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POTASSIUM NITRATE AND SENSITIVITY DURING AND AFTER TEETH WHITENING: A TRIPLE-BLIND RANDOMIZED CLINICAL TRIAL

NITRATO DE POTÁSSIO E SENSIBILIDADE DURANTE E APÓS CLAREAMENTO DENTAL: UM ENSAIO CLÍNICO RANDOMIZADO TRIPLO CEGO

NITRATO DE POTASIO Y SENSIBILIDAD DURANTE Y DESPUÉS DEL ACLARAMIENTO DENTAL: UN ENSAYO CLÍNICO ALEATORIZADO TRIPLE CIEGO

> Johnny Alexandre Oliveira Tavares¹ Luciana Fávaro Francisconi dos Rios² Luiz Renato Paranhos³ Wilton Mitsunari Takeshita⁴ Paulo Francisco César⁵ Jefferson Chaves Moreira⁶ Adriana Oliveira⁷ Flavia Pardo Salata Nahsan⁸

ABSTRACT

This study aimed to assess the effect of using potassium nitrate in gel and dentifrice for reducing sensitivity during and after bleaching. Seventy-five patients were randomly divided into three groups according to treatment: Previous placebo gel + Colgate Total 12 (PL + CT); Previous placebo gel + Sensodyne (PL + SD); Previous 5% potassium nitrate gel + Colgate Total 12 (NT). Tooth sensitivity was registered on a verbal scale and a Visual Analogue Scale at the 40th minute, immediately after removing the bleaching gel, and 24 hours after each session. The descriptive analysis of color was performed and Cochran's Q test was applied for the comparative analysis of sensitivity. The Kruskal-Wallis test, Dunn's post-test, and Friedman's ANOVA were used for sensitivity intensity. The intergroup assessment showed that in PL + CT, the occurrence of sensitivity was significantly higher than in PL + SD and NT (p < 0.05). The assessment 24 hours after the second session showed that patients from PL + SD reported less sensitivity (40.0%) than NT (64.0%) and PL + CT (96.0%). As for color, all groups succeeded after 14 days. It can be concluded that the use of potassium nitrate in both presentations reduces tooth sensitivity.

KEYWORDS

Tooth bleaching; Dentin sensitivity; Dental esthetics; Dental bleaching; Desensitizing agents.

RESUMO

Este estudo buscou avaliar o efeito do uso de gel de nitrato de potássio e dentifrício na redução de sensibilidade durante e após clareamento. Setenta e cinco pacientes foram divididos randomicamente em três grupos de acordo com o tratamento: Anterior placebo gel + Colgate Total 12 (PL + CT); Anterior placebo gel + Sensodyne (PL + SD); Anterior gel de nitrato de potássio a 5% + Colgate Total 12 (NT). A sensibilidade dental foi registrada em uma escala verbal e em Escala Visual Analógica no minuto 40, imediatamente após a remoção do gel clareador, e 24 horas após cada sessão. Foi realizada a análise descritiva de cor e aplicado o teste Q de Cochran para a comparação de sensibilidade. Os testes de Kruskal-Wallis, Pós-teste de Dunn's, e ANOVA de Friedman foram usados para a intensidade de sensibilidade. A avaliação intergrupo mostrou que em PL + CT a ocorrência de sensibilidade foi significativamente maior que em PL + SD e NT (p < 0.05). A avaliação 24 horas após a segunda sessão mostrou que pacientes do PL + SD reportaram menos sensibilidade (40.0%) que NT (64.0%) e PL + CT (96.0%). Para a cor, todos os grupos tiveram sucesso após 14 dias. Pode ser concluído que o uso de nitrato de potássio em ambas as apresentações reduz a sensibilidade dental.

PALAVRAS-CHAVE

Clareamento; Sensibilidade dentinária; Estética dental; Clareamento dental; Agentes dessensibilizantes

RESUMEN

Este estudio buscó evaluar el efecto del uso de gel de nitrato de potasio y dentífrico en la reducción de sensibilidad durante y después de aclaramiento. Setenta y cinco pacientes fueron divididos de forma randómica en tres grupos según el tratamiento: Anterior placebo gel + Colgate Total 12 (PL + CT); Anterior placebo gel + Sensodyne (PL + SD); 5% anterior gel de nitrato de potasio + Colgate Total 12 (NT). La sensibilidad dental se registró en una escala verbal y en Escala Visual Analógica en el minuto 40, inmediatamente después de la eliminación del gel aclarador, y 24 horas después de cada sesión. Se realizó el análisis descriptivo de color y se aplicó la prueba Q de Cochran para la comparación de sensibilidad. Las pruebas de Kruskal-Wallis, Post-test de Dunn's, y ANOVA de Friedman fueron utilizadas para la intensidad de sensibilidad. La evaluación intergrupo mostró que en PL + CT la aparición de sensibilidad fue significativamente mayor que en PL + SD e NT (p < 0.05). La evaluación 24 horas después de la segunda sesión mostró que los pacientes de PL + SD indicaron menos sensibilidad (40.0%) que NT (64.0%) y PL + CT (96.0%). Para el color, todos los grupos tuvieron éxito después de 14 días. Se puede concluir que el uso de nitrato de potasio en ambas presentaciones reduce la sensibilidad dental.

