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A Clinical Evaluation of Two In-Office Bleaching Products

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Clinical Relevance

With increased patient demand for esthetic improvements, bleaching has become a popular treatment in dentistry, and new bleaching products are being introduced to the practice. In this study, two in-office products performed similarly. After applying the second in-office bleaching treatment, tooth lightness improved. Hence, a single in-office treatment is not the maximum whiteness that can be achieved for a patient.

SUMMARY

This half-mouth design, two-week treatment phase, combined with an 11-week evaluation double-blinded randomized clinical trial was conducted to compare two in-office bleaching products, StarBrite (35% hydrogen peroxide) with Opalescence Xtra Boost (38% hydrogen peroxide), for degree of color change of teeth, any relapse effect (darkening) associated with discontinued use and gingival irritation and tooth sensitivity associated with use. The degree of color change and relapse was evaluated by using a colorimeter, shade guide and color slide photographs. Participants self-evaluated their gingival irritation and tooth sensitivity. They recorded daily the level of gingival irritation and tooth sensitivity experienced during the first three weeks of the study.

The results of this study showed no statistical difference between products during active treatment periods and any follow-up visits using the three-color evaluation methods. Color relapse began after the bleaching treatments were finished and continued until the fifth week, after which no further significant changes appeared. Also, there was no statistical difference in gingival irritation and tooth sensitivity between the products.

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INTRODUCTION

Cosmetic dentistry has become a very important part of restorative dental practice. The appearance and color of teeth is important to many individuals seeking dental treatment. Dentistry has succeeded in preserving natural teeth, even in older patients, so that lighter-colored teeth have become attainable for most people. Vital bleaching has been accepted as a method for treating discolored teeth. Increased interest in treating tooth staining and discoloration is demonstrated by the

large number of tooth whitening agents appearing on the market. Today, the majority of practitioners perform vital tooth bleaching on patients with discolored teeth with a high rate of success (Christensen, 1998). Bleaching is the most conservative treatment for discolored teeth when compared to other treatment modalities, such as veneers, crowns or composite bonding (Barghi, 1998).

Although at-home bleaching has increased dramatically in popularity, in-office bleaching products are still in demand and strongly promoted by manufacturers (Blankenau, Goldstein & Haywood, 1999). There are still many indications for in-office bleaching. These include cases where a patient cannot wear bleaching trays, or when patients want to have their teeth bleached quickly by applying several in-office treatments and are unwilling to wait two weeks for at-home techniques. Moreover, in selected cases, in-office bleaching sometimes augments the whitening effects of at-home bleaching (Barghi, 1998). Results of a published survey of general practitioners showed that 33% of dentists in the United States use in-office bleaching (Clinical Research Associates, 2001).

This study compared the ability of two different in-office bleaching products to lighten teeth. It was also designed to evaluate any relapse effects associated with discontinued use, and tooth sensitivity and gingival irritation associated with the bleaching treatments.

METHODS AND MATERIALS

Twenty subjects volunteered to participate in this study and signed a consent form prior to participating. All 20 subjects met the inclusion/exclusion criteria (Table 1).

A half-mouth design was used, in which each patient's six maxillary anterior teeth were bleached, with the bleaching products assigned to either the right or left anterior teeth. Each patient served as his or her own control. The assignment was conducted randomly by flipping a coin.

Two commercially available bleaching agents were used; StarBrite (Interdent, Inc, Los Angeles, CA, USA) Bleaching Gel with 35% hydrogen peroxide (which has received the ADA Seal of Acceptance) and Opalescence Xtra Boost (Ultradent Products, Inc, South Jordan, UT, USA) Bleaching Gel with 38% hydrogen peroxide. Manufacturers' instructions for handling and application were followed for both products used in this study.

All subjects received a dental screening and prophylaxis prior to beginning the study, using a fluoridated paste (Nupro Supreme, Dentsply Int, York, PA, USA) to remove extrinsic stains. The prophylaxis was performed one week prior to the active treatment phase being initiated. The preoperative evaluation was performed on the maxillary anterior teeth and their surrounding tissues; however, the gingival index was performed on all teeth using the Loe-Silness Gingival Index (Loe & Silness, 1963).

