

A CLINICAL EVALUATION OF 10 PERCENT VS. 15 PERCENT CARBAMIDE PEROXIDE TOOTH-WHITENING AGENTS

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ABSTRACT

Background. Agents with carbamide peroxide, or CP, in various concentrations are widely prescribed for at-home tooth whitening. It is not clear, however, if the more concentrated gels will whiten teeth to a greater extent, as no controlled clinical trials have been reported. The authors conducted a double-blind study of human subjects to evaluate whether a 15 percent CP tooth-whitening system was more effective than a 10 percent CP system, and to determine if tooth sensitivity increased with use of the higher concentration.

Methods. The authors recruited 57 subjects with maxillary anterior teeth of shade A3 or darker (as gauged against a value-oriented shade guide). The subjects were 18 to 65 years of age and in good general and dental health. After matching the subjects by sex and age, the authors randomly assigned them to either a control group, which used a 10 percent CP whitening agent, or an experimental group, which used a 15 percent CP agent.

Results. The results indicated that there was

no significant difference in shade change between the groups after one week of treatment ($t = 1.455$, $P = .05$), but there was a significant difference at the end of the treatment period ($t = 2.303$, $P < .05$), as well as two weeks after treatment concluded ($t = 2.248$, $P < .05$). There was no significant difference in sensitivity ($t = 1.399$, $P > .05$).

Conclusions. There was a significant difference in color change between the 10 percent CP and 15 percent CP groups at the end of the study period. There was no significant difference in level of tooth sensitivity between the two groups, and the incidence was equal; there was, however, a significant difference in variability of tooth sensitivity between the two groups.

Clinical Implications. If performed under the careful guidance of a dentist, at-home whitening is an effective treatment, regardless of whether 10 percent CP or 15 percent CP is used. There may be added color change and varying sensitivity with the use of 15 percent CP.

Tooth bleaching is not a new technique in dentistry; it was reported more than a century ago.¹⁻⁴ In 1937, Ames⁵ reported a technique for treating mottled enamel that made use of a mixture of hydrogen peroxide, or HP, and ethyl ether on cotton, heated with a metal instrument, for 30 minutes per visit for five to 25 visits. Younger⁶ used this technique in 1942 in 40 children with dental fluorosis. This and similar techniques using concentrated HP and heat have been accepted treatment since the 1930s.⁷

In 1968, Dr. William Klusmeier, an orthodontist, described a technique using Gly-Oxide

(Marion Merrell Dow Inc.), a 10 percent carbamide peroxide, or CP, oral antiseptic. He placed Gly-Oxide in the orthodontic positioners of some patients to improve their gingival health and noted that the treatment resulted in whitened teeth, as well as tissue improvement. In 1972, he switched to Proxigel (Reed and Carnrick Pharmaceutical Co.), which also contained 10 percent CP, in a laboratory-fabricated custom-fitted night-guard, because the viscosity of the Proxigel allowed it to stay in the tray.⁸

The first commercially available 10 percent CP product specifically for tooth bleaching was mar-

keted by Omni International in 1989. The product had its roots in the findings of Dr. John Munro,⁹ a general dentist who used a 10 percent CP solution to control inflammation after root planing in a vacuum-formed plastic splint and noted an additional result of whitened teeth.

Haywood and Heymann¹⁰ published the first clinical study on tooth whitening using Proxigel in vacuum-formed custom trays. This is the technique known as "nightguard vital bleaching," a whitening method in common use today. Drs. Haywood and Heymann conducted laboratory and clinical investigations of this technique and reported the technique and their findings in the literature in 1989.¹⁰ In their technique, the nightguard is custom-fabricated to hold the whitening gel in contact with the enamel surface. The CP reacts with moisture to yield free peroxide radicals or nascent oxygen to change the color of enamel and dentin and produce a whitening effect.¹⁰ The dental profession rapidly recognized the benefits of an at-home bleaching treatment, and the technique has become a popular method of lightening teeth.¹¹

