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Efficacy of Home-use Bleaching Agents Delivered in Customized or Prefilled Disposable Trays: A Randomized Clinical Trial

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Clinical Relevance

Home-use bleaching agents delivered in customized or prefilled disposable trays are equally effective in promoting tooth color change but may cause tooth sensitivity that may intensify during treatment. Users seem to find customized trays more comfortable.

SUMMARY

The purpose of this study was to evaluate bleaching methods containing hydrogen peroxide (HP) or carbamide peroxide (CP), dispensed in customized or prefilled trays, in terms of color change, tooth sensitivity, gingival irritation, acceptance, and comfort. Seventy-five volunteers were randomly selected and distributed according to the whitening agent (n=25): 10% HP dispensed in prefilled trays (Opalescence Go 10%) and 9.5% HP (Pola Day) and 10% CP both delivered in customized trays (Opalescence PF 10%). HP was applied for 30 min/d for 14 days (d), and CP for 8 h/d for 14 days. Evaluations were performed at baseline and at 7 days and 14 days of treatment. Color change was measured with Commission internationale de l'éclairage color coordinates (L*, a*, b*), Vita Classical, and 3D Master scales. A visual analog scale was used to assess tooth sensitivity, acceptance of the method and degree of comfort of the tray. Gingival irritation was evaluated as present or absent and localized or generalized. Regarding gingival irritation, tray acceptance, and tooth sensitivity, no differences were observed among the groups at any time ($p>0.05$). As for degree of comfort, 10% HP showed lower scores (comfortable) than 10% CP, with significant differences ($p<0.05$) from the other groups (comfortable to very comfortable). In terms of

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ΔL, Δa, and ΔE, no difference was observed among the groups or between the time periods ($p>0.05$). The Δb average was higher at 14 days ($p<0.05$), and there was no difference among the groups ($p>0.05$). Localized gingival irritation was observed in both tray methods. Mild tooth sensitivity was observed with time, regardless of the bleaching agent concentration or the application time. Color change was similar for all the groups at 7 days and 14 days, but there was a greater reduction in the yellow hue at 14 days. All the bleaching methods were highly accepted and effective in promoting whitening. Although prefilled trays are generally comfortable, they proved less comfortable than customized trays.

INTRODUCTION

Supervised dental bleaching using dental trays is one of the most commonly used approaches to modify tooth color.[1-3] The main advantages of this technique are related to the patient's ease of use, reduced chair time, and a comparatively similar or lower prevalence of tooth sensitivity and gingival irritation during treatment in relation to chairside methods using high concentrations of peroxides.[4-11]

Ten percent carbamide peroxide has traditionally been the most suitable bleaching agent for this procedure;[1,10] however, to increase the efficacy of bleaching products, higher concentrations have been used,[12-14] and new bleaching agents containing 3% to 10% hydrogen peroxide have been released.[11,14,15]

Hydrogen peroxide in customized trays was proposed to reduce bleaching time, while maintaining effectiveness, compared with carbamide peroxide.[10,11,13,14,16] A carbamide peroxide gel containing desensitizing agents that could be applied in a shorter time has also been proposed to reduce the intensity of tooth sensitivity.[17]

Other home-use dental bleaching methods have become available, particularly those involving prefilled trays, such as Opalescence Go (Ultradent Products, South Jordan, UT), and containing a combination of carbamide and hydrogen peroxide, resulting in a total of 10% hydrogen peroxide. The use of prefilled trays can make application of the whitening treatment easier by eliminating the need for impressions, plaster casts, and tray customization, thus speeding up the bleaching treatment with proven effectiveness in tooth color change.[15] Prefilled trays may be adapted to the dental arches and resemble customized tray bleaching treatments, but they must be done under the supervision of a dentist.[15,18] Nevertheless, because prefilled trays do not provide adequate sealing, there may be overflow of the whitening product into the oral cavity, causing discomfort to the patient. In this regard, there have been no clinical studies showing a combination of effects, such as tooth whitening, tooth sensitivity, treatment acceptance, and level of comfort, when using this alternative prefilled approach, in comparison to other bleaching methods using carbamide peroxide or hydrogen peroxide in customized trays.

The objective of this study was, therefore, to compare the effects of whitening techniques using carbamide peroxide or hydrogen peroxide dispensed in customized or prefilled trays on color change, tooth sensitivity, gingival irritation, and treatment acceptance and comfort. The null hypothesis tested was that there would be no difference in terms of clinical parameters among the bleaching products containing 10% hydrogen peroxide in prefilled trays versus 9.5% hydrogen peroxide and 10% carbamide peroxide in customized trays.

