One-Year Clinical Evaluation of the Efficacy of a New Daytime At-Home Bleaching Technique

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ABSTRACT

The aim of this study was to compare the clinical efficacy and side effects of a new daytime at-home bleaching technique (28% carbamide peroxide [CP] gel) with the overnight application of 10% CP and to determine the change of tooth color 1-year post-treatment. Twenty healthy volunteers were assigned to one of two sample groups of 10. All participants employed one of the two at-home bleaching systems: (1) the new daytime at-home bleaching system including 28% CP gel with a non-custom-fit tray (Meta Tray, Remedent, Deurle, Belgium) for 20 minutes, and (b) the conventional overnight at-home bleaching system with a 10% CP gel and a custom-fit tray (Opalescence PF, Ultradent, South Jordan, UT, USA) for 6 to 8 hours. Digital images and CIE (International Commission on Illumination) L^*, a^*, and b^* spectrophotometric measurements were taken at baseline, after the bleaching treatment and 1-year post-treatment. Tooth and gingival sensitivity was measured with a specially designed 4-point scale. Significant differences were found in L^*, a^*, and b^* values, between initial and post-treatment, for both bleaching systems ($p < 0.05$). However, no significant difference was detected between post-treatment and 1-year follow-up. The bleaching effectiveness of Opalescence PF was found to be superior to that of Meta Tray, considering the color parameter of ΔE ($p < 0.05$). Meta Tray provoked less tooth sensitivity ($p < 0.05$), however gingival sensitivity appeared more in this group ($p < 0.05$). Within the limitations of this study, it can be concluded that the new daytime at-home bleaching system tested (Meta Tray) produced significant bleaching effects. However, the clinical efficacy of the overnight bleaching system was found to be superior to the daytime at-home bleaching system evaluated in this study. The whitening effect remained similar 1-year after the bleaching treatment for both at-home bleaching systems.

CLINICAL SIGNIFICANCE

Although the new daytime at-home bleaching system tested exhibited significant bleaching effects, overnight bleaching with a 10% CP gel resulted in a higher bleaching effectiveness than this new system. Although the participants using the new bleaching system exhibited less tooth sensitivity probably because of the reduced contact time of bleaching gel with tooth surfaces, the application of the bleaching agent with a non-customized tray provoked more gingival sensitivity in this group.

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INTRODUCTION

Nightguard vital bleaching or at-home bleaching has become a popular method for restoring the color of discolored vital teeth since 1989.[1] The current bleaching methods are based upon hydrogen peroxide (HP) or carbamide peroxide (CP) as the active agent that penetrates through the tooth structure and produces free radicals, reactive oxygen molecules, and HP anions.[2,3] These reactive molecules attack the long-chained, dark-colored molecules and split them into smaller, less colored, and more diffusible molecules.

Vital tooth bleaching can be performed at home and in office. In-office bleaching agents contain high concentrations of CP (35–37%) or HP (30–35%), whereas at-home bleaching agents consist of low concentrations of both peroxides and are employed in a custom tray under the supervision of a dentist.[4,5] Home-administered vital bleaching in customized trays for overnight was described by Haywood and Heymann in 1989.[1] This procedure generally presents the same indications as in-office bleaching systems, with the added advantage of minor adverse effects.[6] At-home vital bleaching is probably the safest, most patient-pleasing method of obtaining effective tooth bleaching because of the noninvasive nature of this treatment. The most commonly employed active ingredient is 10% CP gel, which has shown satisfactory clinical results.[7–9] A meta-analysis of seven clinical studies indicated a significant mean change from baseline of 6.4 shade guide units according to the Vitapan Vita guide scale by the use of tray-based bleaching systems utilizing 10% CP gels.[7]

Although the overnight bleaching with the application of 10% CP exhibited desirable whitening effects, the long duration of the treatment directed the manufacturers toward developing new systems with shorter treatment times and with CP concentrations higher than 10%. Bleaching gels of 15 to 20% CP for 2 to 4 hours daytime application were developed. The investigations regarding these bleaching gels indicated that although the lower concentrations of CP take longer to whiten the teeth, eventually, they achieve the same result as the higher concentrations.[10] Then, bleaching systems with a CP concentration of more than 20% were marketed for 1 hour or less than 1 hour daytime applications. These bleaching systems have some advantages compared with the conventional overnight at-home bleaching systems, such as the shorter treatment period and the possibility of less tooth sensitivity because of the reduced contact time of bleaching gel with tooth surfaces. However, it is not clear whether using higher peroxide concentrations for less than 1 hour is as effective as longer treatments with lower concentrations because of the lack of clinical trials regarding this concept.

