One-year follow-up of at-home bleaching in smokers before and after dental prophylaxis

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ABSTRACT

Objective: This clinical study evaluated the color longevity after one-year of at-home bleaching with 10% carbamide peroxide (CP) in smokers and nonsmokers.
Methods: Sixty patients, 30 smokers and 30 non-smokers were subjected to bleaching with 10% CP during three hours daily for three weeks. The color was measured at baseline and one week, one month and one year after the completion of dental bleaching using the spectrophotometer Vita Easyshade (ΔE^*), shade guide Vita classical organized by value and Vita Bleachedguide 3D-MASTER (ΔSGU). In the one-year recall, the color was assessed before and after dental prophylaxis with Robinson brush and prophylaxis paste. Data from color evaluation were analyzed by two-way repeated measures ANOVA and Tukey's test for the contrast of means ($\alpha = 0.05$).
Results: Twenty-seven smokers and 28 non-smokers attended the one-year recall. For both study groups, only the main factor assessment time was statistically significant for ΔSGU (Vita classical) and ΔE^* ($p < 0.001$). Effective whitening was observed for both groups at baseline, which was stable at one-month and one year after dental prophylaxis. A slight darkening was observed after one year when the color was measured without prophylaxis. For the Vita Bleachedguide 3D-MASTER, color rebound was observed irrespectively of dental prophylaxis.
Conclusion: The bleaching with 10% CP remained stable in both groups as long as extrinsic stains from diet and cigarette smoke were removed by professional dental prophylaxis. Clinical trials registry: NCT02017873.
Clinical relevance: The results of this study indicate that the bleaching is effective in smokers even after one-year, but dental prophylaxis may be necessary to remove extrinsic stains caused by diet and smoking.

1. Introduction

Currently, people give much value to the body and aesthetics. A large number of people wish not only to have a perfect body, but also a perfect smile [1]. In this context, smokers are likely good candidates for cosmetic dental procedures since the prevalence of self-assessed tooth discoloration in smokers is almost twice that reported by non-smokers [2]. They represent a significant portion of the population, since there are around 1.2 billion smokers in the world [3].

Unfortunately, clinical trials of bleaching agents usually exclude smokers from their clinical trials [4–13], which prevent us from assessing the feasibility of this cosmetic procedure in such patients. An earlier publication of de Geus et al. [14] demonstrated that effective whitening is achieved regardless of whether the patient is a smoker. It was reported that the magnitude of color change after at-home whitening is equivalent between smokers and non-smokers at one week [14]; however this equivalence was not seen one month after bleaching, with smokers having slightly darker teeth than non-smokers. This situation may be even more evident after some months as cigarette smoke deposits a dark extrinsic stain on the dental surface [2,15]. However, to the extent of our knowledge, no clinical study has evaluated the longevity of at-home bleaching in smokers.

Apart from that, we should be able to diagnose if the color rebound results from the deposition of dyes or smoke on the dental

surface or from the reversal of the oxidizing action of the bleaching agent or dentin deposition over time. Therefore, the evaluation of the "real" whitening outcome in long-term recalls would require color assessment before and after removal of extrinsic staining by mechanical cleaning and dental prophylaxis [16].

Although there are numerous studies of at-home dental bleaching, only a few of them evaluate the color stability over time [7,8,17–24]. None of these studies have attempted to appraise the bleaching longevity after dental prophylaxis. Therefore, the aim of this controlled clinical trial was to compare the one-year color change of at-home bleaching in smokers and non-smokers before and after dental prophylaxis. The following null hypotheses will be tested in this study: (1) no difference in color change of teeth will be observed between the immediate and one-year results for both study groups; (2) the color change before and after dental prophylaxis will be the same for both study groups.