METHODS AND MATERIALS

Experimental Design and Bleaching Agents Used

Three groups were investigated: 10% hydrogen peroxide prescribed in the form of prefilled trays (Opalescence Go 10% Mint [OPAGO], Ultradent Products), 9.5% hydrogen peroxide prescribed in the form of customized trays (Pola Day [POD], SDI), and 10% carbamide peroxide prescribed in the form of customized trays (Opalescence 10% PF Mint [OPA], Ultradent Products). The patients were evaluated at baseline before beginning treatment and after 7 days and 14 days of bleaching. The materials used, as well as their specifications and application protocols, are shown in Table 1. The pH value of the bleaching agents was measured in triplicate at different times using a benchtop pH meter (MS Tecnopon Special Equipment Ltd, Piracicaba, Brazil): baseline, 15 minutes, and 30 minutes (OPAGO and POD agents); and baseline, 15 and 30 minutes, and 1, 2, 4, 6, and 8 hours (OPA). All the measurements were made upon removal of the gel with a spatula, directly from the preloaded impression tray (OPAGO) or after being dispensed from a syringe (POD and OPA). The following pH values were obtained for the agents, according to the respective measurement periods: OPAGO (6:02; 6:01; 5.97); POD (6.25; 6.24; 6.14); OPA (6:53; 6:51; 6:52; 6:52; 6:56; 6:55; 6:55; 6:59).

Table 1: *Bleaching Agents, Compositions, and Manufacturers*

Bleaching Treatments	Bleaching agents/ Manufacturer (City, State, Country)/Lot Number	Composition (Percentage in Weight)	Daily Time of Use/Total Number of Treatment Days
OPAGO (10% hydrogen peroxide delivered in prefilled disposable trays)	Opalescence Go Mint/ Ultradent Products (South Jordan, UT, USA)/D005R, D002U	7.9% hydrogen peroxide (<13), 7.5% carbamide peroxide (<8), sodium fluoride (<0,3), sodium hydroxide (<5), glycerin (<39), potassium nitrate (≤3)	30 minutes a day/14 days
POD (9.5% hydrogen peroxide delivered in custom-made trays)	Pola Day 9.5%/ SDI (Melbourne, Victoria, Australia)/P130308Z	9.5% hydrogen peroxide, < 47% additives, 30% glycerol, 20% water, 0.1% flavoring, potassium nitrate	30 minutes a day/14 days
OPA (10% carbamide peroxide delivered in custom-made trays)	Opalescence PF 10% Mint/ Ultradent Products/D003K,D00LT	10% carbamide peroxide (<25), polyacrylic acid (<10), 0.3% sodium fluoride (<0.25), 3% sodium hydroxide (<5)	8 hours at night/14 days

Patient Selection

Seventy-five participants of both sexes were selected. The minimum sample size was established at 60 participants for the experiment, 20 participants per group, according to a previous study.[9] Twenty-five participants were recruited per group (n=25) to compensate for possible subject withdrawals or loss.

Participants were included or excluded from the study based on history-taking and clinical examination considering the following inclusion criteria:[9] age between 18 and 30 years, presence of at least 20 sound teeth, and presence of central and lateral incisors, or maxillary and mandibular canines, with at most 1/6 of the buccal surface restored. Exclusion criteria were[9] teeth with an initial color of B1 assessed using a shade scale (Vitapan Classical, VITA Zahnfabrik, Bad Sackingen, Germany) or spectrophotometer (VITA Easyshade Advance, (VITA Zahnfabrik, Bad Säckingen, Germany), people wearing dentures or fixed/removable orthodontic appliances, pregnant or breast-feeding women, smokers, history of dentin sensitivity, presence of active caries in enamel or dentin, periodontal or other oral disease, tetracycline-pigmented teeth, and previous tooth bleaching.

Tooth Color Shade Evaluation

The bleaching treatment was randomly assigned to each participant using a sequence of random software generated numbers. Tooth color evaluation was performed in a dental office using natural light (light from a window), in addition to artificial lighting from the fluorescent lamps in the dental office. The same examiner was responsible for assessing tooth color at all times.

A spectrophotometer (VITA Easyshade Advance) was used to measure the color at the middle third of the labial surface of the maxillary right central incisor at baseline. Color evaluation was performed using a probe tip supported and seated at a right angle with the tooth surface. This measurement was immediately duplicated to improve accuracy. When the two readings were the same for the Vita Classical scale, the value measured was noted after obtaining the second reading and the other parameters. If the two readings did not match, a new measurement was taken until agreement was reached between two readings. In sum, tooth color was verified using the Vita Classical shade guide, the Vita 3D Master, and Commission internationale de l'éclairage color coordinates where L represents the lightness, a represents the point on a red-green scale, and b the point on a yellow-blue scale (CIELab). Since all the evaluations for the Vita Classical shade guide, the Vita 3D Master, and the CIELab system parameters were performed using a spectrophotometer, no color-matching competency of the examiner was applied.

