

Clinical Research

Effects of At-home Bleaching in Smokers: 30-month Follow-up

JL de Geus • E Fernández • S Kossatz • AD Loguercio • A Reis

Clinical Relevance

The results of this study indicate that bleaching is effective in smokers and nonsmokers but a slight color rebound was observed for both groups of patients after 30 months.

SUMMARY

Objective: This clinical study evaluated the color longevity after 30 months of at-home bleaching with 10% carbamide peroxide (CP) in smokers and nonsmokers.

Methods: Sixty patients, 30 smokers and 30 nonsmokers, were subjected to bleaching with 10% CP (Whiteness Perfect-FGM) for three hours daily for three weeks. The color was measured at baseline and at one month and 30 months after the completion of dental bleaching using the shade guide Vita classical organized by value (Δ SGU) and the shade guide Vita Bleachedguide 3D-MASTER. At the 30-

month recall, the color was assessed before and after dental prophylaxis. Data from color evaluation were analyzed by two-way repeated-measures analysis of variance and Tukey test for the contrast of means ($\alpha=0.05$).

Results: Twenty-one smokers and 22 nonsmokers attended the 30 month recall. For both shade guides, only the main factor of assessment time was statistically significant ($p<0.001$). Effective whitening was observed in both groups at the baseline, which was stable at one month. However, color rebound was observed after 30 months for both groups of participants when color was measured before and after dental prophylaxis.

Conclusion: Thirty months after at-home bleaching with 10% CP gel, dental darkening was detected in both groups, which cannot be solely attributed to stains caused by extrinsic staining from daily food, drinks, and smoke (in smokers).

Juliana L de Geus, MS, PhD, School of Dentistry, School Paulo Picanço, Fortaleza, Ceará, Brazil

Eduardo Fernández, PhD, Department of Restorative Dentistry, University of Chile, Santiago, Chile and Instituto de Ciencias Biomédicas, Universidad Autónoma de Chile, Santiago, Chile

Stella Kossatz, MS, PhD, Department of Restorative Dentistry, State University of Ponta Grossa, Ponta Grossa, Brazil

*Alessandro D Loguercio, MS, PhD, Department of Restorative Dentistry, State University of Ponta Grossa, Ponta Grossa, Brazil

Alessandra Reis, PhD, Department of Restorative Dentistry, State University of Ponta Grossa, Ponta Grossa, Brazil

*Corresponding author: Av. General Carlos Cavalcanti, 4748, Ponta Grossa, Parana, 84030-900, Brazil; e-mail: aloguercio@hotmail.com

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INTRODUCTION

Currently dental bleaching is one of the most requested treatments by patients as a result of the fact that white and well-aligned teeth are considered important factors in the concept of a beautiful smile.¹ At-home dental bleaching using 10% carbamide peroxide (CP) gel with custom trays is the most widely used bleaching technique for tooth discoloration treatments.²

Although many studies of at-home bleaching have been conducted, most of them exclude smokers from their clinical trials,³⁻⁷ which prevents us from assessing the effect of this cosmetic procedure on such patients. Contrary to this widespread concept, an earlier publication of de Geus and others⁸ demonstrated that effective whitening is achievable regardless of whether or not the patient is a smoker.

However, smokers' teeth tend to develop tobacco stains over time.^{9,10} Considering that these stains may vary from yellow to black and given that the severity is highly dependent on the length and frequency of the smoking habit, concerns about the longevity of such treatment were raised. The whitening outcome in smokers was shown to remain stable one year after the bleaching treatment so long as teeth were submitted to dental prophylaxis before color evaluation.¹¹ These results suggest that color rebound after bleaching results from the deposition of pigments or cigarette smoke on the dental surface in such a short, one-year follow-up period.

