# **ORIGINAL ARTICLE**



# Photobiomodulation therapy and 3% potassium nitrate gel as treatment of cervical dentin hypersensitivity: a randomized clinical trial

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#### **Abstract**

**Objectives** This randomized controlled trial aimed to evaluate different protocols for dentin hypersensitivity treatment with low-power lasers and desensitizing agents, and the association between low-power lasers and desensitizing agents.

Materials and methods Fifty-four patients (303 teeth) were randomly allocated to three groups: G1, 3% nitrate potassium gel, UltraEZ (n=17); G2, photobiomodulation therapy (PBM) with a low-level infrared laser (n=17), 100 mW, spot size of 0.028 cm<sup>2</sup>, and dose of 1 J per point; and G3, nitrate potassium+PBM (n=20). Treatments were applied to the buccal cervical region at intervals of 72 h, and all protocols were performed in three sessions. The patients' response to evaporative stimuli was rated using the visual analog scale (VAS). Re-evaluations were performed immediately after each application and 1 week, 1 month, and 3 months after treatment. A two-way repeated measures test and Tukey's post hoc test were used for multiple comparisons ( $\alpha=5\%$ ).

**Results** There was a reduction in pain levels at the end of treatment in all groups. There were no significant differences in VAS score changes between the groups immediately after treatment and after the third month, compared to the baseline (p > 0.05).

**Conclusion** Under the limitations of this in vivo study, the proposed three-session protocol was effective in reducing dentin hypersensitivity after 3 months, regardless of the desensitization mechanism used. Conservative and long-term protocols are interesting for the control of pain caused by dentin hypersensitivity.

**Clinical relevance** The increase in cervical dentin hypersensitivity prevalence warrants easy-to-apply and long-lasting desensitizing protocols for pain control.

**Keywords** Cervical dentin hypersensitivity · Clinical trial · Low-power laser · Potassium nitrate

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## Introduction

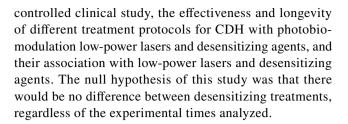
Cervical dentin hypersensitivity (CDH) is defined as short, sharp pain that occurs in response to thermal, chemical, evaporative, tactile, or osmotic stimuli [1]. A recent systematic review found that the prevalence of CDH is variable in the adult population, ranging from 1.3 to 92.1%, with a global average of 33.5% [2]. The etiology is multifactorial, involving an association of factors such as tension (parafunctional habits, traumatic occlusion, and malocclusion), friction (abrasion), and corrosion (degradation caused by acid from intrinsic and extrinsic sources) [2–5].

The hydrodynamic theory proposed by Brännström in 1964 is most accepted to explain the CDH mechanism of pain. According to this theory, when the dentinal tubules are exposed to the oral environment and there is stimulation on the tooth surface, the fluid inside the tubules moves inward and outward, depending on the type of stimulus. This displacement of intratubular fluid can activate mechanical receptors in the nerves, stimulating and deforming the nerve fibers present between odontoblasts, generating a painful sensation. Therefore, blocking the dentinal tubules or depolarizing nerve fibers is necessary to control CDH. Examples include the application of potassium oxalate, potassium nitrate, strontium chloride, fluorinated varnishes, and sodium fluoride, irradiation with high- and low-power lasers, application of adhesive systems, and restorative procedures [6–9].

Potassium-based agents promote an increase in the concentration of potassium ions in nerve endings, decreasing the nerve's ability to conduct sensory stimulation and altering its action potential [10, 11]. However, laser irradiation interacts with the tissue, causing different tissue reactions, according to its active medium, wavelength, power density, and optical properties of the target tissue. High-power lasers can create a melting surface in dentin and block the entrance of dentinal tubules. However, low-power lasers through photobiomodulation therapy (PBM), whose action is a biomodulator of cellular responses, will promote a decrease in pain levels through the depolarization of nerve fibers and increase the formation of tertiary dentin [8, 12, 13].

