

Photobiomodulation Therapy for Analgesia: A Split-Mouth Randomized Control Trial.

INTRODUCTION

- Dental anxiety and the fear of procedural pain frequently result in children avoiding essential oral care. **Photobiomodulation therapy (PBMT)** has emerged as a non-invasive alternative for achieving dental analgesia without tissue damage.
- This technology could offer a valuable tool for improving pediatric cooperation and long-term oral health outcomes by creating more positive dental experiences.
- This study aims to evaluate whether a novel PBMT device can reduce physiological stress (as measured by change in heart rate) and self-reported pain during routine diagnostic tests (cold pulp testing and gingival probing) in school-aged children.

MATERIALS AND METHODS

- Healthy children 7–12 years old requiring routine dental examination and treatment were recruited.
- Sample size was calculated for a split-mouth design using paired t-test analysis.
- Heart rate (HR) change was the primary outcome.
- Based on published pediatric data¹: A minimum of 19 participants was required to achieve 80% power ($\alpha = 0.05$). The final sample size was set at 29 participants.
- Additional outcomes (cold response, cooperation level using the Frankl scale, and duration of PBMT soft tissue analgesia) were reported descriptively.
- Randomization was generated using a computer-generated sequence and concealed in sequentially numbered.
- PBMT was delivered using a near-infrared photobiomodulation device (Nuralyte, Dentroid) with an intraoral tip containing multiple photonic emitters.

STUDY PROTOCOL

Figure 1.

- Two healthy contralateral primary teeth selected.
- Device positioned near the buccal gingival tissue of the randomized selected tooth (non-contact).
- 20-second light application aimed at buccal surface & occlusal surface.
- 2-minute waiting period before testing.
- Diagnostic procedures (gingival probing and cold testing) performed. The gingival probing was tested every five minutes for a total of 20 minutes.
- Control: The control site underwent the same diagnostic procedures without PBMT application.
- HR was measured using pulse oximetry, pain using Wong-Baker Facial Pain Rating Scale, and anxiety using Numeric Rating Scale. Outcomes were self-reported by the patient.
- A data and safety monitoring plan included regular review of enrollment, protocol adherence, and adverse events.

