

# Daily Use of Whitening Strips on Tetracycline-Stained Teeth: Comparative Results After 2 Months

## CE 4

**Abstract:** This article reviews the efficacy of a new 6.5% hydrogen peroxide tooth-whitening gel strip for bleaching teeth that have been intrinsically stained from tetracycline. Given the severity of staining in the cases presented during a recently conducted clinical trial, the resulting efficacy is dramatic. Additionally, the continuous use of these strips for 30 minutes per day, twice daily for 2 months with no meaningful adverse effects is noteworthy.

In cases requiring esthetic enhancement of discolored dentition, those involving tetracycline stains are among the most challenging. These intrinsic stains, which cannot be removed with polishing or abrasive mechanisms, may result from the administration of tetracycline during childhood for the treatment of disease. The color and severity of stains vary and are influenced by the duration of tetracycline use, and the stage of tooth development at the time the medication was prescribed.

While some patients may select veneers or full-coverage crown restorations to brighten their smiles, others may desire a more conservative approach. To that end, tooth whitening offers a simplified and economical alternative for changing tooth color.

When clinicians are faced with the prospect of whitening a patient's intrinsically stained teeth, considerations for treatment include the shade and location of discoloration,<sup>1</sup> as well as which formulation of whitening solutions to use. Whether whitening should take place in the office or at home under the dentist's supervision, along with the longevity of the whitening protocol, must also be decided. It has been suggested that when discoloration appears at the cervical area of the tooth, the whitening results may be poorest; when the stain is dark gray or blue, the prognosis is similarly unimpressive. When whitening tetracycline-stained teeth, patients may need to commit to a course of treatment lasting several weeks or months.<sup>2-4</sup>

Treatment commonly involves the use of at-home vital bleaching kits, which were first introduced in 1989.<sup>5</sup> According to some reports, tetracycline-stained teeth have demonstrated a favorable prognosis depending on the treatment protocol, although they are the most resistant to bleaching.<sup>6</sup> Specifically, one report showed that 97% of patients with tetracycline stains experienced successful tooth lightening when a carbamide peroxide whitening solution was used in a nightguard.<sup>2</sup>

A recently introduced 6.5% hydrogen peroxide whitening delivery system (Crest® Professional Whitestrips<sup>®</sup>) shows promise for whitening tetracycline-stained dentition when used at home for 2 months under a dentist's supervision. The hydrogen peroxide-coated polyethylene strips represent an alternative for patients who cannot afford other whitening treatments and/or do not have time for multiple dental visits.<sup>7</sup> This article presents the recent research findings of a clinical trial designed to evaluate the efficacy of two at-home vital bleaching systems on tetracycline-stained teeth.

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### Learning Objectives

After reading this article, the reader should be able to:

- discuss the efficacy of long-term bleaching on tetracycline-stained teeth.
- describe several common adverse effects of long-term bleaching, including tooth sensitivity and gingival irritation.
- compare the efficacy of a polyethylene film whitening system with a tray whitening system.

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A randomized clinical trial compared the efficacy of two at-home vital bleaching systems on tetracycline-stained teeth. Daily bleaching was conducted for 2 months. Eligibility was limited to healthy adult volunteers who had 16 or more natural teeth, including at least 3 gradable maxillary incisors with significant tetracycline staining. Individuals demonstrating tooth sensitivity or an immediate need for dental treatment were excluded from participating in this trial.

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The study protocol, informed consent, and advertising were reviewed and approved by Tuft University's Institutional Review Board. Written and verbal informed consent was received before study initiation. After informed consent was obtained and baseline measurements were made, subjects were randomized 3:1 to a strip-based, hydrogen peroxide tooth-whitening system (Crest® Professional Whitestrips) or a marketed tray-based, carbamide peroxide whitening system control (Opalescence®<sup>b</sup> 10%).

Both groups were given a standard dentifrice (Crest® Cavity Protection Regular Paste<sup>a</sup>) and an extrasoft toothbrush (Crest® Complete<sup>a</sup>) for use throughout the study. All test

<sup>b</sup>Ultradent Products, Inc, South Jordan, UT 84095; 800-552-5512

products were packaged in 1-month product kits, and all labeling was identical except for a unique subject identification number.

The first product application was supervised for instructional purposes, but all other treatment was unsupervised. Only the maxillary arch was treated. Participants in the strip group were instructed to wear a whitening strip for 30 minutes twice daily. Individuals in the tray group had a custom soft, full-arch bleaching tray fabricated with gingival scalloping and gel reservoirs using materials supplied by the manufacturer. Subjects in that group were instructed to place half to three quarters of the contents of a bleaching syringe into the custom tray and wear the device for 2 hours daily.

Clinical response was evaluated at the beginning of the study and again each month after treatment. First, the level of tetracycline staining on the maxillary anterior teeth was assessed using a modified standard index.<sup>8</sup> This modification recognized the possibility of successfully bleaching teeth with relatively severe tetracycline stain (Table 1). These baseline values, along with age, were used for balance and assignment during treatment randomization. Efficacy was assessed using a standard 16-step value-oriented tooth shade guide<sup>c</sup> to match artificial crowns to the natural dentition. Shade assessments were made in a neutral-colored dental operatory under color-balanced lighting conditions by a trained and calibrated examiner. Tolerability was assessed by intraoral examination and subject report at each study visit.

