Clinical evaluation of a combined in-office and take-home bleaching system

SIMONE DELIPERI, D.D.S.; DAVID N. BARDWELL, D.M.D., M.S.; AIKATERINI PAPATHANASIOU, D.D.S.

ABSTRACT

Background. Tooth whitening is one of the fastest growing areas in cosmetic and restorative dentistry. An increasing number of patients are demanding faster ways to bleach their teeth. Therefore, clinicians are being pushed to seek quicker and easier means to bleach their patients' teeth, while maintaining safety in bleaching procedures.

Methods. The authors included in the clinical trial 10 subjects 18 years of age or older, each of whom had six caries-free maxillary anterior teeth without restorations on the labial surfaces and no tooth sensitivity. For each subject, one-half of the maxillary arch received a 35 percent hydrogen peroxide (Group 1) gel application for 30 minutes, and the other one-half of the maxillary arch received a 38 percent hydrogen peroxide (Group 2) gel application for 30 minutes. The in-office bleaching treatment was maintained and reinforced using a 10 percent carbamide peroxide at-home bleaching agent for 60 minutes. Subjects repeated both the in-office and take-home bleaching treatments for three consecutive days.

Results. The shade change was 8.5 for Group 1 and 9 for Group 2. There was no statistically significant difference between the two groups ($P = .3434$). An average shade rebound of two shades was recorded at seven days for both treatment systems. No sensitivity was reported during or after the bleaching treatment.

Conclusions. When combined with 10 percent carbamide peroxide at-home applications, use of the Group 1 and Group 2 bleaching materials resulted in significant tooth lightening.

Clinical Implications. By using the clinical technique presented, clinicians can reduce the time required to complete tooth-whitening treatment. Using the correct tray design and improved chemical formulations of tooth whiteners may reduce gingival and tooth sensitivity, thus increasing safety.

Bleaching is the most conservative treatment for discolored teeth, compared with resin-bonded composites, porcelain veneers and crowns. Since the introduction of carbamide peroxide for home bleaching,[1,2] new techniques and materials with improved properties have been developed,[3,4] and clinicians have had increasing success with them. Safety and effectiveness of night-guard vital bleaching, or NGVB, has been reported.[5-7] The slow response to NGVB in some cases[8] and patients' demand for faster ways to bleach their teeth, have pushed clinicians to look for easier, safer and quicker means of helping patients obtain whiter teeth.

Both treatments resulted in an average shade rebound of two shades.

The introduction of high-intensity plasma curing lights and argon lasers in the market are the result of this increasing demand. However, no study has demonstrated that the combination of high-intensity curing lights with bleaching agents is more effective than traditional bleaching methods.[3] There is evidence that these light-curing systems do not bleach teeth without the use of hydrogen peroxide and that the increased temperature resulting from the use of these light-curing systems may increase tooth sensitivity.[9,10]

The use of hydrous gel[8] and the development of a light-cured gingival barrier[11] have simplified the in-office bleaching procedure. The association between in-office

DISCLOSURE
Ultradent Products, South Jordan, Utah, provided materials and financial support for this study.

Copyright ©2004 American Dental Association. All rights reserved.

and at-home bleaching has demonstrated encouraging results.[8,12,13] The use of more stable and less caustic hydrogen peroxide bleaching materials and 10 percent carbamide peroxide containing fluoride and potassium nitrate may help satisfy patients' demands to achieve whiter teeth more quickly with more predictable results and reduced risk of tooth sensitivity.

We conducted our study to evaluate the effectiveness of tooth color modifications produced by a combination of in-office and at-home bleaching agents in three consecutive treatments for three consecutive days. We also evaluated subjects' responses to tooth-whitening treatment and the incidence of soft-tissue irritation.

We hypothesized that the combination of in-office and at-home bleaching would produce a tooth color modification greater than five shades on the Vita Classical Shade Guide (Vident, Brea, Calif.) arranged in value order. This would reduce the time required for the bleaching efficacy, while maintaining long-term safety.

SUBJECTS, MATERIALS AND METHODS

Five men and five women participated in this blinded parallel pilot study. The Human Investigational Review Committee at Tufts University, Boston, reviewed and approved the research protocol and the informed consent form. All subjects received a dental screening and a dental prophylaxis two weeks before the start of bleaching, and we obtained their informed consent before the study began.

