

Prevention of Tooth Stain Formation by a Tartar Control Whitening Dentifrice

R.L. Isaacs¹, M.B. Jones^{*2}, T.S. Owens², D.P. Stevens², P.A. Walters², R.W. Gerlach²

¹Indiana University, Indianapolis, IN, USA; ²Procter & Gamble Co., Cincinnati, OH, USA

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ABSTRACT

Pellicle rapidly accumulates on tooth surfaces after prophylaxis and may acquire cosmetically unacceptable levels of stain. A 3 month clinical trial was conducted to evaluate the prevention of stain by an experimental silica-based tartar control whitening dentifrice (Crest[®] Extra Whitening) compared to marketed whitening and regular dentifrice controls. Prior to the trial, a one month screening exercise was conducted to identify adult subjects who accumulated extrinsic tooth stain after dental prophylaxis. A total of 674 subjects were stratified based on tooth whiteness, gender and tobacco usage, then given a dental prophylaxis and randomized to one of the three dentifrice treatment groups. All dentifrice use was unsupervised. Change in tooth whiteness (DL) was determined by comparing Chromameter (Minolta) measurements collected on the facial surfaces of the 4 central incisors at 1 and 3 months to baseline. Ninety-six percent of subjects completed the 3 month study and were evaluable. At both 1 and 3 months, the two whitening dentifrices did not differ from baseline in terms of DL. In contrast, the regular control had DL values of -0.25 and -0.39 at 1 and 3 months respectively, differing from baseline at both time points. Each of the whitening dentifrices differed statistically from the regular control in stain accumulation ($p < 0.001$) at 1 and 3 months, but these whitening dentifrices were not different from each other. In general, all 3 test dentifrices were well tolerated. **These data demonstrate the effectiveness of the experimental tartar control whitening dentifrice in preventing stain accumulation after dental prophylaxis compared to the marketed regular dentifrice control.**

INTRODUCTION

A proteinaceous membranous layer known as a pellicle forms on teeth within minutes of mechanical polishing. Unstained pellicle is initially invisible but can, over time, incorporate extrinsic stains of various colors, particularly from darkly pigmented foods or tobacco. A number of studies have demonstrated that dentifrices with high abrasivity can remove or reduce the formation of this type of tooth stain. However, it has been shown that with increasing abrasivity, these products can remove dentin and cementum from the tooth.

Silica, which is generally considered to be less damaging to tooth structure, may remove or reduce the formation of extrinsic stain. Recent advances in the silica manufacturing process allowed for the addition of larger amounts of the abrasive in dentifrice formulations without effecting hard tissue safety.

OBJECTIVE

The purpose of this study was to demonstrate a dentifrice containing a high percentage of silica effectively retards the formation of extrinsic tooth stain. The primary objective of the study was to evaluate cleaning/whitening efficacy as measured by the differences among the changes in tooth whiteness as defined by the Chromametric L* values before and after subject use of Crest[®] Extra Whitening (CEW), a marketed whitening control (MWC), or a regular control (RC) dentifrice.

STUDY DESIGN

This study was a single site, double-blind, parallel group design. A total of 674 subjects were enrolled into the study based on arrayed DL* scores obtained from a screening exercise conducted at the site immediately prior to this trial. The subjects were randomly assigned to one of the three treatments groups. Subjects received a prophylaxis (anterior teeth only) and baseline OST examination prior to the Chromameter reading. Subjects were asked to use their assigned test product unsupervised, at least twice daily, during the 3-month test period. At the end of the first and third month of product usage, the subjects returned for an OST examination and color measurement via the Chromameter.

RESULTS

Subject Disposition: Of the 674 enrolled subjects, 672 were randomized to treatment: 225 subjects in the Crest[®] Extra Whitening group, 222 subjects in the marketed control group, and 225 subjects in the regular control group.

Of the randomized subjects, 648 (214 subjects in the Crest[®] Extra Whitening group, and 217 in each of the control groups) completed the study, and 654 were evaluable for efficacy analysis at Month 1 and/or Month 3.

Demographics: For these 654 subjects, treatment groups were comparable in demographics: mean age was 43 years (range=20-81 years); 72% were female; 79% were Caucasian and 15% were Black; 18% were smokers at the time of the study.

Efficacy: Within both the CEW and MWC groups, there were no statistically significant (two-sided $p \geq 0.058$) differences from the immediately post-prophylaxis L* baseline values at either month. Within the RC group, there were statistically significant (two-sided $p \leq 0.001$) mean decreases in L* from baseline at both Months 1 and 3.

Analysis of Covariance Results for DL*		
Treatment Group	Adjusted Means ^a	
	Month 1	Month 3
CEW	-0.03 (n=217)	-0.07 (n=214)
MWC	0.05 (n=214)	0.03 (n=215)
RC	-0.25 (n=217)	-0.39 (n=217)
RMSE ^d	0.737	0.770
Pairwise Treatment One-Sided P-Values		
CEW vs MWC	NS	NS
CEW vs RC	<0.001	<0.001
MWC vs RC	<0.001	<0.001

^a Means are adjusted for screening DL*
^d Root mean square error from common slope ANCOVA

Safety: A total of 98 adverse events (AEs) were reported by 82 randomized subjects: 31 (14%) subjects in the CEW group reported 41 AEs, 33 (15%) subjects in the MWC group reported 37 AEs, and 18 (8%) subjects in the RC group reported 20 AEs. All but 4 of the reported 98 AEs were considered mild in severity by the investigator.

CONCLUSION

-Subjects brushing with the Crest[®] Extra Whitening and the marketed whitening control dentifrices had significantly whiter teeth at Months 1 and 3 than those brushing with the regular control dentifrice.

-There were no significant differences between the Crest[®] Extra Whitening and marketed whitening control dentifrices.