

Tray Whitening: What the Evidence Shows

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In recent years, many dental professionals have changed their philosophy regarding the use of trays with at-home bleaching regimens. However, facts do not change—and successful vital tooth bleaching still occurs only when tooth surfaces are in direct contact with the appropriate concentration of active whitening agent for a specific amount of time. Because the science of tooth whitening is still in its infancy—this article reviews a series of remaining questions regarding vital tooth bleaching based on current scientific information and research findings on products using trays.

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Among the most widely accessible and relatively easy means of achieving a more youthful appearance is vital tooth bleaching. While the value of whiter teeth is clearly increasing among the general population, the philosophy of many dental professionals regarding the use of customized trays with dentist-dispensed at-home bleaching agents has changed within the past 3 years, although the science behind the treatment has not.

As previously addressed by this author in an article from the first Symposium on Tooth Whitening,¹ the facts do not change. Successful vital tooth bleaching only occurs when any active gel of an appropriate concentration is in contact with tooth surfaces for a reasonable duration. Exposure time and concentration of tooth whitening gel continue to be the two most important elements of successful bleaching.

Realistically, the science of tooth whitening is still in its infancy, and many questions and concerns remain. As more information about tooth bleaching becomes available, it either strengthens existing concepts or allows us to make appropriate modifications to conform to new findings.

Among the concerns regarding tooth bleaching are what concentration of active ingredient is best, the effects of bleaching on the pulp of vital teeth, whether actual concentration is consistent with manufacturer claims, the usefulness of reservoirs, and the appropriate duration of bleaching regimens. Additionally, questions regarding the efficacy of tray bleaching compared to in-office bleaching, as well as tray bleaching against stubborn stains, require further investigation. While there are many opinions on each of these items, this article addresses these questions and concerns in terms of current scientific information and research findings.

The Case for 10% Carbamide Peroxide

The American Dental Association (ADA) established guidelines for the acceptance of at-home tooth whitening agents.² When these guidelines were initially formulated 9 years ago, the ADA carefully selected tests that products had to undergo and satisfactorily complete before they could be accepted as “safe” and “effective.” Safe, as defined by the ADA, does not mean clinically safe, but biologically safe. The same safety standards that were implemented at that time are still in effect today. Efficacy levels must

Learning Objectives:

After reading this article, the reader should be able to:

- discuss concerns regarding what concentration of an active ingredient is best for tooth whitening.
- identify the efficacy of tray bleaching vs in-office bleaching.
- describe the reasons for using 10% carbamide peroxide and compare how 10% carbamide peroxide effects pulpal tissues.
- discuss the usefulness of reservoirs.

Table 1—Tray-Used Dentist-Dispensed Products With Their Assayed Concentrations

Manufacturer	Product	Carbamide Peroxide or Hydrogen Peroxide	Concentrations	+/- (%)
Access Dental ^a	Stark White™	Carbamide Peroxide	10, 16, 22	-2.64
Ivoclar Vivadent ^b	Vivastyle®	Carbamide Peroxide	10, 16	-1.32
Discus Dental ^c	Nite White® Excel 2	Carbamide Peroxide	10, 16	-1.32
SDI Inc ^d	Polanight	Carbamide Peroxide	10	-1.22
Spectrum Dental Inc ^e	Contrastp.m.®	Carbamide Peroxide	10, 15, 20	-1.20
Colgate®	Platinum™ Daytime	Carbamide Peroxide	10	-0.73
DENTSPLY Professional	Nupro® White Gold	Carbamide Peroxide	10, 15	-0.36
Omnii Oral Pharmaceuticals ^g	White & Bright®	Carbamide Peroxide	10, 16, 22	-0.29
Patterson Dental ^h	Patterson Brand	Carbamide Peroxide	10	-0.22
Ultradent Products Inc ⁱ	Opalescence®	Carbamide Peroxide	10, 15, 20	-0.20
Temrex Corporation ^j	Star White	Carbamide Peroxide	16	0.28
Ultradent Products Inc ⁱ	Opalescence® PF	Carbamide Peroxide	10	0.35
3M Dental ^k	Zaris™	Carbamide Peroxide	10, 16	0.69
Den-Mat ^l	Rembrandt® Xtra Comfort	Carbamide Peroxide	10*, 16, 22, 30	0.91
Discus Dental ^c	Day White®2	Hydrogen Peroxide	7.5, 9.5	-0.46
Premier Dental Products ^m	Perfecta® Ultra	Hydrogen Peroxide	4.5, 6	-0.05

