



Nd:YAG laser and calcium sodium phosphosilicate prophylaxis paste in the treatment of dentin hypersensitivity: a double-blind randomized clinical study

Vinícius Maximiano¹ · Alana Cristina Machado¹ · Mirian Lumi Yoshida¹ · Claudio Mendes Pannuti² · Tais Scaramucci¹ · Ana Cecilia Correa Aranha³

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Abstract

Aim This double-blind, placebo-controlled, randomized clinical trial evaluated the effectiveness of Nd:YAG laser and a calcium sodium phosphosilicate-containing paste (NovaMin®) in the treatment of cervical dentin hypersensitivity (CDH).

Materials and methods Seventy patients were randomly allocated into the following experimental groups: control-placebo, calcium sodium phosphosilicate paste (NovaMin®), and Nd:YAG laser (1 W, 10 Hz, 85 J/cm²). Pain was evaluated by means of a visual analog pain scale (VAS) after evaporative stimulation with a jet of air and tactile stimulation with an exploratory probe, before treatment (baseline) and after 5 min, 1 week, and 4 weeks. When patients presented more than one tooth with CDH, the mean of the values obtained was calculated. Irradiation with Nd:YAG laser was performed twice in the mesial-distal and twice in the occlusal-gingival direction. The NovaMin®-containing paste was applied with a rubber cup at low speed for 60 s. Patients of the placebo group received simulations of the two treatments. As the data presented normal distribution, the two-way ANOVA repeated measures test was used.

Results In all the experimental times, reduction in pain was demonstrated in comparison with baseline for all treatments ($p < 0.05$); however, there was no difference among the experimental groups in any of the time intervals evaluated ($p > 0.05$).

Conclusion All treatments were equally effective in reducing the pain of CDH.

Clinical relevance Nd:YAG laser irradiation and the calcium sodium phosphosilicate paste could reduce the symptoms of CDH; thus, they stand out as viable alternatives for the treatment of this condition.

Keywords Cervical dentin hypersensitivity · Calcium sodium phosphosilicate · Nd:YAG laser · Non-carious cervical lesion · Clinical study

✉ Ana Cecilia Correa Aranha
acca@usp.br

¹ Department of Restorative Dentistry, School of Dentistry, University of São Paulo, Av. Prof. Lineu Prestes 2227, São Paulo, SP 05508-000, Brazil

² Department of Periodontics, School of Dentistry, University of São Paulo, Av. Prof. Lineu Prestes, 2227, São Paulo, SP 05508-000, Brazil

³ Special Laboratory of Lasers in Dentistry (LELO), Department of Restorative Dentistry, School of Dentistry, University of São Paulo, Av. Prof. Lineu Prestes, 2227, São Paulo, SP 05508-000, Brazil

Introduction

With the reduction in the incidence of caries disease, in response to the successful oral health promotion strategies, more attention has been paid to other oral conditions, such as non-carious cervical lesions (NCCLs) [1]. These lesions are defined as loss of dental structure at the cemento-enamel junction (CEJ), unrelated to bacterial activity [2–4]. Taking into consideration the region above the cemento-enamel junction, the most important factor for dentin exposure is the occurrence of a NCCL; therefore, they are considered the predisposing factor for cervical dentin hypersensitivity (CDH) [5].

Classically, CDH has been defined as an acute pain of short duration resulting from typically evaporative, osmotic, chemical, tactile, or thermal stimuli incident on an area of exposed dentin, which cannot be attributed to any other

dental defect or pathology [4, 6]. In the literature, the prevalence of DH in the different populations studied may vary widely between 3.8 and 85% [7–12]. This may be explained by the methodological differences of each study and the different populations studied, as well as their dietary habits, such as the frequency of consuming foods and drinks with low pH [8]. The most accepted mechanism for explaining the origin of pain in CDH is the hydrodynamic theory, proposed by Brännström in 1964. According to this theory, when the dentinal fluid present in the tubules is moved by some stimulus, there is an increase or change in the direction of flow, resulting in activation of the δ -A fibers adjacent to the odontoblasts, and causing pain [13].

