

ABSTRACT

Repeated exposure to chlorhexidine and tea has long been recognized to promote extrinsic tooth stain (Addy, *Br Dent J* 1985). Previously, we established the merits of a modified, rapid clinical trials model using chlorhexidine and tea in combination with restricted brushing to accelerate staining (Gerlach, *J Dent Res* 1998). New research was conducted to compare selected chemical and mechanical approaches for stain removal using this model. After prophylaxis, stain was induced during a 3 week pre-treatment period, and then the healthy adult volunteers were randomized to one of three treatment groups—a novel dentifrice using a polyphosphate as an antitartar agent, a marketed alumina-based high abrasive dentifrice or a regular lower abrasive dentifrice which served as the experimental control. Stain area and intensity were assessed after 3 and 6 weeks treatment using a standard method. A total of 94 subjects completed the study. Treatment effects were limited to reductions in stain area, and after 3 weeks, both the chemical and abrasive dentifrices showed statistically significant reductions in stain area ($p < 0.03$) relative to the control. After 6 weeks, adjusted mean stain area scores were 0.36, 0.39 and 0.50 for the polyphosphate, alumina and regular dentifrice groups respectively. While both the polyphosphate and alumina dentifrices showed directional benefits, only the polyphosphate differed statistically ($p = 0.02$) from the control. There were no statistically significant differences in stain levels between the polyphosphate and alumina dentifrice groups at any time. **This study demonstrates that polyphosphate-containing dentifrices are effective in removing extrinsic tooth stain with performance comparable to that seen with more conventional abrasive dentifrices.**

INTRODUCTION

Tea drinking combined with frequent use of chlorhexidine mouthrinse has been reported to readily promote extrinsic tooth stain formation, with measurable accumulation often in a few days (Addy, *J Clin Periodontol* 1995). A clinical model for product evaluation employing this type of rapid stain acceleration method paired with restricted toothbrushing has proven valuable in simplifying subject recruitment and

shortening overall clinical cycle times (Gerlach, *J Dent Res* 1998). This new clinical trial was conducted to compare the relative stain removal efficacy of dentifrices with chemical (polyphosphate) or mechanical (alumina abrasive) ingredients versus a control dentifrice in a pre-treatment rapid stain induction model.

MATERIALS AND METHODS

Products Tested

Novel Tartar Control Polyphosphate Dentifrice:
(0.243% NaF); **RDA = 109** The Procter & Gamble Company

Marketed High Abrasive Aluminum Oxide Dentifrice:
Ultradent® Advanced Whitening Formula
(0.76% NaMFP); **RDA = 145**; Colgate-Palmolive Company

Marketed Control Dentifrice:
Crest® Regular
(0.243% NaF); **RDA = 95**; The Procter & Gamble Company

Study Design

This 9-week randomized and controlled, double-blind, parallel group clinical trial assessed the relative stain removal effectiveness of three dentifrices. Following a prophylaxis, extrinsic dental stain was induced in generally healthy adults over a 3-week period via daily at-home rinsing with 15 mL of 0.12% chlorhexidine gluconate and brewed tea, together with limited brushing with a marketed low abrasive dentifrice. At the end of the induction period, stain was measured using the standard Lobene method (Lobene, *JADA* 1968), wherein stain area and intensity were graded on four surfaces of each of the incisor teeth. Eligible subjects were randomly assigned based on stain scores and smoking status to one of the 3 test groups: either a novel polyphosphate anti-tartar dentifrice, a marketed high abrasive dentifrice, or a marketed low abrasive control dentifrice. Subjects brushed unsupervised in their customary manner twice daily, with Lobene stain assessments at Week 3 and Week 6 of product use.

RESULTS

The evaluable study population completing the trial included 94 adults who had a mean age of 38 years, were predominately female (81%), Caucasian (89%), and non-smokers (84%). The treatment groups were well-balanced for demographic parameters. Post-induction stain levels were considerable, but there were no significant between-group differences ($p \geq 0.081$), with stain area averaging 0.60 and stain intensity averaging 0.50 (Table 1).

Table 1. Post-Induction (Day 0) Lobene Stain (Evaluable Subjects)

Dentifrice Group	(n=)	Area Mean (SEM)	Intensity Mean (SEM)	2-sided p-value
Polyphosphate	(35)	0.52 (0.077)	0.48 (0.075)	
High Abrasive	(27)	0.72 (0.103)	0.61 (0.109)	
Control	(32)	0.55 (0.077)	0.42 (0.071)	≥ 0.081

SEM = Standard Error

As shown in Table 2, after 3 weeks of test product use, subjects brushing with either the polyphosphate or high abrasive dentifrices experienced significant ($p \leq 0.027$) reductions in extrinsic stain area relative to the control group. After 6 weeks, only the polyphosphate group showed statistically significant ($p = 0.025$) stain area reductions vs. the control group, representing a 28% relative reduction.

Table 2. Lobene Stain ANCOVA Results by Time (Evaluable Subjects)

Dentifrice Group	Area Week 3	Adjusted Means ^a		Intensity Week 6
		Area Menu (SEM)	Intensity Week 3	
Polyphosphate	0.421*	0.357*	0.466	0.324
High Abrasive	0.404*	0.387	0.441	0.395
Control	0.565	0.496	0.473	0.394

*superior to negative control ($p \leq 0.027$, one-sided)
^aMeans are adjusted with post-induction (day 6) score as the covariate

There were no statistically significant stain level differences ($p \geq 0.142$) between the polyphosphate and high abrasive dentifrices or between any of the products for stain intensity at either the Week 3 or Week 6 assessments (Table 2). All test dentifrices were well-tolerated.

CONCLUSION

In comparing the abilities of a novel polyphosphate dentifrice and a marketed high abrasive dentifrice to remove chlorhexidine/tea-induced stain relative to a control dentifrice, both were efficacious after 3 weeks, but only the polyphosphate dentifrice showed statistically significant stain reduction vs. control after 6 weeks of use.