The Oral Malodor Reduction Efficacy of a 0.454% SnF2 Dentifrice

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ABSTRACT

Objectives: To compare the oral malodor reduction efficacy of a 0.454% stannous fluoride dentifrice relative to a positive and a negative control dentifrices using Halimeter as the measurement.

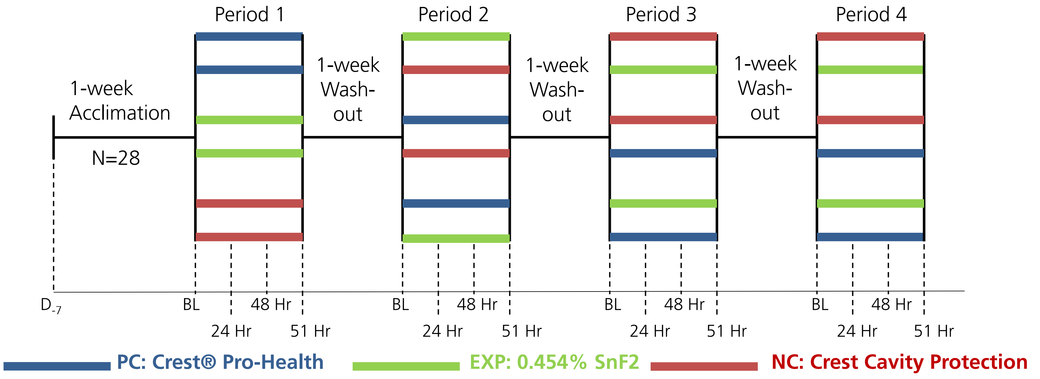
Methods: This was a controlled, randomized, double-blind, 3-treatment, 4-period cross-over study. Twenty-eight subjects who met study entrance criteria were enrolled into the study. Following an acclimation period, subjects were randomly assigned to a treatment sequence comprising three treatments: experimental 0.454% stannous fluoride dentifrice, positive control Crest Pro-Health dentifrice (0.454% Stannous Fluoride), negative control Crest Cavity Protection dentifrice (0.243% Sodium Fluoride). Volatile sulfur compound (VSC) levels were measured using a Halimeter during each treatment period at four time points: Baseline prior to treatment, overnight 24 and 48 hours post-baseline, and daytime 51 hours post-baseline. VSC levels were analyzed using analysis of variance (ANOVA) for crossover studies. Statistical comparisons were two-sided, with a significance level of 0.05.

Results: A total of 23 subjects completed study. The adjusted mean VSC levels were significantly lower for the experimental SnF2 dentifrice at overnight 24 hour, 48 hour, and daytime 51 hour ($p \leq 0.0099$) as compared to negative control. The Experimental SnF2 paste had lower VSC scores at overnight 24 hour ($p<0.03$) and 48 hour ($p=0.05$), and no statistically differences at 51 hour ($p=0.25$) as compared to the positive control.

Conclusions: This present study demonstrated the oral malodor reduction efficacy of the stannous fluoride dentifrices. All test dentifrices were well tolerated.

MATERIALS AND METHODS

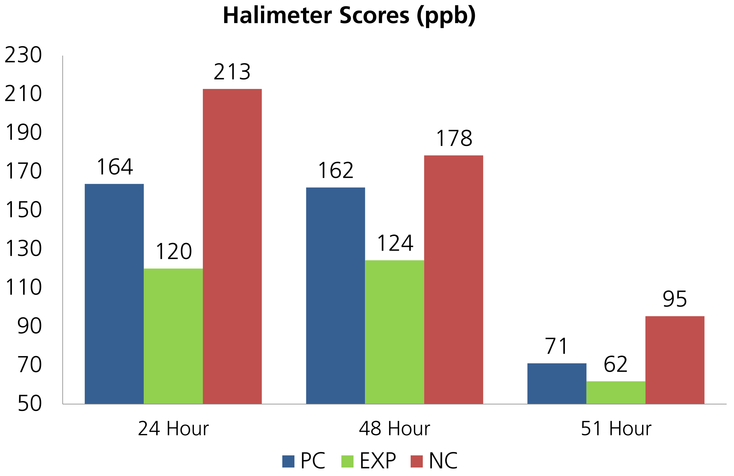
This randomized, double-blind, controlled clinical study evaluated the anti-malodor efficacy of an experimental 0.454% SnF_2 dentifrice relative to a positive and a negative control. Subjects used the assigned test product twice daily. Oral malodor was measured using a calibrated halimeter at baseline and 3 time points post baseline (24, 48, and 51 hours).



VSC scores measured by the Halimeter was analyzed using analysis of variance (ANOVA) for crossover studies. Treatment comparisons were two-sided at the 5% significance level .

RESULTS

Subject age ranged from 31 to 59 years with mean ± SD of 47.8 ± 7.11. Seventeen (61%) subjects were female. Subject ethnicities were: Asian Oriental (n=1, 4%), Black (n=3, 11%), Caucasian (n=21, 75%), Hispanic (n=1, 4%), and Asian Indian (n=2, 7%).



Efficacy: The adjusted mean VSC levels were significantly lower for the EXP at overnight 24 hour, 48 hour, and daytime 51 hour ($p \leq 0.0099$) as compared to NC. The EXP paste had lower VSC scores at overnight 24 hour ($p<0.03$) and 48 hour ($p=0.05$), and no statistically differences at 51 hour ($p=0.25$) as compared to PC.

Safety: All dentifrices were well tolerated. There were no treatment related adverse events reported in this study.

CONCLUSIONS

This present study demonstrated the oral malodor reduction efficacy of the 0.454% stannous fluoride dentifrices. All test dentifrices were well tolerated.

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