

Clinical effectiveness and tooth sensitivity associated with different bleaching times for a 10 percent carbamide peroxide gel

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Dentist-supervised bleaching is the most conservative treatment for discolored teeth compared with placement of resin-based composites, porcelain veneers and crowns. In esthetic dentistry, at-home bleaching with carbamide peroxide (CP) gel likely is the most widely used technique because of its easy application, low cost and wide acceptance by patients.¹ Introduced by Haywood and Heymann² in 1989, the technique involves the application of a 10 percent CP gel in a custom-fitted soft plastic tray. The authors recommended that patients use the product at night, for about six to eight hours, for up to six weeks.

However, since then, clinicians and researchers have followed different application regimens with variations mainly in the time that the gel remains in contact with the

ABSTRACT

Background. The daily application time for 10 percent carbamide peroxide (CP) typically is between four and eight hours. However, to the authors' knowledge, no investigators in clinical studies have compared different application times; this is the aim of this study.

Methods. The authors recruited 60 patients and categorized each of them into one of four groups. All participants used 10 percent CP in a bleaching tray. The daily application times were 15 minutes, 30 minutes, one hour or eight hours. Participants bleached their teeth for 16 days and those who were not satisfied with the results extended the bleaching time until they were satisfied. Patients recorded their tooth sensitivity on a 0 to 4 scale. The authors measured the shade changes by using a digital spectrophotometer and shade guide. They performed appropriate statistical analysis of the data ($\alpha = .05$).

Results. Participants in the one- and eight-hour groups bleached their teeth for 18 and 16 days, respectively ($P > .05$), while statistically longer periods were required for participants in the other two groups ($P < .001$) to be satisfied with the results. Participants' tooth sensitivity ratings were similar for the 15-minute, 30-minute and one-hour application times ($P > .05$), and they were statistically lower than those for participants in the eight-hour group.

Conclusions. The eight-hour bleaching protocol yielded faster bleaching; however, participants experienced higher sensitivity levels. The one-hour group most closely approached the eight-hour group with regard to bleaching speed, while those in the one-hour group experienced lower sensitivity levels.

Clinical Implications. In this study, the difference in bleaching speed between the eight- and one-hour application times after 16 days was small, and the results showed less tooth sensitivity for patients in the one-hour group.

Key Words. Bleaching; hydrogen peroxide; tooth sensitivity. *JADA 2010;141(10):1213-1220.*

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enamel surfaces. Several authors³⁻⁶ have described night bleaching, consisting of six to eight hours of use,⁷⁻¹⁰ as well as shorter daily regimens such as 15 minutes, 30 minutes, one hour or two hours.

The addition of some thickening agents such as carboxypol and glycerin improves adherence of the bleaching agent to the enamel surfaces, allowing for a prolonged time for the release of CP.^{7,11} However, Matis and colleagues¹² demonstrated that CP activity decreases exponentially after the first hour, achieving only 52 and 10 percent of bleaching effectiveness after two and 10 hours, respectively. These findings suggest that wearing the tray for six to eight hours may be inadvisable, although no clinical study, to our knowledge, has addressed this issue.

Therefore, the purpose of this clinical investigation was to compare the bleaching effectiveness and tooth sensitivity associated with the traditional eight-hour nightguard vital bleaching with 10 percent CP gel with the effectiveness and sensitivity associated with shorter application times.

PARTICIPANTS, MATERIALS AND METHODS

The scientific review committee and the committee for the protection of human participants of the institutional review board at the Federal University of Santa Catarina, Florianópolis, SC, Brazil, approved this clinical investigation (protocol number 0172/05). We enrolled 60 undergraduate students from the School of Dentistry whose central incisors were shade A2 or darker, as judged by two of us (P.C.C., L.C.C.V.) with a value-oriented shade guide (Vita Lumin, Vita Zahnfabrik, Bad Säckingen, Germany) in a single-masked controlled clinical trial. All participants received a dental screening and a dental prophylaxis from one of us (P.C.C.) two weeks before the start of bleaching treatment and signed an informed consent form before the study began.