With the increase in life expectancy of the population, it is correct to deduce that people will maintain their natural dentition in the oral cavity for a longer period of time and that NCCLs accompanied by CDH will probably become more prevalent [5]. Concomitantly, new dietary habits, such as the frequent consumption of acidic food and beverages, will lead to an increased wear of the teeth, and consequently, CDH [5, 14].

There are two strategies for the treatment of CDH, desensitizers with neural or obliterating action. The products with neural action have the objective of blocking neural activity, resulting in depolarization of nerve fibers such as potassium nitrate, oxalates, and low-power laser therapy (photobiomodulation) [15]. When it comes to tubular occlusion, several treatments can be mentioned, such as glutaraldehyde, varnishes, oxalates, bioglass, and high-power lasers. Because of the large variety of treatments available, with different results, the most adequate choice of treatment for CDH continues to be a challenge to clinicians [16].

The active agent calcium sodium phosphosilicate (CSP) is an inorganic, amorphous (bioglass) compound found in different products with the purpose of combating the symptoms of CDH [17]. NovaMin is the commercial name for a formulation of CSP. This bioglass reacts in an aqueous medium and releases hydroxycarbonate apatite (HCA), a mineral compound similar to that of enamel and dentin [18].

Another option for the treatment of CDH is low- and high-power lasers that could be considered as an innovative and contemporary approach for CDH. They act through photothermal effects, causing melting and recrystallization of the dentin surface, thus promoting blockage of the dentinal tubules [19]. The Nd:YAG lasers are most indicated for this purpose, since they generate a glazed surface that partially or totally obliterates the dentinal tubules. However, few studies are available to show its effectiveness.

In view of the foregoing, the aim of this randomized clinical trial was to evaluate the effect of desensitizing treatments based on a prophylaxis paste containing 15% CSP (NovaMin®) and irradiation with Nd:YAG laser, on reduction of the pain of CDH after 1 month of clinical follow-up.

Materials and methods

Ethical aspects and study design

This clinical study was a placebo-controlled, randomized, double-blind and parallel clinical trial. It was conducted in accordance with the criteria described in the Helsinki Declaration (World Medical Association Declaration of Helsinki, 2008). The study was approved by the Research Ethics Committee of the Dental School of the University of São Paulo - CEP FOU SP (Report No. 2291636) and was registered in the Brazilian Register of Clinical Trials (“Registro Brasileiro de Ensaios Clínicos – REBEC”) (U1111-1213-5135).

