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An 8-week randomized controlled trial comparing the effect of a novel oscillating-rotating toothbrush *versus* a manual toothbrush on plaque and gingivitis

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Purpose: To compare a novel oscillating-rotating (O-R) electric rechargeable toothbrush with micro-vibrations (Oral-B iO) to a manual brush for gingivitis and plaque reduction. **Methods:** Adult subjects with gingivitis and plaque were randomized to use either the O-R or the manual toothbrush with standard fluoride dentifrice twice daily. Efficacy was assessed at baseline, week 1, and week 8 using the Rustogi Modification of the Navy Plaque Index (RMNPI), Modified Gingival Index (MGI), and Gingival Bleeding Index (GBI). Gingivitis status ('healthy'/'not healthy') was also assessed, per the American Academy of Periodontology/European Federation of Periodontology criteria. **Results:** One hundred and ten subjects were enrolled and completed the randomized controlled trial. The baseline mean number (SD) of bleeding sites for all subjects was 32.11 (16.703). At week 8, 82% of subjects using the O-R toothbrush were categorized as 'healthy' (<10% bleeding sites), *versus* 24% of subjects using the manual brush ($P < 0.001$). Subjects using the O-R toothbrush showed statistically significantly greater reductions ($P < 0.001$) in the number of bleeding sites, GBI scores and MGI scores *versus* those using a manual toothbrush as early as 1 week and throughout the 8-week study. The O-R toothbrush also provided statistically significantly greater reductions ($P < 0.001$) in all plaque measures, including subregions, *versus* the manual toothbrush after a single brushing and at weeks 1 and 8. **Conclusions:** The novel O-R electric toothbrush with micro-vibrations provided statistically significantly greater plaque and gingivitis reductions *versus* a manual toothbrush, with performance benefits demonstrated after a single brushing and continuing throughout the 8-week study.

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

INTRODUCTION

Periodontal disease is highly prevalent in the United States, with up to 90% of adults reported to have gingivitis and nearly 50% of adults estimated to have periodontitis[1-3]. The development of periodontal disease is initiated through a host immune response to the oral bacteria present in dental plaque[4,5]. The plaque-host interaction can be mediated by daily plaque control through at-home dental hygiene[6].

Clinical evidence has shown that electric (i.e. power) toothbrushes are superior to manual toothbrushes for gingivitis reduction and plaque removal[7-10]. These findings are corroborated by a recent long-term observational study which found consumers using an electric toothbrush retained 20% more teeth over an 11-year period than manual toothbrush users[11]. Two major categories of electric toothbrushes currently available are oscillating-rotating (O-R) and sonic, and direct comparisons have shown that O-R brushes provide greater gingivitis reduction and plaque removal benefits over sonic brushes[9,12-16].

Recently, a novel O-R toothbrush has been developed that incorporates micro-vibrations to represent the next generation in O-R toothbrushes (Oral-B iO). The novel brush design uses a linear magnetic drive, allowing energy to be directed to the bristles as an effective site for plaque removal. A by-product of the novel design is a quieter sound than previous models of O-R toothbrushes, which may be preferred by a subset of consumers because sound can be polarizing[17]. This clinical trial was conducted to evaluate and compare this novel O-R electric brush to a standard manual brush for gingivitis and plaque reduction over 8 weeks in adults with evidence of gingivitis and plaque accumulation.

METHODS

Study objective

The objective of this randomized, examiner-blind, parallel-group study was to compare the efficacy of a novel O-R electric rechargeable toothbrush with a round brush head to that of a standard soft manual toothbrush for reduction of gingivitis and plaque over an 8-week period in adult subjects with evidence of 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 and was registered with clinicaltrials.gov (NCT# NCT03624647). Institutional review and approval were obtained for the study protocol and informed consent form (Veritas IRB; approval number 16257). All participants provided written informed consent.

Assessments and outcomes

The Modified Gingival Index (MGI) and the Gingival Bleeding Index (GBI) were used to measure gingivitis[16,18,19]. Rustogi Modification of the Navy Plaque Index (RMNPI) was employed to measure plaque on up to 28 teeth (excluding third molars, crowns, and surfaces with cervical restorations)[16,20].