^aAccess Dental, San Diego, CA 92117; (858) 496-0574
^bIvoclar Vivadent, Amherst, NY 14228; (800) 533-6825
^cDiscus Dental, Inc, Culver City, CA 90232; (800) 422-9448
^dSDI Inc, Bensenville, IL 60106; (800) 228-5166
^eSpectrum Dental, Inc, Culver City, CA 90232; (800) 556-7606
^fDENTSPLY Professional, York, PA 17404; (800) 989-8826
^gOmnii Oral Pharmaceuticals, West Palm Beach, FL 33409; (800) 445-3388
^hPatterson Dental, St. Paul, MN 55120; (800) 328-5536
ⁱUltradent Products, Inc, South Jordan, UT 84095; (800) 522-5512
^jTemrex Corp, Freeport, NY 11520; (800) 645-1226
^k3M ESPE, St. Paul, MN 55144-1000; (800) 634-2249
^lDen-Mat Corp, Santa Maria, CA 93456; (800) 445-0345
^mPremier Dental Products, Plymouth Meeting, PA 19462; (888) 773-6872
*only available as Rembrandt® Lighten Bleaching Gel 10%

be measured for up to 6 months postinitiation of treatment, and an observable change is required up to that time to gain product acceptance from the ADA.

There are only five tooth whitening products accepted by the ADA as safe and effective.³ These products are: Colgate® Platinum™ Daytime Professional Whitening System 10%^a, Rembrandt® Lighten Bleaching Gel 10%^b, Nite White® Classic Whitening Gel 10%^c, Patterson Brand Tooth Whitening Gel 10%^d, contrastP.M.® 10% Whitening Gel^e, and Opalescence® Whitening Gel 10%^f. All of them use 10% carbamide peroxide dispensed in trays. No product with a greater than 10% carbamide peroxide concentration that is used outside of the dental office is accepted as safe and effective by the ADA.

^aColgate Oral Pharmaceuticals, Inc, Canon, MA 02021; (800) 821-2880

^bDen-Mat Corp, Santa Maria, CA 9356; (800) 445-0345

^cDiscus Dental, Inc, Culver City, CA 90232; (800) 422-9448

^dPatterson Dental, St. Paul, NM 55120; (800) 328-5536

^eSpectrum Dental, Inc, Culver City, CA 90232; (800) 556-7606

^fUltradent Products, Inck Sout Jordan, UT 84095; (800) 552-5512

Regardless, some dentists do not use even 10% carbamide peroxide because they are concerned about the effects of the agents on the dental pulp. Very few clinical studies on the reaction of the pulp to bleaching agents have been conducted. However, the question of how 10% carbamide peroxide effects pulpal tissues can now be answered with scientific validity.

In a study by Gonzalez-Ochoa,⁴ four bicuspid teeth that were going to be extracted for orthodontic reasons were bleached with an ADA-accepted 10% carbamide peroxide bleaching gel. One of the bicuspids was the control tooth; one tooth was bleached overnight for 4 days; another tooth for 2 weeks; and another for 2 weeks followed by 2 weeks of no bleaching. All teeth were extracted at the same time. The Scandinavian Institute of Dental Research conducted the evaluation of the pulp response.

