

Comparison of Two At-home Whitening Products of Similar Peroxide Concentration and Different Delivery Methods

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Clinical Relevance

Tooth whitening products of similar peroxide concentrations provide similar whitening effects when applied for the same amount of time regardless of the delivery method.

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SUMMARY

Purpose: This study compared the whitening efficacy, side effects, and patients' preferences/perceptions of two whitening systems of similar peroxide concentration but different formulation and delivery methods.

Methods: The tooth color change of 24 participants was measured using a shade guide (BSG) and a spectrophotometer (ES). Color difference was calculated: $\Delta E^* = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$. One whitening treatment was randomly applied to the right or left maxillary anterior teeth and the other was applied to the contralateral teeth, at-home with 35% carbamide peroxide in a tray (TW) or with 14% hydrogen peroxide in strips (WS). The tooth color was evaluated at baseline, 15 and 30 days (15 days postwhitening). Participants rated their tooth and soft tissue sensi-

tivity (1–10 scale) and completed a questionnaire on their preferences. Results were analyzed by repeated measurement regression analysis/Tukey and Mann-Whitney ($p < 0.05$).

Results: At 15 days, the teeth treated with TW and WS presented $\Delta E^* = 7$ and 6, respectively ($\Delta BSG = 3$ for both), and at 30 days, they presented $\Delta E^* = 7.5$ and 6.5, respectively ($\Delta BSG = 3$ for both). There was no significant difference in tooth and soft tissue sensitivity between treatments. No participant reported tooth and gingival sensitivity at the postwhitening appointment. Of the participants, 83% preferred the TW over WS.

Conclusion: Both ΔE^* and ΔBSG showed no significant difference in tooth color change between TW and SW at either time point. By the end of the study no participants reported tooth and gingival sensitivity. Participants preferred TW over SW.

INTRODUCTION

The at-home whitening procedure was first published by Haywood and Heymann in 1989.¹ The 10% concentration of carbamide peroxide (CP) used in trays overnight has been considered the “gold standard.” This technique is still the most common whitening procedure, and literature heavily supports the efficacy of this method.^{1–14} Despite the great amount of research on at-home tray whitening with 10% CP, some patients do not desire to wear trays over a long period of time and still aspire to have whiter teeth faster. In order to achieve a faster whitening effect in a shorter period of time, dental product manufacturers have increased the peroxide concentration of the whitening products. Higher-concentration tooth whitening studies are scarce. Two studies evaluated whether higher concentration of peroxide, 20% CP vs 7.5% hydrogen peroxide (HP)¹⁵ and 6% HP¹⁶ could be used safely and effectively to reduce treatment time. Overall, these studies demonstrated the safety and effectiveness of these higher-concentration gels, with minor teeth sensitivity and oral tissue irritation. Recently, a manufacturer introduced to the market a new whitening system, Opalescence PF 35% CP (Ultra-dent, South Jordan, UT, USA). To date, there are no studies that have evaluated the efficacy of this high-concentration peroxide gel.

In 2000, a trayless whitening system, Crest Whitestrips (Procter & Gamble, Manson, OH, USA) was introduced on the market, in which a measured

dose of HP gel was applied on the anterior teeth using a flexible polyethylene strip instead of a custom tray.¹⁶ Initially, the whitening strips presented 6% HP, equivalent to 20% CP, and the manufacturer recommended applying them for 30 minutes twice daily. Several randomized controlled clinical trials showed the efficacy of this product.^{13,17–24} Originally the strips were available over the counter. In 2004, the strips whitening gel concentration was increased, and they were designed to be professionally dispensed.²⁵ To date, there is one study comparing different professionally dispensed strips with 10% HP,²⁶ and there are a few studies that have evaluated the efficacy of higher concentration of whitening strips, 14% HP, Crest Whitestrips Supreme.^{25,27,28}

The 14% HP Whitestrips Supreme, which corresponds to approximately 40% CP, is similar in concentration to the Opalescence PF 35% CP. Both products are dentist supervised and recommended to be performed at home, twice a day, for 30 minutes per each daily application. Unlike the strips, the 35% CP whitening gel is applied via a whitening tray. To the authors' knowledge, there are no studies that evaluated the efficacy of these high-concentration peroxide gels using different dispensing methods.

