |     |
| Before treatment| 95                       | 0.05±0.22| Paired t-test | −4.819    | 19  | 0.000 |
| After treatment | 35                       | 0.60±0.50|           |            |     |     |
| Group 2         |                          |         |          |            |     |     |
| Before treatment| 85                       | 0.15±0.36| Paired t-test | −4.819    | 19  | 0.001 |
| After treatment | 35                       | 0.65±0.48|           |            |     |     |
| Between Group 1 and Group 2 |                  |         |          |            |     |     |
| Before treatment|                          |         |          |            |     |     |
| After treatment |                          |         |          |            |     |     |

SD=Standard deviation

### Table 4: Paired differences in visual analog scale score of each session in Group 1

| Paired differences (mean±SD) | t    | df  | P   |
|-----------------------------|------|-----|-----|
| Pair 1 - day 0 to 8th session | 3.5±1.96 | 7.985 | 19 | 0.000 |
| Pair 2 - day 0 to 1 month    | 4.5±1.503 | 13.534 | 19 | 0.000 |
| Pair 3-8th session to 1 month| 1.05±1.234 | 3.804 | 19 | 0.001 |

SD=Standard deviation

### Table 5: Paired differences in visual analog scale score of each session in Group 2

| Paired differences (mean±SD) | t    | df  | P   |
|-----------------------------|------|-----|-----|
| Pair 1 - day 0 to 8th session | 3.0±1.4 | 8.623 | 19 | 0.000 |
| Pair 2 - day 0 to 1 month    | 3.4±1.63 | 11.943 | 19 | 0.000 |
| Pair 3-8th session to 1 month| 0.4±1.04 | 2.373 | 19 | 0.001 |

SD=Standard deviation

Figure 7: Mean visual analog scale score of Group 1 and 2

There is still no consensus on the way TMD diagnosis and measurement of the presence and severity of pain. The use of RDC for TMD to identify targeted groups of TMD patients to receive selected treatment is consistent with the overall rationale for developing the RDC/TMD – namely to make an evidence-based diagnostic and assessment instrument available for TMD researchers.

The RDC/TMD criteria for both Axis I and II have been used in numerous clinical research studies to characterize physical, psychological, and psychosocial factors associated with TMD as well as the relationship among these factors and the RDC/TMD has been suggested as a model system for the diagnosis and assessment of all clinical chronic pain conditions.[8] However, there are no standardization of the diagnostic criteria.[9] Schiffman et al. (2014) established diagnostic criteria for TMD which is derived from research, clinical usage, and field trials. It describes the concise examination protocol for routine clinical use and in addition to that headache is included in this criteria.[10]

The age of the subjects in the study ranged from 18 to 40 years. Epidemiological data indicate that TMDs are most prevalent in the age group of 17–45 years old. The incidence of TMD is significantly higher in this age group as compared to older subjects.[11] The lower prevalence of signs and symptoms of TMD in the older age groups supports the probability that most TMDs are self-limiting.[12]

In the present study, a female predilection was noted with 85% in Group 1 and 70% in Group 2. This is in accordance with most of the studies which have reported that the incidence of TMDs is up to four times more frequent in women, and they tend to seek treatment for their TMJ.
problems three times more often than males. The high prevalence of TMD in females could also be explained on the basis of physiological characteristics, particularly hormonal variations and structures in the connective tissue and muscle. The greater laxity of these tissues, related to estrogen levels, explains that these tissues have a lower capacity to support the functional pressure, thus leading to TMD. A study found that variations in clinical pain intensity in women with TMD during the menstrual cycle, where the highest values of pain coincided with the period of higher concentration of estrogen.

The etiology of TMD is multifactorial. Parafunctional habits, emotional distress, acute trauma from blows or impacts, trauma from hyperextension of the neck, instability of maxillary and mandibular relationships, laxity of the joint, comorbidity of other rheumatic or musculoskeletal disorders, and poor general health have been proposed as etiologic factors. These factors may initiate, aggravate, and perpetuate a TMJ disorder.