The literature demonstrates a lack of clinical trials and divergent results [8] concerning the use of low-level lasers. There is a need for more controlled studies emphasizing the effectiveness of PBM and nitrate potassium gel in controlling CDH. In view of the treatments mentioned above, it is necessary to evaluate clinical protocols for the control of CDH over time, to support its use, and establish measures to prevent and control pain.

In view of the above discussion, the objective of this research was to evaluate, through a randomized and



# **Methods**

This study was a parallel arm randomized, double-blind controlled trial conducted at the School of Dentistry of the University of São Paulo from September 2019 to March 2020. The study was approved by the university's local ethics committee (number 3.612.518), and follows the CONSORT guidelines [14]. The study was registered with the Brazilian Clinical Trials Registry (UTN: U1111-1273–4113).

This study was conducted in accordance with the principles of the Declaration of Helsinki (World Medical Association Declaration of Helsinki, 2008). Participation in the study was voluntary, and informed consent was obtained from all participants.

# **Eligibility criteria**

Participants of both sexes were recruited and were considered eligible if they were aged between 18 and 45 years and in good general health, had at least one tooth, and had CDH equal to or greater than 4 on the visual analog scale (VAS). The initial evaluation was performed using an evaporative test with air jets from a dental syringe. Participants who had active carious lesions or defective restorations, had loss of dental tissue that required restorative treatment, performed any professional desensitizing treatment in the last 6 months, used desensitizing pastes within 3 months, used anti-inflammatory drugs or analgesics at the time of recruitment, and were pregnant or breastfeeding were excluded from this study.

# Sample size calculation

The sample size calculation was based on the comparison of means, with a minimum expected difference of 2 units between groups in VAS and a standard deviation of 2. Considering an alpha of 5% and 80% power, 17 patients per group would be necessary [15]. To compensate for possible loss to follow-up, 54 participants were included.

#### Randomization

After the clinical examination, 54 participants were randomly allocated into three groups, with 303 teeth to be



treated. A random sequence was generated by a researcher not involved in the study using the Excel program from the Microsoft Office package. Stratified randomization was performed. The researcher allocated the groups according to cards placed in sequential numbers in opaque and sealed envelopes, which mentioned one of the three treatment groups. The envelopes were opened only at the time of the procedure by operator 1. Patients and researcher evaluators (operator 2) did not know which group they were assigned to, and the evaluators were blinded to the patients' pain level. The flowchart of the study is presented in Fig. 1.

# **Dentin hypersensitivity assessment**

The stimulus adopted to trigger CDH was the evaporative stimulus (triple syringe), as used in previous studies [9, 13, 15–18]. The level of CDH was determined using the VAS, a one-dimensional instrument to assess pain intensity numbered from 0 to 10, with 0 being "no pain" and 10 being "worst pain." The participants were then asked to indicate the level of CDH felt after the application of the stimulus on the scale [9, 13, 15–18].

The clinical evaluation consisted of the application of a triple syringe air jet perpendicularly, at 1 cm from the cervical region of the tooth, lasting 2 s. Adjacent teeth were isolated with the aid of cotton rolls to avoid interference with the measurement of that specific tooth. Immediately after the evaporative stimulus test, the patient indicated the level of sensitivity experienced on the VAS and the record was included in the clinical chart. The examiner for the CDH level was previously calibrated.

All treatments were performed by the same researcher (operator 1). Stimulus and pain measurements were performed by a previously calibrated examiner (operator 2). To minimize errors and avoid bias, operator 2 (who was not aware of the treatments) assessed the response of each tooth to air stimuli, and then measured and recorded the levels of dentin hypersensitivity.

# Interventions

After clinical examination, anamnesis, and total agreement to participate in the study, patients were treated according to their allocation. Two weeks before the beginning of the study, the participants went through a wash-out period, during which they used only the oral hygiene products indicated by the researchers, which should be used until the end of the study. The oral hygiene kit consisted of one soft toothbrush (Professional Lab Series, Colgate Palmolive Company), a fluoridated toothpaste (Colgate Total 12, 1450 ppm F, Colgate Palmolive Company), and one dental floss (Colgate, Colgate Palmolive Company).