The objectives of this study were 1) to compare the whitening efficacy of two whitening systems of similar peroxide concentration using visual and instrumental shade matching methods, 2) to evaluate possible side effects such as gingival irritation and tooth sensitivity, and 3) to evaluate patients' preferences for and perceptions of both systems. The null hypotheses to be tested were that there is no difference in whitening effect (as measured by spectrophotometer and shade guide) and tooth and tissue sensitivity (as measured by visual analog scale) between Opalescence PF 35% CP and Crest Whitestrips Supreme 14% HP whitening systems over a 30-day evaluation period in maxillary anterior incisors and canines.

MATERIALS AND METHODS

This was a randomized, single-blinded, split-mouth design clinical study. One clinician gave instructions on materials to the patients, and another clinician evaluated the tooth color change. A total of 25 patients were selected for this study according to specific inclusion and exclusion criteria (Table 1).

During the screening appointment, the participants signed the institutional review board authorization and consent form. The Loe and Silness

Table 1: Inclusion and Exclusion Criteria for Acceptance as Participants

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> - Be at least 18 years old - Willing to sign a consent form - Willing to return for postwhitening evaluation - Presence of all six maxillary teeth equal or darker than 1M2 VITA Bleachedguide in the value order - Have no maxillary anterior teeth with more than one-sixth of the facial surface covered with a restoration 	<ul style="list-style-type: none"> - History of any medical disease that may interfere with the study or require special consideration - Presence of gross pathology - Use of tobacco products during previous 30 days - Current or previous use of whitening agent - Loe and Silness²⁹ gingival score greater than 1.0 - Pregnant or lactating women - Tetracycline-stained teeth

gingival index²⁹ of the upper anterior teeth was used to ensure that participants did not have moderate to severe periodontal tissue inflammation. One impression of the maxillary arch was taken. The model was used for bleaching tray and positioning jig fabrication. A reservoir was placed on the stone teeth prior to tray fabrication using a block-out resin (LC Block-Out Resin, Ultradent) and the trays were scalloped. The positioning jig was fabricated in order to position the tip of the spectrophotometer in the same position at every color measurement. An impression of the tip of the probe of the spectrophotometer was made and a cast was fabricated. The spectrophotometer probe cast was used as a stamp guide to mark the positioning jig. The facial middle third of the maxillary teeth of the custom positioning jig was marked with the spectrophotometer tip cast using an ink pad. The facial marks were cut out of the jig, leaving an opening for placement of the spectrophotometer probe. Prior to color measurement, the custom jig was positioned in the patient's mouth, and the spectrophotometer probe was positioned into the jig opening. At the same appointment, the participants received a dental prophylaxis to remove any extrinsic stains.

At the baseline appointment, the participants received a nonwhitening toothpaste (Crest Cavity Protection, Procter & Gamble) and soft-bristled manual toothbrush (Oral B, Iowa City, IA, USA) and were asked to brush before and after the whitening procedure in addition to their standard home care regimen. The whitening treatments were randomly assigned, by flip of a coin, to the right (teeth nos. 6–8) or left (teeth nos. 9–11) maxillary anterior teeth. The 35% CP Opalescence PF (TW; Ultradent) was applied in a tray to the right or left maxillary anterior teeth, and the contralateral maxillary anterior teeth were treated with 14% HP Crest Whitestrips Supreme (WS; Procter & Gamble), which corresponds to 40% CP. The participants were

instructed to whiten half the arch with the 40% CP strip and the other half with 35% CP in the whitening tray at the same time for 30 minutes. They were asked to whiten their teeth twice a day and to separate the times they whiten by at least three hours. They were instructed to whiten their teeth for two weeks. Participants only received half of the tray designated to be used with 35% CP gel, thus there would be no confusion as to which should be used with 35% CP. The tray was well adapted to the teeth, and the patients were asked to wipe off any excess material in order to prevent leakage to the adjacent tooth and to avoid gingival sensitivity. They were asked to adapt the strip to the teeth and not to overlap the tray. The participants also received a diary in which they indicated on a daily basis the level of tooth and gingival sensitivity that they experienced and the times they used the at-home whitening systems. They were asked to rate their tooth and soft tissue sensitivity experience using a visual analog scale (VAS) in one of 10 categories. The VAS is designed to present to the respondent a rating scale with minimum constraints. A 1 VAS corresponds to *no pain* and 10 VAS corresponds to *severe pain*.