For each subject, an alginate impression was taken of the maxillary arch using Jeltrate Plus (Caulk Division Dentsply International Inc, Milford, DE, USA), into which Silky-Rock stone (Whip Mix Corp, Louisville, KY, USA) was poured. The resulting cast was used to construct a positioning jig with palatal coverage to ensure consistent positioning of the colorimeter (Chroma Meter CR-321, Minolta, Ramsey, NJ, USA). The Eichhold Positioning System with Pindex dual-pin precision attachment (Coltene/Whaledent Inc, Mahwah, NJ, USA) was used in this study (Mokhlis & others, 2000). At each appointment, color evaluation was performed using the following three methods:

1. Photographs recorded with Ectachrome Elite 100, 35-mm film (Kodak, Rochester, NY, USA) at each appointment in the same area with color corrected lighting. At the end of the study, slide photographs were projected onto an image of 3.0 x 4.5 feet and compared for color differences between the right and left sides by two independent evaluators. The degree of color difference was ranked: 0=no change; 1=slight; 2=moderate and 3=significant difference.

2. Subjective shade guide matching by an independent, experienced evaluator using the Trubyte Bioform

Table 1: *Inclusion and Exclusion Criteria*

Inclusion Criteria	Exclusion Criteria
Candidates must have all six maxillary teeth	Candidates with a history of any medical disease that may interfere with the study or require special considerations
The maxillary anterior teeth should not have more than 1/6 of the labial surface restored, and the location of the restoration, if any, must not interfere with placement of the colorimeter	Candidates who have had professionally applied in-office or at-home bleaching procedures in the past three years
Candidates must be willing to sign a consent form	Candidates who have used tobacco products during the past 30 days
Candidates must be at least 18 years of age	Candidates who have gross pathology in the oral cavity
Candidates must be able to return periodic examinations	Candidates with a gingival index score for greater than 1.0
Candidates must be willing to refrain from using tobacco products during the study period	Candidates who are pregnant or lactating
The maxillary anterior teeth must be darker than B -54 and lighter than B-4 shade tabs on the Truebyte Bioform Color Ordered shade guide	Candidates with tetracycline-stained teeth

Color Ordered Shade Guide (Dentsply Int, York, PA, USA).

3. Colorimeter measurements (Matis & others, 1998; Zekonis & others, 2003). During evaluations, each of the six anterior maxillary teeth was color measured three different times. The colorimeter was calibrated before each subject. The colorimeter measures the color of teeth based on the CIE L* a* b* color space system. This system was defined by the International Commission on Illumination in 1967 and is referred to as CIELAB. The L* represents the value (lightness or darkness); a* is the measurement along the red-green axis and b* is the measurement along the yellow–blue axis. A positive a* value indicates the red direction, while negative a* value indicates the green direction. Also, a positive b* value indicates the yellow direction, while a negative b* value indicates the blue direction. Total color differences or distances between the two colors (ΔE) were calculated using the formula:

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

A rubber dam was used to isolate and protect the soft tissue. Also, OpalDam (Ultradent Products, Inc), a light-cure resin was used at the midline as a barrier to separate the two bleaching gels. It was extended interproximally between the central incisors into the incisal embrasure at a width of 2 mm facially and 6 mm-8 mm lingually, then cured for 10 seconds (Figure 1).