The aim of this study was to compare the clinical efficacy and side effects of a new daytime at-home bleaching system (28% CP gel) with the overnight application of 10% CP and to determine the change of tooth color 1 year after the bleaching procedures.

MATERIALS AND METHODS

Material Selection

Two different at-home bleaching systems were used. Meta Tray (Remedent, Deurle, Belgium) including 28% CP gel with a non-custom-fit tray was used in the experimental group, and Opalescence 10% CP gel (Ultradent, South Jordan, UT, USA) with a custom-fit tray was used in the control group.

Participant Selection

After approval of the study protocol by the Committee for Medical Ethics of Ege University, 20 adult subjects, aged between 20 and 30 years, requesting tooth bleaching were selected to participate in this randomized, controlled clinical trial. The written consent from each participant was obtained after the nature of the study and the possible risk of the treatments

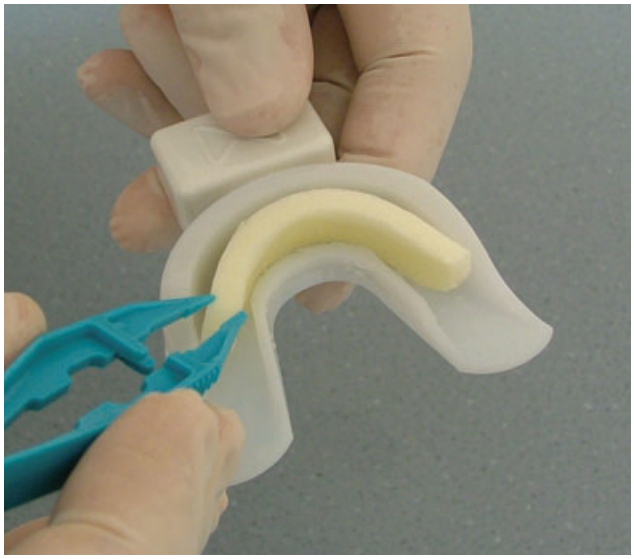

Figure 1. MetaFoam strip with 28% carbamide peroxide in the Meta Tray bleaching system.

had been explained. The inclusion/exclusion criteria were as follows:

Inclusion Criteria

1. Have all maxillary and mandibular anterior teeth with a shade mean of C1 or darker
2. No caries and restoration on the teeth to be bleached
3. Be between 20 and 30 years old
4. Be able to return for periodic controls
5. Consuming the products that stain teeth (coffee, red wine, tea, etc.) not more than five times in a day

Exclusion Criteria

1. Poor general or dental health
2. Fixed orthodontic appliances
3. Having hypersensitive teeth
4. Smoking
5. Current or previous use of bleaching agents
6. Pregnant or lactating women
7. Tetracycline-stained teeth
8. A history of allergies to tooth-whitening products

The participants received a professional tooth cleaning prior to the study and were asked to brush their teeth twice daily with a non-whitening dentifrice and a soft-bristled manual toothbrush. Initial L^*, a^*, and b^* values of the lower and upper left or right incisors and canines (60 teeth per each group) were measured using an intraoral dental spectrophotometer (Vita-Easyshade, Vident, Brea, CA, USA) by an examiner who did not know the treatment details of the patients. Three measurements were taken from the middle of each tooth. The L^* presents 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, a negative a^* value indicates the green direction, a positive b^* value indicates the yellow direction, and a negative b^* value indicates the blue direction. The initial photographs of all participants were taken by a digital camera.

