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A double-blind randomized controlled clinical trial of 10 percent versus 16 percent carbamide peroxide tooth-bleaching agents

One-year follow-up

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At-home dentist-supervised tooth bleaching with custom trays¹ is considered the modality most frequently used to treat discolored teeth.²⁻⁵ The American Dental Association (ADA) published guidelines for the acceptance of dentist-dispensed home-use tooth-bleaching products.⁶ On the basis of the results of published clinical trials,⁷⁻⁹ these guidelines ensure the benefits, safety and effectiveness of carbamide peroxide applied in a tray at a concentration of 10 ± 1 percent (mean \pm standard deviation). However, new products and methods are available for at-home vital tooth bleaching, including gels, rinses, chewing gums, toothpastes, paint-on films and whitening strips.^{3,6,10-12}

In an attempt to increase the effectiveness and longevity

ABSTRACT

Background. The use of high-concentration tooth-bleaching agents has been associated with increased longevity of the whitening effect. The authors conducted a randomized controlled clinical trial to evaluate the longevity of the whitening effect at one year of two at-home tooth-bleaching agents.

Methods. The authors randomly assigned 92 participants with a mean shade of C1 or darker for six maxillary anterior teeth into two equal-sized groups according to carbamide peroxide concentration: 10 percent (CP10) or 16 percent (CP16). Treatment involved the use of a whitening agent in a tray for two hours daily for three weeks. The authors evaluated tooth shade with a shade guide and a spectrophotometer at baseline and one week, six months and one year after bleaching. Participants in both groups answered questions about their dietary and oral hygiene behaviors.

Results. At the one-year recall appointment, the teeth in both groups remained significantly lighter than at baseline. At this time, participants from the CP10 and CP16 groups consumed staining beverages and foods at a level as high as at the six-month recall appointment, and this consumption level was not statistically significant between groups ($P > .5$).

Conclusions. One year after bleaching, both treatment groups had the same median tooth shade, which remained lighter than at baseline.

Clinical Implications. Higher carbamide peroxide concentration does not increase the longevity of the whitening effect of at-home tooth-bleaching agents.

Key Words. Carbamide peroxide; tooth bleaching; randomized controlled clinical trials.

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of the whitening effect, manufacturers have increased the carbamide peroxide concentrations used in vital bleaching with trays.¹³⁻¹⁶ Despite this attempt, low-concentration agents can provide effects similar to those obtained with high-concentration agents.^{7,16,17}

Most studies about the longevity of the whitening effects obtained with tray-based systems for home bleaching^{8,9,18,19} have relatively short-term follow-up periods, with some having a follow-up period of less than six months.^{4,7,15,17,20} Therefore, there is a lack of randomized controlled clinical trials in the literature in which investigators study whether high-concentration agents can improve the efficacy and longevity of at-home tooth-bleaching agents. To date, investigators have not reported on possible factors associated with shade regression, such as dietary behavior (for example, consumption of staining beverages or foods).

We conducted a randomized controlled clinical trial to evaluate at one year the longevity of the whitening effect of two custom tray bleaching systems (10 percent carbamide peroxide concentration [CP10] or 16 percent carbamide peroxide concentration [CP16]). We also investigated aspects related to participants' diet and oral hygiene behaviors to evaluate their influence on the longevity of the whitening effect of the bleaching treatment.

PARTICIPANTS, MATERIALS AND METHODS

The local ethics committee at Federal University of Pelotas, Rio Grande do Sul, Brazil, approved our double-blind randomized controlled clinical trial. Before we enrolled the participants, we gave each one an informed consent form containing all of the information regarding the risks and benefits of treatment. All participants signed the consent form.

Examiners' technique calibration. Before the study began, we calibrated two examiners' techniques for determining anterior tooth shade.²¹ Working with 16 participants, the study supervisor (S.S.M.) recorded the tooth shades by using a digital spectrophotometer (Vita Easyshade, Vita Zahnfabrik, Bad Säckingen, Germany). The examiners also determined shades by using a

value-oriented shade guide (Vitapan Classical, Vita Zahnfabrik). Without communicating with each other, they selected shades in the afternoon with sunlight and under fluorescent light.

We numbered the 16 tabs in the shade guide from 1 (highest/lightest value, B1) to 16 (lowest/darkest value, C4) for statistical analysis. The examiners visually compared the shade guide tabs with the middle one-third of the six maxillary anterior teeth. We added the scores and determined the mean shade for each participant.

