

# Clinical Comparison of Two Self-Directed At-home Bleaching Systems

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## ABSTRACT

**Objective:** The aim of this study was to evaluate the clinical efficacy of two commercially available paint-on tooth whiteners over a 21 day usage period. **Methods:** A total of 38 subjects were randomised to Colgate® Simply White™, an 18% carbamide peroxide paint-on liquid in an applicator bottle, or Crest® Night Effects™, a 19% sodium percarbonate bleaching film in unit dose sachets. Study participants were supplied with manufacturers written instructions for use, Colgate Simply White was used twice daily for 30 minutes and Crest Night Effects was used once a day, overnight. Study duration was 21 days. Efficacy and safety measurements at baseline and 21 days comprised of oral soft tissue examinations and digital image analysis (DIA). Whitening efficacy was determined by evaluating changes from baseline in tooth yellowness ( $\Delta b^*$ ) and tooth brightness ( $\Delta L^*$ ). Statistical analysis was by ANCOVA. **Results:** After 21 days both treatments showed a significant reduction in tooth yellowness and significant increase in tooth brightness ( $p \leq 0.0003$ ). Crest Night Effects giving a  $\Delta b^*$  of  $-1.53$  and a  $\Delta L^*$  of  $1.28$  and Colgate Simply White giving a corresponding  $\Delta b^*$  of  $-0.46$  and a  $\Delta L^*$  of  $0.78$ . Between group comparisons showed significantly ( $p < 0.05$ ) greater colour improvements for Crest Night Effects compared to Colgate Simply White. Both treatments were well tolerated. **Conclusion:** Crest Night Effects provided superior whitening compared to Colgate Simply White over three weeks use.

## OBJECTIVE

This randomized clinical trial was conducted to evaluate the efficacy and safety of two commercially available paint-on tooth whiteners.

## METHODS

In this parallel group, examiner blind, single centre study, 38 healthy adult volunteers were randomised to one of the following treatments:

- 19.0% Sodium Percarbonate bleaching film (Crest Night Effects)
- 18.0% Carbamide Peroxide paint-on gel (Colgate Simply White)

Subjects were asked to treat their maxillary and mandibular arches following manufacturers usage instructions; twice daily for the paint-on gel and once a day, just prior to going to bed, for the percarbonate bleaching film. Efficacy was measured using  $L^*a^*b^*$  colour 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 response was colour change from baseline and the covariant was colour at baseline.

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## RESULTS

The 34 evaluable subjects ranged in age from 18 to 48 years. At all time points both treatments showed a statistically significant ( $p < 0.05$ ) reduction in yellowness ( $\Delta b^*$ ) and lightness improvement ( $\Delta L^*$ ). The 19% sodium percarbonate bleaching film provided 3 times greater whitening efficacy with respect to  $\Delta b^*$  relative to the 18% carbamide peroxide product with adjusted means after 21 days treatment of  $-1.53$  and  $-0.46$ , respectively, with these groups differing significantly ( $p < 0.0001$ ). The 19% sodium percarbonate bleaching film also provided a significant improvement in tooth brightness relative to the 18% carbamide peroxide product ( $p < 0.0153$ ).

The composite measures,  $\Delta W^*$  and  $\Delta E^*$ , also showed significant color improvements for the 19% sodium percarbonate bleaching film relative to the 18% carbamide peroxide paint-on ( $p = 0.0003$  and  $0.0001$  respectively after 21 days treatment) (Table 1).

Table 1: EFFICACY RESPONSE

Treatment	Day 7	Day 14	Day 21	Between Treatment $p$ -value (Day 21)
<b><math>\Delta b^*</math></b>				
19% Percarbonate film	-0.84	-1.43	-1.53	0.0001
18% Carbamide Peroxide	-0.34	-0.44	-0.46	
<b><math>\Delta L^*</math></b>				
19% Percarbonate film	0.89	1.13	1.28	0.0153
18% Carbamide Peroxide	0.32	0.55	0.78	
<b><math>\Delta W^*</math></b>				
19% Percarbonate film	-1.22	-1.8	-1.98	0.0003
18% Carbamide Peroxide	-0.49	-0.73	-0.9	
<b><math>\Delta E^*</math></b>				
19% Percarbonate film	1.49	1.99	2.18	0.0001
18% Carbamide Peroxide	0.71	0.93	1.09	

## 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 3 subjects treated with the 18% carbamide peroxide paint-on. Mild tooth sensitivity was reported by 2 subjects using 18% carbamide peroxide paint-on and two subjects using the 19% sodium percarbonate bleaching film. No subjects discontinued treatment due to bleaching-related adverse events.

## CONCLUSION

The 19% sodium percarbonate bleaching film provided superior whitening compared to the 18% carbamide peroxide paint-on over three weeks use.