Instant and Rapid Sensitivity Relief of a Stannous Fluoride Dentifrice

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ABSTRACT

Objective: To evaluate the instant and rapid sensitivity relief effect of a stannous fluoride dentifrice relative to a positive control.

Methods: Eighty subjects who met inclusion criteria were enrolled into a controlled and randomized, examiner-blind parallel 2-week study. Test products included a stannous fluoride dentifrice (experimental dentifrice) and a positive control dentifrice (Colgate® Pro-argin). At Baseline, Efficacy assessments (thermal, Schiff air index and VAS Score) were taken. Subjects were randomly assigned to one of two treatments and used the product twice daily for 2 weeks following manufacturer's usage instructions. Post treatment clinical examination was conducted at immediate, Day 3 and Week 2. Analysis of covariance was used to analyze data. All comparisons were two-sided with a significance level of 0.05.

Results: After 2 weeks product usage, the stannous fluoride dentifrice provided superior sensitivity protection relative to the Positive Control immediately after the first use and at Week 2 based on the Thermal Schiff Air Index (p=0.005 for Immediate; p<0.001 at Week 2). The stannous fluoride dentifrice provided superior sensitivity protection relative to the Positive Control immediately after the first use, at Day 3, and at Week 2 based on the Thermal Air Visual Analog Scale (p<0.0001 at all time points).

Conclusions: The study demonstrated the instant and rapid sensitivity relief efficacy of the stannous fluoride dentifrice.

INTRODUCTION

Dentinal hypersensitivity is a short and sharp pain condition, arising from the exposed dentine in response to any of a number of exogenous stimuli. Stannous fluoride has been incorporated into oral hygiene products to reduce dentinal hypersensitivity since the 1960s. The desensitizing action for stannous fluoride is chemical precipitation of stannous ion which occludes dentinal tubules and thus prevents the stimulation of free nerve endings. Recently several published clinical studies have shown the fast onset desensitizing effectiveness of an 8% Arginine dentifrice. The present study is to evaluate the instant and rapid sensitivity relief of a 0.454% stannous fluoride dentifrice relative to the positive control Arginine dentifrice.

MATERIALS AND METHODS

Study Design:

This was a randomized, controlled, examiner-blind, parallel-group trial. Institutional review and informed consent were obtained prior to study initiation. Subjects were randomly assigned to one of the two test dentifrices based on baseline sensitivity scores, age, and gender. Product was used following manufacturer's usage instructions.

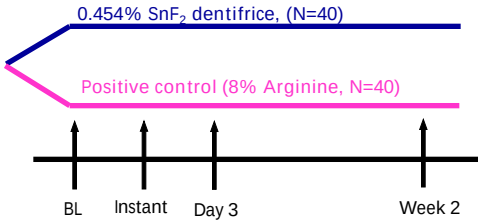
Clinical Evaluation

(BL, Immediately after 1st product use, Day 3, Week 2):

Cold air stimuli - apply 1 sec cold air from a dental syringe (40-60 psi, 70 F 5 F)

Schiff Air Index (by a qualified examiner): 0 - 3 scale, increasing level of sensitivity

Visual Analogue Scale (VAS, by subjects): 0 - 10 scale, increasing level of sensitivity



Statistical analysis:

Analysis of covariance with BL score as a covariate. Two-sided, 5% significance level.

RESULTS

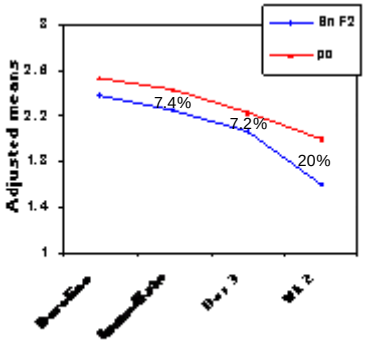
A total of 80 subjects qualified and 78 completed all study procedures.

Age, gender, and BL sensitivity scores were balanced between the groups.

	0.454% SnF_2 N=40	Pos. control N=40	p-Value
Age in Years, Mean (SD)	42.4 (6.72)	44.9 (8.90)	0.160
Gender, N (% Female)	39 (98%)	38 (96%)	0.556
Schiff air index, Mean (SD)	2.38 (0.39)	2.53 (0.41)	0.096
VAS, Mean (SD)	6.88 (1.13)	7.19 (1.29)	0.265

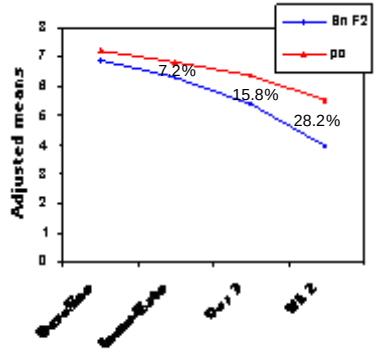
Schiff Air Index

- 0.454%SnF_2 dentifrice significantly ($p<0.01$) better than the positive control, at immediate and Week2 visits
- Positive control significantly ($p<0.01$) better than BL, at Day 3 and Week 2 visits



VAS

- 0.454%SnF_2 dentifrice significantly ($p<0.0001$) better than pc, at all post-treatment visits
- Positive control significantly ($p<0.01$) better than BL, at all post-treatment visits



CONCLUSIONS

- The study demonstrated fast onset sensitivity relief efficacy of the 0.454% stannous fluoride dentifrice.
- Both test Products were well tolerated.

Research presented at the 89th General Session of the IADR, March 16-19, 2011, San Diego, California

P&G Oral Health