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# Comparative Evaluation of Low-Level Laser Therapy and Systemic Analgesic in the Management of Temporomandibular Disorders: A Randomized Control Study

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### KEYWORDS

Low-Level Laser Therapy, Myofascial Pain, NSAIDs, Orofacial Pain, Temporomandibula

### ABSTRACT:

**Background:** Temporomandibular disorders (TMDs) are a leading cause of orofacial pain, often linked to parafunctional habits, stress, and muscular overactivity. Although NSAIDs and muscle relaxants are commonly prescribed, their long-term use may lead to systemic adverse effects. Low-level laser therapy (LLLT) has recently gained attention as a non-invasive alternative with anti-inflammatory and analgesic benefits.

**Objective:** To compare the efficacy of LLLT with a systemic analgesic–muscle relaxant



r Disorders.

combination in managing chronic TMD-associated pain.

**Methods:** A randomized controlled study was conducted on 40 TMD patients diagnosed using RDC/TMD criteria. Participants were randomly divided into two groups (n=20 each). Group 1 received oral ZERODOL-MR (Aceclofenac 100 mg + Tizanidine 2 mg) twice daily for six days, while Group 2 underwent LLLT (830 nm, 4 J/cm<sup>2</sup>, six sessions over three weeks). Pain was evaluated using the Visual Analogue Scale (VAS) at baseline, one week, one month, and six months. Statistical analysis used Mann-Whitney and Friedman tests ( $p \leq 0.05$ ).

**Results:** Both groups showed significant pain reduction ( $p < 0.001$ ). At one month, LLLT showed complete pain relief (VAS=0) versus residual pain in Group 1 (VAS=0.65,  $p=0.019$ ). Relief persisted at six months, with no adverse effects in the LLLT group.

**Conclusion:** LLLT provides safe, sustained pain relief and is an effective alternative to pharmacotherapy for chronic TMD management.

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## Introduction

Temporomandibular disorders (TMDs) represent a significant and prevalent cause of orofacial pain that adversely impacts multiple dimensions of patient well-being, including daily function, sleep quality, and psychological health<sup>[1–3]</sup>. These disorders comprise a diverse group of musculoskeletal and neuromuscular conditions involving the temporomandibular joint (TMJ), masticatory muscles, and related structures. The TMJ is a unique ginglymoarthrodial joint capable of both hinge (rotational) and gliding (translational) movements, unlike typical uniaxial synovial joints.<sup>[4,5]</sup>

This dual functionality, coupled with the TMJ's complex anatomy and development, makes it vulnerable to biomechanical and pathological stresses contributing to TMD pathogenesis. Clinically, TMD presents with myofascial pain, joint sounds (clicking or crepitus), restricted or deviated mandibular movements, and functional limitations in chewing or speaking<sup>[6–9]</sup>.

These symptoms often stem from multifactorial causes such as parafunctional habits (bruxism, clenching), emotional stress, trauma, and neuromuscular imbalances. Epidemiological data indicate that TMD affects 5–12% of the population, with about 65% experiencing pain severe enough to require treatment. Beyond physical discomfort, TMD is frequently linked to anxiety, depression, and reduced social participation, reflecting its complex biopsychosocial nature.<sup>[10–12]</sup>

Pharmacological management, particularly the use of non-steroidal anti-inflammatory drugs (NSAIDs), remains a cornerstone in TMD treatment due to their

efficacy in mitigating inflammation and nociceptive pain<sup>[13–15]</sup>. However, the adverse effects associated with prolonged NSAID use—such as gastrointestinal irritation, renal impairment, and hematological changes—limit their long-term use. Consequently, low-level laser therapy (LLLT), a non-invasive photobiomodulation technique using specific light wavelengths to promote tissue repair and analgesia, has emerged as a promising alternative<sup>[16–19]</sup>.

Mechanistically, LLLT enhances mitochondrial metabolism, boosting adenosine triphosphate (ATP) production, cellular respiration, and vasodilation while modulating inflammatory mediators such as prostaglandin E2 and COX-2. These effects collectively reduce pain, suppress inflammation, and accelerate healing through enhanced collagen synthesis and proliferation of fibroblasts and endothelial cells<sup>[20–22]</sup>.