STUDY PROTOCOL ILLUSTRATION

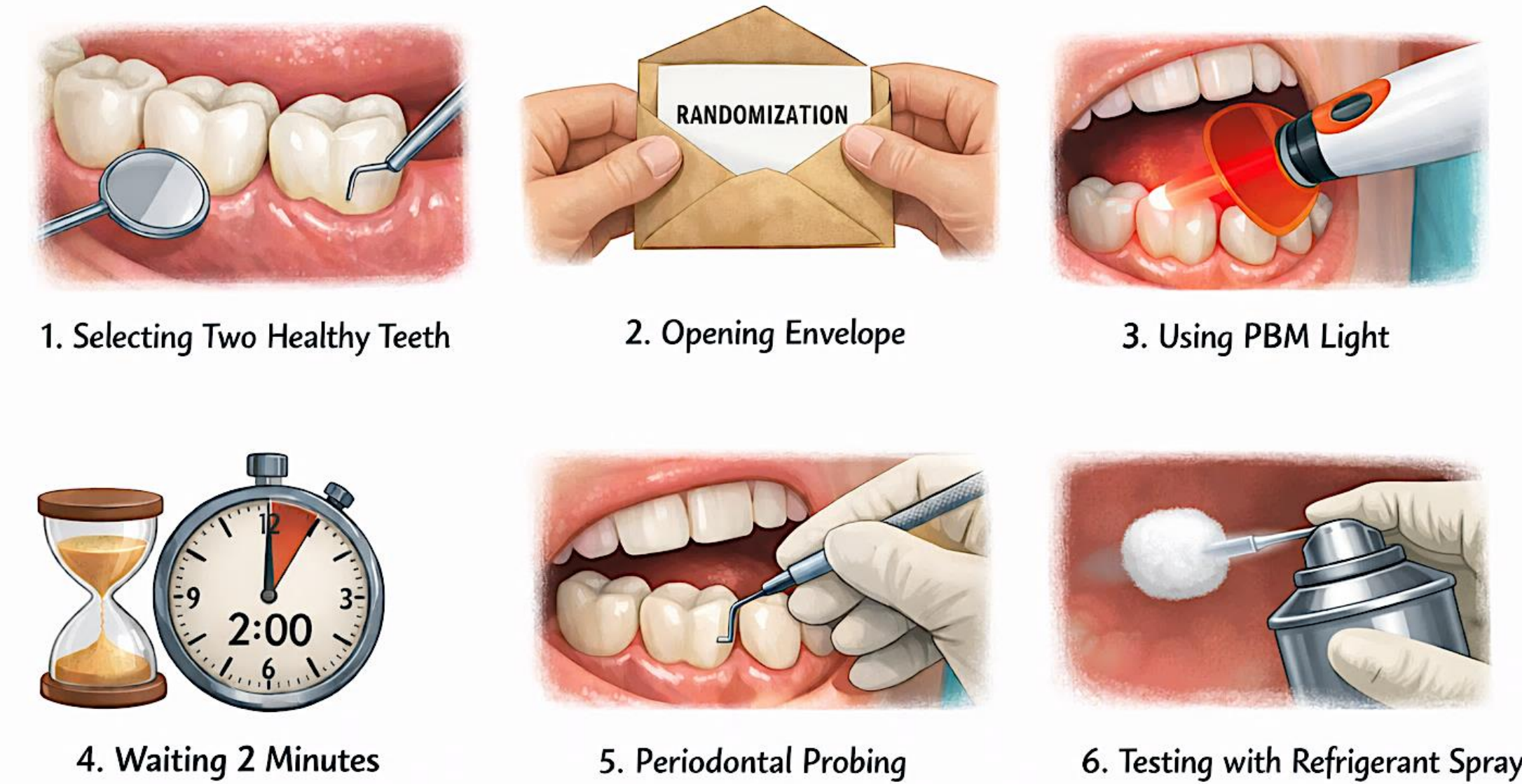


Figure 1. PBMT Trial Steps (Figure was AI generated).

