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Clinical Effects of Desensitizing Prefilled Disposable Trays in In-office Bleaching: A Randomized Single-blind Clinical Trial

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Clinical Relevance

The prefilled disposable tray can be used to decrease self-reported tooth sensitivity without influencing the bleaching efficacy.

SUMMARY

Objectives: This study aimed to evaluate the desensitizing effect of a prefilled disposable tray containing potassium nitrate and fluoride on the self-reported tooth sensitivity (TS) and the bleaching efficacy of 40% hydrogen peroxide bleaching agent used for in-office bleaching in comparison with potassium nitrate and fluoride gel applied in a conventional-delivered tray system in an equivalence clinical trial.

Methods and Materials: Seventy-eight patients, with a right maxillary canine darker than A3, were selected for this single-blind (evaluators), randomized clinical trial. Teeth were bleached in two sessions with a one-week interval in between. Before in-office bleaching, the prefilled disposable tray or conventional tray containing potassium nitrate and fluoride was used for 15 minutes. Subsequently, the bleaching agent was applied in two 20-minute applications (per the manufacturer's directions) in each session. The color change was evaluated by subjective (Vita Classical and Vita Bleachedguide) and objective (Easyshade Advance Spectrophotometer) methods at baseline and 30 days after the first bleaching session. TS was recorded for up to 48 hours using a 0-10 visual analog scale. The absolute risk was evaluated by chi-square test, while

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the intensity of TS was evaluated by McNemar test (α=0.05). Color change in shade guide units and ΔE was analyzed by Student *t*-test for independent samples (α=0.05).

Results: Significant whitening was observed in both groups after 30 days of clinical evaluation. The use of different methods of desensitizer in a tray did not influence the absolute risk and intensity of TS ($p>0.05$), although a tendency of lower risk of TS with the prefilled disposable tray containing potassium nitrate and fluoride was observed.

Conclusion: The use of a prefilled disposable tray containing potassium nitrate and fluoride before the application of the in-office bleaching product did not affect the whitening degree and decreased self-reported TS when compared with a conventional-delivered tray system.

INTRODUCTION

Tooth bleaching represents the most common elective dental procedure for treatment of discolored teeth,[1] and according to Dutra and others,[2] an estimated more than 1 million Americans whiten their teeth annually, driving nearly $600 million in revenues for dental offices. A great part of the success of the bleaching therapy is that this procedure is a very conservative, simple, and low-cost procedure.[3]

Unfortunately, tooth sensitivity (TS) is the most frequently reported side effect associated with bleaching, particularly with in-office bleaching protocols that employ relatively high concentrations of hydrogen peroxide.[4-6] Even though the sensitivity will be only transient and will be resolved a few days after the end of the bleaching procedure, it is an unpleasant experience[7,8] and can be severe and irritating enough to lead patients to withdraw from treatment in some cases.[9]

This adverse effect has motivated clinicians and researchers to develop strategies for the prevention of bleaching-induced TS.[1] Several approaches, such as administration of analgesics, anti-inflammatories, antioxidants, and corticosteroids,[10-13] have failed to minimize this side effect caused by bleaching products. The most useful and effective agent for the management of bleaching-induced TS is potassium nitrate associated or not associated with sodium fluoride when compared with a placebo group.[14-17]

A recent systematic review[18] showed that usually a 3%-5% potassium nitrate gel was applied for 10-30 minutes prior to the in-office bleaching procedure in a tray or directly in the office.[14-17] Only recently, as a response to the demand for an alternative way of bleaching, a new product has become available on the market: a prefilled disposable tray containing potassium nitrate (UltraEZ, Ultradent Products Inc, South Jordan, UT, USA). Prefilled disposable tray systems are comfortable and have a low cost, as the professional does not need to fabricate a custom bleaching tray (impression, model buildup, tray fabrication, etc), and the procedure can be done at home[19] or in the office in the waiting room immediately before in-office bleaching. However, to the extent of our knowledge, no clinical studies have been performed comparing potassium nitrate–based products delivered via different methods, which was the main objective of the present study.

Therefore, the aim of this equivalent clinical trial was to compare bleaching-induced TS between the application of a prefilled disposable tray containing a desensitizer agent prior to in-office bleaching and a conventionally delivered tray system with a desensitizer agent. The following null hypotheses were tested: 1) the preventive use of desensitizer agents in different trays will not affect the absolute risk and intensity of bleaching-induced TS, and 2) the preventive use of desensitizer agents in different trays will not affect the color change after bleaching.

METHODS AND MATERIALS

Study Design

This was a randomized, single-blinded (evaluators) equivalence trial with an equal allocation rate between groups. This clinical trial was approved by the Local University Ethics Committee (59645816.3.0000.5020). The study was also registered on the Clinical Trials website and took place within the dental clinics of the two universities from September 2015 to February 2016.