Inclusion and exclusion criteria. We included patients in this clinical trial if they

- were 18 years of age or older;
- had six caries-free maxillary anterior teeth without restorations on the labial surfaces;
- were willing to sign a consent form;
- had teeth shade A3 or darker.

We excluded patients from the study if they

- had undergone tooth-whitening procedures;
- had labial anterior restorations;
- were smokers;
- were pregnant or nursing;
- had tooth sensitivity;
- had severe internal discoloration (tetracycline stains, fluorosis, pulpless teeth);
- had a gingival index score greater than 1.

Study design. We took an alginate impression of each subject's maxillary arch, poured it with dental stone and trimmed and prepared the resultant cast for a custom stent. We placed a light-cured resin block-out material (Ultradent LC Block-out Resin, Ultradent Products, South Jordan, Utah) on the labial surface of the cast, and extended it 1 millimeter from the gingival, mesial and distal margins. We fabricated trays with a 0.035-inch thick, 5 × 5-inch soft tray material in a heat/vacuum tray-forming machine. We trimmed the trays to fit each model perfectly before giving the trays to the subjects. We instructed the subjects on how to care for and use the trays correctly.

Before the start of in-office bleaching, we pumiced the teeth and isolated the gingival tissue using a light-cured resin dam (OpalDam, Ultradent Products). We applied a 35 percent hydrogen peroxide gel (OpalescenceXtra, Ultradent Products) to one-half of the maxillary arch (Group 1) for 30 minutes, and we applied a 38 percent hydrogen peroxide gel (OpalescenceXtra Boost, Ultradent Products) to the other one-half of the maxillary arch (Group 2) for the same amount of time. We refreshed the in-office bleaching agents every 10 minutes during the 30-minute application periods. We maintained and reinforced the in-office bleaching treatment using a 10 percent carbamide peroxide at-home bleaching agent (Opalescence PF 10 percent, Ultradent Products) for 60 minutes. Subjects repeated both the in-office and take-home bleaching treatments for three consecutive days.

Shade evaluation. We selected shades from the shade guide arranged by value order from lightest to darkest, using three independent evaluators who were precalibrated at 85 percent reliability. To evaluate the degree of color change, the evaluators recorded the shade of each subject's teeth at baseline and immediately after each in-office and at-home bleaching treatment for both the left and right arches. At the seven-day follow-up appointment, the evaluators performed a new evaluation to check for rebound trends.

Periodontal and sensitivity evaluation. We asked the subjects to record daily for three days any tooth or soft-tissue sensitivity, using the following criteria: 1 = none, 2 = mild, 3 = moderate, 4 = considerable and 5 = severe.[14] If a subject reported having considerable or severe sensitivity, we had the subject wear the custom tray containing a 3 percent potassium nitrate gel (Ultra EZ, Ultradent Products) for 30 minutes before the start of the in-office bleaching procedure. We conducted a periodontal evaluation at baseline, after each office appointment and at the

Copyright ©2004 American Dental Association. All rights reserved.

TABLE 1

TOOTH COLOR EVALUATIONS AT BASELINE, AFTER BLEACHING TREATMENT AND AT THE SEVEN-DAY RECALL.

SUBJECT NO.	GROUP 1 SHADES (NUMBER OF SHADE CHANGES FROM BASELINE)			GROUP 2 SHADES (NUMBER OF SHADE CHANGES FROM BASELINE)		
	Baseline	After Bleaching	Seven-Day Recall	Baseline	After Bleaching	Seven-Day Recall
1	D3	B1 (9)	A1 (8)	D3	B1 (9)	A1 (8)
2	A3	B1 (8)	A1 (7)	A3	B1 (8)	A1 (7)
3	D3	B1 (9)	A1 (8)	D3	B1 (9)	A1 (8)
4	D3	B1 (9)	A1 (8)	D3	B1 (9)	A1 (8)
5	A4	A1 (13)	A2 (10)	A4	A1 (13)	A2 (10)
6	A4	A2 (10)	B2 (12)	A4	A2 (10)	B2 (12)
7	A3	B1 (8)	A2 (4)	A3	B1 (8)	A2 (4)
8	A3	B1 (8)	D2 (5)	A3	B1 (8)	D2 (5)
9	A3	B1 (8)	A2 (4)	A3	B1 (8)	A2 (4)
10	A3	A1 (7)	B2 (6)	B3	A1 (9)	A2 (6)

