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COVER STORY

A CLINICAL EVALUATION OF CARBAMIDE PEROXIDE AND HYDROGEN PEROXIDE WHITENING AGENTS DURING DAYTIME USE

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Bleaching vital teeth has become one of the most popular esthetic dental services offered to patients. Many changes have occurred in this process during the last 30 years—from power bleaching with a heat lamp to laser bleaching today.^{1,2} Vital-tooth bleaching can be done in the office by the dentist using high concentrations of hydrogen peroxide, or HP, or at home by the patient using lower concentrations of carbamide peroxide, or CP. Carbamide peroxide breaks down into HP and urea, with the HP concentration being approximately one-third of the original CP percentage.

These at-home agents are applied in a tray worn through the night or for limited periods during the day. Some companies have introduced low-concentration HP products as at-home whitening agents. They claim that these new systems are more effective than equivalent concentrations of the more popular CP-containing whitening agents.

The purpose of this in vivo study is to evaluate the degree of color change, any rebound effects and any sensitivities associated with using two at-home daytime bleaching agents in a split-mouth technique for one hour twice a day for two weeks. One side of the anterior dental segment contained 7.5 percent HP and the other side contained 20 percent CP.

ABSTRACT

Background. Vital tooth bleaching for esthetic reasons has gained in popularity during the last few years. However, few studies have investigated the efficacy of daytime bleaching products. The purpose of this double-blind in vivo study was to evaluate the efficacy of 20 percent carbamide peroxide, or CP, and 7.5 percent hydrogen peroxide, or HP, during daytime use. The degree of color change, any color relapse, and tooth or gingival sensitivity were evaluated.

Methods. Twenty-four patients participated in this study. The bleaching gels were randomly applied to the right and left maxillary anterior teeth. Patients were shown how to place the two bleaching agents in a custom tray for one hour, twice a day for two weeks. Patients returned in one, two, three, six and 12 weeks for color evaluation with the colorimeter and shade guides as well as to have color slide photographs taken. The authors evaluated sensitivity by asking the patients to record daily for 21 days any tooth or gingival sensitivity they experienced.

Results. Use of the 20 percent CP resulted in significantly more lightness than the 7.5 percent HP during the first 14 days of the study, but at the end of the study, there was no significant difference between products with regard to tooth lightness. In addition, the authors found no statistically significant difference between products with regard to gingival or tooth sensitivity.

Conclusions. Both CP and HP are effective at-home bleaching agents when daytime bleaching is preferred.

Clinical Implications. Dentists who choose to use daytime bleaching can select either CP or HP.

LITERATURE REVIEW

Although the first article on home bleaching with 10 percent CP, by Haywood and Heymann,³ was not published until March 1989, the use of CP can be traced back to World War I, when it was used as an anti-inflammatory antiseptic.⁴ In the 1960s, Klusmier noted tooth lightening using an antiseptic (Gly-Oxide, Marion Merrell Dow Inc.) to assist in posttraumatic tissue healing during orthodontic treatment.⁵ During the late 1980s, several practitioners noted that the same CP antiseptic (Gly-Oxide) used for treatment of soft-tissue injury and aphthous ulcers as well as a generalized oral cleansing agent after oral or periodontal surgery resulted in significant whitening of teeth, especially when delivered in a custom-fitted tray.⁶

In a survey of general practitioners, the results of which were reported in 2000, Weisman⁷ found that at-home whitening agents were dispensed by 95 percent of dentists. In contrast, only 43 percent indicated that they performed in-office whitening procedures. The advantages of the at-home technique include ease of application, reduced chair time and cost, high success rate and safety of materials used.²

There is little disagreement concerning the short-term lightening effect of dentist-supervised home bleaching with 10 percent CP. However, there are some concerns among dental professionals regarding the long-term effect because of the various degrees of color relapse reported in several studies.⁸⁻¹¹ Matis and colleagues¹² reported

that an observable color change was maintained in the maxillary anterior teeth of 19 (66 percent) of 29 patients 22 weeks after they underwent bleaching with 10 percent CP bleaching gel. Leonard and colleagues¹³ reported that 83 percent of subjects with tetracycline staining whose teeth were whitened reported no obvious change or only a slight darkening, which was not noticed by others, 54 months after they had undergone six months of bleaching.

