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ORIGINAL ARTICLE

# Effect of photobiomodulation therapy on postoperative pain after endodontic treatment: a randomized, controlled, clinical study

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## Abstract

**Objective** The aim of this prospective, randomized, clinical study was to assess the effect of photobiomodulation therapy (PBM) with low-level laser irradiation (LLLI) on postoperative pain after endodontic treatment.

**Materials and methods** Sixty patients, diagnosed with irreversible pulpitis in lower molar teeth, participated in the study. All treatments were performed by a single operator. Participants were randomly divided into two groups: in the experimental group (EG), endodontic treatment was performed with a reciprocating system, immediately followed by PBM with LLLI; and only endodontic treatment was performed in the control group (CG). Postoperative pain was assessed by a second examiner, who was blinded, using two scales: verbal rating scale (VRS) and numerical rating scale (NRS). Assessment was carried out at 6, 12, and 24 h after treatment. Data were analyzed using chi-squared, Fisher's exact, Mann-Whitney tests, ordinal, and non-parametric regression analyses.

**Results** For the prevalence of pain, the difference between the groups was significant for the evaluations performed after 6 h ($p = 0.04$) and 24 h ($p = 0.02$). The difference after 24 h remained significant after stratification by sex and extrusion of filling material. Increased pain intensity was associated with extrusion of root canal filling material to the periapical region in the two scales used.

**Conclusion** The effect of PBM therapy after endodontic treatment showed a significant decreasein prevalence of postoperative pain.

**Clinical relevance** The PBM reduces the prevalence of postoperative pain and may benefit patients who need endodontic treatment.

**Keywords** Clinical trial · Intervention study · Postoperative pain · Photobiomodulation therapy

## Introduction

Postoperative pain resulting from endodontic treatment can be explained by the inflammatory process caused by the possible extrusion of contaminants by the apical foramen, which exacerbates neuropeptide expression C-type nerve fibers present in the periodontal ligament, resulting in a longer regeneration time of the region affected [1–3].

Pain symptomatology may be present in about 40% of the cases after endodontic treatment, irrespective of the instrumentation technique used [3, 4], which may impact the quality of life of patients after endodontic treatment [5, 6]. Odontogenic pain is one of the main reasons for behavioral changes, as it affects mood and the ability to perform daily activities, such as working, performing household tasks, sleeping, eating, and even talking [7–9].

Endodontic science is dedicated to offer comfort and safety by advancing its techniques. One of these advances was the reciprocating system, which has been widely used by professionals in the area due to its effectiveness in root canal instrumentation [10, 11]. However, there is clinical evidence of different levels of postoperative pain after the use of reciprocating systems [2, 5, 12].

In an endeavor to offer greater comfort to patients undergoing endodontic treatment, innovative methods have been proposed to reduce postoperative pain. One of the methods is the photobiomodulation therapy with low-level laser irradiation (LLLI) that has been used in dentistry as a tool for analgesia, modulation of inflammation, and regeneration of several cells and tissues [13–19].

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Analgesia produced by LLLI can be attributed to factors such as removal of substances responsible for inducing pain due to increased blood circulation, inhibition of the production of inflammatory factors, stimulation of lymphocytes, improvement of cellular respiration, and release of neurotransmitters in the inflamed tissue [13, 16–19].

Therefore, considering that postoperative pain after endodontic treatment is prevalent in patients, the aim of this clinical study was to assess the application of a photobiomodulation protocol with LLLI after endodontic treatment with the reciprocating system. The primary outcome of the study was the effect of photobiomodulation therapy on pain after endodontic treatment.

## Materials and methods

### Trial design and ethics committee approval

The study was approved by the Research Ethics Committee of the Federal University of Amazonas (CAAE: 49719015.0.0000.5020) and published in the Brazilian Registry of Clinical Trials—REBEC (U111111757812). This is a randomized, controlled, double-blind, parallel-controlled clinical study. The study was conducted at the dental clinic of the Federal University of Amazonas, in Manaus, from January 2016 to September 2016, with participants who needed endodontic treatment.