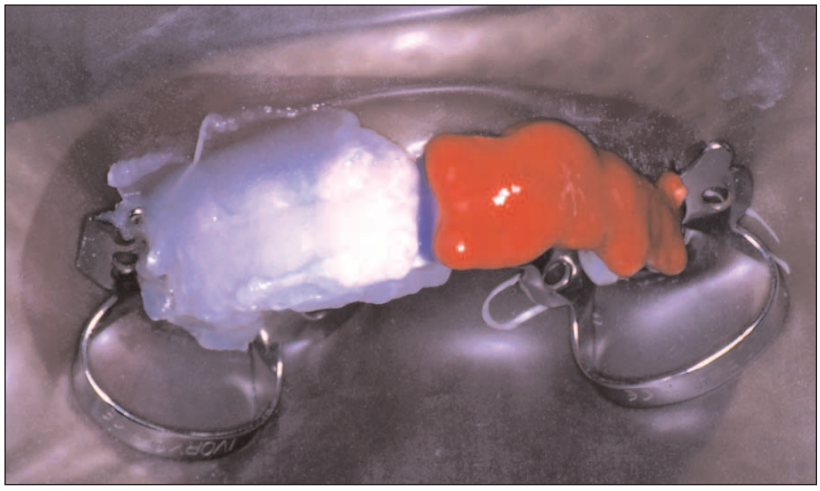

Figure 1. *Isolation technique and gel application.*

At the initial appointment, the subjects received a color evaluation of their maxillary anterior teeth using the three measurement methods to determine the initial color (baseline). At the same appointment, the sides of the arch on which the products would be used were determined on a random basis. The specified isolation techniques were performed, and both products were applied on their respective sides. No color evaluation was conducted immediately after the bleaching process because of the dehydration effect of the bleaching treatment. At week one, subjects returned for color measurement and the second bleaching procedure. Only color evaluations were accomplished on the second, fifth and eleventh week appointments. Table 2 shows the data collection design.

StarBrite and Opalescence Xtra Boost were mixed and handled according to manufacturers' instructions. For StarBrite, two hydrogen peroxide ampoules were added to one powder tub, then two energizer ampoules were added to the mix prior to applying the gel. For Opalescence Xtra Boost, activator and bleaching agent were mixed using the syringes provided by the manufacturer. After applying for five minutes, both whitening gels were stirred using a brush, while remaining on the teeth. The gels were allowed to remain on the teeth for a total of 10 minutes. The gels were then rinsed off and the teeth dried. Both procedures were repeated two more times at the same sitting, providing a total of 30 minutes of bleaching with both agents.

During the 11 weeks of the study, subjects were asked to brush their teeth with fluoridated, non-desensitizing, non-whitening toothpaste twice daily. They were given a form on which they recorded daily the level of tooth sensitivity and gingival irritation they experienced during the first three weeks of the study. Tooth sensitivity was defined as any sensitivity from cold temperature, while gingival irritation was defined as any sensitivity or discomfort from food and tooth brushing. Candidates recorded any gingival irritation or tooth sensitivity (indicating the side of the arch) into one of five categories: 1) none, 2) slight, 3) moderate, 4) considerable or 5) severe.

Table 2: *Data Collection Design*

Base Line		Week 1 (1 Week After 1st Bleaching Treatment)		Week 2 (1 Week After 2nd Bleaching Treatment)	Week 5	Week 11
Color measurement	1st bleaching treatment	Color measurement	2nd bleaching treatment	Color measurement	Color measurement	Color measurement

STATISTICAL METHODS

Analysis of variance (ANOVA) was used for comparing baseline L*, a*, b*, shade guide rank, ΔL*, Δa*, Δb*

