

# The Effects of Use of a Powered and a Manual Home Oral Hygiene Regimen on Plaque and Gum Health in an Orthodontic Population

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## Abstract

- **Objective:** The objective of this study was to compare the effect of two home use oral hygiene regimens on plaque, gingivitis, and gingival bleeding on subjects undergoing orthodontic treatment with fixed appliances.
- **Methods:** This was a randomized, parallel, single-center clinical trial. Eligible study subjects fit the following profile: age 12–65 years; non-smoker; plaque score of  $\geq 2.0$  per Bonded Bracket Index (BBI) on dentition with fixed orthodontic hardware; minimum of 10 orthodontic brackets in each arch or on all teeth from first molar to first molar; presenting with mild to moderate gingivitis, defined as a score of  $\geq 1$  on at least 20 sites per Gingival Bleeding Index (GBI). Subjects with advanced periodontal disease or gingival recession were not eligible. Eligible subjects were randomized to one of two home use oral hygiene regimens: manual toothbrush plus string floss (used with a threading device) for interdental cleaning (MTF regimen); or Philips Sonicare EasyClean power toothbrush with InterCare brush head and AirFloss Pro powered device, used with BreathRx mouthrinse for interdental cleaning (Sonicare Orthodontic Regimen or SOR). All subjects brushed twice daily with standard fluoridated dentifrice and performed interdental cleaning once daily. Efficacy and safety examinations were performed at Baseline and following three and six weeks of home use of the study products, and included assessments of BBI, GBI, Modified Gingival Index (MGI), and Modified Plaque Index (MPI).
- **Results:** Of 228 enrolled subjects, 223 were included in the primary analysis. For the primary endpoint, reduction in BBI score following three weeks of product use, the overall least squares (LS) mean (95% CI) reduction was 0.89 (0.84, 0.95) for SOR and 0.06 (0.01, 0.12) for MTF. Expressed as percent reduction (95% CI) from Baseline, this was 33.1% (31.1%, 35.2%) for SOR and 2.01% (-0.06%, 4.07%) for MTF. The differences between regimens were statistically significant,  $p < 0.0001$ . Statistically significant differences between regimens were observed in BBI following six weeks of product use, and also for all other efficacy variables (GBI, MGI, MPI) at Week 3 and Week 6.
- **Conclusion:** The powered oral hygiene regimen was significantly more effective than a manual regimen in reducing plaque on bracketed and non-bracketed teeth, and in reducing gingival bleeding and gingival inflammation in orthodontic subjects following three weeks of use and persisting following six weeks of use. All products were safe on oral tissues and fixed orthodontic appliances.

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## Introduction

Treatment with fixed orthodontic appliances is not without risk to the oral health of the patient. There are clinically observable adverse responses in the surrounding hard and soft oral tissues that are commonly associated with treatment. As the presence of brackets and arch wires can hinder a patient's ability to comprehensively clean tooth surfaces, along the gingival margin and in interproximal spaces, residual food and debris are more readily retained and removed with more difficulty in this population. Protracted retention of debris can alter the quantity and character of the surrounding plaque biofilm,<sup>1,2</sup> increasing the periodontopathogens and the pH-based cariogenicity in the oral environment.<sup>3</sup>

Local changes in the biofilm, consistent with a lower pH, favor the proliferation of acidogenic and aciduric bacterial species such as *Streptococcus mutans* and *Lactobacilli*. The proliferation of these organisms and their by-products can hamper remineralization mechanisms<sup>4,5</sup> which creates an enamel environment that is susceptible to the development of white spot lesions (WSL) or caries.<sup>6</sup>

Periodontal health can also be affected by the presence of fixed orthodontic appliances, with gingival inflammation, gingival bleeding, or pocket depths observed to negatively increase during treatment.<sup>7-11</sup>

Gingival enlargement, resulting from inflamed gingival tissue, further complicates the patient's ability to comprehensively remove plaque from tooth surfaces.<sup>4</sup> This sets the stage for a physiologic and ecological feedback loop that favors disease-promoting factors. And while these effects may be transient in some patients, returning to a more baseline character once brackets are removed,<sup>12</sup> there can be significant detriments such as chronically enlarged soft tissues, WSL or caries, all of which may require invasive intervention after debonding. It is incumbent on the dental practitioner to educate the patient on adequate oral hygiene practices at the onset of, and during, orthodontic treatment, thus to limit these potential risks of treatment.

The ultimate goal is patient motivation and compliance, with optimal oral hygiene practices throughout often lengthy treatment. A particular challenge is that orthodontic patients, predominantly

adolescents, are a population group who may not be inclined toward preventive health habits. The oral hygiene habits a patient brings to treatment are difficult to change, especially so because orthodontic appliances makes each oral hygiene encounter more laborious.

