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Evaluation of an oscillating-rotating toothbrush with micro-vibrations *versus* a sonic toothbrush for the reduction of plaque and gingivitis: results from a randomized controlled trial

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Purpose: To compare a novel oscillating-rotating (O-R) electric rechargeable toothbrush with micro-vibrations to a marketed premium sonic toothbrush for reduction of gingivitis and plaque in an 8-week randomized controlled trial. **Methods:** Adult subjects with evidence of gingivitis and plaque were randomized to use either the novel O-R brush (Oral-B iO) or the sonic brush with sodium fluoride dentifrice twice daily. Assessments at baseline and week 8 included the Rustogi Modification of the Navy Plaque Index (RMNPI), Modified Gingival Index (MGI), and Gingival Bleeding Index (GBI). Gingivitis status ('healthy'/'not healthy') was classified per the American Academy of Periodontology/European Federation of Periodontology criteria. **Results:** Ninety subjects were randomized to treatment and completed the study. Subjects had a mean age of 49.2 years; 68 were females. At baseline, the mean number (standard deviation [SD]) of bleeding sites for all subjects was 32.8 (16.43). At week 8, the O-R brush group had a higher percentage of 'healthy' gingiva subjects than the sonic brush group (84% *vs.* 53% *P* = 0.003). In the between-group comparisons at week 8, the O-R brush group showed statistically significantly greater reductions (*P* < 0.001) compared to the sonic group for MGI, GBI, and number of bleeding sites. The O-R brush group also had statistically significantly greater plaque removal (*P* ≤ 0.011) than the sonic brush group for whole mouth plaque as well as plaque in the proximal regions and along the gingival margin. **Conclusions:** The novel O-R brush with micro-vibrations provided greater plaque and gingival margin. **Conclusions:** The novel O-R brush with micro-vibrations provided greater plaque and gingivitis reductions than the marketed premium sonic toothbrush with micro-vibrations provided greater plaque and gingivitis reductions than the marketed premium sonic toothbrush over 8 weeks.

Key words: Dental plaque, gingivitis, micro-vibrations, oscillating-rotating, sonic, toothbrush

INTRODUCTION

Periodontal disease, including gingivitis and periodontitis, is a significant global public health concern¹. The earliest stage of the disease, gingivitis, is associated with gingival inflammation and gingival bleeding, leading to difficulty performing oral hygiene². The backbone of periodontal disease prevention is adequate plaque control³, because bacteria present in dental plaque are causative factors in disease development^{4,5}.

Effective home-based dental hygiene is a fundamental component of plaque control, and toothbrush choice is an important consideration. A number of studies have found that electric toothbrushes provide greater gingivitis reduction and plaque removal compared to manual toothbrushes⁶⁻⁹. However, the benefits for gingivitis reduction and plaque removal conferred by electric toothbrushes vary by brush type, with head-to-head studies and meta-analyses demonstrating that oscillating-rotating (O-R) electric toothbrushes provide greater gingivitis reduction and plaque removal when compared with sonic toothbrushes^{8,10-20}. This seems to be particularly evident in gingival marginal, lingual, and proximal ('hard-toclean') regions¹⁹.

A novel, next-generation O-R toothbrush has recently been developed (Oral-B iO) that uses a linear magnetic drive. The new design produces oscillationrotations with micro-vibrations, directing energy to the bristles for effective plaque removal. An additional benefit, which may be appealing to a certain group of consumers, is a quieter brushing experience compared to some other electric toothbrushes²¹. This study was undertaken to evaluate this novel O-R electric brush *versus* a premium sonic brush for the reduction of gingivitis and plaque over 8 weeks in generally healthy adult subjects with evidence of gingivitis and plaque accumulation.

METHODS

Study objective

The objective of this randomized, open-label, parallelgroup study was to compare the efficacy of a novel O-R electric rechargeable toothbrush to that of a marketed sonic toothbrush for reduction of gingivitis and plaque over an 8-week period in adult subjects with evidence of mild-to-moderate gingivitis and plaque at baseline. The study was conducted in compliance with the Declaration of Helsinki and the International Conference on Harmonization's Good Clinical Practice Consolidated Guidelines. Institutional review and approval of the protocol and informed consent form were obtained (Veritas IRB; approval #16322). All participants provided written, informed consent.