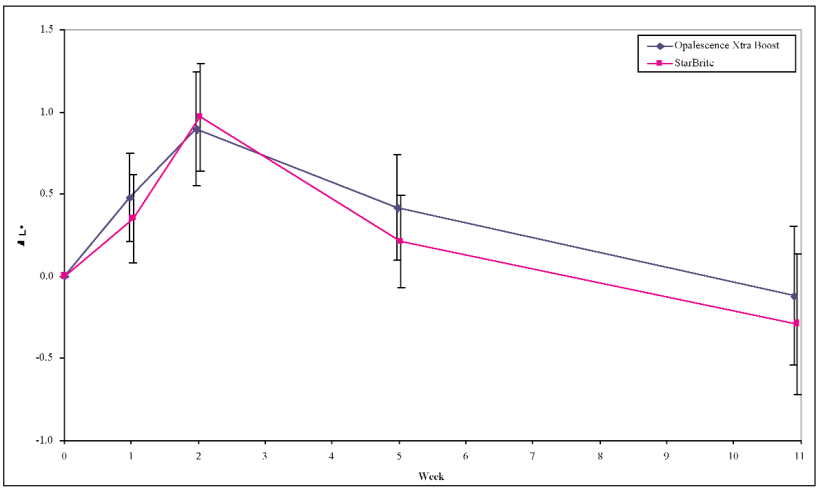

Figure 2. *ΔL* for Opalescence Xtra Boost and StarBrite showing error bars.*

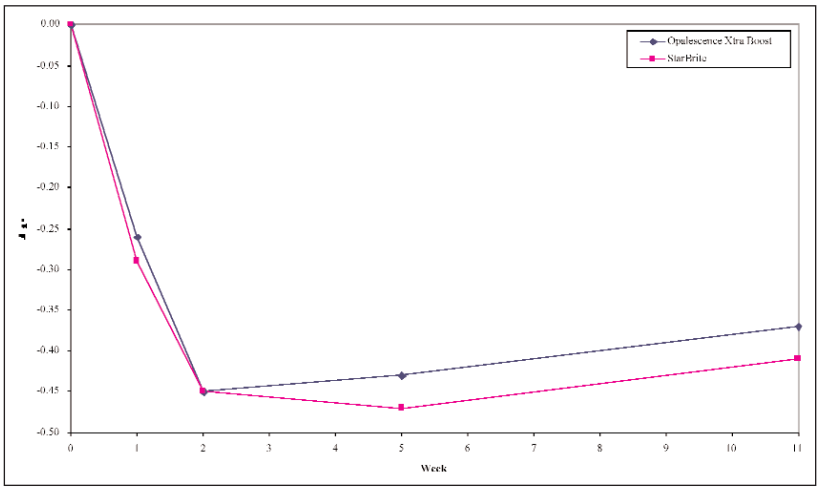

Figure 3. *Δa* for Opalescence Xtra Boost and StarBrite.*

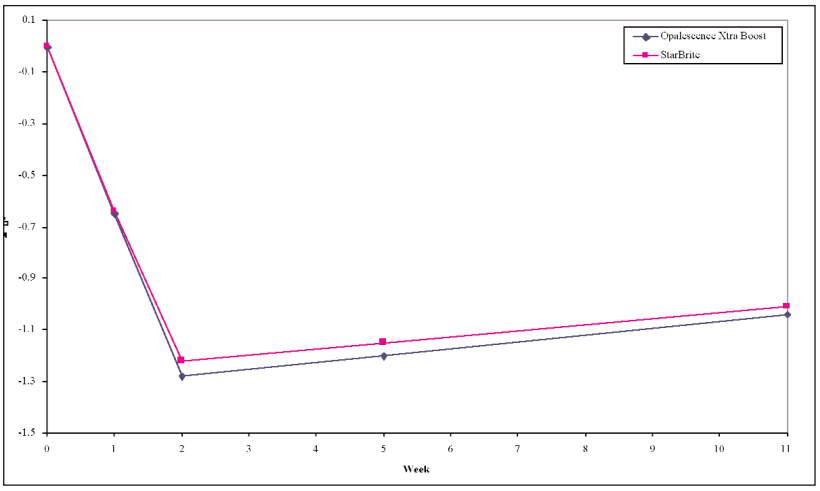

Figure 4. *Δb* for Opalescence Xtra Boost and StarBrite.*

ΔE and Δ shade guide. It was also used for comparing daily gingival irritation and tooth sensitivity. Wilcoxon Sign Rank tests were used to determine significant differences in tooth color by slide assessment.

RESULTS

Twenty subjects were enrolled and completed the study. Ten participants were female (50%) and 10 male (50%), with an age range from 30 to 71 years, with an average age of 55 years.