Although there are numerous studies¹²⁻¹⁶ that evaluated the longevity of at-home bleaching, even for periods as long as 12 years, none of them have attempted to appraise bleaching longevity after dental prophylaxis in patients who were smokers. Therefore, the aim of this controlled clinical trial was to compare the 30-month color change associated with at-home bleaching with 10% CP in smokers and nonsmokers before and after dental prophylaxis. The null hypotheses tested were that 1) no significant difference will be detected between smokers and nonsmokers after 30 months and 2) no color rebound will be detected in both groups of participants before and after dental prophylaxis.

METHODS AND MATERIALS

This study is the 30-month follow-up of an earlier study⁸ registered at clinicaltrials.gov under the identification number NCT02017873. This earlier study was conducted in Chilean and Brazilian centers,⁸ but the follow-up was only performed on the Brazilian participants.

Inclusion and Exclusion Criteria

We evaluated participants in a dental chair, after dental prophylaxis with pumice and water, to check whether they met the study's eligibility criteria. Participants included in this clinical trial were between 18 and 54 years of age and had good general and oral health. Each participant had at least one central incisor of shade A2 or darker, as

assessed by means of comparison with a value-oriented shade guide (VITA classical, VITA Zahnfabrik, Bad Säckingen, Germany). Color A2 is the fifth color in the light-to-dark value VITA classical shade guide scale, so there are still five shades to allow measurement of color changes with this scale. This minimal color shade was already employed in many other clinical trials.⁴⁻⁷

We did not include participants who had undergone previous dental bleaching procedures during orthodontic treatment or those who were pregnant, lactating, or who exhibited bruxism habits. In addition, we excluded participants with noncarious cervical lesions and buccal restorations in anterior teeth as well as those having veneers or full crowns, dental fluorosis, gingival recession, spontaneous tooth pain, internal tooth discoloration, and endodontically treated anterior teeth. Patients with bruxism habits were excluded as they usually have a high prevalence of noncarious cervical lesions, which are frequently associated with dentin sensitivity.¹⁷

Study Groups

We asked the participants who met the inclusion criteria about their daily smoking habits. Those who did not smoke were part of the nonsmoker group, and those who smoked at least 10 cigarettes per day belonged to the group of smokers. We included 30 participants in each group.

Bleaching Procedure

We made alginate impressions of each participant's maxillary and mandibular arch, pouring the impressions with dental stone. We did not apply block-out material to the labial surfaces of the teeth.¹⁸ We used a 1-mm-thick soft vinyl material provided by the manufacturer (Whiteness, FGM, Joinville, SC, Brazil) to fabricate the custom-fitted tray to hold the bleaching gel. We trimmed the bleaching tray 1 mm beyond the marginal gingiva and delivered the tray and the 10% CP gel (Whiteness Perfect, FGM) to each participant with oral instructions for use. We instructed all participants to wear the tray with the bleaching agent for three hours daily for three weeks.

We instructed the participants to remove the tray after the daily bleaching period, wash it with water, and brush their teeth as usual. We also provided verbal instructions about oral hygiene, encouraging participants to brush their teeth regularly with fluoridated toothpastes without whitening components.

Color Evaluation

We checked the color in the middle one-third area of the labial surface in the anterior central incisor, according to the American Dental Association guidelines.¹⁹ We used the Vita Bleachedguide 3D-MAS-TER (VITA Zahnfabrik), which is originally oriented from lightest to darkest color, and the VITA classical shade guide (VITA Zahnfabrik). The 16 classical shade guide tabs (VITA classical, VITA Zahnfabrik) were arranged from lightest to darkest as follows: B1, A1, B2, D2, A2, C1, C2, D4, A3, D3, B3, A3.5, B4, C3, A4, and C4. Although this scale is not linear, we treated the changes as continuous, with linear ranking used in several clinical trials on dental bleaching.^{4,6}

We calculated the color changes from the beginning of the active phase through the individual recall times by the change in shade guide units (Δ SGU) that occurred toward the lighter end of the value-oriented list of shade tabs. In cases in which operators disagreed about color matching, we reached a consensus before dismissing the patient.