### Description of trial design

Men and women, aged 18–60 years, diagnosed with irreversible pulpitis with indication for endodontic treatment in mandibular molar teeth, except forthird molars, with little or none pain according to verbal rating scale (VRS), were included in the study. Diagnosis was confirmed by cold pulp test if the molar responded positively to the test in which case it was eligible for the study (Table 1).

Patients at any stage of pregnancy, who were on medication at the time of treatment, immunocompromised, hypersensitive to non-steroidal anti-inflammatory drugs, presented occlusal disorders, anatomical abnormalities, calcifications, dental fractures, or severe periodontal disease were excluded from the study, as these conditions could interfere with the analysis of the presence of pain after endodontic treatment.

**Table 1** Demographic and clinical data of patients recruited

| | GE ($n = 30$) | GC ($n = 30$) |
|---|---|---|
| Mean age | 30.4 ± 8.15 | 28.1 ± 8.51 |
| Gender | | |
| Men | 15 (50%) | 8 (26.7%) |
| Women | 15 (50%) | 22 (73.3%) |
| Extrusion of material filling | | |
| Yes | 10 (33.3%) | 13 (43.3%) |
| No | 20 (66.7%) | 17 (56.7%) |
| Systemic diseases | None | None |
| Mandibular first molar | 17 | 16 |
| Mandibular second molar | 13 | 14 |

Sample size was calculated using G*Power, version 3.1.9.2 [20]. A total of 60 patients (30 patients in each group) would be required to achieve 80% power, with an $\alpha$ value of 5%, and a difference of 30% in the prevalence of any postoperative pain between the control and the experimental groups.

Randomization was performed using the Sealed Envelope® software (sealedenvelope.com—Exmouth House, London, UK) by a third researcher who was not involved in the research protocol. A list of 60 numbers was prepared, divided into 4 blocks. Each sequence of randomized numbers was individually placed in opaque, sealed, and numbered envelopes. Once the patient was considered eligible for the study, the entire endodontic treatment protocol was performed and only then was the randomization envelope opened to know in which group the patient would be allocated. The patients were unaware of their allocation.

Of the 106 patients considered eligible for the study, 46 did not meet the inclusion criteria and were excluded. Thus, a total 60 patients participated in the study and they were divided into two groups: 30 patients in the intervention group (EG) and 30 in the control group (CG), as shown in the flow diagram below (Fig. 1).

### Study intervention

Endodontic treatment protocol was performed in the same way for both groups. After anamnesis and periapical radiographic examination, cold spray (Endo-Frost; Coltene-Whaledent, Langenau, Germany) was applied on the occlusal and vestibular surfaces of the tooth for 5 s with the aid of a cotton swab to assess tooth vitality. Recruitment of the patient occurred only if the tooth responded positively to the test and presented clinical evidence of pulpitis.

Anesthesia was obtained with 3.6 mL of 2% lidocaine with 1:100,000 epinephrine (Alphacaine; DFL Indústria e Comércio Ltda, Rio de Janeiro, RJ, Brazil) by inferior alveolar nerve block. After absolute isolation, the pulp chamber was prepared with spherical drills. A glide path was establishedwith manual K-files #10, #15 and #20. Odontometry was performed with the electronic apex locator (Novapex; Forum Technologies, Rishon Le-Zion, Israel), and radiography was performed for confirmation.

The selection of the Waveone® system for instrumentation (Dentsply, Maillefer, Ballaigues, Switzerland) was performed in accordance with the manufacturer's recommendation. If the size 10 K-file was introduced with difficulty up to the middle third of the root canal, the small instrument (21.06) was selected. If the size 10 K-file was passively introduced into the canal, the primary instrument (25.08) was selected; if the size