According to a 1991 use survey, 78 percent of general practitioners performed tooth-whitening procedures, and 59 percent recommended the dentist-prescribed at-home method.¹² In another survey that year, 9,846 dentists reported using at-home whitening techniques, and 79 percent of those recognized the technique's usefulness and overall clinical success.¹³ Ninety-one percent of 8,143 dentists responding to a 1995 survey stated that they had used vital tooth bleaching;

79 percent of the respondents reported success with the treatment, and 12 percent reported that they were not satisfied with it.¹⁴

Four types of peroxide-containing tooth-whitening materials are available¹⁵:

- professional products for use only in the dental office, which contain 30 to 35 percent HP (either alone or activated by heat or light) or 35 percent CP;
- professionally dispensed products for use by patients at home, which contain 5.5 percent and 7.5 percent HP and 10 percent, 15 percent or 22 percent CP;

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- over-the-counter, or OTC, products for home use, which contain up to 6 percent HP and 10 percent CP;

- OTC dentifrices with low concentrations of HP or calcium peroxide.

With the introduction of so many agents, several with different concentrations, dentists have many options when prescribing at-home whitening. Much research has shown the safety and efficacy of 10 percent CP.¹⁶⁻²¹ However, it is not known if the more concentrated gels—which contain 15 percent, 16 percent or 22 percent CP—will whiten teeth to a greater

extent; no controlled clinical trials have been reported, only clinicians' anecdotal reports and manufacturers' claims. Only one published study has shown that higher concentrations of CP will whiten teeth more quickly; it was performed on extracted teeth using 16 percent CP.²² In addition, no in vivo studies have been published that establish whether increasing the concentration will increase the commonly reported side effect of transient tooth sensitivity.

We conducted a double-blind study with human subjects to evaluate the two formulations of the NUPRO Gold Tooth Whitening System (Dentsply Preventive Care) to determine whether the 15 percent CP formulation whitened teeth to a greater extent than the 10 percent CP formulation. We also assessed and compared tooth sensitivity experienced by subjects in the two groups to evaluate whether the higher CP concentration worsened this side effect.

MATERIALS AND METHODS

Fifty-seven subjects with maxillary anterior teeth of shade A3 or darker as judged by comparison with a value-oriented Vita Lumin (Vita Zahnfabrik, Germany) shade guide were enrolled in a double-blind clinical trial conducted in the advanced general dentistry clinic at the University of Maryland Dental School. Subjects were 18 to 65 years of age, and all were in good general and dental health.

We divided subjects into a 10 percent CP group (the control group) and a 15 percent CP group (the experimental group) through a matching process