Early diagnosis and treatment of TMDs remains problematic. Reduction of muscular tension, cessation of parafunctional habits as well as correction of the postural imbalance by an appropriate exercise regimen might play an important role in the management of TMD. Studies have reported that self-care has beneficial effect in the management of TMDs. However, exercise therapy has not shown to be equally effective in improvement of symptoms such as pain and locking. In the present study, all the patients were advised self-care including soft diet, moist heat application, and TMJ exercise during the treatment.

Majority of the subjects in this study belonged to RDC/TMD Axis I-Class II A, i.e., internal derangement with reduction. Based on the clinical RDC/TMD Axis I, patients with internal derangement with reduction with myofascial pain were diagnosed in 12 patients (65%) in Group 1; whereas in Group 2, it was nine patients (45%), one patient (5%) had only myofascial pain in Group 1, two patients (10%) had myofascial pain in Group 2, the remaining patients diagnosed as internal derangement with reduction. Studies have reported that internal derangement with reduction is the most common finding in TMD and is characterized by several stages of dysfunction involving the condyle-disk relationship and it is self-limiting.

The efficacy and value of LLLT in the management of TMD have been controversial in literature. However, LLLT has biostimulating, anti-inflammatory, and analgesic effect. Bio-stimulation occurs through metabolic activation, stimulation of the cellular respiratory chain in the mitochondria, and increasing vascularization and fibroblast formation.

The anti-inflammatory and analgesic effects of LLLT are probably due to increasing beta-endorphin level in the spinal fluid and increase the urinary excretion of glucocorticoids, which are inhibitors of the synthesis of beta-endorphins. It also increases the pressure pain threshold through a complex electrolytic nerve fiber blocking mechanism and causes a decrease of the release of histamine and acetylcholine and a reduction of the synthesis of bradykinin.

This study used a specific type of LLLT treatment (GaAlAs diode laser, 810 nm, 0.1 W, 6 J/cm², continuous wave) involving direct irradiation on painful TMJ, applied 2–3 times/week over 8 sessions.

In general, the most commonly used therapeutic laser in laser research has been the Ga-As-Al, semiconductor laser, which belongs to the group of continuous wave lasers that provide treatment through biostimulant, anti-inflammatory, and analgesic effects.

There is no consensus on dose, area, duration of laser therapy. The findings of this study are restricted to a specific set of parameters; however, optimal treatment parameters (e.g., wavelength, dosage, number of treatment sessions) have not been agreed upon.

Of 13 patients in Group 1, five patients did not show complete pain relief after 1-month follow-up, six patients in Group 2 did not show complete pain relief after 1 month. This could be attributed that depth of penetration of laser in musculoskeletal tissue is unknown. A study reported that 632.8-nm wavelength penetrates more deeply into musculoskeletal tissues than shorter wavelengths, and a trend for improved pain outcome with the 632 nm compared to 820 nm has been reported.
In the present study, the most common symptom which is evaluated in subjects during examination was joint sounds. Nineteen patients (95%) in Group 1 reported joint sounds before treatment. Of these 19 patients, 12 patients showed no clicking after treatment. In Group 2, 17 (85%) patients presented with TMJ clicking before treatment and out of 17, 10 patients showed no clicking after treatment. A significant reduction in clicking was found in both Group 1 ($P = 0.000$) and Group 2 ($P = 0.001$).

However, no significant difference was observed between the groups before and after treatment ($P = 0.304$ and $P = 0.752$, respectively).

Pain during function was accomplished by patient self-assessment using a VAS score 0–10. The assessment was performed at three different points of time; before treatment (day 0), after the final treatment (8th session), and 30 days after the final treatment.

The mean VAS score of day 0, 8th session, and at 1 month in Group 1 is 5.0, 1.5, and 0.45, respectively, and in Group 2 is 4.3, 1.35, and 0.95, respectively. It shows a significant difference between day 0, 8th session, and after 1-month treatment both in Group 1 and 2. However, there is no statistical difference in the VAS score between the groups in each session.