Chroma Meter Data

At baseline, the products did not have significantly different L* (p=0.38), a* (p=0.96) or b* (p=0.84) colorimeter measurements. At 1, 2, 5 and 11 weeks, the products were not significantly different in ΔL* (p=0.74) (Figure 2), Δa* (p=0.41) (Figure 3), Δb* (p=0.76) (Figure 4) and ΔE (p=0.36) (Figure 5). This was for overall examinations and any individual follow-up examination (ΔL* p=0.99, 0.94, 0.88 and 0.97), (Δa* p=0.89, 1.00, 0.77 and 0.78), (Δb* p=1.00, 0.98, 0.99 and 1.00) and (ΔE p=0.98, 0.91, 0.22 and 1.00) for all teeth and separately for centrals, laterals and cuspids, respectively.

Shade Guide Data

At baseline, the products did not have a significantly different shade guide (p=0.74). The products were not significantly different in the delta shade guide overall (p=0.65) or for any individual follow-up examination (p=1.00, 1.00, 1.00 and 0.97 for one week, two weeks, five weeks and 11 weeks, respectively) for all teeth and separately for centrals, laterals and cuspids (Figure 6).

Slide Assessment Data

At baseline, the products did not have significantly different slide assessments (p=1.00) or at any follow-up examination (p=0.25 at one week, p=1.00 at all other examinations) (Table 3). Figures 7-9 show clinical pictures at baseline and after one and two in-office bleaching applications.

Sensitivity Data

Opalescence Xtra Boost and StarBrite did not have significantly different gingival irritation (p=0.27) and tooth sensitivity (p=0.36) for all days pooled or for any of the individual days (gingival p>0.13) (tooth p>0.37) (Figures 10-11).

DISCUSSION

In this study, the authors did not measure the changes in tooth color immediately after

bleaching treatment, because they did not want dehydration of the teeth to affect the measurements. It has been found that rubber dam isolation can cause the teeth to dehydrate, and the researchers needed to wait at least 30 minutes after isolation removal in order to rehydrate the teeth (Russell, Gulfraz & Moss, 2000). Color evaluation was postponed until one week after the bleaching treatment. This avoided any dehydration effect from being included erroneously in the color evaluation data. Changes were measured before the first and second bleaching treatment and at week two, five and 11 after baseline. The amount of change in CIE L*a*b* and shade guide that occurred immediately after the bleaching treatment and during the seven days following the bleaching treatment were not measured and, therefore, the maximum changes and rebound effects during that period are unknown.

Because of the half-mouth design used for this study, all comparisons were within-subject and the standard deviations shown in the tables were between-subject. This design helps to reduce patient variations.