Two calibrated evaluators, with a previous agreement of at least 85% as determined by means of weighted k statistics, recorded the shade of the maxillary right central incisor at the baseline and at one week, one month, 12 months, and 30 months after finishing the bleaching protocol. At 12 and 30 months, the evaluation was performed before and after dental prophylaxis with a rotating brush and prophylaxis paste (Herjos, Vigodent Coltene SA Indústria e Comércio, Rio de Janeiro, Brazil). After dental prophylaxis, teeth were rehydrated in the patient's mouth for 15 minutes before color assessment. This care was taken because the teeth became lighter as they were dehydrated,²⁰ which could have affected the reliability of the data collected.

Satisfaction Assessment

In the 30-month recall, the participants were asked to answer some closed-ended questions about their satisfaction level concerning the bleaching outcome, their perception of color change, and their perception of color rebound after 30 months.

Statistical Analysis

We performed all of the analyses using the statistical software Statistica for Windows (StatSoft Inc, Tulsa, OK, USA), with a 5% significance level. Two statistical analyses were performed using the per-protocol (only for the available data) and the intention-to-treat approaches. In the latter, the last

Table 1: Demographic Characteristics of the Participants Included in This Randomized Clinical Trial

Characteristics	Groups	
	Smokers	Nonsmokers
Baseline color, shade guide VITA classical (mean \pm SD)	6.8 \pm 2.3	7.3 \pm 2.5
Baseline color, shade guide Bleachedguide 3D-MAS-TER (mean \pm SD)	7.8 \pm 1.1	8.2 \pm 1.3
Age, y (mean \pm SD)	26.3 \pm 6.5	24.1 \pm 6.8
Sex, % male	63.3	53.3
Cigarettes/d (mean \pm SD)	13.2 \pm 4.0	—
Cigarettes/d at 30 mo (mean \pm SD)	11.8 \pm 5.1	—
Average smoking years (mean \pm SD)	8.0 \pm 5.9	—

Abbreviations: SD, standard deviation; SGU, shade guide unit.

observation was carried forward for the missing data. The color change in Δ SGU from both shade guide units was submitted to two-way repeated-measures analysis of variance (ANOVA) (group vs assessment period) and Tukey test for pairwise comparisons. As a result of the exploratory nature of the satisfaction assessment data, we did not submit these data to statistical analysis; only descriptive analyses were performed.

RESULTS

At the baseline, we screened 305 patients to obtain 60 participants from the Brazilian center who met the eligibility criteria (Figure 1). The average age and baseline color of the participants were similar between the groups. Most of the participants were men (Table 1). The 12-month data were published earlier.¹¹ At the 30-month recall, smoking habits did not change among the majority of participants from the smoking group. Only five of the participants stopped smoking, while four reduced the number of cigarettes smoked per day (to less than 10 cigarettes a day).

All participants included in this controlled clinical trial finished the bleaching protocol and attended the one-week and one-month recall visits (Figure 1); however, 17 patients did not attend the 30-month recall. The reasons for not attending the recall included the change of housing location and a single participant lacking time availability to return to the university for a new color assessment.

Per-protocol vs Intention-to-treat Analysis

All statistical analyses were performed with data imputation for missing outcomes (intention-to-treat)

