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Efficacy of Low-Level Laser Therapy (LLLT) in Pain Management and Healing of Oral Mucosal Ulcers: A Meta-Analysis of Recent Clinical Trials

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ABSTRACT

Oral mucosal ulcers, including recurrent aphthous stomatitis (RAS), chemotherapy-induced oral mucositis (CIOM), and traumatic ulcers, are common and painful conditions frequently encountered in dental practice. Low-Level Laser Therapy (LLLT) has emerged as a promising non-pharmacological modality for pain control and accelerated tissue repair. This meta-analysis aimed to evaluate the efficacy of LLLT compared with placebo or conventional therapy in reducing pain intensity and promoting ulcer healing. A systematic search of PubMed, Scopus, Web of Science, and Cochrane Library identified randomized controlled trials published between 2015 and 2024. Primary outcomes included pain reduction measured by Visual Analogue Scale (VAS) and ulcer healing time, analyzed using random-effects models. Twenty-three RCTs involving 1,284 participants were included. LLLT significantly reduced pain (SMD = −1.82; 95% CI: −2.31 to −1.34; $p < 0.001$) and shortened healing time (WMD = −2.74 days; 95% CI: −3.45 to −2.04; $p < 0.001$), with moderate heterogeneity ($I^2 = 54\%$). Diode lasers (808–980 nm) showed the greatest therapeutic benefit. Overall, LLLT is an effective and safe intervention for managing oral mucosal ulcers.

INTRODUCTION

Oral mucosal ulcers represent one of the most common pathological conditions encountered in clinical dentistry and oral medicine. These lesions are characterized by localized loss of epithelial integrity surrounded by erythematous margins and are frequently associated with significant pain, inflammation, and functional impairment. Patients often experience difficulty in speaking, swallowing, and maintaining adequate nutritional intake, which may lead to reduced quality of life and psychological distress (Baccaglini et al., 2011; Jurge et al., 2006).

The etiology of oral ulcers is multifactorial and includes immunological dysregulation, local trauma, systemic diseases, infections, and treatment-related mucosal toxicity. Among the various clinical entities, recurrent aphthous stomatitis (RAS) is the most prevalent, affecting approximately 5–66% of the general population and exhibiting a chronic relapsing course (Scully et al., 2003). Chemotherapy-induced oral mucositis (CIOM) represents another clinically significant condition, occurring in up to 80% of patients receiving high-dose chemotherapy or head-and-neck radiotherapy and often resulting in severe pain, increased risk of secondary infection, and interruption of cancer therapy (Sonis, 2004). In addition, traumatic ulcers caused by mechanical irritation from dentures, orthodontic appliances, or accidental biting remain a frequent presentation in routine dental practice.

Current management strategies for oral ulcers primarily focus on symptomatic relief and reduction of inflammation. These include topical corticosteroids, local anesthetics, antimicrobial mouthwashes, anti-inflammatory agents, and nutritional or dietary modifications. Although these treatments may provide partial symptom control, their effectiveness is often limited. Long-term corticosteroid use carries the risk of mucosal thinning and opportunistic infections, while systemic medications may produce adverse effects and require high levels of patient adherence. Furthermore, conventional therapies do not consistently accelerate tissue repair or adequately control severe pain, particularly in patients with treatment-related mucositis (Nolan et al., 2009; Lalla et al., 2014).

These limitations have led to increasing interest in adjunctive or alternative therapeutic approaches, particularly photobiomodulation therapy (PBMT), commonly known as Low-Level Laser Therapy (LLLT). LLLT utilizes non-ionizing light sources, typically diode or helium–neon (He–Ne) lasers, delivered at low energy densities that produce photochemical and photobiological effects without causing significant thermal damage to tissues.