BOX

CLASSICAL VITA SHADE GUIDE* ARRANGED IN VALUE ORDER

SHADE	VALUE	SHADE	VALUE
B1	1	A3	9
A1	2	D3	10
B2	3	B3	11
D2	4	A3.5	12
A2	5	B4	13
C1	6	C3	14
C2	7	A4	15
D4	8	C4	16

* Classical Vita Shade Guide is manufactured by Vident, Brea, Calif.

seven-day follow-up appointment using the Löe-Silness Gingival Index, in which 0 = no inflammation, 1 = slight inflammation, 2 = moderate inflammation and 3 = severe inflammation.[15]

RESULTS

We report the results of this study in Table 1. We determined the subjects' tooth shades using the shade guide arranged in value order (Box).

We observed severe gingival inflammation in one subject after the placement of the light-cured resin dam. This adverse reaction may have been related to the subject's having an allergic reaction to the light-cured resin dam's formulation. At the seven-day recall appointment, periodontal evaluation yielded no gingival inflammation.

We evaluated the results, using statistical analysis. Paired-samples *t* tests revealed no statistically significant difference between Group 1 and Group 2 after the three-day combination treatment ($P = .3434$). Paired-samples *t* tests revealed a statistically significant difference immediately after the last bleaching treatment when compared with the seven-day recall appointment for both groups (Group 1, $P = .0165$; and Group 2, $P = .0101$) (Table 2 and Table 3).

DISCUSSION

The combination of three consecutive days of in-office and at-home bleaching treatments was responsible for dramatic tooth-shade modifications for both groups. The 38 percent hydrogen peroxide gel demonstrated effectiveness similar to that of 35 percent hydrogen peroxide gel when associated with a carbamide peroxide take-home bleaching agent. We obtained a similar result with extracted teeth using the same study design.[16] Even though the benefits of such a combination—in-office and take-home bleaching systems—have been reported,[8,12,13] no other study has reported the result of the application of an in-

Copyright ©2004 American Dental Association. All rights reserved.

office bleaching material for three consecutive days. Researchers and clinicians may have been reluctant to adopt such therapies because of the tooth sensitivity issue, which has been reported to be a common side effect whether using carbamide peroxide or hydrogen peroxide.[2,5-7,17-22] In our clinical trial, we used a combination of carbamide peroxide and hydrogen peroxide, which can increase sensitivity. For this reason, we limited at-home bleaching with carbamide peroxide to one hour for each application. Conversely, all of the subjects reported having no tooth sensitivity during the bleaching treatment. This phenomenon may be attributed to the improved formulation of tooth whiteners. The potassium nitrate and fluoride formulation introduced in some carbamide peroxide gels may play an important role in preventing sensitivity. Both in-office bleaching products contain 35 to 37 percent water, which may help reduce sensitivity. Owing to their slow release, fluoride and potassium nitrate are not used in these products, because little benefit could be expected with a 10-minute exposure time.

TABLE 2

PAIRED-SAMPLE *T* TEST COMPARISONS OF MEAN SHADE CHANGES AT BASELINE AND SEVEN-DAY RECALL: MEAN SHADE CHANGE, SD,* SE† AND 95% CI‡.

BLEACHING MATERIAL§	N MEAN	SHADE CHANGE	SD	SE	95% CI
Group 1 After Bleaching	10	8.900	1.6633	0.5260	7.710 to 10.090
Group 1 at Seven-Day Recall	10	7.200	2.5734	0.8138	5.359 to 9.041
Group 2 After Bleaching	10	9.100	1.5239	0.4819	8.010 to 10.190
Group 2 at Seven-Day Recall	10	7.200	2.5734	0.8138	5.359 to 9.041

* SD: Standard deviation.
† SE: Standard error.
‡ CI: Confidence interval.
§ Subjects in Group 1 received applications of 35 percent hydrogen peroxide gel, and subjects in Group 2 received applications of 38 percent hydrogen peroxide gel.

TABLE 3

PAIRED-SAMPLE *T* TEST COMPARISONS OF MEAN SHADE CHANGES AT BASELINE AND SEVEN-DAY RECALL: MEAN SHADE CHANGE, IQR* AND 95% CI†.