Inclusion and exclusion criteria. Participants in this clinical trial ranged in age from 17 to 30 years and had good general and oral health. We included in this study only people who did not smoke and who had a gingival index score of 1 or less.¹³ We required participants to have six caries-free maxillary anterior teeth without restorations on the labial surfaces, be willing to sign a consent form and have central incisors determined to be shade A2 or darker.

We excluded people from the study if they had undergone tooth-whitening procedures, had labial anterior restorations, were pregnant or lactating, had severe internal tooth discoloration (tetracycline stains, fluorosis, pulpless teeth), had bruxism habits or had any gross pathology in their mouths. We also excluded those who had noncarious cervical lesions, exposed dentin in incisal anterior teeth or spontaneous tooth pain. The week before the start of treatment, we asked participants to record whether they experienced tooth sensitivity, according to the following criteria: 0 = none, 1 = mild, 2 = moderate, 3 = considerable and 4 = severe.^{14,15} We excluded those who reported that they experienced sensitivity (that is, scores of 1 or above).¹⁴

Study design. We randomly assigned participants to the four groups according to the daily application time for 10 percent CP (Opalescence Take Home Whitening Gel, Ultradent Products, South Jordan, Utah). Participants in group 1 wore the bleaching tray for 15 minutes daily, and those in groups 2, 3 and 4 wore the trays for 30 minutes, one hour and eight hours, respectively. Only the evaluators were unaware of the groups to which the participants had been assigned.

The clinician (P.C.C.) made an alginate impression (Jeltrate Plus, Dentsply Caulk, Milford, Del.) of each participant's maxillary and mandibular arch and filled it with dental stone. To produce study models, she applied block-out material (Ultradent Products) to the labial surfaces of the teeth. The clinician used a 0.035-centimeter soft vinyl material to fabricate the custom-fitted tray for the bleaching gel. She trimmed the excess material from the labial and lingual surfaces 1 millimeter away from the gingival margins. She tested the fit of the bleaching tray in each patient with regard to adaptation, and she adjusted areas of interference.

A clinician (L.C.C.V.) delivered the tray and 10 percent CP gel to each participant with instructions for use. The product does not contain any active desensitizing agent, such as potassium nitrate. A second clinician (P.C.C.) instructed participants to wear the agent according to the protocol for the group to which they had been assigned. She instructed them to remove the tray after the bleaching period, wash it and brush their teeth with fluoridated toothpaste (Sorriso Fresh, Colgate-Palmolive, São Paulo). This tooth-

ABBREVIATION KEY. CP: Carbamide peroxide.

paste also does not contain an active desensitizing agent, such as strontium chloride or potassium nitrate. The clinician instructed participants to wear the bleaching tray for 16 days consecutively. In addition, she told them that they could stop the bleaching protocol if they wanted to drop out of the study or if they experienced intolerable tooth sensitivity.

Shade evaluation. One examiner (P.C.C.) measured tooth shades by using a digital spectrophotometer (Vita Easyshade Compact, Vident, Brea, Calif.) and two other examiners (L.C.C.V., L.N.B.) used a value-oriented shade guide (Vitapan Classical, Vita Zahnfabrik, Bad Säckingen, Germany) to assess tooth shades. They performed these measurements before the study began, after the 16-day bleaching protocol and when participants reported that they were completely satisfied with the results.

Before the spectrophotometer measurement, the clinician (P.C.C.) made an impression of the maxillary arch of each of the 60 participants by using a dense silicone putty (Zetalabor, Zhermarck, Badia Polesine, Italy). She extended the impression to the upper canine, and it served as a standard color measurement guide for use with the spectrophotometer. The clinician created a window on the labial surface of the molded silicone guide (that is, the impression), which enabled her to evaluate the central incisors. The clinician used a metallic device with well-formed borders (3 mm in radius) to create the window.¹⁶

After 16 days of treatment, we instructed the participants to tell the researchers if they felt satisfied with the bleaching results. Some participants reported that they were completely satisfied after 16 days, and the examiners did not perform the third shade measurement. However, other participants continued with treatment for 30 days, at which time the examiners conducted the third shade measurement. The examiners conducted the second shade evaluations after 16 days of treatment because this is the average bleaching time used with 10 percent CP.^{9,10}

