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A Clinical Evaluation of Two In-office Bleaching Regimens With and Without Tray Bleaching

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Clinical Relevance

In-office tooth bleaching, followed by at-home bleaching with trays, was shown to be more effective than in-office bleaching without at-home bleaching. Three 15-minute applications of an in-office bleaching agent were more effective than one 40-minute application.

SUMMARY

This study evaluated the degree of color change of teeth, the rebound effect and the sensitivities of teeth and gingiva associated with the use of an in-office bleaching agent followed by an at-home bleaching agent to lighten stained teeth in an *in vivo* study. Thirty-seven subjects who met the Inclusion/Exclusion criteria were divided into two cells. Twenty-five subjects received three 15-minute in-office bleaching treatments in succession with 36% hydrogen peroxide (HP) on the maxillary anterior teeth, followed by at-home overnight bleaching with 15% carbamide peroxide (CP) for seven days on one side of the dental arch. Twelve other subjects received a 40-minute in-office bleaching treatment on their maxillary anterior teeth, followed by at-home overnight bleaching for seven days on one side of the dental arch with the same product. The cells of teeth on the other side of the dental arch received the same in-office treatment but were not bleached overnight for seven days.

Color was subjectively evaluated using the Vitapan Classical Shade Guide and was objectively evaluated using the Chroma Meter at the baseline appointment, immediately after in-office bleaching and at 4, 7 and 14 days and 3

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months after the in-office treatment. For two weeks, the subjects completed sensitivity evaluations of gingival tissues and hard tooth tissues.

The cells that did not receive the at-home bleaching had significantly less color change than the cells that received at-home bleaching. The cell that was bleached for 40 minutes and received the at-home treatment had significantly less overall change (ΔE) at 14 days and 3 months than the cell that received three 15-minute treatments with the at-home treatment.

Throughout the study, the subjects in the three 15-minute treatment cells had less gingival and tooth sensitivity than the other cells.

INTRODUCTION

Cosmetic dentistry has become a very important part of the restorative dental practice. Patients have rated teeth as the most important feature of an attractive face.[1] Cosmetic procedures have become increasingly more desirable and, with improvements in the standard of living, patients are asking dentists about tooth whitening. Whiter teeth are perceived as being associated with health and beauty. It is the responsibility of dentists to offer techniques and expertise that can help patients achieve their goals safely. Vital tooth bleaching is a more conservative treatment for discolored teeth compared with restorative treatments, such as porcelain veneers, crowns or composite bonding.[2]

Hydrogen peroxide's ability to lighten tooth color is not fully understood, although it is known to diffuse through enamel and dentin relatively easily, because of its molecular weight.[3] There is a chemical theory that explains hydrogen peroxide's bleaching action. Active hydrogen peroxide breaks down into $H_2O + O_2$ and forms a perhydroxyl-free radical (HO_2) for a short period of time. The great oxidative power of the free radical may break-up the large macromolecular stain into smaller stain molecules.[4] The simpler molecules formed by the bleaching process reflect more light, changing the tooth's appearance to a lighter shade.[5]

Another theory for the mechanism of action of a peroxide is that it opens the carbon-ring of pigment molecules, converting them to chains that are lighter in color. Yellow double-bond carbon compounds are converted into almost colorless hydroxyl compounds.[6]

Bleaching with carbamide peroxide differs from hydrogen peroxide. First, carbamide peroxide breaks down into urea and hydrogen peroxide. Ten percent carbamide peroxide breaks down into two products: 6.6% urea + 3.4% hydrogen peroxide. The urea further breaks down into carbon dioxide and ammonia.[8] The hydrogen peroxide breaks down into $H_2O + O_2$ through an intermediary perhydroxyl free radical, HO_2.

Throughout the past decade, tooth bleaching has undergone significant changes. Currently, patients have the choice of undergoing vital tooth bleaching procedures in the dental office or at home. About 10 years ago, a study was reported[7] where in-office and at-home bleaching treatments were used consecutively.