There were no histological changes in any of the sections from the control teeth. After 4

Table 2—Tray-Used OTC Products With Their Assayed Concentrations

Manufacturer	Product	Carbamide Peroxide or Hydrogen Peroxide	Concentrations
Natural White ^a	Extreme [®]	Carbamide Peroxide	9.40
Den-Mat Corp ^b	Rembrandt [®] Plus	Carbamide Peroxide	10.08
SAS Group, Inc ^c	OptiWhite [®]	Carbamide Peroxide	13.65
Unilever ^d	Mentadent System	Hydrogen Peroxide	0.70
Natural White ^e	Rapid White	Hydrogen Peroxide	3.14
CCA Industries, Inc ^e	Plus+White [®]	Hydrogen Peroxide	4.71

^aNatural White, Tonawanda, NY 14150; (800) 263-2290
^bDen-Mat Corp, Santa Maria, CA 93456; (800) 445-9448
^cSAS Group, Inc, Tarrytown, NY 01519; (914) 332-7878
^dUnilever, Greenwich, CT 08630; (800) 778-5135
^eCCA Industries, Inc, East Rutherford, NJ 07073; (800) 524-2720

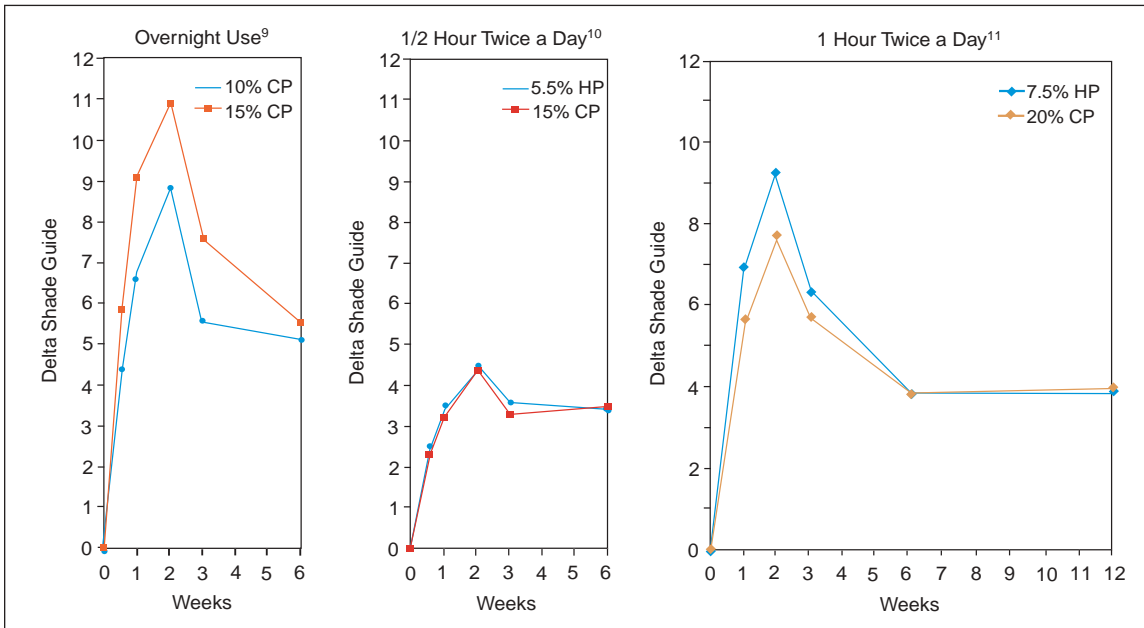


Figure 2—Objective evaluation of an overnight study using 10% and 15% carbamide peroxide, a daytime study using 5.5% hydrogen peroxide and 15% carbamide peroxide, and another daytime study using 7.5% hydrogen peroxide and 20% carbamide peroxide.

days of exposure to the carbamide peroxide, 17% exhibited a mild reaction; 14% had a mild reaction with 14 days of exposure to carbamide peroxide; and 8% exhibited a mild reaction with 14 days of exposure followed by 14 days without the carbamide peroxide challenge. None of the participants exhibited moderate or severe pulpal reactions as determined by histological changes to the pulp.