Comparison Between Mean Heart Rate for Cold Testing vs Gingival Probing

Change in HR During Cold Testing

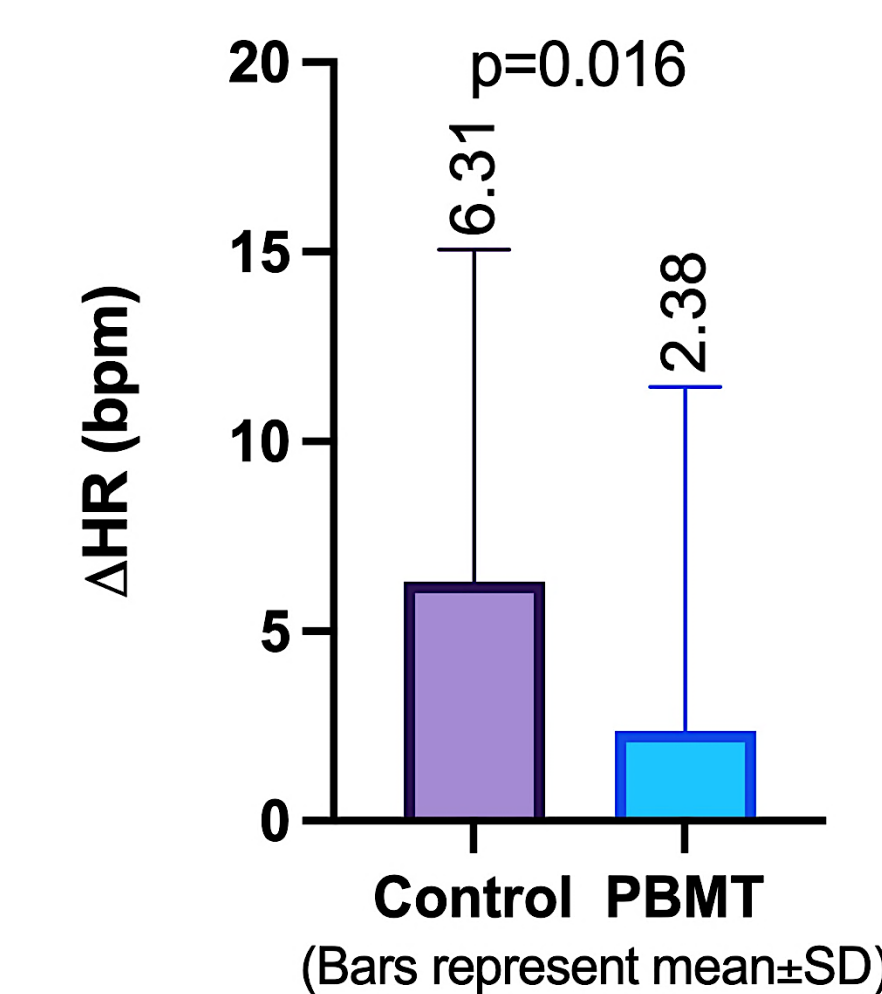


Figure 2. Mean Heart Rate Change during Cold Testing: The mean difference for HR was significantly lower for PBMT than control during cold test (2.38 vs 6.31)

Change in HR During Gingival Probing

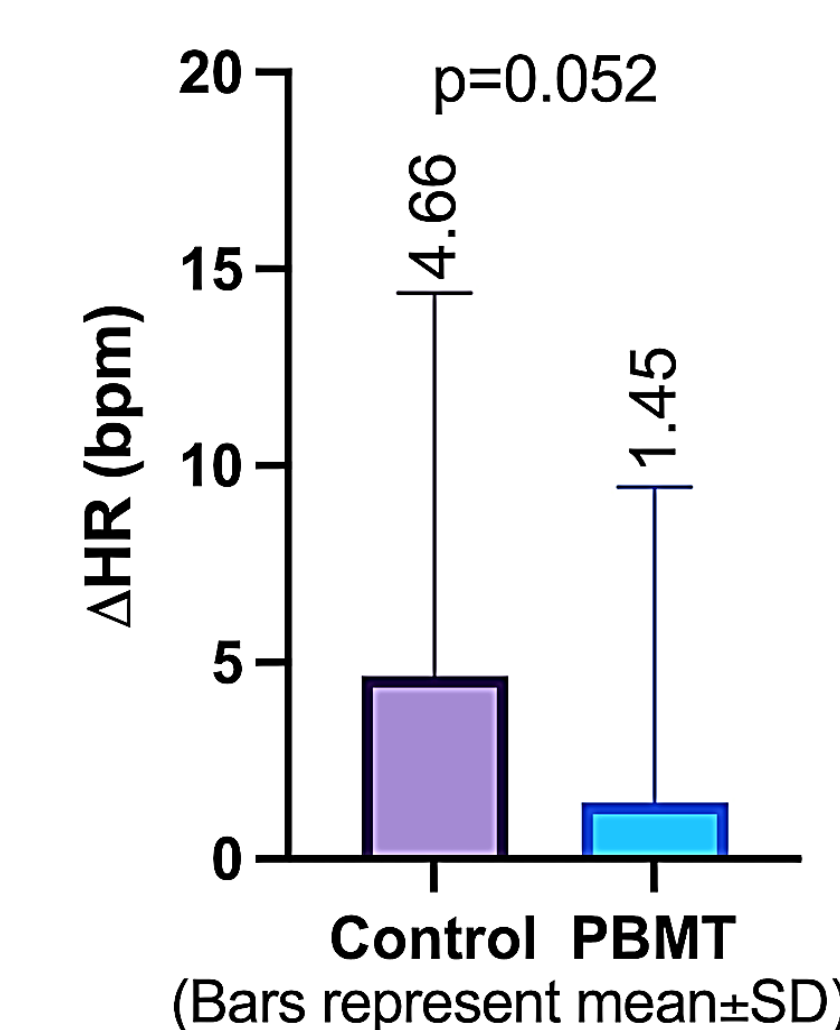


Figure 3. Mean Heart Rate Change during Gingival Probing: The mean difference for HR was lower for PBMT than the control during gingival probing (1.45 vs 4.66). However, it was not statistically significant.