In-office bleaching uses 15-38% hydrogen peroxide gel or liquid.[8] Because of the high concentration of the agents used, oral soft tissues must be protected during the procedure. Protecting the soft tissues and isolating the teeth can be accomplished with a rubber dam,[9-10] light polymerized resins[6] or other materials. Following placement of a tissue protectant, hydrogen peroxide gel or liquid is applied to the discolored teeth.

Carbamide peroxide and/or hydrogen peroxide is used for at-home bleaching treatments. There are many different concentrations of carbamide and hydrogen peroxide offered by manufacturers. They range from 10% to more than 45% for carbamide peroxide and from 3% to 14% for hydrogen peroxide. Ten percent carbamide peroxide is equivalent to approximately a 3.4% solution of hydrogen peroxide.[6]

Today, many of the manufacturers recommend at-home bleaching after the initial in-office procedure. When bleaching with carbamide peroxide, the manufacturers recommend patients use custom-fitted trays overnight or for a minimum of two hours a day. When bleaching with hydrogen peroxide, the manufacturers recommend 30 minutes to one hour a day.

The current study: 1) evaluated the effectiveness of a 36% hydrogen peroxide in-office system used once for 40 minutes or 3 times for 15 minutes each, 2) evaluated the effectiveness of use and non-use of a 15% carbamide peroxide agent in a tray for seven nights on one-half of the maxillary arch of teeth whitened in the dental office 3) and, in the above cases, documented reversal in tooth whitening for three months. The results of the current study will help clinicians choose the best methods and times for tooth whitening.

METHODS AND MATERIALS

Prior to participating in this bleaching study, patients signed a consent form. The form and research protocol were reviewed and approved by the Institutional Review Board at Indiana University-Purdue University, Indianapolis (IUPUI), Indianapolis, IN, USA. The inclusion and exclusion criteria used in the study are listed in Table 1.

All subjects received a complete oral prophylaxis by a licensed hygienist or dentist at least one week, but not more than two months prior to starting the bleaching process. Extrinsic stains were removed with a fluoride dental prophylaxis paste (NUPRO Paste, Dentsply Professional Division, York, PA, USA).

The subjects were informed that this study required in-office bleaching followed by at-home bleaching. The four study groups (Table 2) were defined using a 2 x 2 factorial design with three 15-minute applications or a single 40-minute application of NUPRO White Gold in-office tooth whitener (NGWIO) (Dentsply Professional Division) containing 36% HP with and without the use of NUPRO White Gold at-home gel (NWGAH) (Dentsply Professional Division) containing 15% CP in a tray for seven days. The tooth whitening process was performed on the subjects' maxillary anterior teeth. Because of the split-mouth design, both sides of the subjects' mouths received the same number of in-office applications, with only one side of the maxillary anterior dental arch receiving the at-home gel application. Twenty-five subjects received three 15-minute applications NGWIO (D3) and 12 subjects were given one 40-minute application of the same whitening gel (D1).

At the beginning of the baseline appointment, a color evaluation was performed using two methods: 1) subjective shade guide matching of the middle-third of the maxillary anterior teeth with the Vitapan Classical Shade Guide (Vita Zahnfabrik, Bad Sackingen, Germany) arranged by value order (lightest to darkest) (Table 3) and 2) use of a color measuring device to determine the color of the middle-third of the teeth (Chroma Meter, Model CR-321, Minolta, Ramsey, NJ, USA). Three independent readings were taken and the mean of their value was plotted. All the evaluations were conducted in the same geographic location with color-corrected overhead lighting, with the same examiner performing all of the evaluations.

The colorimeter was used to measure 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.[11] 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 depth of red, while a negative a* value indicates green. Alternatively, a positive b* value indicates the depth of yellow and a negative b* value indicates blue. The total color difference or distance between two colors (ΔE) was calculated using the formula: $\Delta E = [(\Delta L^*)^2+(\Delta a^*)^2+(\Delta b^*)^2]^{1/2}$.[11]

The soft tissues were evaluated on all maxillary and mandibular teeth using a Loe-Silness Gingival Index.[12] The Loe-Silness Gingival Index criteria are: 0=no inflammation; 1=slight inflammation (no bleeding); 2=moderate inflammation (delayed bleeding); 3=severe inflammation (spontaneous bleeding). At the same appointment, all subjects had one alginate maxillary arch impression taken with Jeltrate PLUS (Dentsply LD Caulk Division, Milford DE, USA), from which a study model was made from Silky-Rock stone (Whip Mix Corp, Louisville, KY, USA). A custom tray was fabricated with reservoirs for the maxillary arch. The tray was trimmed on the labial and lingual surfaces so that it was slightly shy of the gingival soft tissue margin.

