



## Effectiveness and Safety of Tooth Bleaching in Teenagers

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### Abstract

**Purpose:** The purpose of this study was to compare the efficacy and safety outcomes of a currently marketed, peroxide-containing, tray-based, tooth-whitening system to a peroxide-containing, "trayless" tooth-whitening system.

**Methods:** Fifty-seven subjects, 12 to 17 years of age, participated in this study and were divided into 2 balanced groups. Twelve subjects received custom trays with 10% carbamide peroxide gel that they were instructed to wear overnight. Forty-five subjects received 10% hydrogen peroxide polyethylene strips to wear for 30 minutes twice a day. Teeth were bleached for 2 weeks. Digital image analysis measured color in B, L, and A color spaces, where B indicated yellowness, L indicated lightness, and A indicated redness. Oral examinations and interviews were used to ascertain any adverse events that may have occurred during treatment.

**Results:** Fifty-one patients completed this study. Both whitening systems yielded significant ( $P < .001$ ) color improvement, as evidenced by decreased yellowness, increased lightness, and decreased redness. Groups did not differ significantly ( $P > .39$ ) regarding color improvement for B, L, or A on either the maxillary or mandibular teeth. Twelve subjects (27%) in the polyethylene strip group reported adverse events compared to 5 subjects (42%) in the tray-delivered group. Minor and transient tooth sensitivity and oral irritation were the most common adverse events.

**Conclusions:** Both the daytime strip and overnight tray groups significantly ( $P < .0001$ ) whitened teeth; there were no significant differences between the 2 groups in any of the color parameters; both whitening systems were well tolerated, and most adverse events were mild in severity. (*Pediatr Dent* 2005;27:298-302)

**KEYWORDS:** BLEACHING, TOOTH WHITENING, CHILDREN, TEENAGERS

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There has been a tremendous increase in vital tooth bleaching since it was introduced to the dental profession.<sup>1</sup> Although there have been reports of concern associated with vital tooth bleaching,<sup>2,3</sup> such as surface enamel alteration, tooth sensitivity, and oral soft tissue irritation, numerous clinical studies have suggested this procedure's safety and efficacy.<sup>4-15</sup> Likewise, a microscopic evaluation by White et al found no difference between bleached and nonbleached teeth, and Li reported the safety of peroxide-containing tooth whiteners.<sup>16,17</sup>

A majority of clinical studies evaluating tooth-whitening products have been conducted on adult subjects. There

have been reported tooth bleaching cases in children,<sup>18,19</sup> however, there is only limited controlled clinical research in this population.<sup>20, 21</sup>

This study's purpose was to compare the efficacy and tolerability of oral hard and soft tissues exposed to tooth whitening in teens following use of a novel peroxide-containing gel delivered on a disposable polyethylene strip system with a currently marketed, carbamide peroxide gel delivered in a tray-based system as an experimental control.

### Methods

This controlled, randomized, 4-week clinical trial compared 2 different bleaching systems and regimens:

1. a 10% hydrogen peroxide strip system (Crest Whitestrips Premium, The Procter and Gamble Company, Cincinnati, Ohio) used for 30 minutes twice daily;
2. a 10% carbamide peroxide tray system (Opalescence, Ultradent Products, Inc, South Jordan, Utah) used overnight.

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The strip system was a very thin (0.13 mm) and concentrated peroxide gel, compared to the tray-based control. The volunteer study population was limited to 12- to 17-year-old children who wished to whiten their teeth. To be eligible, subjects had to have all permanent anterior teeth erupted and the teeth were required to match a Vita (Vita Zahnfabrik, D-79713 Bad Sackingen, Germany) shade guide score of A2 or darker. Some individuals were excluded because of previous vital bleaching, apparent caries, periodontal disease, orthodontic appliances, anterior restorations, or a history of dentin hypersensitivity.

The study protocol was explained to patients and parents, and then informed consent and child assent were obtained in a manner reviewed and accepted by the Institutional Review Board of the University of Texas Health Science Center at San Antonio, San Antonio, Tex. During every visit, all subjects were required to brush their teeth with a soft-bristle toothbrush, provided on-site for clinical appointments, before digital images were exposed. No professional prophylaxis was provided.