PALABRAS CLAVE

Aclaramiento; Sensibilidad dentinaria; Estética dental; Aclaramiento dental; Agentes desensibilizantes.

1 INTRODUCTION

In-office tooth bleaching is a good esthetic alternative for obtaining lighter teeth, because it is effective, simple, safe, and conservative (WANG *et al.*, 2015; REZENDE, *et al.*, 2016; PONTES *et al.*, 2020; LIMA *et al.*, 2022; ORTEGA-MONCAYO *et al.*, 2022). Its action mechanism is speculated to work by the diffusion of hydrogen peroxide into the dental enamel up to the dentinal portion. In alkaline conditions, free radicals are formed, which oxidize and break chromophores into less complex molecules that reflect more light (HAYWOOD, 2005a; JOINER, 2006; ARAUJO *et al.*, 2010; COSTA *et al.*, 2010; MARKOWITZ, 2010; THIESEN *et al.*, 2013). Although the use of concentrations of 20-35% of hydrogen peroxide present effective and fast clinical results, the most common side effect (63% in average) is the sensitivity reported by patients, who may interrupt the treatment in some cases (AL-MEIDA *et al.*, 2012; EIMAR *et al.*, 2012; BONAFÉ *et al.*, 2014).

Sensitivity may occur when oxygen bubbles run through the dentinal tubules and cause the movement of dentinal fluid, thus activating neural activity (MARKOWITZ, 2010). However, there is no scientific evidence on such theory (MARKOWITZ, 2010). An action mechanism described for sensitivity is that it occurs through the fast diffusion of hydrogen peroxide into the tissues, reaching the chemosensitive ion channel present in the afferent fibers of the dental pulp. This channel is called Transient Receptor Potential Ankyrin 1 (TRPA1) and it activates the intradental nerves, causing discomfort (MARKOWITZ, 2010; BRISO *et al.*, 2018).

The search for reducing sensitivity has been studied (ARAUJO *et al.*, 2010; COSTA *et al.*, 2010; AL-MEIDA *et al.*, 2012; REZENDE *et al.*, 2016; DE GEUS *et al.*, 2016; VOCHIKOVSKI *et al.*, 2023) with the use of desensitizing agents, before and during treatment in cases of at-home bleaching, or after the bleaching procedure (BONAFÉ *et al.*, 2014). A protocol commonly tested is the use of desensitizing agents based on potassium nitrate, which indicates the reduction of either sensitivity (TAY, *et al.*, 2009; REIS *et al.*, 2011; WANG *et al.*, 2015) or the intensity of the painful stimulus (BONAFÉ *et al.*, 2014).

The treatment of sensitivity with desensitizing agents based on 5% potassium nitrate may be explained with two action mechanisms (THIESEN *et al.*, 2013). The gel hinders nerve repolarization after initial depolarization, reducing excitability (REIS *et al.*, 2011). The dentifrice, in addition to the neural action, presents strontium chloride, which is responsible for obliterating the dentinal tubules and consequently decreasing permeability (THIESEN *et al.*, 2013).

Nonetheless, a great amount of potassium ions is required to penetrate the dentinal tubules and cause neural inhibition and the variability of dentinal thickness of each individual (WANG *et al.*, 2015; DE GEUS *et al.*, 2016). It is also believed that tubule obliteration prevents the hydrogen peroxide to

reach the pulp fast, consequently preventing the inflammatory process instead of only inhibiting the neural stimulus (TAY *et al.*, 2009).

The meta-analysis performed by Wang *et al.* (2015) and a systematic review made in 2022 (KRISH-NAKUMAR *et al.*, 2022) suggest that nitrate reduces sensitivity. However, the type of presentation for a greater effect in reducing sensitivity during and after tooth bleaching is questioned. Thus, the aim of this study was investigating whether the use of nitrate in different forms (gel and dentifrice) affects the sensitivity caused by high-concentration bleaching, during and after the procedure.

The benefit of this research will be to propose a clinical protocol for prescribing a desensitizing agent to reduce sensitivity caused by in-office dental bleaching. The null hypothesis is that the use of nitrate does not affect both the sensitivity caused by tooth bleaching and the final result of the treatment regarding the color established.