2. Methods

The State University of Ponta Grossa (protocol 669.914/2014) and the Ethic Committee approved this equivalence clinical trial. This study is the one-year follow-up of an earlier study [14] registered at the clinicaltrials.gov under the identification number of NCT02017873. This earlier study was conducted in the Chile and Brazil centers [14], but the follow-up was only performed in the Brazilians participants. We have followed the recommendation of the STROBE checklist (Strengthening the Reporting of Observational studies in Epidemiology) for the report of this study.

2.1. Bleaching procedure

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

We made alginate impressions of each participant's maxillary and mandibular arch and poured the impressions with dental stone. We did not apply block-out material to the labial surfaces of the teeth [25]. We used a 1-millimeter-thick soft vinyl material provided by the manufacturer (Whiteness, FGM Dental Products) to fabricate the custom-fitted tray to hold the bleaching gel. We trimmed the bleaching tray one mm beyond the marginal gingiva and delivered the tray and the 10% CP gel (Whiteness Perfect, FGM Dental Products) to each participant with oral instructions for use. We instructed all participants to wear the tray with the bleaching agent for 3 h daily for 3 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.

2.2. Sample size

This study is the one-year follow-up of an earlier study [14]. We based the sample size calculation on the color change measured with the spectrophotometer, the primary outcome of this study.
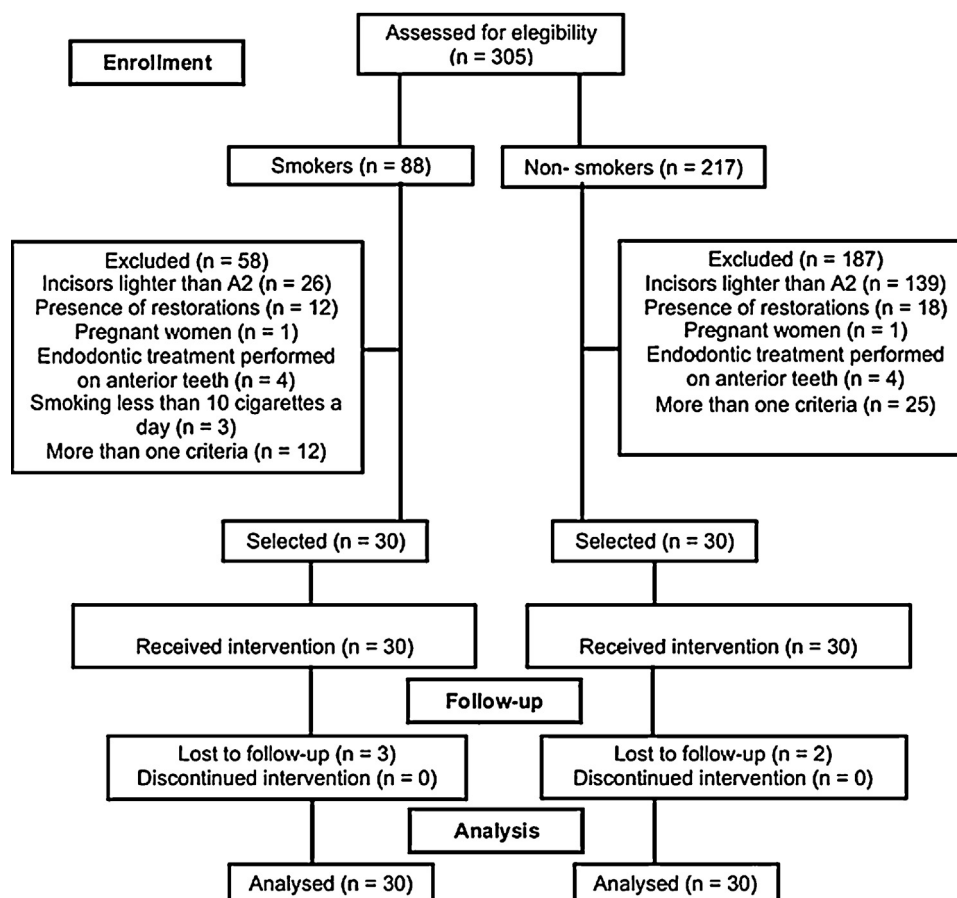

Fig. 1. Flow diagram of the clinical trial, including detailed information regarding the excluded participants.

