# Clinical Study of Bleaching Gel Storage Temperature on Tooth Color and Sensitivity

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## **Clinical Relevance**

Bleaching gels stored at room temperature or kept refrigerated before immediate use showed similar results for color stability, tooth sensitivity, and pH. However, the consistency of the gels when dispensed may be affected by storage temperature.

#### **SUMMARY**

Objective: The objective of this triple-blind, split-mouth, randomized clinical trial was to evaluate the bleaching efficacy and tooth sensitivity of an in-office bleaching agent submit-

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ted to different storage temperatures (room temperature at 21.04°C $\pm$ 3.13°C or refrigeration at 5°C).

Methods and Materials: Thirty volunteers were selected who had central incisors with color A2 or higher. The volunteers' maxillary hemiarches received either the bleaching treatment with room temperature or refrigerated storage temperatures (two sessions of 3×15 minutes, one-week interval). Color variation was evaluated by subjective (Vita Classic and Vita Bleachedguide) and objective methods (Vita Easyshade spectrophotometer). Tooth sensitivity was evaluated with the visual analog scale (0-10) and the numerical rating scale (five points). The consistency of bleaching gels was evaluated by flow test, and pH was measured, both in triplicate. Color variation (SGU) and  $\Delta E$  were analyzed by paired *t*-test ( $\alpha$ =0.05). The absolute risk of pain was assessed by McNemar test ( $\alpha$ =0.05), data from the numerical rating scale by the Wilcoxon signed-rank test ( $\alpha$ =0.05), and visual analog scale by paired t-test. Comparison between the times within each group was analyzed by Friedman test. Gel consistency and pH were analyzed by one-way analysis of variance and Tukey post-test.

Results: Regarding the absolute risk of tooth sensitivity, no significant difference was observed between the groups. The relative risk for tooth sensitivity was 1.13 (95%, confidence interval 0.70-1.82). Both tooth sensitivity scales were statistically similar. The results of the subjective evaluation (Vita Classic: p=0.73, Vita Bleachedguide: p=1.00) and the objective evaluation (p=1.00) of bleaching efficacy corresponded to the hypothesis of equality between groups after bleaching. Both pH values were around 7, and for the consistency test, there were significant differences between the groups (p=0.002).

Conclusions: Storage temperature of the analyzed in-office bleaching agent had no influence on tooth color effectiveness and tooth sensitivity.

## INTRODUCTION

The quest for lighter teeth has become increasingly frequent in dental practice. Since Haywood and Heymann introduced whitening in 1989, the development of conservative and effective treatments, with rapid results, has made dental whitening one of the most popular procedures in modern dentistry. <sup>3,4</sup>

Dental dyschromia may be caused by intrinsic and/or extrinsic factors. The bleaching technique used for each type of dyschromia may vary. However, all techniques are based on the use of hydrogen or carbamide peroxide, with concentration and application time changing according to the technique used: home or in-office therapy. With the in-office technique, activation by heat or light may be used to accelerate and enhance bleaching, as widely discussed in the literature. However, some recent studies have suggested that the use of light as a bleaching agent activator could be detrimental, as it may possibly cause an increase in the temperature of the pulp chamber and the risk of tooth sensitivity.

Bleaching agents are described in the literature as chemically unstable substances, <sup>11</sup> their stability being related to local factors such as temperature, light, moisture, pH, and impurities. <sup>12</sup> Increasing the temperature helps degrade hydrogen peroxide by accelerating the release of the hydroxyl radicals from the peroxide, according to the following equation:  $H_2O_2 + 211 \text{ kJ/mol} \rightarrow 2 \text{ HO}\bullet$ . For each additional  $10^{\circ}\text{C}$  increase in temperature there is an increase in the degradation rate of the peroxide in the order of 2.2. This increased release of hydroxyl radicals (called thermocatalysis) may increase bleaching

efficacy.<sup>13</sup> However, light activation does not make any difference in tooth lightening, although the heat from the external light units considerably increases the temperature of the hydrogen peroxide.<sup>6,7,10,13</sup>