At the baseline appointment tooth color was evaluated visually using the VITA Bleachedguide 3D-Master (BSG; Vita Zahnfabrik, Bad Sackingen, Germany) by one independent experienced evaluator and instrumentally using an intraoral spectrophotometer (ES; Vita Easyshade, Vident, Brea, CA, USA). Shade matching with the BSG was performed under a color-corrected light (Rite-Lite, Addent, Danbury, CT, USA), having a correlated color temperature of 5500 K that simulates northern-sky daylight. The ES measures the color of the teeth based on the CIELAB color notation system (Commission Internationale de l'Eclairage 2004), in which L* denotes lightness (achromatic), whereas a* and b* denote green-red and blue-yellow coordinates,

Table 2: Questions to and Answers (by %) From the Study Participants

1) Which method of treatment do you prefer?
• Tray whitening (83%)
• Whitening strips (4%)
• I have no preference (13%)
2) Which method is more comfortable for your teeth?
• Tray whitening (75%)
• Whitening strips (21%)
• Equally comfortable (4%)
3) Which method is more comfortable for your gums?
• Tray whitening (38%)
• Whitening strips (58%)
• Equally comfortable (4%)
4) Can you see a difference in tooth color between right and left teeth?
• Yes (25%)
• No (75%)
5) Was it easy to do the procedure twice a day?
• Yes (92%)
• No (8%)

respectively. ΔE^* is the total color difference or the distance between two colors. The total color difference was calculated using this formula³⁰: $\Delta E^*_{ab} = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$.

The color measurements were taken prior to tooth whitening (baseline), 15 days after the whitening treatment was started, and at 30 days (15 days postwhitening) in order to evaluate tooth color relapse.

At the last appointment the participants were asked to complete a questionnaire (Table 2), and if

desired, they were given an upper whitening tray and whitening gel, Opalescence 10% CP (Ultradent Products), to keep whitening the upper teeth. The participants who wished to have the lower teeth whitened came back to have lower teeth impressions made and to produce trays for delivering the whitening gel.

STATISTICAL ANALYSIS

The results were analyzed with computer software (Sigmastat 3.1, Systat Software, Chicago, IL, USA) and SAS v.9.1 (SAS Institute, Cary, NC). A *t*-test ($p < 0.05$) was used to compare the $L^*a^*b^*$ of the right and left upper anterior teeth obtained with the spectrophotometer at baseline. The Mann-Whitney rank sum test ($p < 0.05$) was used to evaluate the BSG results of right and left upper anterior teeth at baseline.

The individual ΔL^* , Δa^* , Δb^* , and ΔE^* were computed by subtracting the baseline measurements from the follow-up measurements. The results were analyzed by repeated measurement regression analysis to evaluate color change over time for each treatment. A compound symmetry covariance structure was used to evaluate the variability and correlations between times and treatments. Data were adjusted for multiple testing by applying the Tukey test ($p < 0.05$). The delta shade-guide rank results were analyzed by Mann-Whitney rank sum test. Both parametric and nonparametric tests evaluated two factors: whitening system (TW and SW) and time (baseline, 15 days, and 30 days).

The tooth and gingival sensitivity average score of tooth whitening were compared using Kruskal-Wallis one-way analysis of variance on ranks ($p < 0.05$) for each whitening system and time.

The responses to the questionnaire are reported in percentages.

RESULTS

A total of 25 participants enrolled and 24 completed the study. One participant did not present for the last tooth-color evaluation. Of the participants, 12 were men and 12 were women, with an age range from 21 to 75 years. There were no statistically significance differences in the mean (ES) and median (BSG) baseline shade of the right and left teeth.

Both treatments had significant mean color change from baseline to after treatment (Table 3). The teeth became lighter, less yellow, and less red. There was no difference in ΔL^* , Δa^* , Δb^* , ΔE^* , and BSG values between time for each treatment and

Table 3: Spectrometric and Visual Results of Both Whitening Treatments at 15 and 30 Days (15 Days Postwhitening), Mean \pm Standard Deviation

Treatment	Time, days	ΔL^*	Δa^*	Δb^*	ΔE^*	ΔBSG
TW	15	4.2 ± 2.6	-1.7 ± 1.2	-4.83 ± 2.5	7.0 ± 3	-3.0 ± 1.5
TW	30	4.0 ± 2.2	-1.7 ± 1	-5.6 ± 2.7	7.5 ± 3	-3.0 ± 1.4
WS	15	3.5 ± 2	-1.4 ± 1	-4.34 ± 2.6	6.0 ± 3	-3.0 ± 1.6
WS	30	3.42 ± 2	-1.5 ± 1	-4.7 ± 3	6.5 ± 3	-3.0 ± 1.6

Abbreviations: TW, tray whitening; WS, whitening strips.

between treatments at each time evaluated (Table 3).