The subjects and all personnel involved with the treatment wore protective eyewear during the in-office whitening procedures. Isolation of the gingival tissue from the bleaching agent was accomplished using a light-cured resin dam (NUPRO White Gold Gingival Dam, Dentsply Professional Division).

Table 1: *Inclusion and Exclusion Criteria*

Inclusion Criteria	Exclusion Criteria
• Have all six maxillary anterior teeth. • Have no maxillary anterior teeth with more than 1/6 of their labial surface covered with a restoration. • Be willing to sign a consent form. • Be at least 18 years of age. • Be able to return for periodic examinations. • Be willing to refrain from the use of tobacco products during the study period. • Have maxillary anterior teeth that are between A-3 and C-4 shades on the Vita Classic Shade Guide.	• Have a history of any medical disease that may interfere with the study or require special considerations. • Use tobacco products during past 30 days. • Have current or previous use of professionally applied or prescribed "in-office" or "at-home" bleaching agents. • Have a gross pathology in the oral cavity (excluding caries). • Have a gingival index score greater than 1.0. • Pregnant or lactating women. • Tetracycline-stained teeth.

Table 2: *Study Groups*

	Three 15-minute In-office Applications (36% HP)	One 40-minute In-office Application (36% HP)
7 day at-home gel (15% CP)	D3+	D1+
No at-home gel	D3-	D1-

Table 3: *Vitapan Classical Shade Guide Tabs From Lightest to Darkest in Numeric Order*

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

NWGIO was applied to the facial surfaces of the teeth and allowed to remain during treatment. The teeth were then rinsed and dried, but not desiccated. After drying, the resin dam was removed. Shade tab matching, photographs and colorimeter readings were accomplished immediately after the in-office bleaching process.

The subjects were asked to flip a coin to randomly select on which side, right or left, they would wear the at-home bleaching tray. The tray was cut, and the subjects were shown how to load it with gel, place it on the teeth and remove the gel from the tray after using it overnight. The subjects were given the half-mouth-bleaching tray to wear overnight on one-half of their maxillary arch for seven days. The patients placed NWGAH in the tray and used it overnight, starting with the day of the in-office bleaching. The subjects returned at 4, 7, 14 and 84 days after the in-office procedure for the same color evaluations and photos that were obtained during the baseline evaluation.

Throughout the 84 days of the study, the subjects were asked to brush their teeth with a non-whitening dentifrice (Crest Cavity Protection, Procter & Gamble, Cincinnati, OH, USA) at least twice a day to standardize their oral hygiene. All subjects were given a sensitivity sheet on which to record daily the maximum level of tooth and gingival sensitivity on the bleached side of their maxillary arch during the bleaching treatment and for the seven days after completing the at-home treatment. The subjects used a VAS (Visual Analog Scale) scale to record their daily tooth and/or gingival sensitivity. VAS is an instrument that measures a characteristic or attitude that is believed to span a continuum of values and cannot be objectively measured.[13] Subjects who had more than a moderate degree of sensitivity on either side of their maxillary arch were asked to return to the dental school to receive a potassium nitrate desensitizing gel.

Analyses of the whitening effect were performed separately for the D1 and D3 subgroups. The treatments were compared for differences in sensitivity, baseline color and color change using repeated measures analysis of variance (ANOVA). The ANOVAs for gingival and tooth sensitivity included terms for treatment, day and treatment-by-day interaction. The ANOVAs allowed for a correlation between the two treatments within a subject, different variances for each day and different correlations between days within a treatment. The analyses for sensitivity were performed using the ranks of scores that satisfy the ANOVA assumptions. The ANOVAs for baseline color included terms for tooth type, treatment and type-by-treatment interaction, as well as correlating the teeth within a subject. The ANOVAs for color change included terms for baseline color, tooth type, treatment, exam and interactions between the tooth type, treatment and exam. The ANOVAS allowed for a correlation between the two treatments within a subject, different variances for each exam and different correlations between exams within a treatment. The analyses for gingival and tooth sensitivity were similar; *p*-values were not adjusted for multiple comparisons.