Other authors found that increasing temperature had a negative effect on the pH stability of bleaching agents. 14 Bleaching gel stored in a refrigerator (4°C±1°C) showed higher pH than bleaching gel stored at room temperature (23°C±1°C). The value of pH may decrease when there is an increase in the ions of H+, as maintaining the product at higher temperatures may induce dissociation of some components, leading to a high concentration of H+ ions and consequent reduction of pH in the long term. Bleaching agents with acid pH have a higher rate of oxygen ions (O<sup>-2</sup>), while agents with more neutral pH have a higher rate of perhydroxyl ions (HO<sub>2</sub><sup>-</sup>). <sup>14</sup> Furthermore, Marson and others concluded that the longer the bleaching gel is stored at higher temperatures (37°C), the higher the decrease in peroxide concentration compared with that of bleaching agents maintained between 5°C and 25°C after 6 months. 15 These findings can be attributed to Le Châtelier's principle, which states that the effect of chemical equilibrium is related to some conditions, such as temperature; in other words, if there is a change in temperature, the position of the chemical equilibrium will change in one direction, where it will reduce stress, and thus restore a new chemical balance. 16 One way to maintain the pH stability of the bleaching gels is to keep it refrigerated. 14,15 However, some manufacturers report that there is no need to keep bleaching gel cool because ambient temperatures should be sufficient to ensure satisfactory chemical properties in hydrogen or carbamide peroxide gels. Others advise that the bleaching agents should be kept at ambient temperatures between 5°C and 25°C: the first value represents refrigeration, and the second is the average ambient temperature in several places. These factors play a key role during the shelf life of bleaching gels 17,18 and during their transport and storage at dental offices.

The physical properties of the bleaching agent should also be discussed. These products should have good flowability to facilitate insertion, an adequate degree of elasticity, and high viscosity at low tension so the product remains in contact with the dental surface, <sup>19</sup> thereby improving its effectiveness by increasing product contact with the tooth. Furthermore, it would prevent the substance from reaching other locations, since it is known that the bleaching gel may have adverse effects on adjacent oral

tissues.<sup>20-25</sup> Also, some at-home and in-office bleaching agents use Carbopol as a thickener; in this type of component, temperature influences the rheologic characteristics,<sup>26</sup> which in turn, may change the bleaching gel viscosity.

The literature contains only in vitro data on the effect of temperature on the properties of bleaching agents. Storage temperature may influence the pH of these agents, as refrigerated gels had a higher pH than those kept at room temperature. 14 Moreover, lower pH values may lead to more adverse effects on dental structures<sup>27,28</sup> and enhanced tooth sensitivity.<sup>29</sup> However, there are no *in vivo* studies on the influence of storage temperatures on clinical parameters. Therefore, the objective of this triple-blind, split-mouth, randomized clinical trial was to evaluate the effect of an in-office bleaching agent stored at room temperature or refrigerated on bleaching efficacy and tooth sensitivity. The null hypotheses were that the storage temperature would not influence bleaching efficacy or tooth sensitivity.

#### **METHODS AND MATERIALS**

## **Study Design**

This study was designed according to the CONSORT statement.<sup>30</sup> The study was conducted at the clinic of the School of Dentistry. All participants were informed about the nature and objectives of the study. Written informed consent was obtained from all participants before starting the treatment. This was a triple-blind and split-mouth randomized clinical trial with two experimental groups.

# **Participant Recruitment**

Recruitment was performed by posting written advertisements on the university walls. All volunteer participants signed an informed consent form before being enrolled in the study.

## **Inclusion and Exclusion Criteria**

Thirty nonsmoker patients between 18 and 40 years old were included, all with good general and dental health, healthy maxillary and mandibular anterior teeth, a good level of oral hygiene, no cervical lesions, no white spot lesions or caries, and no periodontal disease. The maxillary central incisors of each patient were evaluated, specifically the medium third of the facial surface, according to American Dental Association recommendations. These teeth presented color A2 or higher, according to the Vita scale (VITA Classic, VITA Zahnfabrik, Bad Säckingen, Germany) and Vita Easyshade (Easyshade;



Figure 1. Initial color registration of the maxillary central incisors and their color 1 month after the procedure. (A): Baseline. (B): After one month

Vident, Brea, CA, USA). All evaluations were conducted under the same illumination in the same room by the same two examiners, who recorded the initial color of the maxillary central incisors and their color 1 month after the procedure (Figure 1). For calibration purposes, five participants who were not included in the study sample participated in the training phase. The two examiners (DH and BFB), who were blinded to the allocation assignment, scheduled these patients for bleaching and evaluated their teeth against the shade guide at the baseline (one week after bleaching) and 30 days after the procedure. The two evaluators presented superior color-matching competency according to the ISO/TR 28642.<sup>32</sup> This means they had an agreement of 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, the evaluators needed to reach a consensus before the participant was dismissed.