Assessments and outcomes

Gingivitis assessments were conducted using the Modified Gingival Index (MGI) and the Gingival Bleeding Index (GBI)^{14,22,23}.

Plaque was assessed using the Rustogi Modification of the Navy Plaque Index (RMNPI) on up to 28 teeth^{14,24}. Third molars, surfaces with cervical restorations, and crowns were not evaluated.

Investigational products

The two toothbrush products used in this study were the novel O-R electric rechargeable toothbrush with micro-vibrations (Oral-B iO and Ultimate Clean brush head M7/OC15; The Procter & Gamble Company, Cincinnati, OH) and a premium sonic toothbrush (Philips Sonicare DiamondClean Smart Sonic rechargeable electric toothbrush and Premium Plaque Control brush head, HX9903/11; Philips Oral Healthcare, Bothell, WA). Standard 0.243% sodium fluoride dentifrice (Crest Cavity Protection; The Procter & Gamble Company) was given to all subjects for use during the study.

Eligibility criteria

Subject recruitment was done by All Sum Research (Mississauga, Ontario, Canada) in February 2019. Included subjects were adults who typically use a manual toothbrush as part of their at-home, usual dental hygiene regimen. Other inclusion criteria were (i) at least 16 natural teeth with facial and lingual scorable surfaces, (ii) a baseline pre-brushing MGI

score >1.75 but \leq 2.5, (iii) a baseline pre-brushing RMNPI score of >0.5, and (iv) a baseline pre-brushing number of bleeding sites (sites with a GBI score of 1 or 2) of at least 20 but not more than 90. Exclusion criteria included the need for antibiotic treatment prior to dental treatment; severe periodontal disease; active treatment for periodontitis, cancer, or a seizure disorder; pregnancy or nursing; teeth that were grossly carious, fully crowned, or extensively restored; use of antibiotics or chlorhexidine mouth rinse in the 2 weeks prior to baseline; fixed facial orthodontic appliances or removable partial dentures; peri/oral piercings; pacemaker or other implanted devices; or history of oral or periodontal surgery in the 2 months prior to baseline. Eligible subjects were required to refrain from antibiotic treatment, use of chlorhexidine mouth rinse, use of any non-study oral hygiene products, and dental prophylaxis or any elective dentistry.

Study design

This was an 8-week, randomized, single-centre, examiner-blind, parallel group clinical trial. Assessments were conducted at baseline and at week 8. Subjects were instructed to abstain from brushing teeth or performing any oral hygiene for 12 hours prior to the visits and to abstain from eating, drinking, chewing gum, and tobacco use for 4 hours prior to the visits.

At the baseline visit, subjects gave informed consent, followed by a review of their medical history, demographic information, and study inclusion/exclusion criteria. Subjects received a pre-brushing oral examination followed by MGI and GBI evaluations by an experienced examiner ^{10,14,25,26}. Next, plaque was disclosed using Chrom-O-Red erythrosine FD&C red 3 disclosing solution (Germiphene Corp., Bradford, Ontario, Canada) according to the manufacturer's instructions. The experienced examiner^{10,14,25,26} conducted an RMNPI plaque assessment after disclosure.

Qualifying subjects were stratified based on MGI score ($\leq 2.1 \ vs. > 2.1$), whole mouth mean RMNPI ($\leq 0.62 \ vs. > 0.62$), number of bleeding sites ($\leq 32.0 \ vs. > 32.0$), and use of tobacco (present or absent). A balance and assignment procedure was used on site based on a computer-generated schedule provided by the study sponsor, to randomize subjects 1:1 to the two toothbrush groups. The randomization and assignment process along with test product distribution were conducted in an area that ensured the examiner was blind to treatment.

Kit boxes containing standard sodium fluoride dentifrice plus either the novel electric toothbrush or the sonic toothbrush were distributed to subjects as appropriate according to the randomization. Subjects were given supervised oral hygiene instructions and were told to use their assigned products, as stated by each manufacturer's instructions, twice per day for 8 weeks. Subjects then brushed in front of a mirror in a secure area according to the provided usage instructions with their assigned toothbrush and the standard sodium fluoride toothpaste.