A week before starting the bleaching treatment, the participants underwent a run-in period to standardize the study toothbrush (Oral B Indicator Plus, Procter & Gamble, São Paulo, Brazil) and 1500 ppm fluoride toothpaste (Colgate Maximum Anticaries Protection, Colgate-Palmolive, São Bernardo do Campo, Brazil).

Bleaching Treatments

In terms of the OPAGO bleaching agent, the participants were instructed on how and when to use the tray correctly; basically, 30 minutes a day for 14 consecutive days, following the manufacturer's recommendations.

In terms of the POD and OPA bleaching agents, alginate impressions (Jeltrate, Dentsply International, Milford, DE, USA) were taken from both dental arches and study models fabricated in dental stone (Type 3, Gesso Pedra, Rio de Janeiro, Brazil). No relief or reservoirs were made on the models, since there is no evidence of any added benefit of these maneuvers on bleaching effectiveness[19] or gingival inflammation.[20] All the teeth in the oral cavity were whitened and included in the manufactured tray. The trays were made in a vacuum laminator (P7, Bio-Art Dental Equipment Ltd. São Carlos, Brazil) using a 1-mm-thick ethylene vinyl acetate (EVA) rubber plate (Soft, Bio-Art Dental Equipment Ltd). Afterward, the trays were trimmed at 3 to 5 mm over the gingiva to provide greater retention and stability without risking gingival irritation.[21] Instructions were given to the participants regarding placement of the gel in the tray and the tray over the teeth. In regard to the POD agent, the participants were instructed to apply this bleach to their teeth for 30 minutes a day, for 14 consecutive days, following the manufacturer's recommendations. In regard to the OPA agent, the participants were instructed to perform this bleaching treatment for 8 hours at night (while sleeping), for 14 consecutive days, following the manufacturer's recommendations.

The subjects in all of the groups were instructed to rinse with water[18] and brush their teeth with the provided toothbrush and toothpaste after wearing the trays. They were instructed to return for follow-up appointments after 7 and 14 days from the start of treatment to monitor the bleaching process and to evaluate tooth color change and other clinical parameters evaluated in this study.

The tooth color obtained from the Vita Classical scale was converted into numeric values, as previously established in the literature,[4,8,9,12] according to an arrangement of colors from number 1 (shade B1) to 16 (shade C4), in order of brightness or value. Thus, the lower the numeric value, the higher the brightness and the whiter the tooth. The conversion was also performed according to degree of brightness from number 1 (OM1) to 29 (5M3) for the Vita Master D shade scale.

After obtaining the values of ΔL, Δa, and Δb for each treatment and time period, the ΔE was calculated using the following mathematical formula: $\Delta E = \sqrt{(\Delta L)^2 + (\Delta a)^2 + (\Delta b)^2}$ where ΔE is the color change; $\Delta L = L_{final} - L_{initial}$; $\Delta a = a_{final} - a_{initial}$; $\Delta b = b_{final} - b_{initial}$. The value of $\Delta E > 3.3$ was considered clinically noticeable.[23,24]

Tooth Sensitivity, Gingival Irritation, Treatment Acceptance, and Comfort

An evaluation questionnaire was administered after 7 and 14 days from onset of the whitening treatment. A visual analog scale (VAS) was used to assess tooth sensitivity.[8,22] The patients were asked to draw a vertical line cutting a horizontal line. The scores for the sensitivity levels were 0-1 = no sensitivity; 2-3 = mild sensitivity; 4-6 = moderate sensitivity, 7-8 = severe sensitivity; 9-10 = unbearable sensitivity. The scores to evaluate gingival irritation were absent, localized, or generalized. A VAS was also used to evaluate the degree of acceptance of the bleaching technique and the degree of comfort of the whitening tray used: patients were asked to draw a vertical mark on a horizontal line. The scores used to assess the degree of acceptance to the technique were 0-2 = totally unacceptable; 3-4 = difficult to tolerate; 5-7 = acceptable; and 8-10 = totally acceptable. The scores assessing the degree of comfort were 0-1 = very uncomfortable; 2-4 = uncomfortable; 5-8 = comfortable; and 9-10 = very comfortable. Any other relevant information given by the patients regarding the bleaching treatment for any of the techniques was reported weekly in the questionnaire in a blank space where the patients' exact words were recorded. The information regarding tray loosening/movement and experiences with bleach overflow were collected as a free recording.

