

# A Comparison of the Effect of Two Power Toothbrushes on the Reduction of Gingival Inflammation and Supragingival Plaque

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## Abstract

- **Objectives:** To compare the effect of the Philips Sonicare DiamondClean Smart and Oral-B Genius 8000 powered toothbrushes on gingivitis, gingival bleeding, and supragingival plaque reduction following 42 days of home use.
- **Methods:** This was a randomized, parallel, examiner-blinded, prospective clinical trial with two treatment groups. Eligible participants were generally healthy volunteers who were manual toothbrush users, non-flossers, 18–65 years of age. The subject panel included non-smokers with  $\geq 50$  sites of gingival bleeding according to the Gingival Bleeding Index (GBI), and a supragingival plaque score of  $\geq 1.8$  per Modified Plaque Index (MPI) at 3–6 hours following last tooth brushing encounter. Eligible subjects were randomized to use either a Philips Sonicare DiamondClean Smart with Premium Plaque Control brush head (DCS) or an Oral-B Genius 8000 with FlossAction brush head (OBG) for home use. Each toothbrush was used twice daily for two minutes. All subjects used a standardized fluoride-containing dentifrice. All other oral hygiene measures were prohibited. Subjects returned at Day 14 for an interim compliance and safety assessment, and at Day 42 for the final safety and efficacy assessments.
- **Results:** Of 222 enrolled and eligible subjects, 219 completed (112 in the SDC group, 107 in the OBG group) the study. The least squares (LS) mean and 95% confidence interval (CI) estimates for gingivitis reduction and percent reduction per Modified Gingival Index (MGI) following 42 days of product home use were 1.38 (1.30, 1.46) and 51.32% (48.45%, 54.19%) for DCS, and 0.53 (0.45, 0.61) and 20.07% (17.14%, 23.00%) for OBG. The differences, expressed as either reduction or percent reduction, were statistically significant between the two groups,  $p < 0.001$ . Statistically significant differences were also observed between products at Day 42 for the gingival bleeding and supragingival plaque reduction endpoints,  $p < 0.001$ . There were two reported adverse events.
- **Conclusions:** The Philips Sonicare DiamondClean Smart powered toothbrush reduced gingival inflammation, gingival bleeding, and supragingival plaque significantly more than the Oral-B Genius 8000 powered toothbrush following a 42-day home-use period. Both products were safe for use.

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## Introduction

Periodontal disease has been shown to be significantly and independently associated with other non-communicable chronic diseases.<sup>1</sup> These include, for example, diabetes,<sup>2,4</sup> rheumatoid arthritis,<sup>5</sup> kidney disease,<sup>6,8</sup> and atherosclerotic cardiovascular disease.<sup>9,12</sup>

The overall impact of non-communicable diseases (NCDs) on health outcomes is significant. In June 2018, the World Health Organization reported on the effects of NCDs on the global population, attributing 41 million deaths each year to these diseases; of which 15 million are premature, occurring between the ages of 30 and 69 years.<sup>13</sup>

That periodontal disease is an associated condition with other NCDs, and is also observed to exert inflammatory stress on tissues, as do other NCDs, preventing and treating periodontal disease is an important part of total patient care.

Fundamental to prevention and treatment is the promotion and maintenance of a health-associated biofilm,<sup>14,15</sup> where the oral microbial ecology is in equilibrium with the inflammatory systems of the host. The speciation and character of the biofilm has been observed to shift in its transition from health to disease.<sup>16,17</sup> This can initiate an

inflammatory response, with the clinical expression of inflammation exhibited as edema, discoloration, and bleeding of oral gingivae. If left untreated, local inflammation can lead to the destruction of the periodontal tissues and osseous structures of teeth. For many of the above-cited NCDs, the common implicating factor between periodontal and other non-communicable disease states is characterized by inflammation, with changes in pro-inflammatory pathways observed to occur.<sup>18–20</sup>

It is with this understanding that the task of daily plaque management becomes more significant than simply “cleaning teeth.” Working with patients to improve and maintain optimal oral hygiene is an imperative of clinical practice, particularly for patients presenting with risk factors for periodontal disease.<sup>21</sup> There are many available tools, medicaments, and techniques intended to aid in this regard. Transitioning patients from manual to powered tooth brushing, for example, can be a frequently recommended option. Powered toothbrushes have features that promote compliance and ease of use. Additionally, these products have motors that initiate brush head motion which far exceed what can be achieved manually.