Sixty participants were required to exclude a difference of means of 2.5 units of ΔE^* at one week and one year (equivalence limit) with a power of 80% and a of 5%. With these calculations, we took into consideration a standard deviation of 3.3 in the ΔE^*. The equivalence limit we chose was lower than the threshold of 3.0 measured with the spectrophotometer, above which color differences become clinically perceptible [26–28].

2.3. Shade evaluation

We evaluated the color of teeth using objective and subjective methods. For both devices, we checked the color in the middle third of the labial surface of the anterior central incisor according to the American Dental Association guidelines [29].

For the objective shade evaluation, we used a digital spectrophotometer (VITA Easyshade, VITA Zahnfabrik) because its reliability more than 96% [30]. For this purpose, we took an impression of the maxillary arch with dense silicone paste (Coltoflax and Perfil Cub, Vigodent), and we created a window on the labial surface of the silicone guide by using a metal device with a diameter of 6 mm. The purpose of this procedure was to standardize the area for color evaluation in all recall periods with the spectrophotometer.

We determined the color using the parameters of the digital spectrophotometer on which were indicated values: L^*, a^*, and b^*, where L^* represents luminosity (the value from 0 (black) to 100 (white)), and a^* and b^* represent color along the red–green axis and color along the yellow–blue axis, respectively. We calculated the difference between baseline and each recall period (ΔE^*), by using the following formula [31]: $\Delta E^* = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$.

For the subjective evaluation, we used the Vita Bleachedguide 3D-MASTER (VITA Zahnfabrik), which is originally oriented from lightest to darkest color and the VITA classical shade guide (VITA Zahnfabrik). For the latter, we arranged the 16 tabs of the shade guide from lightest to darkest as follows: B1, A1, B2, D2, A2, C1, C2, D4, A3, D3, B3, A3.5, B4, C3, A4, C4. Although this scale is not linear in the truest sense, we treated the changes as continuous, with a linear ranking as has been used in several clinical trials on dental bleaching [9,10,32].

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

Two calibrated evaluators with a previous agreement of at least 85% determined by means of weighted k statistics recorded the shade of the maxillary right central incisor at baseline and one week, one month and one year after the end of the bleaching protocol. At one year, the evaluation was performed before and after dental prophylaxis with a Robinson brush and prophylaxis paste (Herjos, Vigodent Coltene SA Indústria e Comércio, Rio de Janeiro, Brazil). After dental prophylaxis, the treated teeth were rehydrated in the patient's mouth for 15 min before color assessment.

2.4. Statistical analysis

We performed all of the analyses using software (Statistica for Windows, StatSoft Inc., Tulsa, OK, USA) and a 5% significance level. Statistical analyses were performed using per-protocol analysis (only for the available data) and the intention-to-treat approach, where the last observation was carried forward for the missing data. The color change in ΔSGU and in ΔE^* was submitted to a two-way repeated measures ANOVA (Group vs. assessment period) and Tukey's test for pairwise comparisons.

3. Results

At baseline, we screened 305 patients to obtain 60 participants from the center in Brazil who met the eligibility criteria (Fig. 1). The mean age and baseline color of the participants were similar between the groups. Most of the participants were men (Table 1). The smoking habit did not change among the majority of participants from the smoking group during the course of the year. Only three of them stopped smoking.

All participants included in this controlled clinical trial finished the bleaching protocol and attended the one-week and one-month recall visits (Fig. 1); however five participants did not attend the one-year recall ($n=3$ in the smokers group and $n=2$ in the nonsmokers group, Fig. 1). The reason for not attending the recall was that the participants lacked time to return to the university for a new color assessment.