Shade determination. We determined the tooth shades by using the parameters of the digital spectrophotometer according to the following values: L^* , (c^*) and (h^*), in which L^* indicates luminosity; (c^*), value; and (h^*), chroma. To compare our results easily with those of other studies, we converted these values to the CIE $L^*a^*b^*$ system, in which L^* represents the value from

0 (black) to 100 (white) and a^* and b^* represent the shade, a^* being the measurement along the red-green axis and b^* being the measurement along the yellow-blue axis.¹⁷ The International Commission on Illumination (Commission Internationale de l'Eclairage) defined the CIE $L^*a^*b^*$ system in 1978.¹⁷ The shade comparison before and after treatment is represented by the difference between the two colors (ΔE), which is calculated by using this formula:¹⁷

$$\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$$

We used 10 sound maxillary central incisors, adequately hydrated, during the training phase of this study. Before beginning the visual evaluations, we required the two examiners to reach an agreement of at least 85 percent (κ statistic). We arranged the shade guide's 16 tabs from highest (B1) to lowest (C4) value. Although this scale is not linear in the truest sense, we treated the color changes as representing a continuous and approximately linear ranking for the purpose of analysis. For both methods (that is, digital spectrophotometer and value-oriented shade guide), we standardized the measurement procedures by controlling the lighting conditions. We placed a scientific light corresponding to daylight (6,500 kelvin) on the ceiling of the examining room. The walls and dental clinic chairs were neutral gray, and we asked participants to wear a gray coat during evaluation of their tooth shades.

Two calibrated evaluators (L.C.C.V., L.N.B.) recorded the shade of each participant's teeth at baseline, after 16 days of bleaching and, for those who were not completely satisfied at day 16, after complete patient satisfaction was achieved. The middle one-third of the facial surface of the upper central incisors was the area of interest for shade matching, according to American Dental Association guidelines.¹⁸

The clinician (P.C.C.) then measured the selected shade tab with the digital spectrophotometer in the same manner described earlier for measurement of the tooth surface. She performed three measurements in each selected shade tab to allow comparison of the results obtained with the digital spectrophotometer with those obtained with the visual shade guide.

Tooth sensitivity evaluation. We asked participants to keep a daily record of any sensitivity they experienced according to the following criteria: 0 = none, 1 = mild, 2 = moderate, 3 = considerable and 4 = severe.^{14,15} We used the par-

TABLE 1

Dissatisfied and satisfied participants after 16 days of bleaching and until complete satisfaction achieved.

BLEACHING APPLICATION PERIOD	PARTICIPANT STATUS	PERCENTAGE OF PATIENTS*			
		15-Minute Group (n = 15)	30-Minute Group (n = 15)	One-Hour Group (n = 15)	Eight-Hour Group (n = 15)
16 Days	Dissatisfied	86.7	66.7	66.7	0
	Satisfied†	13.3 ^b	33.3 ^b	33.3 ^b	100 ^a
Until Complete Satisfaction Achieved	Dissatisfied	0	6.6	6.6	0
	Satisfied†	100 ^a	93.4 ^{a‡}	93.4 ^{a‡}	100 ^a
Mean (± SD) [§] No. of Days to Achieve Complete Satisfaction	Not applicable¶	27.8 ± 6.9 ^A	22.4 ± 8.4 ^{AB}	18.2 ± 2.8 ^{BC}	16.0 ± 1.0 ^C

* Unless otherwise specified.

† The same lowercase letters indicate statistically similar results between treatment groups.

‡ One participant never achieved complete satisfaction.

§ SD: Standard deviation.

¶ The same uppercase letters indicate statistically similar results between treatment groups.

participant's median sensitivity intensity during the first 16 days and when complete patient satisfaction was achieved to represent his or her sensitivity.

