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Clinical Research

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Clinical Relevance

An ADA-accepted at-home bleaching treatment is more effective, more acceptable to patients and requires less chairtime compared to an ADA-accepted in-office bleaching treatment.

SUMMARY

This three-month, single-blind clinical study compared two whitening treatments, at-home with 10% carbamide peroxide and in-office with 35% hydrogen peroxide, for the degree of color change of teeth, color relapse and tooth and gum sensitivity. The degree of color change and color relapse was evaluated by using a colorimeter,

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shade guide and color slide photography. Teeth and gum sensitivity were self-evaluated by the subjects, who recorded daily the tooth and gum sensitivity they experienced during the two weeks of treatment and one week post-treatment.

A 14-day at-home treatment was compared with 60 minutes of in-office treatment (two appointments, each with three 10-minute applications). The at-home treatment produced significantly lighter teeth than the in-office treatment during all active-treatment periods and follow-up visits according to all three-color evaluation methods. Color relapse for both treatments stabilized by six weeks. At-home treatment resulted in statistically significant higher gum sensitivity than inoffice treatment during the latter part of the first week. For tooth sensitivity there were no significant differences between the treatments. Eighty four percent of the subjects reported at-home treatment to be more effective and 16% found no difference between the treatments. There were no subjects who reported the in-office treatment to be superior in tooth whitening to the at-home treatment.

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INTRODUCTION

Cosmetic dentistry has become an important part of restorative dental practice in recent years. The appearance of teeth is very important to patients of all ages and is often associated with a perception of health and fitness. Cosmetic procedures have become more available as standards of living have improved. Dentistry has also succeeded in reducing the frequency and severity of caries and periodontal diseases, which has led to the preservation of natural teeth even in older patients. Since white teeth are believed to be associated with health and beauty, lighter-colored teeth have become desirable. It is up to our profession to offer the treatment to allow patients to achieve their goals safely. Vital tooth bleaching can be performed with a high rate of success as a more conservative measure than restorative treatment, such as porcelain veneers, crowns or composite bonding (Barghi, 1998).

In-office vital tooth bleaching has been used for many years in dentistry and is known to be a reliable technique for quickly lightening discolored teeth (Faunce, 1983; Jordan & Boksman 1984; Nathanson & Parra, 1987). Today, patients have the choice of having the procedure done in-office or at-home. At-home vital tooth bleaching also has been shown to produce a significant perceivable change in color, reducing chair time and, therefore, it has become very popular (Jones & others, 1999; Kihn, Barnes & Romberg, 2000; Swift, May & Wilder, 1999).

This study evaluated the degree of color change of teeth, color relapse and tooth and gum sensitivity associated with ADA-accepted in-office and at-home tooth whitening agents.

METHODS AND MATERIALS

At the screening visit, subjects were evaluated to determine if they met the inclusion (Table 1) and exclusion (Table 2) criteria. During the same appointment all subjects had two alginate impressions of their maxillary arch taken with Jeltrate Plus (Caulk Division, Dentsply International Inc, Milford, DE 19963, USA). Study models were made from Silky-Rock stone (Whip Mix Corp, Louisville, KY 40217, USA). One model was used to fabricate the night-time bleaching tray for athome bleaching according to the manufacturer's recommendations.

The labial surfaces of anterior teeth of the study model were blocked out from approximately 1.0 mm incisal to the gingival margin to the incisal edge with LC Block-Out Resin (Ultradent Products, Inc, South Jordan, UT 84095, USA). This created reservoirs for the bleaching gel in the custom tray. The custom maxillary tray was fabricated from a 0.035-inch soft tray (Sof-Tray, Ultradent Products, Inc) by a vacuum formTable 1: Inclusion Criteria

- 1. Have all six maxillary anterior teeth darker than B-54 and lighter than B-85 on the Trubyte Bioform Color Ordered shade guide.
- 2. Have no maxillary anterior teeth with more than 1/6 of the labial surface of their natural tooth covered with a restoration.
- 3. Be at least 18 years of age.
- Be willing to refrain from the use of tobacco products during the study period.

