

Removal of Long-Standing Tooth Stain by a Tartar Control Whitening Dentifrice

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ABSTRACT

Removal of long-standing tooth stain without excessive hard tissue abrasion may represent one of the more difficult challenges for whitening dentifrices. An 8 week clinical trial was conducted to evaluate stain removal by an experimental silica-based, enamel safe tartar control whitening dentifrice (Crest® Extra Whitening) compared to a marketed baking soda dentifrice control. First, a screening exercise was conducted to identify individuals with long-standing extrinsic dental stain. This targeted adults who reported "stained teeth" and coffee/tea drinking or smoking, but who had no recent history of dental prophylaxis. Targeted subjects were examined for stain (Lobene Index) and tooth shade/color (Vita). A total of 291 adults having extrinsic stain and tooth color A3 or darker were enrolled in the study. Subjects were randomized to one of the two treatment groups, and all dentifrice use was unsupervised. Tooth color was measured at 4 and 8 weeks from shade values collected from the 8 incisors, and averages were determined from a linear ordering of the shade guide. A total of 279 evaluable subjects completed the 8 week study. Overall, the experimental dentifrice group experienced an improvement in color, differing statistically from baseline ($p < 0.001$) and from the marketed control ($p < 0.05$). After 8 weeks use, the experimental dentifrice was effective in reducing maximum color (darkest shade of any of the incisor teeth) by 0.8 units, differing statistically from baseline ($p < 0.001$) and from the marketed control ($p < 0.05$). Safety profiles for the two dentifrices were generally similar. **Compared to the marketed baking soda control, the experimental tartar control whitening dentifrice was effective in removing long-standing dental stain, and reduced maximum or worst stain.**

OBJECTIVE

The purpose of this study was to evaluate removal of natural dental stain by Crest Extra Whitening relative to a marketed baking soda (BS) dentifrice control.

MATERIALS AND METHODS

Study Design: This was an 8-week randomized, double-blind, parallel study design, conducted at a single center. Screening was conducted to identify subjects having an average overall incisor Vita Shade Guide tooth color of A3 or darker and a minimal amount of stain on the facial surfaces of incisors (Lobene Stain scores stain of at least 1 in intensity and area on at least 3 of the 8 incisor teeth or a total Lobene score of 5 on at least 2 incisor teeth). Safety and efficacy measurements were performed at baseline and after 4 and 8 weeks of product use.

Efficacy Measurements: Product efficacy assessments were performed on a rank ordering of the Vita Shade Guide according to the manufacturer's recommendation (Fig. 1).

Figure 1.

Vita Shade Ranking Guide															
Darkest								Lightest							
C4	A4	C3	B4	A3.5	B3	D3	A3	D4	C2	C1	A2	D2	B2	A1	B1
16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1
Rank Ordering															

Changes in tooth color were performed on:

1. the average rank scores for all evaluable teeth per subject
2. the average rank scores for teeth with extrinsic stain at screening
3. the maximum rank for all evaluable teeth
4. the maximum rank for teeth with extrinsic stain at screening.

RESULTS

Product Efficacy: A total of 278 subjects were evaluable for efficacy analysis. Table 1 summarizes the demographics for the evaluable subject population. Statistical analyses of Vita Shade differences from baseline for all evaluable teeth are summarized on Table 2. Analyses for only those teeth having stain at the baseline examination are summarized in Table 3.

Table 1.

Subject Demographics			
	Crest® Extra Whitening	BS Control Dentifrice	Total
Mean Age	43.6	44.2	43.9
Gender:			
Female	67 (47%)	72 (54%)	139 (50%)
Male	77 (53%)	62 (46%)	139 (50%)
Current Smoker:			
Yes	81 (56%)	77 (57%)	158 (57%)
No	63 (44%)	57 (43%)	120 (43%)

Table 2.

Summary of Vita Shade Difference from Baseline All Evaluable Teeth					
	Crest® Extra Whitening		Baking Soda Control Dentifrice		
	Mean (SE)	Within Treatment p-Value	Mean (SE)	Within Treatment p-Value	Between Treatment p-Value
Ave. DRank:					
Week 4	1.04 (0.152)	<0.001	0.53 (0.134)	<0.001	0.046
Week 8	1.42 (0.168)	<0.001	0.96 (0.145)	<0.001	0.020
Max. DRank:					
Week 4	0.62 (0.175)	<0.001	0.21 (0.180)	0.091	0.072
Week 8	0.81 (0.204)	<0.001	0.18 (0.185)	0.088	0.049

Safety: A total of 116 (40%) of the 291 randomized subjects reported 148 Adverse Events (AEs). There were no differences between treatment groups in the number or types of adverse events.

CONCLUSION

- Crest® Extra Whitening was superior to a marketed baking soda dentifrice in removing natural tooth stain.
- Crest® Extra Whitening successfully removed natural stain on the maximally discolored teeth.
- Both test products were well tolerated by subjects and were considered to be safe in use.

Table 3.

Summary of Vita Shade Difference from Baseline Teeth with Lobene Stain at Screening Visit					
	Crest Extra Whitening		Baking Soda Control Dentifrice		
	Mean (SE)	Within Treatment p-Value	Mean (SE)	Within Treatment p-Value	Between Treatment p-Value
Ave. DRank:					
Week 4	1.14 (0.155)	<0.001	0.75 (0.145)	<0.001	0.146
Week 8	1.60 (0.175)	<0.001	1.18 (0.159)	<0.001	0.039
Max. DRank:					
Week 4	0.79 (0.168)	<0.001	0.26 (0.185)	0.046	0.027
Week 8	1.03 (0.205)	<0.001	0.33 (0.191)	0.023	0.040