An Eight-Week Clinical Evaluation of an Oscillating-Rotating Power Toothbrush with a Brush Head Utilizing Angled Bristles Compared with a Sonic Toothbrush in the Reduction of Gingivitis and Plaque

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Abstract

- **Objective:** To evaluate and compare the efficacy of an oscillating-rotating (O-R) power toothbrush with a brush head utilizing angled bristles to a marketed sonic toothbrush in the reduction of plaque and gingivitis over an eight-week period.

- **Methods:** This study used a randomized, examiner-blind, single-center, two-treatment, parallel group, eight-week design. Subjects with mild-to-moderate plaque and gingivitis were evaluated for baseline whole mouth, gingival margin, and approximal plaque, gingivitis, and gingival bleeding. Clinical assessments were performed using the Modified Gingival Index, Gingival Bleeding Index, and the Rustogi Modified Navy Plaque Index. Subjects received either the O-R brush (Oral-B® Professional Care 1000 [D16u] with Oral-B® CrossAction brush head [EB50]) or the sonic brush (Sonicare® DiamondClean with the standard DiamondClean brush head). Subjects brushed twice daily for two minutes per brushing with the assigned brush and a standard fluoride dentifrice for eight weeks before returning for plaque and gingivitis evaluations using the same methods. Prior to baseline and Week 8 measurements, participants abstained from oral hygiene for 12 hours.

- **Results:** One hundred and forty-eight subjects completed the study; 75 in the O-R group and 73 in the sonic group. Both brushes demonstrated statistically significant reductions in plaque and gingivitis over the eight-week study period (p < 0.001). The O-R brush was statistically significantly more effective in reducing plaque and gingivitis than the sonic brush. Whole mouth, gingival margin, and approximal plaque reductions were 27.7%, 46.8%, and 29.3% greater, respectively, compared with the sonic brush, while the reductions in gingivitis, gingival bleeding, and number of bleeding sites were 34.6%, 36.4%, and 36.1% greater, respectively, for the O-R brush than for the sonic brush (p < 0.001 for all six measures). No adverse events were observed for either brush.

- **Conclusion:** The plaque and gingivitis reductions for the O-R power brush incorporating the angled-bristled brush head were significantly greater than for the sonic power brush.

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Introduction

Gingivitis is known to affect approximately half of adolescents and adults in the United States, and is a common affliction experienced by up to 75% of the population worldwide.[1,2] Gingivitis involves an inflammatory response to the presence of dental plaque, and develops within days.[3] While reversible in its early stages, gingivitis becomes established over a period of several weeks and over time may lead to periodontitis of increasing severity with clinical attachment loss.[4-7] Dental plaque thus plays a key etiological role in the development of gingivitis and more advanced periodontal disease. Therefore, effective oral hygiene with thorough plaque removal and control is essential.[8] As a result, considerable resources have been applied to designing and introducing safe and effective toothbrushes for optimal plaque removal.

One breakthrough technology incorporated into the Oral-B® CrossAction® manual toothbrush (Procter & Gamble, Cincinnati, OH, USA) is the CrissCross filament arrangement.[9] Bristles are inclined at 16° along the horizontal brush head to ensure the filaments are used at an optimal angle during brushing. The ability to effectively remove plaque from all tooth surfaces and hard-to-reach areas without requiring a special brushing technique is a further advantage of this novel filament arrangement. Compared to numerous other commercially available manual toothbrush designs, superior plaque removal efficacy has been demonstrated for the Oral-B CrossAction brush head design.[9] Superior plaque reductions have been found for this brush in both clinical and laboratory studies, leading to the conclusion in a five-year literature review that this brush offered advantages compared to all other tested brushes.[10]

This angled bristle technology has since been incorporated into an oscillating-rotating (O-R) power brush head, marketed as

Oral-B CrossAction (Procter & Gamble, Cincinnati, OH, USA). The CrossAction power brush head design has an outer circular row inclined at +16° and an inner circular row inclined at -16°. Filaments are optimally angled for both the forward (clockwise) and backward (counter-clockwise) motion of the O-R handle. In this manner, the angled bristles are coupled with short movements with a high number of directional turning points at high frequency to optimize removal of plaque. The bristle configuration enables the effective application of shear forces for plaque disruption and removal. O-R power brushes have been rigorously evaluated, including in a recent systematic review that led to the conclusion that O-R power brushes were proven superior to manual brushes for plaque and gingivitis reduction.[11] Combining the brush head with angled bristles with the O-R handle builds on the already-proven superior efficacy of both advanced technologies.

