A Comparison of the Effects of a Powered and Manual Toothbrush on Gingivitis and Plaque: A Randomized Parallel Clinical Trial

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Abstract

- Objective: To compare the effect of a powered and a manual toothbrush on gingivitis and plaque following two and four weeks of home use.
- Methods: This was a randomized, parallel-design, single-blind clinical trial. Eligible participants were generally healthy non-smoking manual toothbrush users aged 18–65 years, with a plaque score of ≥ 1.8 per Lobene and Soparkar Modified Plaque Index (MPI) following a 3–6 hour plaque accumulation period, and mild to moderate gingivitis defined as a Gingival Bleeding Index (GBI) ≥ 1 on at least 20 sites. Subjects with advanced periodontal disease, xerostomia, excessive gingival recession, uncontrolled diabetes, and heavy deposits of calculus or rampant decay were excluded. Enrolled participants were randomly dispensed either a Philips Sonicare powered toothbrush used with the InterCare brush head (PTB) or an American Dental Association (ADA) reference manual toothbrush (MTB). Efficacy and safety variables were assessed at Baseline, and at two and four weeks following twice-daily product home use. The primary endpoint of the study was reduction of gingivitis per the Modified Gingival Index (MGI) after four weeks of home use.
- Results: All 148 randomized subjects (74 per group) completed the study. A statistically significant difference in MGI reduction was observed between the two study groups (p < 0.001). The least square (LS) mean and standard error reduction from Baseline was 0.72 (0.04) for the PTB group compared to 0.09 (0.04) for the MTB group. Expressed as percent reduction from Baseline, the LS mean values were 35.77% (2.19%) and 4.22% (2.19%) for PTB and MTB, respectively. Statistically significant differences were also observed for MGI reduction at Week 2, as well as for MPI and GBI reduction at Weeks 2 and 4.
- Conclusion: The powered toothbrush was statistically significantly superior to a manual toothbrush in reducing gingival inflammation, gingival bleeding, and plaque following two and four weeks of home use.

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Introduction

Regular mechanical removal of the biofilm that coats tooth surfaces is crucial to preserve and sustain oral health.¹ The simple task of brushing away biofilm helps prevent caries,^{2,3} as well as inflammation⁴ in the adjacent gingival tissues. The effect of mechanical cleaning disrupts the ability of the bacteria that comprise dental plaque to adhere and organize into a biofilm. This biofilm enables synergistic network associations between bacteria, the genes they express, and their resultant byproducts.⁵ The absence of regular mechanical plaque removal can potentiate a dysbiotic and virulent oral biofilm environment.⁶⁷ Indeed, the clinical expression of diseased oral tissue, such as in periodontitis, has a correspondingly different community microbial profile than that of clinically healthy tissue^{8,9}

In 2010, de Oliviera, *et al.*¹⁰ published a study in which it was shown that poor oral hygiene (measured by frequency of tooth brushing of subjects) was observed to associate with an increased risk of cardio-vascular disease. This is one of several findings that underscore the potential importance of daily mechanical plaque removal. Not only does it have an effect on local tissues, oral health status may associate more broadly with other co-morbidities.

For example, the presence of periodontal disease has been shown to be independently and significantly associated with the presence or exacerbation of other non-communicable chronic diseases. These include: Type II diabetes,¹¹ chronic kidney disease,¹² rheumatoid arthritis,¹³ and chronic obstructive pulmonary disease.¹⁴ From this perspective, the simple task of regular mechanical plaque removal shifts, underscoring the value of educating patients on the importance of their daily oral hygiene techniques and habits.

There have been many innovations in the oral health space aimed to assist patients to improve the quality of their daily oral hygiene. Powered tooth brushing, for example, has been shown to be more effective than manual tooth brushing at removing plaque and reducing gingival inflammation^{15,18} Generally speaking, powered devices are designed to improve each brushing encounter with mechanical and digital features that reduce the opportunities for user error, commonly observed to diminish the quality and effectiveness of manual brushing.

That said, not all powered toothbrushes are equally capable of doing so, and it is only following clinical validation that a recommendation to adopt a powered over a manual tooth brushing regimen should be considered. Thus, the current study was conducted to evaluate the safety and efficacy profile of a Philips Sonicare powered toothbrush with the InterCare brush head, compared to a standardof-care manual toothbrush control. The study endpoints included surface plaque removal and the reduction in the symptomatic expression of gingivitis; soft tissue edema and bleeding.