The exclusion criteria were participants needing endodontic treatment or those with nonvital teeth, pregnant or breast-feeding women, participants with known allergies to bleaching materials or any other material used in this study, those taking anti-inflammatory, analgesic or psychotropic drugs, the presence of restorations in the anterior teeth, parafunctional habits, those with severe internal tooth discoloration (tetracycline stains, fluorosis, pulpless teeth), those who smoked, and those who had undergone tooth-whitening procedures.

During the first appointment, tooth sensitivity was measured using an air stream in the cervical region of the anterior teeth and vertical/horizontal percussion. Patients who demonstrated pain (on a verbal scale from 0 to 4) were excluded from the study.

# **Randomization and Group Allocation**

Randomization was performed using opaque envelopes containing the group allocation, which was

revealed when opening the envelopes at the time of the bleaching procedure.

## Blinding

This study was a triple-blind clinical trial, as the patients, the operator and the data analyst were kept blind.

#### Intervention

All patients received oral hygiene instructions and prophylaxis before initiating the bleaching procedure. The patients were randomly bleached in a split-mouth design according to the two storage temperatures (n=30): room temperature (21.04°C±3.13°C) and refrigerated (5°C). Bleaching gels were allocated at their respective temperatures for one month before the study and were maintained until the end of the study, for 3 months. The product was used before the expiration date. Each patient served as his or her own control. After placement of a lip retractor (Arcflex, FGM, Joinville, SC, Brazil) the operator isolated the gingival tissue of the teeth to be bleached using a light-cured resin dam (Top Dam, FGM), which was light cured for 20 seconds on each three-tooth group (Radii-cal, SDI, Bayswater, Victoria, Australia). Another operator manipulated the bleaching gel, to ensure operator blinding. The researcher applied the 35% hydrogen peroxide gel (Whiteness HP Maxx, FGM), inserting the gel in a Luer disposable syringe (three 15-minute applications for both groups), in accordance with the manufacturer's directions. The researcher refreshed the in-office bleaching agent every 15 minutes during the 45-minute application period. Two bleaching sessions were performed one week apart.

#### **Tooth Sensitivity Evaluation**

Tooth sensitivity was evaluated during bleaching and up to one hour, 24 hours, and 48 hours after bleaching in both sessions. Participants were instructed to record the tooth sensitivity they experienced for each period listed earlier, using a five-point verbal numerical rating scale and a visual analog scale. For the numerical rating scale, participants had to choose one score from 0 to 4 to represent the intensity of tooth sensitivity using the following scale: 0 indicating no pain; 1, mild pain; 2, moderate pain; 3, considerable pain; and 4, severe pain. <sup>33-36</sup> For the visual analog scale, participants had to mark a line perpendicular to a 10-mm line, where: 0 indicated no pain and the 10-mm end indicated severe pain. <sup>29,33,34,37</sup>



Figure 2. Tip of the spectrophotometer placed in the labial perforation of the silicone matrix, which was used for individual evaluation of the right and left maxillary central incisors.

## Sample Size

Sample-size calculation was based on the primary outcome of the study, color alteration ( $\Delta E$ ), measured using a spectrophotometer. With a significance level of 5% and power of 90%, 30 patients were required to detect a difference of means of three units of  $\Delta E$  and standard deviation of two. The selected equivalence limit of  $\Delta E$ =3.0 is that at which color differences become clinically perceptible.