We chose analysis with a digital spectrophotometer as the gold standard, because it can be used to determine tooth shade by means of two methods. These methods are related to grouping shades according to the 16 shade tabs in the shade guide (B1 to C4) and the CIE $L^*a^*b^*$ color

system, which was defined by the International Commission on Illumination in 1967 and is referred to as "CIELAB." In the CIE $L^*a^*b^*$ color system, the L^* value is a measure of the lightness or darkness, the a^* value is a measure of the redness (positive a^*) or greenness (negative a^*), and the b^* value is a measure of the yellowness (positive b^*) or blueness (negative b^*). Whitening occurs mainly by increasing the lightness (higher L^*) and reducing the yellowness (lower b^*), as well as, to a lesser extent, by reducing the redness (lower a^*).^{6,22}

The examiners were trained in 13 clinical sessions across 13 days. At each session, they measured the shades of the six maxillary anterior teeth three times, with the active point of the spectrophotometer in the middle one-third of each tooth. The spectrophotometer automatically averaged the three readings for each tooth by using the CIE $L^*a^*b^*$ color system and the shade guide. We compared these readings with the visual assessment results. We calculated the total color difference or distance between two colors as

In an attempt to increase the effectiveness and longevity of the whitening effect, manufacturers have increased the carbamide peroxide concentrations used in vital bleaching with trays.

ABBREVIATION KEY. ADA: American Dental Association. CP10: 10 percent carbamide peroxide concentration. CP16: 16 percent carbamide peroxide concentration. Δa^* : Measure of redness or greenness. Δb^* : Measure of yellowness or blueness. ΔE^* : Total color difference or distance between two colors. ΔL^* : Measure of lightness or darkness.

follows: $\Delta E^* = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$.²² Δ is the difference between before and after measurements.

After the examiners completed the training and calibration processes, we prepared matrices to compare the degree of agreement of the examiners with the gold standard. We calculated the κ coefficient by using either all of the colors of the shade guide (weighted κ) or by grouping all of the colors according to chroma (simple κ), which represents the degree of saturation of color. For κ calculation purposes, if we classified the color as A3.5 according to the gold standard, then we recorded the chroma value as 3. We began the study after both examiners achieved more than 70 percent agreement with the gold standard, according to grouping by chroma.²¹

Sample size. We calculated sample size according to the results of a previous study.¹⁶ To calculate the sample size, we set the following parameters: mean difference of two units or more in shade change between the two study groups, standard deviation of the difference between the means of 2.5, β error of 10 percent (type II error) and one-tailed α error of 5 percent (type I error). On this basis, we determined that a sample size of 80 volunteers would be necessary. We increased the sample size by 15 percent to 92 participants to account for potential loss of participants or their refusal to participate. We invited people to participate in this clinical trial through advertisements in newspapers and on radio stations in Pelotas, Rio Grande do Sul, Brazil, and on the university's Web site.

Eligibility criteria, randomization and blinding. Each participant filled out a medical history form before undergoing a dental examination, including complete dental prophylaxis to remove extrinsic stains.²³ We examined 183 people to find 92 who met the inclusion and exclusion criteria. The participants had to be 18 to 55 years old and in good general and dental health. They had to have six maxillary anterior teeth with a mean shade of C1 or darker. The anterior teeth could not have more than one-sixth of their buccal surfaces covered with a restorative material. We excluded people with active caries, periodontal disease, previous hypersensitivity and tetracycline-stained teeth. We also excluded smokers, pregnant or lactating women, people

who had used tooth whiteners within the past three years and people without schedule availability.

Using a protocol similar to that of the calibration exercise, we used the shade guide and the digital spectrophotometer to perform initial baseline evaluations. We randomly assigned participants to one of two experimental groups of 46 participants each according to carbamide peroxide concentration: CP10 or CP16 (Whiteness Perfect, FGM Dental Products, Joinville, Santa Catarina, Brazil). We used a randomization table to allocate the participants to each study group. An epidemiologist (I.S.S.) who was not directly involved with the clinical part of the study prepared the randomization table in advance.

To mask the treatment used, we removed the concentration label from each bleaching gel syringe. To mask the tubes, which were different colors, the same examiner who was responsible for allocating the participants to the treatment groups covered one-half of the plungers with white adhesive tape. Therefore, the examiners and participants were blinded to the concentration of the agent that was being delivered.