That said, the landscape of powered tooth brushing options is vast, and to put all available technologies in the same category may not result in the desired benefit for patients when a transition from manual to powered tooth brushing is made. The current clinical trial was conducted to evaluate two marketed powered toothbrushes in order to directly compare their effects on gingivitis and plaque in a population of habitual manual toothbrush users who exhibit at least moderate levels of gingivitis.

**Materials and Methods**

**Study Design and Objectives**

This was a prospective, examiner-blinded, randomized, single-center, two-arm, parallel study with three study visits. It was reviewed and approved by the IntegReview Institutional Review Board. The study was designed to compare the safety and effectiveness of the Philips Sonicare DiamondClean Smart (DCS) with Premium Plaque Control brush head (Philips Oral Healthcare, Bothell, WA, USA) and the Oral-B Genius 8000 (OBG) with FlossAction brush head (Procter & Gamble Co., Cincinnati, OH, USA). Both power toothbrushes were used for 2 minutes, twice daily, in their respective “Clean” modes in a “non-connected” state, meaning that none of the App features were active. All subjects used Crest Cool Mint Gel dentifrice (Procter & Gamble Company, Cincinnati, OH, USA).

The objectives of the study included comparisons of safety, and effects on reducing gingivitis (inflammation and bleeding) and supragingival plaque following 42 days of home use of the assigned product. The primary endpoint was designated as the comparison of effects on gingival inflammation at Day 42. In addition, an analysis comparing the proportion of subjects with reduced gingival inflammation, reduced gingival bleeding, and reduced plaque, with pre-defined cut-off reduction values, was planned. Figure 1 provides a study visit schematic.

**Efficacy and Safety Measurements**

Efficacy was evaluated by two examiners trained and calibrated in the visual assessment of plaque and gingivitis per published visual

Visit 1 Screening/Baseline	
<b>Day 0</b> (3-6 hours plaque accumulation) ↓	Informed Consent Medical and Dental History Intraoral Exam MGI, GBI, MPI Enroll Randomization Dispense and Instruct on Product Use Supervised Product Use Subject Safety Interview (AEs) post-brushing Dispense Home Diary
Visit 2	
<b>Day 14</b> ↓	Safety & Compliance Interview Product Instruction and Diary Review Supervised Product Use Subject Safety Interview (AEs) post-brushing
Visit 3	
<b>Day 42</b> (3-6 hours plaque accumulation)	Safety & Compliance Interview Intraoral Exam MGI, GBI, MPI Collect Study Products Dismiss from Study

Figure 1. Study visits and procedures.

clinical metrics. In this study, the following measurement methods were used: Lobene and Soparker Modified Plaque Index (MPI),<sup>22,23</sup> the Modified Gingival Index<sup>24</sup> (MGI), and the Gingival Bleeding Index (GBI).<sup>25</sup> Table I provides the scale and scoring classifications of each index.

Safety was assessed by oral tissue examination and by subject report on a home diary record.