2 MATERIALS AND METHODS

This clinical trial was approved by the Research Ethics Committee of the University Hospital of the Federal University of Sergipe (HU-UFS) (CAAE 82023618.5.0000.5546), under record NCT03523598 at www.clinicaltrials.gov. It was performed between March and August 2018 at the clinics of the Federal University of Sergipe, Lagarto, Brazil.

Based on the preset criteria, 75 volunteers were selected for this study. Fifteen days before the bleaching procedure, the blinded dentifrices were distributed to the participants for previous use in both in-office bleaching sessions. The volunteers also signed the Informed Consent Form.

2.1 EXPERIMENTAL DESIGN

The experimental design followed the CONSORT guidelines. It is an intervention study with allocation ratio of 1:1, including a triple blind (patient, operator, and evaluator), controlled, and randomized clinical trial with equal likelihood of participants to receive any of the three treatments. A triple-blind, controlled, randomized clinical trial was chosen to eliminate bias in patient responses and operator evaluations.

The patients included in this study were men and women aged 18 through 29 years, presenting good oral and general health, and recruited by advertisement. The inclusion criteria were individuals with upper canines with color A3 or darker, assessed by the Classical Vita scale, with healthy upper anterior teeth, and agreeing to the Informed Consent Form. The exclusion criteria were patients with previous tooth bleaching, smokers, pregnant or breastfeeding women, presence of tetracycline stains, enamel hypoplasia, and individuals who did not use dentifrice and presented periodontal disease or tooth sensitivity. The level of tooth sensitivity was assessed with the application of a light air blast on the buccal surface of central incisors, and those with a positive response were excluded.

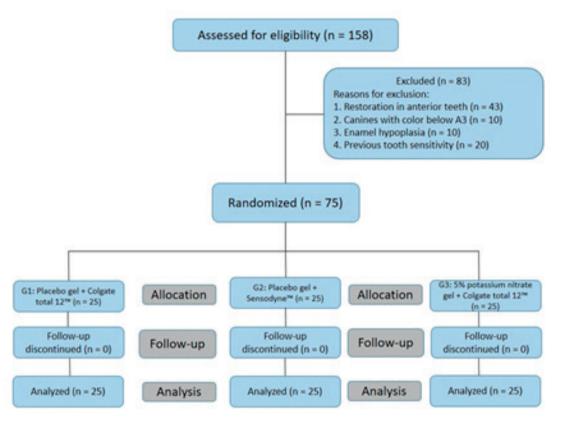
The sample was calculated based on the main outcome of the study (presence of sensitivity) by the following parameters: 5% two-tailed significance level ($\alpha = 0.05$), 95% confidence interval, 80% statis-

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tical power (β = 0.20), ratio of 1:1 for group allocation, and large expected effect size (d \geq 0.80, identified after data analysis from the pilot study with 45 patients performed previously by the researchers). These parameters indicated the need for including at least 25 cases in each group (FAUL *et al.*, 2007). Therefore, the final sample of the study with 75 cases meets these requirements and it is adequate.

The randomization list was produced using the website www.sealedenvelope.com by an operator who was not involved in the research protocol and was in charge of placing it in sealed envelopes. The operator in charge of the bleaching procedure opened the envelope only at the moment of the procedure and the protocol was defined at this time, as Figure 1 shows.

Figure 1 - Flowchart of the clinical trial, highlighting the selection of volunteers, allocation, follow--up, and analysis during the study.



The groups were distributed according to description of groups, type of treatment, and composition of the product used (Table 1).

| GROUP | TREATMENT | GEL COMPOSITION | DENTIFRICE COMPOSITION |
|---------|---|--|--|
| PL + CT | Placebo gel +Colgate To- tal 12 (Colgate-Palmolive, SP, Brazil) | Placebo gel 2% deionized water, glycerin, thick- ener, and neutralizing agent, pH of 6.7 | Colgate Total 12 0.14% sodium fluoride |
| PL + SD | Placebo gel + Sensodyne Extra Fresh (GlaxoSmith- Kline, RJ, Brazil) | Placebo gel 2% deionized water, glycerin, thick- ener, and neutralizing agent, pH of 6.7 | Sensodyne 0.14% sodium fluoride and 5% potassium nitrate |
| NT | 5% potassium nitrate gel (Desensibilize KF 2%, FGM, Joinville, SC, Brazil) + Colgate Total 12 (Colgate-Palmolive, SP, Brazil) | 5% potassium nitrate gel Based on potassium nitrate and sodium fluoride | Colgate Total 12 0.14% sodium fluoride |

Table 1: Description of groups, type of treatment, and composition of the product used.