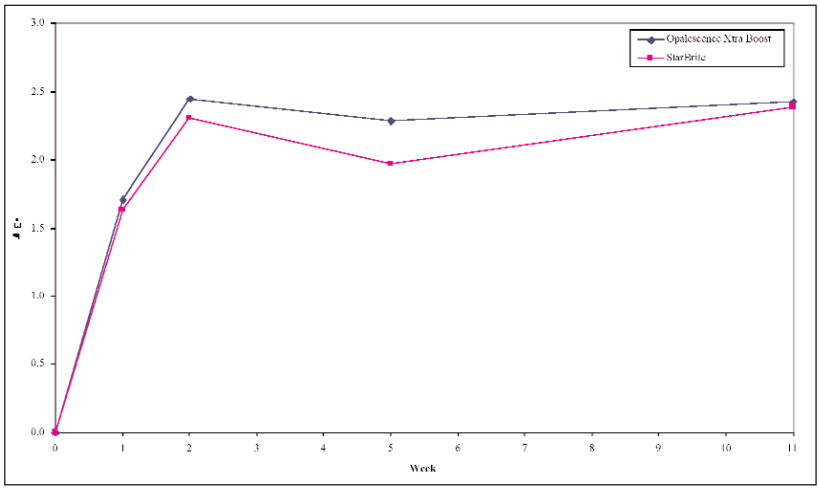

Figure 5. *ΔE for Opalescence Xtra Boost and StarBrite.*

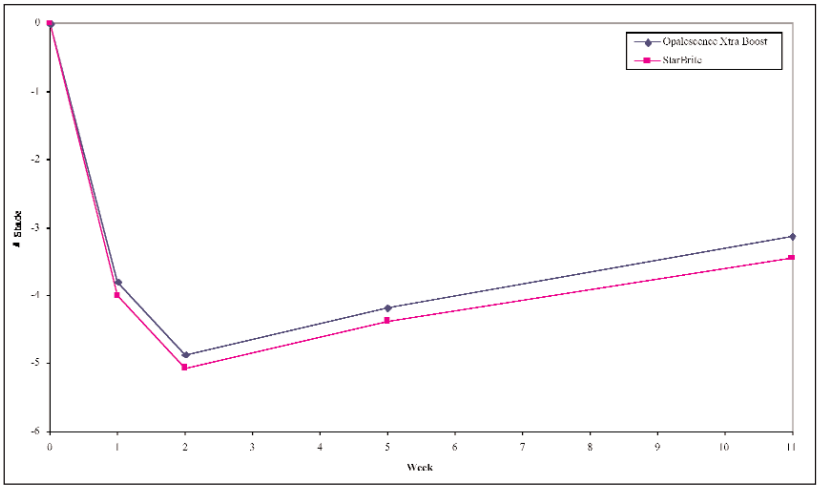

Figure 6. *Δ Shade for Opalescence Xtra Boost and StarBrite.*

One must be careful when comparing results from different bleaching studies. It is generally believed that peroxide concentration is related to efficacy. However, current evidence suggests that the technique for applying the product, including the number of applications and duration of each bleaching application, can be of equal importance (Lu, Margiotta & Nathoo, 2001).

At two weeks, mean ΔE (total color change) reached 2.45 for Opalescence Xtra Boost and 2.31 for StarBrite, which meant that subjects achieved the same results clinically. This disagrees with mean ΔE obtained by Zekonis and others (2003), who compared in-office and at-home bleaching procedures using a half-mouth design. Zekonis and others (2003) reached 4.33 for mean ΔE for the in-office treatment using StarBrite.

Two concepts might explain the difference in brightness attained after two bleaching treatments, which was a Δ 4.4 L* by Zekonis and others (2003) compared to Δ 1.0 L*, which was achieved in this study. The first concept is that the dehydration effect was included in the color evaluation data when the data was recorded 15 minutes after the bleaching treatment in the previously mentioned study. The second concept is that the latent peroxide from the at-home bleaching present in the patients' saliva may have augmented the bleaching effect from the in-office bleaching, because both bleaching treatments were carried out for the same period of time. Studies (Wattanapayungkul & others, 1999; Al-Qunaian, 2003) that investigated the degradation of carbamide peroxide during the first hour found that the total amount of

Table 3: *Slide Assessment Data for Opalescence Xtra Boost and StarBrite*

	StarBrite Lighter		No Difference		Opalescence Xtra Boost Lighter	
Week	#	%	#	%	#	%
0	0	0%	20	100%	0	0%
1	0	0%	17	85%	3	15%
2	0	0%	20	100%	0	0%
5	0	0%	20	100%	0	0%
11	0	0%	19	95%	1	5%