3.1. Per-protocol vs. intention-to-treat analysis

All statistical analyses were performed with data imputation for missing outcomes (intention-to-treat) and without data imputation (per-protocol). The same overall conclusions were reached (data not shown) in all of the analyses. To avoid data repetition we opted to describe only the results obtained in the intention-to-treat analysis.

3.2. Shade guide data

For the Vita classical shade guide, the two-way repeated ANOVA revealed that the cross-product interaction group vs. assessment time ($p=0.153$) and the main factor group ($p=0.345$) was not significant. Only the main factor assessment time was statistically significant (Table 2; $p<0.001$). The lack of difference between the groups can also be seen by the effect size (mean difference) and the 95% confidence interval (Table 2).

A significant average color change (ΔSGU) of approximately 5.6 shade guide units was observed after bleaching for both groups, which was stable one month after the procedure (Table 2). At one year, color change was statistically similar to the immediate result only when the color was measured after dental prophylaxis. Without dental prophylaxis, the color change at one year was statistically different from the immediate result (one week post-bleaching).

For Vita Bleachedguide 3D-MASTER, the two-way repeated measures ANOVA revealed that the cross-product interaction group vs. assessment time ($p=0.80$) and the main factor group ($p=0.05$) was not significant (Table 3). Only the main factor assessment time was statistically significant (Table 3; $p<0.001$). The lack of difference between smokers and nonsmokers can also

Table 1
Demographic characteristics of the participants.

Characteristics	Groups	
	Smokers	Non-smokers
Baseline color (SGU[a]; mean ± SD[b])	7.8 ± 1.1	8.2 ± 1.3
Baseline L×(mean ± SD)	83 ± 19.9	82.6 ± 9.1
Baseline a×(mean ± SD)	0.4 ± 0.6	-0.5 ± 0.4
Baseline b×(mean ± SD)	26.8 ± 5.5	23.4 ± 1.6
Age (years; mean ± SD)	26.3 ± 6.5	24.1 ± 6.8
Sex (male; %)	63.3	53.3
Cigarettes/day (mean ± SD)	13.2 ± 4.0	–
Average smoking years (mean ± SD)	8.0 ± 5.9	–

[a] SGU, Shade Guide Unit.
[b] SD, standard deviation.

Table 2
Means and standard deviations of color change in shade guide units (ΔSGU) 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	Groups	Main factor time[a]	Mean difference (95% CI)	
			Smokers	Non-smokers
Baseline vs. 1 week	5.4 ± 2.0	5.8 ± 2.0	5.8 ± 2.3 a	−0.4 (−1.4 to 0.6)
Baseline vs. 1 month	5.2 ± 2.1	5.7 ± 2.1	5.7 ± 2.3 ab	−0.5 (−1.6 to 0.6)
Baseline vs. 1 year before prophy	4.9 ± 2.1	5.6 ± 2.1	5.6 ± 2.4 b	−0.7 (−1.8 to 0.4)
Baseline vs. 1 year after prophy	5.2 ± 2.2	5.6 ± 2.2	5.6 ± 2.4 ab	−0.4 (1.6 to 0.7)

[a] Groups identified with the same letter are statistically similar.

Table 3
Means and standard deviations of color change in shade guide units (ΔSGU) using the Bleach shade guide at the different assessment points along with the effect size (mean difference) and the 95% confidence interval (CI).

Assessment time	Groups	Main factor time[a]	Mean difference (95% CI)	
			Smokers	Non-smokers
Baseline vs. 1 week	4.4 ± 1.0	5.0 ± 1.4	4.7 ± 1.2 a	−0.6 (−1.2 to 0.03)
Baseline vs. 1 month	4.1 ± 1.1	4.7 ± 1.4	4.4 ± 1.3 b	−0.6 (−1.2 to -0.05)
Baseline vs.1 year before prophy	3.5 ± 1.2	4.2 ± 1.6	3.8 ± 1.4 c	−0.7 (−1.4 to 0.03)
Baseline vs. 1 year after prophy	3.5 ± 1.2	4.2 ± 1.6	3.9 ± 1.4 c	−0.7 (−1.4 to 0.03)

[a] Groups identified with the same letter are statistically similar.