Before treatment, all teeth received dental prophylaxis with a rubber cup, 2% chlorhexidine, and a pumice stone. The area was then washed with air/water spray and dried with cotton. Sequentially, relative isolation was performed with the aid of cotton rolls, and treatments were performed according to the groups.

The treatments were carried out in three sessions, with an interval of 72 h between applications, as previously reported in the literature [9, 12, 15, 17]. The effectiveness of the products was measured immediately after each treatment session using the VAS scale. The participants were called back at 1 week, 1 month, and 3 months, and the VAS level was measured using the same evaporative stimuli. Table 1 summarizes the application of desensitizing therapies in the three groups. Laser parameters were tested before each irradiation using a power meter (Laser Check, MMOptics, São Carlos, SP, Brazil).

The evaluator and patients were blinded to the study. Additionally, patients were unaware of the treatment they were receiving. In group 1, the equipment that simulated the laser irradiation was used. The laser tip was positioned on the tooth surface; however, no emission was observed. In group 2, a placebo gel (water) was applied in the same way as the KNO3 desensitizing gel, according to the manufacturer's instructions. The desensitizing and placebo gels were placed in identical containers so that patients could not identify which product was being applied.

#### Group 1—3% potassium nitrate desensitizing gel

After prophylaxis, a #000 retraction cord (Ultrapack, Ultradent, South Jordan, UT, USA) was inserted into the gingival sulcus, and the desensitizing gel (Ultradent) was applied to the non-carious cervical lesion using a microapplicator (KG Sorensen, Cotia, Brazil) spreading throughout the cervical region from mesial to distal. The desensitizing gel was removed after 5 min. Then, the retractor cord was detached, excess was removed, and gel was applied again for 5 min. The surface was then washed with water until all the visible gels were removed. This protocol followed the manufacturer's recommendations. As the patients did not know which treatment was allocated to them, the researcher simulated irradiation with laser equipment (DMC, São Carlos, São Paulo, Brazil) with the same characteristics as the one used in the research, but without the emission of radiation.

# Group 2—photobiomodulation/low-level laser irradiation

In this group, all participants received photobiomodulation therapy (Laser Therapy EC, DMC Equipment LTDA, São Carlos, Brazil) at a wavelength of 808 nm (infrared laser) under relative isolation with a fixed power of 100 mW, spot size of 0.028 cm<sup>2</sup>, and dose of 1 J per point. The