BLEACHING MATERIAL‡	MEDIAN SHADE CHANGE	IQR	95% CI
Group 1 After Bleaching	8.500	1.000	8.000 to 10.000
Group 1 at Seven-Day Recall	7.500	2.750	4.000 to 10.000
Group 2 After Bleaching	9.000	1.000	8.000 to 10.000
Group 2 at Seven-Day Recall	7.500	2.750	4.000 to 10.000

* IQR: Interquartile range.
† CI: Confidance interval.
‡ Subjects in Group 1 received applications of 35 percent hydrogen peroxide gel, and subjects in Group 2 received applications of 38 percent hydrogen peroxide gel.

Our findings agree with those of a recent study in which the 35 percent hydrogen peroxide gel was used with or without the application of a light source; however, in that situation, the gel was applied once for just 20 minutes.[23]

We did not use a curing light with the in-office bleaching gels in our study. Additionally, the absence of heat—a contributing factor in tooth dehydration and increased sensitivity—was notable. The in-office bleaching materials we used are contained in a carotene base, which is able to absorb light[24] and accelerate the molecular breakdown, thus increasing the whitening effect. Interestingly, we found no difference in tooth sensitivity between Group 1 and Group 2, even though both in-office bleaching agents had differing pHs (35 percent hydrogen peroxide gel, pH = 4.5; 38

Copyright ©2004 American Dental Association. All rights reserved.

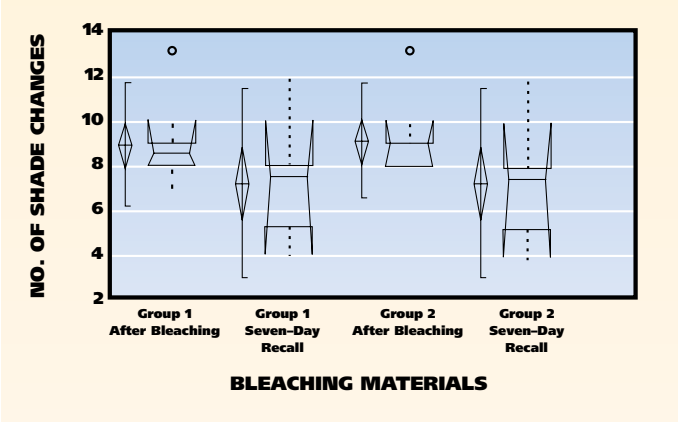


Figure 1. The average tooth color modification after completing the bleaching treatment and the shade rebound trend at the seven-day recall appointment for Group 1 and Group 2. Subjects in Group 1 received applications of 35 percent hydrogen peroxide gel, and subjects in Group 2 received applications of 38 percent hydrogen peroxide gel.

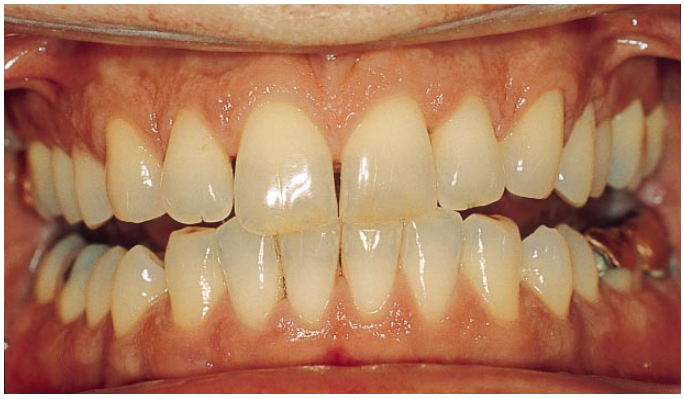


Figure 2. Retracted pretreatment smile at baseline.

percent hydrogen peroxide gel, pH = 7).

Several studies have reported tooth sensitivity as a recurring characteristic when NGVB is used.[5,17,19] However, some of these studies were conducted without an accounting for pretreatment sensitivity. In our study, we excluded patients with tooth sensitivity. As a rule, patients with hypersensitivity, such as those with abfracted lesions, should treat their sensitivity before beginning a bleaching program. Using an adhesive system to cover the exposed dentinal tubules before starting the tooth-whitening process may help patients avoid tooth sensitivity.