Table 2: Exclusion Criteria

- 1. History of any medical disease that may interfere with the study or require special consideration.
- 2. Use of tobacco products during past 30 days.
- 3. Past use of professionally-applied or prescribed in-office or at-home bleaching agents.
- 4. Gingival index score greater than 1.0.
- 5. Pregnant or lactating women.
- 6. Tetracycline stained teeth.



Figure 5. A soft tray was custom-made and cut in half for each patient to use for half-mouth arch only.



Figure 6. In-office treatment was performed for half of the maxillary arch that was not treated by at-home bleaching.

ing technique. The excess was trimmed on the labial and lingual surfaces just incisal to the free gingival margin. The trays were then cut in half between teeth #8 and #9 (Figure 5). Patients received only the side intended for at-home bleaching. The second study model was used to construct a positioning jig with full palatal coverage to ensure proper repositioning of the colorimeter. The Eichhold Coupling System (Mokhlis, 1999; Panich, 1999) with Pindex dual-pin precision attachments (Coltene/Whaledent Inc, Mahwah, NJ 07430, USA) was used in this study.

Twenty subjects qualified to participate in this study; 19 completed the study. One subject was excluded from the study because the facial anatomy did not allow for proper positioning of the colorimeter. Patients signed a consent form approved by the Institutional Review Board at Indiana University-Purdue University Indianapolis (IUPUI). All subjects received a prophylaxis by a licensed hygienist or dentist at least one week prior to beginning the study. Extrinsic dental stains were removed with a fluoride containing dental prophylaxis paste (Nupro Supreme, Dentsply Int, York, PA 17404, USA).

During the baseline appointment and at one, two, three, six and 12 weeks, color evaluation was performed using three methods: 1) subjective shade guide matching by an independent experienced evaluator using the Trubyte Bioform Color Ordered shade guide (Dentsply Int); 2) by comparing clinical photographs recorded on Elite Chrome 100 35 mm slide film (Kodak, Rochester, NY 14650, USA). The slide photographs were projected to an image of 3.0 X 4.5 feet in size and were compared for color changes by two independent evaluators. The evaluators categorized the left and right side of the maxillary arch into one of four gradients: 0-no difference, 1-slight difference, 2-moderate difference, 3-large difference. 3) Objective color measurements using a color measuring device (Chroma Meter CR 321, Minolta, Ramsey, NJ 07446, USA). The six anterior maxillary teeth were measured colorimetrically three different times at each appointment. The colorimeter measures the color of the 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 (Commission Internationale de L'Eclairage, 1978). 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. Total color differences or distances between two colors (ΔE) was calculated using the formula: $\Delta E = [(\Delta L^*)2 +$ $(\Delta a^*)^2$ + $(\Delta b^*)^2$]1/2 (Commission Internationale de L'Eclairage, 1978).

All subjects were given a sensitivity sheet on which they indicated the level of tooth and gum sensitivity they experienced during the two weeks of treatment and for seven days after the treatment. Subjects recorded any tooth and/or gum sensitivity (indicating whether the left and/or right) in one of five categories: 1-none, 2-slight, 3-moderate, 4-considerable, 5-severe. Patients who experienced more than a moderate degree of sensitivity received potassium nitrate desensitizing gel (UltraEZ, Ultradent Products, Inc) and were instructed to place the gel on the sensitive side for 20 minutes three times a day.

Two commercially available bleaching agents, accepted by the ADA, were used in this study: Opalescence Tooth Whitening Gel with 10% carbamide peroxide (Ultradent Products, Inc) for at-home bleaching and StarBrite (Interdent, Inc, Los Angeles, CA 90232, USA) with 35% hydrogen peroxide for in-office bleaching. Manufacturers' instructions for handling and application were followed for all products used in this study. The bleaching treatments were randomly applied to the right or left maxillary anterior teeth. The side was determined by flipping a coin.