Bleaching systems were used according to the manufacturers' instructions. The Meta Tray bleaching system is based on the MetaFoam strips with 28% CP gel (Figure 1). This system is composed of visible light, heat, and pressure. According to the manufacturer, this system delivers appropriate wavelength of visible light to stimulate the active whitening ingredients. The tray's patented heating element gently warms the MetaFoam strip. A proprietary foam strip keeps the peroxide solution warm and applies gentle pressure to keep the whitening gel evenly distributed throughout each treatment. The Meta Tray system includes a non-custom-fitted tray, MetaFoam strips, a rechargeable controller, and tweezers. During its application, the MetaFoam strip was opened and was inserted into

the mouth tray with the help of the tweezers. The tray was inserted into the mouth. The controller button was pressed to activate the tray for a 20-minute cycle. The unit beeps and automatically shuts itself off after 20 minutes to prevent overexposure. Thus, the tray was applied 20 minutes for each arch for 10 days.

Opalescence includes 10% CP gel used in a custom-fitted mouth tray. Alginate impressions of maxillary and mandibular arches were taken, cast models were generated, and treatment trays were fabricated for each patient. A 1-mm buccal reservoir was formed using a block-out material (LC Block-Out Resin, Ultradent). Custom-fitted trays with reservoirs for the teeth to be bleached were made from Sof-Tray® sheets (Ultradent). Scalloped design was used for the custom trays. Opalescence was used 6 to 8 hours during the night for 10 days.

L^*, a^*, and b^* values were always measured on the same upper and lower incisors and canines, and post-bleaching photographs were taken after the bleaching therapy and 1-year post-treatment.

Color differences for each sample were calculated between initial and post-treatment (ΔE1), between post-treatment and 1-year post-treatment (ΔE2), and between initial and 1-year post-treatment (ΔE3) using the following equation[11]:

$$\Delta E = \left[(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2\right]^{1/2}$$

For safety and acceptance monitoring of gingival and tooth sensitivity, participants were asked to record the total of wear daily and any intraoral adverse events in their teeth and gingiva. They evaluated the gingival and tooth sensitivity by a 4-point scale. (0—No changes noted, 1—Mild sensitivity, 2—Moderate sensitivity, and 3—Severe sensitivity).

At the end of the bleaching treatment, the presence or absence of lesions in the marginal gingiva related to treatment was examined. Differences between baseline L^*, a^*, and b^* values of the study groups were analyzed by a chi-square test. Differences in L^*, a^*, and b^* values before and post-treatment, and at 1-year post-treatment were tested with a repeated measure of analysis of variance and Scheffe's F-test. Differences in ΔE values were analyzed by the Mann–Whitney U-test, and differences in tooth sensitivity and gingival irritation were evaluated by a chi-square test.

RESULTS

All 20 participants completed this study. The average ages were 25 and 28 years, respectively, for Meta Tray and Opalescence groups. The average treatment time of each group was 4,340 ± 235 minutes in the Opalescence group and 200 minutes in the Meta Tray group. There were no statistically significant differences in the mean baseline L^*, a^*, and b^* values of the study groups.

Significant differences were found in L^*, a^*, and b^* values, between initial and post-treatment, and between initial and 1-year post-treatment, for both treatment systems ($p < 0.05$). For both Opalescence and Meta Tray groups, initial L^* values were lower, and initial a^* and b^* values were higher than post-treatment and after 1-year values ($p < 0.05$) (Table 1). However, no significant difference was detected between post-treatment and 1-year follow-up.

The Opalescence group demonstrated significantly higher ΔE1 and ΔE3 values than the Meta Tray ($p < 0.05$) (Table 2). However, there were no significant differences between ΔE1 and ΔE3 for both Meta Tray and Opalescence. Meta Tray provoked less tooth sensitivity ($p < 0.05$), however, more gingival sensitivity appeared in this group ($p < 0.05$) (Table 3).

DISCUSSION

In the present study, a spectrophotometer was used to measure the

TABLE 1. MEAN (SD) *L, *a**, AND *b** VALUES OF BOTH PRODUCTS.**

Products	*L**1	*L**2	*L**3	*a**1	*a**2	*a**3	*b**1	*b**2	*b**3
Opalescence PF	74.5 (3.29)	81.5 (4.55)	80.9 (6.63)	2 (0.25)	−2.2 (0.12)	−1.7 (0.2)	16.1 (6.35)	11.6 (2.63)	12.4 (4.71)
Meta Tray	75.5 (4.47)	78.1 (5.2)	77.6 (5.67)	1.6 (0.31)	−0.8 (0.28)	−0.4 (0.18)	15.7 (3.24)	13.2 (3.42)	14.3 (5.02)

*L**1, *a**1, and *b**1 indicate the values measured before bleaching; *L**2, *a**2, and *b**2 indicate the values measured after bleaching; *L**3, *a**3, and *b**3 indicate the values measured after 1 year.