Another important factor in reducing sensitivity is the bleaching tray's design. A previous study[5] reported that nightguards were made of thicker tray materials and without reservoirs; the trays were not scalloped, and they covered tooth and gingival tissues. In this study, we paid particular attention to obtaining a correct tray design and an intimate fit in each subject's mouth. Daily use of the nightguard may have reduced subjects' clenching activity when compared with overnight use. Tooth and gingival sensitivity also have been reported when using a placebo (trays without a bleaching agent).[19]

All of these factors, along with the improved chemistry of the bleaching solutions, may explain the absence of tooth sensitivity in our clinical study. Further studies are needed to corroborate these findings. One subject reported gingival burning after the application of the light-cured resin dam. This was attributed to the subject's having an allergic reaction to the methacrylate compounds of the light-cured resin dam. In this case, we removed the light-cured resin dam and dispensed OraSeal Caulking (Ultradent Products) into the gingival margin to avoid any burning of the gingiva and to ensure a complete seal of the rubber dam. The rubber dam was kept in place with bilateral dental clamps and dental floss to complete the in-office bleaching treatment.

A seven-day recall period may not be enough time to evaluate the color stabilization. The majority of us agree that two to three weeks is an ideal amount of time to re-evaluate shade. By that time, oxygen is released completely and should not interfere with the optical properties of tooth structure.[25] Mokhlis and colleagues[14] and Matis and colleagues[19] recommended a re-evaluation after a four-week cessation of bleaching.

In our study, we evaluated the rate at which the combination of the two bleaching agents created tooth-color modifications in a three-day regimen. We performed an evaluation at the seven-day recall appointment to obtain data on the behavior of this combination. We found that patients can better maintain tooth-color modification with a prolonged at-home bleaching program. Gel degradation seems not to be complete even after six to eight hours in the mouth.[26,27]

Two recent long-term clinical studies have reported that NGVB is a safe and effective procedure by itself.[6,7]

One subject (subject number 6) enrolled in our study experienced a unique clinical result. The subject had a baseline tooth shade of A4, which lightened to A2 after the bleaching regimen was completed. At the seven-day recall appointment, we recorded a tooth shade of B2, which was two shades lighter. Conversely, all other subjects had a trend toward two to three and four to five shade

Copyright ©2004 American Dental Association. All rights reserved.

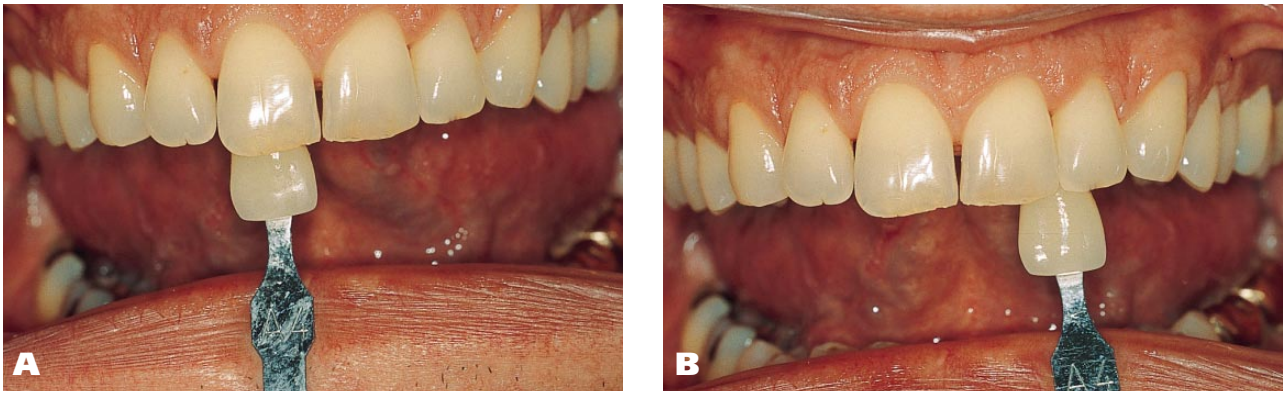


Figure 3. Pretreatment shade evaluation of the right (A) and left (B) sides of the maxillary arch.