Custom-made at-home half-arch bleaching trays were tried in the mouth and adjustments were made so that they were retained snugly. Patients were instructed verbally and by hands-on practical demonstration regarding the use bleaching gels and custommade bleaching trays according to manufacturers' instructions. Patients were asked to continue this procedure for 14 nights. All patients were asked to brush their teeth at least twice a day for oral hygiene standardization.

At the first week appointment a rubber dam was placed and the in-office procedure was accomplished on the side of the maxillary arch not treated by athome bleaching (Figure 6). Both the subjects and all measurement personnel wore protective evewear with side shields during the in-office tooth whitening procedure. The gel was mixed and applied to the teeth according to the manufacturer's recommendations. After five minutes the bleaching gel was stirred on both the lingual and facial tooth surfaces. The gel remained on the teeth for a total of 10 minutes. The teeth were then rinsed and dried. The entire procedure was repeated two more times. Total in-office bleaching procedure time was approximately 30 minutes. After completion of the bleaching procedure, the rubber dam was removed and the teeth were allowed to rehydrate for 15 minutes. A color evaluation was performed using all three methods to determine the color of the teeth. Patients used the at-home bleaching trays with the same instructions for another week and returned for the second in-office bleaching appointment.

During the week two appointment, the same protocol was followed as at the first week's appointment. At this appointment, subjects discontinued at-home bleaching. Subjects returned all used and unused syringes with bleaching gels to ensure completion of the athome bleaching. Subjects returned in three, six and 12 weeks from baseline evaluation for the same type-color evaluation that was conducted during the baseline evaluation.

Subjects completed a questionnaire at their last evaluation visit, recording their personal responses to the questions: 1) did they notice a difference in the color of upper teeth between the right and the left sides and 2) what was their overall impression of the effect of athome bleaching at two weeks and 12 weeks.

STATISTICAL METHODS

The products were compared for differences in baseline mean L*, a*, b* and shade guide rank using repeated measures analysis of variance (ANOVA), with fixed effects for product, tooth type and the product-by-tooth type interaction. The products were compared for differences in mean ΔL^* , Δa^* , Δb^* , ΔE and Δ shade guide rank using repeated measures ANOVA, with fixed effects for product, tooth type, time and all interactions between the three factors and baseline measurements as covariates. ANOVA, with fixed effects for product, day and the product-by-day interaction and random subject effects, were used to compare daily gum and tooth sensitivities. Wilcoxon Sign Rank tests were used to determine significance of differences in tooth color by



Figure 1. ΔE for at-home and in-office treatments.

slide assessment, tooth lightness and tooth and gum sensitivity in the subject survey.

RESULTS

Nineteen subjects completed the study. Ten were assigned the at-home (Opalescence 10% CP) bleaching treatment on the right side of the maxillary arch and nine used the at-home bleaching treatment on the left side. Opposite sides of the maxillary arches were treated with the in-office (StarBrite 35% HP) bleaching gel.

Chroma Meter Data

The products did not have significantly different baseline L* (p=0.56), a* (p=0.76) or b* (p=0.52). The athome treatment had significantly more color change in Δ L*, Δ a*, Δ b* and Δ E overall (p=0.0001) and at each individual follow-up examination (p=0.0001) than the in-office treatment (Figure 1, Tables 3 and 4).

Shade Guide Data

The Δ shade guide rank order for teeth that received the at-home treatment was significantly different from the teeth that received the in-office treatment overall (*p*=0.0001) and at each follow-up examination (*p*=0.0001) (Figure 2, Table 4).

Clinical Slide Data

The assessment of clinical slides showed no significant differences between the right and left sides at baseline (p=1.00). At-home treatment was significantly lighter than in-office treatment at every follow-up examination (p=0.0001) (Table 6).

Sensitivity Data

At-home treatment had significantly higher gum sensitivity than in-office treatment for day four (p=0.0042), day five (p=0.0001), day six (p=0.0269) and day seven (p=0.0269); the overall test, combining all days, was also significant (p=0.0378) (Figure 3). The overall test, combining all days for tooth sensitivity, did not reach statistical significance (p=0.0631). None of the tooth sensitivity comparisons for the individual days were significant between treatments (p>0.15) (Figure 4).