Statistical Analysis

The comparison among groups to determine loss from the study, gender, and gingival irritation was performed using Fisher's exact test. Generalized linear models for repeated measures were used, since the color variable using the Vita Classical shade guide unit and Vita 3D Master shade guide unit (ΔSGU),[4] the acceptance of the technique, the degree of tray comfort, and the ΔL, Δa, and Δb parameters did not meet the assumptions of parametric analyses. There were significant differences in the color shade at the baseline time among the bleaching treatment groups ($p>0.05$), as measured against the Vita Classical and Vita 3D Master scales and verified by generalized linear models for repeated measures. Therefore, comparisons were made by adjustments against the baseline value, which was considered a covariate. Multiple comparisons were performed using the likelihood ratio for the DIFF option of the GENMOD on the SAS program (Release 9.2, 2010, SAS Institute Inc, Cary, NC, USA). The degree of sensitivity and ΔE were analyzed using mixed models for repeated measures

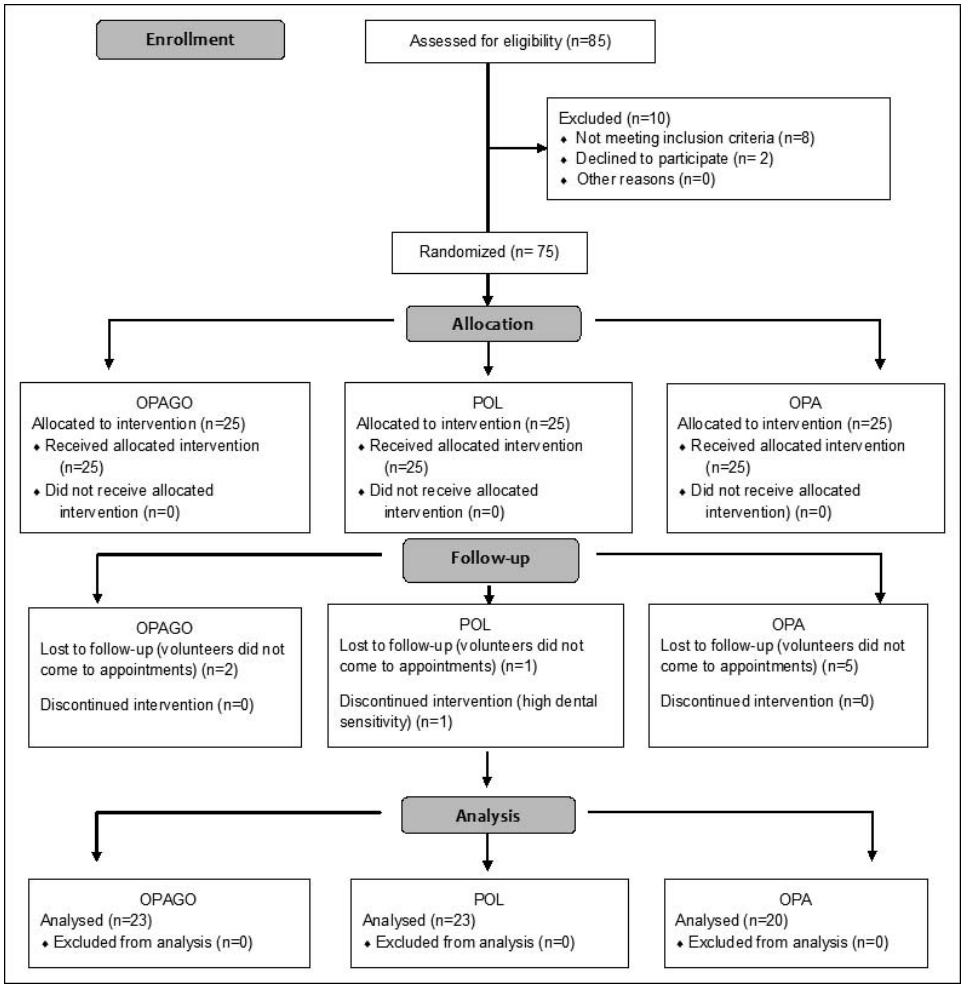

Figure 1. *CONSORT flow diagram of the experiment.*

(PROC MIXED on SAS), and multiple comparisons were performed using the Tukey Kramer test. All the analyses were performed on the SAS software at a significance level of 5%.

RESULTS

Nine patients were lost similarly among the groups, according to Fisher's exact test ($p=0.6173$). The test showed no significant difference among the groups regarding gender distribution ($p=0.1087$). The causes for loss were related to noncompletion of treatment (withdrawal) or missed appointments for evaluation. Only one patient from the POD group gave up treatment due to very strong tooth sensitivity. The flow chart shows the distribution of patients among the groups and gives the reasons for allocation and dropout (Figure 1).