Inclusion and Exclusion Criteria

Participants were examined in a dental chair after dental prophylaxis with pumice and water to check whether they met the study's eligibility criteria. To be included in this study, participants had to be aged 18 years or older and have good general and oral health. Participants had to have at least one shade A3 or darker canine as assessed by a value-oriented shade guide (VITA classical, Vita Lumin, Vita Zahnfabrik, Bad Säckingen, Germany) and had to have at least six anterior maxillary sound teeth. Participants with restorations on the labial surface

of their anterior teeth and noncarious cervical lesions, with full crowns or veneers, visible cracks, gingival recession, endodontically treated teeth, spontaneous tooth pain, or internal tooth discoloration were excluded from this study. Patients who had teeth that had fluorosis, patients who were pregnant or lactating, and patients who had bruxism habits were also excluded from this study.

Sample Size Calculation

The sample size calculation was based on the absolute risk of TS, the primary outcome of the study. If there was truly no difference between the standard and experimental treatment, then 78 patients would be required to be 90% sure that the limits of a two-sided, 90% confidence interval (CI) would exclude a difference between the standard and experimental group of more than 30%.

Random Sequence Generation and Allocation Concealment

Seventy-eight participants were selected according to the inclusion and exclusion criteria for bleaching with Opalescence Boost (Ultradent Products Inc). One group applied a desensitizer agent in a conventional-delivered tray system (Desensitizer KF2%, FGM Ind, Joinville, SC, Brazil), and the other applied the desensitizer in a prefilled disposable tray (UltraEZ, Ultradent Products Inc). A third operator, not involved in the research protocol, conducted the randomization procedure by using computer-generated tables. A blocked randomization (block sizes of two) was used with an equal allocation ratio (www.sealedenvelope.com). The same operator placed the identification groups in sequentially numbered, opaque, and sealed envelopes. Once the participant was eligible for the procedure and had completed all baseline assessments, the operator could open the envelope. Neither the participant nor the operator knew the group allocation before this stage.

Study Intervention

To maintain the allocation concealment before starting the bleaching procedure, a custom-fitted tray was made for all patients. For this purpose, an alginate impression of each subject's maxillary and mandibular arch was made and filled with dental stone. To produce study models, block-out material to the labial surfaces of teeth was not applied. A 1-mm soft vinyl material, provided by the manufacturer, was used to fabricate the custom-fitted tray for the desensitizer gel. The excess material on the labial and lingual surfaces was cut 1 mm from the gingival junction.

Before each bleaching session, subjects were instructed to wear the conventional-delivered tray system containing 5% potassium nitrate and 2% sodium fluoride desensitizing gel (Desensibilize KF 2%) or the prefilled disposable tray containing less than 5% potassium nitrate and less than 1% sodium fluoride desensitizing gel (UltraEZ, Ultradent Products Inc) for 15 minutes according to the randomization of patients.

Immediately after tray removal, subjects were instructed to wash the tray and brush their teeth as usual before the in-office bleaching was performed. For this purpose, the gingival tissue was isolated with a light-cured resin dam (Opal Dam, Ultradent Products Inc). The 40% hydrogen peroxide gel Opalescence Boost (Ultradent Products Inc) was applied in two 20-minute applications (manufacturer's directions) to all maxillary incisors, canines, and premolars of the same patient (Table 1). After seven days, this procedure was repeated using the same protocol. All participants were instructed to brush their teeth at least three times a day using fluoridated toothpaste (Colgate, Colgate-Palmolive, SP, Brazil).

TS Evaluation

Patients were asked to record their perception of TS during the first and second bleaching sessions using the five-point Numeric Rating Scale (NRS; 0 = *none*, 1 = *mild*, 2 = *moderate*, 3 = *considerable*, and 4 = *severe*). Subjects were asked to record their experience with TS during the treatment up to one hour after bleaching, from one hour to 24 hours after bleaching, and from 24 hours to 48 hours after bleaching. They were also asked to record whether or not they experienced TS during the 30-day period after bleaching. As two bleaching sessions were performed, the highest NRS score obtained in both bleaching sessions was considered for statistical purposes.