Table 3: Mean ΔL^* , Δa^* and Δb^* with Standard Deviations (SD) for At-Home (At-H) and In-Office (In-O) Treatments												
Week	Mean ∆L*			Mean ∆a*				Mean ∆b*				
	At-H	SD	In-O	SD	At-H	SD	In-O	SD	At-H	SD	In-O	SD
1	8.57	2.92	3.43	1.72	-1.22	0.42	-0.19	0.26	-5.08	1.52	-1.49	1.05
2	10.16	3.56	4.45	1.86	-1.43	0.53	-0.54	0.28	-6.18	1.56	-2.49	1.03
3	5.90	2.85	3.10	1.69	-1.12	0.58	-0.60	0.45	-4.32	1.98	-1.71	2.36
6	4.92	2.81	2.75	1.18	-0.90	0.54	-0.53	0.34	-3.78	1.18	-1.57	1.02
12	4.91	2.61	2.55	1.43	-0.93	0.45	-0.51	0.27	-3.46	1.34	-1.57	1.04

Survey Data

According to the subjects survey data, at-home treatment produced significantly lighter teeth than in-office treatment (p=0.0001), 84% of subjects reported at-

Table 4: Mean ΔE and Δ Shade Guide (SG) with Standard Deviations (SD) for At- Home (At-H) and In-Office (In-O) Treatments								
Week	Mean ΔE				Mean ∆SG			
	At-H	SD	In-O	SD	At-H	SD	In-O	SD
1	10.30	2.60	4.05	1.62	-12.98	4.19	-9.14	3.72
2	12.32	2.89	5.32	1.93	-15.98	2.50	-10.54	4.13
3	7.83	2.77	4.33	1.95	-14.75	3.53	-10.60	4.57
6	6.64	2.48	3.63	1.12	-13.75	3.35	-9.42	3.53
12	6.39	2.39	3.48	1.27	-13.95	3.94	-9.93	4.46

Table 5: Subjects Survey for Lighter Side and Difference in Sensitivity						
In-Office Lighter	No Difference	At-Home Lighter				
# of subjects (%)	# of subjects (%)	# of subjects (%)				
0 (0%)	3 (16%)	16 (84%)				
In-Office More Sensitivity	No Difference	At-Home More Sensitivity				
# of subjects (%)	# of subjects (%)	# of subjects (%)				
3 (16%)	14 (74%)	2 (11%)				

Table 6: Slide Assessment for At-Home and In-Office Treatments							
	In-Office Lighter	No Difference	At-Home Lighter				
Week							
	# of subjects (%)	# of subjects (%)	# of subjects (%)				
0	0 (0%)	19 (100%)	0 (0%)				
1	0 (0%)	0 (0%)	18 (100%)				
2	0 (0%)	0 (0%)	19 (100%)				
3	0 (0%)	0 (0%)	19 (100%)				
6	0 (0%)	0 (0%)	19 (100%)				
12	0 (0%)	0 (0%)	19 (100%)				
1							



Figure 2. Δ shade for at-home and in-office treatments.

home treatment to be more efficient and 16% reported no difference between the treatments. No subjects found the in-office treatment to be superior to the athome treatment. Sixteen percent of the subjects found

the in-office treatment to cause more sensitivity than the at-home treatment, 74% found no difference between treatments and 11% found that at-home treatment caused more sensitivity than in-office treatment (Table 5).

DISCUSSION

There is a general belief among the general population and anecdotal evidence among dentist practitioners that in-office bleaching is superior to at-home bleaching. Some manufacturers claim that high concentration hydrogen peroxide bleaching agents are superior and faster compared to the low concentration carbamide peroxide at-home products (Technical Specifications, 2001). However, no published studies that compare these two treatments are available in the scientific literature. Haywood and Berry (2001) have stated that the efficacy of in-office bleaching may not be as good as athome bleaching treatment.

