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Clinical Summary

A Randomized, Single-Blind, Clinical Study Assessing the Effects of an Experimental Dentifrice Compared to a Regular Fluoride Dentifrice on Breath Odor When Used Twice Daily for 3 Weeks in a Population with Clinically Diagnosed Gingivitis

Haleon Data on File, 300025, 2022.

Summary

- parodontax Active Gum Repair Breath Freshener formulation demonstrated a **statistically significant reduction from Day 0 in morning oral malodor following 3 weeks of twice-daily tooth brushing as measured by change in mean organoleptic score at Week 3 (pre-brushing) and compared with a reference dentifrice group.**
- parodontax stannous fluoride + zinc reduces pre-brushing morning breath in populations with clinically diagnosed gingivitis and can promote continued use of a product clinically proven to reverse gingivitis.
- **Statistically significant reduction in mean hydrogen sulfide, methanethiol, and total VSC concentration at all timepoints**.
- The change in mean dimethyl sulfide concentration was variable with no clear difference with timepoints. This is possibly because the dimethyl sulfide concentration measured in this study was already low and close to minimum detectable limit.

Aim

- To evaluate and compare the change in oral malodor using an experimental dentifrice containing stannous fluoride and zinc chloride compared to a standard fluoride dentifrice:
- Change in morning oral malodor by organoleptic assessment following 3 weeks of twice-daily tooth brushing.
- Change in morning oral malodor by instrumental volatile sulfur compound (VSC) determination following 3 weeks of twice-daily tooth brushing.
- Change in oral malodor 1-hour post-brushing at baseline, and following 3 weeks of twice daily use.

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HALEON

Clinical Summary

Study products and usage

- Experimental dentifrice: stannous fluoride dentifrice with zinc chloride (parodontax Active Gum Repair Breath Freshener).
- Regular fluoride dentifrice: (Crest Cavity Protection, United States [US] market product).

Method

- Single-center, single-blind (to the examiners undertaking the oral malodor assessments), randomized (stratified by the subject's gender), controlled, 2-arm parallel study in volunteers with clinically diagnosed gingivitis and oral malodor.
- Inclusion criteria: clinically diagnosed, plaque induced gingivitis defined as 10-30% bleeding sites. At screening (visit 1) and baseline (visit 2) mean hydrogen sulfide concentration >150 ppb and mean organoleptic score >2.
- 104 subjects were enrolled into the study and randomized to a treatment group.
- Measures of breath odor included VSC measurement (using the OralChroma instrument) and organoleptic assessments using the odor intensity scale (Rosenberg et al 1991).
- Subjects abstained from oral hygiene and food consumption for at least 8 hours prior to each study visit.
- Visit 1: Screening assessment of oral malodor, oral soft tissue (OST) and oral hard tissue (OHT) examinations and bleeding on probing gingivitis examination.
- Visit 2: Baseline breath VSC and organoleptic assessments were completed.
- Visit 3: pre- and post-brushing evaluation of breath VSCs and organoleptic scores in the same manner as performed at the Baseline visit.

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Clinical Summary

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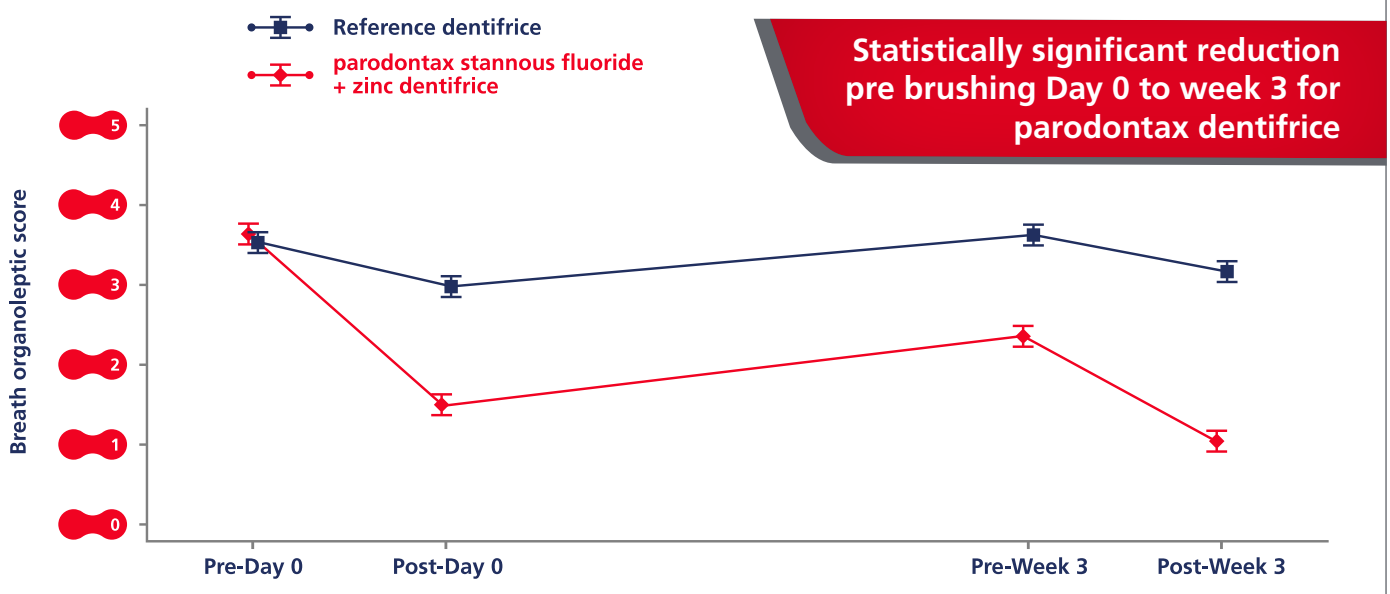
Results