Investigational products

Subjects received either the O-R electric rechargeable toothbrush with micro-vibrations and round brush head (Oral-B iO with Ultimate Clean brush head, M7/OC15; Procter & Gamble, Cincinnati, OH) or a soft ADA manual toothbrush (Chicago, IL). All subjects received standard Crest Cavity Protection dentifrice with 0.243% sodium fluoride (0.15% w/v fluoride ion; Procter & Gamble).

Eligibility criteria

All Sum Research Center Ltd. (Mississauga, Ontario, Canada) recruited subjects between July and September 2019. Eligibility was limited to generally healthy adults 18 years of age or older who typically use a manual toothbrush as part of their at-home, usual dental hygiene regimen. Subjects must have had at least 16 natural teeth with facial and lingual scorable surfaces, a baseline pre-brushing MGI score of at least 1.75, a baseline pre-brushing RMNPI score of >0.5, and a baseline pre-brushing number of bleeding sites (sites with a GBI score of 1 or 2) of at least 20. Exclusion criteria included the need for antibiotic treatment prior to dental treatment; severe periodontal disease; active treatment for periodontitis, cancer, or a seizure disorder; 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. During the study period, enrolled 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-center, examiner-blind, parallel-group clinical trial with study visits at baseline, week 1, and week 8. Before the baseline visit, subjects were instructed to perform their typical oral hygiene routine with two stipulations. First, at least 12 hours were to elapse between the evening oral hygiene routine on the day before the baseline visit and the at-home morning brushing on the day of the baseline visit. Second, subjects were instructed to abstain from performing oral hygiene, eating, drinking, chewing gum, or using tobacco for 3–6 hours prior to coming to the clinic. Small sips of water were allowed up until 45 minutes prior to the visit.

During the study 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 soft tissue assessment and MGI and GBI evaluations by an experienced examiner[12,16,21,22]. After the gingival assessments were completed, 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. A RMNPI plaque assessment was conducted by the experienced examiner[12,16,21,22].

Qualifying subjects were stratified based on average MGI score (≤2.1 *vs.* >2.1), whole-mouth mean RMNPI (≤0.62 *vs.* >0.62), average number of total bleeding sites (≤28.0 *vs.* >28.0), and tobacco use (present or absent). Subject randomization was 1:1 according to a computer-generated schedule the study sponsor provided; participants were assigned approximately equally to each treatment group within each of the specified strata. The randomization process and the distribution of test products were conducted by site personnel in a protected area that ensured blinding of the examiner.

After randomization, subjects received a kit box containing their assigned toothbrush (novel O-R electric toothbrush or a soft manual toothbrush) and standard sodium fluoride dentifrice. Subjects were given

supervised oral hygiene instructions and product usage instructions. Assigned products were to be used twice per day for approximately 8 weeks. Subjects brushed according to the provided usage instructions (manufacturer's instructions for the O-R electric toothbrush and customary manner for the manual toothbrush) with their assigned toothbrush and toothpaste without observation in front of a mirror. After subjects completed brushing, the plaque disclosing procedure described above was conducted and a post-brushing RMNPI plaque assessment was performed by the experienced examiner.

The week 1 visit was conducted 7 ± 2 days from the baseline visit at approximately the same time as the baseline visit. Subjects refrained from brushing their teeth for 12 hours prior to their morning brushing at week 1. Subjects were to refrain from performing oral hygiene, eating, drinking, chewing gum, or using tobacco for 3–6 hours prior to the afternoon visit. Small sips of water were permitted until 45 minutes prior to the appointment. At the visit, continuance criteria were assessed and recorded. Subjects then received pre-brushing OST, MGI, and GBI assessments, in that order, by the experienced examiner. Next, the plaque disclosing procedure described above was conducted, and a pre-brushing RMNPI plaque assessment was performed by the experienced examiner.

Subjects refrained from brushing their teeth for 12 hours prior to their at-home morning brushing at week 8. The week 8 visit was conducted at approximately the same time as the baseline and week 1 afternoon visits. Subjects were also instructed to abstain from performing oral hygiene, eating, drinking, chewing gum, or using tobacco for 3–6 hours prior to the week 8 visit. Small sips of water were allowed up until 45 minutes prior to the visit. Subjects returned to the site and brought their test products. Continuance criteria were assessed and recorded. Subjects then received an oral soft tissue examination and MGI and GBI assessments, in that order, by the experienced examiner. Next, the plaque disclosing procedure described above was conducted, and an RMNPI plaque assessment was performed by the experienced examiner. Finally, subjects returned their assigned toothbrush and toothpaste.