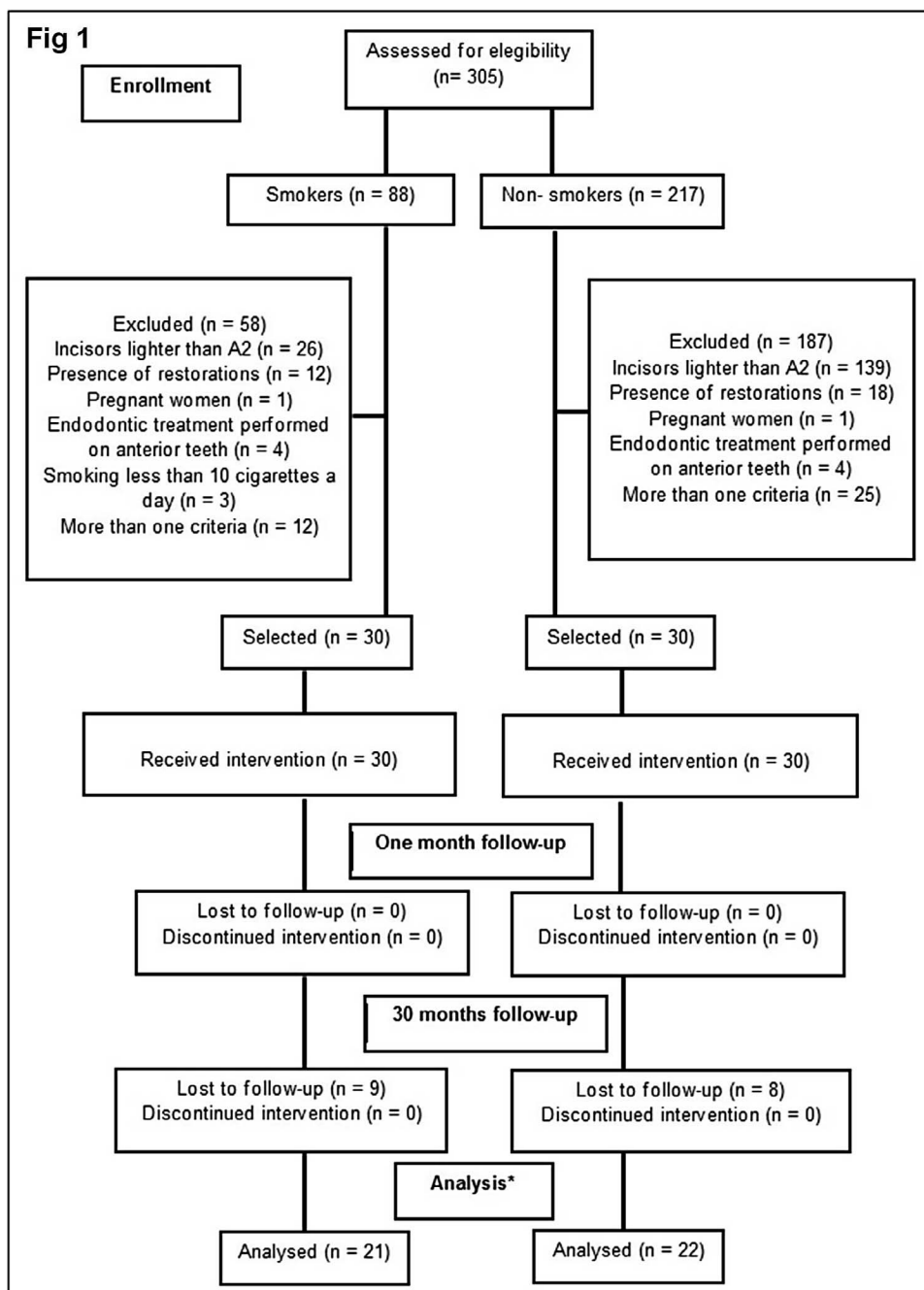


Figure 1. Flow diagram of the clinical trial, including detailed information regarding the excluded participants. An intention-to-treat analysis, in which unit imputation was used for missing information, was also performed, and the overall conclusions were the same as those of the per-protocol analysis.

and without data imputation (per-protocol). In all analyses, the same overall conclusions were reached (data not shown). To avoid data repetition, we opted to describe only the results and statistics obtained in the per-protocol analysis because of the fact that a high percentage of patients (17 out of 60 [28%]) could not be evaluated in the 30-month recall. The distribution of missing data was homogeneous among groups (n=9 in the smokers group and n=8 in the nonsmokers group).