Many bleaching systems are on the market with a CP concentration of more than 10 percent. Matis and colleagues¹⁴ and

The advantages of at-home whitening include ease of application, reduced chair time and cost, high success rate and safety of materials used.

Leonard and colleagues¹⁵ compared the efficacy of 10 percent CP with 15 percent and 16 percent CP, respectively. In both studies, the authors found that the higher CP concentration was more efficient than the lower concentration. However, both studies also concluded that although the lower concentrations of CP take longer to whiten the teeth, eventually they achieve the same result as the higher concentrations.

Patients' compliance with nighttime wear is generally better than that with daytime wear, especially for extended treatment periods of up to a year (for tetracycline-stained teeth).^{4,16} Early objectors to nighttime wear questioned

whether any active bleaching agent was present after the first hour or two.^{17,18} Recent in vivo studies indicate that more than 50 percent of active agent remains in the tray after two hours of bleaching.^{19,20} In the past, sensitivity during overnight use may have been another reason to choose daytime at-home bleaching. However, most of the new whitening agents contain potassium nitrate, which has been shown to reduce sensitivity.²¹

MATERIALS AND METHODS

Twenty-four patients volunteered to participate in this double-blind study, for which they received \$100. The study protocol was reviewed and approved by the Institutional Review Board of Indiana University Purdue University Indianapolis. Patients received a dental screening and prophylaxis by a licensed hygienist or dentist at least two weeks before the study. All 24 subjects met the following criteria:

- six maxillary anterior teeth present and free of any restorative material covering more than one-sixth of their labial surfaces;
- six anterior teeth darker than B-54 and lighter than B-85 on the Trubyte Bioform Color Ordered Shade Guide (Dentsply Trubyte);
- at least 18 years of age, willing to sign a consent form, able to return for periodic examinations, and willing to refrain from use of tobacco products during the study period.

Potential subjects were excluded on the basis of the following criteria:

- a medical condition that might interfere with the study results or require special attention;
- a gingival index score greater than 1.0 or gross pathology in the mouth;
- tetracycline-stained teeth or having undergone endodontic therapy in any of the maxillary anterior teeth;
- use of professionally applied tooth whiteners within the past five years;
- use of any kind of tobacco products during the past 30 days;
- pregnant or lactating women.

Both the 20 percent CP (Opalescence Tooth Whitening Gel PF, Ultradent Products Inc.) and the 7.5 percent HP (DayWhite, Discus Dental Inc.) used in this study were donated by the manufacturers. The subjects were randomized according to the baseline shade guide into two groups by a study monitor not directly involved in the study. At the screening visit, we performed the L \ddot{o} e-Silness gingival index²² on all teeth to qualify the subject for the study.

Study models. Two alginate impressions were taken of each subject to fabricate study models. One model was used to make a custom maxillary mouth tray from a 0.035-inch Sof-Tray (Ultradent Products Inc.) according to the vacuum-formed technique, as recommended by the manufacturers. A 1.0-millimeter distance on the mesial aspect of teeth nos. 8 and 9 was not blocked out to provide a separation of the whitening agents on the right and left sides. We trimmed the excess tray material labially

and lingually just short of the gingival margin. Block-out resin (LC Block-Out Resin, Ultradent Products Inc.) was used to block out the labial surfaces of the anterior teeth from approximately 1.0 mm from the gingival margin to the incisal edge. This block-out area created a reservoir in the tray for the bleaching gel.

The second study model was used to construct a positioning jig with full palatal coverage to ensure proper repositioning of the colorimeter. The Eichhold Positioning System,^{12,14} which uses dual-pin precision attachments (Pindex, Coltène/

The initial color was evaluated at baseline, and the degree of color change and any color rebound were evaluated after one, two, three, six and 12 weeks.

Whaledent), was used in this study.

A study monitor randomly assigned one of the bleaching gels to one side of the mouth and the other gel to the opposite side. The monitor then labeled each box of bleaching gel accordingly. The study monitor also taught each subject how and where to place the two bleaching gels into the tray. All subjects were instructed to insert the tray containing both bleaching systems into their mouths for one hour, twice daily, morning and evening. They continued this regimen for two weeks.