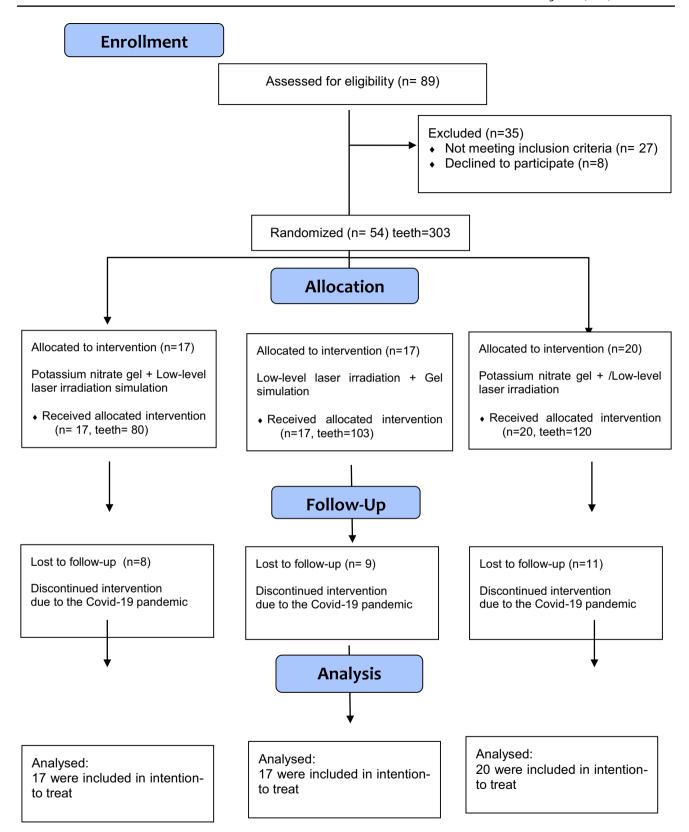


Fig. 1 CONSORT flow diagram of the clinical trial



 Table 1 Description of the division of the evaluated groups

Groups	First session	Second session	Third session
G1	Potassium nitrate gel+low-level laser irradiation simulation	Potassium nitrate gel+low-level laser irradiation simulation	Potassium nitrate gel + low-level laser irradiation simulation
G2	Gel simulation + low-level laser irradiation	Gel simulation + low-level laser irradiation	Gel simulation + low-level laser irradiation
G3	Potassium nitrate gel + low-level laser irradiation	Potassium nitrate gel + low-level laser irradiation	Potassium nitrate gel + low-level laser irradiation

tip was placed perpendicular to the tooth with irradiation at the cervical and apical points, with a total dose of 2 J. In molar teeth, irradiation was performed on the cervical mesial, mesial apical, distal cervical, and distal apical teeth, totaling 4 points and 4 J. The treatment was carried out in three sessions, with an interval of 72 h between sessions.

During all laser treatments, protective glasses were used by both the researcher and patient, and all safety rules were followed. Sequentially, the application of a desensitizing agent was simulated using the same UltraEZ package, but containing water. A retractor cord was then inserted, and a micro-brush was used to spread the gel and left for 10 min, as in group 1.

# Group 3—photobiomodulation associated with gel desensitizer

The subjects in group 3 received the application of the desensitizing gel and laser irradiation immediately after, as described in the protocols in groups 1 and 2.

# Statistical analysis

The VAS value for each participant was calculated as the mean of all affected teeth. Subsequently, means and standard deviations of each group were calculated at each experimental period. Adherence to the normal curve was tested using the Shapiro–Wilk test, and homoscedasticity was verified using the Levene test. As normality and homoscedasticity were observed, two-way analysis of variance was used to compare the groups and change in time in which the two factors were the group and time (repeated measures factor). Tukey's post hoc test was used for multiple comparisons.

Two analyses were performed for the dataset: by protocol (considering all missing data) and intention to treat. In the intention-to-treat analysis, the last observation carryforward method was used as the data-imputation method. In this method, the last observed value of each participant was used to replace the missing data. An alpha value of 5% was considered significant.

# **Results**

Fifty-four participants (303 teeth) were included in this study. There were participants with only one tooth with CDH and others with 15 teeth. The age range was 18–45 years (mean age of the subjects was 26.9 years). Demographic characteristics of the participants are presented in Table 2.

In Table 3, the differences in the mean value of CDH per treatment can be observed. After the three sessions, a decrease in pain levels was noticed. As shown in Table 3, CDH remained relatively stable among the other post-treatment time intervals. There was no significant difference between the groups at any time during the study (p > 0.05). There was a significant intra-group reduction in the three experimental groups compared to baseline (p < 0.05)

Table 3 shows the mean values for pain reduction (baseline and 3 months). These results were analyzed using one-way analysis of variance, and no difference was observed between the groups (p=0.78).