Pulp pathologists agree that mild histological change is reversible. The conclusion of this study states that 10% carbamide peroxide may be considered to be safe for the dental pulp for a 2-week regimen of bleaching treatment. While the same results cannot be assumed for 15% to 22% carbamide peroxide, we do know now that the use of 10% car-

bamide peroxide does not produce irreversible histological changes in the dental pulp.

A study was conducted to determine if there was any difference in how fast teeth bleached using 5%, 10%, and 16% concentrations of carbamide peroxide.⁵ One hundred and ten discolored teeth were divided into four groups. The teeth were immersed for 8 hours in a different concentration of carbamide peroxide or saline in an attempt to duplicate overnight use. The conclusion states, "Lower concentrations of carbamide peroxide take longer to whiten teeth but eventually achieve the same result as higher concentrations."⁵ Therefore, 10% carbamide peroxide may take a little longer, but will lighten to the level of the higher concentrations with time, and without irreversible changes to the dental pulp.

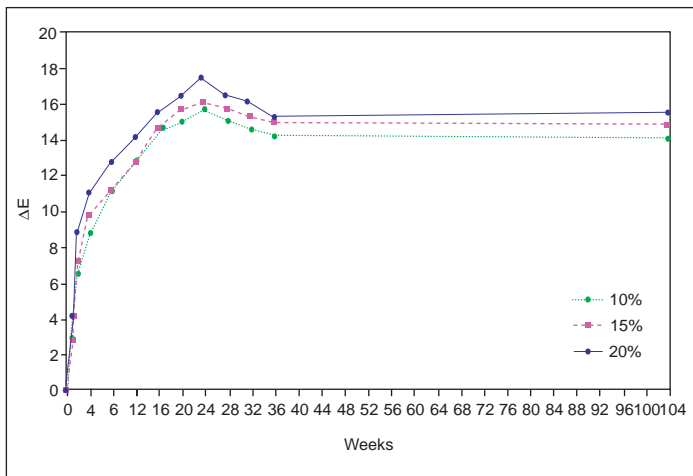


Figure 3—Two-year evaluation of tetracycline stained teeth using 10%, 15%, and 20% carbamide peroxide in trays with reservoirs in a half-mouth study design.

The same study also demonstrated that teeth lighten to a certain level. In this regard, the phrase “inherent lightness potential” is introduced. It is this author’s assertion that all teeth have an inherent lightness potential; however, one patient’s teeth will lighten more than another patient’s teeth. Therefore, dentists should not expect to lighten the teeth of all their patients to the same degree.

The science of tooth whitening is still in its infancy, and many questions and concerns remain. As more information about tooth bleaching becomes available, it either strengthens existing concepts or allows us to make appropriate modifications to conform to new findings.

Specifically, dental professionals must be careful not to promise results. Those who do will certainly be disappointed: even manufacturers admit that a very small percentage of patients will not experience a color change with tooth bleaching. Teeth with yellow stains usually bleach better than teeth with gray stains. One study⁶ found that immediately after bleaching teeth, which were relatively dark (A3 Vita^{®g} shade or B56 in Trubyte[®] Bioform^{®h}) in older adults, approximately 43% obtained a “Hollywood white” appearance, or

a large color change, 43% achieved a moderate color change, 7% a slight color change, and 3% did not experience any change. After 6 months, that rate dropped to 17%, 47%, 21%, and 14%, respectively. This was accomplished with a 10% carbamide peroxide containing product where the subjects bleached overnight for 14 days. Most of those who had the “Hollywood white” appearance at 4 weeks retained that for an extended period of time without rebleaching. This rate of color change, however, will be different in young people who already have lighter teeth.

Verifying Actual Active Ingredient Concentration

In 2002, scientists from the Clinical Research Section at Indiana University School of Dentistry (IUSD) requested that all manufacturers of dentist-prescribed tray whitening gels forward a sample of their various concentrations to them. The over-the-counter (OTC) products recommending tray whitening were purchased and tested for concentrations of carbamide peroxide or hydrogen peroxide (Sorhus J, Matis A. Degradation of hydrogen peroxide and carbamide peroxide bleaching agents in vitro [unpublished study]) using the US Pharmacopeia method.⁷ Testing was done in triplicate (Tables 1 and 2). All products were tested within the labeled use-life, except the OTC products, which have no labeled use-life or labeled concentration.