Color evaluation. The initial color was evaluated at baseline, and the degree of color

change and any color rebound were evaluated after one, two, three, six and 12 weeks. The evaluation was done in three ways:

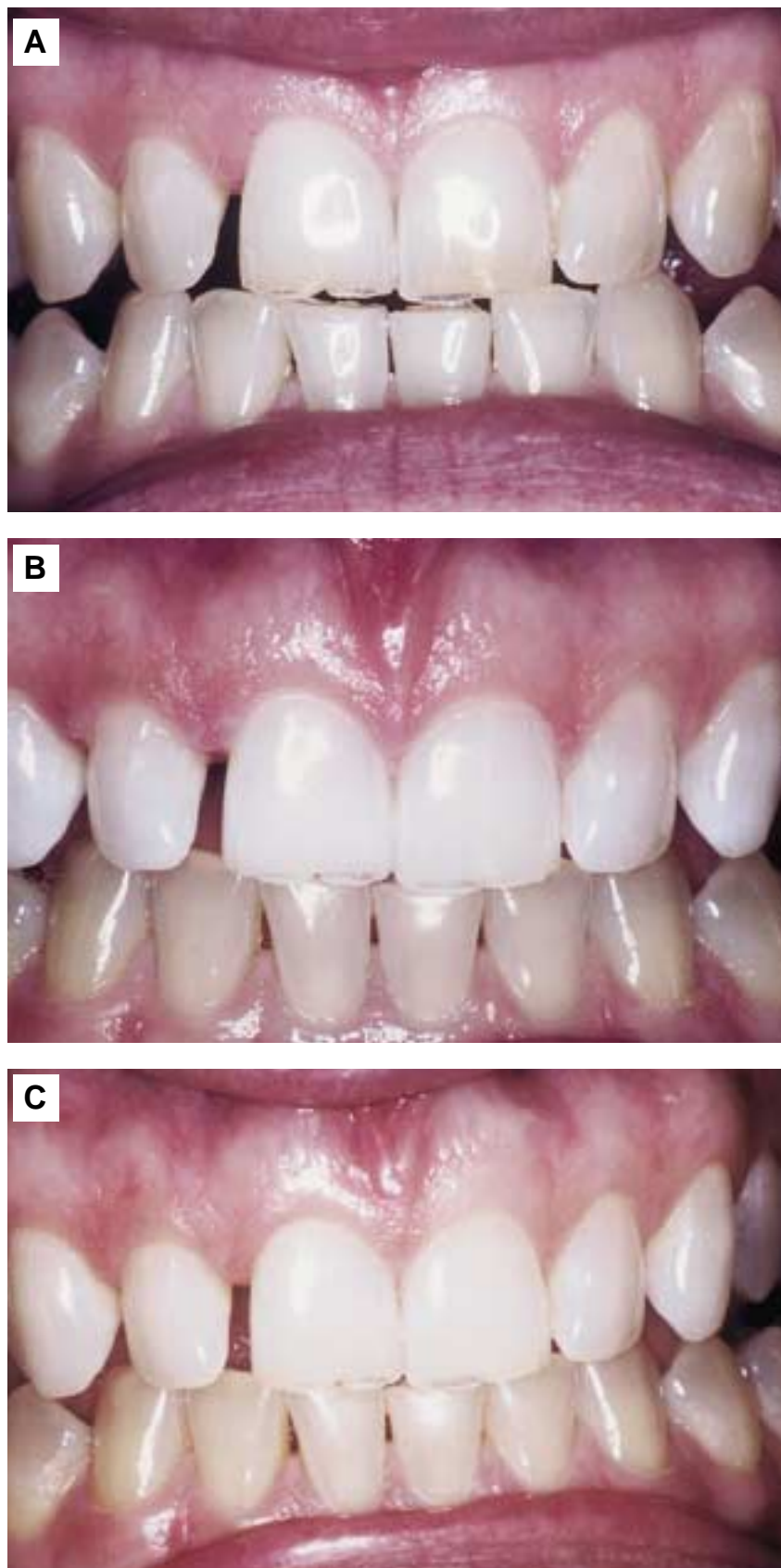
- matching with a shade guide;
- comparing right and left sides of clinical photographs (35-mm color slide film, Kodak Elite II 100, Eastman Kodak Co.);
- using a colorimeter (Chroma Meter 321, Minolta). The colorimeter measures the color of teeth based on the CIELAB color space system, in which L* measures the value (lightness or darkness; 0 = black, 100 = white), a* measures color

along the red-green axis and b* measures color along the yellow-blue axis. ΔE^* is the total color difference or the distance between two colors.

