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Effectiveness of Different Desensitizing Protocols in In-Office Dental Whitening: Clinical, Blind and Randomized Study

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Authors' contributions

This work was carried out in collaboration among all authors. Author BFD participated in the clinical research and wrote the manuscript. Authors VC and JKU designed the study and performed the statistical analysis. All authors read and approved the final manuscript.

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ABSTRACT

Aims: To evaluate the efficacy of ozonated sunflower oil in managing sensitivity during and after in-office dental bleaching.

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Methodology: Thirty patients were selected and allocated into two distinct groups - 5% Potassium Nitrate and 2% Sodium Fluoride (NF) and ozonated sunflower oil (OGO). Desensitization was performed before the application of the bleaching gel for 10 minutes. Hydrogen peroxide was applied for 30 minutes. The evaluation of the degree of sensitivity (DS) was performed on an illustrative scale from 0 to 4, and the patients were questioned during bleaching (05 minutes, 10 minutes, 15 minutes, 20 minutes, 25 minutes, and 30 minutes) and after bleaching (1 hour, 24 hours, 48 hours and 7 days). The degree of whitening (DW) was assessed before and 7 days after treatment. The data were subjected to Wilcoxon statistical analysis ($p<0.05$).
Results: In the intra-group analysis, there was a statistical difference between the times. In the inter-group analysis, ozonated sunflower oil compared to the conventional desensitizing agent resulted in statistical differences for the times of 25 minutes, 30 minutes and 1 hour post-bleaching. In the color saturation analysis, both groups showed statistical differences between the initial color and the final color.
Conclusion: Ozonated sunflower oil demonstrates significant management of sensitivity during and after in-office dental bleaching, in addition to not interfering with the degree of color saturation of the bleached teeth and the efficiency of hydrogen peroxide.

Keywords: Whitening; sensitivity; desensitizing; ozone.

1. INTRODUCTION

Dental staining or discoloration occurs due to extrinsic factors (diet, smoking, poor oral hygiene, among others) and intrinsic factors (metabolic causes, congenital factors, and tetracycline use, among others). The pigments are organic compounds containing long conjugated double bonds [1-4]. When these pigments form a molecule capable of reflecting light at a visible wavelength, the intensity exceeds the light reflected by the dental structure, resulting in a predominance of darkened dental color [1,5].

The pigments incorporated into the dental structure can be removed by bleaching. Bleaching agents act by oxidizing organic compounds, and these agents are highly unstable. When in contact with the tooth, they release free radicals (mainly oxygen) that oxidize the pigments. The released oxygen penetrates the dentinal tubules and acts on highly pigmented carbon compounds, transforming them into lighter compounds. Additionally, pigmented carbon compounds with double bonds are converted into hydroxyl groups, which are colorless [1,5].

Dental bleaching involves the application of bleaching gel - hydrogen peroxide or carbamide peroxide - onto the tooth surface. This procedure can be performed in the clinic or at home by the patient. The selection of the gel and the clinical protocol for the procedure are evaluated and prescribed by the professional, varying depending on the case [2,4].

Dental sensitivity is a common issue in in-office bleaching procedures, as high concentrations of hydrogen peroxide are used [4,6]. Dental enamel is a permeable tissue, and thus, hydrogen peroxide, which has a low molecular weight, penetrates the dental structure to break down pigment molecules. However, some of this peroxide may come into contact with the nerve endings of the dentin and pulp through the dentinal tubules, activating nociceptors and triggering an inflammatory reaction, causing painful stimuli during or after bleaching [7,8].

Several protocols have been proposed for managing sensitivity during dental bleaching, including reducing the concentration and duration of use of the bleaching gel, applying desensitizing agents, administering medications after the procedure to prevent sensitivity, and performing pre-operative analgesia, among others. However, to date, none of these methods have demonstrated absolute efficacy [9,10].