Materials and Methods

Study Design and Objectives

This was a prospective, randomized, parallel, single-blind clinical trial conducted in generally healthy volunteers. The study was reviewed and approved by an accredited Institutional Review Board (US IRB, OHRP-IRB00007024). Eligible subjects were randomized in a 1:1 allocation to one of two oral hygiene treatment groups: power tooth brushing (PTB) in Clean mode with the Philips Sonicare Flexcare toothbrush using the standard size InterCare brush head (Philips, Bothell, WA, USA), or an ADA reference manual toothbrush (MTB), used per subject's usual routine. All products were used with a standard fluoride-containing dentifrice, twice daily. After enrollment, subjects were asked to return following two weeks and four weeks of product use. At each study visit, subjects were required to present with 3–6 hours of plaque accumulation. Figure 1 provides a flow diagram of study visits and the procedures at each visit.

Visit 1: Day 0	Visit 2: Week 2	Visit 3: Week 4
Informed Consent	Intraoral Exam	Intraoral Exam
Medical/Dental History	MGI	MGI
Intraoral Exam	GBI	GBI
MGI	MPI	MPI
GBI	Review Compliance Diary	Review Compliance Diar
MPI	Safety Monitoring	Safety Monitoring
Randomization		
Dispense Products		
Compliance Diary		

Figure 1. Study procedures and timelines.

The primary objective of the study was to compare the effect of use of the powered toothbrush to the ADA reference manual toothbrush on the reduction of gingivitis, as measured by the Modified Gingival Index (MGI), following a four-week home use period.

Secondary objectives included comparisons of reduction in MGI following two weeks of use, and the reduction of surface plaque and gingival bleeding following two and four weeks of product use, as well as a characterization of the safety of the test products.

Efficacy and Safety Measurements

There were three efficacy endpoint measures in this study. These included the Modified Gingival Index,¹⁹ the Gingival Bleeding Index (GBI),²⁰ and the Lobene and Soparkar Modified Plaque Index (MPI).^{21,22} Table I provides a depiction of the scoring methodology for each index. In order to minimize bias, the study examiners were blinded to the treatment assignment of subjects. A single assigned examiner performed the measurement of a given index for all subjects, for all visits, thus eliminating any potential variability due to inter-examiner scoring differences. Intra-calibration of examiner scoring accuracy was previously documented as above acceptability thresholds.

Safety measures were captured by subject diary report of adverse events and by oral tissue exam in the clinic. In the event that a subject was deemed at greater risk for sustaining an adverse event as a result of study product use, or as a result of an intercurrent illness or injury during the course of the study, the study investigator was able to remove the subject, as warranted by clinical judgement.

Study Subjects

Eligible subjects were 18–65 years of age, non-smokers, in generally good health, who were habitual manual toothbrush users that were able to voluntarily provide informed consent for study participation. Subjects were to have a minimum average plaque score of ≥ 1.8 per the MPI following a 3–6 hour plaque accumulation period, and a GBI of ≥ 1 on at least 20 sites. Subjects were not eligible in the event of uncontrolled diabetes, xerostomia, a medical condition requiring antibiotic premedication prior to dental treatment, intercurrent use of prescription-dose anti-inflammatory or antibiotic medications, pregnancy, advanced periodontal disease or gingival recession, or if the subject was a dental student, a dental professional, or a person employed by a dental products or dental research entity.

The use of any other supplementary oral hygiene or tooth bleaching procedures were prohibited during the four-week study period. Compliance to the prescribed regimen and study requirements was tracked by dispensing a home diary to subjects and by interview of study subjects at each study visit.

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Lobene and Soparkar Modified Plaque Index, 6 Sites per Tooth, Excluding 3 rd Molars					
0	1	2	3	4	5
No plaque	Separate flecks of plaque at the cervical margin	plaque (up to 1mm) at the	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
	Ν	Iodified Gingival Index, 2 Site	s per Tooth, Excluding 3 rd Mol	ars	
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 but involving the entire 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 of the marginal or papillary gingiva, spontaneous bleeding, congestion or ulceration	
	(Gingival Bleeding Index, 2 Site	s per Tooth, Excluding 3 rd Mol	ars	
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		

Data Collection and Data Quality

This study was conducted at a single oral health research site (Salus Research, Ft. Wayne, IN, USA). Study data were collected on a webbased electronic data capture (EDC) system. Access to, and use of the system, was controlled based on the role of the user, thus to maintain the study blind. The clinical site utilized paper source document forms where necessary. Data quality safeguards included programmed logic and edit checks in the EDC system, as well as remote and on-site data monitoring by the study project manager. Randomization and subject instruction on device use were performed by designated unblinded study personnel. These personnel did not perform any evaluations or assessments related to study efficacy or safety endpoints.