**Study Subjects**

Eligible subjects were generally healthy manual toothbrush users between the ages of 18 and 65 years, non-smokers, non-flossers, who were able to provide informed consent and follow the planned study

**Table I**  
Scoring Methodology for Efficacy Metrics: Plaque, Gingival Inflammation and Gingival Bleeding

Lobene and Soparker Modified Plaque Index, Six Sites <sup>a</sup> per Tooth, Excluding 3 <sup>rd</sup> Molars					
0	1	2	3	4	5
No plaque	Separate flecks of plaque at the cervical margin of the tooth	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	Plaque covering 2/3 or more of the crown of the tooth
Modified Gingival Index, Lobene, Six Sites <sup>a</sup> per Tooth, Excluding 3 <sup>rd</sup> Molars					
0	1	2	3	4	N/A
Absence of inflammation	Mild inflammation, slight change in color, little change in texture of the marginal or papillary gingival unit	Mild inflammation; slight change in color, little change in texture of the marginal or papillary gingival unit	Moderate inflammation; glazing, redness, edema and/or hypertrophy of margin or papillary unit	Severe inflammation; marked redness, edema and/or hypertrophy or marginal or papillary gingival unit, spontaneous bleeding, congestion or ulceration	
Gingival Bleeding Index, van der Weijden, Six Sites <sup>a</sup> per Tooth, Excluding 3 <sup>rd</sup> Molars					
0	1	2	3	N/A	N/A
No bleeding	Bleeding on gently probing	Bleeding appears immediately upon gently probing	Spontaneous bleeding which is present prior to probing		

a: Sites include: distobuccal, buccal, mesiobuccal, distolingual, lingual, mesiolingual

procedures. The study population included subjects exhibiting moderate gingivitis, defined as  $\geq 50$  sites of bleeding per GBI, and a plaque score of  $\geq 1.8$  per MPI, assessed at 3–6 hours following the subject's last oral hygiene procedure. Subjects with any of the following were excluded from participation: rampant oral decay, significant gingival recession, evidence of periodontitis or heavy deposits of calculus, pregnancy, xerostomia, insulin-dependent diabetes, the presence of orthodontic hardware or current use of prescription-dose anti-coagulant or anti-inflammatory medications. Any dental student or dental professional, clinical research site employee or their relatives were also not eligible to participate.

In the event that a subject required dental or medical care in a context that could affect a safety or efficacy endpoint of the study, or which put the subject at greater risk, the participant was removed from study at the discretion of the study investigator.

#### **Randomization and Controls to Minimize Bias**

All subjects provided informed consent prior to assessment of eligibility. Those who met the eligibility criteria were randomized to receive either a DCS or an OBG powered toothbrush for home use. Randomization was balanced for gender, such that approximately equal numbers of males and females were represented in each treatment group. Study personnel who performed randomization or product dispense and instruction, did not perform any activities related to study endpoints.

The examiners performing all study efficacy evaluations (MGI, GBI, MPI) were blinded to the assigned powered toothbrush allocation for each subject. Scoring proficiency and accuracy of each examiner (intra-calibration) was previously established. The examiner of a given index performed scoring of that index for all subjects, at all visits, eliminating potential bias due to inter-examiner scoring differences.

For study subjects, the use of any other oral hygiene device or medicament was prohibited during the study period.

#### **Data Capture**

Study data were captured on a secure, web-based data system with programmed logic and edit-checks that are compliant to the standards of 21 CFR Part 11. To appropriately maintain the integrity of the data, access to the system was limited by log-in credentials that matched the study role of the user (*e.g.*, blinded or un-blinded). Study data were monitored by sponsor staff or designee to ensure accuracy of recording and reporting.

#### **Statistical Methods**

**Sample Size Determination.** A prior study<sup>26</sup> was conducted in which power toothbrushes from each of these product platforms (Sonicare and Oral-B) were compared. The study included a comparable study population, as well as similar endpoint and timepoint assessments. The outcomes of that study, at Day 42, showed that the Sonicare powered toothbrush was superior to the Oral-B powered toothbrush, with a difference in MGI reduction of 0.48 and an MGI percent reduction difference of 19%, as well as a difference in MPI reduction of 0.50 and an MPI percent reduction difference of 17%.