Interdental cleaning with string floss, for example, requires the use of specialized floss or a threading device, which requires both additional time and dexterity of the user. Tooth brushing is similarly affected. Brushing previously smooth tooth surfaces, now obstructed by bulky brackets and wires, requires additional attention and care in order to adequately remove debris and plaque.

The current clinical study was conducted to explore whether the adoption of a hygiene regimen consisting of powered devices confers clinical benefits compared to a standard of care manual hygiene approach, so as to elicit whether adoption of the powered regimen could potentially help mitigate the commonly observed risks in an orthodontic population.

It has been previously reported that the use of a power toothbrush is superior to a manual toothbrush in reducing plaque and gingivitis.<sup>13-16</sup> As a category, the devices are designed with features that encourage compliance, there are brush head models specifically optimized to target patient-specific conditions, and the devices have powerful motors that drive brush head movement to a much greater extent than could reasonably be achieved manually.

Similarly, novel powered devices have been designed to aid the user in performing interdental cleaning. Powered interdental cleaners, such as the Philips Sonicare AirFloss, were designed to overcome the challenges of usability associated with string floss, while retaining the same level of efficacy.<sup>17</sup>

The regimens tested in this six-week study were comprised of either a manual toothbrush plus string floss (MTF), or a Philips Sonicare EasyClean powered toothbrush with InterCare brush head, and a powered interdental cleaning device, Sonicare AirFloss Pro, used with an antimicrobial rinse, BreathRx, in the fluid reservoir (Philips, Bothell, WA, USA). The clinical endpoints included the assessment of surface plaque on bracketed and non-bracketed surfaces, as well as clinical assessment of gingival inflammation and gingival bleeding.

## Materials and Methods

### Study Design and Objectives

This was a randomized, parallel clinical trial. This study was reviewed and approved by an accredited Institutional Review Board (US IRB; Miami, FL, USA). All subjects screened and enrolled in the study provided informed consent and/or assent, as applicable. The ethical principles regarding the treatment of human subjects on study were consistent with the tenets outlined in the Declaration of Helsinki.

There were a total of three study visits over a period of six weeks. Table I provides a depiction of study visits and procedures. The primary objective of the study was to compare the effect of the Sonicare Orthodontic Regimen (SOR) to a standard control regimen, manual toothbrush plus floss (MTF), to reduce plaque on bracketed teeth, per the Bonded Bracket Index<sup>18</sup> (BBI) following three weeks of home product use.

The secondary objectives of the study were to assess the safety of the products on oral tissues, and to compare the effects of SOR and MTF on the reduction of plaque on bracketed teeth, per BBI, fol-

**Table I**  
Study Visits and Procedures

Visit Number	Time Point	Description of Procedures
1	Day 0	Informed Consent/Assent Medical/Dental History Oral Exam MGI, GBI, BBI, MPI Randomization to SOR or MTF Product Dispense and Instruction Provide Diary for Compliance Tracking
3-6 hours Plaque Accumulation		
2	Week 3	Compliance Monitoring Adverse Events Monitoring MGI, GBI, BBI, MPI Provide Diary for Compliance Tracking
3-6 hours Plaque Accumulation		
3	Week 6	Compliance Monitoring Adverse Events Monitoring MGI, GBI, BBI, MPI Dismiss from Study

lowing six weeks of product home use, and after three and six weeks of product use on the following: reduction of gingival inflammation per Modified Gingival Index<sup>19</sup> (MGI); the reduction of gingival bleeding per Gingival Bleeding Index<sup>20</sup> (GBI); and the reduction of plaque on non-bracketed dentition per Lobene and Soparker Modified Plaque Index<sup>21-23</sup> (MPI).

### Efficacy and Safety Measurements

The BBI was performed to assess plaque on the surface of teeth with orthodontic fixtures. Plaque scores were recorded on four sites per tooth, on a scale of 0 to 3. For teeth without brackets, the MPI was used to assess plaque on 6 sites per tooth, on a scale of 0 to 5.

Gingival inflammation was assessed according to the MGI, full mouth, on four sites per tooth, on a scale of 0 to 4. Gingival bleeding was evaluated using the GBI on four sites per tooth, on a scale of 0 to 3. Table II provides a description and scale utilized for each index.

Safety was assessed by examiner interview at study visits, by intra-oral tissue exam, and by subject report on a home diary card used throughout the study.

The examiners who performed clinical assessments scored a given index for all study subjects, for all visits, thus to eliminate variability as a result of inter-examiner scoring differences.

### Study Subjects

Eligible study subjects met the following study entry criteria: age 12–65 years; non-smoker, presenting with at least 10 orthodontic brackets on teeth in each arch, or brackets on all teeth from first molar to first molar; have a minimum average plaque score of  $\geq 2.0$  based on the BBI following 3–6 hours plaque accumulation; and have a GBI of  $\geq 1$  on at least 20 sites. Subjects were not eligible if any of the following were present: a diagnosis of insulin dependent diabetes; xerostomia; current use of antibiotics; prescription-dose anti-inflammatory medications or anticoagulants, excessive gingival recession or heavy deposits of calculus; or were pregnant or nursing.