The use of desensitizing agents based on potassium nitrate and potassium oxalate combined with fluoride is widely spread, with the mechanism of action involving the blocking of sodium and potassium channels on the nerve cell membrane, preventing the propagation of the nerve stimulus [9,10].

Ozonated sunflower oil has emerged as a promising option as a desensitizing agent [11]. Its effectiveness is attributed to its ability to reduce both the number and diameter of open dentinal tubules, as well as stimulate collagen production. Thus, stability is mainly reduced by

the mechanical blocking of dentinal tubules. Additionally, the potential remineralization of dental surfaces in teeth subjected to bleaching and treated with ozone therapy may significantly contribute to reducing pain perception [9,10,12]. The present study hypothesizes that the use of ozonated sunflower oil will provide more effective management of post-in-office dental bleaching sensitivity compared to the control group, composed of potassium nitrate and fluoride.

2. MATERIALS AND METHODS

2.1 Study Design, Settings and Data Collection Sites

The present study is a randomized, split-mouth, double-blind clinical trial that assessed the performance of desensitizing agents before in-office dental bleaching with 35% hydrogen peroxide. In the control group, 5% Potassium Nitrate with 2% Sodium Fluoride was applied, while in the test group, ozonized sunflower oil was applied, with sensitivity management during and after bleaching.

The study was conducted at the Dental Clinic affiliated with the undergraduate Dentistry program at the Western Paraná State University (Rua Universitária, 2069, Jardim Universitário - ZIP code 85819-110 - Cascavel - PR) and consisted of recruitment, application of clinical protocols, and management evaluations, conducted from January to December 2023.

This randomized clinical trial evaluated the following outcomes: I – dental sensitivity 5 minutes after hydrogen peroxide application; II – dental sensitivity 10 minutes after hydrogen peroxide application; III – dental sensitivity 15 minutes after hydrogen peroxide application; IV – dental sensitivity 20 minutes after hydrogen peroxide application; V – dental sensitivity 25 minutes after hydrogen peroxide application; VI – dental sensitivity 30 minutes after hydrogen peroxide application; VII – dental sensitivity 1 hour after removal of the bleaching gel; VIII – dental sensitivity 24 hours after removal of the bleaching gel; IX – dental sensitivity 48 hours after removal of the bleaching gel; X – dental sensitivity 7 days after removal of the bleaching gel; XI – color change.

2.2 Recruitment

Volunteer participants for the study were recruited through announcements on social media platforms and underwent evaluation by an examiner familiar with the eligibility criteria. Individuals who met the inclusion criteria and did not meet any of the exclusion criteria were invited to participate in the research.

Each participant was verbally and in writing informed about the nature of the study and the procedures involved but remained blinded to the experimental group to which they would be allocated. Additionally, the signing of the