The clinical utility of LLLT has been evaluated extensively in randomized controlled trials and systematic reviews, demonstrating favorable outcomes in the management of chronic musculoskeletal conditions and orofacial pain syndromes, including TMD<sup>[23–26]</sup>. Despite its documented benefits, there remains a lack of consensus regarding the optimal laser parameters, including wavelength, dosage, and treatment frequency, which are critical to maximizing therapeutic efficacy and reproducibility<sup>[27–29]</sup>.

Against this background, the present randomized controlled study was designed to comparatively evaluate the clinical efficacy and safety of LLLT versus a standard systemic pharmacotherapy regimen—combining the



NSAID Aceclofenac and the muscle relaxant Tizanidine, commercially known as ZERODOL-MR—in the management of persistent TMD-related pain. The study aims to provide evidence supporting an effective, non-invasive treatment alternative that could minimize drug-related adverse effects while promoting rapid and sustained symptom relief.

## Materials and Methods

This randomized controlled trial included 40 adult patients (20 males, 24 females; mean age  $42.1 \pm \text{SD}$ ) diagnosed with temporomandibular disorder (TMD) according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD). The sample size was calculated using the formula

$$n = 2(Z_{1-\alpha/2} + Z_{1-\beta})^2 \sigma^2 / \Delta^2,$$

assuming a 95% confidence level ( $\alpha = 0.05$ ), 80% power ( $\beta = 0.20$ ), a standard deviation of 1.8, and an expected mean difference of 1.5 in pain scores (VAS) between groups based on a previous study. The calculated sample size was 18 participants per group, which was increased to 20 per group to account for possible dropouts, giving a total of 40 participants. [Figure 01]

Participants were recruited from the Department of Oral Medicine and Radiology, College of Dental Sciences, Davangere, with physiotherapy support from JJM Medical College. Ethical clearance [ref no. **CODS/1798/2018-19**] and informed consent were obtained before study initiation. Inclusion criteria required a confirmed TMD diagnosis and willingness for treatment and follow-up. Exclusion criteria included recent TMD therapy, systemic or psychiatric disorders, bruxism, removable prosthesis use, and known drug allergies.

Participants were randomly assigned to two groups. The control group (Group 1) received oral ZERODOL-MR (Aceclofenac 100 mg + Tizanidine 2 mg) twice daily after meals for six days. The study group (Group 2) underwent low-level laser therapy (LLLT) twice weekly for three weeks (six sessions). LLLT was delivered using a GaAlAs diode laser (830 nm, 79 mW) applied over 1 cm<sup>2</sup> trigger points in the TMJ or masticatory muscles for 3–5 minutes per point, following strict biosafety protocols.

Pain intensity, the primary outcome, was assessed using a Visual Analogue Scale (VAS, 0–10) at baseline, one week, one month, and six months post-treatment. Secondary outcomes included joint noise, tenderness, and mandibular movement per RDC/TMD guidelines, along with orthopantomograph (OPG) evaluation of condylar dimensions and joint space. Statistical analysis using IBM SPSS v22 applied the Mann-Whitney U test for intergroup and the Friedman test for intragroup comparisons, with significance set at  $p \leq 0.05$ .

## Results

This randomized controlled trial included 40 patients clinically diagnosed with temporomandibular disorder (TMD), divided equally into two groups: Group 1 (control group) treated with ZERODOL-MR and Group 2 (study group) treated with low-level laser therapy (LLLT). The mean age of participants was 42.1 years, and females constituted 60% of the study population.

### Tenderness Distribution (Graph 1)

Tenderness involving both the temporomandibular joint (TMJ) and muscles of mastication (MOM) was the most common presentation, observed in 57.5% of patients overall. Group 1 demonstrated combined TMJ and MOM tenderness in 60% of patients, while Group 2 showed a similar distribution at 55%. Isolated TMJ tenderness was observed in 20% of patients in both groups, whereas isolated MOM tenderness was present in 20% of Group 1 and 25% of Group 2 patients.

### Laterality of Tenderness (Graph 2)

With respect to laterality, right-sided tenderness predominated, affecting 50% of patients overall. Right-sided involvement was more frequent in Group 1 (60%) compared to Group 2 (40%). Left-sided tenderness was reported in 32.5% of patients, while bilateral involvement was noted in 17.5%. Bilateral tenderness was more common in Group 2 (25%) than in Group 1 (10%).