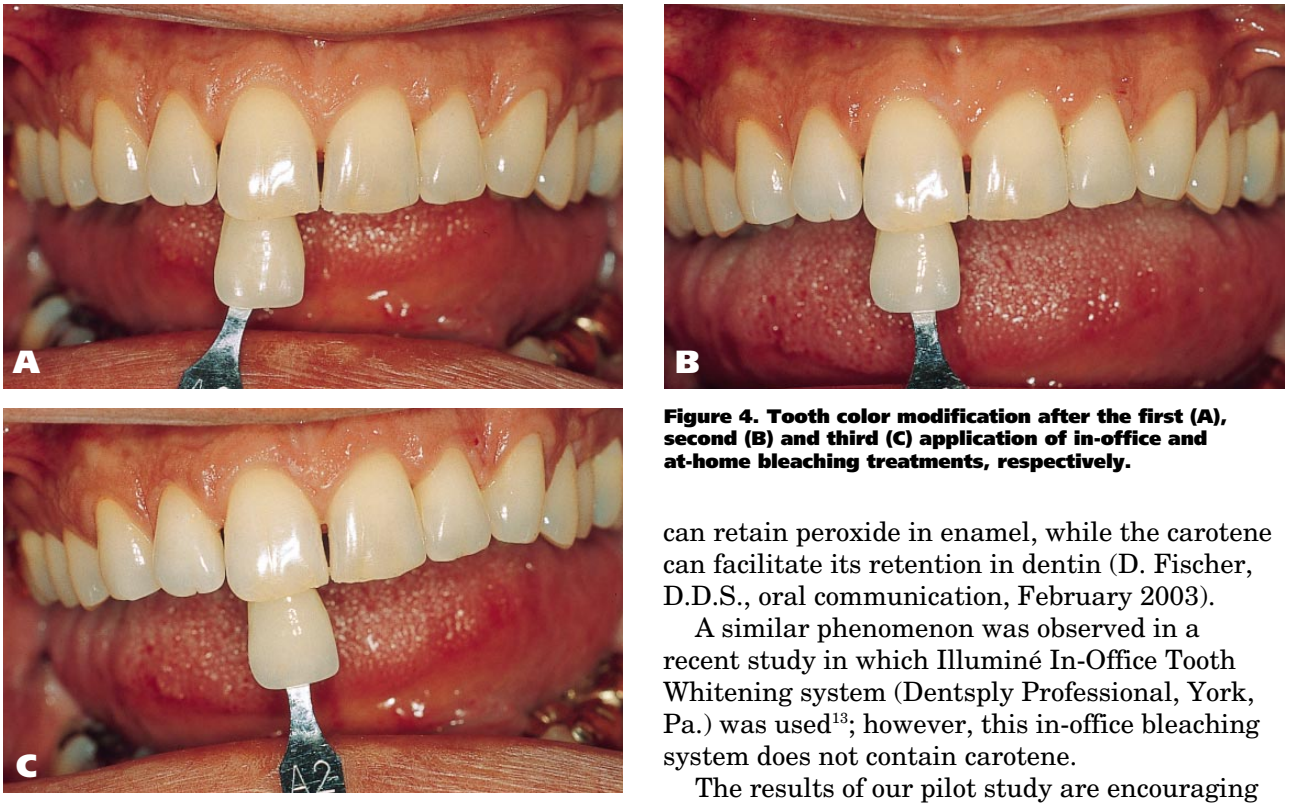


Figure 4. Tooth color modification after the first (A), second (B) and third (C) application of in-office and at-home bleaching treatments, respectively.

rebounds (Table 1 and Figure 1). Figures 2 through 5 show examples of the progressive tooth color modification after the three in-office and at-home bleaching treatments.

The exact mechanism behind subject number 6's further shade improvement is unknown. Histologically, the degree of porosity of enamel and dentin varies by patient, allowing oxygen to be trapped for longer periods in hard dental tissues, thus facilitating further bleaching. Furthermore, the manufacturer of the hydrogen peroxide gels we used in our study claims that the gelling agent may leave an ultrathin coating on the teeth and can retain peroxide in enamel, while the carotene can facilitate its retention in dentin (D. Fischer, D.D.S., oral communication, February 2003).