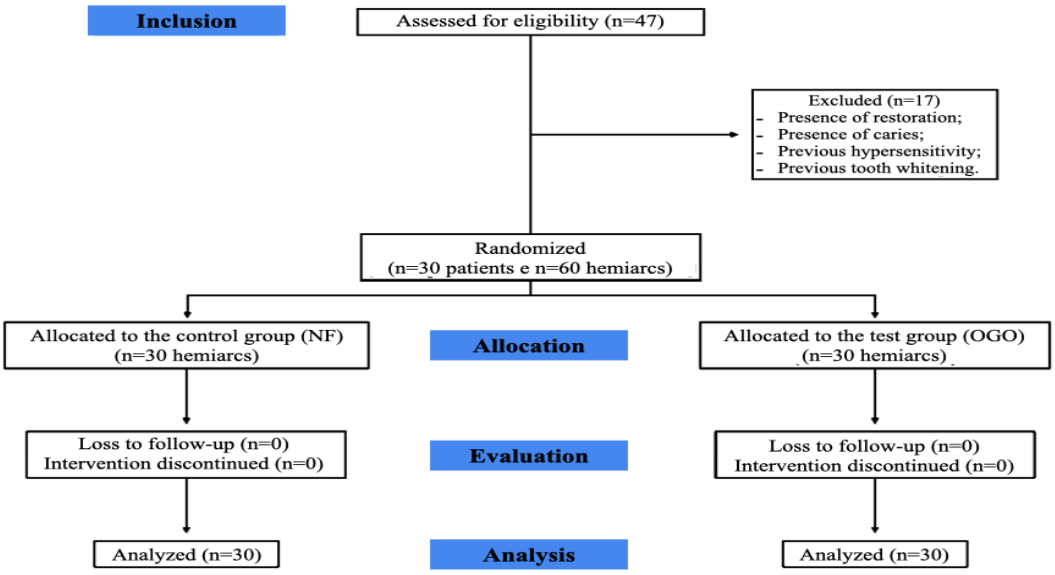

Fig. 1. Flowchart of distribution and dynamics of experimental groups

Informed Consent Form (ICF) was required before commencing the procedures.

2.3 Eligibility Criteria

The study included patients of both sexes, aged between 18 and 35 years, with all vital anterior teeth, never previously bleached or bleached at least 1 year ago, without restorations, and presenting central incisors with color A2 or darker (Fig. 2), as assessed using the Vita shade guide (Vita, Bad Säckingen, Germany).

Patients were excluded from the study if they had missing anterior teeth, were affected by caries lesions, exhibited recession, had any type of restorative or prosthetic treatment, had a history of dental hypersensitivity, presented dental discoloration due to tetracycline or fluorosis, were taking multiple medications, or fell under the condition of being pregnant or lactating.

2.4 Sample Size Calculation

Sample size calculation was performed based on probability distributions of t-tests (Wilcoxon and Mann-Whitney tests for comparison of two groups). The effect size used was 0.8, type 1 error (α) was set at 0.05, and the power of analysis (error β) was set at 0.8, resulting in a total of thirty individuals per group. Sample size calculation was conducted using GPower software, version 3.1.9.2 - University of Düsseldorf.

2.5 Randomization and Allocation Concealment

This was a controlled, randomized, blind, split-mouth clinical trial, with an equal allocation ratio for both groups. Randomization of the experimental groups was conducted through a draw. Blinding was implemented by applying the products without the patient knowing to which experimental group each hemiarch belonged, thus preventing this knowledge from influencing the patient's perception of sensitivity. The distribution and dynamics of the groups, as per the CONSORT (Consolidated Standards of Reporting Trials) flowchart, are depicted in Fig. 1.

2.6 Clinical Intervention

The participants had their upper and lower dental arches randomly divided into 2 hemiarches from the midline, according to the desensitizing agent used prior to the bleaching treatment (n=30) - Control Group (NF - 5% Potassium Nitrate with 2% Sodium Fluoride (Desensibilize KF 2%, FGM, Joinville, Santa Catarina, Brazil)) and Test Group (OGO - Ozonized Sunflower Oil) (Philozon, Balneário Camboriú, Santa Catarina, Brazil).

All participants underwent prophylaxis with pumice and water, and after that, the upper and lower arches were divided at the midline using a polyester matrix stabilized between the central incisors (Fig. 3). Both desensitizing agents were applied to the tooth surface for 10 minutes. Passively for NF (Fig. 4) and actively for OGO with the aid of a low-speed rubber cup (Fig. 5). Subsequently, a light-cured gingival barrier (Top Dam, FGM, Joinville, Santa Catarina, Brazil) was applied (Fig. 6), followed by the application of the bleaching agent (Fig. 7). Both arches were bleached with 35% hydrogen peroxide (Whiteness HP Maxx 35%, FGM, Joinville, Santa Catarina, Brazil), with two 15-minute applications each, following the manufacturer's recommendations. The composition of the materials used in the study is described in Table 1.