Safety

Safety was assessed at each study visit. Safety event data were 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 product related.

Statistical analysis

Power analyses were conducted with $\alpha = 0.05$, using a 2-sided test and a sample size of 55 subjects per group. Assuming the variability of whole-mouth MGI is 0.092, a sample size of 55 subjects per group was to provide 90% power to detect a difference in MGI mean scores of 0.058 units between treatments. Assuming the variability in number of bleeding sites is 3.49, a sample size of 55 subjects per group was to provide at least 90% power to detect a difference in number of bleeding sites of at least 2.18 units between treatments. Similarly, for plaque, assuming the variability of whole-mouth RMNPI is 0.041, a sample size of 55 subjects per group was to provide at least 90% power to detect a difference in RMNPI mean scores of 0.026 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) criteria[23] (e.g. ≥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 chi-square test. A logistic regression analysis was carried out on the week 8 bleeding data to compute the odds ratio of transitioning from 'not healthy' (≥10% bleeding sites) to 'generally healthy' (<10% bleeding sites).

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 1 and baseline minus week 8). The within-treatment difference from baseline gingivitis scores (MGI, GBI, number of bleeding sites) was tested *versus* zero using an ANCOVA model with the respective baseline score as the covariate. ANCOVA was also performed separately by week to determine treatment differences on the whole-mouth average gingivitis reduction with the respective baseline gingivitis score as the covariate.

Whole-mouth, single-brushing plaque reductions from the baseline visit (pre-brushing minus post-brushing) were analyzed for treatment differences using an ANCOVA with the whole-mouth, pre-brushing RMNPI score as the covariate. Similar analyses were carried out for gingival margin and proximal RMNPI scores. Whole-mouth, multiple-brushing plaque reduction analyses were based on the average whole-mouth, pre-brushing RMNPI change from baseline score at each post-baseline visit (baseline pre-brushing minus week post score). Plaque reductions at week 1 and week 8 were analyzed for treatment differences using an ANCOVA with the baseline whole-mouth, pre-brushing RMNPI score as the covariate.

Table 1 Baseline demographics

Demographic characteristic	Manual toothbrush ($n = 55$)	Novel O-R electric toothbrush ($n = 55$)	Overall ($n = 110$)	*P*-value
Age (y)				
Mean (SD)	48.3 (15.8)	46.1 (12.8)	47.2 (14.3)	0.415
Min.–Max.	19–83	18–69	18–83	
Ethnicity				
Hispanic or Latino	2 (4%)	2 (4%)	4 (4%)	1.000
Not Hispanic or Latino	53 (96%)	53 (96%)	106 (96%)	
Race				
Asian	7 (13%)	9 (16%)	16 (15%)	0.301
Black or African American	14 (25%)	15 (27%)	29 (26%)	
Multi-Racial	0 (0%)	4 (7%)	4 (4%)	
Native Hawaiian or other Pacific Islander	2 (4%)	2 (4%)	4 (4%)	
White/Caucasian	32 (58%)	25 (45%)	57 (52%)	
Sex				
Female	40 (73%)	37 (67%)	77 (70%)	0.533
Male	15 (27%)	18 (33%)	33 (30%)	

Table 2 Between-group comparison of 'healthy' *versus* 'not healthy' gingivitis status[23] at weeks 1 and 8 (all subjects were classified as 'not healthy' at baseline)

	'Not healthy' *n* (%)	'Healthy' *n* (%)	*P*-value (manual brush *vs.* novel O-R electric brush)
Week 1			
Manual brush	54 (98.2%)	1 (1.8%)	0.008
Novel O-R electric brush	46 (83.6%)	9 (16.4%)	
Week 8			
Manual brush	42 (76.4%)	13 (23.6%)	<0.001
Novel O-R electric brush	10 (18.2%)	45 (81.8%)	

Similar analyses were carried out for gingival margin and proximal RMNPI scores. The lingual surfaces of the gingivitis and plaque endpoints were analyzed separately for treatment differences as described above.

To assess the consistency of plaque removal between buccal and lingual surfaces during a single-brushing session, an analysis of the whole-mouth RMNPI lingual minus buccal difference score was carried out for the single-brushing plaque endpoint.