The purpose of the current study was to evaluate and compare the efficacy of an O-R power brush with the brush head utilizing angled bristles, to that of a marketed sonic brush in the reduction of plaque and gingivitis over an eight-week period. This sonic brush, which is based on a "side-to-side" mode of action, uses a brush head with diamond-shaped bristles. It is reported to provide significantly greater plaque removal and gingivitis reductions relative to a standard manual toothbrush after two and four weeks of use.[12]

Materials and Methods

This was an eight-week, single-center, randomized, two-treatment, examiner-blind, parallel group study. Institutional Review Board (BRCL) approval was obtained for the study protocol and informed consent form prior to initiating the study. One hundred and fifty potential subjects were asked to sign a written informed consent prior to their participation in the study. At the baseline visit, subjects were given an oral soft tissue examination, followed by assessment of gingivitis using the Modified Gingival Index (MGI) and the Gingival Bleeding Index (GBI), and plaque using the Rustogi Modified Navy Plaque Index (RMNPI) after disclosing plaque with FD&C red erythrosine disclosing solution (Chrom-O-Red, Germiphene Corp., Bradford, Ontario, Canada).[13-15]

To qualify for the study, subjects were required to have a baseline whole mouth mean plaque score greater than 0.5 and a gingivitis score (MGI) greater than or equal to 1.75 and less than or equal to 2.3, and at least 10 bleeding sites (GBI = 1 or 2). In addition, subjects had to be 18 years of age or older, in good general health, and have a minimum of 16 natural teeth with facial and lingual scoreable surfaces. Subjects had to agree not to participate in any other oral care study and to refrain from using non-study oral hygiene products for the duration of the study; not to receive any elective dentistry, including dental prophylaxis, until study completion; and to report any non-study dentistry received during the study. Subjects had to also agree to return for their scheduled visits, follow all study procedures, refrain from brushing their teeth and performing any other oral hygiene procedures for at least 12 hours prior to each visit, and to refrain from eating, chewing gum, using tobacco, and drinking anything for at least four hours prior to each visit, except for small sips of water, up until 45 minutes prior to each visit.

Qualified subjects were stratified according to their baseline MGI scores (≤ 2.0 vs. > 2.0), whole mouth mean RMNPI scores (≤ 0.65 vs. > 0.65), number of bleeding sites (≤ 17 vs. > 17), and tobacco use. Subjects were then randomly assigned to one of two treatment groups:

• Group One: The O-R power brush with the novel brush head incorporating angled CrissCross bristles (Oral-B® Professional Care 1000 [D16u] with Oral-B® CrossAction® brush head [EB50], O-R; Figure 1) and a standard anti-cavity fluoride dentifrice (Crest® Cavity Protection, Procter & Gamble, Cincinnati, OH, USA); or

• Group Two: The marketed sonic toothbrush (Sonicare® DiamondClean with the standard DiamondClean brush head; Phillips Oral Healthcare, Bothell, WA, USA; Figure 1) and the same anti-cavity fluoride dentifrice.

Figure 1. *Oscillating-rotating (left) and sonic (right) test toothbrushes.*

Subjects were given their assigned toothbrush and the dentifrice in a kit box, in an area separate from the examination room to ensure the examiner was blinded to treatment assignment. Subjects then received instruction on oral hygiene and product usage (in accordance with the manufacturer's instructions) before brushing under supervision in front of a mirror; this brushing counted as one of the two daily brushings. Verbal and written instructions were then provided to all subjects to brush for two minutes, twice daily, with their assigned products; they were then scheduled to return for their Week 8 (± two days) assessments. Before their Week 8 visit, subjects were reminded to refrain from brushing for 12 hours prior to their appointment, to refrain from eating, chewing, drinking, or using tobacco, and to bring their assigned products with them.

At the Week 8 visit, after ascertaining that they still met the study criteria, subjects received an oral examination, MGI and GBI evaluations, and RMNPI plaque assessments after disclosing plaque as described above.

Clinical Assessments of Safety and Efficacy

All clinical assessments were performed by the same examiner at the baseline and Week 8 visits. The safety assessment involved visual examination of the dentition, intra-oral and oropharyngeal soft tissues, and the peri-oral area. Any abnormal findings or self-reported adverse events were noted.