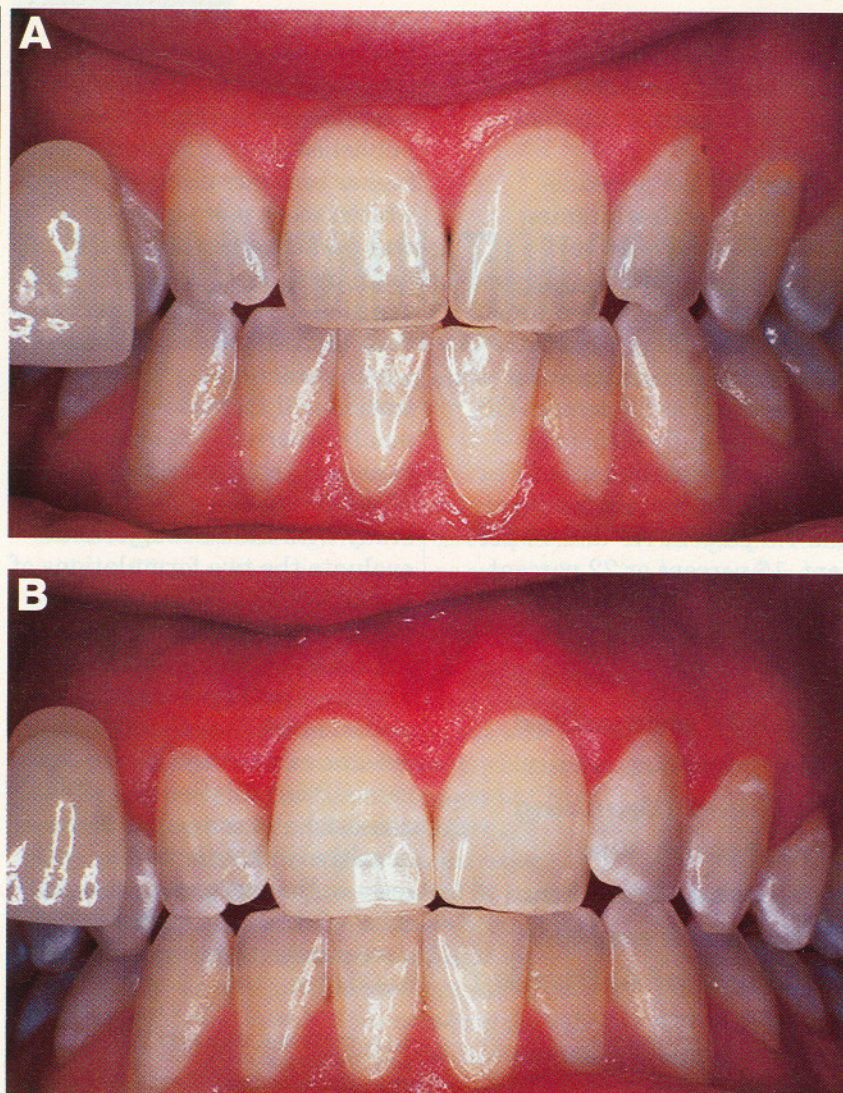


Figure 1. Results of tooth whitening in a patient in the control group, treated with 10 percent carbamide peroxide. A. Baseline. B. Two weeks after treatment.

using two variables: age and sex. A paired list of names was supplied to the manufacturer, which then randomly assigned one member of each pair to the control group and the other to the experimental group. The control group received the NUPRO Gold gel with 10 percent CP (the only version of the NUPRO Gold system on the market when the study was conducted), and the experimental group received the gel with 15 percent CP.

The regimen we prescribed

for all subjects followed the manufacturer's recommendations. For each subject, we recorded a baseline Vita shade and made a color transparency (using Ektachrome 100 Professional Film [Eastman Kodak]) and an intraoral camera at a 1:1 magnification. We made a maxillary alginate impression and poured it in dental stone for fabrication of the custom bleaching tray, using the material and design recommended by the manufacturer. Each subject then underwent a profes-

sional prophylaxis.

Two weeks after this initial evaluation and prophylaxis, the tray and gel were delivered to each subject with instructions for use. All subjects were instructed to wear the agent for at least four hours and as long as overnight, according to the manufacturer's instructions and depending on patient preference. We provided each patient with a daily diary, in which he or she recorded the amount of time the agent was applied. Patients also were instructed to record tooth hypersensitivity using a hash mark on a standardized grading scale ranging from 0 (no sensitivity) to 20 (severe sensitivity). We calculated the sensitivity scores by measuring length of the scale from 0 to the hash mark, and a statistician (E.R.) analyzed this information by using a matched-pairs *t*-test. Patients also were encouraged to write comments in the diary.

After baseline evaluation, patients were examined at the following intervals: after one week of gel use (the treatment period's midpoint), after completing the two weeks of gel use and two weeks after treatment ended. At each evaluation, calibrated clinicians used a Vita value-oriented shade guide to make shade measurements of the maxillary central and lateral incisors. (There are 16 shades in all.) They also made a color transparency with the baseline Vita shade tab in the photographic field. Diaries and extra gel were collected at the two-week posttreatment evaluation. Subjects followed a standardized oral hygiene regimen throughout the study.