Regarding gingival irritation, there was no difference between the groups at any time period ($p>0.05$). Most of the patients experienced no gingival irritation during the treatment; however, when it did occur, it was revealed soon after the treatment began (Table 2).

In Table 3, a significant increase in tooth sensitivity was observed ($p<0.05$) over time in all groups, but mild sensitivity prevailed with no significant difference among the groups ($p>0.05$). The frequency of patients having any degree of sensitivity for each group and the level of sensitivity over time are shown by group in Table 4; 85% of the patients from the OPA group reported some degree of sensitivity in the 14 days of treatment.

There was no significant difference between the treatments regarding acceptance of the bleaching technique ($p>0.05$) (Figure 2). The patients reported that the approach used in each group was "completely acceptable," according to the mean values of the scores. The lowest average score regarding degree of comfort was observed for the OPAGO group, which evaluated the prefilled tray as "comfortable," unlike the other groups ($p<0.05$), which indicated the customized tray as "comfortable" to

Table 2: *Frequency and Percentage of Gingival Irritation According to Group and Time Period*

Time	Group[a]	Gingival Irritation			Total	*p* Value
		Absent	Localized	Generalized		
Baseline	OPAGO	23 (100.0%)	0 (0.0%)	0 (0.0%)	23 (100.0%)	-
	POD	23 (100.0%)	0 (0.0%)	0 (0.0%)	23 (100.0%)	
	OPA	20 (100.0%)	0 (0.0%)	0 (0.0%)	20 (100.0%)	
7 days	OPAGO	11 (47.8%)	11 (47.8%)	1 (4.4%)	23 (100.0%)	0.2540
	POD	15 (65.2%)	8 (34.8%)	0 (0.0%)	23 (100.0%)	
	OPA	15 (75.0%)	5 (25.0%)	0 (0.0%)	20 (100.0%)	
14 days	OPAGO	15 (65.2%)	8 (34.8%)	0 (0.0%)	23 (100.0%)	0.2402
	POD	16 (69.6%)	5 (21.7%)	2 (8.7%)	23 (100.0%)	
	OPA	17 (85.0%)	3 (18.8%)	0 (0.0%)	20 (100.0%)	

[a] *The OPAGO was treated with 10% hydrogen peroxide delivered in prefilled disposable trays; the POD group was treated with 9.5% hydrogen peroxide delivered in custom-made trays; the OPA group was treated with 10% carbamide peroxide delivered in custom-made trays.*

"very comfortable" (Table 5). In regard to the OPAGO group, 18 of the 23 patients (78.26%) reported that the gel overflowed from the tray; 10 of the 23 patients (43.47%) also reported that the tray sometimes became loose during the bleaching treatment. No reports of tray loosening or gel overflow were recorded for the other groups.

The mean color score (ΔSGU) from the Vita Classical scale decreased significantly over time ($p<0.05$) for all three treatments (Table 6), showing that there was an increase in brightness with the whitening treatment. At days 7 and 14, the lowest average was observed in the OPA group, which was the group that obtained the highest brightness using this scale; there was no significant difference between the OPAGO and POD groups ($p>0.05$). In terms of the analysis of the mean shade score using the Vita 3D Master scale, the color shade score dropped significantly over time for all three treatments ($p<0.05$), showing that there was an increase in brightness with the treatment. At days 7 and 14, the lowest average score was observed for the OPA group, which was significantly different from the POD group (Table 6).

The results for ΔL at days 7 and 14, compared with baseline, are shown in Table 7, where no significant differences were observed among the groups or between the time periods ($p>0.05$). Likewise, no significant difference for Δa was verified among the groups or between the time periods (Table 7). The Δb average was significantly higher at 14 days ($p<0.05$), but there was no significant difference among the groups ($p>0.05$) (Table 7). There was also no difference among the groups or between the time periods ($p>0.05$) for ΔE (Table 7).

Table 3: *Mean (Standard Deviation) Values of Tooth Sensitivity Score According to Group and Time Period*[a]

Group[b]	Time		
	Baseline	7 Days	14 Days
OPAGO	0.00 (0.00) Ca	2.05 (2.34) Ba	2.87 (2.61) Aa
POD	0.02 (0.08) Ca	2.62 (2.38) Ba	2.84 (2.52) Aa
OPA	0.01 (0.04) Ca	2.34 (2.20) Ba	3.96 (2.82) Aa

[a] *Means followed by different letters (capital letters in lines and lower cases in columns) are statistically different ($p\leq0.05$).*
[b] *The OPAGO was treated with 10% hydrogen peroxide delivered in prefilled disposable trays; the POD group was treated with 9.5% hydrogen peroxide delivered in custom-made trays; the OPA group was treated with 10% carbamide peroxide delivered in custom-made trays.*

