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ABSTRACT

Objective: To assess efficacy in reducing oral malodor of stannous fluoride (SnF) toothpaste (TheraBreath® Healthy Gums) compared to sodium fluoride (NaF) control (Crest® Cavity Protection).

Methodology: Double-blind, randomized, crossover-design, 7-day clinical study (n = 49). Subjects brushed twice daily for 2 minutes with Crest toothpaste (7-day washout). At each site visit, ~12 hours after toothbrushing, subjects were assessed for Odor Intensity (OI) by 3 trained and calibrated organoleptic judges (6-point scale). On Day 0, following initial assessment, subjects performed supervised brushing with their assigned products. Subjects brushed in the evening and returned on Day 1 for OI assessment. Subjects then brushed at the site, and OI was reassessed 4 and 8 hours later. Subjects brushed twice daily for 7 days with their assigned products. Day-1 procedures were repeated on Day 7. Subject-wise mean OI scores were the average of the scores of the 3 judges. The primary endpoints were mean change in OI scores from baseline to post-brushing (12 hours), and 4 and 8 hours post-brushing on Day 1. Secondary endpoints were: 1. mean change from baseline mean OI score to the mean OI score at 12 hours post-brushing (Day 7), and to the 4- and 8-hour scores (Day 7), and 2. the post-brushing scores of TheraBreath and Crest at each timepoint (analysis of covariance; pre-brushing score as covariate). All statistical tests were two-sided t-tests with a level of significance of $\alpha=0.05$.

Results: For TheraBreath, reductions in OI scores from baseline were statistically significant at all post-treatment timepoints evaluated; % reductions ranged from 73.3–95.0%. For Crest, the reduction from baseline was statistically significant only at 4 hours on Day 1; % reduction was 11.8%. At all timepoints, TheraBreath was statistically significantly more effective than Crest ($p<0.0001$) with improved OI scores of 2.45–3.37 (73–95%).

Conclusion: TheraBreath® Healthy Gums is significantly more effective in reducing oral malodor than Crest® Cavity Protection.

METHODS

This IRB-approved, randomized, double-blind, crossover study used organoleptic odor intensity (OI) scoring to assess the odor reduction potential of two dentifrices over a 1-week test period.

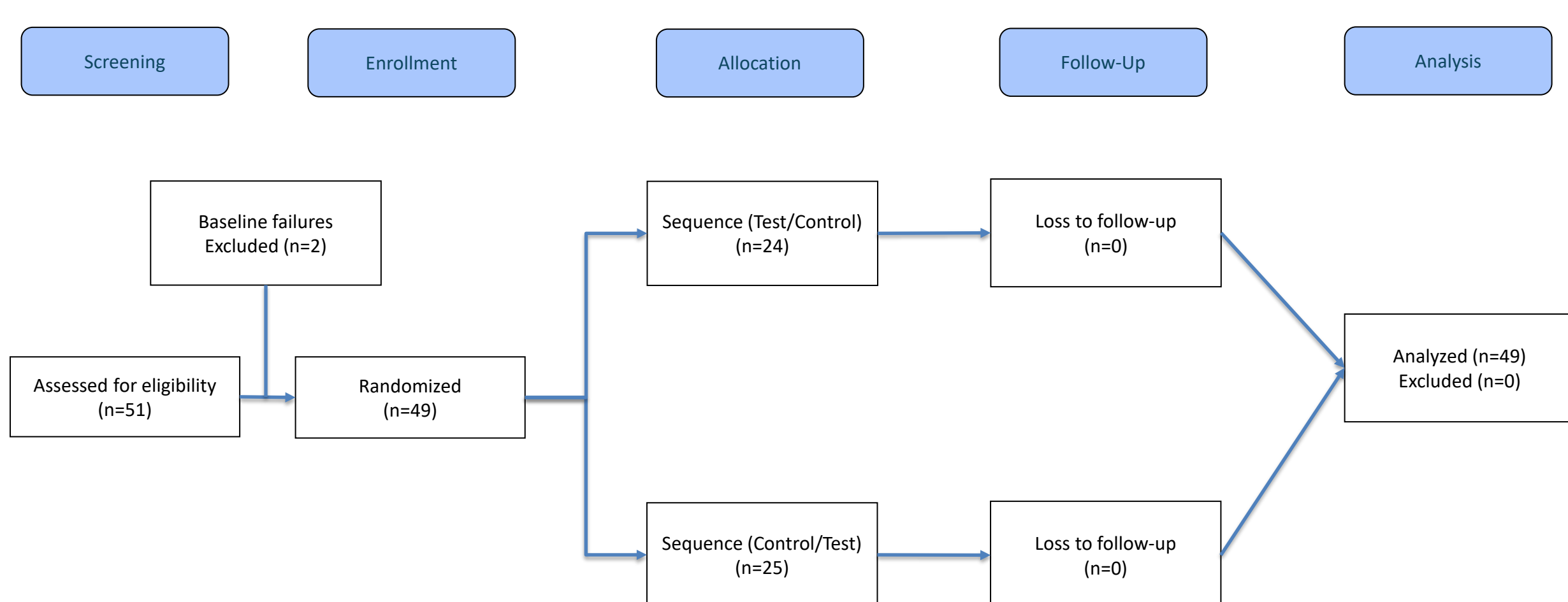
Key Inclusion Criteria:

- Generally healthy adult subjects ≥ 18 years of age
- Minimum of 18 natural teeth
- No medical conditions affecting oral malodor assessment, active oral pathology, recent dental prophylaxis, antibiotic use, smoking, or use of non-study oral hygiene products
- Qualifying baseline odor intensity (OI) score ≥ 2

Treatment Groups:

- Control dentifrice: 0.243% NaF (Crest® Cavity Protection)
- Test dentifrice: 0.454% SnF (TheraBreath® Healthy Gums)

Fig. 1 Consort Diagram Showing Overall Study Flow



Key Study Elements:

- Subjects were instructed to refrain from all oral hygiene, eating and drinking for 12 hours prior to baseline visit
- On Day 0, subjects' oral soft and hard tissue (OSHT) examinations were conducted; subjects were then assessed for baseline OI, followed by supervised 2-minute brushing with assigned dentifrice and toothbrush (Oral-B 35, soft, flat trim; Procter & Gamble, Cincinnati, OH)
- At-home instructions had subjects brush twice daily (morning and evening) for 2 minutes using a timer, with a full brush-length of assigned toothpaste and toothbrush
- On Days 1 and 7, OSHT exams were followed by 12-hour (overnight) post-brushing assessments, supervised product use, then 4- and 8-hour (daytime) post-brushing assessments. Following a 7-day washout with a 0.243% NaF toothpaste (Crest® Cavity Protection) and a soft manual toothbrush, subjects repeated the same procedures for the remaining product
- Compliance ensured by supervised brushing, daily diary assessment (Day 1 and 14), and weighing toothpaste tubes (Day 7)

Clinical Scoring:

- All OI assessments done by the same three trained and calibrated judges^{1,2}
- Judges scored OI using a 6-point scale². See Fig. 2

Fig. 2 Malodor (OI) Scale

| Odor Scores |
|----------------------------|
| 5 = extremely foul odor |
| 4 = strong offensive odor |
| 3 = moderate odor |
| 2 = slight odor |
| 1 = barely noticeable odor |
| 0 = no odor |



RESULTS

Statistics:

- The study was powered (80%, $\alpha=0.05$) to detect a 0.5-unit between treatment difference in OI when $SD=0.7$
- Endpoints: Mean changes in OI from baseline were assessed at 12 hours post-brushing (overnight) and at 4 and 8 hours post-brushing (daytime) on Days 1 and 7. Between-treatment comparisons at each time point
- For all endpoints, analysis by ANCOVA with baseline OI as a covariate and treatment, period, and sequence as fixed effects

Demographics:

Fifty-one subjects were screened; 49 were enrolled, randomized, and completed all phases of the study. There were no statistically significant differences in age or sex across sequence groups. Overall, 73% of participants were female and 27% male; ages ranged from 18–80 years.

Safety:

No adverse events were observed.

Efficacy:

- TheraBreath exhibited statistically significant reductions from baseline OI scores ($p<0.0001$) at all post-brushing timepoints with 12-hour overnight (ON) reductions of 81.3% on Day 1 and 73.3% on Day 7. See Fig. 3
 - TheraBreath achieved high percentages of “no odor” at all post treatment time points. See Table 1
- Crest showed limited and inconsistent OI reductions from baseline, reaching statistical significance only at the 4-hour post-brushing assessments. See Fig. 3
- TheraBreath exhibited statistically significantly greater reductions in OI than the Crest control at all post-brushing timepoints ($p<0.0001$). See Fig. 3