The colorimeter was connected to a personal computer with the SPEC-TRA QC software (Minolta),²³ which is capa-

ble of directly recording and analyzing the readings from the colorimeter. At each evaluation, the color of the upper six anterior teeth was measured three times, and the readings were fed directly into the application software, which automatically averaged the three readings and stored the result in the designated file for each subject.

Tooth and soft-tissue sensitivity. We asked each subject to record, on a daily basis for three weeks, any tooth or soft-tissue sensitivity he or she experienced. The degrees of sensitivity were ranked as follows: 1, none; 2, mild; 3, moderate; 4, considerable; and 5, severe. All subjects returned for evaluation one, two, three, six



and 12 weeks after the study began. The evaluation procedures for each subject were repeated at each visit by the examiner who originally conducted them.

STATISTICAL METHODS

We used a repeated-measures analysis of variance, or ANOVA, model to compare teeth for differences in mean L^* , a^* , b^* measurements and shade-guide ranked order at baseline. Changes in colorimeter (that is, ΔL^* , Δa^* , Δb^* , ΔE^*) and shade-guide measurements (Δ shade guide) were computed by subtracting the baseline measurements from the follow-up measurements. We used a repeated-measures ANOVA to compare the products for differences in ΔL^* , Δa^* , Δb^* , ΔE^* and Δ shade-guide rank order. Wilcoxon Sign Rank tests were used to determine if the products resulted in significantly different tooth lightness,

Figure 1. A. A 42-year-old woman at baseline. Maxillary right anterior values were as follows: color value, or L^* , 49.42; color along red-green axis, or a^* , -0.72; color along yellow-blue axis, or b^* , 3.58; and shade guide, 21.0. Maxillary left anterior values were as follows: L^* , 48.09; a^* , -0.68; b^* , 4.08; and shade guide, 21.0. B. Same subject after two weeks of treatment with 20 percent carbamide peroxide on the right side and 7.5 percent hydrogen peroxide on the left side. Changes in right section values were as follows: ΔL^* , 7.45; Δa^* , 1.24; Δb^* , -4.55; total color difference, or ΔE^* , 9.11; and Δ shade guide, -19.33. Changes in left section values were as follows: ΔL^* , 5.56; Δa^* , -1.01; Δb^* , -5.23; ΔE^* , 7.90; and Δ shade guide, -19.33. C. Same subject 10 weeks after bleaching. Changes in right section values were as follows: ΔL^* , 1.53; Δa^* , -0.81; Δb^* , -3.48; ΔE^* , 4.05; and Δ shade guide, -17.00. Changes in left section values were as follows: ΔL^* , 1.56; Δa^* , -0.79; Δb^* , -3.46; ΔE^* , 4.22; and Δ shade guide, -17.33.

according to the clinical slide assessments at each examination. We used ANOVA to compare the products for differences in daily tooth and gingival sensitivity, with fixed effects for product and day and random-subject effects to correlate the sensitivity values.

RESULTS

All 24 patients completed the study. Thirteen had been randomly assigned to 20 percent CP on the right side of the mouth, and 11 had been randomly assigned to 7.5 percent HP on the right side (Figure 1).

Colorimeter data. The anterior teeth on both sides of the maxillary arch did not have significantly different baseline L^* ($P = .52$), a^* ($P = .62$) or b^* ($P = .26$) values.

ΔL^* . Overall—that is, averaging across examinations—teeth with 20 percent CP were significantly lighter than teeth with 7.5 percent HP ($P = .0033$), but the two products did not have significantly different results at the end of the study ($P = .99$). The overall difference in lightness was due to significant differences at one week ($P = .0064$) and at two weeks ($P = .0014$). Figure 2 shows the ΔL^* for each tooth type.