Treatment satisfaction. After 16 days of bleaching treatment and after participants reported that they were completely satisfied, we asked the following questions in writing:

■ Since the completion of tooth whitening, did you notice no detectable change in the color of your teeth, mild bleaching not noticed by other people, mild bleaching noticed by other people, moderate bleaching or significant bleaching?

■ What is your level of satisfaction with the bleaching treatment—extremely happy, very happy, happy, unhappy or very unhappy?

Statistical analysis. We used the κ statistic to assess the agreement between examiners. We categorized participants' responses to the two questions as "satisfied" or "dissatisfied." We considered the patient to be dissatisfied if he or she answered "no detectable change," "mild bleaching not noticed" or "mild bleaching noticed" for question 1 and "unhappy" or "very unhappy" for question 2. We considered the patient to be satisfied when he or she chose any of the other possible responses. We used the Kruskal-Wallis and Mann-Whitney tests ($\alpha = .05$) to compare the categorized data after 16 days and after complete participant satisfaction was achieved.

We used the McNemar and Fisher exact tests to compare the percentages of satisfied partici-

pants with those of dissatisfied participants in each of the four groups after 16 days of treatment and after complete patient satisfaction was reached ($\alpha = .05$).

We used one-way analysis of variance (ANOVA) and Tukey test ($\alpha = .05$) to evaluate the ΔE after 16 days and at complete participant satisfaction for both methods (digital spectrophotometer and visual shade guide). In addition, we calculated the mean (\pm standard

deviation [SD]) number of days required to achieve participant satisfaction in each of the four groups and statistically evaluated the data by using one-way ANOVA and Tukey test ($\alpha = .05$).

We analyzed the tooth sensitivity results by using the Kruskal-Wallis and Mann-Whitney tests ($\alpha = .05$), and we analyzed the intensity of tooth sensitivity by using ANOVA and Tukey test ($\alpha = .05$). To compare the two methods of measuring shade change, we used the t test ($\alpha = .05$) to evaluate ΔE values in each group (that is, 15 minutes, 30 minutes, one hour or eight hours) obtained by using the spectrophotometer or shade guide.

RESULTS

No participant reported experiencing spontaneous tooth sensitivity in the week before the treatment began, and no one dropped out during the study.

After 16 days, 33 of the 60 participants wanted to continue treatment because they were not satisfied with the bleaching results. However, all participants in the eight-hour group were satisfied after 16 days of treatment (Table 1). This group was significantly different from the other groups with regard to participants' satisfaction levels ($P < .001$). However, after completion of the bleaching treatment, participants' satisfaction levels were similar in all four groups ($P = .12$) (Table 1).

As shown in Table 1, the mean number of days of treatment required for participants to report

TABLE 2

Change in color values measured with a digital spectrophotometer and shade guide* after 16 days of treatment and after achieving complete participant satisfaction.

MEASURING METHOD†	MEASUREMENT TIME	MEAN (\pm SD‡) CHANGE IN COLOR VALUES			
		15-Minute Group (n = 15)	30-Minute Group (n = 15)	One-Hour Group (n = 15)	Eight-Hour Group (n = 15)
Easyshade Compact[§] Digital Spectrophotometer	After 16 days [¶]	3.9 \pm 1.8 ^A	4.4 \pm 1.8 ^A	5.8 \pm 2.1 ^A	8.5 \pm 3.3 ^B
	After complete satisfaction achieved [¶]	5.1 \pm 3.1 ^a	5.5 \pm 2.8 ^a	6.8 \pm 2.5 ^{a,b}	8.5 \pm 3.3 ^b
Vitapan Classical[#] Shade Guide	After 16 days [¶]	3.3 \pm 1.9 ^X	4.8 \pm 2.0 ^X	5.4 \pm 3.1 ^X	8.0 \pm 2.2 ^Y
	After complete satisfaction achieved [¶]	5.1 \pm 3.8 ^x	5.7 \pm 5.6 ^x	7.7 \pm 5.1 ^{x,y}	8.0 \pm 2.2 ^y

* The examiner used the digital spectrophotometer to read the selected shade guide tab to allow comparison between the methods.

† Statistically similar outcomes were detected when teeth in the same group were measured with the two methods ($P > .05$).

