

# Comparative Malodor Effects of Multi-Step Approaches for Daily Oral Hygiene

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## ABSTRACT

**Objective:** A randomized positively-controlled clinical trial was conducted to evaluate effects of a simple two-step oral hygiene program on oral malodor.

**Methods:** The study targeted adult volunteers with evidence of malodor and suboptimal oral hygiene (gingivitis and extrinsic dental stain). Institutional review and informed consent were obtained, and subjects were assigned a regular anticavity dentifrice and manual brush for 1-week acclimation. Baseline measurements were collected, and subjects with malodor, gingivitis and stain were randomly assigned to two-step (experimental group) or multi-step (positive control group) oral hygiene. The two-step group brushed with a 0.454% SnF<sub>2</sub> toothpaste followed by a 3% H<sub>2</sub>O<sub>2</sub> gel (Crest® Pro-Health [HD]<sup>TM</sup>, Procter & Gamble Co.) with a regular manual brush (Oral-B® Indicator). The multi-step control group received 0.454% SnF<sub>2</sub> dentifrice (Crest Pro-Health<sup>TM</sup>), 0.07% cetylpyridinium chloride rinse (Crest Pro-Health), floss (Oral-B Glide Pro-Health Clinical) and an advanced crisscross manual brush (Oral-B Pro-Health Clinical Pro-Flex). Test products were dispensed blinded to treatment in kits with instructions for use. After 1-week, oral malodor was assessed by treatment-blinded judges using a 9-point hedonic scale.

**Results:** At baseline, the population (N=57) exhibited diversity in age (19-65), gender, ethnicity and malodor. Groups were balanced on baseline parameters and malodor, with an overall hedonic breath mean (SD) of 8.58 (0.47). Each group exhibited a highly significant (p<0.0001) reduction in malodor, with Week 1 adjusted mean (SE) hedonic scores of 1.88 (0.20) and 2.08 (0.273) for the two-step and multi-step groups, respectively. Both treatments were well-tolerated.

**Conclusion:** While both treatments were effective, use of a two-step oral hygiene routine of a stannous fluoride dentifrice plus hydrogen peroxide gel yielded approximately a 10% improvement in malodor compared to a multi-step oral hygiene routine.

## MATERIALS & METHODS

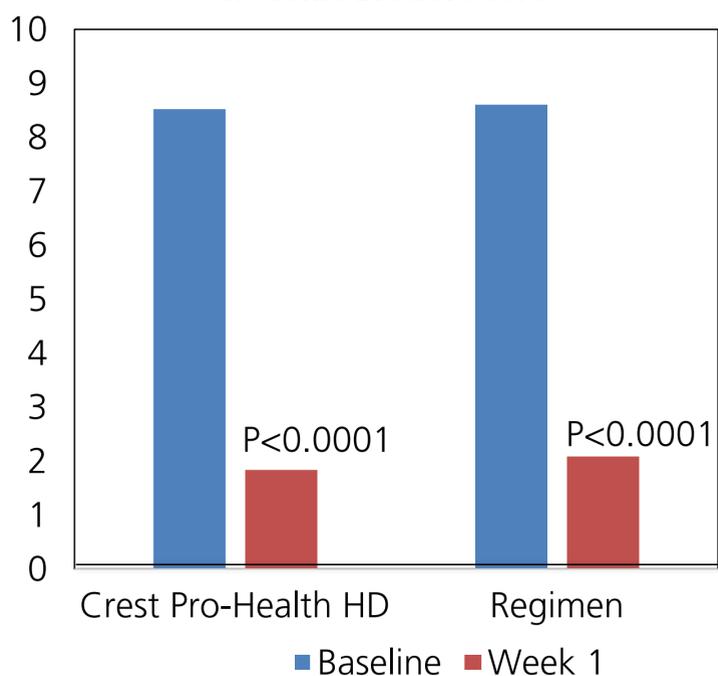
This was a randomized, controlled, examiner-blind, 2-treatment parallel group study. The target population was approximately 60 healthy adult volunteers with oral malodor. All subjects were acclimated with a regular anti-cavity dentifrice and a manual brush for 1 week before the Baseline visit. The subjects were randomly assigned to two treatment groups: 1) Crest® Pro-Health [HD]<sup>TM</sup> and a regular, manual brush or 2) multi-step regimen. Hedonic breath evaluations were made at Baseline and after one week of product use. An analysis of covariance was performed using baseline as a covariate and modeling different variances for each treatment group.

### Hedonic Malodor Evaluation

- 1-Most Pleasant
- 2-Very Pleasant
- 3-Moderately Pleasant
- 4-Slightly Pleasant
- 5-Neither Pleasant nor Unpleasant
- 6-Slightly Unpleasant
- 7-Moderately Unpleasant
- 8-Very Unpleasant
- 9-Most Unpleasant

## RESULTS

### Hedonic Breath Score



### Between Group Analysis of Covariance

	Crest Pro-Health HD	Regimen
N	27	29
Week 1 Adjusted Mean (SE)	1.876 (0.203)	2.081 (0.273)
% Change vs. Regimen	9.9	
2-sided P-value	0.5490	

### Change from Baseline – Hedonic Breath

Treatment	Mean (SD)	P-value	Median	Min.-Max.
Week 1				
Control: Regimen	-6.517 (1.460)	<0.0001	-6.670	-8.000 to -1.670
Test: 2-Step Paste	-6.679 (1.076)	<0.0001	-7.000	-8.000 to -3.340

## CONCLUSIONS

While both treatments were effective, use of a two-step oral hygiene routine of a stannous fluoride dentifrice plus hydrogen peroxide gel yielded approximately a 10% improvement in malodor compared to a multi-step oral hygiene routine.