## **Color Evaluations**

Initial and final color evaluations were performed at baseline (after bleaching) and one month later, respectively. Before baseline color evaluation, a preliminary impression of the maxillary teeth was taken using silicone impression material (Speedex; Vigodent S/A Ind. Com, Rio de Janeiro, RJ, Brazil). This impression served as a guide to standardize the color measurements using a VITA Easyshade spectrophotometer (Easyshade, Vident). A hole the size of the active tip of the Easyshade device was made in the facial surface of the silicon guide. The selected position corresponded to the middle third of the right and left central incisor facial surface (Figure 2). Color was determined using CIE L\*a\*b\* parameters, where L\* indicates luminosity, varying from 0 (black) to 100 (white), and a\* b\* represent the axischromatic, where a\* is the measure along the redgreen axis and b\* the measure along the yellow-blue axis.

The CIE L\*a\*b\* values were measured in each patient. The differences between the baseline and each recall appointment ( $\Delta E$ ) were calculated according to the following equation:  $\Delta E = \left[(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2\right]^{1/2}$ .

For the subjective evaluation, we used the shade guides VITA Classic and VITA Bleachedguide (VITA Zahnfabrik), where the VITA Classic was arranged from whitest to darkest levels, Although the VITA Classic is not a linear scale, it was arranged from the largest value (B1) to the smallest value (C4), 10,42 representing a score for the purpose of analysis. The VITA Bleachedguide is a shade guide for dental bleaching, where it is already organized from the highest (0M1) to the lowest value (5M3). 43,44

## **Consistency Test**

The consistency of the bleaching gels was evaluated by a flow test using two glass plates with constant load for a set time, as described by Panzeri and others. <sup>45</sup> Initially, 1 g of the bleaching gel was weighed and placed over a glass plate. Another glass plate was placed over the gel with a constant load of 761.75 g. After 5 minutes, the highest and lowest halo diameters resulting from the load were calculated using a digital caliper (Diginess, São Paulo, SP, Brazil). Measurements were performed in triplicate.

## pH Measurement

The pH values were verified using a calibrated digital potentiometer (HI 221 Microprocessor pH Meter, Hanna Instruments, São Paulo, SP, Brazil), with a proton selective glass electrode. 46 To calibrate the pH meter, the standard operating procedure was followed: the electrode was inserted and agitated in a beaker with buffer solution (pH 6.86); the sensitivity of the apparatus was adjusted to 95% to measure 6.86. The electrode was removed, washed with distilled water, dried, and inserted into another beaker with 4.00 pH buffer solution. The calibration procedure was repeated, this time to assess the value of 4.00; after this, the calibrated pH meter was ready for use. The analysis of pH was performed in triplicate for each of the three samples of whitening gel used in this research. In a beaker, 1 g of bleaching gel was dissolved in 10 mL of distilled water. 45 Dispersion was achieved using a magnetic stirrer (Fisaton, Sao Paulo, SP, Brazil) for 5 minutes. Then, the proton selective glass electrode was introduced into the beaker containing the dissolved bleaching gel, avoiding touching the bottom of the bottle.

# **Statistical Analyses**

The analyses followed the intention-to-treat protocol.<sup>30</sup> The statistician was blinded to the experimental groups. The absolute risk of tooth sensitivity was compared using the McNemar test ( $\alpha$ =0.05). The

relative risk and confidence interval for the effect size were also calculated.

Differences in the intensity of tooth sensitivity between the groups were analyzed using the Wilcoxon signed-rank test. Comparisons between each group were done by the Friedman test. Comparison of the intensity of sensitivity according to the visual analog scale from the groups at the two recall points was performed by paired t-test. For the comparisons between the recall times, the Friedman test was used. Color variation ( $\Delta$ SGU and  $\Delta$ E between baseline versus after one month) was analyzed by paired t-test. Gel consistency and pH were analyzed by one-way analysis of variance and Tukey post-test.

All analyses adopted a 5% level of significance (SigmaPlot 11.0, Systat Software, San Jose, CA, USA).

#### RESULTS

# **Characteristics of the Participants**

A total of 30 patients were selected for this study (Figure 3), 33% of which were male. Age ranged from 18 to 40 years (mean age:  $27.4\pm6.9$  years). The baseline color was  $8.86\pm2.78$  SGU for the refrigerated group,  $8.93\pm2.79$  SGU for the room temperature group (VITA Classic),  $9.03\pm1.44$  SGU for the refrigerated group, and  $8.96\pm1.51$  for the room temperature (VITA Bleachedguide).

