



Gum Health and Plaque Removal

in vivo study

A Study to Assess the Effects of Philips Sonicare AirFloss Pro, when Used with Antimicrobial Rinse, on Gum Health and Plaque Removal

Mwatha A, Olson M, Souza S, Ward M, Jenkins W, Amini P, Gallob J, Fafard T.

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Objectives

To compare the effect of four home use oral hygiene regimes on gum health and plaque reduction following two and four weeks of use.

Methodology

Two-hundred ninety healthy adults (mean age 35.6 years, 186 female/104 male) were enrolled in this IRB-approved, parallel, examiner-blinded clinical trial. Of these, 286 subjects completed the study. Eligible subjects were non-smokers, aged 18-65 years who were routine manual toothbrush users and irregular flossers (once per week, or less often). Enrolled participants had a minimum average plaque score of ≥ 0.5 per Rustogi Modified Navy Plaque Index (RMNPI) following 2-6 hours plaque accumulation, and a Gingival Bleeding Index (GBI) of ≥ 1 on at least 10 sites. All enrolled subjects were dispensed study products per randomization, either manual toothbrush (MTB) alone twice daily, or manual toothbrush in addition to once daily use of string floss (SF) or Philips Sonicare AirFloss with either BreathRx (AFBX) or Listerine CoolMint (AFL) rinse dispensed to the interproximal space via the device. Subjects were instructed on product use technique and were to utilize the prescribed regimen for the following 28 days. Subjects returned to clinic at an interim time point of 14 days, and finally at 28 days for efficacy and safety evaluations following the 2-6 hour plaque accumulation period. Efficacy measures included gingival inflammation (MGI), gingival bleeding (GBI) and surface plaque (MPI). Safety was assessed per subject report and intraoral examination. Statistical methods included a comparison of interproximal cleaning devices to MTB alone, as well as a non-inferiority test between AFL and AFBX to SF. Study products were collected from study participants at Day 28 and they were dismissed from study.

Results

Modified Gingival Index (MGI)

Following two weeks of product use, the LS Mean (SE) percent reduction from Baseline was 0.22% (0.55%) for MTB, 4.30% (0.44%) for SF, 4.55% (0.45%) for AFL and 4.20% (0.44%) for AFBX.

Following four weeks of product use, the LS Mean (SE) percent reduction from Baseline was 1.10% (0.72%) for MTB, 11.41% (0.58%) for SF, 9.54% (0.58%) for AFL and 8.52% (0.58%) for AFBX.

For both timepoints, the difference between MTB alone to MTB plus interproximal cleaning (SF, AFL, AFBX) was statistically significant, p-value < 0.001 .

Gingival Bleeding (GBI)

Following two weeks of product use, the LS Mean (SE) percent reduction from Baseline was -0.16% (2.81%) for MTB, 22.89% (2.26%) for SF, 26.90% (2.27%) for AFL and 24.61% (2.26%) for AFBX.

Following four weeks of product use, the LS Mean (SE) percent reduction from Baseline was 4.03% (2.85%) for MTB, 43.31% (2.31%) for SF, 40.49% (2.31%) for AFL and 36.79% (2.30%) for AFBX.

For both timepoints, the difference between MTB alone to MTB plus interproximal cleaning (SF, AFL, AFBX) was statistically significant, p-value < 0.001 .

Surface Plaque (RMNPI)

Following two weeks of product use, the LS Mean (SE) percent reduction from Baseline was 5.56% (1.00%) for MTB, 17.07% (0.80%) for SF, 15.95% (0.80%) for AFL and 14.33% (0.80%) for AFBX.

Following four weeks of product use, the LS Mean (SE) percent reduction from Baseline was 5.70% (1.08%) for MTB, 26.48% (0.87%) for SF, 23.96% (0.87%) for AFL and 22.41% (0.86%) for AFBX.