Statistical Methods

Sample Size Determination. In previous similar studies, the observed difference in reduction from Baseline in MGI between a power and manual toothbrush after two and four weeks of home use varied from 0.14 to 0.23, with the pooled standard deviation (SD) ranging from 0.26 to 0.35. When MGI was expressed as percent reduction from Baseline, the differences ranged from 6.4% to 14%, with pooled standard deviation ranging from 12.9% to 16.6%.

Thus, assuming a minimum difference of 0.14 (per MGI) as sufficient to differentiate the two products, and assuming an SD of 0.3, a sample size of 74 subjects in each group (148 subjects overall) would allow for approximately 80% power, using a two-sided t-test with a 0.05 significance level. Similarly, this sample size would allow for approximately 80% power to detect a difference of 6 in the number of bleeding sites (per GBI), assuming an SD of 12, and a difference of 0.20 in plaque reduction (per MPI), assuming a SD of 0.4.

General Analysis Considerations

Continuous variables were summarized using the number of observations, mean, median, standard deviation, and 95% confidence interval (CI) of the mean. Categorical variables were summarized using the frequency, count, and the percentage of subjects in each category. There were no planned interim analyses and no prescribed stopping rules, given the low-risk nature of the products being investigated and short accrual time. All analyses were performed using SAS[®] software (SAS, Cary, NC).

Efficacy Analysis

The primary efficacy measure for this study was the mean MGI score after four weeks of product use at home. For each subject, the overall MGI score was calculated as the sum of scores for all evaluable sites divided by the number of sites. The overall MGI score was treated as a continuous variable, and was analyzed both as a reduction from baseline and as a percent reduction from Baseline. All efficacy analyses were performed according to the intent to treat principle, with the modification that subjects be excluded in the analysis if they were missing either the baseline or the week 4 MGI score. Similarly, subjects with missing GBI and MPI scores at baseline and or Week 4 were excluded from analyses pertaining to those endpoints.

An analysis of variance model (ANOVA), with the baseline MGI and randomization group as predictors, was used to estimate the least square (LS) mean for MGI score at Week 4 for both treatment groups. Standard errors and 95% CIs for the LSMs were also estimated from this model. Comparisons between the treatment groups were performed using an F-Test.

The secondary efficacy endpoints were analyzed using statistical models similar to the one described above.

Safety Analysis

Safety analyses evaluated clinical oral examination findings (presence of abnormalities in the oral cavity) and adverse events (AE) experienced by the subjects. Oral exam findings were analyzed as the number and percent of subjects with abnormal results, while AEs were listed.

Results

One hundred and fifty-two subjects provided informed consent and were screened for study participation; of these, 148 were randomized (74 subjects per group). All randomized subjects completed the study (Figure 2).

		Subjects S	creened			
		N=15	52			
Screen			Enrolled			
Failures			N=148			
N=4						
	Not Randomized					
	Randomized	Randomized N=148				
	N=0					
		I	РТВ	N	4TB	
		N	=74	N	=74	
		Completed Discontinued Completed Discontinued				
	N=74 N=0 N=74 N=0					

Figure 2. Subject enrollment and completion metrics.

Demographics

Of the randomized subjects, the mean age was 42.5 years, with 68.2% female and 31.8% male participants. There were no statistical differences in the distribution of age and gender of subjects between groups.

Efficacy Outcomes

Modified Gingival Index (MGI). Table II provides MGI scores for Baseline, and LS mean MGI reduction and percent reduction from Baseline to Week 2 and Week 4. A depiction of percent reduction from Baseline for each product is provided in Figure 3.



Figure 3. Least squares mean, percent reduction from baseline, Modified Gingival Index.

Visit	Statistic	Sonicare PTB (N=74)	MTB (N=74)	Treatment Difference	p-value ^a
Baseline MGI Score	LS Mean (SE) 95% CI	2.00 (0.04) (1.91, 2.08)	2.09 (0.04) (2.00, 2.18)	-0.10 (0.06) (-0.22, 0.03)	0.1327
Week 2 MGI Score	LS Mean (SE) 95% CI	1.53 (0.03) (1.47, 1.60)	1.97 (0.03) (1.90, 2.04)	-0.44 (0.05) (-0.53, -0.34)	< 0.0001
Reduction from Baseline to Week 2	LS Mean (SE) 95% CI	0.51 (0.03) (0.44, 0.58)	0.07 (0.03) (0.01, 0.14)	0.44 (0.05) (0.34, 0.53)	< 0.0001
% Reduction from Baseline to Week 2	LS Mean (SE) 95% CI	26.11 (1.79) (22.57, 29.65)	3.23 (1.79) (-0.32, 6.77)	22.88 (2.55) (17.85, 27.91)	< 0.0001
Week 4 MGI Score	LS Mean (SE) 95% CI	1.33 (0.04) (1.25, 1.41)	1.96 (0.04) (1.87, 2.04)	-0.63 (0.06) (-0.75, -0.51)	< 0.0001
Reduction from Baseline to Week 4	LS Mean (SE) 95% CI	0.72 (0.04) (0.63, 0.80)	0.09 (0.04) (0.00, 0.17)	0.63 (0.06) (0.51, 0.75)	< 0.0001
% Reduction from Baseline to Week 4	LS Mean (SE) 95% CI	35.77 (2.19) (31.44, 40.11)	4.22 (2.19) (-0.11, 8.55)	31.55 (3.11) (25.40, 37.70)	< 0.0001

