



Oral-Malodor Reduction Efficacy of a Stannous Containing NaF Dentifrice

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ABSTRACT

Objectives:

To compare the oral malodor reduction efficacy of a stannous containing sodium fluoride dentifrice versus a marketed dentifrice (YunNanBaiYao) using Halimeter as the measurement.

Methods:

36 subjects who met study entrance criteria were enrolled into a controlled, randomized, double-blind, 2-treatment, 4-period, and cross-over study. Following an acclimation period, subjects were randomly assigned to two dentifrices, a stannous-containing sodium fluoride dentifrice and an anti-gingivitis dentifrice marketed in China (Yun Nan Bai Yao® dentifrice). VSC levels were measured using a Halimeter during each treatment period at four time points: Baseline prior to treatment, 3 hours after baseline and a single brushing, 24 hours post-baseline and after two brushings, and 27 hours post-baseline following 3 times product uses. 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 34 subjects completed study; The adjusted mean volatile sulfur compound (VSC) levels were significantly lower in the stannous containing sodium fluoride dentifrice group when compared to the YNBY control group (P<0.0034 at Hour 3 post-baseline, P<0.0035 at Hour 24, and P<0.0001 at Hour 27). The stannous containing sodium fluoride dentifrice provided statistically significant better oral malodor protection benefits of 25.0% at Hour 3, 24.8% at Hour 24, and 48.3% at Hour 27. The 24 hour measurement represents the morning breath benefit which is meaningful to consumers.

Conclusions:

This present study demonstrated the superior oral malodor reduction efficacy of the stannous containing sodium fluoride dentifrice compared to the control dentifrice. Both dentifrices were well tolerated.

MATERIALS AND METHODS

Study Design:

This was a randomized, controlled, double-blind, 2-treatment, 4-period cross-over study. Thirty-six healthy adult subjects with reproducible oral malodor signed the informed consent and participated in the study. After one week acclimation, subjects were randomized to one of four treatment sequences based on their age, gender and first period baseline Halimeter data. Test products were used twice daily. Breath measurement was taken at Baseline visit, 3 hours after first product usage, 24 hours the next day morning after twice product usage, and 3 hours after the last product usage.

Product usage:

Brush 2 minutes, without expectorate, swish with remaining toothpaste slurry for 30 seconds, then expectorate, rinse with 15 ml water for 10 seconds, twice per day.



Halimeter Breath Measurement:

Subjects were assessed for volatile sulfur compound (VSC) emissions utilizing a commercially-available portable instrument called a Halimeter (Interscan Corporation, CA). This instrument was sensitive to hydrogen sulfide and methyl mercaptan, two of the primary components of foul breath odor.

Subjects were instructed to keep their mouth closed for 2 minutes and were instructed not to swallow during this time. The subject then placed one end of a clean cylinder, about 1.75 inches long by 1 1/16 inches in diameter, in their mouth. The other end of this cylinder was placed through an opening in a wood screen. While the subject held his/her breathe, the instrument drew air from the mouth (without touching the subject's mouth) and the technician recorded the measured value indicated on the instrument.



Stannous Containing Sodium Fluoride dentifrice (Crest Pro-health, China)



Yun Nan Bai Yao dentifrice (China)

