Removal of Tooth Stain by a Tartar Control Whitening Dentifrice

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ABSTRACT

Tobacco use, coffee or tea drinking, use of chlorhexidine and other practices have been reported to induce or accelerate dental stain accumulation. A 9 week clinical trial was conducted to evaluate the effect of an experimental tartar control whitening dentifrice on induced dental stain. The study model involved 3 weeks of stain induction followed by 6 weeks unsupervised brushing to assess efficacy. To induce stain, 222 healthy adult volunteers received a dental prophylaxis, and then began a limited brushing regimen supplemented by 3 times daily rinsing with tea and once daily rinsing with 15 mL of 0.12% chlorhexidine. This regimen was suspended, and 187 subjects with tooth stain were entered into a 6 week clinical trial where they were randomized to either an experimental silica-based tartar control whitening dentifrice (Crest® Extra Whitening) or a marketed regular dentifrice control, balancing for stain levels and smoking status. At baseline, 3 and 6 weeks, stain area and stain intensity were measured on the 8 anterior teeth using the Lobene Index. A total of 176 subjects completed the 6 week regimen and were evaluable. At 6 weeks, composite Lobene means were 35% lower for the experimental dentifrice compared to the regular control. In addition to the overall reductions, there were statistically significant reductions in stain area ($p<0.015$) and stain intensity ($p<0.01$) at both 3 and 6 weeks. This stain reduction involved both the gingival and tooth body components of extrinsic stain as measured using this index. Safety profiles for the two test dentifrices were generally similar. **After three and six weeks use, the experimental tartar control whitening dentifrice reduced dental stain compared to the marketed control.**

INTRODUCTION

The formation of extrinsic tooth stain is a well-established side effect associated with topical use of chlorhexidine (Heyden, *J Periodontol* 1973). This stain, which may be highly variable in clinical presentation, can accumulate within a few days, and often requires extended professional intervention for removal (Hoyos, *Brit Dent J* 1977). Clinical models have taken advantage of this known staining propensity, using chlorhexidine sometimes in combination with brewed tea to induce stain over a relatively short time period (Addy, *J Clin Periodontol* 1995). This new clinical trial used a modified regimen combining limited brushing with periodic use of chlorhexidine and tea to evaluate the stain removal effectiveness of a novel tartar control whitening dentifrice.

MATERIALS AND METHODS

A 9 week randomized and controlled, double blind, clinical trial was conducted to evaluate the stain removal efficacy of a new whitening dentifrice. After a baseline prophylaxis, extrinsic dental stain formation was induced over a 3 weeks by a limited brushing regimen, one-time daily rinsing with 15 mL of 0.12% chlorhexidine gluconate and three-times-daily rinsing with brewed tea. Stain accumulation was measured at the end of the induction period (Lobene, *J Am Dent Assoc* 1968), then eligible subjects were randomized to a whitening tartar control dentifrice (Crest® Extra Whitening) or a regular control. Dentifrices were supplied in blank white foil laminate tubes that were uniquely labeled to assure blinding. Subjects discontinued rinsing and brushed unsupervised with their assigned dentifrice for 6 weeks to evaluate stain removal.

RESULTS

A total of 222 subjects entered the induction phase. After 3 weeks, 187 met continuance criteria and were randomized to treatment. This treatment population averaged 40.5 years of age, and treatment groups were well-balanced with respect to primary demographic variables.

All 187 subjects completed the 6 week treatment phase, with 176 considered evaluable for efficacy testing. This evaluable population was 79% female and 18% were current smokers. After induction, Lobene scores for this evaluable population averaged 0.96 for area and 0.72 for intensity.

After 3 and 6 weeks treatment, subjects in the Crest® Extra Whitening group had significantly lower Lobene means (i.e., less stained teeth) than subjects in the regular control group (Table 1).

Table 1. Overall Lobene Scores at 3 & 6 Weeks

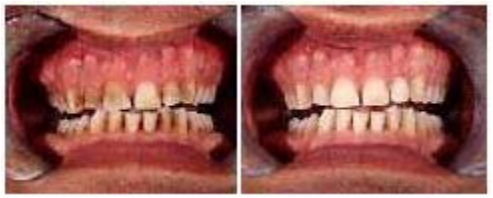
Measure	Time	Crest EW	Control	*p* value
Area	Week 3	0.45	0.56	0.014
	Week 6	0.23	0.36	0.007
Intensity	Week 3	0.37	0.45	0.006
	Week 6	0.22	0.29	0.007
Composite	Week 3	16.72	21.63	0.016
	Week 6	8.58	13.24	0.006

At 6 weeks, this represented a 36% reduction in stain area, a 24% reduction in stain intensity and a 35% reduction in overall (composite) stain for Crest® Extra Whitening compared to the regular dentifrice control. These treatment effects held irrespective of where stain was measured on the tooth, as the Crest® Extra Whitening group experienced 32% less Lobene body stain and 40% less Lobene gingival stain after 6 weeks compared to the regular control.

The clinical manifestations were considerable, as many subjects exhibited extensive stain after the 3 week induction period. Importantly, some subjects experienced noticeable stain removal with as little as 3 weeks use (See Case Study).

Subject 2102
Response at 3 Weeks with Crest® Extra Whitening

Baseline **3 weeks**



Both the stain induction and stain removal regimens were generally well-tolerated. One subject voluntarily discontinued treatment during the stain induction because of excessive tooth stain. No subjects discontinued treatment during the stain removal phase, and all oral soft tissue events during that period were generally mild in nature. The primary cause for early termination was insufficient stain accumulation during the induction phase (26 subjects or 11.7% of the population).

CONCLUSION

-Crest Extra Whitening was superior to the regular dentifrice in stain removal.
-Reductions in this chlorhexidine/tea induced tooth stain were observed at 3 and 6 weeks.
-This may represent a useful clinical model for evaluating stain removal by dentifrices.

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