### Treatment Groups

There were two treatment groups evaluated in this clinical trial. Subjects were assigned to home use of either the Sonicare Orthodontic

**Table II**  
Description of Scoring Methodology; BBI, MPI, MGI, GBI

0	1	2	3	4	5
<b>Bonded Bracket Index (BBI)</b> Partial Mouth; Teeth with Brackets					
No plaque or debris	plaque covering less than 1/3 of the tooth area, separate flecks of plaque on the tooth	plaque covering 1/3 to 2/3 of the tooth area, moderate accumulation of plaque	plaque covering more than 2/3 of the tooth area, high accumulation of plaque	N/A	N/A
<b>Lobene and Soparkar Modification of Quigley and Hein Plaque Index (MPI)</b> Partial Mouth; 3 Sites per Surface; 6 Sites per Tooth Performed on Teeth without Brackets					
No plaque	separate flecks of plaque at the gingival margin	a thin continuous band of plaque (up to 1mm) at the cervical margin of the tooth	a band of plaque wider than 1 mm but covering less than 1/3 of the crown of the tooth	plaque covering at least 1/3 but less than 2/3 of the crown of the tooth	covering 2/3 or more of the crown of the tooth
<b>Modified Gingival Index (MGI)</b> Full Mouth; 4 Sites per Tooth Except for Last Site in Each Arch					
Absence of inflammation	mild inflammation; slight change in color little change in texture of any portion of but not the entire margin or papillary gingival unit	mild inflammation but involving entire margin or papillary unit	moderate inflammation; glazing, redness, edema and/or hypertrophy of margin or papillary unit	severe inflammation; marked redness, edema and/or hypertrophy of marginal or papillary gingival unit, spontaneous bleeding, congestion, or ulceration	N/A
<b>Gingival Bleeding Index</b> Full Mouth; 4 Sites per Tooth Except for Last Site in Each Arch					
No bleeding	bleeding on gently probing	bleeding appears immediately upon gently probing	spontaneous bleeding which is present prior to probing	N/A	N/A

Regimen (SOR), consisting of a Philips Sonicare EasyClean power toothbrush with an InterCare Brush Head, followed by interproximal cleaning with Philips Sonicare AirFloss Pro (Figure 1) utilized with BreathRx mouthrinse (active ingredient: cetylpyridinium chloride 0.075%) in the fluid reservoir, or a standard control regimen (MTF) consisting of an ADA reference manual toothbrush and interproximal cleaning with Reach® Unflavored Waxed Floss (Johnson & Johnson, New Brunswick, NJ, USA), which was utilized with a threading device. Subjects in both treatment groups brushed twice daily using fluoride-containing Crest® Cool Mint Gel dentifrice (Procter & Gamble, Cincinnati, OH, USA) and performed interproximal cleaning once daily. The use of any other hygiene product or device was prohibited during the study period.

#### **Randomization, Controls to Minimize Bias, and Data Capture**

Eligible subjects were randomized to one of two treatment groups, SOR or MTF. Randomization was balanced for gender and age, for approximately equal distribution between treatment groups. The age strata were defined as 12–18 years and 19–65 years. The study examiners who performed the efficacy measurements (BBI, MPI, MGI, GBI) were blinded to the treatment assignment of subjects. Study data were collected on a web-based electronic data capture (EDC) system. Access to the system was limited by log-in credentials of database users based on assigned study role.

#### **Statistical Methods**

**Sample Size Determination.** The primary objective of this study was to compare plaque reduction on bracketed teeth (per BBI) for

SOR and MTF following three weeks of use. Based on previous studies comparing a Sonicare power toothbrush and a manual toothbrush on non-bracketed teeth, the observed difference for MPI ranged from 0.14 to 0.85, with a standard deviation (SD) range from 0.19 to 0.43.



**Figure 1.** Mechanical devices, sonicare ortho regimen. Pictured left: Philips Sonicare EasyClean electric toothbrush with InterCare brush head. Pictured right: Philips Sonicare AirFloss Pro.



Expressed as a percent reduction in MPI, observed differences ranged from 6.4% to 31%, with a standard deviation range from 7.04 to 15.06. Overall, a minimum difference in plaque reduction between a power toothbrush and a manual toothbrush of 0.2 (SD = 0.44) and 10% (SD = 15%) was established to be of clinical relevance.

For this study, due to the addition of adjunct interproximal cleaning (either AirFloss Pro with rinse or string floss), a difference between the regimens of SOR and MTF of approximately 80% of the acceptable difference, as defined above for power and manual toothbrushes (*i.e.*, 0.16 for plaque reduction, 8% for percent reduction), was considered to be clinically relevant. Furthermore, it was assumed that the scoring methodologies of BBI and MPI would produce similar outcomes.

