



Oral Malodor

In vivo study*

The effect of Philips Sonicare TongueCare+ on Oral Malodor versus Standard Tongue Cleaning and Breath Freshening Modalities

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Objectives

The primary objective of this study was to assess the extent to which Philips Sonicare TongueCare+ would improve breath odor compared to Manual Tongue Brushing alone and to Listerine Cool Mint Rinse alone. The primary endpoint was based on an organoleptic assessment 8 hours following a single product use.

The secondary objectives of the study were to:

- Assess the extent to which Philips Sonicare TongueCare+ would improve breath odor compared to Listerine Cool Mint Rinse and versus Manual Tongue Brushing at immediately post, 4 hours, and 8 hours following a single product use.
- Assess the extent to which Philips Sonicare TongueCare+ would improve breath odor compared to Manual Tongue brushing and to Listerine Cool Mint Rinse at immediately post, 4 hours, and 8 hours following 1-week of home use.
- Evaluate the safety of the study products.

Methodology

Healthy adults meeting study requirements were enrolled in this IRB (ethics-committee) approved, parallel, examiner-blinded clinical trial. Eligible subjects were aged 18-70 years, non-smokers defined as the use of 100 cigarettes or less in their lifetime.

Enrolled participants had a minimum organoleptic score of 2.7-4.5 following 12-18 hours of oral hygiene abstention. The organoleptic scores of 0-5 were based on an average score by three calibrated, blinded organoleptic assessors. The eligible participants agreed to abstain from oral odor producing and oral malodor treatment foods, drinks, and interventions for the study period. Subjects were excluded from the study if they had a gagging sensitivity that exceeded 3 per Dickinson & Fiske Gagging Severity Index. Subjects were also excluded if they didn't practice daily oral care, or if they had consumed, or used medicated lozenges, sweets or gum that contained antimicrobial agents including but not limited to Xylitol, Essential Oils, CPC, Chlorine Dioxide and zinc, within the 24 hours.

The test products used in this study were the following:

- Philips Sonicare TongueCare+ (TC+): Tongue Brush with BreathRx Tongue Spray (3 sprays followed by 20 second tongue brushing using Sonicare TongueCare+ three times)
- Listerine Cool Mint Antiseptic Rinse (Full-mouth, 20ml x 30 seconds)
- Manual Toothbrush (MTB) Tongue Brushing (ADA Reference, per ADA DFU)

The duration of the study for each subject was one week of daily treatments. At the first visit, an oral examination, organoleptic evaluation, an H2S measurement, and microbial samples were collected from the subjects before and after the supervised, single product use. Subjects were asked to return after 4 and 8 hours for the same assessments. After the 8-hour assessment, the product was dispensed, and subjects were asked to use the product once a day, and return on the seventh day before the use of the product. An oral examination, organoleptic evaluation, H2S measurement and microbial samples were collected from the subjects before and after a supervised, single product use on the second visit. Subjects were asked to return after 4 and 8 hours for the same assessments. Subjects were then remunerated and dismissed from the study.

Comparisons between treatment groups were performed using an Analysis of variance. Differences between the two control groups (Listerine and MTB) and the test group was performed using contrast statements, Dunnett's procedure for multiple comparisons. Least squares (LS) means, and Dunnett's adjusted standard errors (SEs) of the means, and two-sided 95% CIs was presented.

Results

Out of 168 enrolled participants, 166 were modified intent-to-treat (MITT) evaluable subjects which included all randomized subjects with a pre-treatment and 8-hour evaluation of the organoleptic score post a single product use (mean age 39 years, 91 female/75 male). All results were based on MITT subjects. Philips Sonicare TongueCare+, when used as indicated, reduced oral malodor and maintained reduction below detectable threshold levels (2.0) at all time points for both visits (1.47-1.77 for visit 1; 1.41-1.89 for visit 2) as measured by organoleptic scores. Philips Sonicare TongueCare+ showed a statistically significant superiority ($p < 0.0001$) in organoleptic scores when compared to rinsing with Listerine or tongue brushing with a MTB. For visit 1 the mean organoleptic score 8-hour reduction from baseline were 0.82 (26.19%) for MTB, 0.73 (22.83%) for Listerine and 1.44 (46.67%) for Philips Sonicare TongueCare+. For visit 2 the mean organoleptic score 8-hour reduction from baseline were 0.42 (13.57%) for MTB, 0.40 (12.07%) for Listerine and 0.93 (34.54%) for Philips Sonicare TongueCare+. This indicates that at visit 1 Philips Sonicare TongueCare+ was 2 times more effective at reducing bad breath as measured by the percent reduction in organoleptic scores when compared with rinsing with Listerine, and 1.8 times more effective than brushing