‡ SD: Standard deviation.

§ Easyshade Compact is manufactured by Vident, Brea, Calif.

¶ Comparisons are valid only within rows. The same superscript lowercase and uppercase letters indicate statistically similar means ($P > .05$).

Vitapan Classical is manufactured by Vita Zahnfabrik, Bad Säckingen, Germany.

being completely satisfied differed significantly between the four groups ($P < .001$). Participants in the one- and eight-hour groups reported achieving complete satisfaction after 18 and 16 days of treatment, respectively ($P > .05$). These results were statistically different from the results for the 15- and 30-minute groups ($P < .001$).

Table 2 shows ΔE values after 16 days of treatment and after complete participant satisfaction was achieved. We found similar color changes for the 15-minute, 30-minute and one-hour groups ($P > .05$), but they were statistically different from the changes for the eight-hour group ($P < .001$ for both methods). After complete participant satisfaction was achieved, the results for the one-hour group were similar to those for the eight-hour group.

One participant in the 15-minute group, one in the 30-minute group and two in the one-hour group experienced tooth sensitivity during bleaching treatment, whereas 12 participants in the eight-hour group experienced tooth sensitivity ($P < .001$). The 15-minute, 30-minute and one-hour groups were statistically similar to one another and statistically different from the eight-hour group ($P < .05$) (Figure).

The figure depicts participants' reported tooth sensitivity during the first 16 days of the study. The results did not differ significantly between the 16th day and the end of the study. The mean (\pm SD) tooth sensitivity was significantly higher in participants in the eight-hour group (1.33 ± 1.1) than it

was in participants in the other groups (0.07 ± 0.26 , 0.07 ± 0.26 , and 0.13 ± 0.35 for the 15-minute, 30-minute and one-hour groups, respectively) ($P < .001$).

DISCUSSION

Measuring tooth shade. Investigators have used different methodological approaches to assess tooth shade and changes in tooth shade resulting from bleaching treatments.¹⁹ Shade classification via use of a standard shade guide (for example, Vitapan Classical shade guide) is the most common method of evaluating bleaching efficacy. However, subjectivity and other factors (such as the clinical experience of the examiner, eye fatigue, room colors and décor)¹⁹ can affect tooth shade classification with this standard method. Standardization (by measuring tooth shades at the same time of day, in the same environment and under the same lighting conditions), along with good examiner training, can improve clinicians' ability to classify tooth shades accurately in a clinical context.¹⁹⁻²¹ In the past few years, investigators have used digital systems (spectrophotometers, colorimeters or digital cameras) to measure tooth shades.^{19,22,23}

These systems express color in CIE L*a*b* space, which provides three-dimensional specifications and allows for more accurate assessments.^{15,17,24} These digital systems are precise instruments that produce highly reliable, easily evaluated results. High cost and complex opera-