At the week 8 visit (± 2 days), subjects returned to the site and brought their test products. Continuance criteria were assessed and recorded. Subjects received an oral examination and MGI and GBI assessments by the experienced examiner. Last, the plaque disclosing procedure described above was conducted and an RMNPI plaque assessment was performed by the experienced examiner.

Safety

Safety was assessed at each study visit based on subject self-report. All serious adverse events (AEs) and all oral-related AEs were recorded, as were any non-serious, voluntarily reported whole body AEs that had the potential to be related to the study prod-ucts.

Statistical analysis

Power analyses were conducted with $\alpha = 0.05$, using a 2-sided test and a sample size of 45 subjects per group. Assuming the variability of whole mouth MGI is 0.084, a sample size of 45 subjects per group would provide 90% power to detect a difference in mean MGI scores of 0.058 units between treatments. Assuming the variability of number of bleeding sites is 4.36, a sample size of 45 subjects per group would provide at least 90% power to detect a difference in number of bleeding sites of at least 3.01 units between treatments. Similarly, for plaque, assuming the variability of whole mouth RMNPI is 0.032, a sample size of 45 subjects per group would provide 90% power to detect a difference in RMNPI mean scores of 0.022 units between treatments.

Demographic and baseline variables were summarized by treatment group, and adverse events reported or noted during the study were documented.

The percentage of subjects whose gingivitis status was classified as 'not healthy' per the American Academy of Periodontology (AAP) and the European Federation of Periodontology (EFP) criteria²⁷ (e.g. $\geq 10\%$ bleeding sites or at least 15 bleeding sites for 150 gradable sites) at each visit was computed and compared between treatment groups using a chisquare test. A logistic regression analysis was conducted using week 8 bleeding data to compute the odds of changing from 'not healthy' ($\geq 10\%$ bleeding sites) to 'healthy' ($\!<\!\!10\%$ bleeding sites) gingivitis status.

Statistical analyses for gingivitis efficacy were based on change from baseline scores for whole-mouth average MGI, GBI, and number of bleeding sites (baseline minus 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 with MGI being the primary endpoint. The within-treatment difference from baseline gingivitis scores (MGI, GBI, number of bleeding sites) were tested *versus* zero using an ANCOVA model with the respective baseline score as the covariate.

Statistical analyses for plaque efficacy were based on change from baseline score for whole-mouth average RMNPI (baseline minus week 8). The 8-week plaque reduction was analysed for treatment differences using an ANCOVA with baseline whole-mouth RMNPI score as the covariate. An analysis of variance (ANOVA) was carried out for gingival margin and proximal region RMNPI scores because the baseline scores were 1.0 for all subjects in the gingival margin and the proximal region. All treatment comparisons were considered two-sided with an $\alpha = 0.05$ significance level. Multiple comparison adjustments were not carried out.

RESULTS

Study population

Ninety-two subjects were screened, of which 2 did not meet the eligibility criteria for baseline gingivitis and plaque. Ninety subjects (68 females and 22 males) with a mean (SD) age of 49.2 (13.7) years were randomized and completed the study (*Table 1*).

Gingival health status

For all subjects at baseline, the gingivitis classification status was 'not healthy' per the AAP/EFP criteria²⁷ (e.g. $\geq 10\%$ bleeding sites or at least 15 bleeding sites for 150 gradable sites). At week 8, the novel O-R brush group had a significantly higher number of 'healthy' subjects than the sonic brush group (84% *vs.* 53% *P* = 0.003). A logistic regression analysis found that the odds of transitioning from 'not healthy' ($\geq 10\%$ bleeding sites) at baseline to 'healthy' (<10% bleeding sites) gingivitis status at week 8 was 4.75 times higher when using the novel O-R brush than when using the sonic brush (*P* < 0.001).