Δa^* and Δb^* . We found no statistical difference in Δa^* between teeth that received CP and teeth that received HP, either overall ($P = .30$) or at the end of the study ($P = .99$). Also, there was no statistical difference in Δb^* , either overall ($P = .49$) or at the end of the study ($P = .99$).

ΔE^* . At two weeks, teeth that received CP had significantly higher ΔE^* overall ($P = .0321$) than teeth that received HP, but the results

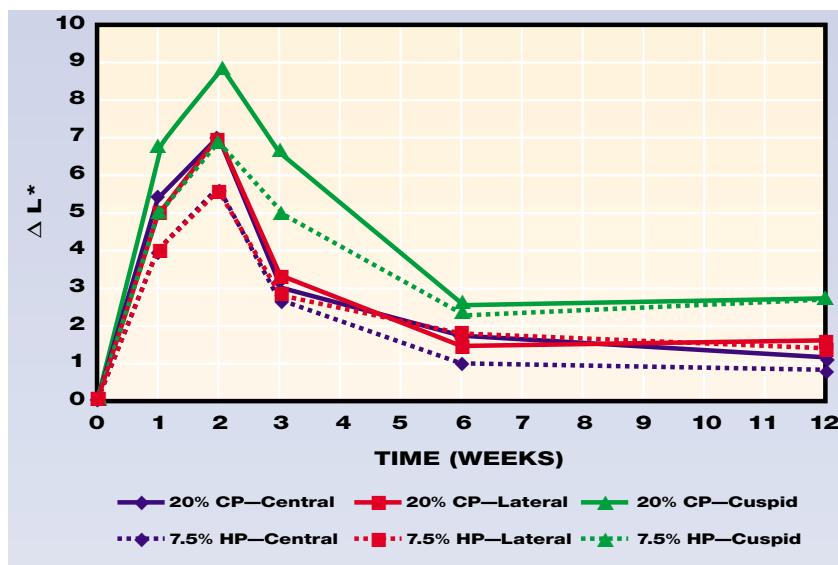


Figure 2. Change in color value, or ΔL^* , according to tooth type. CP: Carbamide peroxide. HP: Hydrogen peroxide.

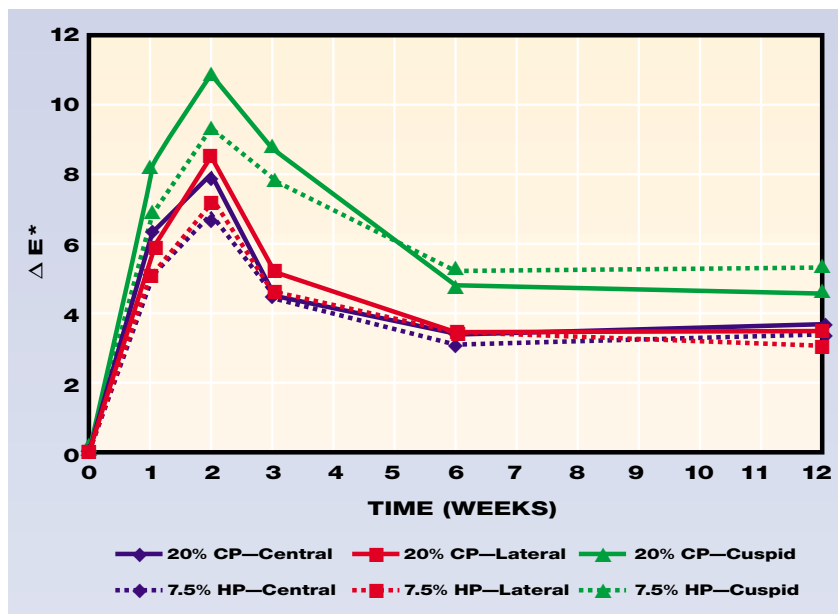


Figure 3. Total color difference, or ΔE^* , according to tooth type. CP: Carbamide peroxide. HP: Hydrogen peroxide.

were not significantly different at the end of the study ($P = .99$). The overall product difference was due to significant differences at one week ($P = .043$) and at two weeks ($P = .0094$). Figure 3 shows the ΔE^* for each tooth type.