Change as measured in mean breath organoleptic score:

- **Pre-brushing Day 0 to Week 3:** There was a statistically significant reduction in the parodontax group (p<0.0001), but not in the reference dentifrice group (p=0.6083).
- **Day 0 (pre-brushing) to Day 0 (post-brushing):** A statistically significant reduction was observed in both groups (p<0.0001). Adjusted mean difference was statistically significant, favoring the experimental dentifrice group (experimental dentifrice vs reference dentifrice: p<0.0001).
- **Day 0 (pre-brushing) to Week 3 (post-brushing):** A statistically significant reduction was observed in both the experimental dentifrice group (p<0.0001) and the reference dentifrice group (p=0.0101). The adjusted mean difference was statistically significant, favoring the experimental dentifrice group (experimental dentifrice vs reference dentifrice: p<0.0001).

Figure 1: Mean breath organoleptic score (±SE) plot over time by study product (mITT Population)



Abbreviations: mITT = modified-Intent-to-Treat; Pre-DO = Day 0 (pre-brushing); Post-DO = Day 0 (post-brushing); Pre-W3 = Week 3 (pre-brushing); Post-W3 = Week 3 (post-brushing); SE = standard error.
Experimental dentifrice: Stannous fluoride and zinc chloride
Reference dentifrice: Regular fluoride dentifrice. Raw means (‡SE) were presented.

Oral odor intensity scale: 0 = no appreciable odor to 5 = extremely foul odor. Mean breath organoleptic score for each study product was presented on the y-axis. Timepoints were presented on the x-axis. Individual SE boundaries were presented in bars.

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Clinical Summary

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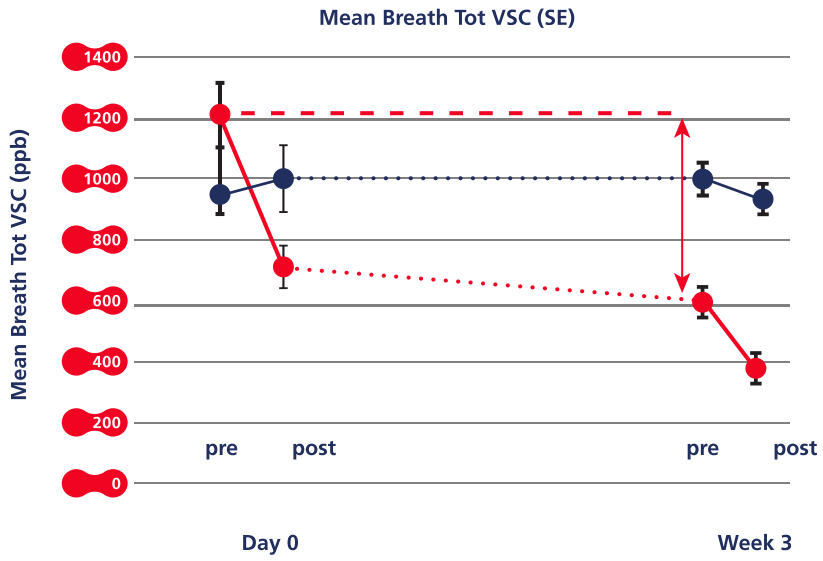
Change as measured in mean total VSC concentration:

- **Day 0 (pre-brushing) to Day 0 (post-brushing):** A statistically significant reduction was observed in the experimental dentifrice group ($p<0.0001$), but not in the reference dentifrice group ($p=0.4532$).
- **Day 0 (pre-brushing) to Day 21 (pre-brushing):** A statistically significant reduction was observed in the experimental dentifrice group ($p<0.0001$), but not in the reference dentifrice group ($p=0.3453$).
- **Day 0 (pre-brushing) to Day 21 (post-brushing):** A statistically significant reduction was observed in the experimental dentifrice group ($p<0.0001$), but not in the reference dentifrice group ($p=0.9667$).



50% improvement in oral malodor pre-brushing in patients with gingivitis†

Total VSC was derived as the sum of the hydrogen sulfide, methanethiol, and dimethyl sulfide concentrations in breath and then the mean over 2 samples to derive one value used for analysis per visit/timepoint.

† after 3 weeks continued twice daily use