For both timepoints, the difference between MTB alone to MTB plus interproximal cleaning (SF, AFL, AFBX) was statistically significant, p-value < 0.001 .

Safety

There were four reported safety events that were deemed mild in severity and resolved.

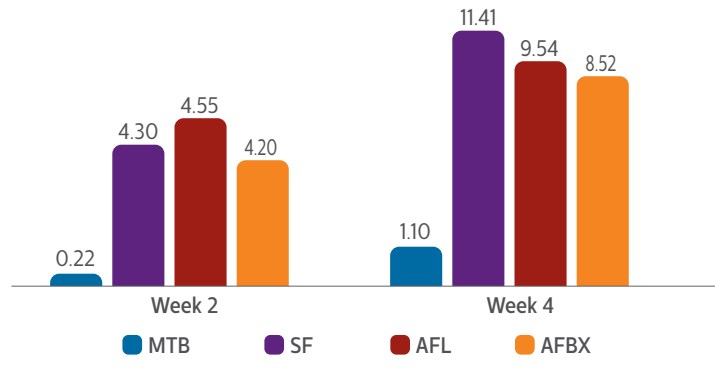
Conclusions

The use of an interproximal cleaning regimen as an adjunct to manual toothbrushing improves gum health and reduces plaque significantly better than manual toothbrushing alone.

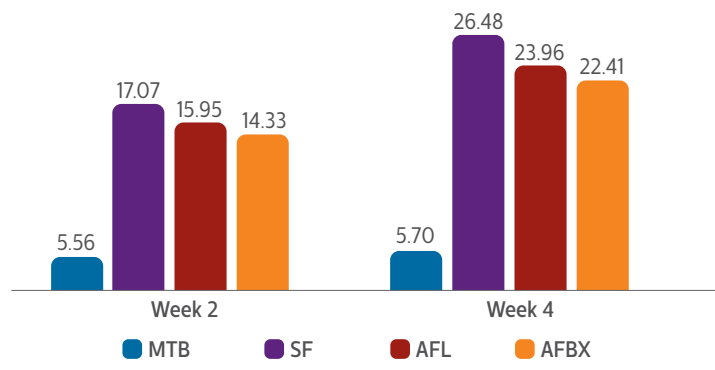
Among the adjunct interproximal cleaning regimens, a non-inferiority test comparing Philips Sonicare AirFloss Pro to string floss showed Philips Sonicare AirFloss Pro to be non-inferior to string floss, p-value < 0.001 , in reducing plaque and gingivitis.

All study products were safe for use.

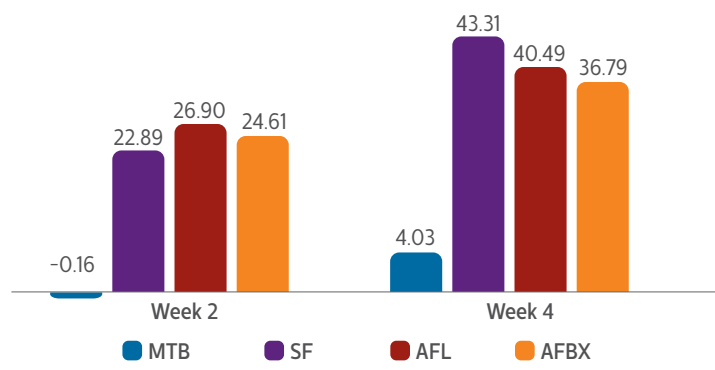
**Least Squares Mean, Modified Gingival Index
Percent Reduction from Baseline to Week 2 and Week 4**



**Least Squares Mean, Rustogi Modified Plaque Index
Percent Reduction from Baseline to Week 2 and Week 4**



**Least Squares Mean, Gingival Bleeding Index
Percent Reduction from Baseline to Week 2 and Week 4**



Key

- Manual toothbrush
- String floss
- AirFloss Pro + Listerine
- AirFloss Pro + BreathRx