Table 2 Characteristics of the participants

Characteristic	Total $(\%, n)$		
Gender			
Male	25.92% (14)		
Female	74.07% (40)		
Age (years)			
18–25	44.44% (24)		
26–35	46.29% (25)		
36–45	9.26% (5)		
How long have you been with sensitivity?			
<1 years	11.11% (6)		
1–5 years	44.44% (24)		
> 5 years	44.44% (24)		
How much does sensitivity bother you?			
A few	1.84% (1)		
Medium	42.60% (23)		
A lot	55.55% (30)		
Visual analogic scale			
Moderate sensitivity (4 to 7)	79.63% (43)		
High sensitivity (8 to 10)	20.37% (11)		



Table 3 Mean, standard deviation, and comparison between groups regarding dentin hypersensitivity. Intention-to-treat analysis

Groups	Baseline	1st session	2nd session	3rd session	1st week	1st month	3rd month
Group 1 (potassium nitrate)	6.23 (1.50)	4.49* (1.95)	4.36* (2.00)	3.74* (1.99)	3.15* (2.04)	2.87* (1.94)	2.87* (1.97)
Group 2 (PBM)	6.78 (1.54)	4.68* (2.19)	4.27* (1.98)	3.62* (1.91)	3.84* (1.98)	3.47* (2.18)	3.45* (2.27)
Group 3 (PBM + potassium nitrate)	6.47 (1.19)	4.83* (1.68)	4.24* (1.93)	3.72* (1.90)	3.76* (2.06)	3.46* (2.11)	3.41* (2.16)

2-way ANOVA; group effect: p = 0.79; time effect: p < 0.001; time x group interaction: p = 0.88. Alpha = 5%

#### Discussion

The implementation of public health policies has increased the life expectancy of the population. Additionally, access to information and awareness of oral health care has led to a decrease in caries prevalence rates. However, people are currently living in a more stressful and anxious world with new behavioral and eating habits. All these previous observations result in a change in society's lifestyle, leading us to face new diseases such as non-carious cervical lesions and, consequently, CDH [2–5, 19]. Epidemiological studies suggest an increase in the prevalence of CDH and a negative impact on daily activities such as eating, drinking, breathing, and brushing teeth [3, 4, 19–21]. In this study, some patients reported that the level of pain was so intense that they needed to warm up the water to brush their teeth. For these reasons, this condition directly impacts the quality of life of patients [17, 18]. Studies that investigate the efficacy and longevity of desensitizing protocols are extremely relevant.

To the best of our knowledge, this is the first clinical study to evaluate the control of dentinal hypersensitivity using a combination of photobiomodulation therapy with a low-power laser and desensitizing gel with a concentration of 3% potassium nitrate. All protocols evaluated proved to be effective in reducing CDH after the application of the protocol of the three sessions in a 3-month follow-up. However, no significant differences were observed between our groups.

Many products with different modes of action can be found in the market; however, there is no universally or standardized protocol accepted for the treatment of CDH. According to the literature, PBM with a low-power laser is a contemporary option for controlling the CDH. It is non-invasive, painless, and conservative therapy [9, 12, 13]. However, a recent systematic review showed that more consistent studies should be conducted to adequately observe the beneficial therapeutic effects of PBM.

Laser therapy is dose-dependent; therefore, it is generally used in sequential appointments with a time interval. Therefore, in this study, it was decided to carry out consecutive applications of potassium nitrate to carry out

a new standardized clinical protocol and to compare the three treatment strategies.

Our results indicated that pain levels were significantly reduced after 3 months in all protocols applied. However, these data should be considered with caution as there is a need for a larger sample size to allow a more robust comparison.

The evaluation of CDH during treatment and follow-up was performed using air jets (evaporative stimulus). The choice of this specific stimulus is due to the fact that it acts by promoting the evaporation of fluid from the interior of the dentinal tubules. It is the easiest and most used stimulus that can be applied by clinicians and has been used for a long time in the literature [9, 11, 19, 20]. For the evaluation of the level of pain, the visual analog scale (VAS) was used precisely because it is easy to apply, is well understood by patients, and is an adequate and reproducible method [8, 11, 22–24].

Considering the results of this study, it took at least three sessions to achieve low levels of CDH. Probably, a single application may not be enough, both for laser irradiation (dose-dependent) and potassium nitrate gel (time-dependent), which suggests that a multiple-session approach can result in the maintenance of the desensitizing effect for longer periods [8, 9, 11, 22, 25, 26].