Although there is a significant reduction in VAS score in both the groups, no significant difference exists between Group 1 and Group 2 at day 0 ($P = 0.214$), 8th session ($P = 0.806$), and 1 month ($P = 0.230$).

In the present study, significant improvement was observed in the active treatment group both in subjective parameter, i.e., pain as well as in objective symptoms such as mouth opening and clicking. However, placebo group also showed a significant improvement of subjective and objective symptoms. It showed no statistical difference between the groups in mouth opening, clicking as well as pain reduction. This is in accordance with the study done by da Cunha et al., where they have used similar laser parameters. A total of forty patients (aged 20–68 years) were divided into two groups, with one receiving LLLT and the other a placebo treatment.[22]

The LLLT was delivered once in a week for 4 weeks using an infrared laser (830 nm, 500 mW, 20 s, 4 J/point) at the painful areas. Pain was assessed using a VAS. It was concluded that both the placebo and the laser treatment afforded these TMD patients equal relief of pain and dysfunction.[22]

In a recent publication of two cases of TMD treated with diode laser, the authors have reported that after thrice a week LLLT for 1 month, patients experience pain relief when followed up for 6 months to 1 year.[23]

In the present study, placebo group also showed a significant improvement both in subjective and objective symptoms. The placebo effect-psychological factors, such as the desire to feel better, may have influenced physiologic processes.[8]

A randomized control trial suggested that educational self-care intervention tailored to patients identified as having low levels of pain-related activity interference could be delivered, on an individualized basis for TMDs.[6] It may be useful to consider possible reason that both laser and placebo are effective in the management of TMDs.

Conti reports that self-limiting aspects of TMD, with remission periods of the symptoms, could in part explain not only some responses to the placebo treatment but also the reduction of the pain in the actual treatment.[24]

The placebo effect has been demonstrated in the treatment of TMD. A good relationship between practitioner and patient, associated with the highly technological appearance of the laser, might explain similarities between outcomes in both the groups.[25]

The laser group showed better improvement in pain reduction even after 1-month follow-up compared to placebo group. This could be attributed to the cumulative effect of laser. This in agreement with the study conducted by Venancio et al. where a persistent effect of lasers was observed even after 6 months after laser treatment.[5]

Although both laser and placebo group showed a significant improvement in symptoms of TMD, laser demonstrated no significant benefit over placebo.

Limitations of this study include, MRI, which is the gold standard for diagnosing TMDs, was not used in conforming the diagnosis of TMDs. However, RDC/TMD is a reliable, valid, and clinically useful research instrument by demonstrating its ability to identify clinically meaningful subtypes of TMD patients i.e., Axis I and Axis II criteria.

There is no consensus on dose, area, duration of laser therapy. Future studies are recommended with the larger sample size, and standardized laser parameters may be helpful in assessing the effectiveness of LLLT in the management of TMDs. A deeper insight into the mechanism of action of lasers will also contribute to scientific evidence of effectiveness of lasers in musculoskeletal disorder including TMDs. The possibility of lasers as an adjunct in the management of TMD also needs to be investigated.

Conclusion

In this study, both laser group and placebo group showed a significant decrease in VAS score after treatment ($P = 0.001$ and $P = 0.001$, respectively). However, no significant difference was observed between the two groups in pain reduction ($P = 0.806$). Although laser demonstrated no significant benefit over placebo group, the mean difference in VAS score after treatment was higher in laser group compared to placebo.
Mouth opening was significantly increased in both laser and placebo group \((P = 0.006 \text{ and } P = 0.021\) respectively). However, no statistical difference was found between the groups \((P = 0.330)\). There is a significant decrease in clicking was found in both laser and placebo group \((P = 0.000 \text{ and } P = 0.00, \text{ respectively})\). However, no statistical difference was found between the groups \((P = 0.752)\).

Due to the noninvasive aspect of this therapy, further studies should be performed with greater sample size and long-term follow-up studies may determine the exact role of laser therapy in the management of TMDs. Further research should focus on optimal treatment parameters such as frequency, wavelength, power, and duration of randomized placebo-controlled trials.

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**Conflicts of interest**

There are no conflicts of interest.

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