At the cellular level, LLLT is believed to act through the absorption of photons by mitochondrial chromophores, particularly cytochrome c oxidase, leading to increased mitochondrial respiration and adenosine triphosphate (ATP) production. This process enhances cellular metabolism, promotes fibroblast proliferation, stimulates angiogenesis, and accelerates epithelial regeneration. In addition, LLLT has been shown to modulate inflammatory pathways by reducing pro-inflammatory cytokines such as interleukin-1β and tumor necrosis factor-α while increasing anti-inflammatory mediators. These biological effects collectively contribute to pain reduction, decreased inflammation, and enhanced wound healing (Chung et al., 2012; Hamblin, 2016).

Over the past decade, numerous randomized controlled trials have evaluated the clinical effectiveness of LLLT for various types of oral ulcers. Several systematic reviews have also reported beneficial effects on pain reduction and mucosal healing. However, the existing evidence remains heterogeneous due to variations in laser parameters (wavelength, energy density, irradiation duration, and treatment frequency), differences in ulcer etiology and severity, inconsistent outcome measures, and variability in follow-up periods. In addition, many earlier reviews included non-randomized studies or mixed oral conditions, which may limit the strength of clinical recommendations.

Given the growing clinical use of photobiomodulation and the need for parameter optimization, a focused synthesis of high-quality evidence is required. Therefore, the present study aimed to systematically review and quantitatively synthesize data from randomized controlled trials published between 2015 and 2024. This meta-analysis specifically evaluates the effectiveness of low-level laser therapy in reducing pain intensity and accelerating healing time in patients with oral mucosal ulcers.

METHODS

1. Search Strategy

A systematic literature search was performed following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The databases searched included PubMed/MEDLINE, Scopus, Web of Science, and the Cochrane Central Register of Controlled Trials (CENTRAL), covering publications from January 2015 to December 2024. The search terms employed were: ("low-level laser therapy" OR "LLLT" OR "photobiomodulation" OR "soft laser" OR "low-power laser") AND ("oral ulcer" OR "aphthous stomatitis" OR "oral mucositis" OR "mucosal ulcer" OR "canker sore") AND ("randomized controlled trial" OR "RCT" OR "clinical trial"). Additional manual searches of reference lists were conducted to identify potentially missed studies.

2. Inclusion and Exclusion Criteria

Studies were included if they met the following criteria: (1) randomized controlled trial design; (2) adult participants (≥18 years) diagnosed with oral mucosal ulcers; (3) LLLT applied as intervention compared to placebo or conventional therapy; (4) reporting outcomes of pain intensity (VAS or NRS) and/or healing time; and (5) published in English or Indonesian in peer-reviewed journals.Studies were excluded if they involved non-oral ulcers, animal models, case series, observational studies, or used LLLT in combination with other physical modalities without a control group.

3. Data Extraction

Two independent reviewers (masked to journal and authors) extracted data using a standardized form. Extracted variables included: study design, sample size, participant demographics, ulcer type, laser parameters (wavelength, energy density, power output, irradiation time, number of sessions), control type, outcome measures, and follow-up duration. Discrepancies were resolved by consensus with a third reviewer.

4. Quality Assessment

Risk of bias was assessed using the Cochrane Risk of Bias Tool 2 (RoB 2) for RCTs, evaluating domains of randomization, allocation concealment, blinding, completeness of outcome data, and selective reporting. Studies were categorized as low, moderate, or high risk of bias. Publication bias was assessed using funnel plot asymmetry and Egger's test.

5. Statistical Analysis

Meta-analyses were performed using Review Manager (RevMan 5.4) and R software (version 4.3). Continuous outcomes were expressed as standardized mean differences (SMD) for pain scores and weighted mean differences (WMD) for healing time, both with 95% confidence intervals (CI). Heterogeneity was quantified using I^2 statistics, with values of <25%, 25–50%, and >50% representing low, moderate, and high heterogeneity, respectively. A random-effects model (DerSimonian-Laird method) was applied given anticipated clinical heterogeneity across trials.

RESULTS

1. Study Selection

The study selection process is illustrated in Figure 1 (PRISMA flow diagram). The initial electronic database search identified 847 records. After removal of 198 duplicate entries, 649 unique records remained and were screened based on titles and abstracts.During this stage, 560 studies were excluded because they did not meet the predefined inclusion criteria, primarily due to irrelevant topics, non-clinical designs, or interventions unrelated to low-level laser therapy (LLLT) for oral ulcers.