Individual shade scores were determined by ranking the 16 shade tabs<sup>c</sup>, arranged from dark to light, according to the rank order suggested by the manufacturer. To account for unusually dark colors (often seen with tetracycline staining) or white colors (often seen postbleaching), this 16-step guide was supplemented by 2 additional values (C4+ and B1-) representing shades darker than C4 or lighter than B1. Effectiveness was determined by calculating the change in shade scores from baseline at each posttreatment visit. Using this method, a decrease in numeric shade score represented an increase in tooth whiteness. Treatment groups were compared using analy-

<sup>c</sup>Vita Zahnfabrik, Germany; distributed in the US by Vident™, Brea, CA 92621; 800-828-3839

**Table 1—Tetracycline Stain Classification\***

Score	Clinical Presentation
0	No tetracycline staining evident
I	Uniform light yellow, brown, or gray stain confined to incisal three quarters of the crown
II	Deep yellow, brown, or gray stain, without banding
III	Dark gray or blue stain with marked banding
IV	More severe or extreme staining

\*Adapted from Boksman and Jordan, 1983.<sup>8</sup>

sis of covariance with the baseline shade as the covariant. Comparisons to baseline were 1-sided, while between-group comparisons were 2-sided using a 5% significance level.

## Results

Of the 40 randomized subjects, 30 were assigned to the strip group and 10 were assigned to the tray group. The study population ranged from 22 to 70 years of age. Approximately half of the subjects presented with moderate-to-severe tetracycline staining (levels II through IV), a third of whom had

the more severe banding that is occasionally reported after childhood antibiotic use. While tobacco use was uncommon (15% of subjects), 95% of the study participants consumed coffee, tea, or cola beverages daily. Treatment groups were generally well balanced with respect to demographic and behavioral parameters and tetracycline stain levels (Table 2).

Both treatments were effective overall in improving the shade of tetracycline-stained teeth (Table 3). Relative to baseline, the 2 groups averaged approximately 4.1 to 6.6 units of shade improvement after 2 months of treat-

**Table 2—Baseline Demographic, Behavioral, and Tooth Shade Information**

Demographic, Behavioral Characteristic	Strip (n = 30)	Tray (n = 10)	Overall (n = 40)	Two-sided P-value
<b>Age (years)</b>				
Mean (SD)	37.7 (9.46)	38.9 (14.72)	38 (10.81)	0.759
Minimum–maximum	22–58	25–40	22–70	
<b>Gender</b>				
Female	19 (63.3%)	3 (30%)	22 (55%)	0.140
Male	11 (36.7%)	7 (70%)	18 (45%)	
<b>Race</b>				
Asian	6 (20%)	4 (40%)	10 (25%)	0.232
White	24 (80%)	6 (60%)	30 (75%)	
<b>Tobacco Use</b>				
No	25 (83.3%)	9 (90%)	34 (85%)	0.999
Yes	5 (16.7%)	1 (10%)	6 (15%)	
<b>Daily Coffee/Tea/Cola Consumption</b>				
No	2 (6.7%)	0 (0.0%)	2 (5%)	0.999
Yes	28 (93.3%)	10 (100%)	38 (95%)	
<b>Tetracycline Stain Levels</b>				
I	15 (50%)	4 (40%)	19 (47.5%)	0.318
II	7 (23.3%)	1 (10%)	8 (20%)	
III	8 (26.7)	4 (40%)	12 (30%)	
IV	0 (0.0%)	1 (10%)	1 (2.5%)	
<b>Tooth Shade</b>				
Mean	11.1	13.5	11.7	0.082
Minimum–maximum	6–17	7–17	6–17	

SD = standard deviation

**Table 3—Tooth Shade by Treatment and Time**

	n	Comparison to Baseline		Between-Group Comparison	
		Mean Shade Change	P-value	Mean Treatment Difference (SE)	P-value
<b>Month 1</b>					
Strip	26	-4.05 (0.397)	< 0.0001	-3.15 (0.852)	0.0005
Tray	9	-0.90 (0.696)	0.1010		
<b>Month 2</b>					
Strip	26	-6.61 (0.417)	< 0.0001	-2.64 (0.991)	0.0097
Tray	7	-3.98 (0.833)	< 0.0001		

SE = standard error

**Table 4—Tooth Sensitivity and Oral Irritation**

	Strip (n = 30)		Tray (n = 10)		Overall (n = 40)	
	Number of Subjects	% of Subjects	Number of Subjects	% of Subjects	Number of Subjects	% of Subjects
<b>Reported</b>						
Gingival irritation	10	33.3	1	10	11	27.5
Tooth sensitivity	13	43.3	4	40	17	42.5
<b>Observed</b>						
Gingival irritation	0	0	0	0	0	0

ment. On average, observed changes were greater after 2 months than after 1 month.