Color Evaluation

Color was recorded before the bleaching procedure and seven days and 30 days after the end of the bleaching treatment using an objective method (Easyshade Advance spectrophotometer, Vident, Brea, CA, USA) and a subjective method (value-oriented shade guide Vita Classic and Vita Bleachedguide). Color evaluation was done in a room under artificial lighting conditions without interference

Table 1: *Products, Composition, and Application Regimens*

Products	Composition[a]	Groups	Application Regimen
Opalescence Boost	Gel: 40% hydrogen peroxide, 20% water and desensitizing agents (3% potassium nitrate and 1.1% fluoride)	Conventional delivered-tray group: Desensitizer KF2 was applied for 15 minutes in a conventional-delivered tray system before the start of the in-office bleaching application (contains 2% sodium fluoride and 5% potassium nitrate)	1. Dry teeth and apply Opal Dam to dental arch slightly overlapping enamel (building the barrier 4- to 6-mm high and 1.5- to 2.0-mm thick) and interproximal spaces. 2. Light cure Opal Dam for 20 seconds per arch using a scanning motion. Carefully check the resin cure with an instrument. 3. Attach both syringes before mixing. Press the plunger of the red syringe in, pushing all the contents into the clear syringe. Forcefully press the small clear stem completely into the larger clear stem. Then press the clear plunger completely into the red syringe. To activate, press the chemical from the red syringe into the clear syringe with thumbs. Reverse action, and mix a minimum of 25 times on each side. 4. Press all mixed gel into the RED syringe. Separate the two syringes and attach the Micro 20ga FX tip onto the red syringe. 5. Apply a 0.5- to 1.0-mm-thick layer of Opalescence Boost to the labial surface of the tooth and slightly onto the incisal surfaces. 6. Leave gel on for 20 minutes. 7. Suction off using a surgical aspirator tip. Do not use water. 8. Repeat gel application for another 20 minutes (40 minutes total). 9. At the end, suction all the gel off, then wash and apply suction. 10. Remove gingival barrier by lifting it from one end.
		UltraEZ prefilled tray group: UltraEZ was applied for 15 minutes before the start of the in-office bleaching application (prefilled disposable tray contains <5% sodium hydrogen, <1% sodium fluoride, and <5% potassium nitrate)	

[a] *According to the manufacturer.*

from outside light. For both devices, color was checked at the middle third of the canine.

For the objective shade evaluation, an impression of the maxillary arch with high-putty silicon paste (Clonage, Nova DFL, Rio de Janeiro, RJ, Brazil) was taken, and a window on the labial surface of the silicon guide was created using a metal device with a 6-mm radius. The purpose of this was to standardize the area for color evaluation in all recall periods with the spectrophotometer. Color was determined using the parameters of the digital spectrophotometer on which the following values were indicated: L*, a*, and b*, where L* represented luminosity (the value from 0 [black] to 100 [white]), and a* and b* represented color along the red-green axis and the color along the yellow-blue axis, respectively. The difference between the baseline and each recall period (ΔE^*) was calculated using the following formula: $\Delta E^* = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$. For the subjective evaluation, the 16 tabs of the shade guide (VITA classical, Vita Lumin, Vita Zahnfabrik, Bad Säckingen, Germany) and the 29 tabs of the shade guide (Vita Bleachedguide, Vita Lumin, Vita Zahnfabrik, Bad Säckingen, Germany) were arranged from whitest to darkest. For calibration purposes, 10 participants whom we did not include in the study sample participated in the training phase. The two examiners scheduled these patients for bleaching and evaluated their teeth against the shade guide at baseline and once again two days after. The two evaluators presented superior color-matching competency according to the ISO/TR 28642.[20] This means that they had an agreement of at least 85% (Kappa statistic) before beginning the study evaluation (85% of correctly matched pairs of tabs in shade guides). If disagreements occurred during the evaluation, they needed to reach a consensus before the participant was dismissed.

Statistical Analysis

The analysis followed the intention-to-treat protocol and involved all the participants who were randomly assigned in the study. The statistician was blinded to study groups. The color change (primary outcome) was used to determine the efficacy of the bleaching treatment. The color change (ΔShade Guide Unit [SGU] and ΔE) between the baseline and 30 days was calculated for each group. The ΔE and ΔSGU data were subjected to paired Students' *t*-test. We compared the study group's absolute risk of TS using the chi-square test. The CI for the effect size was calculated. The comparison of the TS intensity