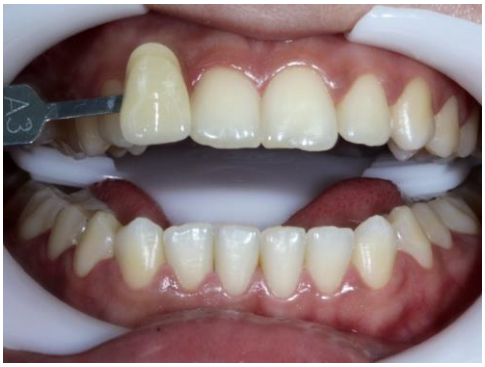

Fig. 2. Initial color take

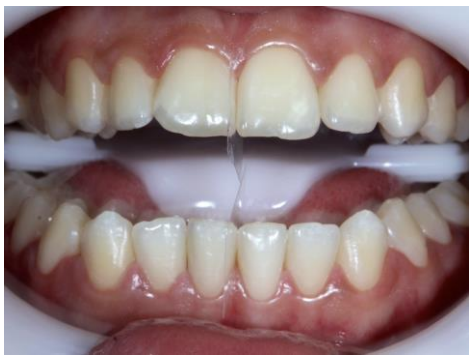

Fig. 3. Upper and lower arches divided in the midline with a polyester strip

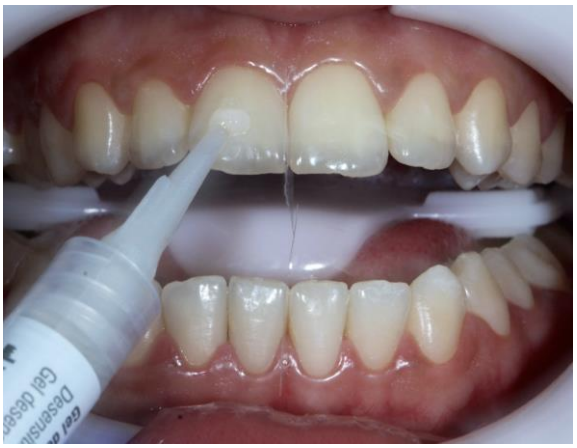

Fig. 4. Application of 5% potassium nitrate with 2% sodium fluoride (control group)

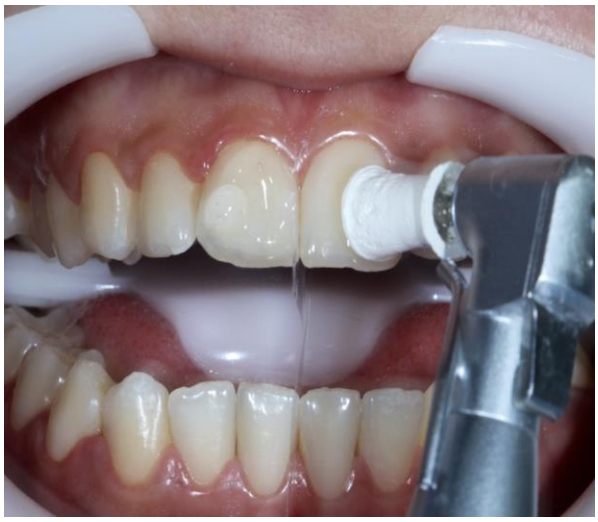

Fig. 5. Application of ozonized sunflower oil (test group)