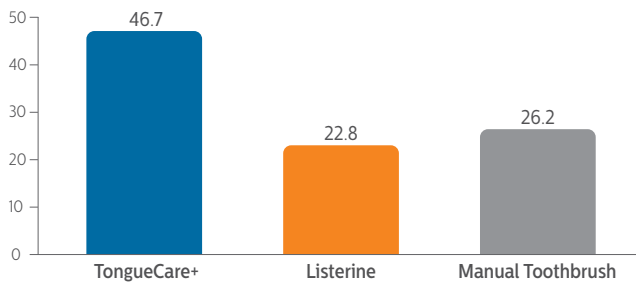
the tongue with a MTB. At visit 2 Philips Sonicare TongueCare+ was 3 times more effective at reducing bad breath as measured by the percent reduction in organoleptic scores when compared with rinsing with Listerine, and 2.5 times more effective than brushing the tongue with a MTB (Fig 1 and 2). P-value = <0.0001.

The reported safety events were mild in severity and were unrelated to test product use.

For the microbial anaerobic data analysis quantified in CFU/cm² there was no statistically significant difference seen among the three groups for the first visit at all time-points. For visit 2, significantly less anaerobic counts in Philips Sonicare TongueCare+ were observed immediately post-treatment when compared to Listerine (p-value = 0.0229).

Fig 1: Organoleptic Score Reduction at 8 Hours After Initial Use

% Organoleptic Score Reduction

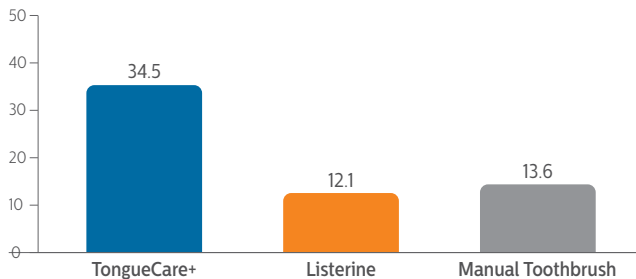


TongueCare+ vs Listerine p<0.0001

TongueCare+ vs Manual Toothbrush p<0.0001

Fig 2: Organoleptic Score Reduction at 8 Hours After One Week Use

% Organoleptic Score Reduction

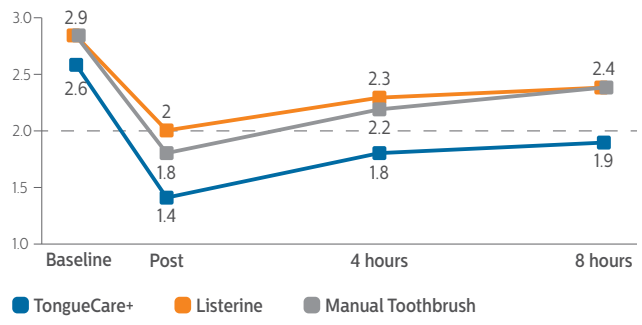


TongueCare+ vs Listerine p<0.0001

TongueCare+ vs Manual Toothbrush p<0.0001

Fig 3: Organoleptic Scores After One Week Use

Organoleptic Scores



0 – Odor cannot be detected
 1 – Questionable malodor, barely detectable
 2 – Slight malodor, exceeds the threshold of malodor recognition
 3 – Malodor is definitely detected
 4 – Strong malodor
 5 – Very strong malodor

Conclusions

Organoleptic measurements after initial use

- Immediately after initial use all three treatment groups reduced oral malodor.
- Eight hours after initial use Philips Sonicare TongueCare+ maintained oral malodor reduction below the threshold of detectable malodor.
- Eight hours after initial use Philips Sonicare TongueCare+ reduced oral malodor 2x more than Listerine Rinse and 1.8x more than brushing the tongue with a MTB. (Fig 1)

Organoleptic measurements after 1 week of home use

- Immediately after use Philips Sonicare TongueCare+ reduced oral malodor significantly more than both Listerine Rinse and brushing the tongue with a MTB.
- Eight hours after treatment Philips Sonicare TongueCare+ maintained oral malodor reduction below the threshold of detectable malodor. (Fig 3)
- Eight hours after treatment Philips Sonicare TongueCare+ reduced oral malodor 3x more than Listerine Rinse and 2.5x more than brushing the tongue with a MTB. (Fig 2)

Bacteria count

- With 1 week of use TongueCare+ reduced baseline levels of oral malodor bacteria.

No adverse events related to test product were reported during the study.