Frequency distributions (by

number and percentage) described shade changes for subjects in both groups. We used a matched-pairs *t*-test to compare average tooth sensitivity during the two weeks between the control and experimental groups. Homogeneity of variance was used to test for significant difference in variance for tooth sensitivity for 10 percent CP as compared with 15 percent CP.²³ We also used matched-pairs *t*-tests to examine changes between the two groups from baseline to one week, baseline to two weeks and baseline to two weeks posttreatment. A probability level of .05 indicated significance.

RESULTS

Of the 56 subjects who began the study, 26 pairs of matched subjects ($n = 52$ individual subjects) completed the study. One subject, with chipped incisal edges of teeth nos. 8 and 9, withdrew from the study after application of the gel for two days owing to sensitivity. One patient was dropped from the study owing to noncompliance in use of the material. We did not include these two subjects or their matched subjects in our analysis of results.

Shade change. Frequency distributions for the change in shade from baseline were calculated for three assessment points: after one week of use, after two weeks of use and two weeks posttreatment. After treatment, we found shade changes of four to 15 shades (as compared with a value-oriented shade guide) in both experimental and control groups.

After one week of treatment, 46 percent of the subjects in the experimental group showed a change of seven to nine shades,

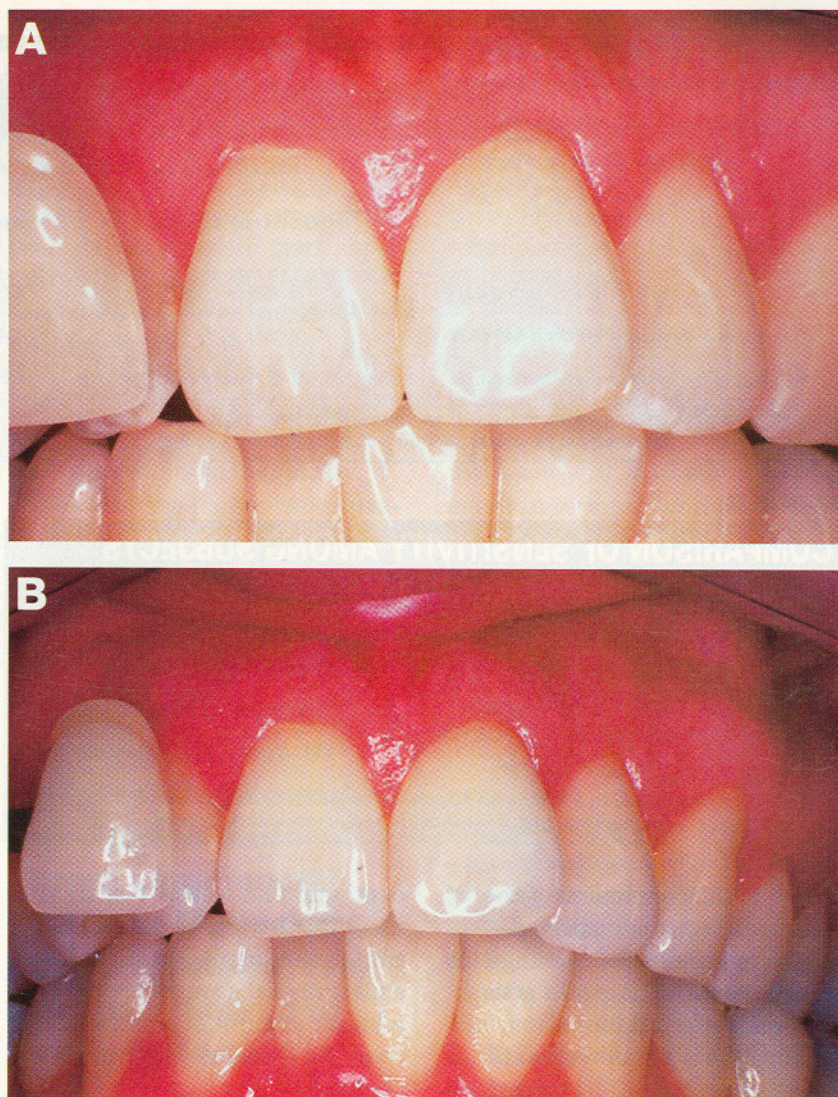


Figure 2. Results of tooth whitening in a patient in the experimental group, treated with 15 percent carbamide peroxide. A. Baseline. B. Two weeks after treatment.

and 54 percent of the subjects in the control group showed a change of four to six shades.