Additional analyses were performed to compare the D1 and D3 studies. The analyses were similar to those described above, with additional terms to match the number of in-office applications and interactions with the number of applications

RESULTS

There were 34 subjects who attended all of the evaluations; two subjects did not attend the three-month examination but were still included in the analyses; one other subject dropped out of the study due to a family emergency and was not included in the analyses. In the D1 group, the mean age was 50.8 years and included six (50%) females and six (50%) males. The D3 group mean age was 56.6 years and had 16 (67%) females and 8 (33%) males. The youngest subject was 35 years in both the D1 and D3 group, while the oldest was age 70 in the D1 group and age 78 in the D3 group.

At the baseline measurements, there were no color differences between D1 + and D1 - (p=0.56 for L*, p=0.26 for a*, p=0.78 for b* and p=1.00 for shade guide). And, there were no baseline color differences between D3 + or D3 - (p=0.78 for L*, p=0.72 for a*, p=0.31 for b* and p=1.00 for shades guide) (Table 4). However, the D3 subjects had a significantly higher baseline b* (p=0.0081) than the D1 subjects. There were no other baseline color differences between D1 and D3 (p=0.88 for L*, p=0.97 for a*, p=0.72 for shade guide). The color changes in E and the shade guide are illustrated graphically in Figures 1 and 2. The data for those graphs are also documented (Table 5).

The D1- and D1+ treatments were not significantly different immediately after in-office bleaching (p>0.22). However, all of the other follow-up examinations after in-office bleaching in the D1- group had significantly less color change (ΔL*, Δa*, Δb*, ΔE, Δshade guide) than D1+ (p<0.04). The color change did not sta-

Table 4: *Mean Baseline Color (SD)*

Group	N	L*	a*	b*	Vita Shade
D3+	24	47.39 (2.61)	-0.46 (0.57)	3.59 (1.92)	13.19 (1.66)
D3-	24	47.48 (2.53)	-0.48 (0.54)	3.93 (2.19)	13.19 (1.66)
D1+	12	48.01 (2.07)	-0.42 (0.32)	1.88 (2.10)	12.97 (1.94)
D1-	12	48.26 (1.92)	-0.53 (0.26)	1.98 (2.02)	12.97 (1.94)