Bleaching procedure. We took two alginate impressions (Jeltrate, Dentsply International, Milford, Del.) per participant and prepared stone molds (Durone IV, Dentsply International). We blocked out the buccal surfaces of the anterior teeth on each mold with five coats of nail polish, starting approximately 1.0 millimeter above the gingival margin. This area created a reservoir about 1.0 mm thick in the tray for the bleaching gel. We fabricated custom trays by using a 0.9-mm-thick soft vinyl material that came with the carbamide peroxide product and a vacuum-formed process. We trimmed the excess material on the buccal and lingual surfaces 1.0 mm above the gingival margin.

Before starting treatment, we recalled the participants and gave them the trays and three bleaching gel tubes. We instructed them to dispense gel into the trays and to insert them in their mouths and cover at least the anterior teeth for two hours per night for three weeks.²³ Participants bleached both their maxillary and mandibular arches at the same time. All participants received a hands-on practical demonstra-

We gave participants toothbrushes and dentifrices without whitening agents in an effort to standardize their oral hygiene regimens.

TABLE 1

Demographic characteristics of the sample, according to treatment group.

VARIABLES	TREATMENT GROUP		P VALUE
	Carbamide Peroxide 10 percent (n = 46)	Carbamide Peroxide 16 percent (n = 46)	
Sex (No. [%])			.5
Male	14 (30.4)	17 (37.0)	
Female	32 (69.6)	29 (63.0)	
Age (Years) (No. [%])			.4
Mean age (standard deviation)	26.4 (± 9.2)	24.2 (± 6.2)	
≤ 20	11 (23.9)	13 (28.3)	.4
21-22	10 (21.7)	12 (26.1)	
23-24	9 (19.6)	6 (13.0)	
25-26	3 (6.5)	7 (15.2)	
≥ 27	13 (28.3)	8 (17.4)	
Education Level (No. [%])			.8
Middle and high school	8 (17.4)	7 (15.2)	
Complete college	10 (21.7)	11 (23.9)	
Incomplete college	28 (60.9)	28 (60.9)	
Profession (No. [%])			.6
Student	33 (71.7)	34 (73.9)	
Self-employed	11 (23.9)	8 (17.4)	
Public servant	2 (4.3)	4 (8.7)	

tion, written instructions concerning the proper use of the bleaching agent, and advice on diet and oral hygiene control during the course of the treatment. We also gave participants toothbrushes and dentifrices without whitening agents in an effort to standardize their oral hygiene regimens.

We instructed each participant to record tooth sensitivity on a daily basis during the three-week treatment.²³ We gave participants potassium nitrate desensitizing gel (Desensibilize KF 2 percent, FGM Dental Products) if they experienced more than a moderate degree of sensitivity, and we instructed them to place the desensitizing gel in the tray and wear the tray for 20 minutes per day as recommended by the manufacturer. During the bleaching treatment, four participants who used CP16 and one who used CP10 requested the desensitizing agent. To measure compliance regarding bleaching gel use, we used a digital precision balance to weigh tubes containing bleaching agents before and after use.²³

We evaluated participants at baseline and one week, six months and one year after bleaching. Examiners were blinded to the participants' study groups. At each evaluation period, we determined tooth shade by following the same protocol we used at baseline. At the one-year

recall appointment, we compared the shade changes for each participant in both treatment groups with their tooth shades at baseline and one week and six months after bleaching.

The study supervisor (S.S.M.) prepared a standardized questionnaire related to diet and oral hygiene behavior specifically for the participants. She trained interviewers in advance on how to administer the questionnaire. At the six-month and one-year recall appointments, the interviewers asked the participants in both treatment groups about whitening toothpaste use, rebleaching their teeth after the active treatment phase was com-

pleted, and daily intake frequency and type of staining beverage and food (for example, coffee, tea, wine, fruit or artificial juices, and cola-containing beverages) and natural-colorant foods (for example, beetroot, carrot and lettuce) or industrialized foods (for example, jelly, chocolate, yogurt, ketchup and mustard).

Eighty-nine of the 92 participants enrolled in the study (96.7 percent) returned for the one-year follow-up appointment. One participant from the CP16 group failed to continue the treatment at the beginning of the trial, and at the six-month recall appointment, two other participants (one from each group) were lost to follow-up. At one year, there were no additional losses of participants. Demographic characteristics of the sample are shown in Table 1. We previously reported reasons for participant loss and results of the study at one week and six months after bleaching.^{23,24}

Statistical analysis. We used the Kolmogorov-Smirnov test to check the data records for normal distribution. We found that the distribution was not normal, and we used the Wilcoxon signed rank test to determine significant differences in tooth shade within the same treatment group. We used the Mann-Whitney *U* test for independent samples to compare the two groups at baseline and after treatment. We used

TABLE 2

Median change and 95 percent confidence interval (CI) from baseline.