Design description

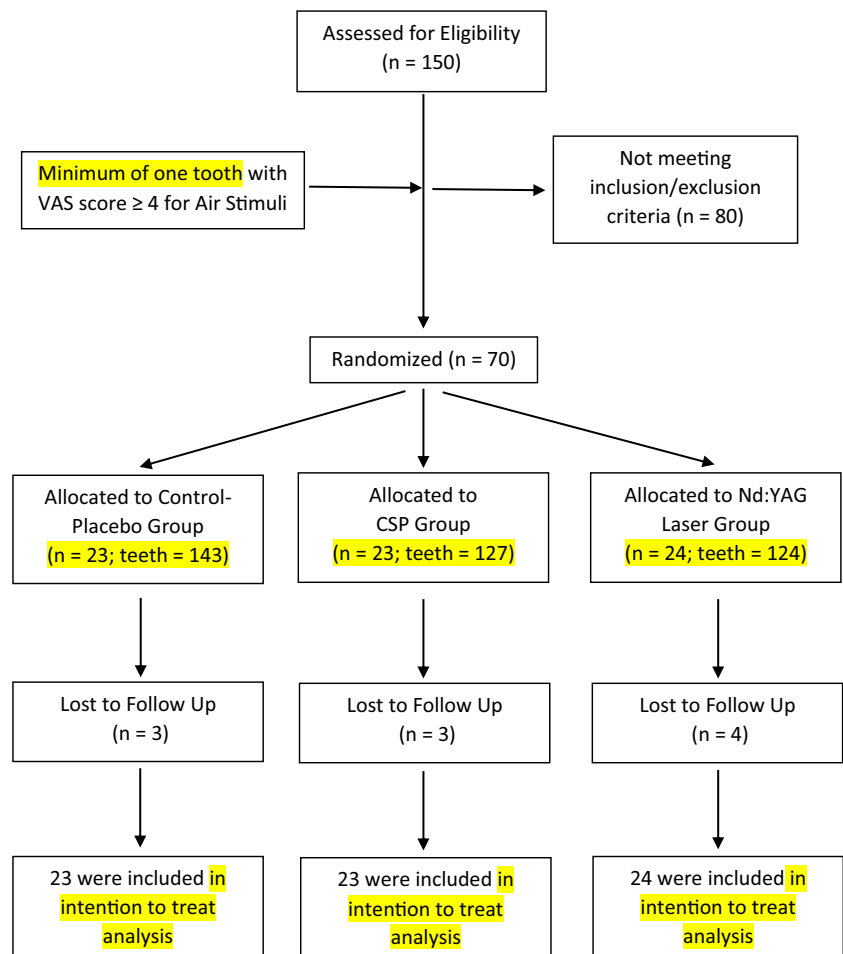
Patients in the age range 18–65 years, of both sexes, with non-carious cervical lesions and/or gingival recessions associated with dentin exposure and symptoms of CDH, and with at least one tooth with a minimum pain level of 4 cm on the visual analog scale (VAS), were included in this study. Diagnosis was made in the first clinical evaluation by means of visual inspection and evaporative tests with jet of air. Pregnant patients or those in the breast-feeding stage, those who made continuous use of analgesic or anti-inflammatory medications, those with active caries lesions or deficient restorations, those undergoing orthodontic treatment, and those with deficient oral hygiene or loss of dental structure that would need restorative treatment were excluded from the study, since these conditions could directly interfere in the results of evaluations.

The sample calculation was based on comparison of the means, with an expected minimum difference of 2 units between the initial and final values of the VAS and standard deviation of 2. Considering an α of 5% and power of 80%, 26 patients per group would be required.

Randomization was performed by a researcher not involved in the study, using the Excel program of the Microsoft Office package. Stratified randomization was performed, considering two strata: moderate (4–6.9 cm) and severe (7–10 cm) pain. Allocation concealment was implemented with sequentially numbered opaque sealed envelopes. Each envelope was only opened by the researcher at the time of performing the treatment. The patients and evaluators did not know what the designated allocation was. The researcher did not know the patients' level of pain.

Seventy (70) patients fulfilled the inclusion criteria in this study and were divided into three groups: 23 patients in the control-placebo group (without treatment), 23 in the group for prophylaxis with CSP paste (NovaMin), and 24 in the group for Nd:YAG laser irradiation. A flowchart of the study can be observed in Fig. 1.

Fig. 1 Flowchart of the study



Pain assessment

After applying each stimulus, the patient was asked to measure the degree of pain by means of a visual analog scale (VAS). This method consisted of a line with 100-mm marks, with its extremities marked “No Pain” and “Unbearable Pain.” On the back part of the scale, invisible to the patient, there was a millimetric ruler 10 cm long. When pulling the cursor of the scale, the patient marked the level of his/her pain between the extremes. From this mark, the distance run was measured on the ruler. Each patient received personalized instructions about how to indicate the intensity of his/her pain. A simple arithmetic mean value was calculated between the marks made per patient when more than one tooth was selected. Each patient made a pain measurement after an evaporative stimulus, with a jet of air applied in the cervical region of the tooth for 3 s at a distance of 1 mm with a pressure of 40 psi, and under relative isolation, covering the neighboring teeth with cotton wool rolls. Another measurement was made after tactile stimulation, with the exploratory probe in contact on the cervical region, passing over the mesial to the distal region and vice-versa under constant pressure. The evaluations were made in

the first session (baseline) and at time intervals of 5 min, 1 week, and 4 weeks after the treatments were performed.