### Jaw Movement Patterns (Graph 3)

Assessment of mandibular movements revealed deviation in 27.5% of patients, predominantly toward the right side. Right-sided deviation was observed in 10% of Group 1 and 25% of Group 2 patients, whereas left-sided deviation was more frequent in Group 1 (15%) compared



to Group 2 (5%). Deflection was relatively uncommon, noted only in 5% of patients, and was seen exclusively on the right side in Group 1.

### Muscle Tenderness Distribution (Graph 4)

Among the muscles of mastication, tenderness was most frequently observed in the temporalis (45%) and masseter (42.5%) muscles. Group 1 showed a higher prevalence of tenderness in the lateral pterygoid (70%) and medial pterygoid (35%) muscles. In contrast, Group 2 demonstrated greater involvement of the masseter (65%) and temporalis (60%) muscles.

### Temporomandibular Joint Sounds (Graph 5)

Joint sound evaluation revealed clicking in 12.5% of patients and crepitus in 5% of patients. Clicking was more commonly observed on the left side, particularly in Group 1 (20%), compared to Group 2 (10%). Right-sided clicking was noted in 10% of Group 1 and 15% of Group 2 patients. Crepitus was infrequent, occurring on the right side in 10% of Group 1 patients and on the left side in 5% of Group 2 patients.

### Pain Intensity Assessment (VAS Scores) (Graph 6)

The mean baseline VAS pain score was  $5.8 \pm 2.40$  in Group 1 and  $5.35 \pm 1.46$  in Group 2. At one-week follow-up, both groups demonstrated a reduction in pain intensity, with no statistically significant intergroup difference ( $p = 0.239$ ). At one month, Group 2 achieved complete pain relief (VAS = 0), whereas Group 1 exhibited mild residual pain (VAS =  $0.65 \pm 1.63$ ), with the difference being statistically significant ( $p = 0.019$ ). At six months, Group 2 maintained complete pain relief, while Group 1 showed minimal pain recurrence. Intragroup analysis demonstrated significant pain reduction over time in both groups ( $p < 0.001$ ), with LLLT showing superior long-term efficacy.

### Discussion

This randomized controlled trial demonstrates that low-level laser therapy (LLLT) provides effective and sustained analgesia for temporomandibular disorders (TMD), matching or surpassing the outcomes of NSAID-based therapy. Its significance lies in achieving comparable efficacy with a markedly superior safety profile. Unlike NSAIDs, which can cause gastrointestinal, renal, hepatic, and hypersensitivity

complications, LLLT offers a safer, non-invasive alternative conducive to long-term management and improved patient quality of life<sup>[13–15,30]</sup>. In contrast, LLLT, being a non-invasive modality, minimizes systemic exposure and thus reduces the risk of such complications, offering a safer therapeutic alternative particularly advantageous in patients with contraindications to NSAIDs or those requiring prolonged treatment.

These results corroborate and expand upon a growing body of evidence reported in meta-analyses and systematic reviews, which consistently demonstrate the moderate to strong analgesic and anti-inflammatory effects of LLLT in chronic orofacial pain conditions, including TMD<sup>[25–27]</sup>. The mechanism by which LLLT exerts these effects is complex and multifactorial, rooted in photobiomodulation principles. At the cellular level, LLLT facilitates the absorption of light photons by mitochondrial chromophores, primarily cytochrome c oxidase, enhancing the electron transport chain activity and leading to increased ATP synthesis. This surge in cellular energy facilitates accelerated tissue repair, enhanced cell proliferation, and modulation of inflammatory responses. Furthermore, LLLT stimulates the release of endogenous opioids such as beta-endorphins, which serve as natural analgesics by modulating nociceptive pathways in both peripheral and central nervous systems. Simultaneously, LLLT downregulates pro-inflammatory mediators including prostaglandin E2 and cyclooxygenase-2 (COX-2), leading to diminished inflammation and edema, which are key contributors to TMD-associated pain and dysfunction<sup>[18–20]</sup>. These cumulative biochemical and physiological effects translate clinically into rapid pain reduction, improved joint mobility, and restoration of normal masticatory function.