Δ Shade-guide rank order. The Δ shade-guide rank order for teeth that received 20 per-

cent CP was not significantly different from that for teeth that received 7.5 percent HP, either overall ($P = .19$) or at the end of the study ($P = .99$). Figure 4 shows the Δ shade-guide rank according to each tooth type.

Clinical slide data. Our assessment of clinical slides showed no significant differ-

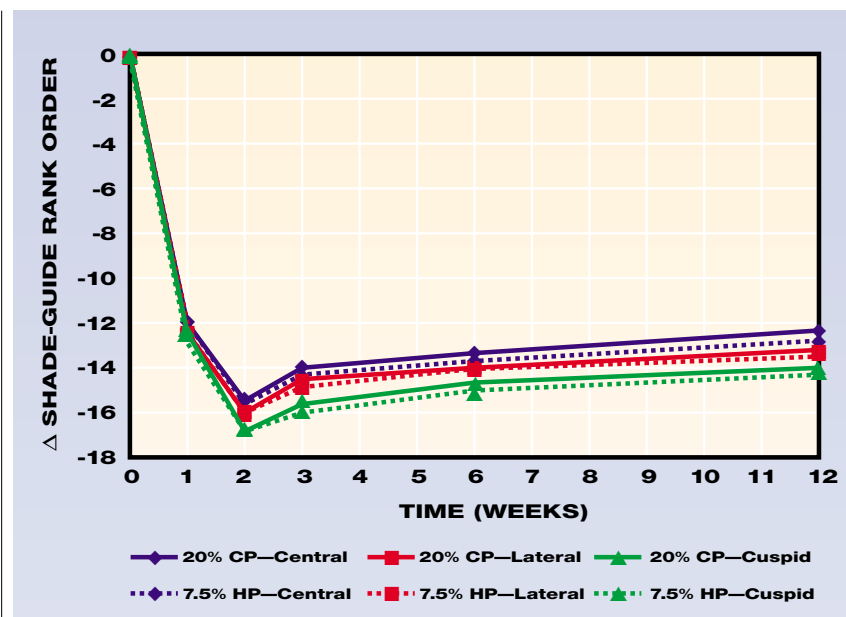


Figure 4. Δ shade-guide rank according to tooth type. CP: Carbamide peroxide. HP: Hydrogen peroxide.

ences between products at baseline ($P = .99$), two weeks ($P = .25$), three weeks $P = .99$, six weeks ($P = .63$) or 12 weeks ($P = .50$). However, at one week, teeth that received CP were lighter than teeth that received HP ($P = .0313$) (Table).

Sensitivity data. We found no significant differences in terms of gingival ($P = .12$) or tooth ($P = .19$) sensitivity between teeth that received CP and those that received HP (Figure 5).

DISCUSSION

Some manufacturers claim that an HP bleaching agent will bring about faster results compared with a CP bleaching agent of similar concentration. These claims are based on the fact that CP has to break down into HP and urea in order to be effective. The 20 percent CP bleaching agent used in our study breaks down to 7.2 percent HP, which is similar to the 7.5 percent HP bleaching agent used in the study.

Few studies have compared similar concentrations of CP and HP. Kowitz and colleagues²⁴ compared 3 percent HP with 10 percent CP in vivo. They found no significant difference in whitening effect after four weeks. In a recent study by Panich,²⁵ 15 percent CP was compared with 5.5 percent HP applied for one-half hour twice daily for two weeks. The author found no significant difference between the products after six weeks in regard to ΔL^* , Δa^* , Δb^* or ΔE^* . In our study, however, the colorimeter data showed that 20 percent CP produced significantly higher ΔL^* and ΔE^* ,

both at one week and at two weeks.

We speculate that the difference between our results and those in Panich's study lies in the different bleaching times. The twofold increase in active bleaching time in our study probably had a strong effect on teeth in the CP group, but a much weaker effect on teeth in the HP group. This is because of the fact that HP degrades at a much faster rate than does CP.