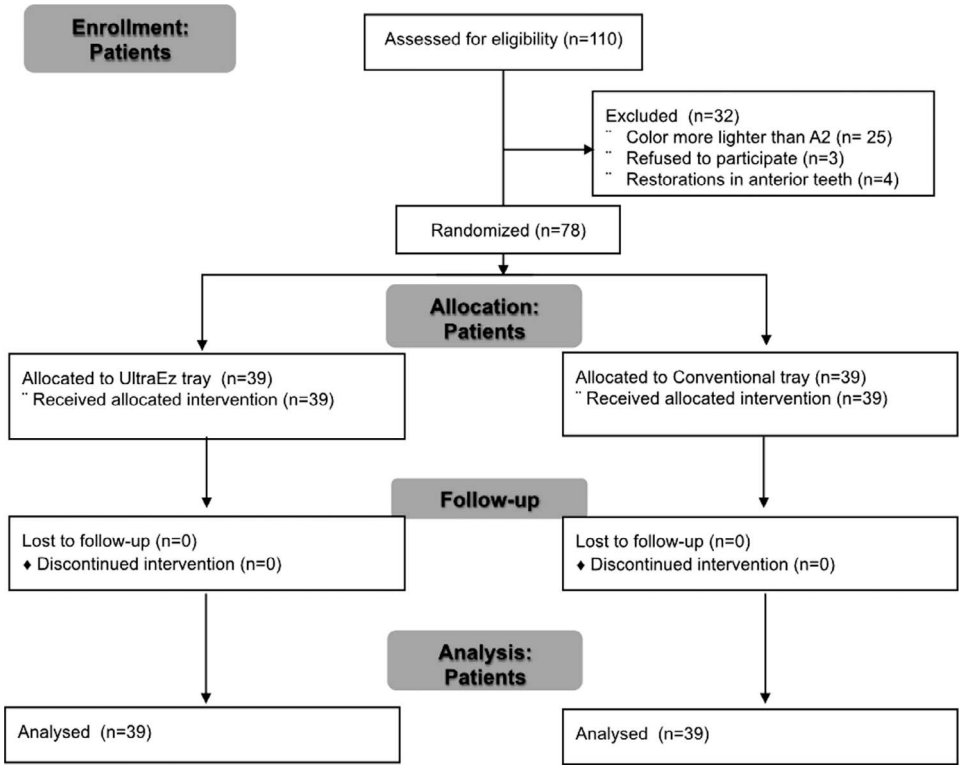

Figure 1. *CONSORT flow diagram detailing the recruitment and enrollment of the clinical trial.*

among time assessments for each group was performed using the McNemar test. The comparison of the intensity of TS among each group for different assessment points (during and following the bleaching process) was performed by applying the McNemar test. In all statistical tests, the alpha was preset at 0.05.

RESULTS

A total of 110 participants were examined in a dental chair to determine if they met the inclusion and exclusion criteria. A total of 79 patients were included in this clinical study (Figure 1). The mean age (years) of the participants and the baseline SGU are described in Table 2. One can observe comparable data among treatment groups by ensuring the comparability of the baseline features. None of the patients discontinued the intervention or presented adverse effects during the intervention. No medication and/or desensitizer were necessary to be prescribed or applied to the participants from this study for the relief of bleaching-induced TS.

Tooth Sensitivity

A total of 26 patients (absolute risk: 67%, 95% CI: 51% to 79%; Table 3) reported pain in the conventional-delivered tray group. Thirty-three patients (absolute risk: 84%, 95% CI: 70% to 93%; Table 3) reported pain in the prefilled disposable tray group. No significant difference was observed between the risks of TS of the two study groups (p=0.37; Table 3).

The TS intensity of both bleaching protocols was statistically similar (p=0.38), and the overall TS intensity at different assessment points is reported in Table 4. In all time assessments, the mean difference ranged from −0.01 to −0.03 and was not clinically important (Table 4). Most of the TS complaints occurred within the first 24 hours after bleaching and moved closer to zero after 24 hours.

Table 2: *Baseline Characteristics of the Participants Included in This Clinical Trial*

Characteristic	UltraEZ Prefilled Tray	Conventional-Delivered Tray
Age, y, mean ± SD	25.8 ± 6.5	24.5 ± 5.6
Baseline color, mean ± SD [median; interquartile range]		
SGU Vita Classical	10.1 ± 2.8 [9; 9-11]	10.0 ± 2.5 [9; 9-11]
SGU Vita Bleachedguide	11.3 ± 1.9 [10; 9-12]	11.0 ± 2.4 [10; 10-13]

Table 3: *Comparison of the Number of Patients Who Experienced Tooth Sensitivity (TS) at Least Once During the Bleaching Regimen in Both Groups Along With Absolute Risk and Risk Ratio*[a]

Treatment	Number of Participants With TS		Absolute Risk[a] (95% CI)	Risk Ratio (95% CI)
	Yes	No		
UltraEZ Prefilled Tray	26	13	67 (51-79) A	1.27 (0.97-1.64)
Conventional-delivered tray	33	06	84 (70-93) A	

[a] *McNemar test (p=0.27). Risks identified with different letters are statistically different.*

Color Change

The intra- and interexaminer kappa values were 0.95 to 0.88 for Vita Classical and 0.91 to 0.91 for Vita Bleachedguide, respectively. A whitening of approximately 7 to 9 SGUs and a ΔE of approximately 12 were detected for both groups 30 days after bleaching (Table 5). No statistically significant difference was observed between the study groups ($p>0.12$). For all color measurements, the mean difference ranged from −0.2 to 1.9 and was not clinically important (Table 5).