Shade Evaluation

For both Vita classical shade guide and Vita Bleachedguide 3D-MASTER, the two-way repeated-measures ANOVA revealed that the cross-product interaction group vs assessment time ($p=0.079$ and $p=0.378$, respectively) and the main factor group ($p=0.517$ and $p=0.051$, respectively) were not significant. Only the main factor assessment time was statistically significant (Tables 2 and 3; $p<0.001$). The lack of difference between the groups (smokers

Table 2: Color Change in Shade Guide Units (Δ SGU) Obtained with the Value-oriented Shade Guide Vita Classical at the Different Assessment Points Along with the Effect Size (Mean Difference) and the 95% Confidence Interval (CI)

Assessment Time	Medians (Interquartile Range)		Mean \pm Standard Deviation			
	Smokers	Nonsmokers	Smokers	Nonsmokers	Main Factor Time ^a	Mean Difference (95% CI)
Baseline vs 1 mo	4 (3.75-6.25)	5.5 (4-8)	5.2 \pm 2.1	5.7 \pm 2.3	5.5 \pm 2.2 A	-0.5 (-1.9 to -0.9)
Baseline vs 30 mo before prophylaxis	4 (3-6)	4.5 (3-7)	4.7 \pm 2.2	5.1 \pm 2.2	5.0 \pm 2.2 C	-0.4 (1.8 to 1.0)
Baseline vs 30 mo after prophylaxis	4 (3.5-6.25)	4.5 (3-7)	5.0 \pm 2.2	5.2 \pm 2.3	5.2 \pm 2.3 B	-0.2 (-1.6 to 1.2)

Abbreviation: CI, confidence interval.
^a Groups identified with the same letter are statistically similar.

vs nonsmokers) can also be seen with the 95% confidence interval (CI) of the effect size (mean difference) (Tables 2 and 3) that does include zero.

A significant average color change (Δ SGU) of approximately five shade guide units in the Vita classical guide (Table 2) and four shade guide units in the Vita Bleachedguide 3D-MASTER (Table 3) was observed one month after bleaching for both groups. At 30 months, a slight but significant color rebound could be detected regardless of whether color was measured before or after dental prophylaxis (Tables 2 and 3; $p < 0.001$).

Satisfaction Assessment

Participants who attended the shade evaluation at 30 months after bleaching treatment were questioned about their satisfaction level (Table 4). The majority of the smokers reported that they still observed moderate bleaching, while participants in the nonsmokers group reported there was still significant bleaching. Most participants from both groups felt happy with the bleaching result and would repeat the procedure. After 30 months of the bleaching procedure, 70% of participants reported that their teeth darkened slightly.

DISCUSSION

As a part of daily life many people smoke; eat dark-colored food; and drink coffee, tea, red wine, and other colored drinks. Some investigators have re-

ported that colored beverages and foods can induce tooth discoloration.^{21,22} This fact, along with the slight demineralization that acidic bleaching gels produce on dental surfaces,²³ led dentists and product manufacturers to request their patients to avoid smoking, drinking, and eating colored beverages and foods during the active bleaching treatment phase.

However, these dentists' recommendations seem to be endorsed by bleaching myths, in relation to efficacy and safety, rather than evidence-based findings.²⁴ It was reported in a recent publication²⁵ that at-home bleaching did not induce DNA damage to gingival tissue during the bleaching period in smokers and nonsmokers. The genotoxicity potential of smoking, as reflected by the mean number of micronuclei in exfoliated cells, was not increased by the at-home bleaching procedure.²⁵

With regard to the effectiveness, the results of the present study highlight that effective whitening is achievable in smokers even without requesting them to stop smoking during the active phase of the bleaching treatment. In a similar trend, an earlier study⁴ reported that exposure to coffee four times a day also did not jeopardize the bleaching efficacy when compared to results in patients that followed a "white diet." "White diet" was a term introduced by Professor Matis in a recent publication²⁴ that refers to a diet that is free of colored drinks and foods. This was also confirmed in a recent published study.²⁴