Interventions

All the treatments were performed by the same researcher. The stimuli and pain measurements were made by two previously calibrated evaluators. After clinical exam and anamnesis, the patients received treatment in accordance with their allocation. CSP patients received the treatment with 15% CSP prophylaxis paste (NUPRO Extra Care powered by NovaMin, Dentsply professional, lot 16050201), applied on the vestibular surface of the selected teeth, with a rubber cup at low speed for 60 s in accordance with the manufacturer’s instructions. Afterwards, the surfaces were washed with water and the patient performed a mouth rinse.

Laser patients received irradiation in the vestibular and cervical regions of the selected teeth, with Nd:YAG laser (Power Laser, Lares Research, San Clemente, CA, USA, process FAPESP 07/55497-0). The equipment worked in a pulsed manner, with a pulse width of 150 μ s and a fixed repetition rate of 10 Hz. Its energy system operated by means of a quartz

fiber optic of 400 μm . Irradiation was performed with the fiber optic perpendicular to the tooth, in contact mode. Four (4) irradiations were made with scanning movements: two in the mesio-distal and two in the occlusal-gingival directions. Each irradiation was made for up to 15 s, with an interval of 10 s between each irradiation, time necessary for thermal relaxation of dentin. The parameter used was 1 W of power, repetition rate of 10 Hz, 100 mJ of energy, and 85 J/cm² of energy density. Protective goggles were used, and compliance with other biosafety rules was ensured.

Control/placebo patients received simulations of the two treatments. Prophylaxis with Nupro® paste was simulated with a rubber cup and water, taking care that the cup did not touch on the cervical region of the teeth in question, to prevent any possible change in the dentin structure, such as obliteration of tubules. Irradiation with Nd:YAG laser was simulated with the laser switched on, but with the display exhibiting 0 W and with the guide light only. Both the patient and operator wore protective goggles and followed all the conventional safety rules normally used in this procedure.

Statistical analysis

By means of descriptive analysis, the results were analyzed separately for the stimuli applied (air spray and exploratory probe), verifying possible significant differences among the groups and follow-up time intervals considered. For all the stimuli applied, the VAS was used to evaluate the painful sensation. Because this concerned a subjective response, since each individual has his/her own pain threshold, the difference in pain threshold among the volunteers was also taken into account in the different experimental time intervals.

Initially, the Kolmogorov-Smirnov test with Lilliefors correction was used to verify normality, and the Levene test was used to verify homogeneity of variances. Since normality and homogeneity of variances were met, repeated measures analysis of variance was used to verify differences between the groups and the changes over the course of time. Differences between groups and experimental periods were verified with post hoc Newman-Keuls test. The significance level was set at 5%.

Results

Evaporative stimulus

In Table 1, the differences in mean pain values per treatment performed may be observed. In the evaluation after 5 min, it was possible to note that there was a drop in the pain levels that remained relatively stable among the remaining post-treatment time intervals. According to the repeated measures ANOVA, there was no significant effect of the group factor

Table 1 Mean (standard deviation) for CDH level—air blast

Group	Baseline	5 min	1 week	4 weeks
Placebo	7.24 (1.62)	<i>4.83</i> (1.96)	<i>5.18</i> (2.31)	<i>4.70</i> (2.62)
NovaMin	6.99 (1.51)	<i>5.02</i> (2.40)	<i>4.93</i> (2.08)	<i>4.43</i> (2.30)
Nd:YAG	6.85 (1.64)	<i>5.07</i> (2.02)	<i>4.34</i> (2.14)	<i>4.29</i> (2.66)

In rows, italicized numbers mean difference in comparison with baseline with $p \leq 0.05$, according to the Newman-Keuls test

($p = 0.80$) and in the interaction between groups and time ($p = 0.62$). There was a significant effect of the time factor, that is, it was possible to verify that there was significant change in the mean pain value between the time intervals, irrespective of the group ($p \leq 0.001$).

According to the Student-Newman-Keuls post hoc test, there was a reduction in pain in all groups, when all experimental time periods were compared to the baseline ($p \leq 0.01$). There were no significant differences between the groups at any of the experimental time periods.