Table 4
Means and standard deviations of color change in shade guide units (ΔE) at the different assessment points along with the effect size (mean difference) and the 95% confidence interval.

Assessment time	Groups	Main factor time[a]	Mean difference (95% CI)	
			Smokers	Non-smokers
Baseline vs. 1 week	10.5 ± 3.9	11.1 ± 3.3	10.8 ± 3.6 ab	−0.6 (−2.5 to 1.3)
Baseline vs. 1 month	8.8 ± 3.9	10.7 ± 4.0	9.7 ± 4.0 a	−1.9 (−3.9 to 0.1)
Baseline vs.1 year before prophy	8.2 ± 4.8	9.2 ± 3.5	8.7 ± 4.2 c	−1.0 (3.2 to 1.2)
Baseline vs. 1 year after prophy	9.9 ± 4.6	10.3 ± 3.7	10.1 ± 4.2 b	−0.4 (2.6 to 1.8)

[a] Groups identified with the same letter are statistically similar.

be seen by the effect size (mean difference) and the 95% confidence interval (Table 3).

According to this shade guide, a significant color rebound was observed over time for both groups (Table 3), and this color rebound was not affected by dental prophylaxis.

3.3. Spectrophotometer data

The two-way repeated measures ANOVA revealed that the cross-product interaction group vs. assessment time ($p = 0.158$) and the main factor group ($p = 0.311$) was not significant. Only the main factor assessment time was statistically significant (Table 4; $p < 0.001$). The lack of statistical difference between the groups can also be seen by the mean difference and the 95% confidence interval (Table 4).

Compared to the ΔSGU obtained with the Vita classical to spectrophotometer data, a similar trend was observed. A significant color change was observed for both groups, which represented an average ΔE^* of 10.8. This color change was statistically similar to that observed after one month and one year when color was measured after dental prophylaxis. Without dental prophylaxis, the color change at one year was statistically different from the immediate result (one week post-bleaching).

4. Discussion

Color matching and measurement in dentistry is performed using visual and/or instrumental methods. The Vita classical shade guide (VITA Zahnfabrik), when arranged from the lightest to the darkest tab, is the most frequent method used for visual evaluation of tooth whitening [9,10,32], thus this shade guide was chosen for color evaluation in the present study.

However, more recently, studies from the group of Paravina [33–35] developed a new shade guide for color assessment in bleaching studies. Vitapan 3D-Master (VITA Zahnfabrik) was found to have broader color range, better color distribution, and smaller coverage error as compared to other shade guides [36,37]. Despite these advantages, this scale is not yet routinely used for color evaluation in dentistry, so using it would prevent us from making comparisons with previous literature studies. In our opinion, this scale should be incorporated in future clinical trials to create a body of evidence regarding of whether it is superior or not to the traditional value-oriented shade guide Vita classical. In the present study the results of Vita Bleachedguide 3D-MASTER were not consistent with the results of the spectrophotometer and the Vita classical. The reason for such a difference among the shade guides and the spectrophotometer is not clear to the authors and should be a focus of future investigations.

There is a general acceptance that the consumption of staining beverages and foods is frequently associated to tooth discoloration [38,39]. This premise is based on the findings of in vitro studies that reported that smoking, coffee, tea, and wine can lead to tooth discoloration [16,40–43] and therefore affect the longevity of tooth bleaching [16,43]. This is the reason of why dentists have been prescribing a white diet and precluding smokers from bleaching, to guarantee that the immediacy and longevity of the bleaching effect is not reduced as a result of diet [44] or smoking habits.