In the current study, a clinically significant difference in MGI reduction greater than 0.2, with a common standard deviation (SD)

of 0.45 and a percent reduction of 8% with a common SD of 18%, was deemed sufficient to differentiate DCS and OBG. Using these assumptions, a minimum sample size of 108 subjects in each group would allow for approximately 90% power to detect a difference between the two products, using a two-sided t-test with a 0.05 significance level.

With regard to the secondary endpoints (GBI and MPI), this sample size would also allow for more than 85% power (0.05 significance level) to detect a difference in GBI reduction of 0.10 (common SD = 0.3) or 13% (common SD = 30%), and more than 90% power (0.05 significance level) to detect a difference in MPI reduction of 0.2 (common SD = 0.45) or 8% (common SD = 18%).

**General Considerations.** The primary efficacy analysis was performed including all randomized subjects with Baseline and Day 42 gingivitis evaluations (modified intent to treat, mITT). Subjects were analyzed according to the randomized treatment assignment. The analysis of safety included all randomized subjects.

All variables were summarized by descriptive statistics. Continuous variables were summarized using the number of non-missing observations, mean, median, standard deviation (SD), minimum, and maximum. Categorical variables were summarized using the frequency count and the percentage of subjects in each category. All analyses were conducted using SAS<sup>®</sup> software (SAS, Cary, NC, USA).

**Efficacy Endpoints.** The efficacy indices, MGI, GBI, and MPI, at each tooth site were scored using the scoring methodology described in Table I. A standardized data collection form was used to capture these data at each study visit. The efficacy endpoints were the reduction from baseline, calculated as the Baseline score minus the post-Baseline score; and percent reduction from Baseline, calculated as the reduction in score divided by the Baseline score times 100. For each subject, these two endpoints were summarized for the whole mouth (Overall) and by region of the mouth (*i.e.*, anterior, posterior, interproximal, and posterior interproximal). For each index, analyses were performed separately for each endpoint and for each region.

**Primary Efficacy Analysis.** The primary efficacy measure for this study was the reduction in gingivitis score from Baseline to Day 42. The efficacy analysis included all randomized subjects with an MGI score at Baseline and Day 42. Comparisons between the two treatment groups for reduction and percent reduction from Baseline were performed using an ANOVA model with the Baseline score as a covariate.

Least square (LS) mean, standard error (SE) of the mean, and two-sided 95% confidence intervals (CI) were presented by treatment group. Comparisons between treatment groups were performed using an F-test.

**Secondary Efficacy Analysis.** The secondary efficacy measures of the study were the reduction in gingival bleeding (GBI) and plaque (MPI) from Baseline to Day 42. The analysis evaluating these endpoints used a similar method as described above for the primary endpoint.

In addition, a proportion analysis was completed for each efficacy endpoint at Day 42 at prescribed cut-off values. The 95% confidence intervals of the proportion analyses were also presented. Furthermore, comparisons of the separate proportions between the two treatment groups were performed using a Chi-square or Fisher's exact test, as

appropriate. The cut-off values of observed reduction of MGI, GBI, or MPI were as follows:

- Reduction from Baseline to Day 42  $\geq$  0.1
- Reduction from Baseline to Day 42  $\geq$  0.2
- Reduction from Baseline to Day 42  $\geq$  0.3
- Percent reduction from Baseline to Day 42  $\geq$  10%
- Percent reduction from Baseline to Day 42  $\geq$  15%
- Percent reduction from Baseline to Day 42  $\geq$  20%

**Safety Analysis**

Adverse events and oral examination abnormalities were presented in data listings.

**Results**

**Demographics**

Two-hundred twenty-eight subjects provided informed consent and were screened for the study. Of these, 222 were enrolled and randomized, with 219 subjects completing the study. Of the three subjects who did not complete the study, two were lost to follow-up and one withdrew from the study. Table II provides a depiction of subject enrollment and completion.