Table 2 shows the mean values for pain reduction (baseline–4 weeks). These results were analyzed by one-way ANOVA, and no difference between groups was observed ($p = 0.99$).

Tactile stimulus

Table 3 represents the mean pain values, per treatment performed. It was possible to note that the variation in the means of the groups did not follow the same pattern for all treatments, and only the group Nd:YAG presented constant reduction in the mean pain value over the course of time. The results of repeated measures ANOVA showed that there was no significant effect of the group factor ($p = 0.99$). There was a significant effect of the time factor ($p \leq 0.001$), and the interaction group \times time was also significant ($p = 0.03$). According to the Student-Newman-Keuls post hoc test, significant difference was verified between all the time periods in comparison with baseline, but only for the placebo and Nd:YAG groups. There was no significant difference between groups in any of the experimental time periods.

Table 4 presents the mean values for pain reduction of the groups (baseline–4 weeks). These results were analyzed by one-way ANOVA, and no difference was verified between groups.

Table 2 Reduction in CDH level—air blast (baseline–4 weeks)

Group	Mean	Standard deviation	<i>p</i>
Placebo	2.53	2.28	0.99
NovaMin	2.55	1.97	
Nd:YAG	2.55	2.20	

Table 3 Mean (standard deviation) for CDH level—probe

Group	Baseline	5 min	1 week	4 weeks
Placebo	2.15 (1.94)	<i>0.80</i> (1.21)	0.96 (1.42)	<i>1.37</i> (1.57)
NovaMin	1.28 (1.42)	0.72 (1.15)	1.05 (1.35)	0.83 (0.87)
Nd:YAG	1.33 (1.45)	<i>0.55</i> (1.08)	<i>0.37</i> (0.55)	<i>0.31</i> (0.54)

In rows, italicized numbers mean difference in comparison with baseline with $p \leq 0.05$, according to the Newman-Keuls test

Discussion

The present study compared the immediate and later effects (5 min and 4 weeks, respectively) of Nd:YAG laser and a paste containing 15% CSP in reducing the pain in CDH, compared with a placebo group. By means of the VAS, the patients indicated the degree of dentin hypersensitivity in response to the evaporative stimuli with air blast and tactile stimulus with the exploratory probe. In all the experimental times evaluated, no statistically significant differences were observed among the groups, because all the treatments diminished the painful sensation in equal proportion.

Due to the important technological advances and improvements in public health policy over the last few decades, the world population is living for a longer time and with better quality of life. The abovementioned factors associated with the reduction in caries indexes and the greater access to health care and awareness of the population relative to taking care of oral hygiene; there is increased probability of persons keeping their natural teeth in the oral cavity for a longer period of time. With an increasingly stressful routine, a large portion of the population has the propensity to develop parafunctional habits. Furthermore, new eating habits, with added frequency of ingesting industrialized products that have a low pH, have considerably increased [20, 21].

The pain reported by the majority of patients in this study was described as an acute pain, in response to an external stimulus that differed for each patient. For some, the pain was triggered by sharp changes in temperature, such as by ingesting cold foods or even variations in ambient temperature. For others, acid or sweet foods were the pain triggers. In many cases, the symptoms were very intense and were an inconvenience to the patients, interfering directly in their quality of life. All of these characteristics are well described in the scientific literature [22, 23]. Knowledge about the painful

Table 4 Reduction in CDH level—probe (baseline–4 weeks)

Group	Mean	Standard deviation	<i>p</i>
Placebo	0.77	1.70	0.59
NovaMin	0.44	1.30	
Nd:YAG	1.02	1.31	

symptomatology related to CDH is one of the first steps in making a differential diagnosis.

In this study, the authors opted to use the VAS for evaluating the patients' pain. The use of this scale is considered as an adequate, reproducible method that is easily understood by patients [24] and has been used in the majority of clinical studies on the same topic.