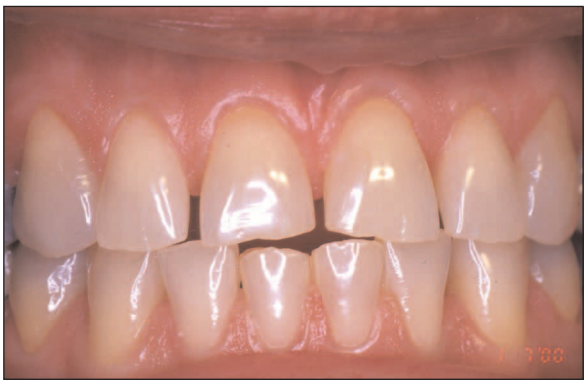

Figure 7. *Clinical picture at baseline.*

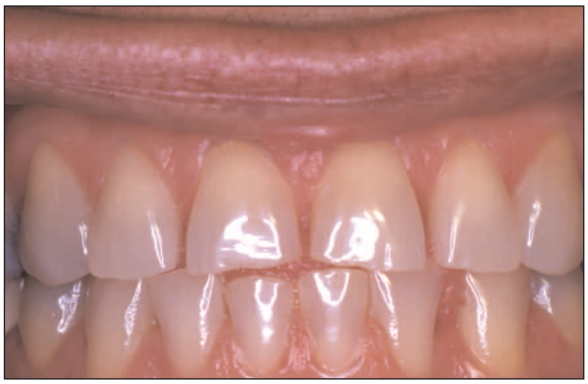

Figure 8. *Clinical picture after the first in-office bleaching application.*

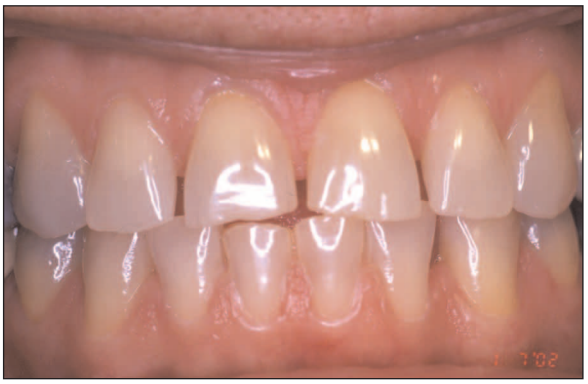

Figure 9. *Clinical picture after the second in-office bleaching application.*

hydrogen peroxide in patients' saliva was highest during the first hour. Wattanapayungkul and others (1999) measured the amount of hydrogen peroxide in patients' saliva when they used 10% carbamide peroxide. Wattanapayungkul and others (1999) found that there was a mean of 2.14 mg of carbamide peroxide in saliva collected up to one hour of wearing the bleaching tray. Dahl and Becher (1995) have shown that a safe amount of ingesting carbamide peroxide is 10 mg with a safety factor of 100.

The labeled hydrogen peroxide concentration for the products is 35% for StarBrite and 38% for Opalescence Xtra Boost. The authors determined by chemical analysis the actual concentration of the products they tested. Matis (2000, 2003) has shown that the labeled concentration is not always the actual concentration. Tests were accomplished in triplicate and showed that the mean hydrogen peroxide percent for StarBrite was 31.5% and 35.8% for Opalescence Xtra Boost.

In this study, color relapse (darkening) began after the bleaching treatments were finished and continued until the fifth week, after which there was no significant change in ΔL^*, Δa^*, Δb^* and ΔE for either product. This relapse pattern agrees with Zekonis and others (2003). This means that two weeks are needed for the color to stabilize after the bleaching treatments have been completed. Therefore, practitioners are recommended to wait at least two weeks post-bleaching when making a good color match, if they are planning to place a tooth-colored restorative material in the anterior teeth.

Subjective shade guide matching was performed using the Trubyte Bioform Color Ordered Shade Guide. At week two, Δ shade guide reached the peak of –4.87 for Opalescence Xtra Boost and -5.07 for StarBrite after two bleaching applications. It is interesting to note that the shade guide rank difference was –3.1 for Opalescence Xtra Boost and –3.4 for StarBrite at the end of the study, yet the ΔL^* values were slightly negative from baseline. This can be accounted for by the fact that there was a decrease in b* (about 1.00), which represented a decrease in yellowness. This decrease in yellowness was probably the reason for the lower shade guide values.

Using the shade guide, the color stabilized by the fifth week ($p>0.05$) at a level significantly different from the baseline for Opalescence Xtra Boost ($p=0.0001$) and StarBrite ($p=0.0001$). It is difficult to compare between studies in subjective data, because disagreement between dentists in shade matching the same tooth has been documented by Culpepper (1970), but the same relapse pattern and color stabilization was also found by Zekonis and others (2003).