DISCUSSION

Opalescence Go bleaching gel is indicated for use with a prescription and under the supervision of a

Table 4: *Frequency and Percentage According to Absence or Presence of Any Type of Tooth Sensitivity Intensity Among Group and Time Period*

Time	Group[a]	Tooth Sensitivity		Total
		Absence	Presence	
Baseline	OPAGO	23 (100.0%)	0 (0.0%)	23 (100.0%)
	POD	23 (100.0%)	0 (0.0%)	23 (100.0%)
	OPA	20 (100.0%)	0 (0.0%)	20 (100.0%)
7 days	OPAGO	11 (47.8%)	12 (52.2%)	23 (100.0%)
	POD	5 (21.7%)	18 (78.3%)	23 (100.0%)
	OPA	7 (35.0%)	13 (65.0%)	20 (100.0%)
14 days	OPAGO	7 (30.5%)	16 (65.5%)	23 (100.0%)
	POD	6 (27.0%)	17 (73.0%)	23 (100.0%)
	OPA	3 (15.0%)	17 (85.0%)	20 (100.0%)

[a] *The OPAGO was treated with 10% hydrogen peroxide delivered in prefilled disposable trays; the POD group was treated with 9.5% hydrogen peroxide delivered in custom-made trays; the OPA group was treated with 10% carbamide peroxide delivered in custom-made trays.*

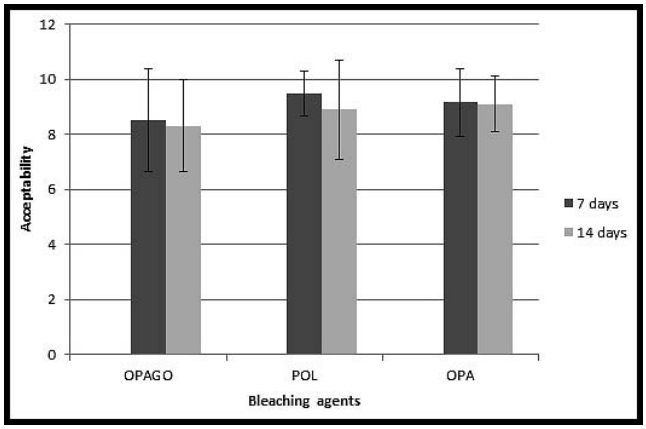

Figure 2. *Mean and standard deviation values of technique acceptability according to group and time periods.*

dentist. This product requires no impressions to be made for customized trays, an advantageous feature that saves customizing time. However, it is important to evaluate how well this alternative approach is accepted in terms of tray comfort before recommending it.

In this study, the null hypothesis tested was accepted. There was no significant difference among the treatments regarding acceptance of the methods by the patients or between the time periods (7 and 14 days). According to the VAS applied, where a value of 10 was considered "totally acceptable," the average acceptance was high (above 8.31), suggesting that the bleaching application methods, regardless of duration (8 hours every night for the OPA or 30 minutes daily for POD and OPAGO), were well accepted by the patients over the number of days needed to accomplish the treatment. The degree of comfort provided by the bleaching tray, however, proved significantly lower for patients in the OPAGO group than in the other groups for both 7 and 14 days of use (average scores of 6.48 and 6.97, respectively, considering that the patients scored this tray as "comfortable"). This degree of comfort could be attributed to the material used to manufacture the tray, which does not allow for tailor fitting or perfect retention to the teeth, thus permitting some movement in the patient's mouth. The whitening gel inside the tray plays a major role in retention of the appliance to the teeth; therefore, detachment of the tray and solubility of the bleaching agent in the saliva may have reduced tray retention, causing the patient some discomfort even for a short period of use (30 minutes). A similar finding was reported by Auschill and others,[25] who observed lower tolerance to the technique when whitening strips were used rather than customized trays. Da Costa and others[26]

Table 5: *Mean (Standard Deviation) Values of Tray Comfort Score According to Group and Time Period*[a]

Group[b]	Time		
	Baseline	7 Days	14 Days
OPAGO	-	6.48 (2.53) Ab	6.97 (2.03) Ab
POD	-	8.45 (1.74) Aa	8.60 (1.81) Aa
OPA	-	8.14 (1.55) Aa	7.96 (1.90) Aa