The MGI gingivitis evaluations were conducted first, scoring inflammation on six gingival areas (distobuccal, buccal, mesiobuccal, mesiolingual, lingual, and distolingual) of all scoreable teeth (excluding third molars and teeth with >50% of the surface restored or with orthodontic appliances), as described in a previously reported six-week study.[16] Whole mouth MGI scores for each subject were determined by summing all scores and dividing by the number of scored sites.[13]

The GBI evaluations were conducted next, using the same protocol as previously described.[16] The GBI whole mouth score for each subject was determined by summing the scores and dividing by the number of scored sites.[13]

Lastly, the RMNPI was used to score dental plaque as present (score = 1) or absent (score = 0) on each of nine tooth areas (A–I) on both buccal and lingual surfaces, again using the previously reported study method[16] (Figure 2).
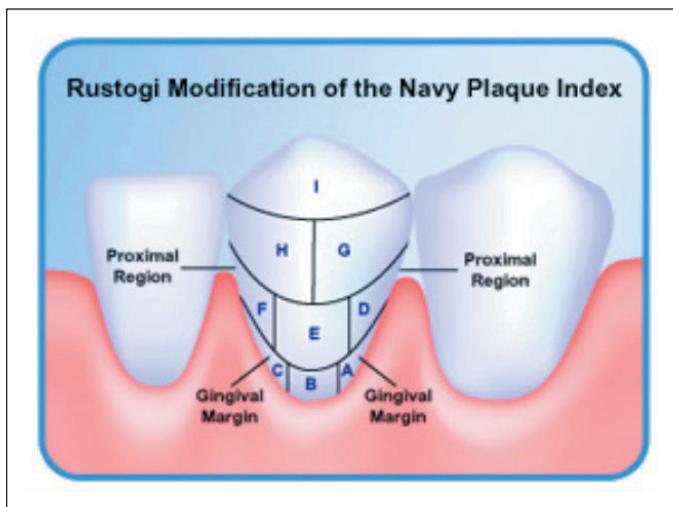

Figure 2. *Tooth areas scored using RMNPI.*

Determination of Sample Size

Sample size was determined by power analyses conducted with α = 0.05, using a two-sided test. Based on whole mouth MGI variability of 0.0698 and whole mouth RMNPI variability of 0.037, a sample size of 75 subjects per group was estimated to provide 90% power to detect a difference of 0.037 MGI units and 0.020 RMNPI units between treatments.

Determination of Treatment Differences

Group differences at baseline were tested using a two-sample t-test for age, a Chi-Square test for gender, and Fisher's Exact test for ethnicity and smoking. The treatment group mean MGI scores, GBI scores, number of bleeding sites, and the whole mouth, gingival margin, and approximal RMNPI scores were calculated separately for the baseline and Week 8 visits. Gingivitis efficacy was evaluated based on the changes in average MGI, GBI, and number of bleed-

ing sites from baseline to Week 8. Analyses for plaque efficacy were carried out on the average RMNPI changes from baseline to Week 8. An analysis of covariance (ANCOVA) was performed to determine treatment differences on the whole mouth average gingivitis reduction with the respective baseline gingivitis score as the covariate. Separate analyses were performed for each gingivitis endpoint. The 8-week plaque reduction was analyzed for treatment differences using an ANCOVA, with baseline whole mouth RMNPI score as the covariate. Similar analyses were carried out for gingival margin and approximal RMNPI, except that an analysis of variance (ANOVA) was carried out for these because the baseline plaque scores were 1.0 for all subjects in the gingival margin and approximal areas.

The within-treatment gingivitis and plaque reductions were tested versus zero using the ANCOVA or ANOVA model that was used for each specific endpoint for determining treatment differences.

All treatment comparisons were considered two-sided with an α = 0.05 significance level. Multiple comparison adjustments were not carried out.

Results

A total of 150 subjects participated in the study and were randomized to one of two treatment groups (75 in each group); 148 subjects completed the study (75 in the O-R group and 73 in the sonic group). The mean ages of subjects in the O-R and sonic groups were 44.3 and 43.5, respectively. Overall, subjects' ages ranged from 18 to 68 years. In addition, 69% of all subjects were female, 55% were Caucasian, and 97% were nonsmokers. Based on statistical analyses, the groups were well-distributed for age, gender, and ethnicity (Table I).