COLOR PARAMETERS*	EVALUATION PERIOD MEDIAN (95 PERCENT CI)				SIGNIFICANT P VALUES (ONE YEAR VERSUS EARLIER EVALUATION PERIOD)
	Baseline†	One Week	Six Months	One Year	
ΔL^*					
CP10‡	78.0 (62.9 to 84.2)	3.7 (–1.0 to 11.1)	2.7 (–2.2 to 7.4)	3.7 (–4.1 to 9.0)	Baseline (< .01) Six months (< .03)
CP16§	78.9 (71.9 to 83.0)	3.5 (–1.5 to 10.8)	3.5 (–0.9 to 7.1)	3.7 (–0.9 to 10.1)	Baseline (< .01)
P value (CP10 versus CP16)	.2	.7	.3	.7	
Δa^*					
CP10	–0.4 (–1.4 to 3.7)	–0.5 (–4.2 to 1.2)	–0.6 (–4.5 to 0.1)	–0.3 (–5.3 to 1.7)	Baseline (< .01) One week (< .001) Six months (< .001)
CP16	–0.3 (–6.0 to 0.5)	–0.6 (–1.9 to 5.2)	–0.7 (–1.7 to 7.7)	–0.3 (–5.0 to 5.3)	Baseline (< .01) One week (< .001) Six months (< .02)
P value (CP10 versus CP16)	.7	.5	.8	.8	
Δb^*					
CP10	0.3 (–4.6 to 4.5)	–0.8 (–4.6 to 1.9)	–1.0 (–5.0 to 1.1)	–0.8 (–4.8 to 2.4)	Baseline (< .01) Six months (< .001)
CP16	0.9 (–2.7 to 4.2)	–1.5 (–3.8 to 1.9)	–1.9 (–4.3 to 1.5)	–1.4 (–4.7 to 2.0)	Baseline (< .01)
P value (CP10 versus CP16)	.02	.6¶	.3¶	.4¶	
ΔE^*					
CP10	—#	4.1 (0.9 to 11.2)	3.8 (1.3 to 7.5)	4.3 (0.6 to 9.0)	$P > .1$
CP16	—	4.2 (1.1 to 10.8)	4.4 (1.5 to 8.5)	4.7 (0.8 to 10.3)	$P > .5$
P value (CP10 versus CP16)	—	.5	.1	.5	

* ΔL^* : Measure of lightness or darkness. Δa^* : Measure of redness or greenness. Δb^* : Measure of yellowness or blueness. ΔE^* : Total color difference or distance between two colors.
† At baseline, L^* , a^* , b^* medians were shown in absolute values.
‡ CP10: 10 percent carbamide peroxide concentration.
§ CP16: 16 percent carbamide peroxide concentration.
¶ Adjusted for b^* parameter at baseline.
—: Not applicable.

χ^2 and McNemar tests to compare the significant differences in categorical variables. We considered differences statistically significant at $P < .05$.

RESULTS

Spectrophotometer data. We previously reported the L^* , a^* and b^* values at baseline and one week and six months after bleaching.^{23,24} At the one-year recall appointment, the teeth in both treatment groups remained significantly lighter than at baseline, according to the color parameters ΔL^* , Δa^* and Δb^* ($P < .01$) or the tooth shade median values ($P < .001$). One year after bleaching, the results of comparisons between the CP10 and CP16 groups were not significantly different for ΔL^* , Δa^* , Δb^* , ΔE^* and tooth shade median values (Tables 2 and 3).

When we compared the longevity of the whitening effect at the one-year recall appoint-

ment within the same treatment group, we observed a statistically significant difference only for Δa^* (decreasing in greenness) for both CP10 and CP16 ($P < .001$) (Table 2). We observed median shade relapse for the CP16 group when we compared the findings one year after bleaching with the findings one week after bleaching ($P < .04$) (Table 3).

Visual assessment with the shade guide.