TABLE 2. MEAN (SD) ΔE* VALUES OF BOTH PRODUCTS.

Products	ΔE1	ΔE2	ΔE3
Opalescence PF	9.3 (2.4)	1.1 (0.32)	8.3 (2.73)
Meta Tray	4.3 (1.84)	1.3 (0.27)	3.2 (1.25)

TABLE 3. THE DISTRIBUTION OF PATIENTS ACCORDING TO THE TOOTH AND GINGIVAL SENSITIVITY SCORES.

Products	Tooth sensitivity				Gingival sensitivity			
	0	1	2	3	0	1	2	3
Opalescence PF	2	5	3	—	10	—	—	—
Meta Tray	8	2	—	—	1	4	5	—

color differences after bleaching treatment. We used CIE *L***a***b** (CIELAB) because it provides a useful tool for quantifying color properties of teeth and it is accepted as the most complete color space by the International Commission on Illumination.[12] Color is described by using a mathematical three-dimensional system based on *L**, and it is measured in terms of a value or brightness. The *a** measures hue and chroma in the red-green direction, whereas *b** measures hue and chroma in the blue-yellow axis. The CIELAB color difference is then determined by calculating the Euclidean distance (ΔE) between the two colors in the CIELAB color space.[13] In the formula used to find the color difference, the squared differences between *L**, *a**, and *b** measures are summed up. Therefore, the formula shows only the magnitude of the change but not the direction of the change. This may create a problem, especially when the first value is positive and the second value is negative, because changing from a positive value to a negative value means both decrease in the magnitude and change in the direction of the color value. In the present study, for both experimental and control groups, although a positive value was obtained for *a**1, negative values were obtained for *a**2 and *a**3. Nonetheless, these changes in the direction of *a** values between experimental groups and control groups may not affect our interpretations because our main concern was to compare the color differences between experimental and control groups, and in both study groups, change in the direction of *a** values showed similar patterns.

After bleaching treatment, *L** is expected to increase, and *a** and *b** are expected to decrease.[14,15] In addition, a ΔE value below 1 is reported as visually not detectable, whereas values up to 3.3 are considered moderate visual differences.[16] In this research, both bleaching systems resulted in significant color improvements compared with baseline according to the *L**, *a**, and *b** color parameters, and revealed color difference values up to 3.3.

The overnight application of 10% CP (Opalescence) revealed greater whitening response for all parameters (*L**, *a**, *b**, and ΔE) measured in this study. Opalescence's higher bleaching effect could be

explained by the longer application time (in minutes). Such results are consistent with previous research demonstrating a favorable impact of treatment duration on tooth color by comparing popular tray and strip-based systems.[17] However, the greater whitening effect of Opalescence may depend on the penetration depth of the bleaching agents through the enamel. A previous study showed that home-bleaching systems with long-term bleaching procedures can penetrate deeper through the enamel in comparison with the other bleaching systems.[18] A reduced bleaching effect in tissue depth following short-term bleaching procedures may depend on the fact that the use of higher concentrations of HP or CP could actually not fully compensate for the reduced contact time between the bleaching product and tissues. In addition, custom-fitted trays used with Opalescence might have protected the CP from the oral environment and might have increased the effectiveness of Opalescence. A previous clinical trial confirmed that protecting peroxide gels from the oral environment increases the magnitude of the whitening ability of bleaching gels.[19]

