



## Gingival health

in vivo study

# Comparison of Plaque and Gingivitis Reduction by a Philips Sonicare Ortho Regimen versus Manual Toothbrush plus String Floss on Orthodontic Patients

Plaque and Gingivitis Reduction by Sonicare Regimen in Orthodontic Subjects.  
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### Objective

To evaluate the effect of Philips Sonicare EasyClean power toothbrush with InterCare brush head plus AirFloss Pro used with BreathRx rinse, and an ADA reference manual toothbrush plus Reach unflavored waxed floss, on plaque and gingivitis in subjects with bracketed dentition following three and six weeks of home use.

### Methodology

Two-hundred and twenty eight subjects (mean age 16; 144 female/84 male) were enrolled and randomized in this IRB-approved, single-center, examiner-blinded, parallel-design study following applicable Informed Consent/Assent. Of those randomized, 223 completed evaluations to Week 3 and are included in the primary analysis. Eligible subjects were routine manual toothbrush users who were non-smokers, aged 12-65 with a minimum of 10 brackets on teeth in each arch, or brackets on all teeth from first molar to first molar. Subjects had a minimum plaque index of 2.0 per the Bonded Bracket Index (BBI) following 3-6 hours plaque accumulation, with a Gingival Bleeding Index (GBI) of  $\geq 1$  on at least 20 sites. Enrolled subjects were to perform oral hygiene twice daily for the following six weeks utilizing one of the following regimens per random assignment:

- Sonicare EasyClean power toothbrush with InterCare brush head, Sonicare AirFloss Pro utilized with BreathRx rinse applied buccal and lingual (Philips Sonicare Ortho Regimen, PSO Regimen)
- ADA Reference Manual Toothbrush, J&J Reach unflavored waxed floss (Control Regimen)

Gingival inflammation was assessed per GBI and Modified Gingival Index (MGI). Surface plaque on bracketed teeth was assessed using the BBI, and for non-bracketed teeth, the Lobene and Soparker Modified Plaque Index (MPI) was utilized. All efficacy metrics were evaluated in clinic by a blinded Examiner at Weeks 3 and 6 following Baseline. Safety was assessed by intraoral exam at all study visits, and per subject report.

### Results

#### *Surface Plaque on Bracketed Teeth per Bonded Bracket Index (BBI)*

At Baseline, the BBI LS Mean(SE) outcome for PSO Regimen was 2.68 (0.02), and for the Control Regimen it was 2.68 (0.02), p-value = 0.9889.

Following three weeks of product use, the LS Mean(SE) for the PSO Regimen group was 1.79 (0.03), and for the Control Regimen it was 2.62 (0.03), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 33.12% reduction for the PSO Regimen, and 2.01% for the Control Regimen.

Following six weeks of product use, the LS Mean(SE) for the PSO Regimen group was 1.66 (0.02), and for the Control Regimen it was 2.57 (0.02), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 37.88% reduction for the PSO Regimen, and 3.74% for the Control Regimen.

#### *Surface Plaque on non-Bracketed Teeth per Modified Lobene and Soparker Plaque Index (MPI)*

At Baseline, the MPI LS Mean(SE) outcome for PSO Regimen was 3.23 (0.05), and for the Control Regimen it was 3.20 (0.05), p-value = 0.5947.

Following three weeks of product use, the LS Mean(SE) for PSO Regimen group was 2.12 (0.04) and for the Control Regimen it was 3.17 (0.04), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 32.65% reduction for the PSO Regimen, and 0.26% for the Control Regimen.

Following six weeks of product use, the LS Mean(SE) for the PSO Regimen group was 2.04 (0.04), and for the Control Regimen it was 3.13 (0.04), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 35.11% reduction for PSO Regimen, and 1.52% for the Control Regimen.

#### *Gingival Bleeding per Gingival Bleeding Index (GBI)*

At Baseline, the GBI LS Mean(SE) outcome for PSO Regimen was 0.44 (0.02), and for the Control Regimen it was 0.44 (0.02), p-value = 0.9351.

Following three weeks of product use, the LS Mean(SE) for PSO Regimen group was 0.11 (0.01) and for the Control Regimen it was 0.38 (0.01), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 73.59% reduction for the PSO Regimen, and 10.96% for the Control Regimen.