All treatment comparisons were two-sided tests with an $\alpha = 0.05$ significance level. Multiple comparison adjustments were not carried out.

RESULTS

Study population

One hundred and ten subjects (77 females and 33 males) were enrolled. All of the enrolled subjects were randomized and completed the study. The mean (SD) age was 47.2 (14.3) years. Demographic characteristics are shown in *Table* 1.

Gingival health status

At baseline, all subjects had a gingivitis status classified as 'not healthy' according to the AAP/EFP guidelines[23] (e.g. ≥10% bleeding sites or at least 15 bleeding sites for 150 gradable sites). At week 1, the novel O-R electric brush group had a significantly higher number of 'healthy' subjects than the manual brush group (16.4% *vs.* 1.8%, $P = 0.008$) (*Table* 2). This difference was pronounced at week 8 (81.8% *vs.* 23.6%; $P < 0.001$). A logistic regression analysis found that the odds of transitioning from 'not healthy' (≥10% bleeding sites) at baseline to 'healthy' (<10% bleeding sites) gingivitis status at week 8 was 14.5 times higher when using the electric brush than when using the manual brush.

Whole-Mouth gingivitis reduction efficacy

At baseline, the mean number of bleeding sites, mean GBI score, and whole-mouth mean MGI score did not differ significantly ($P \geq 0.219$) between the treatment groups (*Table* 3). Both toothbrush groups showed significant improvements from baseline on all three measures at both week 1 and week 8 ($P < 0.002$). Between-group comparisons were statistically significant for all 3 measures, favoring the electric brush group, as early as week 1 and sustained at week 8 ($P < 0.001$ for all). The electric brush group showed statistically significantly greater adjusted mean changes from baseline at week 8 compared to the

Table 3 Results for whole-mouth gingivitis efficacy endpoints

	Baseline (SD)*	Adjusted mean (SE) change from baseline†	Ratio *vs.* manual brush‡	2-Sided *P*-value
MGI Score				
Week 1				
Manual brush	2.159 (0.124)	0.024 (0.007)	–	<0.001
Novel O-R electric brush	2.136 (0.111)	0.089 (0.011)	3.71	
Week 8				
Manual brush	2.159 (0.124)	0.121 (0.012)	–	<0.001
Novel O-R electric brush	2.136 (0.111)	0.356 (0.019)	2.94	
GBI score				
Week 1				
Manual brush	0.246 (0.175)	0.010 (0.003)	–	<0.001
Novel O-R electric brush	0.213 (0.123)	0.030 (0.003)	3.00	
Week 8				
Manual brush	0.246 (0.175)	0.048 (0.004)	–	<0.001
Novel O-R electric brush	0.213 (0.123)	0.144 (0.007)	3.00	
Number of bleeding sites				
Week 1				
Manual brush	34.073 (18.746)	1.356 (0.398)	–	<0.001
Novel O-R electric brush	30.145 (14.280)	3.607 (0.330)	2.66	
Week 8				
Manual brush	34.073 (18.746)	6.662 (0.592)	–	<0.001
Novel O-R electric brush	30.145 (14.280)	19.257 (0.673)	2.89	

*Baseline gingivitis measures did not differ significantly ($P \geq 0.219$) between treatment groups.
†Reductions *versus* baseline were statistically significant at all time points for all measures for the manual brush ($P < 0.002$) and electric brush ($P < 0.001$).
‡Ratio = novel electric brush/manual brush.

manual group for MGI (0.356 *vs.* 0.121), GBI (0.144 *vs.* 0.048), and mean number of bleeding sites (19.257 *vs.* 6.662).

Lingual and molar gingivitis reduction efficacy

The baseline mean MGI and GBI scores on the lingual surfaces were not significantly different between treatment groups, but there was a significant difference between the treatment groups in the baseline mean number of bleeding sites on the lingual surfaces with the manual brush group having more lingual bleeding sites than the electric brush group (23.4 *vs.* 18.9; $P = 0.022$). Both brush groups had significant improvements from baseline at week 1 and week 8 for all three gingivitis measurements on the lingual surfaces, with $P \leq 0.011$ on all measurements for the manual brush group and $P < 0.001$ on all measurements for the electric brush group. For the between-group comparisons, there were significant differences seen at both week 1 ($P \leq 0.037$ for all) and week 8 ($P < 0.001$ for all) favoring the electric brush group for all lingual gingivitis measures.