If we consider ΔL^* and ΔE^* as indicators of whitening, we can say that 20 percent CP demonstrated a faster and greater color change (that is, whitening) compared with 7.5 percent HP during the active two-week bleaching period. The colorimeter data also indicated that during the active bleaching period for both products, lightness increased rapidly during the first week and contin-

The colorimeter data indicated that during the active bleaching period, lightness increased rapidly during the first week and continued to increase at a slower rate through the second week.

ued to increase at a slower rate through the second week.

The colorimeter data for the CP group also agree with the colorimeter data from the study by Poore and colleagues.²⁶ They reported a mean ΔE^* of 4.8 at

two weeks for the two-hour daily exposure of 10 percent CP. In our study, the mean ΔE^* for the two one-hour daily exposures of the 20 percent CP group at two weeks

was 9.22. Increasing the CP concentration from 10 percent to 20 percent for the active bleaching time resulted in an almost twofold increase in the ΔE^* value.

In regard to ΔL^* , Δa^* , Δb^* and ΔE^* , both products exhibited relatively fast color relapse during the third week of the study (that is, one week after bleaching was completed). Color relapse continued at a slower rate until six weeks (four weeks after bleaching), after which there was no significant change in ΔL^* , Δa^* , Δb^* or ΔE^* for either product.

The color stabilized within four weeks after the cessation of bleaching. This agrees with a six-month in vivo study by Matis and colleagues,¹² which showed that for teeth bleached with 10 percent CP, most of the color relapse occurred during the first four weeks after bleaching. The ΔL^* , Δa^* , Δb^* and ΔE^* for teeth in the 20 percent CP group reflected color relapses at a higher rate than that for teeth in the 7.5 percent HP group during the first four weeks after bleaching was discontinued. This explains why there was no statistically significant difference between products at the end of the study.

Overnight application of 10 percent CP bleaching agents has been investigated thoroughly and reported in the literature. Matis and colleagues¹² reported a mean ΔE^* and ΔL^* of 9.2 and 6.7, respectively, at two weeks for the overnight application of 10 percent CP. In another study, Matis and colleagues¹⁴ reported a mean ΔE^* and ΔL^* of 8.8 and 6.5, respectively, at two weeks for the overnight application of 10 percent CP. In the present study, the mean ΔE^* and ΔL^* at

TABLE

SLIDE ASSESSMENT COMPARING 7.5% HP WITH 20% CP.*			
WEEK	NUMBER OF PATIENTS (N = 24)		
	7.5% HP Slightly Lighter	No Difference Between Products	20% CP Slightly Lighter
0	0	23	1
1	0	18	6
2	0	21	3
3	2	20	2
6	3	20	1
12	2	22	0

* HP: Hydrogen peroxide (Day White, Discus Dental Inc.). CP: Carbamide peroxide (Opalescence Tooth Whitening Gel PF, Ultradent Products Inc.).

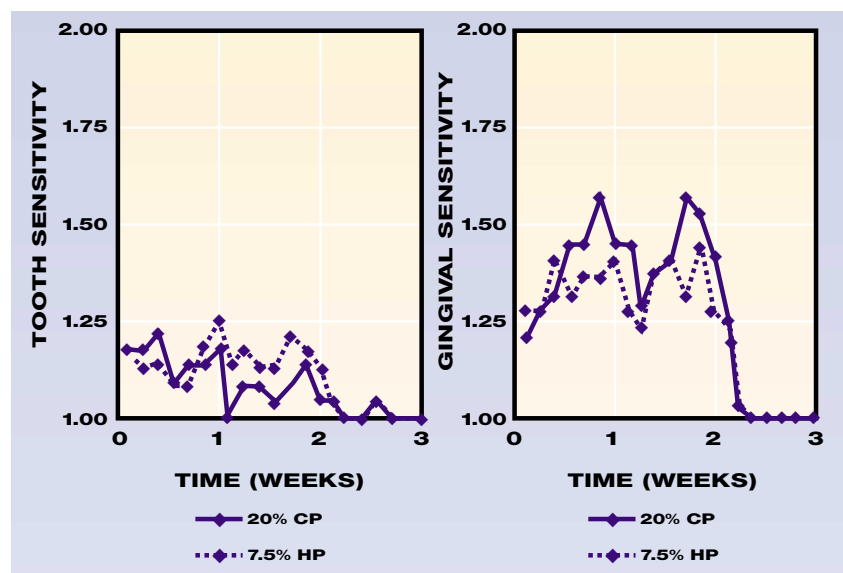


Figure 5. Tooth and gingival sensitivity according to this ranking: 1, none; 2, mild; 3, moderate; 4, considerable; and 5, severe. CP: Carbamide peroxide. HP: Hydrogen peroxide.