**Table II**  
Subject Enrollment and Completion

Subjects Screened N= 228				
Screen Failures N=6	Enrolled N=222			
	Not Randomized N=0	Randomized N=222		
		DCS N=113		OBG N=109
		C <sup>a</sup> N=112	D <sup>b</sup> N=1	C N=107
				D N=2

a: completed  
b: discontinued

The mean (SD) age of subjects was 40.3 (12.4) years. There were 175 (79.9%) female participants, and 44 (20.1%) male participants

**Table III**

Modified Gingival Index, Reduction, Percent Reduction and Proportion Analysis, Overall, at Baseline, and Day 42

Variable	Statistic	DCS (N=112)	OBG (N=107)	Difference	p-value
Baseline (Day 0)	LS Mean (SE)	2.72 (0.02)	2.69 (0.03)	0.02 (0.04)	0.5172
	95% CI	(2.67, 2.77)	(2.64, 2.74)	(-0.05, 0.09)	
Day 42	LS Mean (SE)	1.33 (0.04)	2.18 (0.04)	-0.85 (0.06)	<0.0001
	95% CI	(1.25, 1.40)	(2.10, 2.25)	(-0.96, -0.74)	
Reduction from Baseline					
Day 42	LS Mean (SE)	1.28 (0.04)	0.53 (0.04)	0.85 (0.06)	<0.0001
	95% CI	(1.30, 1.46)	(0.45, 0.61)	(0.74, 0.96)	
Percent Reduction from Baseline					
Day 42	LS Mean (SE)	51.32 (1.46)	20.07 (1.49)	31.25 (2.08)	<0.0001
	95% CI	(48.45, 54.19)	(17.14, 23.00)	(27.14, 35.35)	
Proportion Analysis: Reduction from Baseline at Day 42					
RFB <sup>a</sup> >= 0.3	n (Prop.)	111 (99.1%)	78 (72.9%)		<0.001
	95% CI	(95.1%, 100.0%)	(63.4%, 81.0%)		
Proportion Analysis: Percent Reduction from Baseline at Day 42					
PRFB <sup>b</sup> >= 20%	n (Prop.)	106 (94.6%)	50 (46.7%)		<0.001
	95% CI	(88.7%, 98.0%)	(37.0%, 56.6%)		

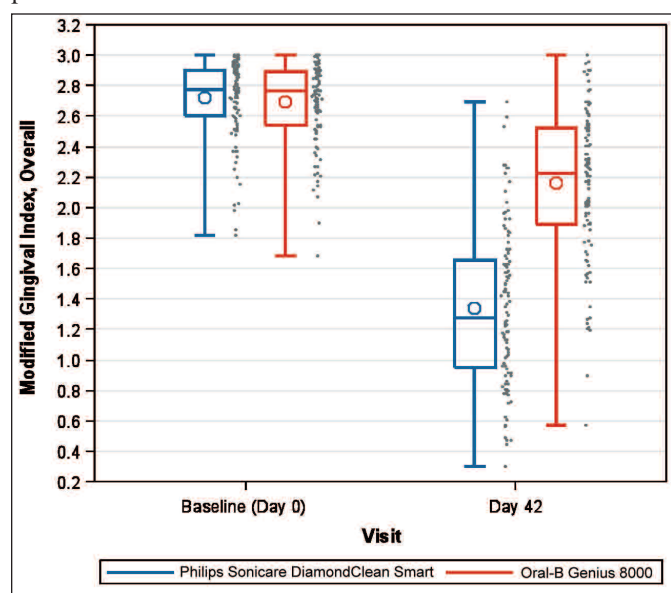
a: Reduction from Baseline  
b: Percent reduction from Baseline

who completed the study. No significant differences were observed in the distribution of age and gender between the two treatment groups.