By testing the dentist-prescribed gels, it was found that one manufacturer’s products were a mean 2.64% lower than what was posted on the label, while another manufacturer’s products were a mean 0.91% higher than what was posted. When the OTC products were tested, it was determined that one of the gels recommended for at-home bleaching using trays was 0.7% hydrogen peroxide, the same concentration as the manufacturer’s dentifrice. It is important for dentists to know the initial actual concentration of products they are recommending.

Appropriate Duration of Bleaching

A study was conducted in which the same concentration of carbamide peroxide was used in one group during the daytime and another group overnight.⁸ Both groups used the same 10% carbamide peroxide agent in trays with reservoirs.

^gVita Zahnfabrik, Germany, distributed in US by Vident, Brea, CA 92621; (800)828-3839

^hDENTSPLY, York, PA 17405-0872; (800) 877-0020



Figure 4—At baseline, a 27-year-old female with tetracycline-stained teeth.



Figure 5—At one month after maxillary teeth were bleached overnight using trays with 20% carbamide on right side, and 10% carbamide peroxide on left side.



Figure 6—Results at 3 months.



Figure 7—Results at 6 months; bleaching was discontinued.



Figure 8—At 9 months, 3 months postbleaching.



Figure 9—At 2 years, 18 months, postbleaching. Patient was given bleaching gel for mandibular teeth after a 9-month bleaching evaluation.

One group bleached for 7 overnight periods of time and the other group for 14 two-hour daytime periods. The value change, or L* change, was not significantly different for the 10% carbamide peroxide overnight for the 7-days group than the 2 hours-a-day for 14 days group.

Three studies have been conducted at IUSD and reported in the scientific literature that help clarify the factors of gel concentration and use time.⁹⁻¹¹ Each had more than 24 subjects, used trays with reservoirs, and followed the half-mouth study design. All of the patients bleached for 14 days and were evaluated not only subjectively, using a shade guide^h, but also objectively using a colorimeter (Chroma Metercⁱ CR-321).

The subjective evaluation using the shade guide demonstrated that the higher the concentration and the longer the tray is worn, the faster the lightening of the teeth would occur (Figure 1).¹¹⁻¹³ The 10% overnight carbamide peroxide agent had the same delta shade guide values as the 20% carbamide peroxide product used twice a day for 14 days. The 15% carbamide peroxide product that was used for only half an hour twice a day demonstrated a much lower delta shade guide value. Therefore, bleaching was shown to be time and concentration dependent.

The objective evaluation using a colorimeter with a positioning jig showed that the Delta

E value, at the end of 6 weeks, was the same for 10% carbamide peroxide and 15% carbamide peroxide concentrations (Figure 2).¹¹⁻¹³ The color of teeth could be pushed, but a higher concentration will rebound more rapidly. The tooth never reached its inherent lightness potential, in the study comparing 5.3% hydrogen peroxide and 15% carbamide peroxide, so there was a minimal rebound of the color.

The effectiveness of using a 20% carbamide peroxide concentration for 1 hour twice a day was the same as a 10% carbamide peroxide concentration used overnight when both were used for 14 days. However, the 20% carbamide peroxide is not accepted by the ADA as safe and effective, and dentists may feel more confident that they are providing patients with the best service by recommending an ADA-accepted 10% carbamide peroxide product.

Usefulness of Reservoirs

One of the existing controversies regarding tray bleaching involves the use of reservoirs. A study involving 27 subjects was conducted with a split-mouth design in which reservoirs were placed on only one side of the tray and no reservoirs were placed on the other side.¹² A 16% carbamide peroxide gel was used in their trays for 2 hours once a day. At the end of 14 days, there was a statistical difference in the objective measurement of Delta E, which continued until the end of the study. However, there was no difference in the subjective measurement of lightening using a shade guide, because visual acuity is unable to differentiate less than one Delta E value.¹³ Therefore, from a clinical standpoint, placing a reservoir in trays made no difference in color.