Table 5: *Mean Color Change (SD)*

Group	Day	N	ΔL*	Δa*	Δb*	ΔE	ΔVita Shade
D3+	Post	24	4.08 (0.31)	-0.42 (0.06)	-2.69 (0.17)	5.05 (0.32)	-6.40 (0.52)
	4	24	6.84 (0.48)	-1.03 (0.09)	-4.25 (0.24)	8.26 (0.48)	-8.44 (0.53)
	7	24	7.72 (0.51)	-1.28 (0.09)	-4.65 (0.25)	9.23 (0.52)	-9.04 (0.56)
	14	24	4.62 (0.50)	-0.95 (0.09)	-3.59 (0.31)	6.13 (0.54)	-8.26 (0.65)
	84	23	2.58 (0.21)	-0.79 (0.08)	-2.58 (0.19)	3.92 (0.22)	-7.45 (0.51)
D3-	Post	24	3.86 (0.35)	-0.40 (0.06)	-3.03 (0.31)	5.10 (0.44)	-6.38 (0.53)
	4	24	2.54 (0.27)	-0.47 (0.05)	-2.02 (0.32)	3.59 (0.35)	-5.82 (0.47)
	7	24	1.29 (0.18)	-0.41 (0.05)	-1.18 (0.27)	2.29 (0.26)	-5.68 (0.46)
	14	24	1.17 (0.18)	-0.35 (0.05)	-1.36 (0.27)	2.25 (0.27)	-5.33 (0.59)
	84	23	1.27 (0.22)	-0.34 (0.05)	-1.28 (0.22)	2.26 (0.23)	-4.87 (0.52)
D1+	Post	12	5.22 (0.48)	-0.36 (0.09)	-2.97 (0.32)	6.10 (0.54)	-6.25 (0.86)
	4	12	6.56 (0.50)	-1.21 (0.09)	-4.12 (0.27)	7.92 (0.50)	-8.58 (0.71)
	7	12	7.12 (0.54)	-1.46 (0.10)	-4.28 (0.35)	8.53 (0.56)	-9.28 (0.57)
	14	12	3.07 (0.57)	-1.09 (0.12)	-2.38 (0.43)	4.49 (0.60)	-8.69 (0.46)
	84	11	1.03 (0.32)	-0.64 (0.06)	-1.34 (0.28)	2.26 (0.31)	-7.27 (0.92)
D1-	Post	12	5.24 (0.48)	-0.40 (0.06)	-3.21 (0.32)	6.26 (0.54)	-6.25 (0.86)
	4	12	2.25 (0.44)	-0.73 (0.07)	-1.95 (0.41)	3.40 (0.51)	-5.61 (0.85)
	7	12	0.62 (0.48)	-0.65 (0.07)	-0.93 (0.39)	2.41 (0.37)	-4.39 (0.66)
	14	12	0.00 (0.43)	-0.47 (0.06)	-0.37 (0.35)	1.77 (0.33)	-4.36 (0.70)
	84	11	-0.08 (0.32)	-0.28 (0.06)	-0.27 (0.46)	1.73 (0.39)	-4.24 (0.75)

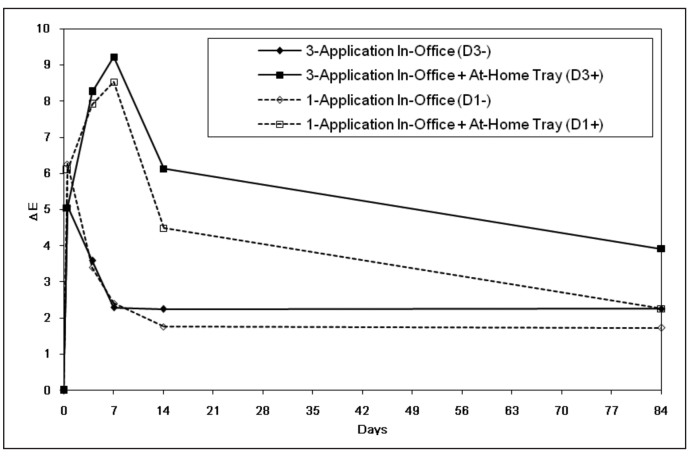

Figure 1: *Mean change in E for in-office and in-office + at-home tray.*

bilize for either product upon completion of the current study.

The D3- and D3+ treatments were not significantly different immediately after in-office bleaching ($p>0.37$). However, all of the other follow-up examinations after in-office bleaching in the D3- group had significantly less color change (ΔL*, Δa*, Δb*, ΔE, Δshade guide) than D3+ ($p<0.0001$). Color change did not stabilize for either D3- or D3+ upon completion of the study, which was an unexpected result. The D1+ group had significantly less overall color change (ΔE) at 2 weeks ($p=0.0417$) and 12 weeks ($p=0.0155$) compared with the D3+ group after at-home bleaching.

There were indications of a treatment-by-day interaction for sensitivity ($p=0.02$ for tooth sensitivity of D1 and $p=0.07$ for D3, $p=0.001$ for gingival sensitivity of D1 and $p=0.06$ for D3), indicating that the treatment comparisons need to be evaluated separately for each day. The D1- group had significantly lower tooth sensitivity (Figure 3) than D1+ for day 5 ($p=0.0471$), and D3- had significantly lower sensitivity than D3+ for days 4, 5 and 6 ($p<0.04$). The D1- group had significantly lower gingival sensitivity (Figure 4) than D1+ for day 1 ($p=0.0116$) and D3- had significantly lower sensitivity than D3+ for days 5 and 6 ($p<0.02$). D1 had significantly higher tooth sensitivity ($p=0.0478$) and gingival sensitivity ($p=0.0029$) than D3.