In the molar regions, the baseline mean MGI score, mean GBI score, and mean number of bleeding sites did not differ significantly between the treatment groups (*Table* 4). At week 1, the electric brush group had significant improvements from baseline for all measures in the molar region ($P < 0.014$) while the manual brush group did not ($P \geq 0.314$). However, at week 8, both toothbrush groups showed significant improvements from baseline for all three measurements in the molar region ($P < 0.001$). For the between-group comparisons, the electric brush group showed significantly greater gingivitis reductions in the molar measurements than the manual group (*Table* 4) at week 1 ($P < 0.049$ for all) and week 8 ($P < 0.001$ for all).

Plaque reduction efficacy with a single brushing

The whole-mouth mean RMNPI scores were not significantly different between treatment groups at baseline (*Table 5*), nor were the proximal or gingival margin mean RMNPI scores ($P \geq 0.608$ for all). As shown in *Table 5*, after a single brushing at the baseline visit, the electric brush group had significantly greater adjusted mean plaque removal in the whole mouth (0.474 *vs.* 0.332), in the proximal regions (0.822 *vs.* 0.591), and along the gingival margin (0.697 *vs.* 0.461) compared to the manual brush group ($P < 0.001$ for all). Similar results were seen for whole-mouth, proximal, and gingival margin mean RMNPI scores on the lingual surfaces and in the molar regions (*Table 5*).

Plaque reduction efficacy at week 1 and week 8

When assessing treatments after only 1 week of brushing, the electric brush was found to have significantly greater plaque removal in the whole mouth (0.104 *vs.* 0.046), in the proximal regions (0.185 *vs.* 0.071), and along the gingival margin (0.045 *vs.* 0.011) compared to the manual brush ($P \leq 0.002$). Significantly greater

Table 4 Results for molar gingivitis efficacy endpoints

	Baseline (SD)*	Adjusted mean (SE) change from baseline†	Ratio *vs*. manual brush‡	2-Sided *P*-value
MGI				
Week 1				
Manual brush	2.251 (0.150)	0.002 (0.016)	–	0.048
Novel O-R electric brush	2.242 (0.179)	0.047 (0.016)	23.50	
Week 8				
Manual brush	2.251 (0.150)	0.072 (0.013)	–	<0.001
Novel O-R brush	2.242 (0.179)	0.223 (0.024)	3.10	
GBI				
Week 1				
Manual brush	0.358 (0.182)	0.002 (0.004)	–	0.001
Novel O-R electric brush	0.355 (0.181)	0.023 (0.005)	11.50	
Week 8				
Manual Brush	0.358 (0.182)	0.029 (0.006)	–	<0.001
Novel O-R electric brush	0.355 (0.181)	0.189 (0.012)	6.52	
Number of bleeding sites				
Week 1				
Manual brush	13.273 (6.193)	0.121 (0.141)	–	0.002
Novel O-R electric brush	12.018 (4.844)	0.732 (0.130)	6.05	
Week 8				
Manual brush	13.273 (6.193)	1.008 (0.243)	–	<0.001
Novel O-R electric brush	12.018 (4.844)	6.133 (0.423)	6.08	

*Baseline gingivitis measures in the molar region did not differ significantly ($P \geq 0.239$) between treatment groups.
†Reductions *versus* baseline were statistically significant in all regions only at week 8 for the manual brush ($P < 0.001$) and at both weeks 1 ($P < 0.014$) and 8 ($P < 0.001$) for the electric brush.
‡Ratio = novel electric brush group/manual brush.

