

Clinical Comparison of Two Paint-on Bleaching Systems

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ABSTRACT

Objectives: The aim of this study was to evaluate the clinical efficacy of a low peroxide containing experimental tooth whitener and a commercially available paint on tooth whiteners over a 21 day usage period.

Methods: A total of 55 subjects were randomized to Crest[®] Night Effects[™], a 19% sodium percarbonate bleaching film, or an experimental film containing 9.7% Sodium Percarbonate. Both products were supplied in aluminum bottles with disposable brushes for each usage occasion. Study participants were supplied with written instructions for overnight use. Study duration was 21 days. Efficacy and safety measurements at baseline, 7, 14, 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 (Δb^*) and tooth brightness (ΔL^*). Statistical analysis was by ANCOVA. **Results: Age ranged from 18-47 years, and groups were balanced on both demographic parameters and baseline $L^*a^*b^*$ tooth color. After 21 days both treatments showed a significant reduction in tooth yellowness and significant increase in tooth brightness ($p = 0.0001$). Color improved significantly ($p < 0.05$) from Day 7 to Day 21. After 21 nights, the Crest Night Effects group had adjusted mean (SE) Δb^* and ΔL^* of -2.0 (0.19) and 1.8 (0.17). For the experimental group, adjusted mean (SE) Δb^* was -1.9 (0.17) and ΔL^* was 1.7 (0.15). The experimental and control groups did not differ significantly ($p > 0.50$) on Δb^* or ΔL^* at Days 7, 14 or 21. Both treatments were well tolerated.**

INTRODUCTION

Barrier-less bleaching systems represent a different type of delivery system for tooth bleaching. These systems are applied by painting the product onto the surface of the anterior teeth, normally via a brush. The level of efficacy achieved by these systems is normally defined by the integrity of the barrier formed by the film and the subsequent prevention of loss of hydrogen peroxide into the oral cavity.

PURPOSE

To evaluate the efficacy of a low peroxide containing paint-on tooth bleaching product versus a currently marketed paint-on product.

MATERIALS AND METHODS

In this parallel group, examiner blind, single centre study, 54 healthy adult volunteers were randomized to one of the following treatments:

- 19.0% Sodium Percarbonate bleaching film (Crest[®] Night Effects[™])
- Experimental bleaching film containing 9.7% Sodium Percarbonate.

Subjects were asked to treat their maxillary and mandibular arches following the same standard usage instructions for both products, once a day, just prior to going to bed. Efficacy was measured using $L^*a^*b^*$ color change collected from digital images of the anterior dentition after 1 week, 2 weeks and 3 weeks of product usage. Analysis of covariance methods were used to compare treatments and to test for statistically significant change from baseline. The response was color change from baseline and the covariant was color at baseline

i. The Procter & Gamble Company, Cincinnati, OH, USA

RESULTS

The 52 evaluable subjects ranged in age from 18 to 47 years. At all time points both treatments showed a statistically significant ($p < 0.0001$) reduction in yellowness (Δb^*) and lightness improvement (ΔL^*) from baseline. The 9.7% Sodium Percarbonate bleaching film did not differ significantly ($p > 0.5005$) from the higher Percarbonate system with respect to both Δb^* and ΔL^* at all measurement times. The level of whitening benefit continued to increase with time for both systems over the duration of the study. After 21 days of treatment the 9.7% Sodium Percarbonate bleaching film had an adjusted mean Δb^* value of -1.9 compared to the 19% Sodium Percarbonate bleaching film, which had an adjusted mean Δb^* value of -2.0 ($p = 0.7558$). The adjusted ΔL^* mean values were 1.7 and 1.8 respectively over the same treatment time period.

The composite measure, ΔW^* , also showed a similar trend to Δb^* and ΔL^* (Table 1).

FIGURES AND TABLES

Table 1: Efficacy Response Mean change (SE) (adjusted for baseline b value)						
Treatment	Day 7	Day 14	Day 21	Between treatment p-value		
				Day 7	Day 14	Day 21
Δb^*						
19% Percarbonate film	-1.0 (0.11)	-1.5 (0.19)	-2.0 (0.19)	0.8225	0.6402	0.7558
9.7% Percarbonate film	-0.8 (0.10)	-1.4 (0.14)	-1.9 (0.17)			
ΔL^*						
19% Percarbonate film	1.1 (0.12)	1.4 (0.16)	1.8 (0.17)	0.9342	0.5005	0.6576
9.7% Percarbonate film	0.8 (0.11)	1.4 (0.15)	1.7 (0.15)			
ΔW^*						
19% Percarbonate film	-1.5 (0.13)	-2.2 (0.19)	-2.8 (0.22)	0.9700	0.6784	0.8154
9.7% Percarbonate film	-1.2 (0.12)	-2.0 (0.18)	-2.5 (0.21)			



Split tooth representation of tooth color both pre-treatment and post-treatment

Safety:

Both treatments were generally well-tolerated. Minor oral irritation or transient tooth sensitivity represented the most common adverse events.

No subjects discontinued treatment due to bleaching-related adverse events.

CONCLUSION

The experimental whitener containing 9.7% sodium percarbonate showed a similar efficacy profile to a commercial brush-applied system throughout the 21-day usage period.