Comparison Between Median Self-Reported Pain

Changes in Pain Score During Cold Testing

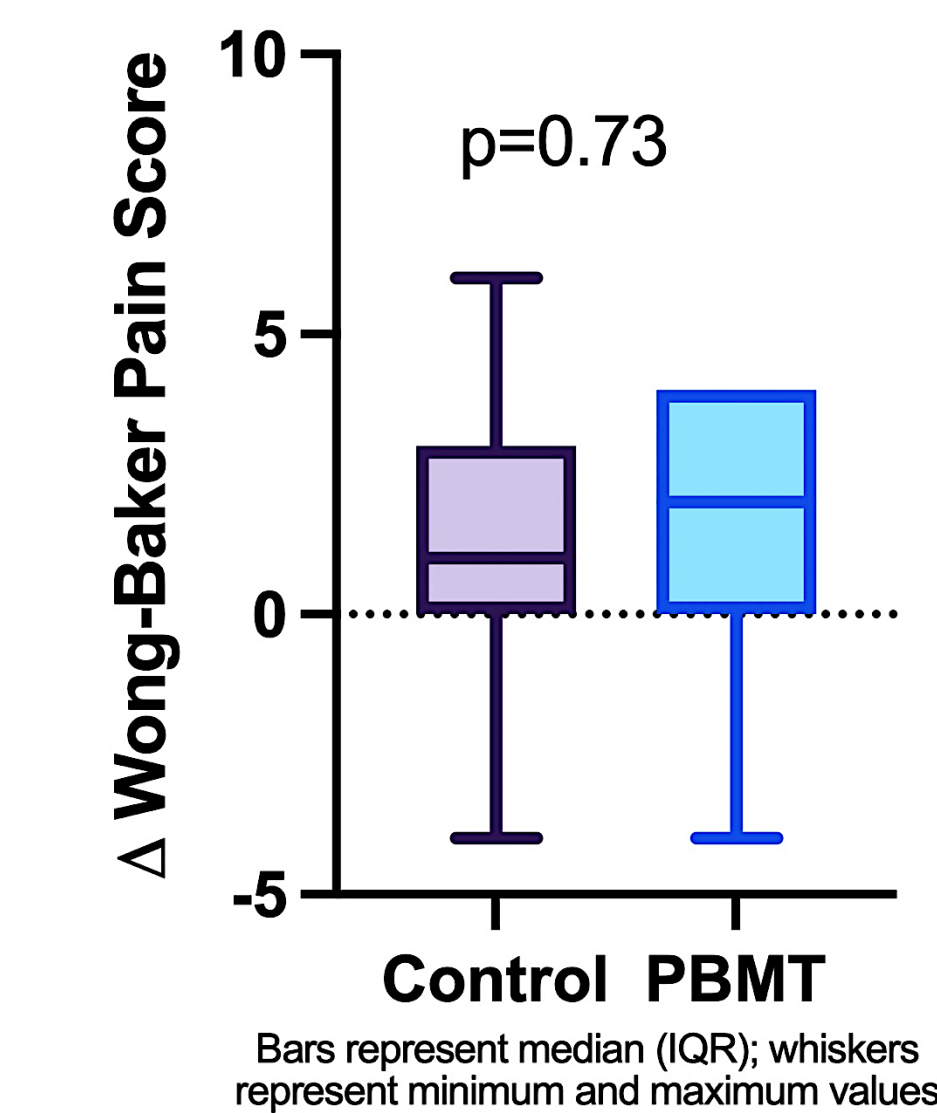


Figure 4. Median Cold Test Self-reported Pain: Self-reported pain on cold testing in PBMT group vs control was not significantly different (1.45 vs 1.48).