**Primary Efficacy Results**

**Modified Gingival Index.** The distribution, mean, median, and 25th-75th percentile of observed values for MGI are presented in a boxplot in Figure 2. The analyses for MGI outcomes at Baseline and Day 42, including reduction and percent reduction, as well as the proportion analysis, are presented in Table III.

For the primary efficacy endpoint, reduction in MGI at Day 42, the Overall LS mean reduction, and percent reduction (95% CI) was 1.38 (1.30, 1.46) and 51.32% (48.45%, 54.19%) for DCS, and 0.53 (0.45, 0.61) and 20.07% (17.14%, 23.00%) for OBG. Both reduction and percent reduction comparisons were statistically significant,  $p < 0.001$ .



**Figure 2.** Boxplot of Modified Gingival Index, overall, by treatment group at Baseline and Day 42. Note: Each dot represents a single observation.

For brevity, only the highest cut-off value (expressed as percent of subjects and 95% CI) in the proportion analysis is presented here, with 99.1% (95.1%, 100.0%) DCS subjects improving by a margin of at least 0.3. For OBG, the corresponding value was 72.9% (63.4%, 81.0%) subjects. The difference between outcomes was statistically significant,  $p < 0.001$ .

**Secondary Efficacy Results**

**Gingival Bleeding Index.** The distribution of observed GBI outcomes is presented in a boxplot in Figure 3. The analysis for GBI outcomes at Baseline and Day 42, including reduction and percent reduction, as well as the proportion analysis, are presented in Table IV.

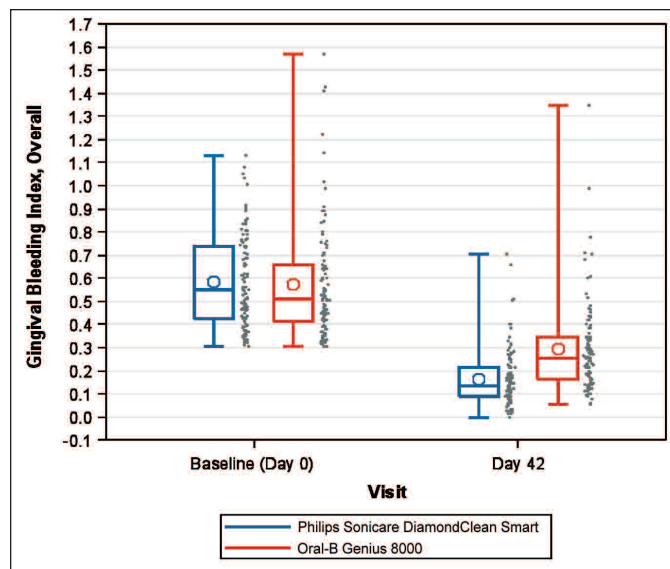
For GBI, the overall LS mean reduction and percent reduction (95% CI) at Day 42 were 0.42 (0.39, 0.44) and 72.78% (68.95%, 76.60%) for DCS, and 0.29 (0.26, 0.31) and 48.86% (44.95%, 52.78%) for OBG. Both reduction and percent reduction comparisons were statistically significant,  $p < 0.001$ .

For the proportion analysis, 74.1% (65.0%, 81.9%) DCS subjects improved GBI score by a margin of at least 0.3. The corresponding proportion for OBG subjects was 38.3% (29.1%, 48.2%). The difference between outcomes was statistically significant,  $p < 0.001$ .

**Modified Plaque Index.** The distribution of observed MPI outcomes is presented in a boxplot in Figure 4. The analysis for MPI outcomes at Baseline and Day 42, including reduction and percent reduction, as well as the proportion analysis, are presented in Table V.

For MPI, the overall LS mean reduction and percent reduction (95% CI) at Day 42 were 0.67 (0.61, 0.73) and 22.20% (20.08%, 24.31%) for DCS, and 0.32 (0.25, 0.38) and 10.56% (8.40%, 12.73%) for OBG. Both reduction and percent reduction comparisons were statistically significant,  $p < 0.001$ .