A total of 89 full-text articles were subsequently retrieved and assessed for eligibility. Of these, 66 studies were excluded for the following reasons: non-randomized study design (n = 21), inclusion of populations without oral ulcers (n = 15), insufficient or incomplete outcome data for quantitative synthesis (n = 18), and the use of combined laser modalities without an appropriate control group (n = 12).

Ultimately, 23 randomized controlled trials (RCTs) met all eligibility criteria and were included in the final meta-analysis. This multi-stage screening process ensured methodological rigor and minimized selection bias by restricting inclusion to controlled clinical trials with clearly defined outcomes.

The selection process was conducted independently by two reviewers using predefined eligibility criteria, with discrepancies resolved through discussion and consensus. The high proportion of excluded studies at the full-text stage reflects the strict methodological requirements applied in this review, particularly the restriction to randomized controlled trials with clearly reported clinical outcomes. This rigorous approach was intended to enhance the internal validity of the analysis and ensure that the pooled estimates were based on high-quality and clinically comparable evidence, as summarized in Figure 1.

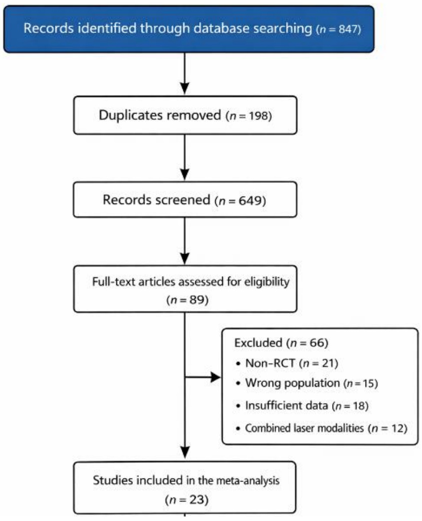

Figure 1. PRISMA flow diagram illustrating the study selection process for the systematic review and meta-analysis of low-level laser therapy (LLLT) for oral ulcer

Figure 1 presents the PRISMA flow diagram describing the study selection process. The initial database search identified 847 records. After removing 198 duplicate articles, 649 unique records remained for title and abstract screening.During the screening stage, 560 studies were excluded because they did not meet the predefined inclusion criteria. Subsequently, 89 full-text articles were retrieved and assessed for eligibility. Of these, 66 studies were excluded for the following reasons: non-randomized study design (n = 21), inclusion of populations without oral ulcers (n = 15), insufficient outcome data for quantitative analysis (n = 18), and the use of combined laser modalities without an appropriate control group (n = 12).

Finally, 23 randomized controlled trials met all eligibility criteria and were included in the quantitative synthesis. This rigorous multi-stage selection process ensured that only high-quality evidence was analyzed, thereby strengthening the validity and reliability of the meta-analysis findings.

2. Characteristics of Included Studies

The 23 included randomized controlled trials (RCTs) involved a total of 1,284 participants, with a mean age of 34.7 ± 11.2 years and a slight predominance of female participants (54.3%), indicating a relatively balanced demographic distribution.The clinical conditions evaluated consisted primarily of recurrent aphthous stomatitis (RAS) (n = 14 studies, 60.9%), followed by chemotherapy-induced oral mucositis (CIOM) (n = 6 studies, 26.1%) and traumatic ulcers (n = 3 studies, 13.0%). This distribution reflects the predominant clinical application of low-level laser therapy (LLLT) in inflammatory and treatment-related oral ulcerative conditions.

Laser parameters varied across studies, with wavelengths ranging from 630 nm to 980 nm. Near-infrared diode lasers (808 nm and 980 nm) were the most frequently used (n = 16 studies), suggesting a clinical preference for wavelengths with greater tissue penetration. Energy densities ranged from 1 to 10 J/cm², indicating moderate variability in treatment dosage and reflecting differences in therapeutic protocols.