Changes in Pain Score During Gingival Probing

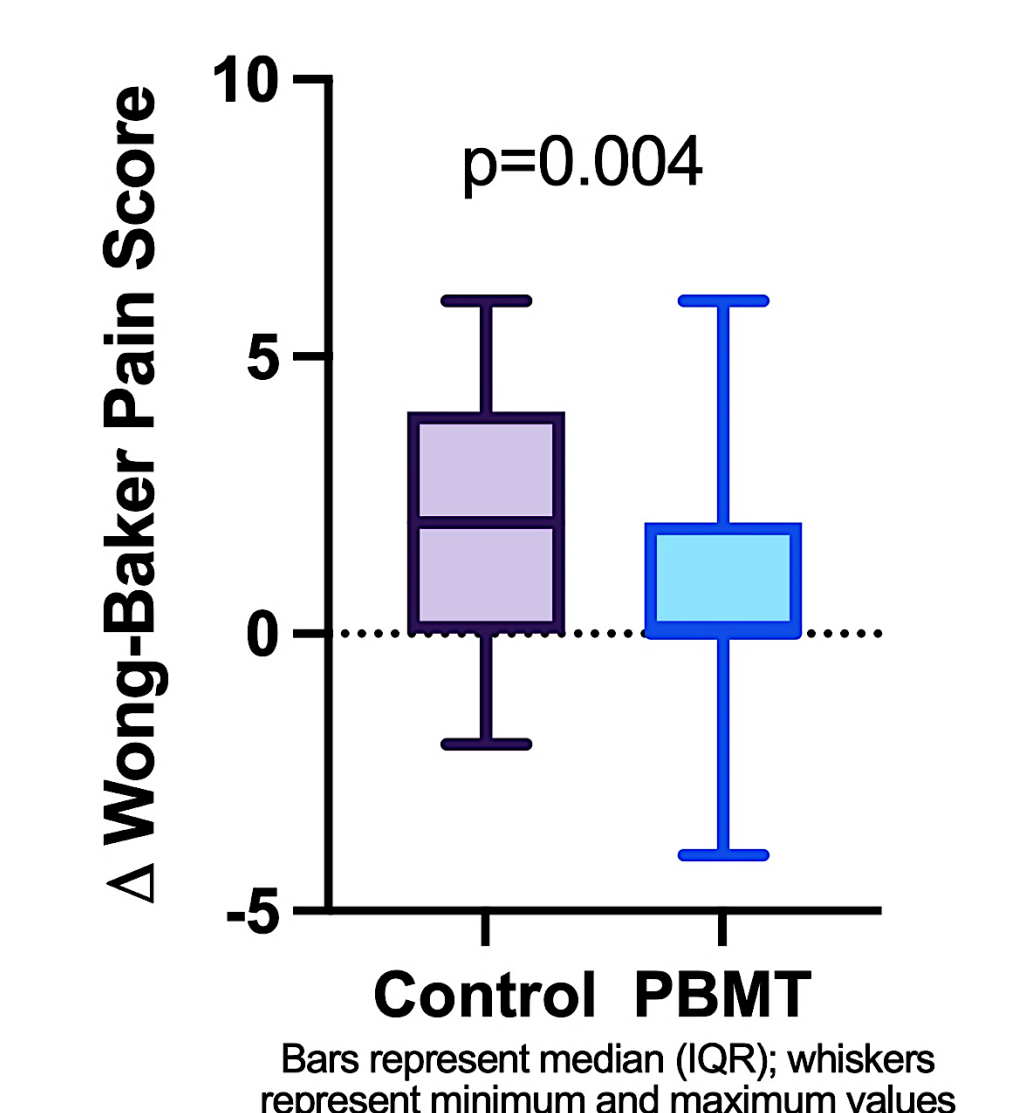


Figure 5. Median Gingival Probing Self-reported Pain: Self-reported pain on gingival probing significantly lower in PBMT group vs control (0.87 vs 2.28)

CONCLUSIONS

- PBMT, using near-infrared wavelengths, mitigates physiological stress during cold testing while preserving sensory perception.
- PBMT reduces self-reported pain during gingival probing. Effect was stable for 20 minutes duration.
- No difference was observed in self-reported anxiety.
- There were no adverse events reported associated with use of PBMT.

LIMITATIONS & FUTURE CONSIDERATIONS

- The study limitations include the single-center design, which may limit generalizability to other clinical settings.
- The inclusion of only cooperative children (Frankl ≥ 2) means findings may not extend to highly anxious patients who might benefit most from non-pharmacological analgesia.
- Future research incorporating more invasive procedures may be necessary to more definitively assess the analgesic efficacy of this intervention.

REFERENCES

- Shekarchi et al. Evaluating the Preemptive Analgesic Effect of Photo-biomodulation Therapy on Pain Perception During Local Anesthesia Injection in Children: A Split-mouth Triple-blind Randomized Controlled Clinical Trial. *Photochem Photobiol* 2022;98(5):1195-200.

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