[a] *Means followed by different letters (capital letters in lines and lower cases in columns) are statistically different ($p \leq 0.05$).*
[b] *The OPAGO was treated with 10% hydrogen peroxide delivered in prefilled disposable trays; the POD group was treated with 9.5% hydrogen peroxide delivered in custom-made trays; the OPA group was treated with 10% carbamide peroxide delivered in custom-made trays.*

also reported that patients had problems maintaining the bleaching strip in place, compared with trays, despite reporting that the strips seemed less harmful to the gums than the trays. Despite the trays being thin and fitting well around the teeth, they still became loose, triggered by even the slightest movements of the lips and salivary flow, corroborating the findings by Sundfeld and others[5] who also evaluated the effects of OPAGO. Furthermore, loosening of the tray within the oral cavity and bleach overflow, as experienced by 43.47% and 78.26% of the patients, respectively, at some time in this study, may have contributed to a lesser degree of comfort with this technique, since no reports of these problems were experienced by the patients from the other groups. It should be highlighted, however, that the assigned scores did not discourage the patients from continuing with this method, since none of them withdrew from the treatment. Although the use of a prefilled tray containing a bleaching agent could pose risks to the patient due to the release of peroxide in the oral cavity,[18] the risks may be minimized by the expectorating effect of increased salivary flow induced by the tray in the mouth, and further reduced by rinsing with water after removing the impression tray from the mouth at the end of the session.

Despite tray detachment and bleach overflow—a situation that was not reported by any patient from the OPA and POD groups—no significant difference in gingival irritation was observed among the groups. Localized gingival irritation was observed in all the groups after 7 and 14 days of bleaching, as opposed to its nonoccurrence at onset. It can be suggested that a patient may develop gingival irritation during treatment, irrespective of the tray type (prefilled or customized), agent (carbamide and/or hydrogen peroxide), or application time (30 minutes for OPAGO and POD; 8 hours for OPA).

Table 6: *Mean (Standard Deviation) Values of Color (ΔSGU) Regarding Vita Classical and 3D Master Scales According to Group and Time Period*[a]

Shade Guide	Group[b]	Time		
		Baseline (Covariable)	7 Days	14 Days
Vita Classical	OPAGO	4.13 (3.21)	2.30 (1.14) Aa	1.74 (1.05) Ba
	POD	3.39 (2.29)	2.09 (0.85) Aa	1.61 (0.50) Ba
	OPA	2.60 (0.99)	1.65 (0.49) Ab	1.15 (0.37) Bb
Vita 3D Master	OPAGO	7.83 (4.21)	5.35 (2.08) Aab	4.65 (1.40) Bab
	POD	8.04 (2.62)	6.00 (1.98) Aa	5.30 (1.87) Ba
	OPA	7.40 (1.60)	4.85 (1.63) Ab	4.25 (0.91) Bb

Abbreviation: ΔSGU, Vita Classical shade guide unit and Vita 3D Master shade guide unit.
[a] *Means followed by different letters (capital letters in lines and lower cases in columns) are statistically different ($p \leq 0.05$) according to each shade guide.*
[b] *The OPAGO was treated with 10% hydrogen peroxide delivered in prefilled disposable trays; the POD group was treated with 9.5% hydrogen peroxide delivered in custom-made trays; the OPA group was treated with 10% carbamide peroxide delivered in custom-made trays.*

Auschill and others[25] also observed no difference in gingival irritation when comparing whitening strips vs trays containing hydrogen peroxide. Leonard and others,[14] however, found that products containing 7% hydrogen peroxide led to higher gingival irritation than those containing carbamide peroxide. One must consider that even a placebo gel in a customized tray may cause gingival irritation. This could be attributed to manufacturing and maladaptation of the tray,[26,27] regardless of whether or not the appliance extended over the gingival tissue.[21] In the present study, localized gingival irritation appeared to be related more to trauma caused by maladaptation of the tray than to the bleaching product itself, which would have caused widespread gingival irritation,[1] or the fact that patients were provided with new toothbrushes at the beginning of the trial, which, despite being soft, may have also contributed to localized gingival irritation.[14,15]

Tooth sensitivity resulting from the bleaching treatment was caused by the penetration and diffusion of peroxides and their by-products, which may have led to inflammatory reactions in the pulp.[28] Between 20% and 60% of patients who undergo home bleaching report this type of symptom.[2,5,9,11,26]. It appears, however, that most people who undergo teeth whitening are able to tolerate the sensitivity caused by this procedure. In this study, only one patient from the POD group gave up treatment due to intense sensitivity. An increase in tooth sensitivity was observed over time for all the groups, despite being described as mild, regardless of the bleaching agent concentration and treatment application time. This finding was also observed by Alonso de la Peña and López Ratón[11] when using various concentrations of hydrogen or carbamide peroxide in customized trays. Some authors[7,12,27] also showed that no difference in tooth sensitivity was reported by participants for 10% and 15%-16% carbamide peroxide agents. It must be mentioned that the bleaching agents assessed had desensitizing components in their composition, such as potassium nitrate (OPAGO and POD) or sodium fluoride (OPA), which would have led to lower levels of sensitivity. In this regard, a meta-analysis carried out by Wang and others[28] reported that the addition of potassium nitrate or sodium fluoride to the composition of bleaching products for home use led to a decrease in tooth sensitivity. Although sensitivity to bleaching agents cannot be prevented altogether, Browning and others[6] and Navarra and others[29] also observed no less intense sensitivity when using a carbamide peroxide product containing sodium fluoride and potassium nitrate compared with the agent without these components. Sundfeld and others[15] found that no patients reported sensitivity when using the OPAGO bleaching agent for a period of 8 days. One should also consider that, although there were some differences in the hydrogen and carbamide peroxide concentrations in the agents studied, tooth sensitivity is a symptom that may vary from person to person.[5,9] While there are studies showing that higher sensitivity may be expected when using agents with higher concentrations,[7-9,14] it is difficult to predict the occurrence and intensity during treatment.