Table I
Demographic Characteristics of Study Participants
(Randomized Subjects)

Demographic Characteristics	Oscillating-Rotating (n=75)	Sonic (n=75)	Total (n=150)
Age (Years)[a]			
Mean	44.3	43.5	43.9
SD	10.91	11.72	11.30
Minimum	18	18	18
Maximum	68	66	68
Sex[b,c]			
Female	50 (66.7%)	54 (72.0%)	104 (69.3%)
Male	25 (33.3%)	21 (28.0%)	46 (30.7%)
Race[b,d]			
Asian Indian	21 (28.0%)	19 (25.3%)	40 (26.7%)
Asian Oriental	1 (1.3%)	4 (5.3%)	5 (3.3%)
Black	9 (12.0%)	11 (14.7%)	20 (13.3%)
Caucasian	44 (58.7%)	38 (50.7%)	82 (54.7%)
Hispanic	0 (0.0%)	2 (2.7%)	2 (1.3%)
Multi-Racial	0 (0.0%)	1 (1.3%)	1 (0.7%)
Smoker[b,c]			
Yes	3 (4.0%)	1 (1.3%)	4 (2.7%)
No	72 (96.0%)	74 (98.7%)	146 (97.3%)
Brush Type[b,c]			
Manual	73 (100%)	73 (100%)	150 (100%)

[a] Two sample t-test was used to compare mean age between the two treatment groups (p = 0.645).
[b] Number and percent of subjects in each category.
[c] Chi-Square test was used to asses gender balance between the two groups (p = 0.596).
[d] Fisher's Exact test was used to asses race (p = 0.396) and smoking status (p = 0.620) balance between the two groups.

MGI and GBI Scores

At baseline, enrolled subjects presented with mild-to-moderate gingivitis (mean baseline MGI scores of 2.093 and 2.099), and with no statistically significant differences between groups for baseline MGI (p = 0.640), whole mouth GBI (p = 0.899), total number of bleeding sites (p = 0.944), or baseline whole mouth mean RMNPI scores (p = 0.615). Mean baseline and Week 8 MGI, GBI, and number of bleeding sites are shown in Table II, together with percentage changes. Reductions for each of these measures were statistically significant at Week 8 for both groups (p < 0.001). Compared to baseline, gingivitis reductions assessed using MGI were 15.6% for the O-R group and 11.6% for the sonic group at Week 8; reductions for GBI were 65.6% and 48.1%, respectively. The number of bleeding sites was reduced by 64.6% for the O-R group and 47.5% for the sonic group. For all three measures, statistically significantly greater reductions were observed for the O-R brush versus the sonic brush (p < 0.001). The difference in adjusted mean reductions between brushes was 34.6%, 36.4%, and 36.1% for MGI, GBI, and the number of bleeding sites, respectively.

Plaque Scores

At baseline, enrolled subjects presented with mild-to-moderate plaque accumulation (RMNPI > 0.50), with no statistically significant between-group differences in whole mouth, gingival margin, or approximal RMNPI scores. At Week 8, statistically significant reductions in all three measures were observed for the O-R and sonic groups (p < 0.001 for each measure; Table III). Whole mouth plaque reductions for the O-R group and the sonic group were 24.5% and 19.2%, respectively. Gingival margin and approximal plaque reductions were 6.9% and 34.9%, respectively

for the O-R group and 4.7% and 27% for the sonic group. For all three measures, statistically significantly greater reductions were observed at Week 8 for the O-R brush versus the sonic brush (p < 0.001); the difference between brushes in mean reductions was 27.7%, 46.8%, and 29.3% for whole mouth, gingival margin, and approximal mean plaque, respectively.

There were no adverse events either observed or reported in this trial.

Discussion

Dental plaque is the single most important etiological factor in the onset and presence of gingivitis. Therefore, the development and availability of a safe and effective brush is important clinically. O-R power brushes have been extensively researched in more than 150 clinical studies compared to manual and power control brushes, with several systematic reviews confirming their efficacy.[11,17,18] A recent update of a systematic review concluded that O-R power brushes are proven clinically superior to manual brushes for plaque and gingivitis reductions.[11] Numerous studies have also demonstrated the superiority of O-R power brushes compared to marketed sonic brushes.[19-27] The O-R technology has the largest body of evidence for power brushes,[11] supporting its use.