DISCUSSION

In-office bleaching has been shown to lighten teeth rapidly; however, there is often a considerable reversal of tooth whitening within two weeks of bleaching.[14-16] At-home mouthguard bleaching usually requires two-to-three weeks of treatment, but, generally, there is less of a reversal of tooth whitening than with in-office treatment. Combining both forms of treatment should shorten the bleaching time for clinicians and increase the "whitening" effect for patients. In the current study, a new in-office bleaching gel with a 36% hydrogen peroxide concentration was evaluated for one week in a single blind, split mouth design study with and without at-home bleaching using 15% carbamide peroxide in a tray with reservoirs. The current study evaluated the subjective and objective evaluation of tooth

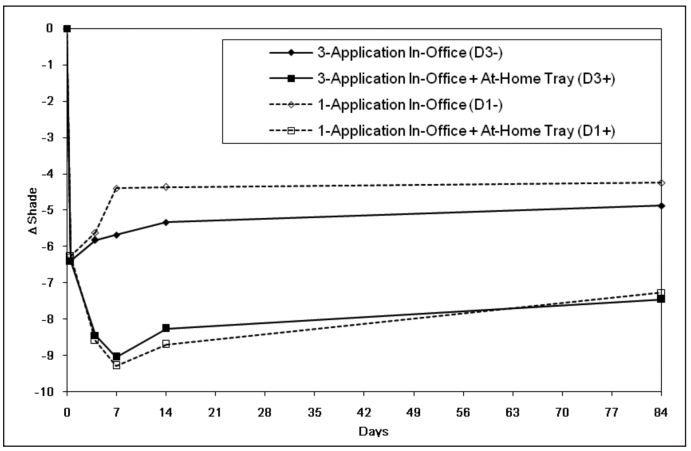

Figure 2: *Mean change in Vita Shade for in-office and in-office + at-home tray.*

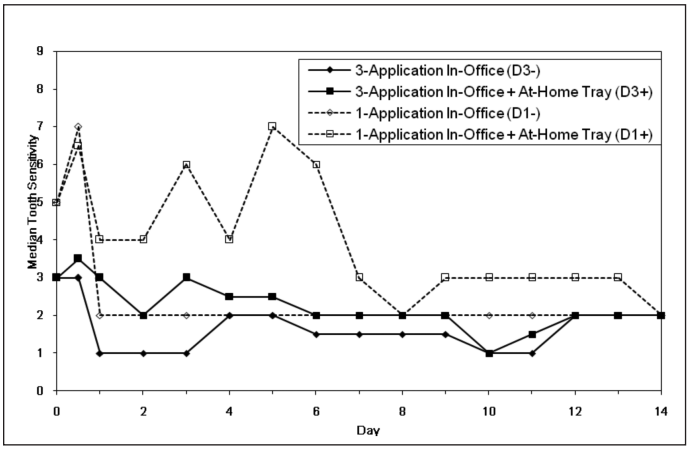

Figure 3: *Tooth sensitivity for in-office and at-home tray.*

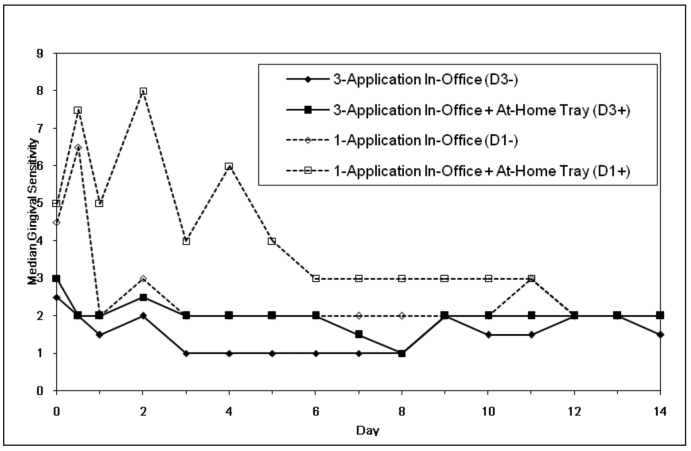

Figure 4: *Gingival sensitivity for in-office and at-home tray.*

color and reversal of color that occurs with one 40-minute gel application on 12 subjects or three 15-minute gel applications on 25 subjects.