Based on these general assumptions, a sample size of 112 subjects per treatment group would allow for greater than 80% power to detect a difference in BBI between SOR and MTF.

**General Considerations.** All analyses were performed on the modified intent to treat (mITT) population, which included all randomized subjects with a complete plaque evaluation post three weeks of product home use. Subjects were analyzed according to the randomized treatment assignment. The analysis of safety included all randomized subjects. All analyses were conducted using SAS® software (SAS, Cary, NC, USA).

**Demographics.** Demographics (*e.g.*, age, gender) were summarized for all mITT subjects by treatment group and overall. For continuous characteristics, number of non-missing observations, mean, SD, 95% confidence interval (CI) of the mean, median, minimum (Min), and maximum (Max) were presented. One way analysis of variance (ANOVA) was used to compare the means between treatment groups. For categorical characteristics, the frequency count and the percentage of subjects in each category were presented. The Chi-Square test or Fisher's exact test, as appropriate, was used to compare the incidence of the categorical variable between treatment groups.

**Primary Efficacy Analysis.** The primary efficacy measure for this study was plaque reduction on bracketed teeth following three weeks of home use of the assigned study products. Plaque score on bracketed teeth was evaluated using the BBI index. Three summary BBI scores were calculated from the whole mouth for each subject as efficacy endpoints, which included: the average score at each visit, calculated as the sum of scores of all evaluable sites divided by the number of evaluable sites; the reduction from Baseline score at each follow-up visit, calculated as Baseline average score minus post-Baseline average score; and percent reduction from Baseline score at each follow-up visit, calculated as the score reduction from Baseline divided by the Baseline average score x 100.

Boxplots are presented to show the distributions of the average BBI score at each study visit for both treatment groups. The lower and upper boundary of the box marks the 25<sup>th</sup> and 75<sup>th</sup>, respectively, percentile of observed values; the line intersecting the box indicates the median; the circle within the box indicates the mean; and the lower and upper whisker denotes the Min and Max, respectively, of the observed values. The least square mean (LSM), the standard error (SE), and the two-sided 95% CI of the mean for the three summary BBI scores were estimated for each treatment group at each visit using ANOVA models, adjusting for the Baseline BBI as a covariate. The two-sided 95% CI for the mean difference between the treatment groups was also constructed.

**Secondary Efficacy and Safety Analysis.** The secondary efficacy measures were the reduction in gingivitis assessed by MGI, the reduction in gingival bleeding assessed by GBI, the reduction in plaque on non-bracketed teeth assessed by MPI after three and six weeks of home use, and plaque reduction on bracketed teeth assessed by BBI after six weeks of home use. Analysis was performed for each study visit for the three summary scores derived from each corresponding index using a similar approach as described above for the primary analysis.

Safety outcomes were provided in listings of adverse events, as well as for abnormal findings indicated on oral exam.

## Results

### Demographics

There were 228 subjects who provided informed consent (including assent, where appropriate) and were screened for the study. All of these subjects were enrolled and randomized. Of these, 223 subjects were included in the mITT analysis at Week 3, with 113 subjects in the SOR group, and 110 in the MTF group (two subjects were lost to follow-up, two subjects decided to terminate early, and one subject missed the Week 3 visit). Summary of demographics for the mITT study population is presented in Table III. The mean age of subjects was 16.0 years with 144 female subjects (64.6%) and 79 male subjects (35.4%). There were no statistical differences in the age and gender distribution of subjects between groups.

### Primary Efficacy Results

**Bonded Bracket Index (Bracketed Teeth).** A boxplot indicating the distribution of average BBI scores at Baseline, Week 3, and Week 6 is presented in Figure 2. The mean Baseline scores were comparable for both treatment groups.

Table IV provides a complete depiction of the primary efficacy results for BBI. The LS mean (95% CI) reduction in BBI following three weeks of product use was 0.89 (0.84, 0.95) for SOR and 0.06 (0.01, 0.12) for MTF. This difference was statistically significant,  $p < 0.0001$ . Expressed as percent BBI reduction from Baseline, the outcomes were 33.1% (31.1%, 35.2%) for SOR and 2.01% (-0.06%, 4.07%) for MTF.

At the Week 6 time point, the LS Mean (95% CI) reduction in BBI was 1.02 (0.98, 1.06) for SOR and 0.11 (0.06, 0.15) for MTF. This difference was statistically significant,  $p < 0.0001$ . Expressed as percent BBI reduction from Baseline, the Week 6 outcomes were 37.9% (36.2%, 39.5%) for SOR and 3.74% (2.06%, 5.42%) for MTF.