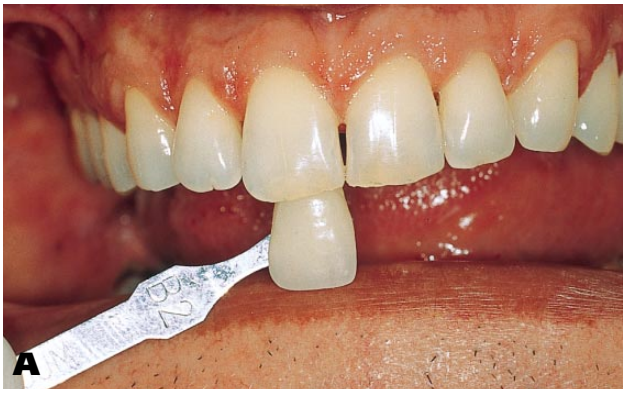
A similar phenomenon was observed in a recent study in which Illuminé In-Office Tooth Whitening system (Dentsply Professional, York, Pa.) was used[13]; however, this in-office bleaching system does not contain carotene.

The results of our pilot study are encouraging with regard to tooth color modification and reduction of sensitivity. Further study, however, is encouraged.

CONCLUSION

In our study, we evaluated the effectiveness of tooth color modifications produced by a combination in-office and at-home bleaching system in three consecutive treatments. The in-office bleaching agents were 35 percent hydrogen peroxide gel and 38 percent hydrogen peroxide gel; both resulted in tooth lightening. When combined with applications of 10 percent carbamide peroxide at home for three days, use of the 35 percent

Copyright ©2004 American Dental Association. All rights reserved.



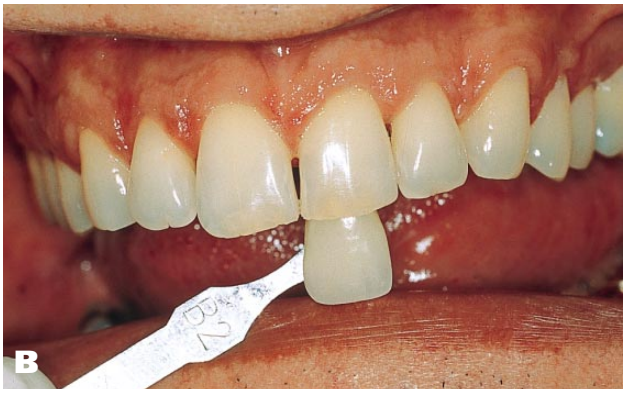


Figure 5. Final shade evaluation of the right (A) and left (B) sides of the maxillary arch at the seven-day recall appointment.

hydrogen peroxide gel resulted in eight and one-half shade changes and use of the 38 percent hydrogen peroxide gel resulted in nine shade changes. Both treatments resulted in an average shade rebound of two shades at the seventh day of bleaching cessation.

Our results corroborated our hypothesis that a combination of in-office and at-home bleaching would produce a tooth color modification greater than five shades on the shade guide arranged in value order. ■

Dr. Deliperi is a visiting instructor and research associate, Department of Prosthodontic and Operative Dentistry, Tufts University School of Dental Medicine, One Kneeland St., Boston, Mass. 02111. Address reprint requests to Dr. Deliperi at Via G. Baccelli,10/b, 09126 Cagliari, Italy, e-mail "simone.deliperi@tufts.edu".

Dr. Bardwell is an associate clinical professor of restorative dentistry and the director of post graduate esthetic dentistry, Department of Prosthodontic and Operative Dentistry, Tufts University School of Dental Medicine, Boston.

Dr. Papathanasiou is an assistant professor and the clinic coordinator, post graduate esthetic dentistry, Department of Prosthodontic and Operative Dentistry, Tufts University School of Dental Medicine, Boston.