Fig. 3 Mean Odor Intensity Scores

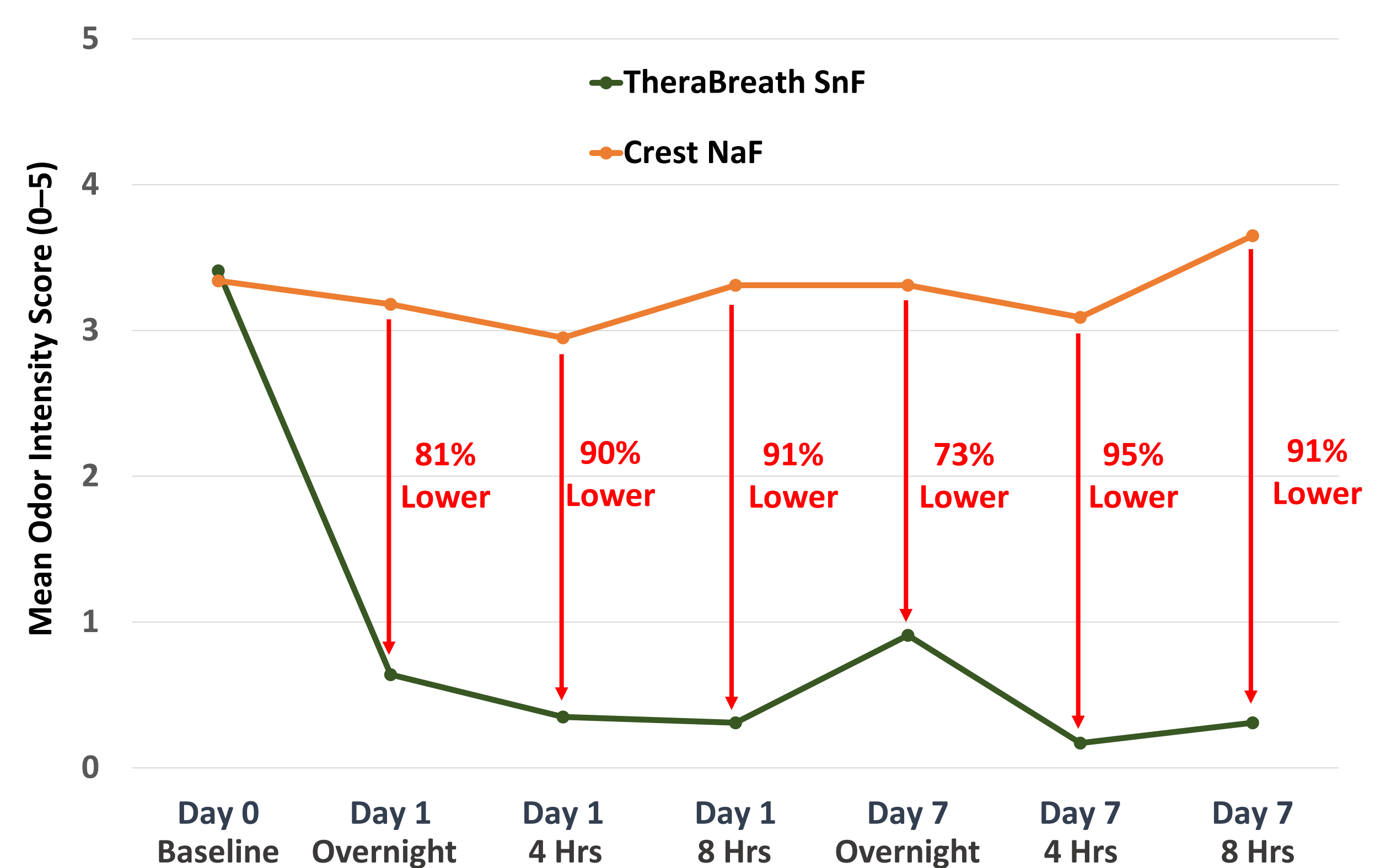


Table 1 Scores of 0 = No Odor

| Day | Timepoint | TheraBreath | | Crest | |
|-----|-------------|-------------|---------|-------|---------|
| | | Count | Percent | Count | Percent |
| 0 | Baseline | 0 | 0% | 0 | 0% |
| 1 | 12 Hrs (ON) | 102 | 69% | 0 | 0% |
| | 4 Hrs | 113 | 77% | 0 | 0% |
| | 8 Hrs | 117 | 80% | 0 | 0% |
| 7 | 12 Hrs (ON) | 90 | 61% | 0 | 0% |
| | 4 Hrs | 135 | 92% | 3 | 2% |
| | 8 Hrs | 123 | 84% | 2 | 1% |

Three judges x 49 subjects = 147 total scores per treatment per timepoint. Overnight = ON

CONCLUSIONS

- TheraBreath® Healthy Gums SnF toothpaste produced more significant and sustained reductions in oral malodor than a regular NaF toothpaste, Crest® Cavity Protection.
- Statistically significant improvements in oral malodor were observed for TheraBreath® Healthy Gums SnF toothpaste at all post-brushing timepoints, including 12-hour overnight assessments on Day 1 and Day 7.

REFERENCES

1. Yaegaki K and Coil JM. Genuine halitosis, pseudo-halitosis, and halitophobia: classification, diagnosis, and treatment. *Compend Contin Educ Dent.* 2000; 21: 880–890.
2. Rosenberg M, Kulkarni GV, Bosy A, and McCulloch CAG. Reproducibility and sensitivity of oral malodor measurements with a portable sulfide monitor. *J Dent Res.* 1990; 70: 1436–1440.

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