

Clinical Trial Comparing Whitening Strips and a Paint-on Tooth Whitener

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ABSTRACT

Objective: This randomized clinical trial was conducted to evaluate the efficacy and safety of a new “paint-on” tooth whitener relative to a marketed control. **Methods:** After balancing for age and baseline color, adult volunteers were randomized to a carbamide peroxide paint-on liquid with a brush applicator, or 6.0% hydrogen peroxide bleaching strips. Subjects were instructed to treat the maxillary and mandibular arches twice daily for 7 days. Whitening was measured objectively as $L^*a^*b^*$ after 7 days from digital images of the anterior dentition. **Results:** The 14 evaluable subjects ranged in age from 23 to 57 years. After 7 days, the strips yielded a statistically significant ($p < 0.05$) reduction in yellowness (Δb^*) and lightness improvement (ΔL^*), while the paint-on did not differ significantly ($p > 0.05$) from baseline. Whitening strips used simultaneously on the maxillary and mandibular teeth provided over 7 times greater whitening efficacy with respect to Δb^* relative to the paint-on whitener with adjusted means and standard errors of -1.31 ± 0.085 and -0.18 ± 0.085 , respectively, with these groups differing significantly ($p < 0.0001$). Only the paint-on exhibited a significant change in redness, though this was in the wrong direction for bleaching agents. After 7 days, the adjusted mean Δa^* was 0.42 ± 0.100 for the paint-on, differing significantly ($p < 0.002$) from baseline. Mild tooth sensitivity was reported for 3 subjects using the hydrogen peroxide strips. There were no other meaningful adverse events, and no subjects discontinued treatment early. **Conclusion:** The 6.0% hydrogen peroxide whitening strips provided over 7 times greater whitening efficacy than a carbamide peroxide paint-on liquid, while the latter significantly increased tooth redness.

OBJECTIVE

This randomized clinical trial was conducted to evaluate the efficacy and safety of a “paint-on” tooth whitener relative to a marketed control.

METHODS

In this parallel group, examiner-blind, single-center study, healthy adult volunteers were randomized to one of the following treatments:

- 6.0% hydrogen peroxide whitening strips (Crest® Whitestrips™ⁱ) (9-12 mg H_2O_2 depending on the arch)
- 10% carbamide peroxide paint-on gel (Xantia™ⁱⁱ).

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METHODS

Subjects were instructed to treat the maxillary and mandibular arches twice daily for 7 days following the manufacturers suggested instructions. Efficacy was measured using $L^*a^*b^*$ color change collected from digital images of the anterior dentition. Analysis of covariance methods were used to compare treatments and to test for statistically significant change from baseline.

- The Procter & Gamble Company, Cincinnati, OH, USA.*
- Dexcel Pharma Technologies Ltd., Jerusalem, Israel.*

RESULTS

Efficacy:

After 7 days, the strips yielded a statistically significant ($p < 0.05$) reduction in yellowness (Δb^*) and lightness improvement (ΔL^*), while the paint-on did not differ significantly ($p > 0.05$) from baseline. Whitening strips used simultaneously on the maxillary and mandibular teeth provided over 7 times greater whitening efficacy with respect to Δb^* relative to the paint-on whitener with adjusted means and standard errors of -1.31 ± 0.085 and -0.18 ± 0.085 , respectively, with these groups differing significantly ($p < 0.0001$).

Only the paint-on exhibited a significant change in redness, though this was in the wrong direction for bleaching agents. After 7 days, the adjusted mean Δa^* was 0.42 ± 0.100 for the paint-on, differing significantly ($p < 0.002$) from baseline. The composite measures, ΔW^* and ΔE^* , also showed significant color improvements for whitening strips relative to the paint-on product ($p < 0.03$) (Table 1).

Safety:

Both treatments were generally well-tolerated. Minor oral irritation or transient tooth sensitivity represented the most common adverse events. Oral irritation was reported by 1 subject treated with 6.0% hydrogen peroxide strips and 2 subjects treated with the paint-on gel. Mild tooth sensitivity was reported by 3 subjects using the hydrogen peroxide strips. No subjects discontinued treatment due to bleaching-related adverse events.

RESULTS (Cont.)

7 Day Efficacy Response				
Outcome/ Treatment	Baseline Mean (SE)	Adjusted Mean (SE)	Changes from Baseline p-value	Between Treatment p-value
Δb^*				
Whitening Strips	15.71 (0.708)	-1.31 (0.085)	< 0.0001	< 0.0001
Paint-on Gel	16.15 (0.539)	-0.18 (0.085)	0.0547	
ΔL^*				
Whitening Strips	75.49 (0.875)	0.55 (0.252)	0.0498	0.4822
Paint-on Gel	75.07 (0.598)	0.29 (0.252)	0.2664	
Δa^*				
Whitening Strips	5.67 (0.240)	-0.02 (0.100)	0.8596	0.0114
Paint-on Gel	5.87 (0.148)	0.42 (0.100)	0.0016	
ΔW^*				
Whitening Strips	29.71 (0.943)	-1.13 (0.236)	0.0006	0.0271
Paint-on Gel	30.29 (0.727)	-0.28 (0.236)	0.2645	
ΔE^*				
Whitening Strips		1.54 (0.142)	< 0.0001	0.0038
Paint-on Gel		0.82 (0.142)	< 0.0001	

CONCLUSIONS

The low dose hydrogen peroxide whitening strips provided over 7 times greater whitening efficacy than a carbamide peroxide paint-on, while the latter significantly increased tooth redness.