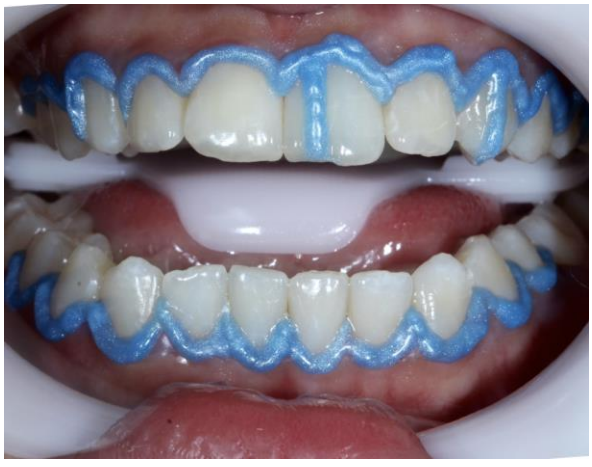

Fig. 6. Application of the light-cured gingival barrier

Fig. 7. Application of the whitening gel

2.7 Evaluation of Sensitivity Level

Each volunteer received a form to assess the potential sensitivity experienced. This data collection instrument consists of five scores where zero indicates absence of sensitivity; one indicates mild sensitivity; 2 indicates moderate sensitivity; 3 indicates considerable sensitivity, and 4 indicates severe sensitivity (Fig. 8).

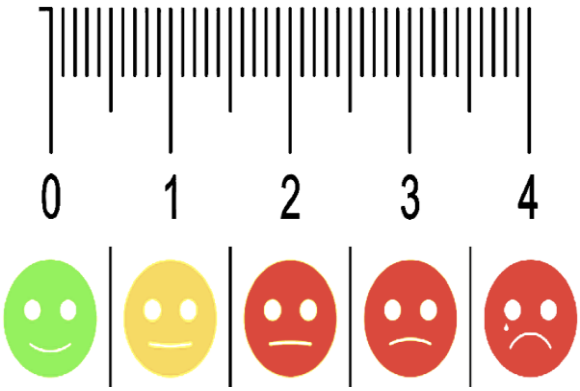

Fig. 8. Sensitivity experienced scale

To facilitate understanding by the patients, the scale was adapted in this research with the insertion of illustrative figures for each level of sensitivity. Data collection was performed every 5 minutes throughout the time the bleaching gel was on the tooth surface (a total of 30 minutes). Patients also noted the sensitivity present after 1, 24, and 48 hours and after 7 days of the end of the bleaching procedure. All participants were instructed not to use analgesic medication, and if they did, they were to inform the treatment provider.

Table 1. Composition of the materials used in the study

Products	Manufactures	Composition
HP Maxx Whiteness Whitening Gel 35%	FGM, Joinville, SantaCatarina, Brazil	35% hydrogen peroxide, thickener, red dye, glycol and deionized water
Desensitize KF 2%	FGM, Joinville, SantaCatarina, Brazil	Potassium nitrate 5% sodium fluoride 2%, deionized water, glycerin, neutralizingand thickening agents
Ozonated sunfloweroil	Philozon, Camboriú,Santa Catarina, Brazil	Contains oxygenatedcompounds, in the form of ozonides andperoxides, acquired during the ozonation process
Top Dam	FGM, Joinville, SantaCatarina, Brazil	HEMA, urethane di-methacrylate monomer, inert filler, pigments and photoinitiators

Table 2. Color evaluation scores

B1	A1	B2	D2	A2	C1	C2	D4	A3	D3	B3	A3,5	B4	C3	A4	C4
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

2.8 Evaluation of Bleaching Degree

The color assessment was conducted before the bleaching treatment, using the upper central incisors as a reference. Subjective evaluation was performed by comparing it with the Vita Classical shade guide (Vita, Bad Säckingen, Germany). Seven days after the completion of treatment, the color registration procedure was repeated for the final assessment of tooth saturation (Fig. 9). Color differences were calculated by the discrepancy in the number of shade guide units (SGU). The color scale was arranged in increasing order of brightness [13], from the brightest hue - B1 - to the least luminous - C4. In this sequence, each hue was assigned a score: B1 being score 1; A1 being score 2, and so forth, making the A3 hue score 9. The scores are presented in Table 2.

The color change (ΔC) before (ΔI) and after (ΔF) bleaching in each experimental group was determined by calculating the difference between the two measured color scores, using the following formula: ΔC = (ΔI) - (ΔF).