The results of the visual evaluation with the shade guide showed that median tooth shades for both treatment groups remained significantly lighter at the one-year recall appointment than at baseline ($P < .001$). In addition, the median shade for teeth treated with CP10 was not significantly different from that for teeth treated with CP16 ($P = .5$). However, when we analyzed the longevity of the whitening effect within the same group, we observed a shade regression for CP16

TABLE 3

Shade changes across time with visual and electronic measurements.					
SHADE EVALUATION METHOD AND TREATMENT GROUP	MEDIAN SHADE VALUE (95 PERCENT CONFIDENCE INTERVAL)				SIGNIFICANT P VALUES (ONE YEAR VERSUS EARLIER EVALUATION PERIOD)
	BASELINE	ONE WEEK	SIX MONTHS	ONE YEAR	
Spectrophotometer					
CP10*	8.5 (6.0 to 15.0)	2.7 (1.3 to 12.0)	3.0 (1.3 to 10.5)	2.7 (1.3 to 11.8)	Baseline (< .001)
CP16†	8.8 (6.0 to 13.5)	2.3 (1.3 to 5.7)	2.4 (1.2 to 5.8)	2.7 (1.3 to 6.0)	Baseline (< .001) One week (< .04)
P value (CP10 versus CP16)	.8	.04‡	.04‡	.3	
Shade Guide					
CP10	8.7 (3.3 to 14.7)	2.3 (1.3 to 14.0)	2.5 (1.5 to 12.0)	2.5 (1.1 to 10.5)	Baseline (< .001)
CP16	8.0 (4.3 to 12.7)	2.0 (1.0 to 5.0)	2.3 (1.0 to 6.2)	2.3 (1.3 to 5.7)	Baseline (= .001) One week (< .001)
P value (CP10 versus CP16)	.2	.01	.06	.5	

* CP10: 10 percent carbamide peroxide concentration.

† CP16: 16 percent carbamide peroxide concentration.

‡ Difference statistically significant between groups ($P < .05$).

one year compared with one week after bleaching ($P < .001$) (Table 3).

Dietary and oral hygiene behavior. The rate of staining beverage or food consumption reported by participants in both treatment groups remained high at the six-month evaluation. Despite this finding, we observed a statistically significant difference with increased staining from beverage consumption in the CP10 group ($P = .004$). There was no statistically significant difference at the one-year compared with the six-month recall appointment for diversity or for daily intake frequency of staining beverages ($P = .7$) or for consumption ($P = .1$), diversity ($P = .9$) or daily intake frequency ($P = .3$) of staining food for the CP10 group. We observed no statistical difference for consumption ($P = .07$), diversity ($P = .999$) or daily intake frequency ($P = .3$) of staining beverages or for consumption and diversity ($P = .6$) and daily intake frequency ($P = .2$) of staining food for the CP16 group at the one-year recall appointment compared with that at the six-month recall appointment (Table 4).

None of the participants reported rebleaching their teeth during the first year after treatment. Regarding the use of whitening toothpaste, only six (13 percent) participants from the CP10 group and 11 (25 percent) from the CP16 group reported using whitening toothpaste ($P = .4$). At the one-year recall appointment, staining beverage or food consumption, diversity and daily intake frequency were not statistically different between

treatment groups ($P > .5$). Table 4 shows the details of the participants' dietary behavior.

DISCUSSION

The results of our study one year after bleaching showed that the teeth in both treatment groups remained at least 5.7 shade guide units lighter than at baseline, which involved a change of more than 4.0 ΔE^* units on the basis of the CIE $L^*a^*b^*$ system, according to efficacy levels established by the ADA.⁶ Although the participants treated with CP16 had median tooth shade values lower than those of the CP10 group at the one-week²³ and six-month²⁴ evaluations, we did not observe this difference at the one-year recall appointment for the spectrophotometer evaluation. The results of short longitudinal studies (those whose participants are followed up for only the first few weeks after an intervention) show that higher-concentration agents are capable of whitening teeth faster than are lower-concentration agents; however, after a few weeks, similar effects can be achieved with both high- and low-concentration agents.^{7,13,17}

In both treatment groups, parameters such as ΔL^* and ΔE^* had a small increase one year after bleaching compared with the findings six months after bleaching. These small variances probably are related to the difference in sunlight intensity when shade measurements were being taken. We determined the tooth color in the dental clinic with sunlight and room illumination, and the

sunlight intensity might have caused some interference in the spectrophotometer color detection. However, this difference was a small difference compared with the findings at the six-month evaluation, and it was not statistically significant and may have been responsible for some color parameter differences between the results of the six-month and one-year evaluations.

In our study, participants used the bleaching agents soon after we received them from the manufacturer. We did not test the concentration of the bleaching agent in each of the tubes, which was a limitation of our study. The manufacturer, however, produces dental materials according to quality control guidelines recognized by the International Organization for Standardization and the European Community, which ensures a high level of production excellence.