Before assessing the initial color, dental prophylaxis was performed and the color of the dental element was assessed with the Vita Classical scale by two previously calibrated evaluators. Confirmation was provided with the Kappa inter-examiner agreement measurement, resulting in (K = 0.873). This means that the evaluators have superior skills to assess color according to the ISO/TR 28642 standard (2016) (LOGUERCIO *et al.*, 2017). The patients included were instructed on the pain scale tags used to measure the study. A verbal sensitivity scale (BONAFÉ *et al.*, 2014) and a Visual Analogue Scale (VAS) were used (LOGUERCIO *et al.*, 2017).

2.2 INTERVENTION

According to group allocation, each patient was called 15 days before the bleaching procedure to receive the dentifrice, which had no label so the dental cream package was not identified. The dentifrice had only a code for posterior analysis (THIESEN *et al.*, 2013).

The dentifrice was used before the bleaching procedure and during the entire treatment. The patients were previously calibrated to use 0.43 grams of dentifrice in each toothbrushing, which was estimated in an analytical balance, with the instruction of brushing three times a day. The prophylaxis of dental elements was performed and the dental arches of the patients were isolated with a mouth opener and a gingival barrier (Total Blanc Office, Nova DFL, Curicica, RJ, Brazil). Next, the desensitizing/placebo gel was applied according to previous randomization, for 20 seconds on each tooth, remaining for 10 minutes (TAY, *et al.*, 2009; REIS *et al.*, 2011; BONAFÉ *et al.*, 2014). Each patient was subjected to in-office tooth bleaching with a 35% hydrogen peroxide bleaching agent (Total Blanc office, Nova DFL, Curicica, RJ, Brazil) following the manufacturer's instructions. Two bleaching sessions were performed with a 1-week interval.

2.3 ASSESSMENTS

The tooth sensitivity reported by patients was measured in the 40th minute before removing the bleaching agent, immediately after the bleaching procedure, and after 24 hours. These sensitivity measurements were performed with the verbal scale (scores from 0 to 4), in which 0 = none, 1 = mild, 2 = moderate, 3 = significant, and 4 = severe (BONAFÉ *et al.*, 2014). A visual analog scale was also used, consisting of a 10-cm-long scale without gradation (HANNIGAN; LYNCH, 2013). Sensitivity was reassessed in the second bleaching session performed seven days after the first one. One week after each bleaching session, the color of elements 13 and 23 were assessed through the Vita Classical scale. Color was reassessed one week after the second session (14 days from the first session).

2.4 STATISTICAL ANALYSIS

The data were analyzed with the IBM SPSS Statistics software (SPSS for Windows, Version 20.0, Armonk, NY, IBM Corp.). Initially, the sample was characterized using descriptive statistics, which corresponded to the calculation of central tendency and variability measures for the quantitative variables and of absolute and percentage frequencies for the categorical variables. The normality assumption of the quantitative variables data was not confirmed after applying the Shapiro-Wilk test. Therefore, the non-parametric tests were used to determine the significance of inter- and intragroup differences (HANNIGAN; LYNCH, 2013). The descriptive assessment of color was performed, calculating the absolute and percentage frequencies for the categorical variables.

In the comparative analysis of the report on sensitivity, the values were converted into a dichotomous variable, that is, value 0 (no sensitivity) and values 1, 2, 3, and 4 (with sensitivity). Later, Cochran's Q exact test with Bonferroni correction was applied for intra- and intergroup assessments. Next, the comparative analysis of sensitivity intensity scores (quantitative variable) used the Kruskal-Wallis test (intergroup assessment) with Dunn's post-test, and Friedman's ANOVA (intragroup assessment), with multiple comparisons using Bonferroni correction. The significance level was 5% (= 0.05) for the tests used (LARSON; FARBER, 2016).

3 RESULTS

Table 2 shows the results of the comparative analysis of sensitivity in each group according to the different assessment times. The intergroup assessment showed that, in PL + CT, the occurrence of sensitivity was significantly higher than in PL + SD and NT (p < 0.05). The assessment 24 hours

after the second session showed that patients from PL + SD reported less sensitivity (40.0%) than NT (64.0%) and PL + CT (96.0%). The intragroup assessment showed that, in PL + CT, the frequency of sensitivity remained high during the assessments performed along the sessions. For PL + SD and NT, the values increased significantly after 24 hours (p < 0.05).