**Table III**  
Subjects Demographics, mITT Population

Parameter	Category	Treatment			p-value <sup>a</sup>
		SOR (N=115, rand)	MTF (N=113, rand)	Total (N=228)	
Age (yrs.)	No. Subjects	113	110	223	0.5233
	Mean(SD)	16.3 (8.9)	15.6 (7.1)	16.0 (8.1)	
	95% CI	(14.7, 18.0)	(14.3, 17.0)	(14.9, 17.0)	
	Median	14	13	13	
	Min, Max	(12, 63)	(12, 47)	(12, 63)	
Gender	Female	73 (64.6%)	71 (64.5%)	144 (64.6%)	0.9930
	Male	40 (35.4%)	39 (35.5%)	79 (35.4%)	

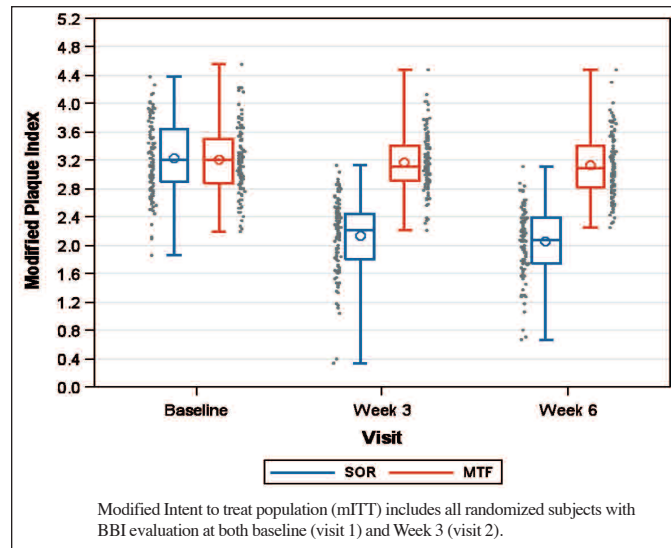
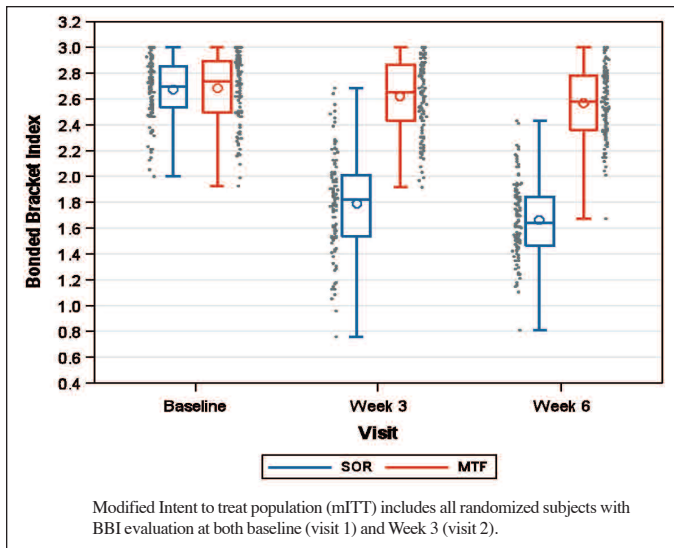
<sup>a</sup>p-value is based on one-way analysis of variance for continuous variables, and Chi-squared test for categorical variables.

**Secondary Efficacy Results**

**Modified Plaque Index (Non-Bracketed Teeth).** A boxplot indicating the distribution of average MPI scores at Baseline, Week 3, and Week 6 is presented in Figure 3. Both treatment groups had a similar distribution at Baseline.

Table IV provides a complete depiction of MPI analyses. For MPI,

the differences observed between products at both the Week 3 and Week 6 time points were statistically significant,  $p < 0.0001$ . At Week 3, the LS mean (95% CI) reduction in MPI was 1.09 (1.01, 1.18) for SOR and 0.05 (-0.04, 0.13) for MTF. Expressed as percent MPI reduction from Baseline, the outcomes were 32.7% (30.2%, 35.1%) for SOR and 0.26% (-2.25%, 2.76%) for MTF.