Table 3: Color Change in Shade Guide Units (Δ SGU) Using the Bleachedguide 3D-MASTER Shade Guide at the Different Assessment Points Along with the Effect Size (Mean Difference) and the 95% Confidence Interval (CI)

Assessment Time	Medians (Interquartile Range)		Mean \pm Standard Deviation			
	Smokers	Nonsmokers	Smokers	Nonsmokers	Main Factor Time ^a	Mean Difference (95% CI)
Baseline vs 1 mo	4 (3.00-4.25)	4.5 (4-5)	4.1 \pm 1.1	4.7 \pm 1.4	4.4 \pm 1.3 A	-0.6 (-1.4 to 0.2)
Baseline vs 30 mo before prophylaxis	3 (2.00-3.25)	3.5 (3-4)	2.6 \pm 1.1	3.3 \pm 1.2	3.0 \pm 1.2 B	-0.7 (-1.4 to 0.0)
Baseline vs 30 mo after prophylaxis	3 (2.75-4.00)	4 (3-4)	3.0 \pm 1.1	3.4 \pm 1.2	3.2 \pm 1.2 B	-0.4 (-1.1 to 0.3)

^a Groups identified with the same letter are statistically similar.

Table 4: Degree of Participants' Satisfaction 30 Months After Bleaching

Question	Smokers	Nonsmokers	Statistical Significance*
1. After the bleaching treatment, you observed that			
a) there was no color change in teeth	0	0	n.s.
b) there was mild whitening, not noticed by others	1	0	n.s.
c) there was mild bleaching, noticed by others	2	5	n.s.
d) there was moderate whitening	10	5	n.s.
e) there was a significant whitening	8	12	n.s.
2. What is your level of satisfaction with the performed bleaching treatment?			
a) Very happy	9	6	n.s.
b) Happy	9	8	n.s.
c) Satisfied	3	8	n.s.
d) Indifferent	0	0	n.s.
e) Dissatisfied	0	0	n.s.
3. Would you repeat the bleaching treatment in case your teeth get darker?			
a) Yes, because I liked the result	16	16	n.s.
b) Yes, because I would like my teeth to become lighter than they are	5	6	n.s.
c) No, I'm satisfied	0	0	n.s.
d) No, because I experienced pain	0	0	n.s.
4. Do your teeth look darker now (30 months after bleaching)?			
a) No	0	1	n.s.
b) A little	14	15	n.s.
c) A reasonable amount	6	5	n.s.
d) Too much	0	1	n.s.
e) I don't know	1	0	n.s.
Abbreviation: n.s., not significant. * Chi-square test, $\alpha = 0.05$.			

Altogether, these three studies provide contrary evidence to this widespread myth that patients should keep a white diet and/or quit smoking while having their teeth bleached. The self-assessment of the participants is also in agreement with the results of the shade guide units; most of the participants from both groups reported themselves to be happy with the whitening degree obtained and would repeat dental bleaching if necessary.

On the other hand, we cannot deny the fact that over time smokers are theoretically more prone to having stain deposition on their dental surfaces than are nonsmokers. Consequently, concerns about durability and longevity of the bleaching protocol in such groups of patients are critical. Tobacco contains a lot of nicotine,²⁶ and though it is an inherently colorless substance, it turns yellow when it comes in contact with oxygen. Nicotine penetrates the nooks and crannies²⁷ of teeth, leading to tooth stains. Apart from nicotine, tobacco smoke contains carbon monoxide, thiocyanate, herbicide, fungicide and pesticide residues, tars, sugar, and cocoa,²⁸ which

cause dental discoloration due to their dark hue and ability to adhere to dental surfaces.⁹