| | PL + CT | | PL + | SD | N | r | |
|--------------------------------|------------------|------|------------------|------|------------------|------|------------------------|
| | n | % | n | % | n | % | p-value ⁽¹⁾ |
| FIRST SESSION | | | | | | | |
| At the 40 th minute | 18 ^{Aa} | 72.0 | 5 ^{Ba} | 20.0 | 6 ^{Ba} | 24.0 | < 0.001* |
| Immediately after | 18 ^{Aa} | 72.0 | 5 ^{Ba} | 20.0 | 6 ^{Ba} | 24.0 | < 0.001* |
| 24 hours later | 17 ^{Aa} | 68.0 | 13 ^{Ab} | 52.0 | 13 ^{Ab} | 52.0 | 0.499 |
| p-value ⁽²⁾ | 0.819 | | 0.001* | | 0.001* | | |
| SECOND SESSION | | | | | | | |
| At the 40 th minute | 23 ^{Aa} | 92.0 | 4 ^{Ba} | 16.0 | 8^{Ba} | 32.0 | < 0.001* |
| Immediately after | 24 ^{Aa} | 96.0 | 4 ^{Ba} | 16.0 | 7 ^{Ba} | 28.0 | < 0.001* |
| 24 hours later | 24 ^{Aa} | 96.0 | 10^{Bb} | 40.0 | 16 ^{Cb} | 64.0 | 0.001* |
| p-value ⁽²⁾ | 0.368 | | 0.002* | | 0.001* | | |

| Table 2 - Comparative analysis of sensitivity in each group according to the different assessment times. |
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|--|

Values expressed in absolute and percentage values; ⁽¹⁾Inter- and intragroup assessments at different times (Cochran's Q test with Bonferroni correction); ⁽²⁾ p<0.05; Different letters mean significantly different results; Capital letters compare values horizontally; Lower-case letters compare values vertically; * p<0.05.

Tables 3 and 4 show the results of the comparative analysis of sensitivity intensity in each group according to the different assessment times. Patient responses to the verbal and visual scales showed statistically significant difference between PL + CT when compared to PL + SD and NT (P < 0.05). Overall, sensitivity intensity was higher for PL + CT. There were no statistically significant differences between PL + SD and NT (p > 0.05). According to Table 5, after 14 days, the most frequent color was A2 in PL + CT (right side = 64.0%, left side = 64.0%), A1 in PL + SD (right side = 64.0%, left side = 64.0%), and A2 in NT (right side = 56.0%, left side = 52.0%).

Table 3. Comparative analysis of sensitivity intensity in each group according to the verbal scale at the different assessment times.

| | Р | L + CT | | Pl | + SD | | | | | | |
|--------------------------------|--------------------|--------|------|--------------------|------|------|----------------------|------|------|------------------------|--|
| Variables | Medi- | IQR | | Madian | IQR | | Madiau | IQR | | | |
| | an | P25 | P75 | Median | P25 | P75 | Median | P25 | P75 | p-value ⁽¹⁾ | |
| FIRST SESSION | | | | | | | | | | | |
| At the 40 th minute | 1.00 ^{Aa} | 0.00 | 1.00 | 0.00^{Ba} | 0.00 | 0.00 | 0.00 ^{Ba} | 0.00 | 0.50 | < 0.001* | |
| Immediately after | 1.00 ^{Aa} | 0.00 | 1.00 | 0.00 ^{Ba} | 0.00 | 0.00 | 0.00^{Ba} | 0.00 | 0.50 | < 0.001* | |
| 24 hours later | 1.00 ^{Aa} | 0.00 | 1.00 | 1.00 ^{Ab} | 0.00 | 1.00 | 1.00 ^{Ab} | 0.00 | 1.00 | 0.873 | |
| p-value ⁽²⁾ | 0. 956 | | | 0.002* | | | 0.002* | | | | |
| SECOND SES- | | | | | | | | | | | |
| SION | | | | | | | | | | | |
| At the 40 th minute | 1.00 ^{Aa} | 1.00 | 1.00 | 0.00 ^{Ba} | 0.00 | 0.00 | 0.00 ^{Ba} | 0.00 | 1.00 | < 0.001* | |
| Immediately after | 1.00 ^{Aa} | 1.00 | 1.00 | 0.00 ^{Ba} | 0.00 | 0.00 | 0.00 ^{Ba} | 0.00 | 1.00 | < 0.001* | |
| 24 hours later | 1.00 ^{Ab} | 1.00 | 1.50 | 0.00 ^{Bb} | 0.00 | 1.00 | 1.00 ^{AB.b} | 0.00 | 2.00 | 0.010* | |
| p-value ⁽²⁾ | 0.028* | | | 0.012* | | | < 0.001* | | | | |

Values expressed in median and interquartile range (IQR = percentage 25 - percentage 75); ⁽¹⁾ Intergroup assessment (Kruskal-Wallis test with Dunn's post-test); ⁽²⁾ Intragroup assessment (Friedman's ANOVA and Bonferroni correction); Different letters mean significantly different results; Capital letters compare values horizontally; Lower-case letters compare values vertically; * p<0.05.