According to the participants' diaries, five participants reported mild (1–3 in the VAS) tooth sensitivity and six participants reported mild soft tissue sensitivity on the side that was whitened with the TW. Four participants reported mild soft tissue and tooth sensitivity on the side that was whitened with the WS. There was no significant difference in tooth and soft tissue sensitivity between the two treatments. No participant reported tooth and gingival sensitivity at the postwhitening appointment.

Of the participants, 83% preferred the TW treatment; 75% found this type of treatment more comfortable to the teeth, though only 38% found it more comfortable to the soft tissue than WS (Table 2). Seventy-five percent of the participants could not see a difference in tooth color between the right and left upper incisors. The 25% of participants who noted a color difference reported that it was on the side that was whitened with the TW. Ninety-two percent found it easy to do the procedure twice a day.

DISCUSSION

According to the ES and BSG results, the hypothesis that both whitening treatments would provide similar results was accepted. HP is different from CP in composition (CP = HP plus urea), concentration (10% CP has 3.5% HP), and duration of activity. HP products are active for 30 to 60 minutes,³¹ and CP products are active for two to 10 hours.³² It was previously believed that an HP whitening agent would bring about faster results compared with a CP whitening agent of similar concentration. These claims were based on the fact that CP has to chemically break down into HP and urea in order to be effective.¹⁵ However, like the present study, a

previous study showed that CP and HP of similar concentrations applied for the same amount of time yielded similar whitening effects when evaluated with a shade guide.¹⁵ The present study showed that the methods of whitening gel delivery, tray vs strip, did not influence the whitening effect. In addition to concentration, the degree of whitening is directly related to the amount of time that the agent is in contact with the tooth.³³

At two weeks' postwhitening, the results were not significantly different from immediately after whitening treatment was ceased for both methods, therefore no color relapse was noted. According to Matis and others,²⁶ it appears that there is minimal reversal in color when wraps and strips are used. They commented that perhaps this is because the teeth's "inherent lightness potential" is not exceeded, and therefore, no color reversal occurs.²⁶ In their study, they evaluated wraps and strips containing 8% and 10% HP, and the time of application was similar to that used in this study. The common factor between Matis and others and this study was that the whitening gels were similar in concentration. Therefore it can be extrapolated that a higher concentration of whitening gels applied for several shorter periods of time can retain color better than low-concentration gels applied for several longer periods of time (eg, 10% tray whitening used overnight) or extremely high concentration applied for a short period of time (eg, in-office whitening).

Noteworthy is the low incidence of side effects with these products, especially in view of the relatively high peroxide concentration. Both whitening systems yielded minimal side effects in the study participants, with no differences between the methods. Of the participants, 21% reported mild tooth sensitivity when they used TW, and no symptoms

were reported at the last appointment. Also, 25% of the participants reported mild gingival sensitivity during TW use, and 16% reported mild transient gingival sensitivity during WS use. None of the participants reported gingival or tissue sensitivity two weeks after treatment for both systems. A study that evaluated the same strips reported that only two of the 13 participants in the experimental group reported mild tooth sensitivity, and only three reported mild soft tissue irritation.²⁷ The high-concentration CP products are relatively new on the market, and there are no studies showing its potential side effects.

The great majority of the participants preferred the TW over the WS. Most of them found the TW more comfortable on the teeth; nonetheless, 58% of them found the WS more comfortable on the soft tissue. Some participants commented that the strips are difficult to place and keep in place. Despite that, they were more gentle to the soft tissue, even though the trays were scalloped and the participants were instructed to wipe off any excess gel. A total of 92% found it easy to do the procedure twice a day.

CONCLUSION

Twice-daily use of 14% HP or 35% CP for two weeks resulted in significant improvement in tooth color relative to baseline that was sustained two weeks after treatment was finalized. There was no difference in effectiveness between treatments of similar peroxide concentration and different delivery methods. The tooth and gingival sensitivity was mild and transient for both groups. The great majority of the participants preferred tray whitening over strip whitening.

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Conflict of Interest Declaration

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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