DISCUSSION

The results of the present study showed that no significant difference in terms of absolute risk and TS intensity was observed for a desensitizer gel containing nitrate potassium and fluoride applied in a conventional tray or in a prefilled disposable tray.

Regarding both substances used, the exact action mechanism of potassium nitrate and sodium fluoride for reducing bleaching-induced TS is not well understood. It is likely that fluoride prevents TS due to deposition of fluoride crystals in the exposed dentinal tubules.[21-23] However, in the present study, patients presenting teeth with visible cracks were excluded, mainly because enamel surface cracks or craze lines are potential factors in increasing bleaching-induced TS,[24] and this helps to explain the lack of preventive action of fluoride when applied alone before bleaching.[25]

On the other side, it is likely that potassium ions are the active component, and potassium nitrate works by reducing dentinal sensory nerve activity due to the depolarizing activity of the $K+$.[21,26-28] However, for this purpose, it was required that the potassium nitrate could be transported within the pulp chamber, preferably before hydrogen peroxide penetration.

Although the more useful protocol for preventing bleaching-induced TS is the topical application of substances containing potassium nitrate,[18,19,29] only recently have two papers shown that potassium nitrate penetrates the pulp chamber.[1,30] According to these papers, the transport within the tooth may be facilitated by the low molecular weight (101.10 g/mol) and water solubility of potassium nitrate gel.[1,30] Kwon and others[30] showed that this penetration occurs within the first five minutes after application, similar to hydrogen peroxide penetration,[31,32] and this is why nitrate potassium desensitizer gel needs to be applied before or together with the bleaching application.

Several factors may be involved in the potassium nitrate penetration, and one of them is material viscosity. The company that markets the prefilled disposable tray also produces the same product in syringes, and this is the most used product when applied in conventional-delivered tray systems.[19,27] However, according to Kwon and others,[1] UltraEZ (Ultradent Products Inc) in a syringe is the most viscous product when compared with other products in the market, and this characteristic negatively affects the penetration of the nitrate potassium. Unfortunately, no information is available regarding

Table 4: *Tooth Sensitivity Intensity (Means ± Standard Deviations) at the Different Assessment Points for Both Study Groups and the Statistical Comparison Along With the Effect Size (95% Confidence Interval) as Well as the* p*-Value of the Pairwise Comparison*[a]

Time Assessment	NRS Scale		Mean Difference (95% CI)
	UltraEZ Prefilled Tray	Conventional-Delivered Tray	
Up to 1 h	1.3 ± 1.7 A	1.4 ± 2.3 A	−0.1 (−1.01 to 0.81)
1 h to 24 h	1.8 ± 2.2 A	2.0 ± 1.3 A	−0.2 (−1.01 to 0.61)
24 h to 48 h	0.4 ± 0.9 B	0.7 ± 1.5 B	−0.3 (−0.86 to 0.26)

[a] *McNemar test (p=0.53) was applied for comparison of time assessments between groups, and McNemar test (p=0.38) was applied for comparison of time assessments within each group. Means identified with the same letters are statistically similar.*

Table 5: *Color Change in Shade Guide Units (SGU) and ΔE (Means ± Standard Deviations) Between Baseline and 30 Days After Bleaching for the Two Treatment Groups Along With the Effect Size (95% Confidence Interval) as Well as the p-Value of the Pairwise Comparison*[a]

Color Evaluation Tools	UltraEZ Prefilled Tray	Conventional-Delivered Tray	Mean Difference (95% CI)	*p*-Value[a]
ΔSGU (Vita Classical)	7.4 ± 2.8 A	7.6 ± 2.5 A	−0.2 (−1.40 to 1.00)	0.72
ΔSGU (Vita Bleachedguide)[b]	8.4 ± 3.4 B	9.3 ± 3.5 B	−0.9 (−2.46 to 0.66)	0.35
ΔE	12.8 ± 4.5 C	10.9 ± 4.3 C	1.9 (−0.09 to 3.89)	0.13

[a] *Student t-test. Means identified with the same letters are statistically similar.*
[b] *A numerical system using numbers 1 through 15 (corresponding to the 15 tabs) was used.*

the viscosity of Desensitizer KF2, although the manufacturer indicated that this is a low-viscosity gel, probably similar to other gels available in the market.[1]

Another factor that must be taken into account is the amount of gel applied. The proper dosage of potassium nitrate for maximum efficacy is still unknown, but it is expected that within certain parameters, a higher dosage of gel means a higher amount of gel inside the pulp chamber.