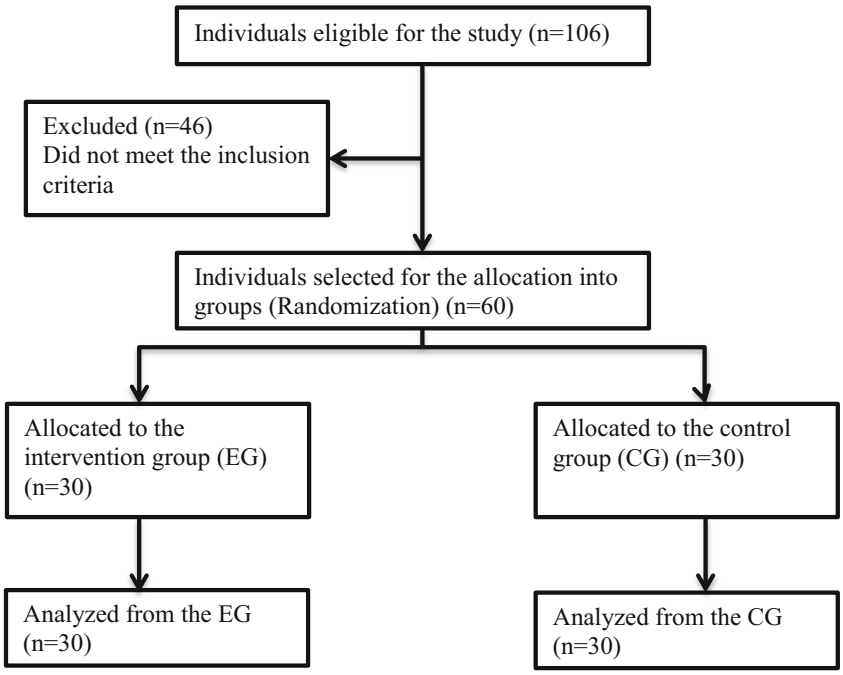


**Fig. 1** Flow diagram CONSORT for randomized clinical trials

20 K-file was passively introduced into the canal, the large instrument (40.08) was selected.

After selecting the instrument, it was introduced into the root canal with short in-and-out movements between 3 and 4 mm. These movements were repeated until the cervical, middle, and apical third of each root canal was completely shaped. During preparation, the instrument was removed and cleaned with gauze, followed by irrigation with 2.5% sodium hypochlorite, for approximately four and five times.

A size 10 K-file was used to verify patency in the working length during endodontic treatment. The instruments were driven by the XSmart Plus® motor (Dentsply, Maillefer; Ballaigues, Switzerland) in reciprocating motion.

The root canals were irrigated with 2.0 mL of 2.5% sodium hypochlorite solution after each introduction of the instrument into the root canal, and the irrigating solution remained in the root canal during the procedure. For both groups, sodium hypochlorite was applied into the canal with the aid of the Max-i-Probe 30-G needle (Dentsply, Maillefer; Baillagues, Switzerland) up to 3 mm of the working length, which was measured by a silicone stop.

The teeth were also irrigated with 2 mL of 17% EDTA prior to obturation. The root canals were then dried with sterile absorbent paper points (WaveOne® system) compatible with the canal diameters. Obturation of all teeth was performed with gutta-percha cones (Waveone® system) compatible with the memory instrument. A radiography was performed to confirm the position of the cones. After that, the cones were introduced into the root canal with endodontic cement AH Plus (Dentsply, Maillefer; Baillagues, Switzerland), which was applied in the first 5 mm. All teeth were sealed using the thermomechanical compaction method with the aid of size 60 McSpadden bur (Dentsply, Maillefer; Baillagues, Switzerland), which was introduced into the root canal up to 5 mm short of the working length.

At the completion of obturation, all teeth were sealed with restorative glass ionomer cement, occlusion was adjusted, and final radiography was performed. The randomization envelope was then opened, and group allocation was performed. The photobiomodulation protocol was performed in the patients who were allocated to the experimental group (EG).

The device used for photobiomodulation therapy (PBM) in this study was an indium-gallium-aluminum laser (PHOTON LASER III®, DMC Equipment, São Carlos, SP, Brazil) with a wavelength of 808 nm and spot size of 0.0283 $cm^2$. The laser was irradiated perpendicularly and in contact with the gingiva, totalling four irradiation points per tooth, two points to the buccal and lingual aspects. Each point corresponded to the apex of each root of the mandibular molar. The therapeutic laser was activated at a power of 0.10 W for 25 s for each point (100 s per tooth), with 2.5 J per point of energy and 90 J/$cm^2$ per point of energy density (360 J/$cm^2$ per tooth).