Digital images of the anterior teeth were collected using a high-resolution digital camera (Fuji HC1000 CCD, Fuji Photo Film, Inc, Edison, NJ) in a standardized

method.<sup>15</sup> The unit was connected to a computer that recorded and analyzed the images. Before daily use and approximately every hour thereafter, the system was calibrated to ensure proper operation. In addition, intraoral clinical photographs were taken at baseline (Figures 1a and 2a) and posttreatment.

Alginate impressions of the maxillary and mandibular dental arches were made, and soft, full-arch, scalloped bleaching trays were fabricated for all participants using materials supplied by the tray system manufacturer.

At baseline, subjects were assigned to either strip or tray treatment (balancing for pretreatment tooth color and age). As this was the first study of teens using the 10% strips, a 3:1 strip-to-tray assignment ratio was used to ensure a sufficient sample in the experimental strip group for the purposes of assessing safety in that group. A definitive and systematic oral hard and soft tissue examination was completed at this baseline appointment and at every appointment thereafter when the bleaching protocol was initiated. All subjects, at each appointment, were asked to describe any abnormal feeling or discomfort they experienced. Subjects were given detailed written and verbal instructions on test product application. The first product use was supervised. Subjects residing in the same household were assigned to the same experimental group. Both groups were provided a 1-week supply of bleaching product (4 syringes of bleaching gel or 14 bleaching strips).

Subjects in the 10% carbamide peroxide gel group were asked to dispense approximately half of the gel in a syringe into the custom-fabricated, plastic delivery tray provided. The tray was filled and placed in the mouth after toothbrushing each night, and worn overnight while sleeping. Subjects assigned to the 10% hydrogen peroxide polyethylene strip group were asked to place 1 strip over the maxillary anterior teeth for 30 minutes twice daily, once in the morning and once in the evening. A standard dentifrice was given to each subject for use throughout the study (Crest Cavity Protection, The Procter and Gamble Company, Cincinnati, Ohio).



Figure 1a. Baseline photograph of anterior teeth to be treated with the polyethylene strip-delivery system.



Figure 1b. Two-week photograph of anterior teeth treated with the polyethylene strip-delivery system. Note the difference between the maxillary teeth that received whitening treatment compared with the mandibular teeth that did not receive whitening treatment.

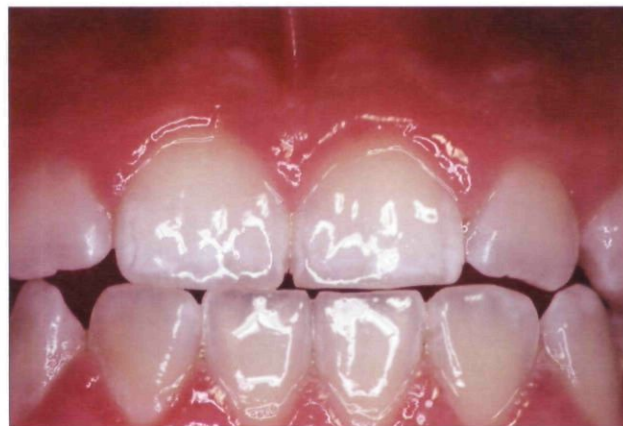


Figure 1c. Photograph of anterior teeth treated with the polyethylene strip-delivery system, when whitening treatment was completed 2 weeks for both arches.

All subjects were requested to return products dispensed at each appointment so that product compliance could be determined.

Subjects returned for follow-up appointments and product resupply 1 week later, when digital images and clinical photographs were taken (Figures 1b and 2b), and an oral soft tissue examination and interview were conducted. After 2 weeks of treatment on the maxillary teeth, the entire process was repeated for the mandibular teeth (Figures 1c and 2c).

The tooth color of the anterior teeth's facial surfaces was computed from the intraoral digital images. Tooth color was represented in a 3-dimensional color space, where B indicates yellowness, L indicates lightness, and A indicates redness. All digital images were analyzed to obtain a single mean B, L, A color value for the facial surfaces of the 6 anterior teeth. Changes in tooth color (B, L, A) were calculated by comparing each parameter with its baseline value. Using this method, whitening was exemplified by -B (reduction in yellowness), +L (increased lightness), and -A (reduction in redness). Analysis of covariance (ANCOVA) methods were used to compare treatments, with the corresponding baseline tooth color included as a covariate. Treatment

comparisons were tested 2-sided, with a 5% significance level using ANCOVA.