The amount of bleaching gel present in a prefilled disposable tray is about 60 mg, as per manufacturer descriptions. To the extent of the authors' knowledge, no studies have measured the amount of desensitizer gels inside the trays; however, different studies have measured the amount of bleaching gels, and these quantities range between 500 and 900 mg per application, mainly because the application depends on the patients' subjective interpretation regarding the amount of gel to insert in the tray.[33,34] Once again, a lower effectiveness of prefilled disposable trays is expected.

However, according to Kwon and others,[1] the most important factor in terms of potassium nitrate penetration is the product concentration. Although the exact concentration of nitrate potassium is a manufacturer property, according to the MSDS of each manufacturer, both delivered methods (conventional-delivered tray system and prefilled disposable tray) containing similar concentrations of potassium nitrate and sodium fluoride (Table 1) help to explain the similar results between both products.

The cause of bleaching-induced TS is not completely understood. According to the "hydrodynamic hypothesis,"[35] thermal and tactile stimuli are effective for evaluating dental sensitivity when dentin is exposed.[36] Since the hydrodynamic theory of dentin sensitivity enjoys wide acceptance as the explanation of dentinal sensation, many authors view bleaching-related pain as a form of dentin sensitivity.[37] Major differences distinguish bleaching-related pain from dentin hypersensitivity.

Although pain in bleached teeth can be evoked by thermal or other stimuli, most patients complain of tingling or shooting pain (zingers)[4] without provoking stimuli. Pain during and following bleaching treatments can affect intact teeth lacking dentin exposure, which is in sharp contrast to dentin sensitivity, in which pain occurs in teeth with exposed dentin. Recently, Markowitz[38] showed an alternative hypothesis related to the bleaching-induced TS. According to this author,[39] bleaching-induced TS arises as a consequence of peroxide penetrating the tooth structure, causing direct activation of a neuronal receptor and not through the hydrodynamic mechanism.

This fact, along with the current need of reporting patient-centered outcomes, led the authors of the present study to use self-reported pain, as done in clinical trials of bleaching that evaluate TS as the primary outcome.[5,10,12,15,19,24,29,39] However, we cannot rule out the fact that there are other methods described in the literature to evaluate TS that are not employed in the present study, and this can be considered one of the study limitations. Among them, we can cite the Schiff Cold Air and Yeaple Probe Tactile methods, commonly used in studies that evaluate dentin hypersensitivity.[40,41] To the extent of the authors' knowledge, they have not been used in bleaching studies yet, but they need to be included in future bleaching studies to determine if they can add significant information.

Regarding the color evaluation, despite one recent clinical study suggesting that potassium nitrate pretreatment may negatively affect whitening efficacy,[15] the results of the present study showed significant whitening at the end of the bleaching protocol, with the use of three different instruments, which is in accordance with the findings of several other clinical trials that evaluated color change.[3,5,10-18] As both desensitizer gels used were colorless, no significant interaction with tooth color was expected.

In the present study, color measurement was performed only in canines because these teeth are darker than incisors,[42,43] and this allows for more sensitive color change evaluation. An earlier article showed that a significantly stronger overall increase in lightness was observed for canines after treatment when compared with incisors. At the end of the bleaching treatment, teeth become more homogeneous in terms of lightness values.[44] In agreement with these findings, Ontiveros and others[45] observed that whitening of canines was 1.4-1.6 times more pronounced that of incisors. A recent study of the literature demonstrated that a higher degree of whitening occurs in teeth with a darker baseline color.[3] By using canines as the reference for color evaluation, the recruitment of patients becomes easier. Patients with incisors of color A3 are rare, but patients with canines of color A3 are quite common.

Although canines did not have a flat labial face, the use of custom molds enabled standardization of the area for color evaluation, thereby securing a correct angulation for placement of the spectrophotometer tip in all recall periods of this study. However, it worth mentioning that at least two previously published clinical studies did not show any significant variations in the color measurement with the spectrophotometer when measured in incisors or canines.[44,45]

Finally, if the use of a prefilled disposable tray to apply the desensitizer agent is taken into account, this new system has an advantage in comparison with the use of conventional custom trays. The professional does not need to fabricate a personalized custom tray (impression, model buildup, tray fabrication, and so on), and the procedure can be done in the waiting room of the office before dental care or even at home, in the same way that the prefilled disposable trays containing hydrogen peroxide can be used.[39]

CONCLUSIONS

The use of a prefilled disposable tray containing potassium nitrate and fluoride before the application of the in-office bleaching product did not affect the whitening degree and did not decrease self-reported TS, which was similar to the use of a conventional-delivered tray system.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Federal University of Amazonas. The approval code for this study is 59645816.3.0000.5020.