Two independent evaluators performed the subjective slide evaluation. The Kappa (k) inter-evaluator reliability was determined to be 0.66, with 98% agreement between the two evaluators. A trend of Opalescence Xtra Boost's side being lighter was found using the subjective slide evaluation, which diminished after the bleaching treatments were finished. Three participants (15%) were assessed having the Opalescence Xtra Boost's side lighter at week one, and one participant (5%) was assessed having the Opalescence Xtra Boost's side lighter at week 11, but it was not statistically sig-

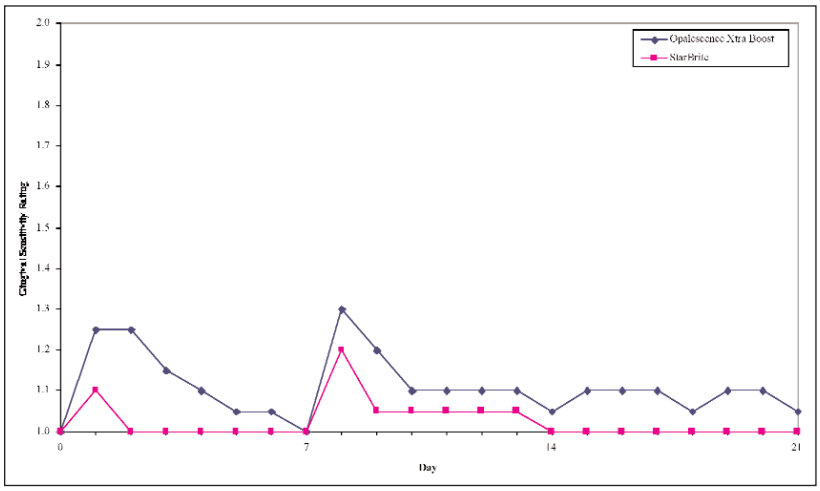

Figure 10. *Gingival irritation for Opalescence Xtra Boost and StarBrite.*

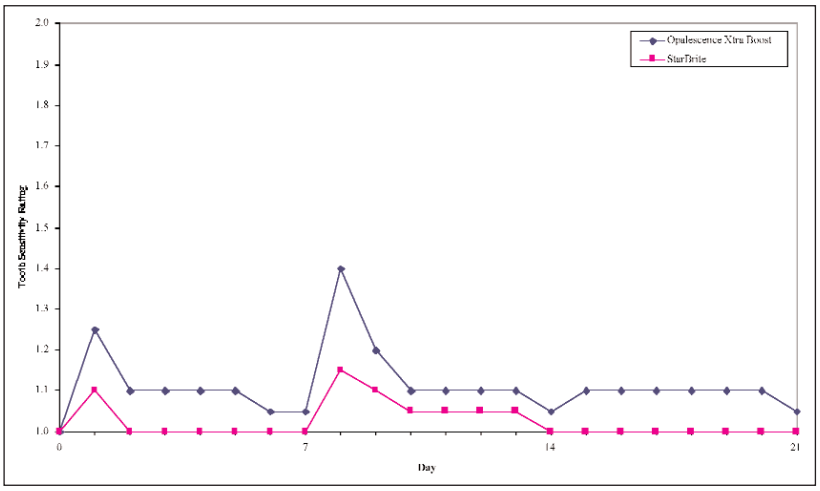

Figure 11. *Tooth sensitivity for Opalescence Xtra Boost and StarBrite.*

nificant. Opalescence Xtra Boost and StarBrite did not have significantly different patient-assessed lightness at any follow-up examination (p=0.25 at one week; p=1.00 at all other examinations).

All participants started with no gingival irritation or tooth sensitivity before any bleaching treatment. Some participants reported slight gingival irritation and tooth sensitivity by both products. However, it took only two days for the gingival irritation and tooth sensitivity to return to the pretreatment level. This pattern could be explained by the acute exposure to high concentration of hydrogen peroxide followed by a week of no bleaching treatment, which allowed the sensitivity to abate.

CONCLUSIONS

The results of this study showed no statistical difference between the two in-office bleaching products during active treatment periods or at any of the follow-up visits according to all three-color evaluation methods. Color relapse began after the bleaching treatments were finished and continued until the fifth week, after which there were no significant changes. Also, there was no statistical difference between products regarding gingival irritation and tooth sensitivity. Within the bounds of this study, the peroxide composition is the most important component of the bleaching materials. Other formula components are much less significant.

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