## Results

This study enrolled 57 children and adolescents aged 12 to 17 years. Forty-five subjects received the 10% hydrogen peroxide polyethylene strip and were instructed to wear the strip for 30 minutes, twice daily. Twelve subjects received the 10% carbamide peroxide gel delivered in the tray-based system overnight.

Table 1 summarizes the efficacy findings. Both the experimental 10% hydrogen peroxide polyethylene strips and the 10% carbamide peroxide night tray exhibited significant ( $P < .0001$ ) tooth-whitening improvement relative to baseline. Clinical response was similar for the 2 groups. For the daytime strip group, the adjusted mean (SE) B was -3.4 (0.20) for maxillary teeth, compared to -3.7 (0.37) for the overnight tray. For L, the strip group had an adjusted mean (SE) of 2.4 (0.14) on maxillary teeth, compared to 2.4 (0.12) for the tray group.

Results were generally similar for A. Between-group comparisons showed no significant efficacy differences ( $P > .39$ ) between the daytime strip and overnight tray systems regarding maxillary arch whitening. Whitening was also clearly evident on the mandibular teeth. For the 2 groups, adjusted means for B, L, and A differed by only 0.3 units or less. As with the maxillary teeth, there were no significant ( $P > .55$ ) between-group differences in whitening on the mandibular teeth.

Both treatment regimens were generally well tolerated. Minor tooth sensitivity and oral irritation (predominantly gingival irritation) were the most common complaints, reported by 27% of the subjects assigned to the strip group and 42% of the subjects assigned to the tray group. All events resolved during or after completion of the study. Subjects were not given any products to help them manage dental sensitivity. They were, however, instructed to contact the authors by telephone if they experienced sensitivity other than mild or if they altered this study's



Figure 2a. Baseline photograph of anterior teeth to be treated with the tray-delivery system.

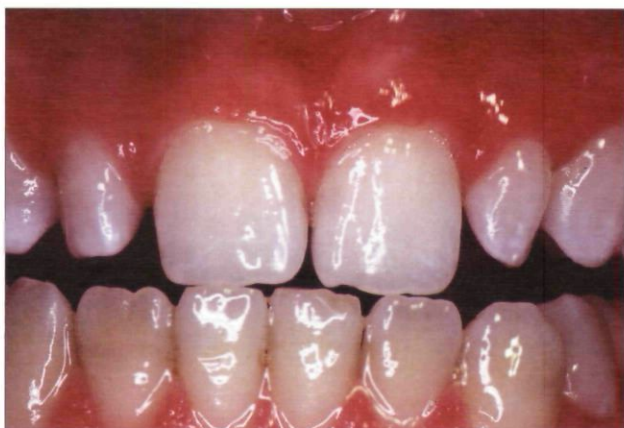


Figure 2b. Two-week photograph of anterior teeth treated with the tray-delivery system. Note the difference between the maxillary teeth that received whitening treatment compared with the mandibular teeth that did not receive whitening treatment.



Figure 2c. Photograph of anterior teeth treated with the tray-delivery system, when whitening treatment was completed 2 weeks for both arches.

recommended bleaching regimens. No subjects had to contact the authors, and, by evaluation of product use, the authors were able to ascertain excellent compliance.

## Discussion

The Procter and Gamble Company already had a 6.5% hydrogen peroxide strip system marketed (Crest Professional Whitestrips). A previous study had demonstrated a 6.5% hydrogen peroxide-impregnated polyethylene strip to be an effective whitening agent over an 8-week clinical trial (4 weeks treatment in the maxillary arch and 4 weeks treatment in the mandibular arch).<sup>20</sup>

This 6.5% hydrogen peroxide polyethylene strip had 200 mg of gel on a maxillary strip, which contained 13 mg of hydrogen peroxide.<sup>22</sup> The 10% hydrogen peroxide strip system (Crest Premium Whitestrips) was introduced to the marketplace to offer tooth whitening with a more comfortable thin layer of gel on the polyethylene strip in a shorter time duration.