In the control group (CG), the placement protocol of the laser tip on the root areas was performed by the operator, but infrared light was not applied for the purpose of patient blinding.

## Assessment of postoperative pain

The primary outcome was the prevalence of postoperative pain in each group. The evaluation of pain was performed by a member of the research team who was unaware of the allocation of the groups. Two scales were used to measure

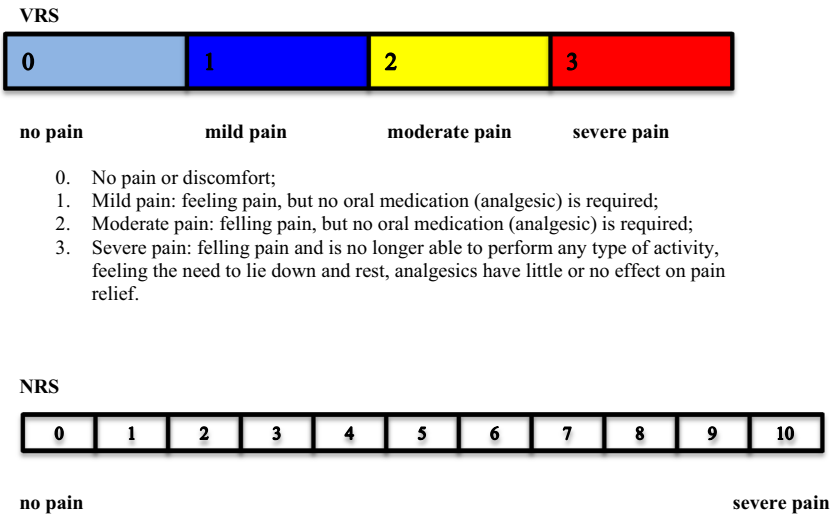


**Fig. 2** Verbal rating scale (VRS) and numerical rating scale (NRS)

pain: VRS and numerical rate scale (NRS) (Fig. 2), 6, 12, and 24 h after endodontic treatment.

The patient could address the researcher in case of doubts at any time. In cases of severe pain, the patients were advised to administerthe anti-inflammatory Ibuprofen (600 mg) every 8 h for 3 days, which was prescribed at the end of the session. Patients did not have to return for follow-up evaluation, as they were contacted by telephone. First, the researcher asked the patient to rate pain using the verbal rating scale and then to rate symptomsat the time of the evaluation from 0 to 10.

## Statistical analysis

The prevalence of pain was described for the two groups over the three periods studied, and proportions were compared using chi-squared and Fisher's exact tests. Proportions were also compared by stratifying by sex and apical extrusion of filling material using Mantel-Haenszel to pool the estimates.

Shapiro-Francia test was used to assess the normality of the data. Since the normality hypothesis was rejected for some measurements for the NRS scale, Mann-Whitney test for non-parametric data was used to compare the intensity of pain between the two groups. To analyze the independent variables in relation to postoperative pain, ordinal regression analysis was performed for the VRS scale and non-parametric regression analysis for the NRS scale. In addition to the intervention, the independent variables sex, age, and extrusion of filling material were assessed. All variables with $p < 0.10$ in the bivariate analyses were included in the multivariate analysis. All analyses were performed in the software Stata/IC, version 15 (StataCorp, TX).

## Results

For the dichotomous outcome, prevalence of pain, the statistical difference between the groups was significant for the evaluations performed after 6 h ($p = 0.04$) and 24 h ($p = 0.02$). The prevalence of pain within 24 h was five times higher in the control group. Stratifying by sex, this difference persisted after 24 h ($p = 0.02$). Stratification by extrusion of filling material indicated that the difference persisted after 6 h ($p = 0.04$) and 24 h ($p = 0.02$).

The primary outcomes of the prevalence of postoperative pain in the two groups are described in Table 2.

