

Single-Session Extraoral Photobiomodulation Reduces Early Postoperative Pain but Not Edema or Trismus After Impacted Mandibular Third Molar Extraction: A Randomized Controlled Trial

ClinicalTrials.gov Identifier: NCT07522918

Date of Document: January 30, 2025

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1. Study Design and Ethical Approval

This prospective, parallel-group randomized controlled clinical trial was conducted at Necmettin Erbakan University. The study protocol was approved by the Institutional Ethics Committee for Non-Drug and Non-Medical Device Research (Decision No: 2025/535). Written informed consent was obtained from all participants prior to enrollment.

2. Patient Selection

A total of 70 patients (age range: 17–25 years) with asymptomatic mesioangular impacted mandibular third molars (Pell–Gregory Class IB) were enrolled. Participants were randomized into a PBM group (n=35) or a control group (n=35) using a computer-generated random sequence.

Inclusion Criteria:

- Indication for extraction of an impacted mandibular third molar.
- ASA I status (absence of systemic disease).
- Healthy status of the impacted tooth and surrounding tissues.

Exclusion Criteria:

- Pregnancy or lactation.
- Regular use of NSAIDs or antibiotics within the preceding week.
- Active smoking.

3. Surgical Procedure

All surgical procedures were performed by a single surgeon following a standardized protocol. Local anesthesia was achieved using 4% articaine hydrochloride with 1:100,000 epinephrine. A full-thickness mucoperiosteal flap was raised, followed by standardized bone removal and tooth sectioning under saline irrigation. Wound closure was performed with 3-0 silk sutures. All patients received a standardized postoperative medication regimen including amoxicillin/clavulanic acid, benzydamine HCl/chlorhexidine gluconate mouth rinse, and dexametopfen.

4. Photobiomodulation (PBM) Protocol

The PBM group received a single session of extraoral therapy immediately following surgery using a dual-wavelength GaAlAs laser (650 nm + 904 nm, GRR Laser).

- **Application Time:** 10 minutes.
- **Total Energy:** 270 J (27 J/min).
- **Power Density:** 4.54 mW/cm².
- **Energy Density:** 2.73 J/cm². The probe was positioned in stationary contact over the mandibular angle–ramus region. The control group received no laser application.

5. Outcome Variables

- **Pain:** Evaluated using a 100-mm visual analog scale (VAS) at postoperative days 2 and 7.
- **Edema:** Measured via facial distance measurements between anatomical landmarks (tragus–labial commissure, gonion–lateral canthus, gonion–labial commissure) at baseline, day 2, and day 7.
- **Trismus:** Assessed by measuring maximum interincisal distance (MID) using a sliding caliper at baseline, day 2, and day 7.
- **Quality of Life:** Evaluated using a 100-mm OHRQoL VAS scale (0 = worst, 100 = normal) at postoperative days 2 and 7.

6. Statistical Analysis

Normality was assessed using Shapiro-Wilk and Kolmogorov–Smirnov tests. Between-group comparisons were performed using Independent Samples t-tests or Mann–Whitney U tests. Repeated measures ANOVA with Bonferroni correction was used for longitudinal data. Significance was set at $p < 0.05$.