For the proportion analysis, 85.7% (77.8%, 91.6%) of DCS subjects improved MPI score by a margin of at least 0.3. The corresponding value for OBG subjects was 51.4% (41.5%, 61.2%). The difference between outcomes was statistically significant,  $p < 0.001$ .



**Figure 3.** Boxplot of Gingival Bleeding Index, overall, by treatment group at Baseline and Day 42. Note: Each dot represents a single observation.

**Safety**

There were two adverse events reported. The first, gingival abrasion, was mild and assessed as possibly related to the study product. The second event, patient reported bleeding gums, was moderate and assessed as related to the study product. Both events occurred in the OBG treatment group and both were resolved upon conclusion of the study.

**Discussion and Conclusions**

Within the limits and controls of this study, the comparison of the two devices on the common hallmarks of oral health indicate that use of the Philips Sonicare DiamondClean Smart powered toothbrush was superior to use of the Oral-B Genius 8000 powered toothbrush in its ability to reduce gingival inflammation, gingival bleeding, and surface plaque after a home use period of 42 days. In addition, with only two adverse events (one mild and one moderate) reported

**Table IV**

Gingival Bleeding Index, Reduction, Percent Reduction and Proportion Analysis, Overall, at Baseline and Day 42

Variable	Statistic	DCS (N=112)	OBG (N=107)	Difference	p-value
Baseline (Day 0)	LS Mean (SE)	0.59 (0.02)	0.58 (0.02)	0.01 (0.03)	0.7319
	95% CI	(0.54, 0.63)	(0.53, 0.62)	(-0.05, 0.07)	
Day 42	LS Mean (SE)	0.16 (0.01)	0.30 (0.01)	-0.13 (0.02)	<0.0001
	95% CI	(0.14, 0.19)	(0.27, 0.32)	(-0.17, -0.10)	
Reduction from Baseline					
Day 42	LS Mean (SE)	0.42 (0.01)	0.29 (0.01)	0.13 (0.02)	<0.0001
	95% CI	(0.39, 0.44)	(0.26, 0.31)	(0.10, 0.17)	
Percent Reduction from Baseline					
Day 42	LS Mean (SE)	72.78 (1.94)	48.86 (1.99)	23.91 (2.78)	<0.0001
	95% CI	(68.95, 76.60)	(44.95, 52.78)	(18.44, 29.38)	
Proportion analysis: Reduction from Baseline at Day 42					
RFB <sup>a</sup> >= 0.3	n (Prop.)	83 (74.1%)	41 (38.3%)		<0.0001
	95% CI	(65.0%, 81.9%)	(29.1%, 48.2%)		
Proportion analysis: Percent Reduction from Baseline at Day 42					
PRFB <sup>b</sup> >= 20%	n (Prop.)	111 (99.1%)	97 (90.7%)		0.0042
	95% CI	(95.1%, 100.0%)	(83.5%, 95.4%)		