Regarding color change, various methods may be used to assess changes in tooth color upon completion of whitening treatments. The shade scales routinely used by professionals in the office, such as the Vita Classical and Vita 3D Master, are considered subjective assessment methods. Nonetheless, they are frequently used by dentists to show their patients the color of their teeth at the beginning of the treatment and to compare it against the final color at the end of the treatment. This

comparison facilitates understanding and communication between patient and professional. Shade scales have also been used in studies that evaluate different color shifts when performing whitening treatments.[4,8,9,11] The use of objective assessment methods, such as a spectrophotometer, in which the measurements can be obtained by the CIELab system, are important not only to evaluate color change in general but also to evaluate how the bleaching treatment may influence the color of the teeth within each light spectra (L), green-red axis (a) and blue-yellow axis (b), as used in this study.

Both the spectrophotometer and the Vita Classical scale revealed that all the bleaching agents were effective in whitening the teeth, with enhanced brightness from 7 to 14 days. A smaller tooth color change was observed for the Vita Classical shade guide in the present study than in other clinical trials[4,8,9,12] due to the lighter color shades at baseline observed for our volunteers (aged 18 to 30 years). Nevertheless, whiter teeth (higher brightness) were obtained when using the OPA bleaching agent in both treatment periods, probably due to the longer application time (8 hours) compared with the other techniques. On the other hand, both the OPA and the OPAGO systems showed similar outcomes in terms of brightness at days 7 and 14, according to the Vita 3D Master scale, despite the effectiveness of various peroxide-based agents in increasing brightness. Any differences could have been related to characteristics inherent to the evaluation method, since the Vita 3D Master scale has a greater number of shades (29 shades vs 16 for the Vita Classical scale), as well as to standardization of brightness by the groups in terms of chroma and hue, which makes Vita 3D Master more suitable for use due to greater uniformity between shades and proximity to reality.[11,17]

Conversely, no difference was observed among ΔL, Δa and ΔE values, between times or bleaching products, when using the objective evaluation by the CIELab system. Thus, it may be inferred that all bleaching agents had the same effect on tooth brightness (L), according to the red-green axis (a) and shade change (E), despite differences in bleach concentration, active agent (carbamide peroxide, hydrogen peroxide, or both) and time of use, with no differences among the results at each time period. The ΔE value obtained from the different products was greater than 3.3 at both evaluation periods; and ΔE values higher than 3.3 are accepted as clinically noticeable, demonstrating the effectiveness of the bleaching procedures,[23,24] especially at day 7. Other studies have also shown that the result for different bleaching agents containing carbamide or hydrogen peroxide in different concentrations for home use did not differ in ΔL or ΔE.[11,22,26]

Differences between time periods were observed only for Δb, which represents changes in the blue-yellow axis, showing a more significant decrease in yellow hues at day 14 than at day 7 for all the products studied. A reduction in parameter b has been reported as the most important indicator of shade change during bleaching, since it occurs more rapidly and to a greater extent than the other components of the CIELab system.[7,30] Therefore, combining this with the fact that no difference was observed in color change (ΔE) compared with baseline, it may be suggested that the bleaching agents evaluated may be indicated for only 7 days of use, thus preventing other signs and symptoms resulting from long-term use, such as gingival irritation and tooth sensitivity.

CONCLUSIONS

The bleaching methods using carbamide peroxide or hydrogen peroxide dispensed in customized or prefilled trays had high acceptance by patients. The prefilled trays were less comfortable than customized trays. Gingival irritation was localized and similar across all the bleaching methods. Tooth sensitivity increased over time in all groups; however, it was reported as mild, regardless of the bleaching agent concentration and the application time. The whitening effect was similar for all bleaching agents at 7 and 14 days, except for parameter b, for which the highest reduction in yellow hue occurred at day 14.

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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 Centro de Pós Graduação São Leopoldo Mandic. The approval code for this study is 32499014.1.0000.5374.

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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