Fortunately, based on two out of the three tools for color evaluation, this was not confirmed in this clinical study and in others [10,14,45]. An earlier study [14], reported that neither smoking habits nor coffee consumption jeopardized the whitening produced by at-home bleaching [10]. This means that in a one-month short-term follow-up, the deposition of cigarette smoke and dyes from coffee, wine, and other colorful foods and drinks does not produce significant color change, and the bleaching outcome is not affected. This was recently confirmed in a questionnaire-based study [44] in which the ingestion of different substances during bleaching was not found to be associated with a lower degree of whitening. Altogether, these findings suggest that the dentin substrate on which carbamide peroxide exerts its oxidizing action is probably similar irrespective of the smoking and dietary habits of the patient during the bleaching [10,14,45].

In regard to the longevity of at-home bleaching, the literature findings report controversial findings. While color rebound was observed after one year [7,46], two years [21,22] or longer follow-up recalls [19,20], other authors reported stable color in periods ranging from one to two years [8,17,18,22–24].

In the present investigation, we observed color stability (color assessed after dental prophylaxis) and color rebound (color assessed without dental prophylaxis) at the one-year recall, depending on the previous dental prophylaxis. Although diet and the smoking habit were not shown to affect the immediate outcome of bleaching [10,14], it is likely that this is the reason for the color rebound observed in the short-term follow-up of one year when dental prophylaxis was not performed. Teeth exposed to coloring agents from diet indeed have greater potential to stain [47]. Similarly, smokers' teeth tend to develop tobacco stains over time [2], which may vary from yellow to black stains, and the severity is highly dependent on the length and frequency of the smoking habit.

Unfortunately, the majority of the clinical studies evaluating the longevity of at-home bleaching did not report the patients' dietary habits during and after tooth bleaching treatment, which prevents us from further comparisons. Only a few studies have attempted to associate the effect of dietary habits with the longevity of at-home bleaching [18,21,46], and they did not reach conclusive findings, which emphasizes the need for future studies.

It is worth mentioning however, that although significant differences were detected between the immediate results and the one-year follow-up without dental prophylaxis, the differences in the ΔSGU (less than 1 shade guide unit) and ΔE^* (approximately 2 ΔE^* units) were probably not within the visually perceptible range.

Visual thresholds for color differences are applied to correlate the instrumental color values with the clinical evaluation. According to Ghinea et al. [48], the threshold for acceptability was reported to be 3.5 color difference (ΔE^*) units, and that for perceptibility was 1.8 ΔE^* units based on the spectrophotometer readings.

In longer follow-ups, color rebound might be associated with other factors. As teeth get older, there is a continuous deposition of secondary dentin by the pulp [49]. As the dentin thickness increases, the teeth appear yellower. Unfortunately, the length of time that it takes to change one Vita shade tab due to deposition of secondary dentin is unknown, and it is probable that it takes longer than the one-year period of the current study.

Although it is not desirable that extrinsic staining may affect the overall perception of whiter teeth, such coloration may be easily removed by professional dental prophylaxis. This also means that evaluation of the color of the dental structure in clinical trials and also in dental offices should be done after professional dental prophylaxis to prevent extrinsic staining from masking the whitening outcome produced by the bleaching procedure.

It is worth mentioning that though no significant difference was detected between smokers and nonsmokers, the data in Tables 2 and 4 highlight that the effect of dental prophylaxis was more evident in smokers than non-smokers. Had we recruited more patients or evaluated this study sample in longer follow-ups, this difference might have become statistically significant. It is likely that this difference becomes more evident and even significant after some years, with smokers eventually having darker teeth than do nonsmokers. This should encourage further clinical trials on this issue with longer follow-up periods.

5. Conclusion

At-home dental bleaching with 10% carbamide peroxide remained stable in both groups at one year as long as extrinsic stains caused by diet and smoking were removed by dental prophylaxis.

Acknowledgments

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