Table 4. Comparative analysis of sensitivity intensity in each group according to the visual analogue scale at the different assessment times.

| | I | PL + CT | | P | L + SD | | NT | | | | |
|--------------------------------|---------------------|---------|-------|---------------------|--------|-------|---------------------|------|-------|-------------------|--|
| Variables | Median | IC | QR | Medi- | 10 | QR | Madian | IQR | | p-val- | |
| | Mealan | P25 | P75 | an | P25 | P75 | Median | P25 | P75 | ue ⁽¹⁾ | |
| FIRST SESSION | | | | | | | | | | | |
| At the 40 th minute | 15.90 ^{Ab} | 0.00 | 18.75 | 0.00 ^{Bb} | 0.00 | 0.00 | 0.00 ^{Bb} | 0.00 | 6.15 | < 0.001 | |
| Immediately after | 16.20 ^{Ab} | 0.00 | 22.50 | 0.00 ^{Bb} | 0.00 | 0.00 | 0.00 ^{Bb} | 0.00 | 6.55 | < 0.001 | |
| 24 hours later | 19.20 ^{Aa} | 0.00 | 23.75 | 12.10 ^{Aa} | 0.00 | 25.50 | 18.10 ^{Aa} | 0.00 | 24.35 | 0.901 | |
| p-value ⁽²⁾ | 0.011* | | | < 0.001* | | | < 0.001* | | | | |

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| | I | PL + CT | | PL + SD | | | NT | | | p-val- | |
|--------------------------------|---------------------|---------|--------------|--------------------|------|-------|--------------------|------|-------|--------------------------|--|
| Variables | | IC | IQR Medi- IC | | IQR | | IQR | | | | |
| | Median | P25 | P75 | an | P25 | P75 | Median | P25 | P75 | <i>ue</i> ⁽¹⁾ | |
| SECOND SESSION | | | | | | | | | | | |
| At the 40 th minute | 19.80 ^{Ac} | 15.55 | 21.80 | 0.00 ^{Bb} | 0.00 | 0.00 | 0.00 ^{Bb} | 0.00 | 14.20 | < 0.001* | |
| Immediately after | 22.00 ^{Ab} | 21.00 | 25.75 | 0.00 ^{Bb} | 0.00 | 0.00 | 0.00 ^{Bb} | 0.00 | 9.10 | < 0.001* | |
| 24 hours later | 23.60 ^{Aa} | 21.90 | 32.35 | 0.00 ^{Ba} | 0.00 | 23.45 | | 0.00 | 42.20 | 0.013* | |
| p-value ⁽²⁾ | < 0.001* | | | < 0.001* | | | < 0.001* | | | | |

Values expressed in median and interquartile range (IQR = percentage 25 - percentage 75); ⁽¹⁾ Intergroup assessment (Kruskal-Wallis test with Dunn's post-test); ⁽²⁾ Intragroup assessment (Friedman's ANOVA and Bonferroni correction); Different letters mean significantly different results; Capital letters compare values horizontally; Lower-case letters compare values vertically; * p<0.05.

Table 5. Comparative analysis of the color assessment observed in each group according to the different assessment times.

| | PL | + CT | PL | PL + SD | | NT | |
|-------------------|----|------|----|---------|----|------|--|
| Variables | n | % | n | % | n | % | |
| RIGHT SIDE | | | | | | | |
| Baseline | | | | | | | |
| A3.5 | 12 | 48.0 | 9 | 36.0 | 15 | 60.0 | |
| A4 | 13 | 52.0 | 16 | 64.0 | 10 | 40.0 | |
| 7 days | | | | | | | |
| A1 | 0 | 0.0 | 0 | 0.0 | 1 | 4.0 | |
| A2 | 10 | 40.0 | 16 | 64.0 | 13 | 52.0 | |
| A3 | 15 | 60.0 | 9 | 36.0 | 10 | 40.0 | |
| A3.5 | 0 | 0.0 | 0 | 0.0 | 1 | 4.0 | |
| 14 days | | | | | | | |
| A1 | 8 | 32.0 | 16 | 64.0 | 11 | 44.0 | |

