Anti-calculus Efficacy of a SnF_2 Dentifrice in a Three-month Clinical

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ABSTRACT

Objectives: The objective of the study was to assess the calculus prevention benefit of an experimental 0.454% Stannous Fluoride (SnF2) dentifrice relative to a negative control dentifrice.

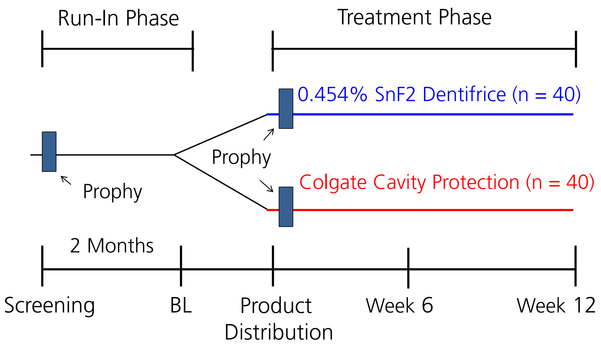
Methods: This was a 3-month, parallel-group, double-blind, randomized and controlled clinical trial in which the 0.454% experimental SnF2 dentifrice was compared to a negative control dentifrice (Colgate Cavity Protection®). Subjects received a dental prophylaxis and then entered a 2-month run-in phase. At the end of the 2 months, subjects received Volpe Manhold Index (V-MI) calculus examination. Qualified subjects who formed a minimum of 9mm of calculus on the lingual surfaces of the six mandibular anterior teeth were re-prophied and randomly assigned to one of the two treatments. Subjects brushed with their assigned product twice daily using a standard manual toothbrush, one minute each time, over the 3-month duration. Safety and efficacy measurements were taken via OST and V-MI exams at Baseline, Week 6 and Month 3. Treatment groups were compared using the analysis of covariance method. All statistical tests were two-sided with a 5% level of significance.

Results: Of the 80 subjects who were randomized to treatment, 78 completed the study. Treatment groups were balanced with demographic variables and Baseline calculus scores (p>0.2). The calculus score for the SnF2 dentifrice group was significantly lower than that of the control group (p=0.05 at Week 6, p<0.01 at Month 3). Both test products were well tolerated.

Conclusions: The research demonstrated superior anti-calculus efficacy of the SnF2 dentifrice relative to the negative control dentifrice in this 3-month clinical trial.

MATERIALS AND METHODS

This was a randomized, double-blind, single-center, parallel group, two treatment clinical trial that consisted of a run-in phase (subject screening & qualification) and a treatment phase.

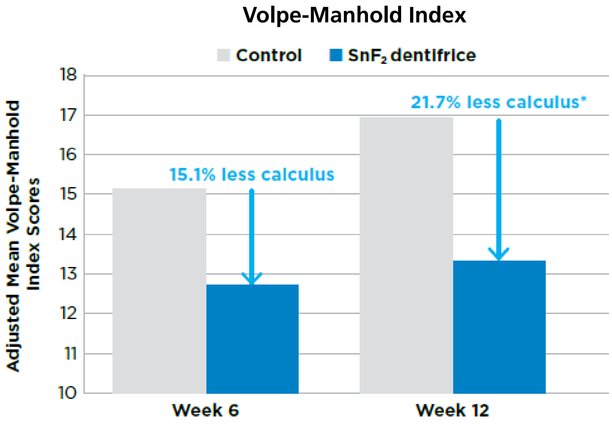


Subjects brushed with a full brush head of their assigned dentifrice with an ADA reference soft manual toothbrush for 1 minute twice daily.

Volpe-Manhold Index (VMI) was used to measure the level of calculus on the lingual surfaces of the lower six anterior teeth. Measurements were made in 0.5 mm increments starting at 0.5..

Treatment groups were compared using the analysis of covariance method. All statistical tests were two-sided with a 5% level of significance.

RESULTS



Efficacy: Treatment groups were balanced at Baseline with respect to demographic characteristics and baseline calculus scores (p>0.29). The calculus score for the SnF2 dentifrice group was lower than that of the control group (p=0.05) at Week 6, and statistically lower (p<0.01) at Month 3.

Safety: Both test products were well tolerated. No adverse events were reported in the study.

Demographics And Baseline Calculus Score			
	SnF2 Dentifrice (N=41)	Control Dentifrice (N=39)	p-value
Age: Mean (SD)	51.2 (12.38)	52.7 (12.13)	0.5739
Baseline VMI Score: Mean (SD)	17.56 (6.23)	18.99 (7.43)	0.3542
Female: N (%)	23 (56%)	23 (59%)	0.8244
Ethnicity: N (%)			
Caucasian	34 (83%)	37 (95%)	0.2998
Black	5 (12%)	2 (5%)	
Other	2 (4%)	0 (0%)	

CONCLUSIONS

The research demonstrated superior anti-calculus efficacy of the 0.454% SnF_2 dentifrice relative to the negative control dentifrice in this 3-month clinical trial.

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