For the VRS, no significant statistical difference in the intensity of postoperative pain was detected between the groups for the 6-h ($p = 0.123$) and 12-h ($p = 0.127$) measurements. However, a significant difference was found after 24 h between the groups ($p = 0.013$). For the NRS, the results were similar and a statistically significant difference between the groups was detected only for the 24-h measurement ($p = 0.015$) (Table 3). The evolution of postoperative pain is shown in Figs. 3 and 4.

**Table 2** Primary outcomes of prevalence of postoperative pain in the two groups studied

| | 6 h | | | |
|---|---|---|---|---|
| | No pain | Mild | Moderate | Severe |
| Experimental | 20 (66.7%) | 5 (16.7%) | 4 (13.3%) | 1 (3.3%) |
| Control | 12 (40.0%) | 15 (50.0%) | 1 (3.3%) | 2 (6.7%) |
| | 12 h | | | |
| | No pain | Mild | Moderate | Severe |
| Experimental | 24 (80.0%) | 4 (13.3%) | 1 (3.3%) | 1 (3.3%) |
| Control | 18 (60.0%) | 10 (33.3%) | 2 (6.7%) | – |
| | 24 h | | | |
| | No pain | Mild | Moderate | Severe |
| Experimental | 28 (93.3%) | 1 (3.3%) | 1 (3.3%) | – |
| Control | 20 (66.7%) | 8 (26.7%) | 2 (6.7%) | – |

Some percentages may not sum 100% due rounding

**Table 3** Postoperative pain, mean (± SD)

| | VRS | | |
|---|---|---|---|
| | 6 h | 12 h | 24 h* |
| Experimental group ($n = 30$) | 0.53 (0.86) | 0.30 (0.70) | 0.10 (0.40) |
| Control group ($n = 30$) | 0.77 (0.82) | 0.47 (0.63) | 0.40 (0.62) |
| | NRS | | |
| | 6 h | 12 h | 24 h* |
| Experimental group ($n = 30$) | 1.43 (2.60) | 0.77 (1.98) | 0.27 (1.05) |
| Control group ($n = 30$) | 1.87 (2.64) | 1.27 (2.18) | 1.00 (2.08) |

*$p < 0.05$, Wilcoxon rank-sum (Mann-Whitney) test

The effect of independent variables (sex, age, and extrusion of root canal filling material) on intensity of postoperative pain after 24 h in ordinal regression analysis for the outcome measured by the VRS scale and in non-parametric regression analysis for the NRS scale are shown in Table 4.

Increased pain intensity was associated with the extrusion of root canal filling material to the periapical region in the two scales used. For the VRS, the odds for pain increase on the scale was 8.4 times higher in the presence of filling material extrusion. On the NRS, the presence of filling material extrusion increased pain intensity by an average of 0.81. The intervention showed a marginally significant protective effect after adjusting by sex and filling material extrusion.

## Discussion

In the control group of the study, approximately 50% of the participants/patients presented painful symptomatology after treatment, which is in agreement with the systematic review of Pak and White [4], who concluded that about 40% of the patients experience pain after endodontic treatment.

In this study, the light-mediated photobiomodulation therapy after endodontic treatment resulted in a lower prevalence