Evaluation was made after applying evaporative and tactile stimuli. Evaporative stimulus by means of an air blast was used under relative isolation of the target tooth, by protecting the adjacent teeth, because the blast of air could attain more than one tooth and change the results. This type of test is more precise when compared with the tactile method, because the air attains the entire cervical region of the tooth simultaneously, diminishing the chances of a false negative result, whereas the tactile test produces results with greater dispersion, because the probe needs to touch a specific region with exposed dentin to produce pain, and it is frequently impossible to differentiate these areas clinically. This greater variation in the tactile test may be noted from the high standard deviation values found in the analysis of the results of this study. As dentin hypersensitivity may differ depending on the nature of the stimulus, two methods were used in the present study [25].

As pain is a subjective variable, it must not be compared in absolute values between different individuals, because each person has a unique threshold of tolerance. Therefore, an individual who marked pain at 10 cm must not be considered a more severe case than that of another individual with pain at 6 cm, for example. In this sense, it was necessary to work with individual mean values, when more than one tooth was being treated, and the mean values per group. Furthermore, an additional analysis comparing the pain reduction between the initial and final time intervals was made.

Clinical studies about CDH, particularly those that involve desensitizing agents, or those with use of technologies tend to have an expressive placebo effect and may vary between 20 and 60% from the values obtained at baseline [26, 27]. In the present study, this effect was also observed. Hypothetically, diverse factors may contribute to the sensation of improvement of patients, such as the very fact that they are participating in a research, by the personalized attendance, by opportunity of treatment at a center of reference in research, and by the use of technologies [19, 28]. Some strategies were implemented to minimize the placebo effect, such as instructing the patients about the possible ineffectiveness of the treatments; the possibility of being allocated to a placebo group and the double-blinded (of both patient and evaluator) design itself of the study [28]. In spite of these strategies, the placebo group was observed to present significant reduction in the pain levels over the course of the evaluation time, not differing from the other treatment groups.

The other two experimental groups tested in this study (laser and bioglass) had mechanisms of action with the same

purpose: obliteration of the dentinal tubules (as recommended by the hydrodynamic theory); however, Nd:YAG laser also presents neural action by interfering in the mechanism of the Na⁺ and K⁺ pumps, changing the cell permeability, and/or altering the sensory nerve terminals of the axons [29–31].

Different available products to clinicians have similar effects of CSP, such as potassium oxalate and glutaraldehyde [32, 33]. Potassium oxalate decreases hydraulic conductance as it forms precipitates into the tubules and may be considered as an obliterating desensitizer in the treatment of CDH, apart from presenting a neural action as well [34, 35]. Glutaraldehyde is water soluble and reaches deep penetration, promoting the formation of precipitates, coagulation and blocking tubules [36, 37]. Concerning the CSP, it has demonstrated promising results for tubular occlusion and pain relief [38–41]. CSP can be found in in-office prophylaxis pastes as well as in toothpastes, in different concentrations [42]. It has been stated that CSP occludes dentinal tubules more efficiently than glutaraldehyde [43, 44].

The capacity for alleviating pain immediately after the use of CSP was clinically proved in this study. The results obtained with the evaporative tests suggested that this bioglass formulation reduced the pain of patients, immediately after application and with later action, though as much as control-placebo group did. Precipitation of the active agents of the paste with CSP diminished the symptoms of CDH by tubular occlusion and was resistant for the evaluated period of 4 weeks. These findings were in agreement with those of other studies that evaluated the obliterative potential of CSP [38, 39]. However, after tactile stimuli with the exploratory probe, no reduction in pain was perceived in any of the experimental time intervals. The variation in pain over the course of the attendances did not differ statistically from the results obtained in the initial consultation (baseline). With the application of CSP, a layer of crystals was created on the dentin surface, and it was supposed that during passage of the exploratory probe, this layer was removed, and thus did not resist the tactile test. Therefore, the tubules over which the probe passed were exposed, and consequently, there was a painful response. The results found in this study were partially proved by the literature in other randomized clinical trials [40, 41].