Following six weeks of product use, the LS Mean(SE) for the PSO Regimen group was 0.09 (0.01), and for the Control Regimen it was 0.36 (0.01), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 78.33% reduction for the PSO Regimen, and 16.15% for the Control Regimen.

#### *Gingival Inflammation per Modified Gingival Index (MGI)*

At Baseline, the MGI LS Mean(SE) outcome for the PSO Regimen was 2.80 (0.02), and for the Control Regimen it was 2.82 (0.02), p-value = 0.5621.

Following three weeks of product use, the LS Mean(SE) for PSO Regimen group was 1.45 (0.03) and for the Control Regimen it was 2.58 (0.03), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 48.54% reduction for the PSO Regimen, and 8.15% for the Control Regimen.

Following six weeks of product use, LS Mean(SE) for the PSO Regimen group was 1.38 (0.03), and for the Control Regimen it was 2.51 (0.03), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 50.99% reduction for PSO Regimen, and 10.54% for the Control Regimen.

**Safety**

There were no adverse events reported.

**Conclusions:**

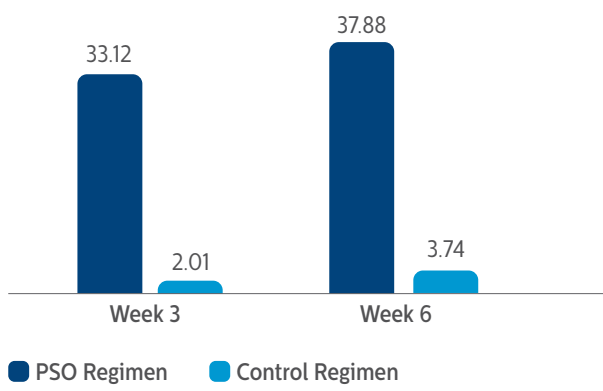
The Philips Sonicare Ortho Regimen was statistically superior to the Control Regimen in reducing plaque on bracketed teeth and non-bracketed teeth following three and six weeks of home use.

The Philips Sonicare Ortho Regimen was statistically superior to the Control Regimen in reducing gingival inflammation and gingival bleeding following three and six weeks of home use.

Both products were safe for home use.

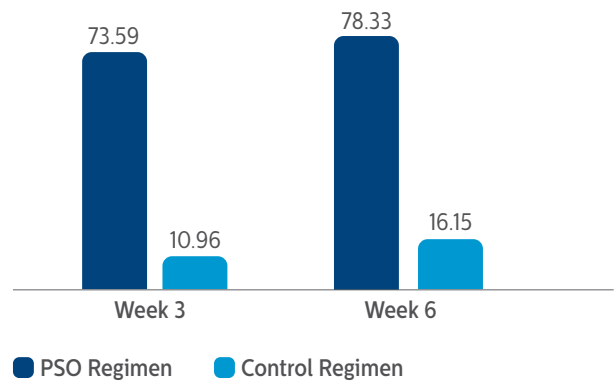
**Least Squares Mean for Bonded Bracket Index**

Percent Reduction from Baseline to Week 3 and Week 6, Overall



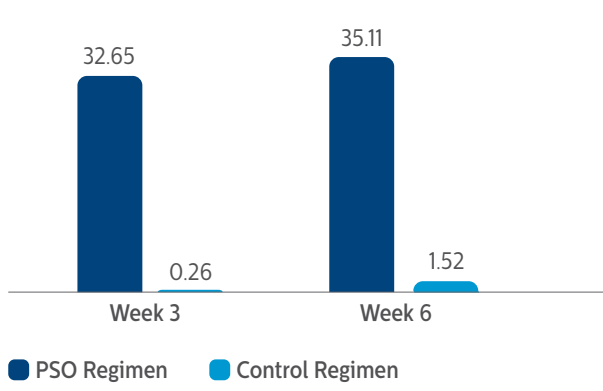
**Least Squares Mean for Gingival Bleeding Index**

Percent Reduction from Baseline to Week 3 and Week 6, Overall



**Least Squares Mean for Modified Plaque Index**

Percent Reduction from Baseline to Week 3 and Week 6, Overall



**Least Squares Mean for Modified Gingival Index**

Percent Reduction from Baseline to Week 3 and Week 6, Overall