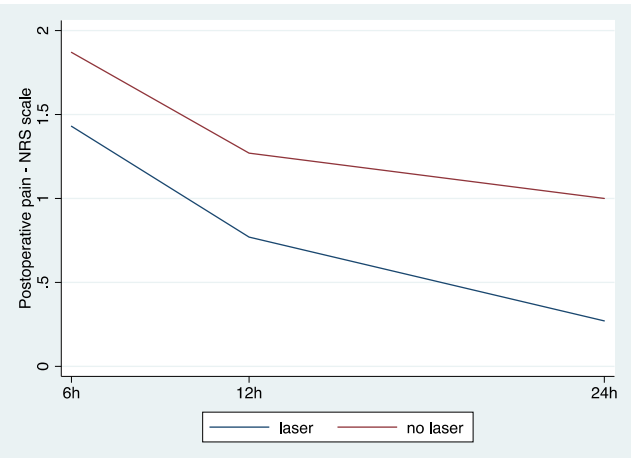


**Fig. 3** Evolution of postoperative pain on the NRS

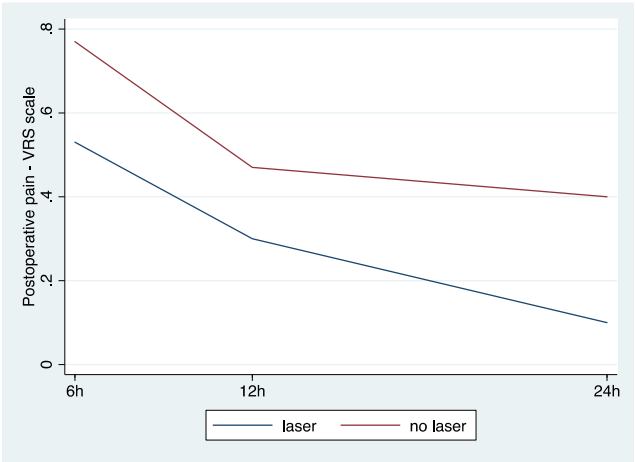


**Fig. 4** Evolution of postoperative pain on the VRS

of postoperative pain. The results in this study are in general agreement with Carroll et al. [20], who had showed the potential benefits of PBM with laser in many healthcare areas, such as improved healing, reduced inflammation, and pain control. The effect of laser on pain decrease might be due to the capacity of the low-level laser to modulate the inflammatory process and decrease the number of inflammatory cells such as leukocytes, neutrophils, mononuclear cells, and mediators such as interleukin-1 [13, 19–22].

In addition, the low-level laser modulates nociception and reduces pain through mitochondrial photoreceptors that absorb laser light, mediating the energy transduction process during electrochemical changes and resulting in a series of intracellular events [21, 22].

According to Chow et al. [23], laser light with irradiance over 300 mW/cm$^2$, when absorbed by the nociceptors, causes analgesia. Thus, it exerts an inhibitory effect on delta A and C-type nerve fibers, slowing conduction velocity, reducing amplitude of compound action potential, and suppressing neurogenic inflammation. In this clinical study, a laser light with irradiance of 3.53 W/cm$^2$ was used, obtaining positive results in the analgesic effect and reducing pain after endodontic treatment.

There are studies in the literature showing that red light irradiation has been highly effective in reducing pain and accelerating healing of irradiated tissues [14, 16, 17]. However, the wavelength range of the light is 606 nm, which probably reduces effectiveness during light penetration in the target cells when the tissues are deeper. The wavelength range of infrared light is longer, 808 nm, which means greater penetration in the tissues as it reaches the cells of the periapex, even if there is light dispersion, and promotes the desired effects of photobiomodulation in that region [13, 23, 24].

Endodontic treatment using the reciprocating technique, according to some clinical trials, is associated with the incidence of postoperative pain as this symptom is related to increased expression of neuropeptides of C-type nerve fibers, possibly caused by extrusion of contaminated debris into the

**Table 4** Factors associated with postoperative pain intensity at 24 h

| Variable | VRS | | | |
|---|---|---|---|---|
| | Crude | | Adjusted | |
| | OR | 95% CI | OR | 95% CI |
| Intervention (ref.: laser) | 6.65 | 1.32 to 33.61[a] | 4.86 | 0.83 to 28.47[b] |
| Sex (ref.: men) | 4.03 | 0.80 to 20.36[b] | 4.14 | 0.62 to 23.69 |
| Age | 1.02 | 0.95 to 1.10 | | |
| Extrusion of filling material (ref.: no) | 7.00 | 1.66 to 29.52[a] | 8.40 | 1.77 to 39.88[a] |
| | NRS | | | |
| | Crude | | Adjusted | |
| | Effect estimate | 95% CI | Effect estimate | 95% CI |
| Intervention (ref.: laser) | 0.49 | − 0.10 to 1.13[b] | 0.17 | 0.00 to 0.37[b] |
| Sex (ref.: men) | 0.54 | − 0.02 to 1.20[b] | 0.17 | 0.04 to 0.35[a] |
| Age | − 0.04 | − 0.10 to 0.05 | | |
| Extrusion of filling material (ref.: no) | 0.87 | 0.19 to 1.88[a] | 0.81 | 0.02–1.63[a] |