In this study, the authors chose to use Nd:YAG laser because, among the high-power lasers, it has been considered the most effective for tubular obliteration and consequent reduction in CDH [45]. Moreover, some studies in the literature have reported an additional analgesic effect associated with the use of this laser, probably related to blockage of the C and A β fibers, and by temporary change in the final portion of the sensory axons [30, 31]. The potential of other wavelengths of high-power laser for the treatment of CDH has been demonstrated in many studies. The erbium lasers (Er:YAG and Er,Cr:YSGG) can cause superficial evaporation of the dentinal fluid, reducing its movement. As a consequence, a

reduction can be seen in pain levels [46, 47]. So, erbium lasers may be considered for CDH treatment, although it seems to present a short recurrence of pain [48]. Other studies report the use of CO₂ laser for CDH treatment. It has been found that when combined with calcium hydroxide paste, it can promote clinical CDH reduction, diminishing dentin permeability and sealing dentinal tubules [49, 50].

Based on a review of the literature elaborated for this study, the authors chose to use the Nd:YAG laser with a protocol of 1 W of power, 100 mJ of energy, and $\cong 85$ J/cm² of energy density, with four irradiations on the cervical region of the teeth. Similar protocols have previously been tested in other studies that analyzed the effects of this irradiation on dentin, by means of image analyses by SEM, as well as clinically [51–54].

In this study, the effectiveness of irradiation with Nd:YAG laser on pain reduction could be noted immediately after treatment, comparable to the results of control-placebo group. After reduction, the mean pain value remained stable during the time intervals of evaluation in this research. The results obtained after tactile stimulation were also similar, with immediate reduction in pain, which remained with lower levels during the other time intervals evaluated. However, during the time of irradiation, all the patients reported pain, similar to that cause by the blast of air. Nd:YAG laser acts by means of photothermal effects, increasing the temperature of the irradiated surface. This sudden change in temperature was responsible for causing a painful response during treatment. Important to emphasize was that as soon as irradiation was concluded, the pain also ceased. The findings of the present study were in agreement with the findings in the literature that showed favorable results for Nd:YAG laser [54–56]. Nevertheless, there is great variation in protocols, making it extremely difficult to draw general conclusions. The results obtained with the laser are closely related to the parameters chosen, and the latter are determinants for the success of treatment.

The fact that the tubules were not sealed in some of the micro-areas may explain why some patients felt pain even after treatment with Nd:YAG laser. As irradiation depends on interaction of molecules of the tissue (particularly pigments, where Nd:YAG laser is concerned), a tooth that presents slightly pigmented dentin would not absorb the radiation in the same proportion as more pigmented teeth, thus resulting in a less effective treatment [57].

During the course of this study, it was observed that for some patients, none of the treatments were effective, namely 2 patients from the control-placebo group, 2 from the CSP group, and 3 from the Nd:YAG laser group. For these participants, the initial pain level did not vary over the course of time. Moreover, these patients presented symptoms compatible with those of CDH but did not have clinical signs of the disease, such as NCCLs and gingival recessions. As the

disease is a cumulative, multifactorial, and progressive process, initial lesions are frequently not visible, precisely because they are localized at subgingival level. In this situation, both the paste and the laser were incapable of attaining the regions of exposed dentin, and therefore, we could infer that the paste and Nd:YAG laser would not be clinically indicated for these cases. On the other hand, patients who also presented no clinical signs of the disease reported improvement, probably by changing their eating habits and lifestyle. For these patients, other alternatives can be used, such as therapy of photobiomodulation with low-power level lasers, flowable chemical desensitizers (e.g., glutaraldehyde and oxalates), occlusal adjustments, and associations of protocols [34, 36, 58, 59]. Apart from that, the clinician must always determine etiological factors of LCNC prior to the recommendation of a desensitizing treatment in order to stop the progression of the disease.

Conclusion

There were no differences between calcium sodium phosphosilicate paste, Nd:YAG laser, and placebo in reduction of pain related to CDH, for both immediate and lasting effects.

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Compliance with ethical standards

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

Ethical approval All procedures performed in studies 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.

Informed consent Informed consent was obtained from all individual participants included in the study.

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