**Figure 2.** Distribution of outcomes, BBI, Baseline, Week 3, Week 6.

**Figure 3.** Distribution of outcomes, MPI, Baseline, Week 3, Week 6.

**Table IV**  
Summary Analysis, Bonded Bracket Index, and Modified Plaque Index

Variable	Statistic	Treatment		Difference <sup>a</sup>	p-value <sup>b</sup>
		SOR (N=113) <sup>c</sup>	MTF (N=110)		
<b>Bonded Bracket Index</b>					
Baseline	LS Mean (SE)	2.68 (0.02)	2.68 (0.02)	-0.00 (0.03)	0.9889
	95% CI	(2.63, 2.73)	(2.63, 2.73)	(-0.07, 0.07)	
Reduction from Baseline					
Week 3	LS Mean (SE)	0.89 (0.03)	0.06 (0.03)	0.83 (0.04)	<0.0001
	95% CI	(0.84, 0.95)	(0.01, 0.12)	(0.75, 0.91)	
Week 6	LS Mean (SE)	1.02 (0.02)	0.91 (0.03)	0.91 (0.03)	<0.0001
	95% CI	(0.98, 1.06)	(0.06, 0.15)	(0.85, 0.98)	
%Reduction from Baseline					
Week 3	LS Mean (SE)	33.12 (1.04)	2.01 (1.05)	31.11 (1.47)	<0.0001
	95% CI	(31.08, 35.16)	(-0.06, 4.07)	(28.20, 34.02)	
Week 6	LS Mean (SE)	37.88 (0.85)	3.74 (0.85)	34.13 (1.20)	<0.0001
	95% CI	(36.21, 39.54)	(2.06, 5.42)	(31.77, 36.50)	
<b>Modified Plaque Index</b>					
Baseline	LS Mean (SE)	3.23 (0.05)	3.20 (0.05)	0.04 (0.07)	0.5947
	95% CI	(3.14, 3.32)	(3.11, 3.29)	(-0.09, 0.16)	
Reduction from Baseline					
Week 3	LS Mean (SE)	1.09 (0.04)	0.05 (0.04)	1.05 (0.06)	<0.0001
	95% CI	(1.01, 1.18)	(-0.04, 0.13)	(0.94, 1.16)	
Week 6	LS Mean (SE)	1.17 (0.04)	0.09 (0.04)	1.09 (0.06)	<0.0001
	95% CI	(1.09, 1.25)	(0.01, 0.17)	(0.97, 1.20)	
%Reduction from Baseline					
Week 3	LS Mean (SE)	32.65 (1.25)	0.26 (1.27)	32.39 (1.79)	<0.0001
	95% CI	(30.18, 35.12)	(-2.25, 2.76)	(28.87, 35.91)	
Week 6	LS Mean (SE)	35.11 (1.26)	1.52 (1.27)	33.59 (1.78)	<0.0001
	95% CI	(32.64, 37.58)	(-0.98, 4.01)	(30.08, 37.11)	

Modified Intent to treat population (mITT) includes all randomized subjects with BBI evaluation at both baseline (visit 1) and Week 3 (visit 2).

Note: Reduction and percent reduction refers to change from pre to post-treatment.

ANOVA Model for Baseline (Pre-brushing): Result=Treatment + error.

ANOVA Model for Post-baseline: Outcome = Baseline Result + Treatment + error.

<sup>a</sup>Diff = Mean (SE) of the treatment difference (PTB+AirFlossPro+BreathRx minus MTB+StringFloss).

<sup>b</sup>p-value is based on a fixed effects ANOVA model F-test (Ho: All treatments are equal).

<sup>c</sup>There were 112 subjects analyzed at Week 6, SOR treatment group

At Week 6, the LS Mean (95% CI) reduction in MPI was 1.17 (1.09, 1.25) for SOR and 0.09 (0.01, 0.17) for MTF. Expressed as percent reduction from Baseline, the outcomes were 35.1% (32.6%, 37.6%) for SOR and 1.52% (-0.98%, 4.01%) for MTF.

**Modified Gingival Index.** A boxplot indicating the distribution of average MGI scores at Baseline, Week 3, and Week 6 is presented in Figure 4. The mean Baseline values were balanced for both treatment groups.

Table V provides a complete depiction of MGI analyses. The differences observed in MGI between products at both the Week 3 and Week 6 time points were statistically significant,  $p < 0.0001$ . At Week 3, the LS Mean (95% CI) reduction in MGI was 1.36 (1.30, 1.41) for SOR and 0.23 (0.17, 0.28) for MTF. Expressed as percent reduction from Baseline, these outcomes were 48.5% (46.6%, 50.5%) for SOR and 8.15% (6.14%, 10.2%) for MTF.

At Week 6, the LS Mean (95% CI) reduction in MGI was 1.43 (1.36, 1.49) for SOR and 0.30 (0.23, 0.36) for MTF. Expressed as percent reduction from Baseline, the outcomes were 51% (48.7%, 53.3%) for SOR and 10.5% (8.21%, 12.9%) for MTF.

**Gingival Bleeding Index.** A boxplot indicating the distribution of average GBI scores at Baseline, Week 3 and Week 6 is presented in Figure 5. The mean Baseline values were balanced for both treatment groups.