 Table II

 Modified Gingival Index, Overall, at Baseline, Week 2, Week 4

^a p-value is based on an ANOVA model F-test (Ho: Both treatments equal).

Post-Baseline ANOVA Models: Result=Baseline + Treatment + error.

Table III
Number of Sites with Gingival Bleeding Overall, at Baseline, Week 2, Week 4

Visit	Statistic	Sonicare PTB (N=74)	MTB (N=74)	Treatment Difference	p-value ^a
Baseline	LS Mean (SE) 95% CI	26.46 (1.18) (24.12, 28.80)	28.47 (1.18) (26.13, 30.81)	-2.01 (1.67) (-5.32, 1.29)	0.2308
Week 2	LS Mean (SE) 95% CI	13.61 (0.80) (12.03, 15.20)	25.54 (0.80) (23.95, 27.12)	-11.9 (1.14) (-14.2, -9.67)	< 0.0001
Week 4	LS Mean (SE) 95% CI	13.08 (0.92) (11.26, 14.89)	27.40 (0.92) (25.58, 29.21)	-14.3 (1.30) (-16.9, -11.7)	< 0.0001

^a p-value is based on an ANOVA model F-test (Ho: Both treatments equal).

 $Post-Baseline\ ANOVA\ Models:\ Result=Baseline\ +\ Treatment\ +\ error.$

For the primary efficacy endpoint, MGI reduction from Baseline following four weeks of product use, the LS mean (SE) outcomes were 0.72 (0.04) for the PTB and 0.09 (0.04) for the MTB. Expressed as percent reduction from Baseline, this was 35.77% (2.19%) for the PTB and 4.22% (2.19%) for the MTB.

Following two weeks of product use, the LS mean (SE) reduction from Baseline outcomes for MGI were 0.51 (0.03) for the PTB and 0.07 (0.03) for the MTB. Expressed as percent reduction from Baseline, this was 26.11% (1.79%) for the PTB and 3.23% (1.79%) for the MTB.

For MGI, statistically significant differences were observed between the PTB compared to MTB, p-value < 0.0001 at both Week 2 and Week 4.

Gingival Bleeding Index (GBI)

Table III provides GBI outcomes, indicated as the number of bleeding sites for Baseline, Week 2, and Week 4. A depiction of mean reduction of number of bleeding sites from Baseline for each product is provided in Figure 4.

Following two weeks of product use, the LS mean (SE) overall number of bleeding sites was 13.61 (0.80) for the PTB and 25.54 (0.80) for the MTB. Following four weeks of product use, the outcomes were 13.08 (0.92) for the PTB and 27.40 (0.92) for the MTB.

For GBI, statistically significant differences were detected for number of bleeding sites for the PTB compared to the MTB, p-value < 0.0001 at both Week 2 and Week 4.

Modified Plaque Index (MPI)

Table IV provides MPI scores for Baseline and LS mean (SE) MPI

reduction and percent reduction from Baseline to Week 2 and Week 4. A depiction of percent reduction from Baseline for each product is provided in Figure 5.

Following two weeks of product use, the LS mean (SE) reduction in MPI was 0.69 (0.04) for the PTB and 0.08 (0.04) for the MTB. Expressed as percent reduction from Baseline, this was 24.82% (1.40%) for the PTB and 2.54% (1.40%) for the MTB.

Following four weeks of product use, the LS mean (SE) reduction in MPI was 0.85 (0.04) for the PTB and 0.00 (0.04) for the MTB.



Figure 4. Least Squares mean, number of bleeding sites at Baseline, Week 2, Week 4.