The half-mouth design was used in five previous at-home or in-office studies.[17-21] Indications of crossover were evaluated between the two sides of the mouth by examining the means of the centrals and laterals, as well as the product comparison conclusions for the centrals and laterals. If crossover occurred, one would expect to see a mixing of the data results for the centrals when there were clear differences for the laterals. No consistent effects were observed throughout the five studies, indicating that there is no crossover effect with this study design.

The findings showed that both in-office bleaching treatments associated with at-home bleaching for seven days provided significant differences in L*, a*, b*, E and shade guide change measurements when compared to the teeth without at-home bleaching treatment. These results show that the new product worked well and that at-home bleaching increased the whitening effect of in-office bleaching treatments.

Comparing the single 40-minute application and the three 15-minute application treatments, there was a significant difference in overall color change (ΔE) at two weeks (p=0.0417) and 12 weeks (p=0.0155). Delta E data indicates that D3+ was significantly lighter than D3- and D1- after three months.

Gingival and tooth sensitivity were less in the D3- cell during the entire study, compared with the other cells in the study. Three 15-minute gel applications increased the whitening effect and decreased gingival or tooth sensitivity.

Several studies compared different in-office tooth whitening application times and agents.[7,22-23] For five days, Kugel and others reported on using 35% HP with and without 15% CP in a tray twice a day for one hour.[7] They reported that, immediately after the tooth whitening regimens, the group receiving only the in-office treatment lightened 4.8 Vita shades, and the group receiving the in-office and at-home treatments lightened 7.1 shades. Deliperi and others compared using 35% HP (Group 1) and 38% HP (Group 2) three times in succession during the same appointment or using it for 30 minutes followed by 10% CP in custom-formed trays for 60 minutes on three successive days.[22] In Group 1, Deliperi and others reported a mean change of 8.9 Vita shades immediately after bleaching and a change of 7.2 shades seven days after bleaching. In Group 2, there was a mean change of 9.1 shades immediately after bleaching cessation and a 7.2 shade change one week after bleaching cessation. Papathanasiou and others had subjects bleach with a 15% in-office bleaching agent for 30, 45 and 60 minutes.[23] One day later, the subjects began using an at-home 10% CP agent in a custom-fitted tray for seven successive nights. Those results documented a 4.9 Vita shade change immediately after a 30-minute in-office

treatment, a 6.4 shade change after a 45-minute treatment and a 5.1 shade change after a 60-minute treatment. After seven days of 10% CP at-home usage, those subjects who had initially bleached for 30 minutes had a shade change of 7.2; those subjects bleaching for 45 minutes had an 8.9 shade change and those who bleached for 60 minutes had a 9.0 shade change. The current study reported a 6.25 to 6.40 Vitapan color shade guide tab change immediately after-in-office bleaching and a 9.04 to 9.28 Vitapan color shade tab change after a combination of in-office and at-home bleaching for one week.

There are only two *in vivo* studies that determined the perceptibility of color using a colorimeter.[24-25] In one study,[24] it was determined that the mean color of 3.7 Delta E units, which existed between composite veneers and sound teeth, was rated as a perfect match in the oral environment. In the other *in vivo* study,[25] half of the observers perceived a color difference of 2.6 Delta E units with interchangeable right and left denture teeth in a denture base. The current study reported that there were differences of 3.9, 2.3, 2.3 and 1.7 Delta E units after three months in the D3+, D3-, D1+ and D1- groups, respectively.

CONCLUSIONS

The use of three applications of NUPRO White Gold in-office whitening significantly lightened teeth in the L*, a*, b*, E and Shade Guide parameters. The use of NUPRO White Gold at-home following the in-office procedure in both cells where it was used produced greater lightening in all the parameters that were measured, compared with either of the other two cells, where at-home bleaching was not used.

The subjects who received three 15-minute treatments had less gingival and tooth sensitivity than any of the other cells throughout the study.

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