Conflict of Interest

The authors of this article certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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REFERENCES

1. Kwon S, Dawson D, Schenck D, Fiegel J, & Wertz P (2015) Spectrophotometric evaluation of potassium nitrate penetration into the pulp cavity *Operative Dentistry* **40(6)** 614-621.
2. Dutra A, Frary J, & Wise R (2004) Higher-order needs drive new growth in mature consumer markets *Journal of Business Strategy* **25(5)** 26-34.
3. Rezende M, Loguercio AD, Kossatz S, & Reis A (2016) Predictive factors on the efficacy and risk/intensity of tooth sensitivity of dental bleaching: a multi regression and logistic analysis *Journal of Dentistry* **45** 1-6.
4. Haywood VB (2005) Treating sensitivity during tooth whitening *Compendium of Continuing Education in Dentistry* **26(9 Supplement 3)** 11-20.
5. Matis B, Cochran M, & Eckert G (2009) Review of the effectiveness of various tooth whitening systems *Operative Dentistry* **34(2)** 230-235.
6. Nathanson D (1997) Vital tooth bleaching: sensitivity and pulpal considerations *Journal of American Dental Associaction* **28(Supplement)** 41S-44S.
7. Hewlett ER (2007) Etiology and management of whitening-induced tooth hypersensitivity *Journal of California Dental Association* **35(7)** 499-506.
8. Markowitz K (2010) Pretty painful: why does tooth bleaching hurt? *Medical Hypotheses* **74(5)** 835-840.
9. do Amaral FL, Sasaki RT, da Silva TC, Franca FM, Florio FM, & Basting RT (2012) The effects of home-use and in-office bleaching treatments on calcium and phosphorus concentrations in tooth enamel: an *in vivo* study *Journal of American Dental Association* **143(6)** 580-586.
10. Charakorn P, Cabanilla LL, Wagner WC, Foong WC, Shaheen J, Pregitzer R, & Schneider D (2009) The effect of preoperative ibuprofen on tooth sensitivity caused by in-office bleaching *Operative Dentistry* **34(2)** 131-135.
11. de Paula EA, Kossatz S, Fernandes D, Loguercio AD, & Reis A (2014) Administration of ascorbic acid to prevent bleaching-induced tooth sensitivity: a randomized tri-

ple-blind clinical trial *Operative Dentistry* **39(2)** 128-135.