Despite these promising therapeutic effects, the literature reveals considerable heterogeneity concerning optimal LLLT treatment parameters, including wavelength, power output, energy density (fluence), exposure duration, and treatment frequency. Reported wavelengths span from the visible red spectrum at 632.8 nm to the near-infrared range up to 1064 nm, with energy densities varying broadly between 1.5 and 112.5 J/cm<sup>2</sup><sup>[28–30]</sup>. This variability complicates direct comparison of



study outcomes and impedes the establishment of standardized clinical protocols. In the present study, the application of an 830 nm gallium-aluminum-arsenide diode laser delivering a dose of 4 J/cm<sup>2</sup> over six treatment sessions yielded significant analgesic benefits, suggesting that this parameter set is effective for TMD pain management. However, given the heterogeneity in patient presentations and TMD subtypes—ranging from myofascial pain to joint disorders—there is an urgent need for large-scale, multicentric randomized trials to systematically evaluate and refine LLLT dosing regimens. These should ideally consider variables such as tissue penetration depth, specific anatomic targets, cumulative dose effects, and long-term outcomes to optimize therapeutic efficacy and safety.

Additionally, TMD is widely recognized as a multifactorial disorder wherein psychosocial stress, anxiety, and depression play a substantial role in symptom onset, exacerbation, and chronicity. Thus, future investigations should integrate comprehensive assessments of psychological status using validated tools such as the Beck Anxiety Inventory (BAI) and objective biomarkers like salivary cortisol to elucidate the interplay between emotional factors and physiological responses to treatment [27-30]. Such integrative approaches will enable personalized treatment strategies, combining LLLT with psychological interventions where appropriate, to address the complex biopsychosocial dimensions of TMD. Ultimately, this holistic perspective will enhance patient outcomes, improve adherence to therapy, and reduce healthcare burdens associated with chronic orofacial pain.

The present findings reinforce LLLT as a potent, non-invasive, and well-tolerated modality for managing TMD pain, meriting consideration as a first-line or adjunctive therapy. Future research priorities include standardizing laser parameters, understanding mechanistic pathways in diverse patient populations, and integrating psychosocial dimensions into treatment algorithms to maximize clinical benefit and patient quality of life.

#### **Future Study Prospects:**

Future research should aim to standardize LLLT parameters such as wavelength, energy density, session frequency, and treatment duration to ensure consistent

therapeutic outcomes. Large multicenter randomized controlled trials with diverse populations are essential to establish robust, evidence-based protocols. Incorporating psychosocial assessments and biomarkers such as salivary cortisol and inflammatory mediators can deepen understanding of the biopsychosocial aspects of TMD. Advances in laser technology may lead to portable or home-use LLLT devices, improving accessibility and adherence, while exploring genetic and molecular predictors of response can support personalized, precision-based therapies.

#### **Limitations:**

This study was limited by a small sample size and relatively short treatment duration, which may affect the generalizability of findings. Although sustained pain reduction was observed, long-term recurrence patterns could not be fully assessed. The reliance on subjective pain assessment using the Visual Analogue Scale (VAS) without incorporating objective physiological or imaging biomarkers is another limitation. Differences in patient compliance and individual healing responses may also have influenced results.

#### **Conclusion:**

Low-level laser therapy (LLLT) is a safe, effective, and non-invasive treatment for chronic temporomandibular disorders, offering sustained pain relief and improved function without systemic side effects. With protocol optimization and broader validation, LLLT holds strong potential as a frontline or adjunctive therapy in TMD management.