| Martabla a | PL | + CT | PL | + SD | NT | | |
|------------|----|-------|----|-------|----|-------|--|
| Variables | n | % | n | % | n | % | |
| A2 | 16 | 64.0 | 8 | 32.0 | 14 | 56.0 | |
| A3 | 1 | 4.0 | 1 | 4.0 | 0 | 0.0 | |
| LEFT SIDE | | | | | | | |
| Baseline | | | | | | | |
| A2 | 0 | 0.0 | 0 | 0.0 | 1 | 4.0 | |
| A3.5 | 12 | 48.0 | 9 | 36.0 | 14 | 56.0 | |
| A4 | 13 | 52.0 | 16 | 64.0 | 10 | 40.0 | |
| 7 days | | | | | | | |
| A1 | 0 | 0.0 | 0 | 0.0 | 2 | 8.0 | |
| A2 | 10 | 40.0 | 16 | 64.0 | 12 | 48.0 | |
| A3 | 15 | 60.0 | 9 | 36.0 | 10 | 40.0 | |
| A3.5 | 0 | 0.0 | 0 | 0.0 | 1 | 4.0 | |
| 14 days | | | | | | | |
| A1 | 8 | 32.0 | 16 | 64.0 | 12 | 48.0 | |
| A2 | 16 | 64.0 | 8 | 32.0 | 13 | 52.0 | |
| A3 | 1 | 4.0 | 1 | 4.0 | 0 | 0.0 | |
| Total | 25 | 100.0 | 25 | 100.0 | 25 | 100.0 | |

4 DISCUSSION

This randomized clinical trial showed statistically significant difference between both nitrate presentations 24 hours after the second bleaching session, in which the dentifrice was superior to gel. The hypothesis of this study is that the use of nitrate does not affect both the sensitivity caused by tooth bleaching and the final treatment result regarding color. Hence, such hypothesis should be rejected for sensitivity and confirmed for color.

The action mechanism of potassium nitrate works through nerve repolarization after initial depolarization, reducing excitability and the nerve ability to transfer painful sensations (TAY *et al.*, 2009; REIS *et al.*, 2011). This desensitizing agent is found in either gel or dentifrice, although some dentifrices are associated with strontium chloride to promote the obliteration of dentinal tubules (THIESEN *et al.*, 2013). This study used the dentifrice composed only of potassium nitrate to assess the 5% potassium nitrate and its neural action mechanism. The studies by Haywood *et al.* (2005b), Tay *et al.* (2009), and Reis *et al.* (2011) similarly apply the same active ingredient to assess tooth sensitivity.

According to the literature, a high prevalence of tooth sensitivity is expected for in-office tooth bleaching (TAY *et al.*, 2009; REIS *et al.*, 2011; BONAFÉ *et al.*, 2014). This was also observed in the present study, in the PL + CT group that did not use desensitizing agents, with sensitivity prevalence of 72% during the first session and 92% during the second session. One justification for such high prevalence may be the rapid diffusion of hydrogen peroxide into the tissues, due to its low molecular weight and neural receptor stimulation, (HAYWOOD *et al.*, 2005a; MARKOWITZ, 2010) as well as the higher concentration available when compared to at-home bleaching, which applies significantly lower concentrations.

The previous use of potassium nitrate reduces the prevalence of tooth sensitivity, as observed in the NT group, corroborating the studies by Tay *et al.* (2009) and Reis *et al.* (2011). However, this was not observed in the study by Bonafé *et al.* (2014), which presented prevalence similarities between control and placebo groups only for reducing the intensity of the painful stimulus.

The intensity levels were reduced in groups PL + SD and NT, regardless of nitrate presentation. Different from some desensitizing agents, which action mechanism obliterate the dentinal tubules and hinder permeability, such as strontium chloride or fluorides, the 5% potassium nitrate diffuses into the dentinal tubules and, when in contact with nerve fibers, it hinders nerve stimulation and blocks the painful transmission. Hypothetically, this may have been the reason for the intensity reduction of the painful stimulus (BONAFÉ *et al.*, 2014), which is shown in Tables 3 and 4.

As for potassium nitrate in dentifrice, the literature shows the study by Thiesen *et al.* (2013), which used the dentifrice before and during the bleaching treatment, but obtained satisfactory results for reducing sensitivity only on the first week. The same study highlights the use of dentifrice with strontium chloride, which action mechanism obliterates the dentinal tubules, reducing dentinal permeability (THIESEN, *et al.*, 2013). The present study showed a reduction in sensitivity in the first and second sessions, which may be seen in the PL + SD group. This result may be explained because of the use of dentifrice containing only 5% potassium nitrate 15 days before and during the entire bleaching treatment and because of the longer action time of the desensitizing agent. Thus, the repolarization of the nerve fiber was hindered and the painful stimulus caused by hydrogen peroxide was propagated more effectively.

Haywood *et al.* (2005b) also assessed the use of dentifrice, but during at-home bleaching, in which most patients did not report sensitivity, as observed in the present study. The literature does not include many studies comparing the effectiveness of 5% potassium nitrate presentations. However, the present study showed statistically significant difference between both presentations only 24 hours after the second session, meaning that, at that moment, dentifrice was superior to gel. A hypothesis for this result may be due to the use of the desensitizing agent during the entire bleaching treatment, using the dentifrice for toothbrushing. Therefore, the dentifrice is a good indication for constantly preventing nerve fiber repolarization.