12. de Paula EA, Loguercio AD, Fernandes D, Kossatz S, & Reis A (2013) Perioperative use of an anti-inflammatory drug on tooth sensitivity caused by in-office bleaching: a randomized, triple-blind clinical trial *Clinical Oral Investigation* **17(9)** 2091-2097.
13. Rezende M, Bonafe E, Vochikovski L, Farago PV, Loguercio AD, Reis A, & Kossatz S (2016) Pre- and postoperative dexamethasone does not reduce bleaching-induced tooth sensitivity: a randomized, triple-masked clinical trial *Journal of American Dental Association* **147(1)** 41-49.
14. Bonafé E, Loguercio AD, Reis A, & Kossatz S (2014) Effectiveness of a desensitizing agent before in-office tooth bleaching in restored teeth *Clinical Oral Investigations* **18(3)** 839-845.
15. Palé M, Mayoral JR, Llopis J, Vallès M, Basilio J, & Roig M (2014) Evaluation of the effectiveness of an in-office bleaching system and the effect of potassium nitrate as a desensitizing agent *Odontology* **102(2)** 203-210.
16. Reis A, Dalanhol A, Cunha T, Kossatz S, & Loguercio A (2011) Assessment of tooth sensitivity using a desensitizer before light-activated bleaching *Operative Dentistry* **36(1)** 12-17.
17. Tay LY, Kose C, Loguercio AD, & Reis A (2009) Assessing the effect of a desensitizing agent used before in-office tooth bleaching *Journal of the American Dental Association* **140(10)** 1245-1251.
18. Wang Y, Gao J, Jiang T, Liang S, Zhou Y, & Matis BA (2015) Evaluation of the efficacy of potassium nitrate and sodium fluoride as desensitizing agents during tooth bleaching treatment—a systematic review and meta-analysis *Journal of Dentistry* **43(8)** 913-923.
19. Leonard RH, Smith LR, & Caplan DJ (2004) Desensitizing agent efficacy during whitening in an at-risk population *Journal of Esthetic and Restorative Dentistry* **16(1)** 49-55.
20. International Organization for Standardization (2011) ISO/TR 28642. Dentistry-guidance on color measurement. Geneva, Switzerland: International Organization for Standardization.
21. Bartold P (2006) Dentinal hypersensitivity: a review *Australian Dental Journal* **51(3)** 212-218.
22. Fugaro JO, Nordahl I, Fugaro OJ, Matis BA, & Mjor I (2004) Pulp reaction to vital bleaching *Operative Dentistry* **29(4)** 363-368.
23. Tal M, Oron M, Gedalia I, & Ehrlich J (1976) X-ray diffraction and scanning electron microscope investigations of fluoride-treated dentine in man *Archives of Oral Biology* **21(5)** 285-290.
24. Özcan M, Abdin S, & Sipahi C (2014) Bleaching induced tooth sensitivity: do the existing enamel craze lines increase sensitivity? A clinical study *Odontology* **102(2)** 197-202.
25. Armênio RV, Fitarelli F, Armênio MF, Demarco FF, Reis A, & Loguercio AD (2008) The effect of fluoride gel use on bleaching sensitivity: a double-blind randomized controlled clinical trial *Journal of the American Dental Association* **139(5)** 592-597.
26. Haywood VB (2005) Treating sensitivity during tooth whitening *Compendium of Continuing Education in Dentistry* **26(9 Supplement 3)** 11-20.
27. Haywood VB, Caughman WF, Frazier KB, & Myers ML (2001) Tray delivery of potassium nitrate—fluoride to reduce bleaching sensitivity *Quintessence International* **32(2)** 105-109.
28. Hodosh M (1974) A superior desensitizer—potassium nitrate *Journal of the American Dental Association* **88(4)** 831-832.
29. Haywood VB, Cordero R, Wright K, Gendreau L, Rupp R, Kotler M, Littlejohn S, Fabyanski J, & Smith S (2005) Brushing with a potassium nitrate dentifrice to reduce bleaching sensitivity *Journal of Clinical Dentistry* **16(1)** 17-22.
30. Kwon SR, Dawson DV, & Wertz PW (2016) Time course of potassium nitrate penetration into the pulp cavity and the effect of penetration levels on tooth whitening efficacy *Journal of Esthetic and Restorative Dentistry* **28(S1)** S14-S22.
31. Kwon SR, Li Y, Oyoyo U, & Aprecio RM (2012) Dynamic model of hydrogen peroxide diffusion kinetics into the pulp cavity *Journal of Contemporary Dental Practice* **13(4)** 440-445.
32. Ilan R, Yarom T, & Israel L (1991) Effect of bleaching time and temperature on the radicular penetration of hydrogen peroxide *Dental Traumatology* **7(5)** 196-198.
33. Dahl JE & Becher R (1995) Acute toxicity of carbamide peroxide and a commercially available tooth-bleaching agent in rats *Journal of Dental Research* **74(2)** 710-714, 10.
34. Li Y (1996) Biological properties of peroxide-containing tooth whiteners *Food and Chemical Toxicology* **34(9)** 887-904.
35. Brännström M (1986) The hydrodynamic theory of dentinal pain: sensation in preparations, caries, and the dentinal crack syndrome *Journal of Endodontics* **12(10)** 453-457.
36. Pashley DH (1986) Dentin permeability, dentin sensitivity, and treatment through tubule occlusion. *Journal of Endodontics* **12(10)** 465-474.
37. Swift EJ Jr (2005) Tooth sensitivity and whitening. *Compendium Continuing Education in Dentistry* **26(9 Supplement 3)** 4-10.
38. Markowitz K (2010) Pretty painful: why does tooth bleaching hurt? *Medical Hypotheses* **74(5)** 835-840.
39. Carlos N, Bridi E, Amaral F, França F, Turssi C, & Basting R (2017) Efficacy of home-use bleaching agents delivered in customized or prefilled disposable trays: a randomized clinical trial *Operative Dentistry* **42(1)** 30-40.
40. Trushkowsky RD & Garcia-Godoy F (2014) Dentin hypersensitivity: differential diagnosis, tests, and etiology *Compendium of Continuing Education in Dentistry* **35(2)** 99-104.

41. Gillam DG (2013) Current diagnosis of dentin hypersensitivity in the dental office: an overview *Clinical Oral Investigation* **17(Supplement 1)** 21-29.

42. Hasegawa A, Motonomi A, Ikeda I, & Kawaguchi S (2000) Color of natural tooth crown in Japanese people *Color Research in Applications* **25(1)** 43-48.

43. Hasegawa A, Ikeda I, & Kawaguchi S (2000) Color and translucency of *in vivo* natural central incisors *Journal of Prosthetic Dentistry* **83(4)** 418-423.

44. Wetter NU, Branco EP, Deana AM, & Pelino JE (2009) Color differences of canines and incisors in a comparative long-term clinical trial of three bleaching systems. *Lasers in Medicine Science* **24(6)** 941-947.

45. Ontiveros JC, Eldiwany MS, & Paravina R (2012) Clinical effectiveness and sensitivity with overnight use of 22% carbamide peroxide gel. *Journal of Dentistry* **40(Supplement 2)** e17-e24.