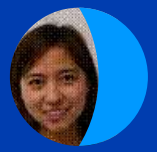

De-sensitizing effect of a Stannous-containing sodium fluoride toothpaste

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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 (experimental dentifrice) and a negative control dentifrice (Colgate® Cavity protection-Super Strong). At Baseline, Efficacy 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, two minutes each time. Post treatment clinical examination was conducted at week 4 and week 8. Analysis of covariance was used to analyze data. All 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 (233%) de-sensitizing efficacy relative to the negative control ($p<0.001$) on tactile measurement, and significantly better (65.8%) de-sensitizing efficacy relative to the negative control ($p<0.001$) on thermal measurement.

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 product was distributed to subjects that met the entrance criteria. The experimental dentifrice and the negative control were used twice daily for 8 weeks. Safety and efficacy assessments including tactile and thermal sensitivity were made at Baseline, Weeks 4 and 8.

Efficacy scores were averaged 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 Schiff and VAS scores were analyzed in a similar fashion. Statistical comparisons were two-sided, with a significance level of 0.05.

RESULTS

A total of eighty (80) subjects were enrolled and they all received test product. At study conclusion, seventy-seven (77) subjects completed all study procedures. The average ages were 43.18 (7.70) and 43.33 (8.70) for the Experimental group and the Negative control group, respectively. There were 38 (95%) females from 40 total subjects in the Experimental group, and 35 (88%) females from 40 total subjects in the Negative control group. The two groups were well balanced on age, gender, and baseline Schiff score, with p value >0.05.

Thermal (Schiff score):

The Experimental group started from 2.46 (0.44) and the Negative control group started from 2.49 (0.40).

At week 4, the Schiff adjusted mean scores were 2.25 (0.06) and 2.20 (0.06) for the Experimental group and the Negative control group, respectively. At week 8, the Schiff adjusted mean scores were 0.80 (0.07) and 2.34 (0.07) for the Experimental group and the Negative control group, respectively. The Experimental group provided a significantly better desensitizing effect than the Negative control with p value=0.001 at week 8 (The Experimental group showed 65.8% reduction vs. Negative control at week 8).

Thermal (VAS score):

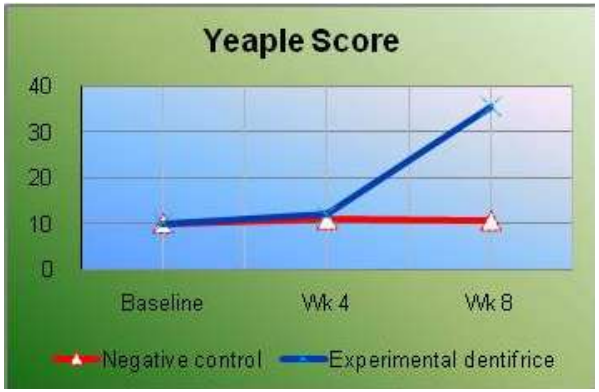
The Experimental group started from 7.51 (1.39) and the Negative control group started from 7.49 (1.45).

At week 4, the Schiff adjusted mean scores were 7.07 (0.16) and 7.05 (0.17) for the Experimental group and the Negative control group, respectively. At week 8, the Schiff adjusted mean scores were 1.99 (0.21) and 7.58 (0.21) for the Experimental group and the Negative control group, respectively. The Experimental group provided a significantly better desensitizing effect than the Negative control with p value<0.001 at week 8 (The Experimental group showed 73.7% reduction vs. Negative control at week 8).

RESULTS (cont.)

Tactile (Yeaple probe score):

Both groups started from 10 at baseline. At week 4, the Yeaple adjusted mean scores were 12.0 (0.68) and 10.9 (0.69) for the Experimental group and the Negative control group, respectively. At week 8, the Yeaple adjusted means were 35.38 (1.37) and 10.64 (1.37) for the Experimental group and the Negative control group, respectively. The Experimental group showed a significantly better desensitizing effect than the Negative control with p value=0.001 at week 8 (The Experimental group showed 232.5% reduction vs. Negative control group).



Safety: There was one AE reported in the Negative control group in this test

CONCLUSIONS

The study demonstrated the long-lasting desensitizing efficacy of the stannous-containing sodium fluoride dentifrice relative to a negative control dentifrice.

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