Table 5 Change from pre-brushing baseline mean RMNPI scores at the baseline post-brushing assessment (single brushing)

	Baseline (SD)*	Adjusted mean (SE) change from pre-brushing baseline	Ratio *vs*. manual brush†	2-Sided *P*-value
Whole mouth				
Manual brush	0.616 (0.035)	0.332 (0.010)	–	<0.001
Novel O-R electric brush	0.620 (0.044)	0.474 (0.008)	1.43	
Whole-mouth proximal				
Manual brush	1.000 (0.000)	0.591 (0.017)	–	<0.001
Novel O-R electric brush	1.000 (0.000)	0.822 (0.013)	1.39	
Whole-mouth gingival margin				
Manual brush	1.000 (0.000)	0.461 (0.017)	–	<0.001
Novel O-R electric brush	1.000 (0.000)	0.697 (0.016)	1.51	
Lingual surfaces				
Whole mouth				
Manual brush	0.620 (0.036)	0.226 (0.015)	–	<0.001
Novel O-R electric brush	0.618 (0.040)	0.421 (0.011)	1.86	
Proximal				
Manual brush	1.000 (0.000)	0.435 (0.027)	–	<0.001
Novel O-R electric brush	1.000 (0.000)	0.763 (0.018)	1.75	
Gingival margin				
Manual brush	1.000 (0.000)	0.267 (0.024)	–	<0.001
Novel O-R electric brush	1.000 (0.000)	0.589 (0.020)	2.21	
Molar surfaces				
Whole mouth				
Manual brush	0.648 (0.043)	0.163 (0.012)	–	<0.001
Novel O-R electric brush	0.651 (0.047)	0.311 (0.016)	1.91	
Proximal				
Manual brush	1.000 (0.000)	0.232 (0.026)	–	<0.001
Novel O-R electric brush	1.000 (0.000)	0.520 (0.033)	2.24	
Gingival margin				
Manual brush	1.000 (0.000)	0.127 (0.017)	–	<0.001
Novel O-R electric brush	1.000 (0.000)	0.331 (0.031)	2.61	

*Baseline plaque measures did not differ significantly ($P \geq 0.608$) between treatment groups.
†Ratio = novel electric O-R brush/manual brush.

Table 6 Mean RMNPI scores at the week 1 and week 8 assessments

	Baseline (SD)*	Week 1			Week 8		
		Adjusted mean (SE) change from pre-brushing baseline	Ratio *vs.* manual brush[†]	2-Sided *P*-value	Adjusted mean (SE) change from pre-brushing baseline	Ratio *vs.* manual brush[b]	2-Sided *P*-value
Whole mouth							
Manual brush	0.616 (0.35)	0.046 (0.005)	–	<0.001	0.060 (0.004)	–	
Novel O-R electric brush	0.620 (0.044)	0.104 (0.008)	2.26		0.152 (0.005)	2.53	<0.001
Whole-mouth proximal							
Manual brush	1.000 (0.000)	0.071 (0.010)	–	<0.001	0.114 (0.013)	–	
Novel O-R electric brush	1.000 (0.000)	0.185 (0.021)	2.61		0.364 (0.023)	3.19	<0.001
Whole-mouth gingival margin							
Manual brush	1.000 (0.000)	0.011 (0.002)	–	0.002	0.008 (0.002)	–	
Novel O-R electric brush	1.000 (0.000)	0.045 (0.010)	4.09		0.050 (0.005)	6.25	<0.001
Lingual surfaces							
Whole mouth							
Manual brush	0.620 (0.036)	0.022 (0.006)	–	<0.001	0.049 (0.004)	–	
Novel O-R electric brush	0.618 (0.040)	0.072 (0.007)	3.27		0.129 (0.007)	2.63	<0.001
Proximal							
Manual brush	1.000 (0.000)	0.024 (0.008)	–	<0.0001	0.081 (0.014)	–	
Novel O-R electric brush	1.000 (0.000)	0.112 (0.019)	4.67		0.306 (0.027)	3.78	<0.001
Gingival margin							
Manual brush	1.000 (0.000)	0.004 (0.002)	–	0.017	0.003 (0.002)	–	
Novel O-R electric brush	1.000 (0.000)	0.019 (0.006)	4.75		0.034 (0.005)	11.33	<0.001
Molar surfaces							
Whole mouth							
Manual brush	0.648 (0.043)	0.039 (0.004)	--	<0.001	0.052 (0.004)	–	
Novel O-R electric brush	0.651 (0.047)	0.077 (0.006)	1.97		0.099 (0.005)	1.90	<0.001
Proximal							
Manual brush	1.000 (0.000)	0.002 (0.002)	–	0.005	0.022 (0.007)	–	
Novel O-R electric brush	1.000 (0.000)	0.043 (0.014)	21.5		0.112 (0.018)	5.09	<0.001
Gingival margin							
Manual brush	1.000 (0.000)	0	–	0.031	0	–	
Novel O-R electric brush	1.000 (0.000)	0.010 (0.005)	>18		0.003 (0.001)	>18	0.004

*Baseline plaque measures did not differ significantly ($P > 0.320$) between treatment groups.
[†]Ratio = novel electric O-R brush/manual brush.

plaque reduction benefits ($P < 0.001$) for the electric brush continued in all regions after 8 weeks. Similar results were seen for whole-mouth, proximal, and gingival margin mean RMNPI scores on the lingual surfaces and in the molar regions at weeks 1 and 8 (*Table* 6).