At the conclusion of two weeks of treatment, 54 percent of the subjects in the experimental group showed a change of seven to nine shades, and 12 percent showed a change of 13 to 15 shades after two weeks of use, whereas 0 percent showed this change after one week of use. In the control group, 38 percent of subjects showed a change of seven to nine shades, and 15 percent showed a change

of 13 to 15 shades at the conclusion of treatment, whereas 0 percent showed this change after one week of treatment.

At two weeks posttreatment, 54 percent of the subjects in the experimental group and 38 percent of the subjects in the control group showed a change of seven to nine shades. Twelve percent of the subjects in the experimental group and 15 percent of the subjects in the control group showed a change of 13 to 15 shades. These results were the same as those we

TABLE 1

COMPARISON OF CHANGE IN SHADE BETWEEN ASSESSMENT POINTS FOR THE TWO TREATMENT GROUPS.

ASSESSMENT POINT	MEAN \pm STANDARD DEVIATION		t-TEST	P VALUE
	Control Group*	Experimental Group†		
After one week of treatment	5.65 \pm 3.05	6.69 \pm 2.65	1.455	> .05
After two weeks of treatment	7.69 \pm 3.03	9.42 \pm 2.32	2.303	< .05
Two weeks posttreatment	7.73 \pm 2.96	9.38 \pm 2.26	2.248	< .05

* Control group received treatment with 10 percent carbamide peroxide.

† Experimental group received treatment with 15 percent carbamide peroxide.

TABLE 2

COMPARISON OF SENSITIVITY AMONG SUBJECTS IN THE TWO TREATMENT GROUPS.

TREATMENT GROUP	MEAN \pm SD*	t-TEST	P VALUE
Control group†	2.78 \pm 2.44	1.399	> .05
Experimental group‡	4.19 \pm 4.58	—	—

* SD: Standard deviation.

† Control group received treatment with 10 percent carbamide peroxide.

‡ Experimental group received treatment with 15 percent carbamide peroxide.

found at the conclusion of the two-week treatment period.

The average shade change for the 10 percent CP group after one week was a mean of 5.65 \pm a standard deviation of 3.05 shades; for the 15 percent CP group, it was 6.69 \pm 2.65 shades. The average shade change for the 10 percent CP group after two weeks of treatment was 7.69 \pm 3.03 shades; for the 15 percent CP group, it was 9.42 \pm 2.32 shades. The average shade change for the 10 percent CP group two weeks posttreatment was 7.73 \pm 2.96 shades and for the 15 percent CP group, 9.38 \pm 2.26 shades (Figures 1 and 2). We found no significant difference in shade change from baseline between the two groups after one week of treatment ($t = 1.455$, $P = .05$, nonsignificant). At both the two-week ($t = 2.303$, $P < .05$, signifi-

cant) and two-weeks-posttreatment ($t = 2.248$, $P < .05$, significant) assessment points, the experimental group showed a larger amount of shade change than did the control group (Table 1).

Tooth sensitivity. We found no significant difference in average tooth sensitivity over the two weeks of treatment between the control group and the experimental group ($t = 1.399$, $P > .05$, nonsignificant).

Sensitivity for the control group was 2.78 \pm 2.44 (mean \pm standard deviation) and for the experimental group was 4.19 \pm 4.58 (Table 2). We found a significant difference in tooth sensitivity variability associated with use of 10 percent CP vs. use of 15 percent CP (10 percent = 2.44² and 15 percent = 4.58², respectively). Incidence of tooth sensitivity was equal between the two

groups. Two of the 26 subjects in each group did not experience any tooth sensitivity.