DH can be managed using two neural strategies. The first is related to the use of a physical method using a low-power laser. Second, chemical agents are used to desensitize the sensory nerves, blocking the transmission of noxious stimuli from the dentinal tubules to the central nervous system. Both laser irradiation and potassium nitrate are considered neural strategies because they do not obliterate the dentinal tubules but act directly on the transmission of pain.

Potassium nitrate for the treatment of CDH has been used in the form of a gel or mouthwash, or incorporated into toothpaste [27]. In this study, it was used in the gel form, which is one of the most routinely used neural desensitizing agents in dental clinics. Potassium nitrate acts in the transmission of nerve impulses and prevents repolarization. Depolarization occurs when the concentration of potassium ions increases in nerve endings, inactivating the action potential and preventing pain [1]. Potassium ion



<sup>\*</sup>Significant difference from baseline

concentrations above 0.08% around the axons are required to support the nerve depolarization [28]. In this study, the product was able to reduce, on average, 47.36% of the level of pain in patients after the three sessions; after 3 months, a reduction of 74% was observed, demonstrating the efficacy of potassium in reducing the levels of CDH, in agreement with results in previous studies [11, 22, 26, 27, 29–32].

The second proposed protocol was a physical neural mechanism using a low-power laser. Laser therapy has been widely explored in the treatment of CDH, and unlike high-power lasers, it does not lead to mechanical changes in the dentinal surface. Low-power lasers act on cell membrane electrical potential, activating Na+/K+ATPase pumps, bringing benefits such as analgesics, modulation of anti-inflammatory effects, and biomodulation of the tissue [9]. The results of this study were satisfactory for reducing CDH levels. After three sessions of irradiation, a pain reduction of 55.75% was observed; after 3 months, it was 64.30%, corroborating the present literature [8, 9, 11, 33–35].

Comparing all tested protocols for the initial and 3-month CDH levels, no significant differences were found. In other words, all products were effective regardless of the mechanism of action. Therefore, these results support the use of three sessions to promote a stable and effective reduction of CDH. Considering the significant decrease in the VAS pain score after a few weeks, it is assumed that the performance of neural desensitizing agents may become more prominent if the observation period is longer [31]. Initially, this study followed the patients for at least 6 months, and data collection was already underway. However, due to restrictions resulting from the coronavirus disease 2019 pandemic, it was not possible to continue the research for a longer follow-up period.

In view of the above limitations and difficulties of this clinical research protocol, such as patient compliance and the necessity of teamwork for treatments and evaluations, it can be hypothesized that the combination of PBM with potassium nitrate could significantly reduce sensitivity over a longer period, even if a significant difference was not observed with other desensitization treatments over the 3-month period performed in this study. As there is a lack of literature data on this combination, more research, and clinical trials with a longer follow-up period to confirm this hypothesis is needed.

It is necessary to emphasize that the dentist must first identify the etiological factors involved in CDH so that it is possible to remove or modulate them. Occlusal factors (distribution of occlusal contact and presence of parafunctional habits), oral hygiene habits (brushing technique, applied force, and types of toothpaste), and the presence of acids of different origins in the oral cavity (acid diet

and gastroesophageal disorders) are necessary to evaluate, remove, correct, or modulate.

In view of the results and the literature, when CDH is present, using only a desensitizing agent in the management of pain can lead to limited and short-term results [2, 3, 5, 19, 36–38]. The removal and modulation of etiological factors for CDH, together with the establishment of a strategy for the decrease of pain, is the best way to achieve success in desensitizing treatments.

# **Conclusion**

The proposed three-session protocol is an effective and conservative method in reducing CDH after 3 months, regardless of the desensitization mechanism used.

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# **Declarations**

Ethics approval All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Consent to participate** Informed consent was obtained from all individual participants included in the study.

**Conflict of interest** The authors declare no competing interests.

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