Although the percentage of hydrogen peroxide is higher, the actual dose of hydrogen peroxide is similar. The 10% hydrogen peroxide strip has 130 mg of gel on the maxillary strip, which contains 13 mg of hydrogen peroxide.<sup>23</sup> Results from this new research showed for teens that daytime use (1-hour total) of 10% hydrogen peroxide strips resulted in whitening similar to overnight use of a 10% carbamide peroxide tray system.

No significant difference in whitening and associated sensitivity between the 10% hydrogen peroxide strip system and the 10% carbamide peroxide gel system is not surprising, when the actual active peroxide bleaching components of each system are compared. The 10% carbamide peroxide is equal to approximately 3% hydrogen peroxide. This relates to 3 mg of hydrogen peroxide for every 100 mg of 10% carbamide peroxide placed into the tray for overnight bleaching. The typical half tube of 10% carbamide peroxide to be dispensed into the delivery tray, which was utilized in this study, contains 680 mg of 10% carbamide peroxide gel or a comparable 20 mg of hydrogen peroxide.

This study indicated the 10% hydrogen peroxide polyethylene strip to be well tolerated, with no statistically significant safety differences between the polyethylene strip group and tray-delivered 10% carbamide peroxide gel. Mild tooth sensitivity or mild gingival irritation were the most common adverse events (>70%). Twelve subjects (27%) in the polyethylene strip group reported adverse events, compared to 5 subjects (42%) in the tray-delivered group. Certainly, the 10% hydrogen peroxide polyethylene strip, the 6.5% hydrogen peroxide polyethylene strip, and the 10% carbamide

peroxide gel have all demonstrated minimal discomfort during use.

The research involved use of a very thin and concentrated gel on a whitening strip. Each of these strips carried only 130 mg of bleaching gel per application in a very thin layer (0.130 mm). This represented approximately one third less gel compared to other strip studies involving teens.<sup>20,21</sup> Previous research has shown the feasibility of strip-based bleaching in adults with a very thin gel at a concentration of 14% hydrogen peroxide.<sup>24,25</sup> This new study extends these findings to include use of very thin 10% hydrogen peroxide gel whitening strips for daytime vital bleaching in teens.

This clinical study, involving children, as well as others noted in the dental literature,<sup>20,21</sup> demonstrates whitening effectiveness and minimal sensitivity. The question may arise, however, as to why children might desire or need to have their teeth whitened. Several reasons may present the desire to have children's teeth whitened. Brantley, Barnes and Haywood presented a child that had a single tooth discoloration secondary to trauma and wished to have the tooth whitened.<sup>26</sup> Likewise, minor developmental tooth discolorations can effectively be treated with bleaching,<sup>18,21,26,27</sup> the increased prevalence of fluorosis being an example.<sup>28,29</sup> Finally, bleaching can be very effective alone or when used in conjunction with enamel microabrasion to make enamel discolorations much more esthetically pleasing.<sup>18,19,27</sup> A limitation of this study is the long-term whitening duration. One could assume that the whitening effectiveness would have relatively good maintenance over several years, as other dental literature has demonstrated.<sup>12,30,31</sup>

## Conclusions

Based on this study's results, the following conclusions can be made:

1. A 10% hydrogen peroxide strip system and a 10% carbamide peroxide tray system were equally effective at bleaching teeth over a 4-week period, with both systems producing significant whitening.
2. Each system was well tolerated, and most of the reported adverse effects for both products were mild.

**Table 1. Treatment Comparisons (ANCOVA) by Arch**

Color parameter	Adjusted mean change (SE)		2-sided <i>P</i> value
	Strip	Tray	
Maxillary teeth			
B	-3.4 (0.20)	-3.7 (0.37)	.390
L	2.4 (0.14)	2.4 (0.24)	.779
A	-1.2 (0.06)	-1.3 (0.12)	.510
Mandibular teeth			
B	-2.6 (0.15)	-2.4 (0.29)	.832
L	2.0 (0.17)	2.2 (0.32)	.553
A	-1.1 (0.09)	-1.0 (0.17)	.997

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