Wang *et al.* (2015) showed low scientific evidence for color change when using desensitizing agents. The present study performed such assessment, as well as other research (TAY *et al.*, 2009; REIS *et al.*, 2011; THIESEN *et al.*, 2013). The results of color assessment indicate that using 5% potassium nitrate in both presentations does not change bleaching effectiveness. After 14 days, the most

frequent color was A2 in PL + CT (right side = 64.0%, left side = 64.0%), A1 in PL + SD (right side = 64.0%), left side = 64.0%), and A2 in NT (right side = 56.0%, left side = 52.0%). Two potential explanations for this would be the absence of dye in the composition (DINIZ *et al.*, 2018) or for not affecting the diffusion of hydrogen peroxide due to the low molecular weight of the oxidation molecule (REIS *et al.*, 2011). Other studies (TAY *et al.*, 2009; REIS *et al.*, 2011; THIESEN *et al.*, 2013) also showed no change in bleaching effectiveness when using desensitizing agents.

The literature did not show any established protocol for desensitization. The meta-analysis by Wang *et al.* (2015) shows that potassium nitrate is a good alternative of desensitizing agent. Hence, this study assesses which of both presentations of 5% potassium nitrate is indicated, showing that they may be determined as treatment.

5 CONCLUSION

A new perspective for further studies would be the previous association of gel and the use of dentifrice during the treatment to either establish a protocol or assess whether it would result in lower sensitivity prevalence.

The limitation of this clinical study was the control of dentifrice use by the patients, because when sensitivity occurred, some patients reported brushing their teeth more times per day. As for the color results, a lighter color may be observed, that is, A1 for group PL + SD. This may be attributed to the composition of Sensodyne Extra Fresh, which features titanium dioxide (abrasive substance), considering that patients were still using the dentifrice at the time of assessment, and no assessment was performed 30 days after the first session.

The clinical use of 5% potassium nitrate in gel and dentifrice reduced significantly the presence of tooth sensitivity caused by high-concentration in-office tooth bleaching and it reduced the intensity of painful stimulus. The use of desensitizing agents did not compromise the final bleaching result. Thus, the first null hypothesis was rejected, while the second was accepted.

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1 Graduado em Odontologia. Doutor em Ciências da Saúde. Departamento de Odontologia, Centro Universitário Maurício de Nassau, Aracaju, SE, Brasil. ORCID: 0000-0002-5492-4407. E-mail: johnny.1993@yahoo.com.br

2 Cirurgiã-Dentista, Doutora em Ciências Odontológicas Aplicadas (Dentística). Professora Assistente. Faculdade de Odontologia, Universidade de São Paulo, São Paulo, SP, Brasil, ORCID: 0000-0002-9581-7544, E-mail: luff@usp.br

3 Graduado em Odontologia, Doutor em Biologia Patologia Buco Dental. Professor. Departamento de Odontologia Preventiva e Social, Faculdade de Odontologia, Universidade Federal de Uberlândia, Uberlândia, Brasil. ORCID: 0000-0002-7599-0120. E-mail: Paranhos.Lrp@gmail.com

4 Graduado em Odontologia, Doutor em Radiologia Odontológica. Professor Adjunto. Departamento de Diagnóstico e Cirurgia, Faculdade de Odontologia, Universidade Estadual Paulista "Júlio de Mesquita Filho", Aracatuba, SP. Brasil, ORCID: 0000-0001-5682-1498. E-mail: wmtakeshita2@gmail.com

5 Graduado em Odontologia, Doutor em Odontologia (Materiais Dentários). Professor associado, Faculdade de Odontologia, Universidade de São Paulo, São Paulo, Brasil. ORCID: 0000-0001-5834-105X E-mail: paulofc@usp.br

6 Cirurgião-dentista, Mestre em Dentística. Programa de Pós-graduação em Odontologia. Faculdade de Odontologia. Universidade de São Paulo, São Paulo, SP, Brasil. ORCID: 0000-0003-4276-4810 E-mail: chaves.moreira@usp.br

7 Graduada em Odontologia, Mestre em Odontologia. Programa de Pós-Graduação em Odontologia, Universidade Federal de Sergipe, Aracaju, SE, Brasil. ORCID: 0000-0002-7456-3784. E-mail: adrii.olliveira@gmail.com

8 Graduada em Odontologia. Doutorado em Dentística. Professora adjunta, Programa de Pós-Graduação em Odontologia, Universidade Federal de Sergipe, Aracaju, SE, Brasil. ORCID: 0000-0002-3547-8886. E-mail: flavia odonto@hotmail.com

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