2.9 Statistical Analysis

Statistical analysis was conducted by a blinded researcher, who was unaware of which treatment protocol had been applied to each experimental group. The results were tabulated and subjected to statistical analysis using JAMOVI software, version 1.2.24. For the analysis of data related to both the degree of sensitivity experienced by the patients and the color change, the Wilcoxon test was performed ($p<0.05$).

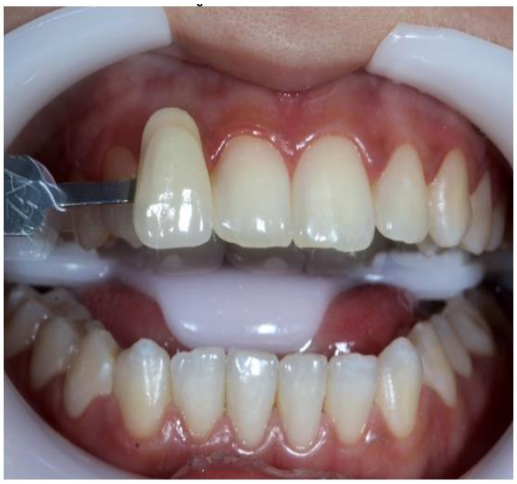

Fig. 9. Final color take

3. RESULTS AND DISCUSSION

The results obtained were assessed for normality and subjected to statistical analysis using the non-parametric Wilcoxon test ($p < 0.05$). Evaluation of sensitivity levels revealed a statistically significant difference between the assessed time points in the intra-group analysis for both groups.

Table 3. Median and interquartile range of sensitivity levels during the bleaching protocol with the use of desensitizer X and Y at different assessment time points

Groups	**Time (Minutes)**					
	5	**10**	**15**	**20**	**25**	**30**
Control	0.0 ± 0.0 Aag	0.0 ± 1.0 Ab	0.05 ± 0.0 Abc	0.25 ± 1.0 Abd	0.9 ± 1.0 Abef	1.0 ± 1.38 Ae
Test	0.0 ± 0.0 Aac	0.0 ± 0.875 Aab	0.25 ± 1.0 Ab	0.25 ± 1.0 Ab	0.0 ± 1.0 Babc	0.0 ± 1.0 Bab
Groups	**Time (Hours)**			**Time (Days)**		
	1	**24**	**48**	**7**		
Control	0.0 ± 1.0 Aacde	0.0 ± 0.0 Af	0.0 ± 0.0 Agf	0.0 ± 0.0 Af		
Test	0.0 ± 0.0 Bcd	0.0 ± 0.0 Ade	0.0 ± 0.0 Ae	0.0 ± 0.0 Ae		

**Different lowercase letters in the row indicate significant differences with p < 0.05 in the intra-group analysis by Wilcoxon's test.*

*** Different uppercase letters in the column indicate significant differences with p < 0.05 in the inter-group analysis by Wilcoxon's test.*

Table 4. Median and interquartile range of color score in groups X and Y

Color	Groups	
	Control	Test
Initial	5.0 ± 4.0 a	5.0 ± 4.0 a
Final	2.0 ± 2.25 1b	2.0 ± 2.25 b

** Different lowercase letters in the column show significant differences with p<0.05 in the intra-group analysis using the Wilcoxon test.*

Table 5. Median and interquartile deviation of the difference between the initial color and the final color in groups X and Y

Groups	
Control	Test
4.0 ± 1.0 a	4.0 ± 1.0 a

** Different lowercase letters in the line - show significant differences with p<0.05 in the intra-group analysis using the Wilcoxon test*

Meanwhile, in the inter-group analysis, the use of ozonized sunflower oil compared to conventional desensitizing agents resulted in statistically significant differences for the time points of 25 minutes, 30 minutes, and 1 hour after bleaching. The data are presented in Table 3.