Another study analyzed the amount of carbamide peroxide recovered after 2 hours of use in 2 products without reservoirs, and one product with reservoirs.¹⁴ Approximately the same amount of agent was placed into trays with and without reservoirs. The investigators were able to recover twice as much of the initially placed agent in the trays that had reservoirs compared to the trays that did not have reservoirs. In nine trials, no active agent could be assayed from one of the products that recommended using no reservoirs.

The lost gel exuded from the tray without reservoirs was probably ingested, which would

inhibit its ability to lighten the teeth if the gel was intended to be left on for a longer period of time. The ingestion of the additional oxidant is also a factor for concern. While it is not known how much oxidant is safe to ingest, one study reported that amount to be 10 mg, with a safety factor of 100.¹⁵ The amount ingested should be minimized until more scientific evidence of the ability of anti-oxidants available in the oral cavity to overcome the increased oxidant level that results from bleaching can be established.

Efficacy of Tray Bleaching Compared to In-Office Bleaching

A split-mouth design study was completed¹⁶ in which 2 in-office treatments and 2 weeks of bleaching in trays with reservoirs were conducted on 24 subjects. Two ADA accepted tooth-whitening agents, one for in-office use and the other for at-home use, were compared side-by-side for color changes, both subjectively and objectively. Objectively, at the end of 3 months, the overall color change or E value of the teeth bleached with the ADA-accepted at-home bleach was twice the value compared to the side that was bleached using the in-office tooth whitening agent. The subjective values indicated that the at-home side was about one-third lighter in Delta Shade Guide rank. Although patients sometimes request in-office treatment, when providing this service, the recommendation should be to follow it up with at-home tray bleaching.

Efficacy of Tray Bleaching Against Stubborn Stains

A recently published tetracycline study reported results for 59 subjects in a half-mouth design study.¹⁷ The subjects used 10% vs 15% vs 20% carbamide peroxide on different sides of the maxillary arches, overnight, in trays with reservoirs, for 6 months. The subjects also recorded the maximum amount of sensitivity they experienced each day on their right and left sides (Figure 3).

There was a significant difference among the shade guide values in the 10%, 15%, and 20% carbamide peroxide groups after 2 years. Twenty percent and 15% carbamide peroxide caused significantly more tissue sensitivity than 10% carbamide peroxide. There was no

significant difference in tooth sensitivity. Subjects reported being happy to be able to lighten their teeth with the use of trays with all of the concentrations. Therefore, when each option is effective, but it takes a little longer to do it safely, it is this author's assertion that the safe way should be more seriously considered (Figures 4 through 9).

Summary

Tray whitening is effective in removing stains. All of the products in this category appear to be effective, whether 5% to 22% carbamide peroxide or 3% to 9.5% hydrogen peroxide. However, 10% carbamide peroxide has been accepted as safe by the ADA, while higher concentrations have not. It is also important for dentists dispensing gel for tray use to know the actual concentrations of the products they prescribe. With overnight use, patients will achieve the greatest benefit from the gel and require a shorter number of bleaching days, although manufacturer's instructions should be followed. There will be no difference in how rapidly bleaching occurs in the daytime regardless of whether reservoirs are used, but patients will swallow less of the product if reservoirs are used. If in-office bleaching is performed, it should be followed by tray bleaching for maximum effectiveness.

Using a lower concentration of bleaching agent may require more time, but doing so may bring the peace of mind that comes with using an ADA-accepted product. If problems arise—and there has already been litigation involving the use of products containing 10% carbamide peroxide—and the manufacturer's directions have been followed, the ADA will stand by you and defend your use of the ADA-accepted product, if it becomes necessary. For this author, peace of mind and patient protection is of primary importance.

Disclosure

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International, Life-Like Cosmetic Solutions, and Southern Dental Industries, Inc.

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