To date, the overnight application of 10% CP bleaching agents has been thoroughly investigated in the literature. After 2 weeks overnight application of 10% CP, Matis and colleagues[9] found a mean ΔE* and Δ*L** of 9.2 and 6.7, respectively. In another study of Matis and colleagues,[20] a mean ΔE* and Δ*L** of 8.8 and 6.5, respectively, was reported after application of 10% CP for 2 weeks. In the present study, although the mean ΔE1* and Δ*L*1* was 9.3 and 7, respectively, for teeth that received overnight applications of 10% CP, the mean ΔE1* and Δ*L*1* was 4.3 and 2.6, respectively, for 20 minutes daytime application of 28% CP. The values of ΔE1* and Δ*L*1* from the present study indicate that 20 minutes daytime applications of a 28% CP bleaching agent result in lower bleaching efficacy than the overnight application of a 10% CP bleaching agent. To our knowledge, there is not much research on the comparison of overnight and daytime bleaching systems provided in the literature. Only Matis and colleagues[21] compared nine published studies on the comparison of the effectiveness of overnight, daytime, in-office, and over-the-counter bleaching methods by conducting a meta-analysis. Their analysis showed that ΔE* values were 9.7 and 6.6 for overnight and daytime bleaching groups, respectively, just after the treatment. After 10 weeks post-treatment, the ΔE* value was 4.7 for the overnight bleaching group and 3.4 for the daytime bleaching group. Based on these findings, the authors concluded that overnight bleaching was more effective than daytime bleaching. Our results are also consistent with their conclusion.

In most of the previous clinical trials, measurements were achieved at the end of the treatment, which does not consider the rebound effect that occurred within the following days and weeks.[22,23] It has been demonstrated that the bleaching process induces enamel alterations ranging from minimal to pronounced depending on the concentration of the gel,[24–26] but this damage was less than that seen after phosphoric acid-etch.[26] Previous in vitro studies reported that enamel permeability may be increased after bleaching treatment depending on the external bleaching procedure.[27,28] Thus, it is important to assess the clinical efficacy of bleaching not only immediately after completion of the treatment but also after a few months at least, so that an objective comparison of different treatment methods can be performed. A follow-up of 30 patients who applied 10% CP revealed that 43% perceived their tooth color as stable 10 years after bleaching.[29] Swift and colleagues[30] examined the effects of the 10% CP, which was used nightly for 2 weeks, and found that the teeth were eight shade units lighter on the Vita shade guide on average. After 2 years, the teeth darkened two units on average, and this regression

occurred during the first 6 months after bleaching. In the present study, patients included in different treatment groups were controlled at the end of the 1-year follow-up. Nearly all participants treating their teeth with either Meta Tray or Opalescence exhibited negative rebound, but not at a statistically significant level. The negative rebound of bleaching treatment may be related to the increased enamel permeability of bleached teeth, hydration of teeth within time, and the oral hygiene and nutrition habits of the patients.

In our study, gingival and tooth sensitivity was evaluated using a subjective scale (4-point scale). Previous investigators also employed this scale during the evaluation of gingival and tooth sensitivity.[23,31] Tooth sensitivity is a common side effect of vital bleaching treatments.[32] Various studies of 10% CP demonstrated that from 15 to 65% of the patients reported increased tooth sensitivity.[29,33–35] Higher incidence of tooth sensitivity (from 67 to 78%) was reported after HP with heat.[36,37] In our study, Opalescence provoked more tooth sensitivity, and this could be attributed to the longer contact period of Opalescence gel with the teeth.

Higher concentrations of HP are caustic to mucous membranes and may cause "burns" when in contact with gingiva. Thus, it is advised that the bleaching systems have to comply with a well-designed tray in order to prevent gingival exposure.[38] In this respect, the newly introduced bleaching systems without a customized tray may be unfavorable, as the bleaching gel will come into contact with the gingiva. Meta Tray caused significantly more gingival sensitivity. In a previous study that evaluated the efficacy of whitening wraps and strips, these products without a customized tray also demonstrated gingival sensitivity.[39] More gingival sensitivity of the Meta Tray could be explained by its non-customized, standard mouth tray.

CONCLUSION

Within the limitations of this study, it can be concluded that the new daytime at-home bleaching system tested (Meta Tray) produced significant bleaching effects. However, the clinical efficacy of the overnight bleaching system was found superior to this new daytime at-home bleaching system. Although the new bleaching system exhibited less tooth sensitivity probably because of the reduced contact time of the bleaching gel with tooth surfaces, the application of the bleaching agent with a non-customized tray provoked more gingival sensitivity in this group. The whitening effect remained similar 1 year after the bleaching treatment for both at-home bleaching systems.

DISCLOSURE

The authors do not have any financial interest in the companies whose products are included in this article.

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