Response was faster in the strip group. During the first month of treatment, the strip group averaged more than a 4-unit reduction in tooth shade, which represented a statistically significant ( $P < 0.0001$ ) improvement vs baseline. In contrast, the tray group averaged less than a 1-shade reduction during the first month, not differing statistically from baseline ( $P > 0.10$ ). Adjusting for baseline, the strip group averaged 2.6 to 3.2 units greater shade reduction than the tray-group control. With respect to between-group comparisons, the strip group experienced statistically significant superior reductions ( $P < 0.01$ ) in shade compared with the tray group at both the 1- and 2-month time points (Table 3).

Both treatments were generally well tolerated. Mild and transient tooth sensitivity and oral irritation were the most common adverse events associated with daily bleaching (Table 4). These events typically were reported early in the treatment regimen, and there were no

clinical manifestations present at the 1-month or 2-month clinical examinations. Seven subjects discontinued treatment during the first 2 months (3 in the tray group and 4 in the strip group). Of these, 2 individuals in the tray group reported the regimen was inconvenient and withdrew after the 1-month visit. The remaining patients withdrew because of an inability to make the scheduled recall appointments. No one withdrew early or reported modifying their treatment regimen because of an adverse event.

**T**he strip group averaged 2.6 to 3.2 units greater shade reduction than the tray-group control.

**Discussion**

This study was designed to evaluate clinical response after longer-term, daily use of



**Figure 1A**—Pretreatment tooth color.



**Figure 1B**—After 2 months of daily bleaching with whitening strips compared with corresponding shade tab.



**Figure 1C**—After 2 months of daily bleaching with whitening strips compared with pretreatment shade tab.



**Figure 2A**—Pretreatment tooth color.



**Figure 2B**—After 2 months of daily bleaching with whitening strips compared with corresponding shade tab.



**Figure 2C**—After 2 months of daily bleaching with whitening strips compared with pretreatment shade tab.

6.5% hydrogen peroxide whitening strips. The researchers elected to test extended treatment in individuals with tetracycline staining because this clinical condition is reported to require extended treatment of several weeks or months to achieve meaningful whitening.<sup>9</sup> A marketed 10% carbamide peroxide, tray-based system was selected as the control group because this agent has been used previously and reported to be effective in longer-term studies of tetracycline staining.<sup>10,11</sup> Other concentrations may have yielded different results.

Both the strip- and tray-bleaching systems were effective, with both groups differing significantly from baseline at the end of the 2-month monitoring period. Color response in the strip group was superior to the tray group, as evidenced by the significant ( $P < 0.01$ ) between-group treatment differences, favoring the “trayless” whitening strip system, at both 1 and 2 months. Onset of these clinical benefits was more rapid in the strip group. After 1 month of treatment, the strip group showed an average improvement of more than 4 shades compared to less than 1 shade in the tray group. Also, only the strip group experienced statistically significant improvements in tooth color after 1 month. After 2 months, the strip group averaged a 66%

greater shade improvement overall compared to the tray control group. While overnight tray use may improve clinical response in that group, such daily treatment conducted over the long term could also affect subject compliance.

**The use of whitening strips has been proposed as a viable option for longer-term whitening because of favorable compliance, lower systemic exposure, and other factors associated with this easy-to-use bleaching system.**

Treatment response in some individuals was impressive (Figures 1A through 2C). However, this study confirms early observations that extended contact time is needed in many tetracycline-stained teeth. After 2 months of daily treatment, involving approximately 60 hours of strip use or 120 hours of tray use, no subjects had yet reached the predetermined bleaching cutoff, B1. Additional treatment time may be necessary in these subjects to affect maximum color change. Previous

reports suggest a minimum of 2 months of treatment, hence the time point elected for this study.<sup>12</sup> The researchers expect to continue treatment and observation of this study population for up to 6 months to further assess the effectiveness and tolerability of these agents with even longer-term exposure.

Twice-daily use of the 6.5% hydrogen peroxide whitening strips was well tolerated over the 2-month treatment period. The side effects in this study—transient tooth sensitivity and gingival irritation—generally were similar in nature and severity to the primary events reported in other longitudinal trials using the at-home tray-bleaching systems.<sup>9</sup> In the current study, where the whitening strips were used for a total of 60 contact hours over a 2-month period, no subject in the strip group discontinued treatment because of an adverse event. This extended exposure associated with long-term, daily treatment of tetracycline stain corroborates and extends the safety of strip-based tooth whitening as reported in earlier, shorter-duration clinical trials.<sup>13-19</sup>

### Conclusion

The use of whitening strips has been proposed as a viable option for longer-term whitening because of favorable compliance, lower systemic exposure, and other factors associated with this easy-to-use bleaching system.<sup>14</sup> New clinical research involving extended treatment of tetracycline stain for 2 months confirms this proposition. In the current study, daily treatment for 1 month with a 6.5% hydrogen peroxide whitening strip provided efficacy similar to 2 months of treatment with a 10% carbamide peroxide tray system.

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### Disclosure

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