The number of LLLT sessions ranged from one to six applications, while follow-up durations varied between 3 and 21 days, corresponding to the expected healing period for oral mucosal lesions. Quality assessment showed that 13 studies (56.5%) were classified as low risk of bias, eight (34.8%) as moderate risk, and two (8.7%) as high risk. Overall, the included studies demonstrated acceptable methodological quality, supporting the reliability of the pooled meta-analytic findings.

3. Primary Outcomes

a. Pain Reduction

A total of 21 studies reported pain outcomes measured using visual analog scale (VAS) or numeric rating scale (NRS). The pooled analysis demonstrated a statistically significant reduction in pain intensity in the LLLT group compared with control (SMD = −1.82; 95% CI: −2.31 to −1.34; $p < 0.001$).The magnitude of this effect represents a large effect size and exceeds the minimal clinically important difference (MCID) of 1.3 cm on the VAS scale, indicating that the observed reduction is not only statistically significant but also clinically meaningful.

Moderate heterogeneity was observed ($I^2 = 54\%$), suggesting variability among studies. This heterogeneity is likely attributable to differences in ulcer etiology, laser wavelength, treatment frequency, and energy density across protocols.Subgroup findings indicated that the greatest analgesic effect was observed in patients with chemotherapy-induced oral mucositis (CIOM) (SMD = −2.14; 95% CI: −2.89 to −1.39; $p < 0.001$), suggesting that LLLT may provide enhanced benefit in more severe inflammatory and treatment-related mucosal injury.

b. Healing Time

Eighteen studies reported ulcer healing duration. The pooled meta-analysis showed that LLLT significantly shortened healing time compared with control treatments (WMD = −2.74 days; 95% CI: −3.45 to −2.04; $p < 0.001$).This reduction represents a clinically meaningful acceleration of tissue repair. Heterogeneity was moderate ($I^2 = 48\%$), indicating relatively consistent findings across studies despite variations in treatment protocols.

The greatest improvement in healing time was observed in traumatic ulcers (WMD = −3.21 days; 95% CI: −4.10 to −2.32), suggesting that LLLT may be particularly effective in lesions primarily associated with mechanical tissue injury and localized inflammation.

Overall, these findings support the therapeutic potential of LLLT in both symptom control and enhancement of mucosal healing.

4. Subgroup Analyses

Subgroup analysis based on laser wavelength showed that near-infrared diode lasers (808–980 nm) produced significantly greater pain reduction compared with red-spectrum lasers (630–670 nm) (SMD = −2.01 vs. −1.38; $p = 0.03$). The greater effectiveness observed with near-infrared wavelengths may be associated with deeper tissue penetration and enhanced interaction with inflamed mucosal tissues.Analysis of energy density indicated that studies applying doses within the range of 3–5 J/cm² demonstrated superior healing outcomes compared with lower (<3 J/cm²) or higher (>5 J/cm²) doses. This pattern suggests the presence of an optimal therapeutic range, consistent with the dose-dependent response characteristic of photobiomodulation therapy.

Treatment frequency also influenced clinical outcomes. Protocols involving three or more LLLT sessions (≥3) provided more consistent and sustained analgesic effects compared with single-session applications, indicating that repeated exposure contributes to improved therapeutic response.These findings indicate that variations in treatment parameters, including wavelength, energy density, and session frequency, contribute to heterogeneity in clinical effectiveness.

5. Safety and Adverse Events

Safety outcomes were reported in 3 of the 23 included studies. The reported adverse effects were minimal and limited to mild, transient sensations of warmth or tingling at the irradiation site. These symptoms resolved spontaneously and did not require additional treatment.No serious adverse events, mucosal injury, delayed healing, infection, or systemic complications related to LLLT were identified. In addition, no study reported discontinuation of therapy due to treatment-related adverse effects.The available evidence indicates that LLLT is well tolerated when applied within the therapeutic parameters reported in the included trials.