two weeks was 9.22 and 7.67, respectively, for teeth that received two one-hour daily applications of 20 percent CP.

The values of ΔE^* and ΔL^* from the three studies described above indicate that the two one-hour daytime applications of 20 percent CP bleaching agent can bring about results similar to those from the overnight application of a 10 percent CP bleaching agent. Further studies are needed to support this finding.

The present study is the first, to our knowledge, to use the SPECTRA QC software. This software stores the data in the designated file for each patient. It also has the capability of transforming the stored data into a spreadsheet for statistical analysis. This capability virtually eliminates the process of manually inserting the data into a spreadsheet, a process that has a great potential for error.

We also performed subjective



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shade-guide matching using the Trubyte Bioform Color

Ordered Shade Guide. Our results agree with the shade-guide data of Panich²⁵ in her comparison of 15 percent CP with 5.5 percent HP; however, our results do not always agree with the results obtained with the colorimeter. Because the shade guide is subjective and the colorimeter is objective, disagreements between the two methods were not unexpected.

Two experienced evaluators performed the subjective clinical slide assessment. The evaluators were calibrated by means of slides selected to show the four different categories used during the evaluation (that is, 0, none; 1, slight; 2, moderate; and 3, large). Consensus was required whenever there was disagreement between the evaluators regarding the right and left sides of the upper jaw.

With this evaluation method, teeth in the 20 percent CP group were significantly lighter than teeth in the 7.5 percent HP group at one week ($P = .0313$). The products did not produce significantly different results at weeks two, three, six and 12. These results are supported by the data obtained with the colorimeter, except that the colorimeter data indicated that CP caused signifi-



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cantly more lightness than HP at both one week and two weeks.

Some patients reported that they experienced mild sensitivity during the active bleaching period, but this sensitivity disappeared even before the bleaching ceased. Only two patients experienced greater tooth and gingival sensitivity during treatment, and they were given a desensitizing gel containing 3 percent potassium nitrate and 0.11 percent-by-weight fluoride ion to be applied via the bleaching tray for 20 minutes before the bleaching material was applied. In regard to the severity of sensitivity, we found no significant difference between teeth that received CP and those that received HP. These results do not agree with those of Panich,²⁵ who reported greater daily gingival sensitivity associated with 15 percent CP than with 5.5 percent HP.

CONCLUSIONS

We conducted this 12-week double-blind clinical study to compare two daytime whitening agents—20 percent CP and 7.5 percent HP—with equivalent concentrations of active agent, in regard to the degree of tooth color change, color relapse, and tooth and gingival sensitivity. The degrees of color change and color relapse were evaluated with a colorimeter, a shade



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guide and clinical slide photography. Tooth and gingival sensitivity were evaluated by the patients, who recorded any tooth or gingival sensitivity that they experienced during the first three weeks of the study. Because of the inherent subjectivity of the shade-guide evaluations, we relied on the objective colorimeter measurements to provide more reliable and accurate conclusions.

Teeth in the CP group were significantly lighter than teeth in the HP group at one week and two weeks, but there was no significant difference in tooth lightness at the end of the 12-week study. We also found no significant difference in tooth or gingival sensitivity with either whitening agent. For dental professionals who choose daytime bleaching, either CP or HP is acceptable. ■

This study was funded partially by a grant from Ultradent Products Inc. The whitening agents used in this study (20 percent carbamide peroxide, Opalescence Tooth Whitening Gel PF, Ultradent Products Inc., and 7.5 percent hydrogen peroxide, DayWhite, Discus Dental Inc.) were donated by the manufacturers. Patient compensation was provided by Ultradent Products Inc.

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