DISCUSSION

It is evident that the CP whitening system whitened the teeth as compared with baseline. Results showed significant whitening from baseline for both the control and experimental groups. The reported change in shade was quite noticeable by patients and clinicians in both groups. The time frame for use of the agents in this study was based on the manufacturer's instructions at the time, which ranged from four hours to overnight (depending on patient preference) for a two-week period. The average time of use was 6.22 hours per night among members of the experimental group and 6.25 hours per night among members of the control group.

Statistically, there was no significant shade change between the two groups after one week of treatment. The experimental group showed a statistically larger amount of shade change than did the control group at both the two-week and the two-weeks-posttreatment evaluations, as would be expected intuitively with higher concentrations of CP. In this study, the

average shade change after two weeks and two weeks posttreatment in the group using the 15 percent concentration of CP was roughly 9.4 ± 2 shades; it was roughly 7.7 ± 3 shades for the group using 10 percent CP. It is interesting that the 15 percent CP gel did not whiten the teeth more quickly, as we originally had thought it would. In many cases, the difference was not noticeable until the full two-week regimen was completed.

References to transient tooth and gingival sensitivity have been reported with use of CP. Approximately two-thirds of patients undergoing treatment will experience one or both side effects.¹⁶ Our investigation compared the average degree of tooth sensitivity between the 10 percent CP and 15 percent CP groups. We found no significant difference between the two groups in the average degree of tooth sensitivity during the two weeks of treatment, and the incidence of sensitivity was the same in both groups. The 15 percent CP group showed more variability in tooth sensitivity than the 10 percent CP group, but all patients reported that the sensitivity ceased immediately after finishing the two-week active phase of treatment and that they had no lingering sensitivity.

Research indicates that 10 percent CP, as found in the NUPRO Gold Tooth Whitening System, is safe when administered properly under the supervision of a dentist.¹⁶⁻²¹ Our study shows that both 10 percent CP and 15 percent CP gels are effective in whitening teeth. The 15 percent CP group, however, showed a larger amount of shade change during the course of this study with no significant increase in sensitivity, except in

variability, than did the 10 percent CP group. It has been shown that lower concentrations of CP will achieve the same results as higher concentrations; it merely takes longer.²³ Our study indicates that the higher concentrations do lighten teeth more significantly than do the lower concentrations over the recommended period of use. With no significant difference in average tooth sensitivity noted between the groups and with patients wanting results more quickly, it seems that the higher concentrations may be a better choice to meet patient demands.

Many manufacturers have

Our study indicates that the higher concentrations of carbamide peroxide do lighten teeth more significantly than do the lower concentrations over the recommended period of use.

addressed the issue of tooth sensitivity by incorporating fluoride or potassium nitrate—or a combination of the two—to reduce sensitivity. Anecdotal data have indicated that these materials significantly reduce sensitivity. One study showed no significant difference in sensitivity between a group using an agent with potassium nitrate and a group using one without.²⁴ Another study confirmed these results, showing no significant difference in sensitivity during use; however, patients using the potassium nitrate-containing gel appeared to return to baseline at a lower level of sensitivity.²⁵ Fur-

ther studies must be completed with both 10 percent CP and 15 percent CP whitening agents to determine the cause of tooth sensitivity and the best method of managing it, as well as differences in color stability of whitened teeth over a period of several years.

CONCLUSIONS

In a double-blind study with human subjects aimed at comparing a 10 percent CP whitening agent with a 15 percent CP agent in terms of whitening efficacy and creation of tooth sensitivity, we found no significant difference in color change after one week of use between the control and experimental groups, as well as no significant difference in the incidence or average level of tooth sensitivity between the control and experimental groups. However, we did find a significant difference in color change between the control and experimental groups at the conclusion of the two-week treatment and at two weeks posttreatment. We also found a significant difference in the variability of tooth sensitivity between the two groups.

At-home whitening is an effective treatment when it follows careful diagnosis and treatment planning, regardless of whether 10 percent CP or 15 percent CP is used. The practitioner must monitor the procedure carefully and communicate well with the patient to maximize the benefits, minimize the risks and, thereby, ensure success. ■

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