Visit	Statistic	Sonicare PTB (N=74)	MTB (N=74)	Treatment Difference	p-value ^a
Baseline MPI Score	LS Mean (SE) 95% CI	2.80 (0.04) (2.71, 2.89)	2.82 (0.04) (2.74, 2.91)	-0.02 (0.06) (-0.15, 0.10)	0.7193
Week 2 MPI Score	LS Mean (SE) 95% CI	2.13 (0.04) (2.05, 2.20)	2.74 (0.04) (2.66, 2.81)	-0.61 (0.05) (-0.71, -0.51)	< 0.0001
Reduction from Baseline to Week 2	LS Mean (SE) 95% CI	0.69 (0.04) (0.62, 0.76)	0.08 (0.04) (0.01, 0.15)	0.61 (0.05) (0.51, 0.71)	< 0.0001
% Reduction from Baseline to Week 2	LS Mean (SE) 95% CI	24.82 (1.40) (22.06, 27.59)	2.54 (1.40) (-0.22, 5.31)	22.28 (1.98) (18.37, 26.19)	< 0.0001
Week 4 MPI Score	LS Mean (SE) 95% CI	1.96 (0.04) (1.88, 2.04)	2.81 (0.04) (2.74, 2.89)	-0.85 (0.06) (-0.96, -0.74)	< 0.0001
Reduction from Baseline to Week 4	LS Mean (SE) 95% CI	0.85 (0.04) (0.77, 0.93)	0.00 (0.04) (-0.08, 0.08)	0.85 (0.06) (0.74, 0.96)	< 0.0001
% Reduction from Baseline to Week 4	LS Mean (SE) 95% CI	30.65 (1.49) (27.71, 33.60)	-0.52 (1.49) (-3.46, 2.43)	31.17 (2.11) (27.00, 35.33)	< 0.0001

 Table IV

 Modified Plaque Index, Overall, at Baseline, Week 2, Week 4

^a p-value is based on an ANOVA model F-test (Ho: Both treatments equal).

Post-Baseline ANOVA Models: Result=Baseline + Treatment + error.



Figure 5. Least Squares mean percent eduction from baseline for Modified Plaque Index.

Expressed as percent reduction from Baseline, this was 30.65% (1.49%) for the PTB and -0.52% (1.49%) for the MTB.

For MPI, statistically significant differences were observed between the PTB compared to the MTB, p-value < 0.0001 at both Week 2 and Week 4.

Safety Outcomes

There was one adverse event of "food burn" reported during the study. The event was assessed as mild in severity and unrelated to the study by the investigator.

Conclusion and Discussion

Within the limits and controls of this single-center randomized clinical trial, the powered toothbrush was shown to be statistically significantly superior to the manual toothbrush in reducing gingival inflammation, gingival bleeding, and surface plaque following a period of home use. These differences were observed within the first two weeks of the study, and were sustained upon study completion at Week 4. These outcomes are consistent with prior observations comparing high-frequency, high-amplitude sonic powered toothbrushes with manual toothbrushes on the reduction of plaque and gingivitis.¹⁶⁻¹⁸

Whereas the outcomes of a straightforward plaque and gingivitis study may seem prosaic in scope, it is, nevertheless, performed with a rigor that recognizes the value of effective oral hygiene. While there are many factors that influence a patient's transition from oral health to disease, specifically to periodontal disease, the transition doesn't happen overnight. Beyond a patient's oral health habits and status, the risk-factor spectrum for periodontitis includes smoking, genetics, nutrition, stress, and other chronic inflammatory conditions^{23,24}

From an oral hygiene perspective, however, the first line of defense against developing periodontal disease is plaque removal. In this study, subjects in the power toothbrush group exhibited a rapid reduction in plaque by Week 2, which continued to improve at Week 4. Whereas, only a modest reduction was observed at Week 2 in the manual toothbrush group, and this essentially disappeared by Week 4. This may suggest that manual toothbrush users reverted to their habitual brushing techniques following an initial "on study" period in which, at the onset of the study, additional time and attention may have been given to their brushing routine.

The design and user features of a powered toothbrush help to overcome these engrained habits of manual brushing. Timed quadrant brushing, coupled with high-frequency/high amplitude brush head motion, helps to ensure that patients consistently reach all tooth surfaces in each brushing session. It is also noted that the brushing technique for the powered toothbrush directs users to glide the brush head along the gumline, where plaque accumulates. This is the site of the interface between the host and the dynamic microbiome. As such, thorough mechanical removal of plaque along the gingival margin is a critical aspect of maintaining oral health. The outcomes observed in this trial provide clinical validation that the powered toothbrush tested here effectively does so.

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Conflict of Interest: E. M. Starke, A. Mwatha, M. Ward, K. Argosino, and W. Jenkins are employed by Philips Oral Healthcare. J. Milleman and K. Milleman are employed by Salus Research.

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