a: Reduction from Baseline

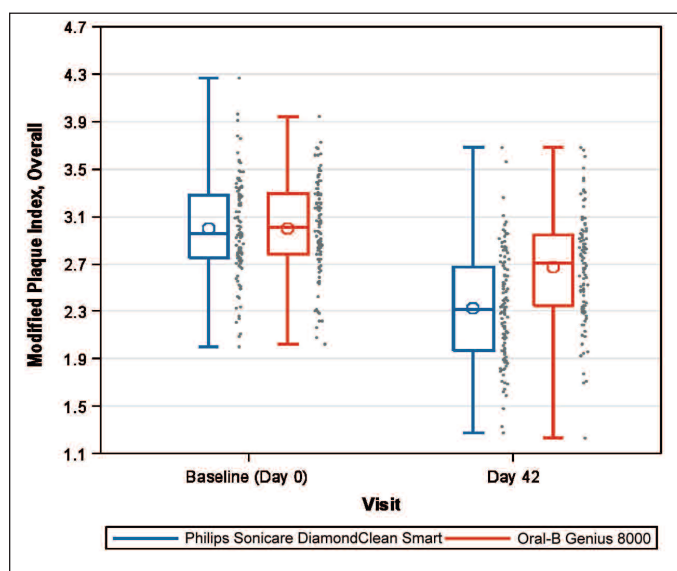
b: Percent reduction from Baseline

**Table V**  
Modified Plaque Index, Percent Reduction and Proportion Analysis, Overall, at Baseline, Day 14, Day 42

Variable	Statistic	DCS (N=112)	OBG (N=107)	Difference	p-value
Baseline (Day 0)	LS Mean (SE)	3.00 (0.04)	3.00 (0.04)	0.00 (0.05)	0.9965
	95% CI	(2.92, 3.07)	(2.92, 3.07)	(-0.11, 0.11)	
Day 42	LS Mean (SE)	2.33 (0.03)	2.68 (0.03)	-0.35 (0.05)	<0.0001
	95% CI	(2.26, 2.39)	(2.62, 2.74)	(-0.44, -0.26)	
Reduction from Baseline					
Day 42	LS Mean (SE)	0.67 (0.03)	0.32 (0.03)	0.35 (0.05)	<0.0001
	95% CI	(0.61, 0.73)	(0.25, 0.38)	(0.26, 0.44)	
Percent Reduction from Baseline					
Day 42	LS Mean (SE)	22.20 (1.07)	10.56 (1.10)	11.63 (1.54)	<0.0001
	95% CI	(20.08, 24.31)	(8.40, 12.73)	(8.61, 14.66)	
Proportion analysis: Reduction from Baseline at Day 42					
RFB <sup>a</sup> >= 0.3	n (Prop.)	96 (85.7%)	55 (51.4%)		<0.0001
	95% CI	(77.8%, 91.6%)	(41.5%, 61.2%)		
Proportion analysis: Percent Reduction from Baseline at Day 42					
PRFB <sup>b</sup> >= 20%	n (Prop.)	62 (55.4%)	16 (15.0%)		<0.0001
	95% CI	(45.7%, 64.8%)	(8.8%, 23.1%)		

a: Reduction from Baseline

b: Percent reduction from Baseline



**Figure 4.** Boxplot of Modified Plaque Index, Overall, by Treatment Group at Baseline and Day 42. Note: Each dot represents a single observation.

from a population of 219 subjects, both products are concluded as safe for daily use.

In addition to observed reductions in the clinical endpoints, the proportion analysis also was indicative of a consistent trend, with the DCS powered toothbrush exerting more pronounced effects compared to OBG. For all clinical measures evaluated here, the percent of subjects with reductions greater than 0.3 was statistically significantly higher for DCS compared to OBG.

A clinical recommendation to transition a patient from manual to powered tooth brushing is often done with the intent that such a transition will aid patients in improving efforts to remove plaque. In doing so, the clinical expression of gingivitis is also expected to improve. Indeed, there are a number of studies that support this perspective, reporting that powered tooth brushing is more effective than manual tooth brushing in reducing plaque and gingivitis.<sup>27-30</sup> Overall, the rationale is that improved plaque control through compliance,

ease of use, and powered brush head motion features on these devices help to establish and maintain a more health-associated biofilm, thus reducing the inflammatory response in the host.

In the current study, all clinical markers improved for each powered toothbrush following the six-week home use period. As the eligibility profile included habitual manual toothbrush users, it is reasonable to conclude that these outcomes continue to support the view that powered tooth brushing can be more effective than manual brushing. That said, among the two products evaluated here, there appears to be an incremental benefit to users of the DCS product, where high-frequency, high-amplitude brush head movement and a brushing procedure that targets the gumline was significantly better at improving all clinical measures.

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