De-sensitizing effect of a Stannous-containing sodium fluoride dentifrice
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ABSTRACT

Objective: To evaluate the de-sensitizing effect of a stannous-containing sodium fluoride toothpaste relative to a negative control.

Methods: Eighty subjects who met inclusion criteria were enrolled into a controlled and randomized, double-blind parallel 8-week study. Test products included a stannous-containing sodium fluoride (1450ppm F) dentifrice and a marketed MFP containing dentifrice (Colgate® Cavity protection). At Baseline, tactile and thermal desensitizing assessments including tactile (2000A Yeaple, Pittsford, NY) and thermal (Schiff air index) were taken. Subjects were randomly assigned to one of two treatments and used the product twice daily for 8 weeks, one minute each time. Clinical examination was again conducted at week 4 and week 8. Statistical comparisons were two-sided with a significance level of 0.05.

Results: After 8 weeks product usage, the stannous-containing sodium fluoride dentifrice provided statistically significantly better de-sensitizing efficacy relative to the negative control (p<0.05) on tactile measurement with average of 23.1 and 17.1 respectively, and significantly better de-sensitizing efficacy relative to the negative control (p<0.05) on thermal measurement with average of 1.67 and 1.96 respectively.

Conclusions: The study demonstrated the de-sensitizing efficacy of the stannous-containing sodium fluoride dentifrice.

MATERIALS AND METHODS

A single center, randomized, double-blind, and parallel group clinical trial was conducted to evaluate the de-sensitizing effect of a stannous-containing sodium fluoride toothpaste (experimental dentifrice) and a negative control (Colgate® Cavity protection- Super Strong). 80 subjects with tested moderate dentinal hypersensitivity were enrolled in the study. At baseline, subjects reviewed and signed an informed consent and received a copy. Medical history, demographic information, and inclusion/exclusion criteria were collected. Test products were distributed to subjects that met entrance criteria. The experimental dentifrice and the negative control were used twice daily for 8 weeks, one minute each time. Safety and efficacy assessments including tactile and thermal sensitivity were made at Baseline, Weeks 4 and 8.

Efficacy scores were averaged across both sites for each subject, separately at each time point and endpoint. Four and eight week tactile scores were analyzed separately using Analysis of Covariance models with Baseline as a covariate. Cold air sensitivity Schmitt and VAS scores were analyzed in a similar fashion. Statistical comparisons were two-sided, with a significance level of 0.05.

RESULTS

Eighty (80) subjects were enrolled and they all received test products. Ten (10) subjects dropped due to personal reasons. At study conclusion, seventy (70) subjects completed all study procedures. The average ages were 42.1 and 36.2 for the Experimental group and the Negative control group, respectively. There were 60 females from 35 total subjects in the Experimental group, and 32 females from a total of 35 subjects in the Negative control group. The two groups were well balanced on age, gender, baseline Yeaple and Schiff score, p value >0.05.

Thermal (Schiff score):

The Experimental group started from 2.67(0.44) and the Negative control group started from 2.54(0.41). At week 4, the Schiff adjusted means were 2.11(0.58) and 1.97(0.51) for the Experimental group and the Negative control group, respectively. At week 8, the Schiff adjusted means were 1.67(0.58) and 1.96(0.56) for the Experimental group and the Negative control group, respectively. The Experimental group showed significantly better desensitizing effect than the Negative control with p value=0.04 at week 8. (The Experimental group showed a 14.8% reduction vs. Negative control at week 8).

Tactile (Yeaple probe results):

The Experimental group adjusted mean started from 11.1(2.1), and the Negative control group adjusted mean started from 11.6(2.9). At week 4, the Yeaple adjusted means were 20.1(1.5) and 15.1(5.4) for the Experimental group and the Negative control group, respectively. At week 8, the Yeaple adjusted means were 23.1(12.0) and 17.1(8.3) for the Experimental group and the Negative control group, respectively. The Experimental group showed significantly better desensitizing effect than the Negative control with p value=0.02 at week 4 and week 8. (The Experimental group showed a 33.1% and 35.1% reduction vs. the Negative control group at Weeks 4 and 8, respectively).

CONCLUSIONS

The study demonstrated the long-lasting anti-sensitivity effect of the stannous-containing sodium fluoride dentifrice relative to a negative control.