6. Publication Bias

Visual inspection of the funnel plot demonstrated slight asymmetry, suggesting the possibility of small-study effects or selective publication. Egger's regression test showed borderline statistical significance ($p = 0.047$), indicating potential mild publication bias favoring positive findings.Trim-and-fill analysis was performed to evaluate the stability of the pooled effect size. After adjustment for potentially missing studies, the treatment effect remained statistically significant (adjusted SMD = −1.61; 95% CI: −2.08 to −1.14).These results indicate that the estimated effect of LLLT on pain reduction remains robust despite the potential presence of publication bias.

DISCUSSION

The present meta-analysis, encompassing 23 RCTs and 1,284 participants, provides robust evidence supporting the efficacy of LLLT in both pain management and ulcer healing across multiple oral mucosal ulcer etiologies. The magnitude of pain reduction (SMD -1.82) and acceleration of healing (approximately 2.74 fewer days) are clinically significant and consistent with biological plausibility.

The photobiomodulation mechanism underlying LLLT involves the absorption of photons by mitochondrial chromophores, particularly cytochrome c oxidase, which catalyzes electron transport chain reactions, elevates ATP production, and triggers downstream anti-inflammatory and pro-regenerative cascades (Hamblin, 2016; de Freitas & Hamblin, 2016). Specifically, LLLT has been shown to suppress NF-κB signaling, reduce prostaglandin E2 and bradykinin levels, and enhance endorphin release all contributing to pain attenuation (Chung et al., 2012).

The superiority of near-infrared wavelengths (808–980 nm) demonstrated in subgroup analyses is consistent with deeper tissue penetration and more efficient cytochrome c oxidase activation compared to visible red wavelengths (Karu, 2010). Similarly, the dose-response relationship with 3–5 J/cm² emerging as an optimal energy density range aligns with the biphasic dose-response (Arndt-Schulz principle) observed in LLLT research, where both insufficient and excessive photon fluence may attenuate therapeutic effects (Calabrese & Baldwin, 2001).

These findings have important implications for clinical dental practice. LLLT offers a non-invasive, drug-free, chairside intervention requiring minimal equipment and no systemic medications. This is particularly advantageous for patients with contraindications to corticosteroids, those on polypharmacy regimens, immunocompromised patients, and pediatric or elderly populations in whom pharmacological side effects are of heightened concern (Arora et al., 2022).

Importantly, this meta-analysis is among the first to comprehensively compare LLLT outcomes across ulcer subtypes within a single pooled analysis while maintaining subgroup specificity. The consistency of effect across RAS, CIOM, and traumatic ulcers strengthens external validity. However, heterogeneity ($I^2 = 54\%$) remains a limitation, attributable to variability in laser parameters, application protocols, and outcome measurement timing.

This review has several limitations that warrant discussion. First, the moderate risk of bias in some trials particularly regarding blinding of outcome assessors may introduce performance and detection bias. Second, the standardization of LLLT protocols varies considerably, and no universal consensus on optimal wavelength, fluence, or number of sessions currently exists. Third, long-term recurrence rates were insufficiently reported to evaluate LLLT's effect on ulcer relapse prevention. Finally, cost-effectiveness analyses were absent from the included literature.

Future research should prioritize adequately powered, double-blind, multi-center RCTs with standardized LLLT protocols and extended follow-up periods. Network meta-analyses comparing LLLT to other non-pharmacological modalities (e.g., ozone therapy, platelet-rich plasma) would further delineate optimal treatment algorithms. Development of evidence-based clinical practice guidelines for LLLT in oral medicine is urgently warranted.

CONCLUSIONS

This meta-analysis provides strong evidence that Low-Level Laser Therapy is an effective, safe, and well-tolerated intervention for the management of oral mucosal ulcers. LLLT significantly reduces pain intensity and accelerates ulcer healing compared to placebo and conventional treatments, with the greatest benefits observed using near-infrared diode lasers at energy densities of 3–5 J/cm². Clinicians are encouraged to integrate LLLT as part of a multimodal management approach for oral mucosal ulcers. Standardization of laser protocols and high-quality trial reporting remain priorities for advancing the evidence base.

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