However, our results demonstrated that color rebound was equal in both groups of participants. We expected that the teeth of smokers would be darker than those of nonsmokers, a hypothesis that was not proven by the findings of the present investigation. Perhaps 30 months is still too short term a follow-up for nicotine and tar to penetrate the tooth and change its color intrinsically. Another factor to be considered is that dental prophylaxis was performed in the 12-month assessment¹⁸ so the extrinsic pigments observed in the 30-month recall were the result of an 18-month accumulation. Furthermore, some participants stopped or decreased smoking during this 30-month follow-up. Perhaps the evaluation of such a sample through longer-term follow-ups might allow us to detect if indeed differences in the longevity of the bleaching outcomes in smokers compared to nonsmokers may become evident in longer follow-ups.

Professional mechanical cleaning, such as dental prophylaxis and enamel polishing, are effective means by which to produce partial or complete stain removal.²⁹ Indeed, this was observed in the present investigation and in the one-year follow-up of this study. By removing the extrinsic stains presented on the dental surface of the smoker group (produced by diet + cigarette smoke) and in the nonsmokers group (produced by diet), teeth became significantly whiter. This was likely one of the reasons that reduced the patient's overall perception of whiter teeth after 30 months of follow-up.

On the other hand, the present study demonstrated that stain deposition is not the single factor responsible for the color rebound observed in the present investigation. Contrary to what was observed in the one-year follow-up,¹¹ the ΔSGU baseline vs 30-month after prophylaxis result was not statistically similar to the whitening degree obtained one month postbleaching, meaning that other factors, apart from superficial dental staining, might be associated with such slight but significant color rebound.

As teeth get older, there is continuous enamel wear and deposition of secondary dentin by the pulp.³⁰ As the dentin thickness increases and enamel thickness decreases,³¹ teeth become increasingly yellow regardless of the individual's dietary conditions or smoking habits. Interestingly, most of the patients reported that they felt their teeth were darker at the 30-month recall than immediately after bleaching. In the 30-month recall most of the participants in both groups reported that their teeth had darkened slightly.

The participant's perception is important for clinicians, since a positive correlation was found between participants' self-assessment of their tooth shade and that of the clinician.³² One of the most important factors in determining satisfaction with self-appearance is the tooth color.³³ In the present study most participants, both smokers and nonsmokers, felt happy with the bleaching treatment result, which was previously shown in a study designed to assess patient satisfaction with the whitening treatment performed.³⁴ Some participants reported that the bleaching treatment provided a slight color change, which may or may not have been noticed by other people. It has been shown³⁵ that patient expectations regarding the outcome of the bleaching treatment are higher than those of dentists, which could lead to a divergence between them, meaning that clinical trials should include more patient-centered outcomes rather than evaluator-centered outcomes, since the patient's satisfaction or treatment success perception is more

important than the care provider's perception. It is worth pointing out, however, that the data provided by the questionnaire included in this trial are simply exploratory, as we have not used a validated instrument.

The literature findings report controversial findings regarding the longevity of at-home bleaching. Some authors^{12,13,16} reported stable color in periods ranging from one to two years. Other authors reported color rebound after one year^{36,37} and two years^{13,38} and also after longer follow-up recalls,^{39,40} as demonstrated in this study. Indeed, the longevity of such bleaching procedures is yet to be determined. Despite this, 70% of patients reported that they observed a slight color change in their teeth.

Additionally, the majority of clinical trials that evaluated the longevity of at-home bleaching did not report the patients' dietary habits during and after dental bleaching treatment. Only a few studies^{12,37,38} have attempted to associate the effect of dietary habits with the longevity of at-home bleaching, although they did not reach conclusive findings, which emphasizes the need for future studies.

CONCLUSION

After a follow-up of 30 months, we detected a significant color rebound in smokers and nonsmokers with use of 10% CP, which cannot be attributed to extrinsic stains only, as even after dental prophylaxis, teeth appeared slightly darker than the immediate whitening result.

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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 State University of Ponta Grossa. The approval code for this study is 16211/2014.

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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