Objective Evaluation

At two weeks, average ΔE reached 12.32 for at-home treatment and 5.32 for in-office treatment. Clinically, this could mean that patients would need longer in-office treatment time to achieve the same results as with at-home treatment. The average ΔE for at-home treat-



Figure 3. Gum sensitivity for at-home and in-office treatments.

ment obtained in this study agrees with the average ΔE obtained by Matis and others (1998), who reached an average 10.4 for average ΔE after two weeks of bleaching with 10% carbamide peroxide. Another study by Mousa (1998) investigated tooth color change with 10%



Figure 4. Tooth sensitivity for at-home and in-office treatments.

and 15% carbamide peroxide. He found that after two weeks of bleaching with 10% carbamide peroxide, average ΔE reached 8.79.

There is no available scientific literature to compare in-office (35% hydrogen peroxide) treatment results with results received for the same product with the chroma Meter CR-321 (Minolta) color-measuring device. In this study, color relapse began after bleaching treatments were finished and continued until the sixth week, after which there was no significant change in ΔL^* , Δa^* , Δb^* and ΔE for either treatment, however, there were significant differences between the treatments.

The at-home treatment color relapse pattern agrees with a six-month *in vivo* study by Matis and others (1998), a six-week study by Mousa (1998) and a 12-week study by Mokhlis (1999). In-office treatment color change and color relapse was at a lower rate compared to the at-home treatment. Color stabilized by six weeks for both at-home and in-office treatments at a level significantly different from baseline. At six weeks ΔE

Figure 7 a-f: Subject #14 was a 25 year-old female patient. The subject's right side was treated with at-home agent; the left side was treated with in-office agent.



Figure 7a. Baseline.



Figure 7c. Week 2.



Figure 7b. Week 1.



Figure 7d. Week 3.



Figure 7e. Week 6.

decreased to 6.64 for at-home treatment and to 3.63 for in-office treatment. In the study by Matis and others (1998), the six-week ΔE value for 10% carbamide peroxide was 5.7. Mousa (1998) found that the six-week ΔE value was 5.13.

Subjective Evaluation

Subjective shade guide matching was performed using the Trubyte Bioform Color Order Shade Guide, which consists of 24 shade tabs. After two and six weeks of bleaching with at-home and in-office treatments, Δ shade guide rank reached the peak of -15.98 and -10.54, respectively. The Δ shade guide rank obtained in this study agrees with the study by Mousa (1998). where Δ shade guide rank reached the peak of -15.40 after two weeks of bleaching with 10% carbamide peroxide and with the study by Matis and others (1998), where peak Δ shade guide reached -17.5. In this study, during color relapse Δ shade guide rank decreased to -13.75 for at-home and to -9.42 for in-office treatment at six weeks. These results agree with studies by Mousa (1998) and Matis and others (1998), where sixth week Δ shade guide rank values decreased to -13.13 and -12.2, respectively. The subjective slide evaluation in this study showed a statistically significant difference between the treatments, both during the active treatment period and at each follow-up visit. The colorimeter and shade guide measurements agree and reinforce this finding (Figure 7 a-f).

Some subjects experienced mild gingival or tooth sensitivity associated with at-home bleaching, which lasted up to two weeks. One subject experienced moderate tooth and gum sensitivity during the first week of athome treatment. The subject used desensitizing gel for 20 minutes before at-home bleaching treatment for a couple days, which reduced sensitivity.

CONCLUSIONS

A 14-day at-home treatment was compared with 60 minutes of in-office treatment (two appointments, each



Figure 7f. Week 12.

with three 10-minute applications). The at-home (10% carbamide peroxide) treatment sides were significantly different from the in-office (35% hydrogen peroxide) treatment sides during all active treatment periods and during follow-up visits according to all three color evaluation methods.

At-home treatment had significantly higher gum sensitivity than in-office treatment during the latter part of the first week of the study. For tooth sensitivity, there were no significant differences between treatments.

Eighty four percent of the subjects reported the athome treatment to be more efficient and 16% reported no difference in lightness between the treatments. None of the subjects reported the in-office bleaching treatment to be superior to the at-home bleaching treatment.

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