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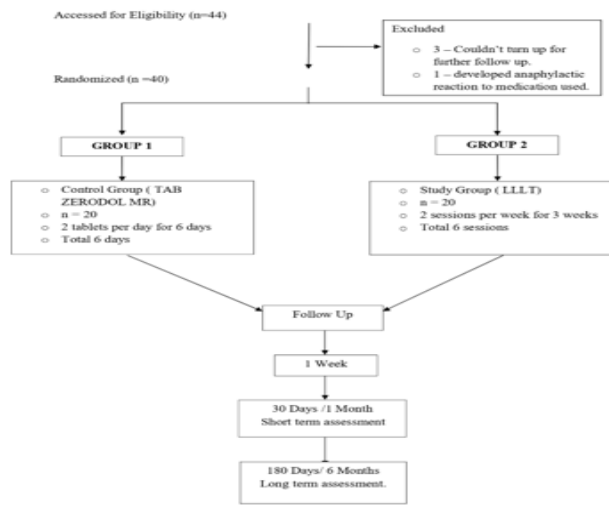
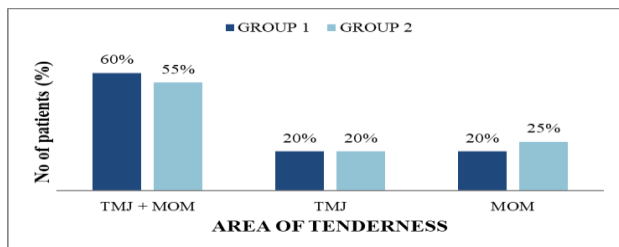
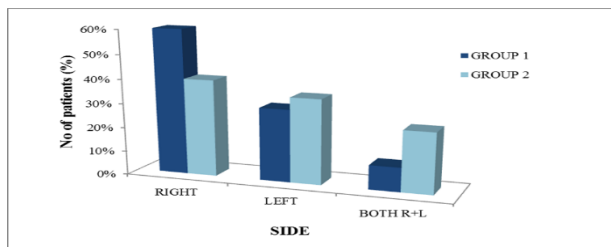


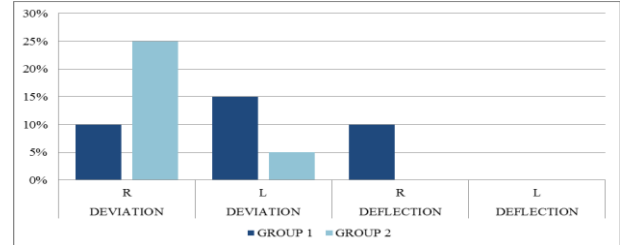
FIGURE 01- Flowchart representing the study pattern



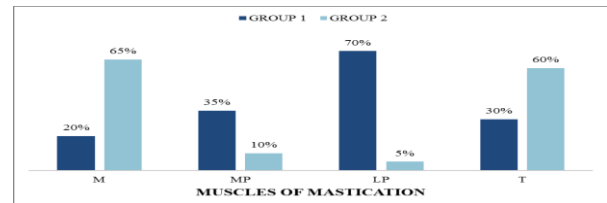
Graph 1 Distribution of Tenderness in Temporomandibular Joint (TMJ) and Muscles of Mastication (MOM) Across Patient Groups



Graph 2 Distribution of Tenderness by Laterality (Right, Left, and Bilateral) in Temporomandibular Joint and Muscles of Mastication Across Patient Groups

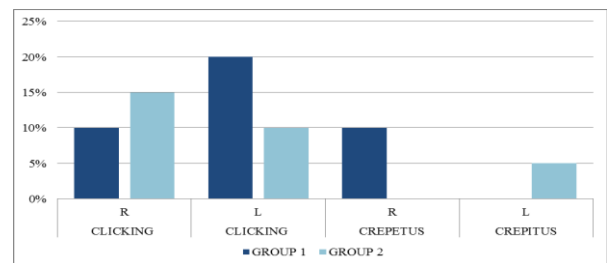


Graph 3 Distribution of Jaw Movement Patterns (Deviation and Deflection) on Right and Left Sides Across Patient Groups

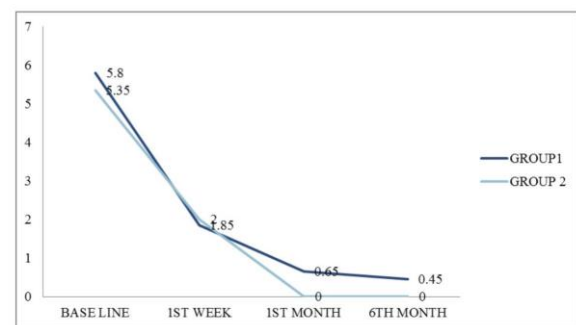


Graph 4 Distribution of Muscle Tenderness in Muscles of Mastication Across Patient Groups

(Masseter, Temporalis, Medial Pterygoid, Lateral Pterygoid)



Graph 5 Distribution of Temporomandibular Joint Sounds (Clicking and Crepitus) on Right and Left Sides Across Patient Groups



Graph 6 Comparison of Pain Intensity (VAS Scores) Between Group 1 and Group 2 at Different Time Intervals