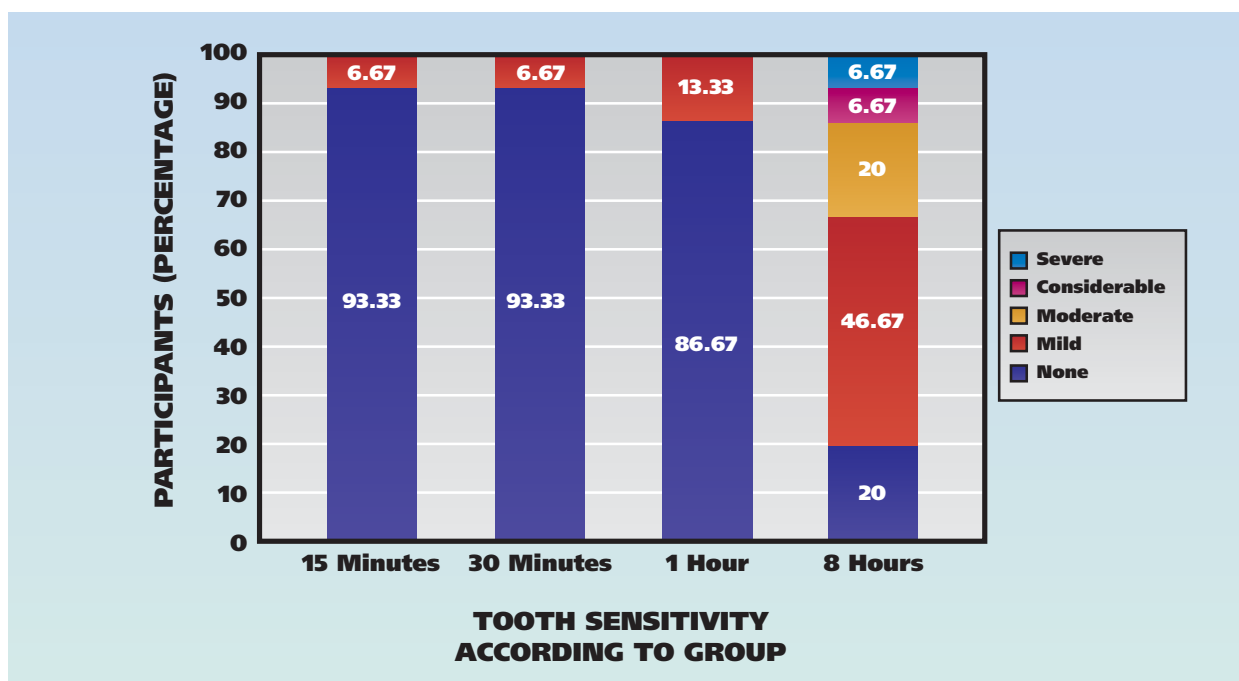


Figure. Tooth sensitivity reported by participants during the study according to treatment group (15 minutes, 30 minutes, one hour and eight hours). Only the eight-hour group was statistically different from the other groups ($P < .05$). 0 = none, 1 = mild, 2 = moderate, 3 = considerable and 4 = severe.^{14,15}

tion, however, restrict their use to laboratory or clinical research.

Evaluation methods. In our study, we obtained similar overall outcomes (ΔE values) using a value-oriented shade guide and the digital spectrophotometer. This might be the result of several precautions taken to increase the sensitivity of the visual method. We used ideal ceiling lighting with a color temperature corresponding to daylight of about 6,500 K, which emits a balanced and consistent light spectrum. In addition, the color of the walls, dental chair and participant's coat (gray) was standardized, and the evaluators were trained before the study began to reach an agreement of at least 85 percent.

Guan and colleagues²⁵ reported an excellent correlation between the digital spectrophotometer and visual assessment of tooth color in extracted teeth. Meireles and colleagues²⁶ confirmed these results in a clinical study in which they grouped the Vitapan Classical shade guide tabs by chroma.

To elicit additional evidence regarding the reliability of visual assessment, we converted each selected shade tab to the CIE $L^*a^*b^*$ system via use of the spectrophotometer, allowing calculation of ΔE values. Ruyter and colleagues²⁷ and Um and Ruyter²⁸ suggested that a one-unit ΔE is visually

perceptible and 3.3 units are clinically acceptable. In our study, ΔE was higher than these thresholds, indicating a visible whitening effect for all groups. The use of shade guides seems to be an adequate method of measuring tooth color, providing trained dentists with a reliable method of discriminating between light and dark teeth. However, clinicians should use a shade guide only when a spectrophotometer is unavailable, as they can obtain qualitative measures only with this method.

Hydrogen peroxide is the active agent in tooth bleaching products used today. It can be applied directly or produced in a chemical reaction from sodium perborate²⁹ or CP.³⁰ Hydrogen peroxide acts as a strong oxidizing agent through the formation of free radicals,³¹ reactive oxygen molecules and hydrogen peroxide anions³² that attack long-chained dark-colored chromophore molecules and split them into smaller, less colored and more diffusible molecules. The bleaching procedure outcome depends on the concentration of the bleaching agent, the ability of the agent to reach the chromophore molecules, the number of times the agent is in contact with chromophore molecules and the duration of the contact.³³