Demographic/clinical measurement	Sonic brush $(n = 45)$	Novel O-R brush $(n = 45)$	Overall $(n = 90)$	P-value
Age (y)				
Mean (SD)	46.4 (14.19)	51.9 (12.82)	49.2 (13.72)	0.059
Minmax.	18-75	24-70	18-75	
Sex				
Female	39 (86.7%)	29 (64.4%)	68 (75.6%)	0.026
Male	6 (13.3%)	16 (35.6%)	22 (24.4%)	
Race	, , , , , , , , , , , , , , , , , , ,	× ,	× ,	
Asian	12 (26.7%)	17 (37.8%)	29 (32.2%)	0.336
Black or African American	11 (24.4%)	6 (13.3%)	17 (18.9%)	
Multi-racial	1 (2.2%)	0 (0.0%)	1 (1.1%)	
White/Caucasian	21 (46.7%)	22 (48.9%)	43 (47.8%)	
Smoker	× 7	х <i>г</i>	× ,	
No	44 (97.8%)	43 (95.6%)	87 (96.7%)	1.000
Yes	1 (2.2%)	2 (4.4%)	3 (3.3%)	

 Table 1 Baseline demographic characteristics

Whole-mouth gingivitis reduction efficacy

At baseline, the whole-mouth mean MGI score, mean GBI score, and mean number of bleeding sites did not differ significantly ($P \ge 0.497$) between the treatment groups (*Table 2*). Both toothbrush groups showed significant improvements from baseline on all three gingivitis assessments at week 8 (P < 0.001 for all). In the between-group ANCOVA comparisons at week 8, the O-R brush group showed significantly greater (P < 0.001) MGI reductions *versus* the sonic group, with adjusted mean changes from baseline of 0.437 *versus* 0.269, respectively. The O-R brush group also showed statistically significantly greater (P < 0.001) adjusted mean changes from baseline at week 8 compared to the sonic group for GBI (0.174 *vs.* 0.115) and mean number of bleeding sites (23.6 *vs.* 14.8).

Plaque reduction efficacy

The plaque measures (whole mouth RMNPI, gingival margin RMNI, and proximal RMNPI) were not significantly different between treatment groups at baseline ($P \ge 0.130$; *Table 3*). All three plaque measures were significantly improved from baseline for both

treatment groups at week 8 (P < 0.001 for all). However, at week 8, the O-R brush group was found to have statistically significantly greater ($P \le 0.011$) adjusted mean changes from baseline than the sonic brush group in whole mouth plaque (0.158 *vs.* 0.123), plaque in the proximal regions (0.458 *vs.* 0.324), and plaque along the gingival margin (0.058 *vs.* 0.039) in the between-group ANCOVA comparisons.

Safety

There were no adverse events reported during this study.

DISCUSSION

Consistent with studies demonstrating greater gingivitis and plaque reduction benefits of marketed O-R electric toothbrushes over marketed sonic toothbrushes^{8,10-20}, the current randomized controlled trial demonstrated that a novel O-R electric rechargeable toothbrush with micro-vibrations had greater efficacy *versus* a marketed sonic electric rechargeable toothbrush for reduction of gingivitis and plaque over an 8-week period in adult subjects. All three measures of

Table 2 Results for whole-mouth gingivitis efficacy endpoints at baseline and week 8

	Baseline mean (SD)*	Adjusted mean (SE) change from baseline [†]	Percent treatment difference relative to sonic [‡]	2-Sided <i>P</i> -value
MGI score				
Sonic brush	2.113 (0.087)	0.269 (0.0184)	_	< 0.001
Novel O-R brush	2.128 (0.116)	0.437 (0.0184)	62.5%	
GBI score				
Sonic brush	0.226 (0.128)	0.115 (0.0069)	_	< 0.001
Novel O-R brush	0.246 (0.167)	0.174 (0.0069)	51.3%	
Number of bleeding sites	× ,	X /		
Sonic brush	32.2 (15.26)	14.8 (0.78)	_	< 0.001
Novel O-R brush	33.4 (17.67)	23.6 (0.77)	59.5%	

*Baseline gingivitis measures did not differ significantly ($P \ge 0.497$) between treatment groups.

[†]Reductions *versus* baseline were statistically significant for all measures for both brushes (P < 0.001).

[‡]Percent treatment difference relative to sonic = 100 * (novel O-R – sonic)/sonic.