## Adherence to Protocol

All patients completed the bleaching treatment and returned to the recall appointments one month after bleaching.

#### **Tooth Sensitivity**

In terms of the absolute risk of sensitivity, no differences were observed between the groups, as shown in Table 1 (p=0.29). The relative risk was 1.13 (95% confidence interval, 0.70–1.82). Data on tooth sensitivity from both scales were statistically similar (p>0.05, Tables 2 and 3).

# **Color Evaluation**

At the end of the bleaching procedure, variation of six SGUs was found for both groups using the VITA Classic guide and eight SGUs for the VITA Bleachedguide. The  $\Delta E$  varied by approximately 12 units (Table 4), demonstrating significant color alteration. Comparisons between the two groups using the subjective evaluations (Vita Classic: p=0.73; Vita Bleachedguide: p=1.00) and the objec-

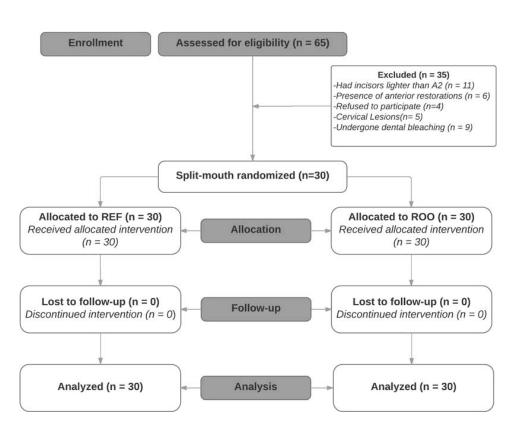


Figure 3. Flow diagram of study design phases, including enrollment and allocation criteria.

tive evaluation (p=1.00) showed no significant differences. There were no significant differences in tooth color between groups, regardless of the method used to evaluate tooth color (Table 4).

# Consistency Test and pH

No significant differences in pH were observed between the groups according to Table 5 (p=0.25). All pH values were close to 7. The consistency test revealed significant differences between the groups (p=0.002), with the refrigerated group showing higher values than the room temperature group.

#### DISCUSSION

The present study confirmed the null hypothesis that the storage temperature of the bleaching gel did not influence the effectiveness of bleaching in terms of tooth color. Both groups showed similar results after two  $3\times15$  min sessions. Moreover, the subjective and objective evaluations demonstrated that both groups showed effective bleaching (Figure 4). The color change observed for VITA Classic was six SGUs, which is consistent with previous studies.  $^{29,34,42,47-49}$ 

The null hypothesis regarding tooth sensitivity was confirmed. No differences were found between the two groups. Slightly lower sensitivity was observed for the group treated with refrigerated bleaching agent  $(0.3\pm1.0)$  compared with the room temperature agent  $(0.7\pm1.5)$ . However, this result did not appear to be clinically relevant. The absolute risk of tooth sensitivity in this study was low and similar. On the other hand, other studies have presented higher absolute risks of sensitivity, varying from 67% to 100%.  $^{47,50-53}$  These differences may

Table 1: Comparison of the Number of Patients Who Experienced Tooth Sensitivity During the Bleaching Procedure in Both Experimental Groups, Absolute Risk and Relative Risk<sup>a</sup>

Treatment	Tooth sensitivity (No. of patients)		Absolute risk (95% Confidence Interval)	Relative risk (95% Confidence Interval)
	Yes	No		
Room temperature	17	13	57 (39–73)	1.13 (0.70–1.82)
Refrigerated	15	15	50 (33–67)	
<sup>a</sup> McNemar test (p=0.29).				