1. Haywood VB, Heymann HO. Nightguard vital bleaching. Quintessence Int 1989;20(3):173-6.
2. Haywood VB. History, safety, and effectiveness of current bleaching techniques and applications of nightguard of vital bleaching technique. Quintessence Int 1992;23:471-88.
3. Garber DA. Dentist-monitored bleaching: a discussion of combination and laser bleaching. JADA 1997;128(supplement):26S-30S.
4. Settembrini L, Gultz J, Kaim J, Scherer W. A technique for bleaching nonvital teeth: inside/outside bleaching. JADA 1997; 128:1283-4.
5. Haywood VB, Leonard RH, Nelson CF, Brunson WD. Effectiveness, side effects, and long-term status of nightguard vital bleaching. JADA 1994;125:1219-26.
6. Leonard RH, Bentley C, Eagle JC, Garland GE, Knight MC, Phillips C. Nightguard vital bleaching: a long-term study on efficacy, shade retention, side effects, and patients' perceptions. J Esthet Restor Dent 2001;13:357-69.
7. Ritter AV, Leonard RH Jr, St Georges AJ, Caplan DJ, Haywood VB. Safety and stability of nightguard vital bleaching: 9 to 12 years post-treatment. J Esthet Restor Dent 2002;14:275-85.
8. Barghi N. Making a clinical decision for vital tooth bleaching: at-home or in-office? Compend Contin Educ Dent 1998;19:831-8.
9. Cohen SC. Human pulpal response to bleaching procedure on vital teeth. J Endod 1979;5(5):134-8.
10. Seale NS, McIntosh JE, Taylor AN. Pulpal reaction to bleaching of teeth in dogs. J Dent Res 1981;60:948-53.
11. Barghi N, Berry TG, Ghorbanian A. Clinical comparison of two in office bleaching systems. Contemp Esthet Restor Pract 1997;1:10-5.
12. Kugel G, Perry RD, Hoang E, Scherer W. Effective tooth bleaching in 5 days: using a combined in-office and at-home bleaching system. Compend Contin Educ Dent 1997;18:378-83.
13. Papathanasiou A, Bardwell D, Kugel G. A clinical study evaluating a new chairside and take-home whitening system. Compend Contin Educ Dent 2001;22:289-98.
14. Mokhlis GR, Matis BA, Cochran MA, Eckert GJ. A clinical evaluation of carbamide peroxide and hydrogen peroxide whitening agents during daytime use. JADA 2000;131:1269-77.
15. Loe H, Silness J. Periodontal disease in pregnancy, part 1: prevalence and severity. Acta Odontol Scand 1963;21:533-51.
16. Deliperi S, Bardwell DN, Papathanasiou A, Wegley C. In vitro evaluation of a combined in-office and take home bleaching system (abstract 981). J Dent Res 2003;82(special issue A).
17. Leonard RH, Haywood VB, Phillips C. Risk factors for developing tooth sensitivity and gingival irritation associated with nightguard vital bleaching. Quintessence Int 1997;28:527-34.
18. Heymann HO, Swift EJ Jr, Bayne SC, et al. Clinical evaluation of two carbamide peroxide tooth-whitening agents. Compend Contin Educ Dent 1998;19:359-69.
19. Matis BA, Cochran MA, Eckert G, Carlson TJ. The efficacy and safety of a 10% carbamide peroxide bleaching gel. Quintessence Int 1998;29:555-63.
20. Haywood VB, Caughman WF, Frazier KB, Myers ML. Tray delivery of potassium nitrate-fluoride to reduce bleaching sensitivity. Quintessence Int 2001;32(2):105-9.
21. Tam L. Effect of potassium nitrate and fluoride on carbamide peroxide bleaching. Quintessence Int 2001;32:766-70.
22. Zekonis R, Matis BA, Cochran MA. In vivo evaluation of an ADA-accepted in-office and at-home bleaching agent (abstract 1293). J Dent Res 2003;82(special issue A).
23. Papathanasiou A, Kastali S, Perry RD, Kugel G. Clinical evaluation of a 35% hydrogen peroxide in-office whitening system. Compend Contin Educ Dent 2002;23:335-44.
24.Gultz J, Kaim J, Scherer W, Gupta H. Two in office bleaching systems: a scanning electron microscope study. Compend Contin Educ Dent 1999;20:965-70.
25. Goldstein RE, Garber DA. Complete dental bleaching. Chicago: Quintessence; 1995.
26. Matis BA, Gaiao U, Blackman D, Schultz FA, Eckert G. In vivo degradation of bleaching gel used in whitening teeth. JADA 1999; 130:227-35.
27. Matis BA. Degradation of gel in tray whitening. Compend Contin Educ Dent 2000;21(supplement):S28-S35.

Copyright ©2004 American Dental Association. All rights reserved.