For the assessment of the degree of whitening in the intra-group analysis, there was a statistically significant difference between the initial and final color in both tested groups, indicating a reduction in the degree of color saturation for both groups (Table 4). However, when evaluating the difference between the initial and final color after dental bleaching, there was no statistically significant difference between the groups (Table 5).

The hypothesis of the present study, that the use of ozonized sunflower oil would provide a more effective management of post-office dental bleaching sensitivity compared to the control group, was accepted, as ozonized sunflower oil showed a significant decrease in sensitivity at 25 minutes, 30 minutes, and 1 hour after bleaching.

This finding can be explained by the analgesic action of ozonized oil when diffused into the dentinal tubules, reaching the nerve endings. In addition to its obliterating action by reacting with calcium and collagen fibers, resulting in reduced sensitivity through mechanical blockage of the dentinal tubules [14]. The topical action of ozonized sunflower oil provides a remineralization effect on the enamel surface, resulting in reduced pain perception [10]. The study [6] emphasized that the combination of ozonized sunflower oil with potassium nitrate was statistically relevant in achieving more efficient tubular occlusion, resulting in a significant decrease in sensitivity during and after dental bleaching compared to the isolated use of potassium nitrate. Similarly, the authors [12] highlighted that the combination of ozonized sunflower oil with glutaraldehyde was more effective in controlling sensitivity during dental bleaching compared to potassium nitrate. These findings are supported by scientific evidence corroborating the efficacy of ozonized sunflower oil in sensitivity control in comparative studies. Supporting the complementary action of ozonized oil in pain management during and after dental bleaching, the study [15] compared the efficacy of ozonized sunflower oil associated with tea tree oil and potassium nitrate. However, no statistically relevant differences were observed, as the test group applied the product to the enamel surface for up to 7 minutes, while this study used ozonized sunflower oil and potassium nitrate for the same period of 10 minutes. However, it is important to note that the action of the control paste was similar, although it was applied for a shorter period, only 2 minutes. This finding suggests that the application time may be a determining factor in the efficacy of the paste for pain management during dental bleaching. Perhaps if the paste were used for the same duration as the control, the results could be superior to those found. This prompted the choice of the present study to use ozonized sunflower oil for the same duration as the control group. And indeed, a superior result was found for the oil when used for the same duration as potassium nitrate. The efficacy of 35% hydrogen peroxide for bleaching was evident, as all patients showed a reduction in color saturation. Furthermore, the maintenance of the initial color was observed, as no patient demonstrated a

decrease in renal luminosity during the 7-day or longer reassessment period. In both groups, there was noticeable bleaching, and no significant differences were found between the group treated with potassium nitrate (NF) and the group treated with ozonized sunflower oil (OGO), suggesting that it does not affect the efficacy of hydrogen peroxide for dental bleaching. These results are in line with the findings of several researchers [6,10,12]. However, for a more complex and comprehensive understanding, it would be highly recommended to conduct additional studies to monitor color stability over longer periods[16,17]. This approach would enable a more accurate assessment of the durability of the results achieved, providing valuable information on the longevity of dental bleaching.

4. CONCLUSION

One can conclude that ozonized sunflower oil presents a statistically significant effect in managing sensitivity during and after in-office dental bleaching, besides being a safe product for use as a desensitizing protocol, mainly because it does not interfere with the efficacy of hydrogen peroxide and the degree of saturation of bleached teeth.

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of manuscripts.

CONSENT

All authors declare that written informed consent was obtained from the patient.

ETHICAL APPROVAL

The study was submitted to the Ethics Committee for Research with Human Subjects (CEP) of the Western Paraná State University – UNIOESTE (Cascavel, Paraná, Brazil), and its approval was obtained under protocol number 5.725.780. Additionally, it was registered in the Brazilian Registry of Clinical Trials (ReBEC) under identification number RBR-76dknt8

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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