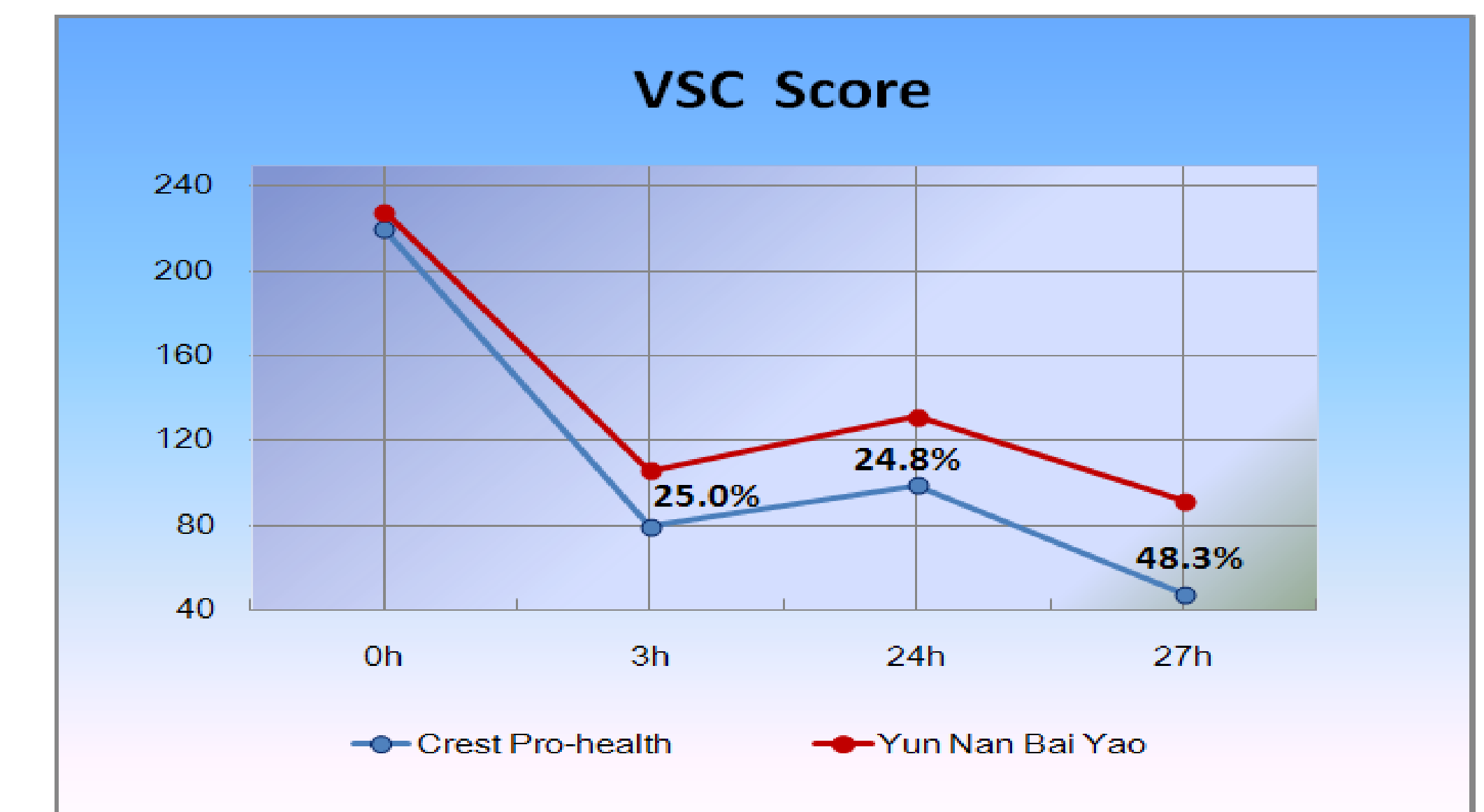
RESULTS

A total of 36 subjects were enrolled and received test products. 34 subjects completed all study procedures. The average age was 32.9, there were 28 (82%) females from 36 subjects.

- The Stannous Containing NaF dentifrice showed statistically significantly better breath benefits via VSC reduction compared to YNBY dentifrice at all three time points with P<0.0034 at Hour 3 post-baseline, P<0.0035 after 24 hours ("overnight"/"morning breath"), and P<0.0001 at Hour 27;
- The Stannous Containing NaF dentifrice provided superior oral malodor protection benefits of 25.0% at Hour 3 post-baseline, 24.8% after 24 hours ("overnight"/"morning breath"), 48.3% at Hour 27, and 23.7% at AUC. The benefits increased over time.

Safety: No AEs were reported in this test.

Comparison between treatments in Adjusted Mean VSC



The Stannous Containing NaF dentifrice (Crest Pro-health) demonstrated superior oral malodor reduction efficacy when compared to the Yun Nan Bai Yao dentifrice.

Both products were well-tolerated.