Table 2: Medians and Interquartiles from Tooth Sensitivity Intensity in Different Recall Times Using the Numerical Rating Scale <sup>a</sup>

Recall Times	Refrigerated**	Room Temperature**	p Value*
During bleaching	0 (0 to 0) <sup>A</sup>	0 (0 to 2) <sup>A</sup>	0.64
1 hour after	0 (0 to 1) <sup>A</sup>	0 (0 to 1) <sup>A</sup>	1.00
24 hours after	0 (0 to 0) <sup>A</sup>	0 (0 to 0.75) <sup>A</sup>	0.09
48 hours after	0 (0 to 0) <sup>A</sup>	0 (0 to 0) <sup>A</sup>	0.38
a Wilcoxon* and Friedman** tests; p>0.05. Within each column, significant differences are represented by distinct uppercase letters.			

be attributed to the formulations of the bleaching gels and other environmental factors. The presence of tooth sensitivity associated with bleaching procedures using hydrogen peroxide is well documented but is not completely understood. Alternatives are being investigated to avoid this adverse effect. <sup>29,33,35,37,38,48,53</sup>

Hydrogen peroxide gels are described in the literature as chemically unstable compounds<sup>11</sup> and their stability has been related to physical factors such as temperature. 12 When temperature increases, it has a negative effect on pH stability. <sup>14</sup> For this reason, it would be expected that the bleaching gel stored at refrigerated temperature showed lower tooth sensitivity, due to higher pH values. More acidic bleaching agents can lead to adverse effects on tooth enamel, such as a significant increase in surface roughness, wear of the dental enamel, and greater dental sensitivity. 27-29 However, the bleaching gel of this study did not demonstrate these findings as pH did not vary by storage temperature. No variance of the bleaching gel pH according to the storage temperature may be due to a number of factors, including stabilizers, such as phosphoric or other inorganic acids, which allow prolonged storage that avoids short-term chemical rebalancing.<sup>54</sup>

Loguercio and others<sup>29</sup> evaluated two bleaching gels with different pH values and concluded that

Table 3: Means and Standard Deviations of Tooth Sensitivity Intensity in Different Recall Times Using the Visual Analog Scale

Recall Times	Refrigerated	Room Temperature	p Value <sup>a</sup>
During bleaching	1.3±2.6 <sup>A</sup>	1.5±2.4 <sup>A</sup>	0.63
1 hour after	1.4±2.4 <sup>A</sup>	1.5±2.6 <sup>A</sup>	0.83
24 hours after	0.3±1.0 <sup>B</sup>	0.7±1.5 <sup>A,B</sup>	0.02
48 hours after	$0.1 \pm 0.5^{B}$	0.2±0.6 <sup>B</sup>	0.25

<sup>&</sup>lt;sup>a</sup> According to t-test. Within each column, significant differences are represented by distinct uppercase letters.

Table 4: Means and Standard Deviations of ΔSGU
Obtained from Vita Classic and Vita
Bleachedguide; ΔL, Δa, Δb, and ΔE Obtained by
Easyshade; Baseline Versus One-month
Measures, and p Values

Color Evaluation	Gro	Groups	
	Refrigerated	Room Temperature	
Subjective Evaluation	on (∆SGU)		
Vita Classical	6.7±2.7	6.4±2.6	0.73
Vita Bleached	8.0±2.9	8.0±3.1	1.00
Objective evaluation	(spectrophotome	ter-CIELab para	meter)
ΔL	5.9±5.5	5.5±5.8	0.77
Δα	-2.3±1.9	-2.2±1.9	0.72
Δb	-8.9±3.9	-9.0±3.7	0.91
ΔΕ	12.0±3.7	12.2±4.1	1.00
<sup>a</sup> Paired t-test.	_	_	

neutral pH gels help to reduce tooth sensitivity. These findings may explain why there was no significant difference between the experimental groups in this study, as pH analysis of the gels demonstrated that both gels had an almost neutral pH, and thus the risk of tooth sensitivity was similar.

One of the factors that may have influenced the lower tooth sensitivity values was that bleaching treatment with 35% hydrogen peroxide was done only on the maxillary teeth. Other studies used 35% hydrogen peroxide on both the maxillary and mandibular arches. <sup>33,50-53</sup> The mandibular teeth are more likely to have a high risk of sensitivity, as reported by Haywood,<sup>55</sup> because the teeth are smaller. Because they have a thinner layer of enamel and dentin, the hydrogen peroxide can penetrate the dental pulp more rapidly, thus reducing the time required for a pulpal response compared with that in a tooth with thicker enamel and dentin.<sup>56</sup> Histopathological studies conducted by Costa and others revealed notable damage in pulp tissue of the mandibular incisors after whitening compared with premolars, which are bulkier.<sup>56</sup> In the present study, bleaching treatment of the mandibular arch was

