Effectiveness and Tolerability of a Direct Application Percarbonate Bleaching Film: Evidence from 6 Clinical Trials

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ABSTRACT

Objective: This integrated research was conducted to evaluate the efficacy and safety response of a direct application percarbonate tooth whitening system. **Methods:** A total of 6 randomized, parallel group, placebo controlled clinical trials were conducted involving 218 subjects (aged 12-55 years). All subjects received either a 19% sodium percarbonate bleaching film or its equivalent non-percarbonate placebo to use in the evening, once per day, for 14 days. Product was applied directly to the facial surfaces of anterior teeth leaving the film *in situ* on the teeth overnight until removal in the morning. Efficacy (L*a*b*) and safety (oral soft tissue examinations) measures were made at baseline and then after 14 days of treatment. In these trials, digital image analysis was used to objectively measure pre- and post-treatment, anterior tooth color in CIE Lab color space as b* (yellow-blue), L* (lightness) and a* (green-red) values. **Results:** A meta-analysis examining change from baseline of the pooled subject data revealed a significant ($p<0.001$) change in tooth colour relative to baseline and versus placebo for those subjects assigned to the active bleaching product. An adjusted mean Δb^* value (with standard error) of –1.59 (0.06) and adjusted mean ΔL^* value of 1.61 (0.07) were recorded for the percarbonate film versus –0.08 (0.07) and 0.22 (0.07) respectively for the placebo product. Analysis of the composite parameters ΔE^* and ΔW^* revealed similar findings. Reports of tooth sensitivity were higher for the active treatment vs placebo ranging 0 – 15% whilst observed/ reported tissue irritation ranged 0 – 32% being similar across both groups. **Conclusions:** Composite results from these 6 multi-national studies confirm the direct application bleaching film to be well-tolerated and provide a significant tooth whitening benefit after 14 days treatment.

INTRODUCTION

A recently introduced tooth whitening system, Crest® Night Effects™, utilises a novel 19% sodium percarbonate peroxide source in a silicone polymer based suspension. This paint-on technology forms a substantive film that adheres effectively to enamel delivering peroxide into the tooth as the matrix slowly degrades over time. A comprehensive multi-national research program was undertaken to characterize the clinical efficacy and safety response. A meta-analysis from six placebo-controlled clinical studies is presented.

MATERIALS AND METHODS

All of the studies employed a similar randomized, parallel leg (n=20/ group), blinded (double where possible), placebo controlled design evaluating 2-weeks overnight usage of test product. Tooth whitening effects were measured using Digital Image Analysis to derive CIE L*a*b* tooth color values at baseline and day 14. Safety evaluations were made via examinations of the oral soft/ hard tissues and subject questionnaires conducted at the same time-points.

Statistical analyses of treatment comparisons were made using analysis of covariance.

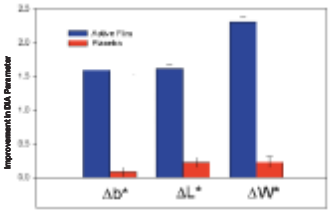
RESULTS

A total of 218 subjects, aged 18-55 years, who completed treatment usage were considered eligible for inclusion in the meta-analysis. The majority of subjects were female, 67% and non-smokers, 75%. In all studies treatment groups were balanced for age, smoking and baseline tooth colour.

Efficacy Results:

All six studies demonstrated a significant whitening benefit after 14 days overnight use of the percarbonate bleaching film. The results from the meta-analysis of pooled subject data from these studies are described in the table below:

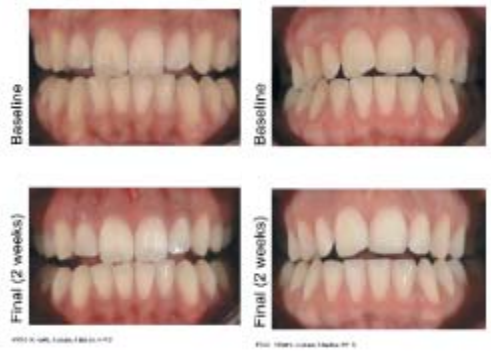
Change in Tooth Color	Treatment	N	Baseline (SE)	Adjusted Mean Change from Baseline	Standard Error	Treatment Comparison
Δb*	Percarbonate Bleaching Film	113	18.38 (0.15)	-1.59	0.062	P<0.001
	Placebo Film	105	18.57 (0.15)	-0.08	0.069	
ΔL*	Percarbonate Bleaching Film	113	74.74 (0.15)	1.61	0.069	P<0.001
	Placebo Film	105	74.61 (0.18)	0.22	0.074	
ΔW*	Percarbonate Bleaching Film	113	32.14 (0.17)	-2.30	0.074	P<0.001
	Placebo Film	105	32.37 (0.19)	-0.23	0.079	



Safety Results:

Adverse Event Type	Bleaching Film Total No. of AEs (%) (N = 113)	Placebo Film Total No. of AEs (%) (N = 105)
Reported Tooth Sensitivity	19 (17%)	7 (8%)
Observed/ Reported Oral Soft Tissue Irritation	29 (26%)	25 (24%)

Pre- and Post-treatment images of anterior teeth following use of percarbonate bleaching film



CONCLUSION

Composite results from 6 multi-national studies confirm the direct application bleaching film to be well-tolerated and provide a significant tooth whitening benefit after 14 days treatment.

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