Safety

No adverse events were reported.

DISCUSSION

This randomized, examiner-blind, parallel-group study demonstrated that use of a novel O-R electric toothbrush with micro-vibrations and a round brush head 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 standard manual toothbrush. Plaque reduction benefits were apparent after a single-brushing episode, with the electric brush group showing significantly greater plaque removal in the whole mouth (by 1.4 times), in the proximal regions (by 1.4 times), and along the gingival margin (by 1.5 times) than the manual brush group. During the 8-week trial, plaque removal efficacy with the O-R electric brush continued to increase, with significantly greater plaque removal compared to the manual brush by 2.5 times in the whole mouth, by 3.2 times in the proximal regions, and by 6.3 times along the gingival margin. For all whole-mouth gingivitis efficacy endpoints at week 8, the electric brush group had significantly greater gingivitis reduction (by approximately three times) compared to the manual brush group. Consistent with other research reported in this issue[24], the O-R electric brush group showed an increase in brushing evenness as evidenced by superior benefits in hard-to-reach areas (e.g. lingual, molar regions). Both the O-R electric brush and the manual brush were well tolerated by subjects, with no adverse events.

The findings from this trial are consistent with earlier studies and meta-analyses involving thousands of subjects indicating greater plaque and gingivitis reduction benefits with an O-R electric brush compared with a manual brush[7-9]. A recent meta-analysis of sixteen Oral-B O-R electric toothbrush clinical trials, involving over 2,100 gingivitis subjects, showed that O-R electric toothbrushes provide statistically significant gingivitis

reductions irrespective of the subject's baseline disease level[25]. Collectively, these findings demonstrate benefits provided by O-R electric toothbrushes are generalizable to the representative population.

Although all subjects in this study had a baseline gingivitis status classified as 'not healthy'[23], by week 8 there were over three times as many subjects with a 'healthy' gingivitis status in the O-R electric brush group than in the manual brush group (81.8% *vs.* 23.6%). Improvement in gingival health is a highly relevant clinical finding. Long-standing bleeding on probing is associated with greater attachment loss and greater risk of tooth loss over time[11,26,27]. Furthermore, a number of studies have shown that even mild gingivitis can be associated with pain, discomfort, and difficulties performing oral hygiene[28-30]. Improvement in gingival health is thus associated with improvements in health-related quality of life[31,32].

As with all research, there are limitations to this study. While significant benefits were seen with the novel O-R electric brush *versus* the manual brush during this 8-week study, longer-term research would be useful to quantify benefits with further extended use. In addition, research among specific populations, such as studies done with earlier O-R models among orthodontic patients and implant patients[33-35], would provide additional insights to the plaque removal efficacy and gingival health benefits of the toothbrush when compared to use of control brushes. Finally, the role of interactive features with use of the novel O-R electric toothbrush will be evaluated in future research to understand if they provide improvements in brushing behavior seen with other interactive O-R toothbrushes[36,37].

CONCLUSIONS

Use of a novel O-R electric toothbrush with micro-vibrations produced improved reduction of gingivitis and plaque over 8 weeks in adults with evidence of gingivitis and plaque at baseline when compared with use of standard manual toothbrush. Plaque reduction benefits were apparent after a single-brushing episode and continued to increase over time. For gingival endpoints, there were over three times as many subjects with healthy gingiva in the novel electric brush group than in the manual brush group at week 8. Gingivitis reduction benefits were particularly pronounced in the hard-to-reach lingual surfaces and molar regions. Further studies of the novel electric brush are warranted.

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Conflicts of interest

J.G. and R.A. are employees of The Procter & Gamble Company. C.R.G. and J.Q. report no conflicts of interest.

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