Table 5: Means and Standard Deviations of Flow Test (in Millimeters) and pH Measurements Obtained in Triplicate<sup>a</sup>

Group	Flow (mm)	pН
Room temperature	98.81±2.20 <sup>a</sup>	6.88±0.29 <sup>c</sup>
Refrigerated	83.66±3.28 <sup>b</sup>	6.62±0.16 <sup>c</sup>

<sup>&</sup>lt;sup>a</sup> Lowercase letters showed significant differences between lines (p<0.05). One-way analysis of variance and Tukey post-test.

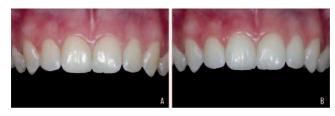


Figure 4. Color change observed in a patient at different evaluation periods. (A): Baseline. (B): After one month.

available to all patients, and the tooth sensitivity data were not collected. In addition, all patients chose to use an individual tray and at-home bleaching for the mandibular arch after the end of this clinical trial.

Another factor that may have influenced some studies that reported greater tooth sensitivity is the use of 35% hydrogen peroxide for an uninterrupted 45-minute period, contrary to the manufacturer's instructions. An example is a study in which the risk of tooth sensitivity was 90% (compared with 57% in the current study in which the in-office bleaching agent was refreshed every 15 minutes during the 45minute application period).<sup>51</sup> The type of whitening technique may also determine tooth sensitivity; Basting and others found the highest risk of tooth sensitivity in the group using at-home 20% carbamide peroxide (71.4%) and a lower risk of sensitivity in the groups who used 35% and 38% hydrogen peroxide in office (47% and 15%, respectively).<sup>53</sup> The in-office bleaching agent contained desensitizing agents, a fact that may have supported the lower tooth sensitivity results.

In the flow test, the refrigerated bleaching gel showed higher consistency than the room temperature gel. The temperature rise relaxes the polymer network of the Carbopol thickener, decreasing gel viscosity. The temperature decrease could restore the prerelaxed network, increasing the bleaching agent viscosity. This may be seen as an advantage, as better control would be achieved when the gel is applied. The higher viscosity ensures that the bleaching gel maintains contact only with the facial surface of the teeth, preventing the substance from reaching other sites; this is advantageous as it is known that bleaching gel may have adverse effects on adjacent oral tissues. <sup>20-25</sup>

As already mentioned, rheologic features improve bleaching effectiveness by increasing the product contact with teeth.<sup>19</sup> The viscosity of the whitening agent will affect product distribution and how it flows from the syringe. The viscosity test demon-

strated that the gel subjected to refrigerated temperature possessed a higher viscosity; thus, better application control was ensured. Otherwise, the gel at room temperature, in which viscosity was lower, should require more caution when applying, in order to guarantee that it stays in place on the tooth surface and does not reach adjacent tissues. However, the higher viscosity of the refrigerated bleaching gel may hinder its application once it becomes more resistant to flow from the syringe and may not distribute the product equally on the tooth surface. This may be one of the main reasons why manufacturers recommend leaving the product at room temperature before application.

It is worth mentioning that further clinical studies are required to evaluate other bleaching gels with different pH values and at higher room temperatures, as some locations have average temperatures above 25°C.

#### CONCLUSION

The results of this study show that the storage temperature conditions studied had no influence on color stability or tooth sensitivity for the analyzed inoffice bleaching gel. The pH values were similar for both groups; however, the refrigerated bleaching gel was more viscous than the gel kept at room temperature, which may suggest an improvement during application of the product. Furthermore, hydrogen peroxide gel should not be stored at room temperature in places where room temperature is higher than 25°C. In these conditions, the in-office bleaching gel must be kept refrigerated to avoid deleterious effects.

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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 Ethics Committee of the Centro de Ensino Superior dos Campos Gerais. The approval code for this study is: 1.437.224. This study was registered in the Brazilian Clinical Trials Registry under the identification number RBR-5td5hg.

#### **Conflict of Interest**

The authors of this manuscript 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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