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.

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

<table>
<thead>
<tr>
<th></th>
<th>MTB</th>
<th>SF</th>
<th>AFL</th>
<th>AFBX</th>
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<tbody>
<tr>
<td>Week 2</td>
<td>4.30</td>
<td>0.22</td>
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<td></td>
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<tr>
<td>Week 4</td>
<td>4.55</td>
<td>11.41</td>
<td>9.54</td>
<td>8.52</td>
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</tbody>
</table>

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

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<thead>
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<th>MTB</th>
<th>SF</th>
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<th>AFBX</th>
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<tbody>
<tr>
<td>Week 2</td>
<td>22.89</td>
<td>-0.16</td>
<td>26.90</td>
<td>24.61</td>
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<td>Week 4</td>
<td>26.48</td>
<td>26.48</td>
<td>40.49</td>
<td>36.79</td>
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Least Squares Mean, Rustogi Modified Plaque Index
Percent Reduction from Baseline to Week 2 and Week 4

<table>
<thead>
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<th>MTB</th>
<th>SF</th>
<th>AFL</th>
<th>AFBX</th>
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<tbody>
<tr>
<td>Week 2</td>
<td>17.07</td>
<td>5.56</td>
<td>15.95</td>
<td>14.33</td>
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<tr>
<td>Week 4</td>
<td>26.48</td>
<td>5.70</td>
<td>23.96</td>
<td>22.41</td>
</tr>
</tbody>
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Key
- Manual toothbrush
- String floss
- AirFloss Pro + Listerine
- AirFloss Pro + BreathRx