The Oral-B CrossAction manual brush with its innovative brush head has also been extensively studied. In a recent systematic review of 59 papers with 212 brushing exercises, including 10,806 participants, the efficacy of manual brushes was evaluated using the mean pre- and post-brushing plaque scores to calculate an overall weighted mean percentage plaque score reduction.[28] The reductions ranged from 24% to 61% depending on the brush head bristle design, with

Table II
Mean Baseline and Week 8 MGI, GBI and Number of Bleeding Sites

	Baseline Mean (SD)	Week 8 Adj. Mean Reduction (SE), % Change*	Difference in Adjusted Mean Reductions (%)	Between-group Differences (p-value)
Modified Gingival Index				
Oscillating-rotating	2.099 (0.0886)	0.327 (0.0093), 15.6%	34.6%	p < 0.001
Sonic	2.093 (0.0826)	0.243 (0.0094), 11.6%		
Gingival Bleeding Index				
Oscillating-rotating	0.157 (0.1485)	0.105 (0.0034), 65.6%	36.4%	p < 0.001
Sonic	0.154 (0.1210)	0.077 (0.0034), 48.1%		
Number of Bleeding Sites				
Oscillating-rotating	22.53 (18.952)	14.63 (0.463), 64.6%	36.1%	p < 0.001
Sonic	22.73 (15.774)	10.75 (0.470), 47.5%		

*All reductions versus baseline were statistically significant (p < 0.001)

Table III
Mean Baseline Plaque and Week 8 Plaque Reductions from Baseline

	Baseline Mean (SD)	Week 8 Adj. Mean Reduction (SE), % Change*	Difference in Adjusted Mean Reductions (%)	Between-group Differences (p-value)
Whole Mouth Plaque				
Oscillating-rotating	0.619 (0.0372)	0.152 (0.0036), 24.5%	27.7%	p < 0.001
Sonic	0.616 (0.0297)	0.119 (0.0037), 19.2%		
Gingival Margin Plaque				
Oscillating-rotating	1 (0)	0.069 (0.0033), 6.9%	46.8%	p < 0.001
Sonic	1 (0)	0.047 (0.0034), 4.7%		
Approximal Site				
Oscillating-rotating	1 (0)	0.349 (0.0140), 34.9%	29.3%	p < 0.001
Sonic	1 (0)	0.270 (0.0142), 27.0%		

*All reductions versus baseline were statistically significant (p < 0.001)

angled bristle designs demonstrating the greatest efficacy. For studies using the Navy Plaque Index, a weighted mean reduction of 61% was observed for the angled bristles vs. 47% and 54%, respectively, for flat-trim and multi-level bristle designs. Based on the studies using the Quigley-Hein Plaque Index, the relative efficacy of the three bristle designs followed the same pattern, with angled bristles being most effective.

The current study compared an advanced O-R power brush, incorporating a CrossAction design brush head, with an advanced sonic brush that has demonstrated superior plaque and gingivitis reductions compared to a standard manual brush.[12] In addition, since thorough plaque removal from all surfaces of the teeth is required for optimal oral hygiene and oral health, and since the onset of periodontal disease occurs at the gingival margins and interproximally, plaque evaluations included assessments of whole mouth plaque reductions, as well as reductions from the harder-to-reach gingival margin and approximal surfaces. Gingivitis reductions were evaluated using MGI, GBI, and the number of bleeding sites, and for all three measures the O-R power brush offered statistically significant benefits compared to the advanced sonic brush ($p < 0.001$). The O-R power brush with the CrossAction brush head also offered statistically significantly greater whole mouth, gingival margin, and approximal plaque reductions.

Results from this investigation corroborate other published research evaluating the Oral-B CrossAction brush head used with an O-R brush handle against other brushes. Three separate investigations by Klukowska, *et al.* have shown significant plaque and gingivitis benefits for the power brush head relative to manual and sonic toothbrush controls.[16,29,30] Compared to a standard manual brush, in one six-week study the O-R brush provided a significantly greater reduction in whole mouth and interproximal plaque, respectively, with a more than two-fold reduction.[29] A second study compared the brush head on a premium O-R handle to another sonic model[30] and the O-R brush provided significantly greater plaque and gingivitis benefits for all measures compared to the sonic brush. A third six-week study compared the brush head on a premium O-R handle to the premium sonic model tested in this trial.[16] Consistent with results seen in this trial, which involved a mid-range O-R power toothbrush handle, the premium O-R brush showed significantly greater reductions versus the sonic brush for whole mouth plaque, plaque in approximal areas, plaque along the gingival margin, gingivitis, and gingival bleeding.[16] Thus, not only does a premium O-R toothbrush provide greater gingivitis and plaque reductions versus the sonic model tested in this investigation, which is one of the advanced models in the sonic line-up, but a mid-range O-R model provides significantly greater benefits as well.

Collectively, these data translate into an opportunity to further reduce plaque and gingivitis through improved oral hygiene and plaque control using the Oral-B CrossAction brush head and O-R brush handle.

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