Table V provides a complete depiction of GBI analyses. For GBI,

the differences observed between products at both the Week 3 and Week 6 time points were statistically significant,  $p < 0.0001$ . At Week 3, the LS Mean (95% CI) reduction in GBI was 0.33 (0.31, 0.35) for SOR and 0.07 (0.05, 0.09) for MTF. Expressed as percent reduction

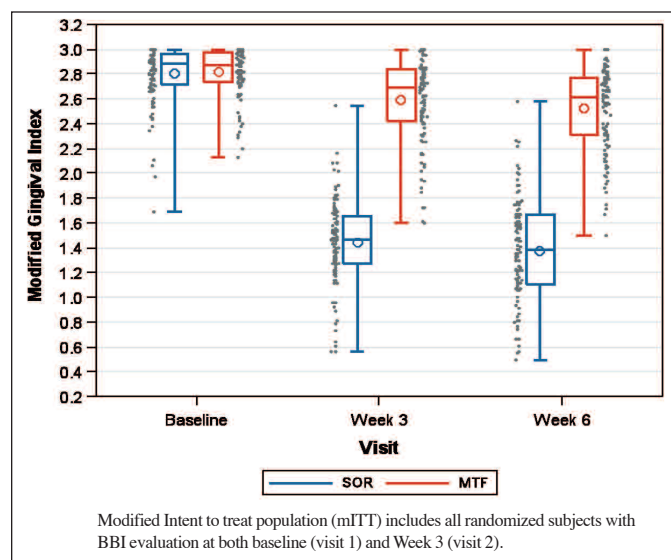


Figure 4. Distribution of outcomes, MGI, Baseline, Week 3, Week 6.

**Table V**  
Summary Analysis, Modified Gingival Index, and Gingival Bleeding Index

Variable	Statistic	Treatment		Difference <sup>a</sup>	p-value <sup>b</sup>
		SOR (N=113) <sup>c</sup>	MTF (N=110)		
<b>Modified Gingival Index</b>					
Baseline	LS Mean (SE)	2.80 (0.02)	2.82 (0.02)	-0.02 (0.03)	0.5621
	95% CI	(2.76, 2.84)	(2.78, 2.86)	(-0.07, 0.04)	
Reduction from Baseline					
Week 3	LS Mean (SE)	1.36 (0.03)	0.23 (0.03)	1.13 (0.04)	<0.0001
	95% CI	(1.30, 1.41)	(0.17, 0.28)	(1.05, 1.21)	
Week 6	LS Mean (SE)	1.43 (0.03)	0.30 (0.03)	1.13 (0.05)	<0.0001
	95% CI	(1.36, 1.49)	(0.23, 0.36)	(1.04, 1.22)	
%Reduction from Baseline					
Week 3	LS Mean (SE)	48.54 (1.01)	8.15 (1.02)	40.40 (1.43)	<0.0001
	95% CI	(46.56, 50.53)	(6.14, 10.15)	(37.57, 43.22)	
Week 6	LS Mean (SE)	50.99 (1.17)	10.54 (1.18)	40.46 (1.66)	<0.0001
	95% CI	(48.69, 53.30)	(8.21, 12.86)	(37.18, 43.73)	
<b>Gingival Bleeding Index</b>					
Baseline	LS Mean (SE)	0.44 (0.02)	0.44 (0.02)	-0.00 (0.02)	0.9351
	95% CI	(0.41, 0.47)	(0.41, 0.48)	(-0.05, 0.04)	
Reduction from Baseline					
Week 3	LS Mean (SE)	0.33 (0.01)	0.07 (0.01)	0.26 (0.01)	<0.0001
	95% CI	(0.31, 0.35)	(0.05, 0.09)	(0.24, 0.29)	
Week 6	LS Mean (SE)	0.35 (0.01)	0.09 (0.01)	0.27 (0.01)	<0.0001
	95% CI	(0.33, 0.37)	(0.07, 0.10)	(0.24, 0.29)	
%Reduction from Baseline					
Week 3	LS Mean (SE)	73.59 (2.25)	10.96 (2.28)	62.64 (3.20)	<0.0001
	95% CI	(69.17, 78.02)	(6.47, 15.44)	(56.33, 68.94)	
Week 6	LS Mean (SE)	78.33 (2.12)	16.15 (2.14)	62.18 (3.02)	<0.0001
	95% CI	(74.14, 82.51)	(11.93, 20.38)	(56.23, 68.12)	

Modified Intent to treat population (mITT) includes all randomized subjects with BBI evaluation at both baseline (visit 1) and Week 3 (visit 2).

Note: Reduction and percent reduction refers to change from pre to post-treatment.

ANOVA Model for Baseline (Pre-brushing): Result=Treatment + error.

ANOVA Model for Post-baseline: Outcome = Baseline Result + Treatment + error.

<sup>a</sup>Diff = Mean (SE) of the treatment difference (PTB+AirFlossPro+BreathRx minus MTB+StringFloss).

<sup>b</sup>p-value is based on a fixed effects ANOVA model F-test (Ho: All treatments are equal).