Bleaching duration. The results of our study demonstrate clearly that the duration of contact

between the bleaching agent and the tooth surfaces plays an important role in bleaching efficacy. Although shorter application periods such as 15 minutes, 30 minutes and one hour can result in complete satisfaction—meaning clinical success—these treatment regimens do not bleach teeth to the same degree as does the eight-hour regimen even after prolonged treatment. We detected statistically different ΔE values between the 15- and 30-minute groups and the eight-hour group. This difference can be attributed in part to the minimal time available for hydrogen peroxide action. However, the optimal time that patients should wear the bleaching tray probably is far less than the conventional six to eight hours recommended for 10 percent CP. In this study, participants in the one-hour group achieved complete satisfaction after 18 days, only two days more than the traditional regimen of eight hours per day for 16 days.

We should point out that the examiners performed the first color measurement after 16 days (as this is the mean bleaching time used in most clinical trials³⁴⁻³⁷). Participants in the eight-hour group might have attained optimally white teeth before the 16th day of treatment. However, none of the teeth in the eight-hour group were whiter than the lightest tab from the shade guide, so we do not believe that these participants were overtreated.

For the process of lightening to occur, some active agents must be available. The similar findings for the eight- and one-hour groups likely are the result of the faster initial degradation rate of CP,¹² which is 3.4 times higher in the first hour than that during the subsequent nine hours.¹² According to Wattanapayungkul and colleagues,³⁸ the degradation of CP is exponential and seems to decrease slowly.¹² The saturation and diffusion of hydrogen peroxide and oxygen into the tooth likely are responsible for the rapid initial degradation of the product. Once the tooth is saturated with these agents, the reaction may slow down, reducing the benefits of longer contact between the bleaching gel and tooth structures.

Sensitivity. Tooth sensitivity is the most common adverse effect of bleaching and is the main deterrent to patients' successfully completing treatment.³⁹ In several studies of 10 percent CP, between 15 and 65 percent of participants reported experiencing increased tooth sensitivity.⁴⁰⁻⁴² The mechanisms that cause tooth

sensitivity after external bleaching have not been fully established; however, it seems likely that sensitivity results from the increase in enamel and dentin permeability^{43,44} and the resulting easy passage of peroxide through the enamel and dentin to the pulp, which takes five to 15 minutes.⁴⁵

With regard to bleaching speed, the results for the one-hour group closely approached those for the eight-hour group. On the other hand, a statistically higher percentage of participants in the eight-hour group reported tooth sensitivity. Eighty-seven percent of participants in the one-hour group did not report any tooth sensitivity throughout the study, while only 20 percent of participants in the eight-hour group did not experience any tooth sensitivity. Moreover, in participants in the one-hour group who experienced sensitivity, the median intensity was mild, whereas 33.4 percent of participants in the eight-hour group reported experiencing moderate to severe sensitivity. Because sensitivity results from the insult of the peroxide to the nerve fibrils (which may be considered a reversible pulpitis), the longer the aggressive agent remains in contact with the pulpal tissue, the less likely that the pulpal tissue will degrade the hydrogen peroxide. This likely increased the chance of pulpal inflammation and tooth sensitivity among participants in the eight-hour group.

We should emphasize that the results of this investigation apply only to 10 percent CP gels that do not contain any active desensitizing agent. Use of bleaching gels that contain desensitizing agents is associated with lower tooth sensitivity rates³⁵ and, therefore, may result in a different response if evaluated under the experimental conditions of our investigation.

Although investigators in some clinical trials have reported that the tooth shade immediately after bleaching did not differ from that some weeks later,³⁴⁻³⁷ further clinical trials should be conducted to evaluate the long-term outcomes of different application times.

CONCLUSION

The results of this study show that although the traditional eight-hour application time yielded the fastest bleaching results, participants who underwent it reported higher levels of tooth sensitivity after 16 days of treatment. The one-hour group most closely resembled the eight-hour group in terms of bleaching speed, with the benefit of having low rates of tooth sensitivity. ■

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Ultradent Products, South Jordan, Utah, provided the material for fabrication of the custom-fitted bleaching trays.

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