Although the whitening effect obtained one week after bleaching was maintained in the CP10 group, the results of visual and spectrophotometric analyses indicated a decrease in the whitening effect for the CP16 group. There is a lack of long longitudinal studies (those whose participants are followed up for longer than a few months after an intervention) in which investigators compare the longevity of the whitening effect obtained with at-home tooth-bleaching agents with different carbamide peroxide concentrations. Investigators in

most studies evaluated the longevity of the whitening effect associated with CP10.^{4,8,9,19} In addition, they did not investigate factors related to shade regression. The investigators in one study reported that more than 80 percent of patients treated with CP10 gel had a satisfactory result two years after treatment.⁹ Investigators in another study evaluated 44 participants who bleached their tetracycline-stained teeth with CP10 or 15 percent or 20 percent carbamide peroxide concentrations. Five years after

TABLE 4

Dietary behavior of participants at six-month and one-year recall appointments.

VARIABLES RELATED TO DIETARY BEHAVIOR	EVALUATION PERIOD					
	Six Months			One Year		
	CP10* (n = 45)	CP16† (n = 44)	P value (CP10 versus CP16)	CP10 (n = 45)	CP16 (n = 44)	P value (CP10 versus CP16)
Staining Beverage Consumption			.2			.8
Yes	25	32		37	38	
No	1	1		1	1	
Sometimes	19	11		7	5	
Diversity of Staining Beverage Intake			.4			.9
One type	13	10		7	9	
Two types	10	12		12	12	
Three types	9	11		15	14	
Four types	7	6		4	4	
Five types	5	4		6	4	
None	1	1		1	1	
Daily Intake Frequency of Staining Beverages			.5			.8
Once a day	20	18		18	16	
Two or three times a day	17	22		23	21	
Four or more times a day	7	3		3	6	
Anytime	1	1		1	1	
Staining Food Consumption			.3			.8
Yes	22	18		28	26	
No	2	6		3	2	
Sometimes	21	20		14	16	
Diversity of Staining Food Intake			.2			.7
One type	6	7		12	11	
Two types	9	14		9	14	
Three types	20	11		10	9	
Four types	8	6		10	8	
None	2	6		4	2	
Daily Intake Frequency of Staining Foods			.4			.5
Once a day	37	31		32	35	
Two or three times a day	6	7		8	7	
Four or more times a day	2	6		2	0	
Anytime	0	0		3	2	

* CP10: 10 percent carbamide peroxide concentration.

† CP16: 16 percent carbamide peroxide concentration.

bleaching, the authors concluded that more than 65 percent of the whitening effect remained for all three concentrations tested.¹⁸

One year after bleaching, we observed no significant differences between groups for median tooth shade or Δb^* . In addition, one year after bleaching, the Δa^* values increased for both treatment groups when compared with those obtained one week and six months after bleaching. The results of a literature review addressing tooth color and its measurements indicated that the a^* and b^* parameters approach zero for neutral colors (white and gray) and increase in magnitude for more saturated or intense colors.²⁵ However, the whiteness change seemed to correlate, to a minor extent, for L^* or a^* . Whitening reduces the b^* values more rapidly and to a greater extent than it reduces the other parameters.^{26,27}

Investigators in some studies associated tooth staining with extrinsic factors such as staining caused by diet.^{25,28} Overall, in our study one year after bleaching, participants from the CP10 and CP16 groups continued to consume a lot of staining beverages and foods, similar to the levels seen at the six-month evaluation.²⁴ Although at the six-month evaluation consumption of staining foods and beverages did not interfere with the longevity of the whitening effect, one year after bleaching we observed a small regression of median tooth shade for CP16 compared with that seen one week after bleaching. Our results suggest that the influence of staining from dietary sources on the longevity of the whitening effect is slow and gradual. Thus, long-term clinical studies are needed to evaluate the longevity of the whitening effect of at-home tooth-bleaching with different carbamide peroxide concentrations, as well as to evaluate the factors related to tooth shade stability.

Participants receiving both CP10 and CP16 treatment achieved the same color change, and the whitening effect remained stable for at least one year without rebleaching. Rebleaching is not required periodically but is indicated by darkening of the teeth. In our study, there was no need for rebleaching after one year because the darkening was absent or minimal and without clinical relevance.

CONCLUSIONS

One year after bleaching, we concluded that although some reversal of the whitening effect could be noted for the group treated with CP16,

the teeth in both treatment groups had the same median tooth shade and remained lighter than at baseline. ■

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