[a] $p < 0.05$

[b] $p < 0.10$

periapex [2, 5]. However, according to Caviedes-Bucheli et al. [1], the expression of these neuropeptides and consequent pain is more associated with the cross-sectional shape of the instruments than with their kinematics. In addition, when evaluating the quantity of bacteria apically extruded with rotating and reciprocating systems, Turker et al. [25] observed that the single reciprocating instrument caused less bacterial extrusion. In the clinical trial of Relvas et al. [12], no difference was observed in the incidence of postoperative pain when the rotary system was compared with the reciprocating system.

According to Williamson and Hoggart [26], patients prefer the VRS because it is simple, but it is the least sensitive of the scales. On the other hand, the NRS is more efficient, relatively easy to interpret and has greater statistical sensitivity. In this clinical study, both scales presented similar statistical values. These pain scales were chosen due to their efficiency and ease of evaluation through telephone calls, thus avoiding the need for a second session.

Ostrom et al. [27] found in their clinical study that women are more sensitive to pain than men, which was measured as follows: pressure, mechanical, and thermal pain sensitivity. However, Wiesenfeld-Hallin [28] attributes the difference in sensitivity between men and women to the inherent biological mechanisms and further adds that sex hormones influence pain threshold and tolerance. This variation in the literature can be explained because women present a higher prevalence of pain than men [29]. However, this conclusion may be misleading since it depends on pain stimulus. In brief and acute stimuli, women tend to feel more pain than men, but it was found that women report better pain adaptationto prolonged painful stimuli [30].

A total of 23 men and 37 women were treated during this clinical study. Of these, 10 men and 23 women presented pain after treatment. Although more women participated in the study, all patients were randomly allocated to the groups, correcting a possible bias. Furthermore, the ordinal (VRS) and non-parametric (NRS) regression analyses have considered this variable as a potential confounder.

The authors of this clinical trial observed that unintentional cement extravasation to the periapical region representeda high risk for postoperative pain in both groups. The data are similar to those estimated in the literature. Since the mid-1980s, Nitzan, Stabholz, and Azaz [31] have reported a series of cases in which the extrusion of root canalfilling material should be prevented as this event causes unnecessary mechanical and chemical irritation, hindering the regeneration of the periapical tissues.

Scarparo, Grecca, and Fachin [32] have histologically observed that the extrusion of root canal filling material leads to cellular inflammatory components, increased fibrous condensation, and formation of micro-abscesses. Ruparel et al. [33] evaluated in vitro the direct effect of various endodontic luting agents when in contact with nerve cells and concluded that all cements somehow increased neuropeptide expression of nerve fibers; in addition, they activate nociceptors and possibly increase neurogenic inflammation.

In the systematic review of case reports of Rosen et al. [34], extrusion of filling materials exacerbates postoperative pain due to injury to nerve cells when the material comes into contact with them. Despite this, most cases recover over time and no intervention is required.

The limitations of this clinical trial include the subjectivity of gauging pain, as well as the preoperative conditions of the teeth and their anatomical condition. To minimize this effect, only mandibular molars were selected and those diagnosed with irreversible pulpitis. Regarding the possible influence

of the irrigating solution on postoperative pain, 2.5% sodium hypochlorite was usedin all patients with the irrigation tip at 3 mm short from the working length to prevent possible extravasation to the periapical region, pain, and possible toxicity to cells [35].

Consideringthat possible pain is caused by occlusal trauma, all teeth were adjusted so that the temporary restoration did not influence pain assessment. As for the factors such as sex and age, the randomization of patients ensured that these variables were distributed equally between the groups.

## Conclusion

The light-mediated photobiomodulation therapy after endodontic treatment was associated with lower prevalence of postoperative pain.

**Funding** No funding was received.

### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** All the procedures were performed in accordance with the ethical standards of the Research Ethics Committee involving humans of the Federal University of Amazonas and the 1964 Declaration of Helsinki and its subsequent amendments or comparable ethical standards.

**Informed consent** Written consent was obtained from all individuals who participated in this clinical trial.

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