	Baseline mean (SD)*	Adjusted mean (SE) change from baseline [†]	Percent treatment difference relative to sonic [‡]	2-Sided P-value
Whole-mouth RMNPI				
Sonic brush	0.607 (0.039)	0.123 (0.0073)	_	< 0.001
Novel O-R brush	0.603 (0.043)	0.158 (0.0073)	28.5%	
Gingival margin RMNPI	× ,	× ,		
Sonic brush	1.000(0.001)	0.039 (0.0053)	_	0.011
Novel O-R brush	0.999 (0.003)	0.058 (0.0053)	48.7%	
Proximal region RMNPI	(, , , , , , , , , , , , , , , , , , ,	,		
Sonic brush	0.976 (0.049)	0.324 (0.0234)	_	< 0.001
Novel O-R brush	0.990 (0.031)	0.458 (0.0234)	41.4%	

Table 3 Results for whole-mouth plaque efficacy endpoints at baseline and week 8

*Baseline plaque measures did not differ significantly ($P \ge 0.130$) between treatment groups.

[†]Reductions *versus* baseline were statistically significant for all measures for both brushes (P < 0.001).

^{*}Percent treatment difference relative to sonic = 100 * (novel O-R – sonic)/sonic.

gingivitis were significantly improved at week 8 in the O-R brush group compared with the sonic group, by 62.5% for the adjusted mean MGI score, 51.3% for the adjusted mean GBI score, and 59.5% for the adjusted mean number of bleeding sites. Similarly, all three plaque measures showed greater improvements at week 8 in the O-R brush group than in the sonic brush group, by 28.5% for the whole-mouth plaque, 48.7% for plaque along the gingival margin, and 41.4% for plaque in the proximal regions.

The benefits seen with the novel O-R brush in the current study are consistent with, or more pronounced than, those from previous studies demonstrating improved plaque and gingivitis reduction with marketed O-R brushes when compared with marketed sonic brushes^{8,10-20}. For example, a review of six head-to-head clinical trials involving 462 subjects found that O-R brushes had significantly superior plaque removal benefits compared to sonic brushes on the order of 18-34% greater on lingual surfaces, 32-49% greater on lingual proximal surfaces, 32% greater in lingual mandibular regions, and 31% greater in lingual mandibular anterior regions¹⁹. The benefits of an O-R electric brush are even apparent when an entry-level marketed O-R brush model is compared with a premium marketed sonic brush, as shown in recent randomized 8-week studies^{13,14}.

Recently, the AAP and the EFP workgroup revised the criteria for the classification of gingivitis status as 'healthy' or 'not healthy'²⁷. The current study found that, although all subjects had a gingivitis classification status of 'not healthy' at baseline, by week 8, 84% of the novel O-R brush group were classified as 'healthy' compared with only 53% of the sonic brush group. In the logistic regression analysis, the odds of transitioning from 'not healthy' at baseline to 'healthy' at week 8 was 4.75 times higher when using the novel O-R brush than when using the sonic brush, a highly significant difference. This finding has important clinical relevance for patients and dental professionals given the deleterious effects of periodontal disease on overall health and quality of life. For example, gingivitis is associated with discomfort and difficulties performing oral hygiene while long-standing bleeding on probing is associated with greater attachment loss and greater risk of tooth loss over time^{2,28,29}.

Additional longitudinal studies would be useful to further assess long-term relative efficacy. Future comparative studies of these toothbrushes could evaluate quality of life measures and/or gingival health transitions among special populations. The impact of interactive technology on compliance and brushing behaviour is another potential area of study.

CONCLUSIONS

Use of a novel O-R electric toothbrush with micro-vibrations produced improved reduction of gingivitis and plaque over an 8-week period in adult subjects with evidence of gingivitis and plaque at baseline when compared with use of a marketed sonic electric toothbrush. The benefits of the experimental, nextgeneration O-R brush over the sonic brush were on the order of 51.3-62.5% for gingivitis measurements and 28.5-48.7% for plaque measurements. Plaque reduction benefits were particularly pronounced in the hard-to-clean gingival margins and proximal regions. Further, the odds of transitioning from a gingivitis classification of 'not healthy' at baseline to 'healthy' at week 8 was 4.75 times higher when using the novel O-R brush than when using the sonic brush, a highly significant difference.

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Conflicts of interest

RA and JG are employees of The Procter & Gamble Company. CRG and JQ report no conflicts of interest.

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