Stain Removal of Experimental Nighttime Dentifrice and Power Brush/Dentifrice Control

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ABSTRACT

Objectives: This research was conducted to evaluate the clinical effectiveness of an experimental nighttime whitening dentifrice versus a marketed power brush with stain removal evidence as the study control.

Methods: A total of 30 generally healthy adults with visible extrinsic facial stain on 6 anterior teeth were randomly assigned to one of two regimens. The experimental group received a manual soft brush, a regular anticavity toothpaste (Crest® Cavity Protection) for the AM use, and an experimental whitening dentifrice for the PM use. The control group received a power toothbrush (Sonicare® Advance 4100) and the regular anticavity dentifrice for AM and PM usage. Subjects were instructed to brush twice daily for two minutes using the assigned regimen over a 14-day period. Stain area and intensity were measured using a standard index (Modified Lobene) at baseline, and after 7 & 14 days treatment.

Results: Mean (SD) age was 47.9 (13.12) years, and all subjects completed the 14-day study. The population presented with appreciable stain at baseline, with composite stain mean (SD) of 2.71 (0.554) and 2.76 (0.924) in the experimental and control groups, respectively. Both groups exhibited significant ($p < 0.0001$) stain reduction at Week 1. There was incremental stain removal from Week 1 to Week 2. At the end-of-treatment, median composite stain was 85% removed in the experimental group and 89% in the control. Groups did not differ significantly ($p = 0.37$) on Week 2 composite stain. Both regimens were well-tolerated.

Conclusion: Use of the daytime/nighttime dentifrice combination removed appreciable extrinsic stain, similar in magnitude to a power toothbrush plus regular anticavity dentifrice.

MATERIALS AND METHODS

This was a parallel group, examiner-blinded clinical trial which assessed absolute "whitening" through extrinsic stain removal. A total of 30 generally healthy volunteers, between the ages of 25 and 71 years of age, exhibiting a Lobene score of = 1.0 on the facial surfaces of at least 6 anterior teeth were enrolled and completed the trial. Of the 12 anterior facial surfaces scored at the Baseline visit, only the 6 teeth with the highest Lobene score were followed for the duration of the study. The subjects were stratified to one of two treatment groups based on Baseline average modified Lobene composite scores of the 6 study teeth (= 2 and > 2) and gender.

MATERIALS AND METHODS (Cont.)

Fifteen subjects were assigned to a combination regimen of an experimental whitening dentifrice used at night with Crest® Cavity Protection dentifrice used in the morning and a manual toothbrush. The remaining 15 subjects were assigned to the positive control group using the Sonicare® Advance 4100 with Crest® Cavity Protection dentifrice. All subjects were told to discontinue the use of all other oral hygiene products, and asked to brushed twice daily with the assigned treatments for two minutes each in front of a mirror.

Efficacy was measured using the Modified Lobene Index, and safety was assessed from clinical examination and subject report at the Baseline, Week 1, and Week 2 visits.

For Lobene stain scores, treatment group comparisons to baseline were performed using pair-difference t-tests. An analysis of covariance was used for between group comparisons of the Lobene stain score using Baseline scores as a covariate. All statistical comparisons were two-sided with a 5% significance level.

Demographics and Baseline Lobene Stain Score

	Experimental Dentifrice	Power Toothbrush
Subjects: N	15	15
Age: Mean (SD)	48.5 (14.01)	47.3 (12.62)
Composite Stain: Mean (SD)	2.71 (0.554)	2.76 (0.924)
Female: N(%)	9 (60.0%)	7 (46.7%)
Tobacco Users: N(%)	12 (80.0%)	11 (73.3%)
Coffee/Tea/Dark Cola Drinkers: N(%)	15 (100.0%)	14 (93.3%)

RESULTS

Safety:

There was one adverse event in the study. The examiner observed one subject in the power tooth brush group with mild desquamation that was probably treatment related. No subjects in the experimental dentifrice group had any adverse events reported and/or observed. No subjects discontinued treatment due to an adverse event.

RESULTS (Cont.)

Efficacy:

For Weeks 1 and 2, each treatment group exhibited statistically significant ($p < 0.001$) Lobene area, intensity, and composite stain reduction from baseline. At Week 1, the median % reductions of the composite score were 59% for the experimental dentifrice and 67% for the power tooth brush. At Week 2, the median % reductions of the composite score were 85% for the experimental dentifrice and 89% for the power tooth brush.

At Week 1, the adjusted means and standard errors for Lobene Composite whole tooth stain removal were -1.54 ± 0.106 and -1.80 ± 0.106, for the experimental dentifrice and the power tooth brush, respectively. At Week 2, the adjusted means and standard errors for Lobene Composite whole tooth stain removal were -2.31 ± 0.055 and -2.38 ± 0.055, for the experimental dentifrice and the power tooth brush, respectively. The adjusted means were not statistically different at Week 1 nor at Week 2 ($p > 0.10$) from each other.

CONCLUSION

- Use of the daytime/nighttime dentifrice combination removed appreciable extrinsic stain, similar in magnitude to a power toothbrush with a regular anticavity dentifrice.

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