<sup>c</sup>There were 112 subjects analyzed at Week 6, SOR treatment group



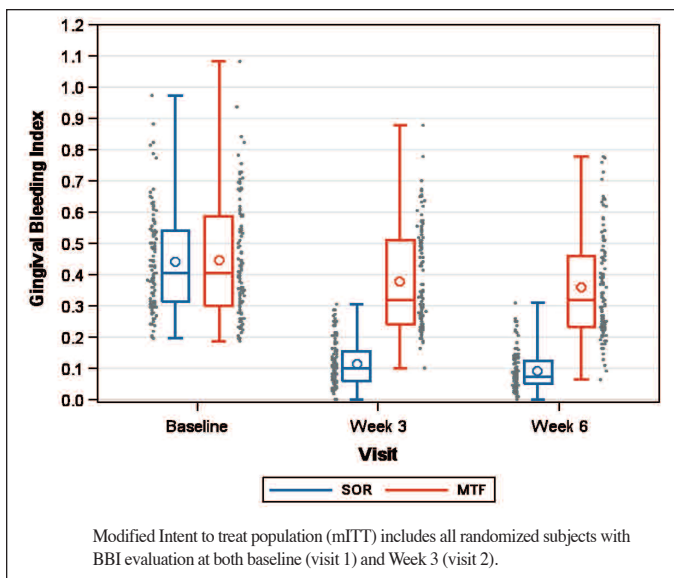


Figure 5. Distribution of outcomes, GBI, Baseline, Week 3, Week 6.

from Baseline, the outcomes were 73.6% (69.2%, 78.0%) for SOR and 11.0% (6.47%, 15.4%) for MTF.

At Week 6, the Overall LS Mean (95% CI) reduction in GBI was 0.35 (0.33, 0.37) for SOR and 0.09 (0.07, 0.10) for MTF. Expressed as percent reduction from Baseline, the outcomes were 78.3% (74.1%, 82.5%) for SOR and 16.2% (11.9%, 20.4%) for MTF.

### Safety

There were no adverse events reported in the study.

## Discussion and Conclusions

Within the limits and controls of this study, the outcomes indicate that the use of the powered regimen for home oral hygiene was statistically significantly superior to standard-of-care manual toothbrush plus floss regimen, in all clinical measures, at all time points, in a population of subjects with fixed orthodontic hardware. This includes the reduction of surface plaque on both bracketed and non-bracketed teeth, the reduction of inflamed gingival tissue, and the reduction in gingival bleeding.

The outcomes observed here are important for several reasons. First, it provides the practitioner with evidence from a randomized, controlled clinical trial setting that implementation of the regimen tested here has been demonstrated to be both safe and significantly more effective than the standard of care approach. This may be particularly important in an adolescent population, where compliance to the practitioner-prescribed home care regime can be a significant challenge over the course of orthodontic treatment.

Second, the more pronounced surface plaque removal observed in the powered regimen group may disrupt the feedback loop that elevates the risk of associated sequelae commonly observed during treatment as effects to periodontal health, and the development of white spot or carious lesions. That is to say, where fixed hardware harbor food and debris, promoting biofilm proliferation of a more disease-associated character, reducing the burden of surface plaque through powered brushing and interdental cleaning may help to minimize these effects. As these changes to the oral environment have been clinically established as risk factors,<sup>24</sup> and which pervasively per-

sist in spite of myriad management efforts,<sup>25</sup> hygiene solutions aimed at minimizing plaque proliferation and an ensuing transition to microbiological dysbiosis, may stand to have a salient and sustainable impact on a patient's oral health over the course of orthodontic treatment. The growing body of evidence that associates an inflammatory oral environment with other inflammation-associated human diseases<sup>26-28</sup> underscores the importance of practitioner-driven education, and greater patient-centric care, aimed at the minimizing changes to a patient's gingival status during orthodontic treatment.

It is acknowledged that this study was limited in scope to only those metrics that can be clinically observed and quantified within a reasonably finite time period. Additional studies to measure the effects upstream of clinical expression would be interesting to evaluate, thus to adequately understand the mechanisms that are affected following introduction of plaque control via the powered regimen. Are the clinical changes in surface plaque, gingivitis, and bleeding reflective of a change of character of the microbial milieu and the environmental pH, for example? Further, does optimized plaque control help minimize the incidence and severity of white spot and/or carious lesions over the course of orthodontic treatment? As also concluded in a systematic review regarding fluoride use and enamel demineralization during orthodontic treatment,<sup>29</sup> longer-term, controlled studies, including these endpoints, would be needed to answer these important questions.

The partnership between the practitioner and the patient is to help ensure that the aesthetic and functional benefits of orthodontic treatment are not at the cost of a patient's oral health. The results of the powered home hygiene regimen tested here provide evidence that there are measurable advantages that are both quickly evident (within three weeks) and sustained (at Week 6) in plaque biofilm removal and gingivitis reduction, over a standard of care approach. These outcomes may facilitate clinical decisions that are aimed at improving oral health management over the course of a patient's orthodontic treatment.

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**Conflict of Interest:** K. Nammi, E. M. Starke, S-S Ou, M. Ward, and W. Jenkins are employed by Philips Oral Healthcare. J. Milleman and K. Milleman are employed by Salus Research.

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