A randomized controlled trial evaluating a novel oscillating-rotating electric toothbrush versus a sonic toothbrush for plaque and gingivitis

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Abstract: Purpose: To assess the relative efficacy of a new entry-tier oscillating-rotating (OR) electric toothbrush versus a sonic electric toothbrush over 4 weeks of use for plaque and gingivitis reduction. **Methods:** This single-center, examiner-blind, two-treatment, parallel-group, randomized clinical study enrolled adult participants who had evidence of gingivitis and plaque at baseline. Participants were randomly assigned to use either an entry-tier OR toothbrush (Oral-B iO2) with the Ultimate Clean brush head in Daily Clean mode or an advanced sonic toothbrush (usmile Marble-Art) used with the usmile Advanced Whitening brush head in Clean mode (and at the high-intensity level). Both groups brushed with a standard sodium fluoride dentifrice. Participants were assessed for gingivitis (Modified Gingival Index and the Gingival Bleeding Index) and plaque (Rustogi Modification of the Navy Plaque Index) at baseline and after 4 weeks of twice-daily use. Plaque was also assessed after a single use at baseline. **Results:** Both toothbrushes statistically significantly reduced gingivitis after 4 weeks of use and plaque after a single use and after 4 weeks ($P< 0.001$ for all). The OR toothbrush, relative to the sonic toothbrush, demonstrated a statistically significantly greater reduction in Modified Gingival Index score and number of bleeding sites ($P< 0.001$) and was associated with a significantly greater number of users transitioning from gingivitis to a state of gingival health (i.e., < 10% bleeding sites; $P= 0.038$) by the end of the study. The OR toothbrush likewise demonstrated greater efficacy with respect to plaque reduction after a single use (whole mouth, interproximal, and gingival margin; $P< 0.001$ for all) and after 4 weeks of use (whole mouth and interproximal; $P< 0.001$ for both). (*Am J Dent* 2025;38:3-8).

Clinical significance: The novel entry-tier OR toothbrush offers significantly greater plaque control and gingivitis reduction relative to the advanced sonic toothbrush model.

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Introduction

Poor oral hygiene leads to periodontal disease, a prevalent health challenge. According to the 2019 Global Burden of Disease Study, the burden of severe periodontitis is considerable and has increased over the past three decades.[1] This widespread problem can be traced to its initiating stage, gingivitis.[2] This inflammatory response is triggered by the accumulation of dental bacterial plaque,[2,3] which can easily and swiftly arise from inadequate oral hygiene.[3,4] As plaque accumulates, the oral microbiome shifts from predominantly gram positive to gram negative bacteria.[4,5] The combination of sheer bacterial accumulation and this microbial shift are associated with the persistent inflammation that characterizes gingivitis.[2] When the accumulated plaque is removed and the inflammatory trigger is quelled, the symptoms of gingivitis can be reversed, and hygiene maintenance can prevent its recurrence.[3]

A key to gingival health, therefore, is at-home, mechanical plaque removal via toothbrushing,[6,7] and the more effectively patients can control their dental plaque, the more they can expect their gingival health to improve.[8] The electric toothbrush was developed to improve upon traditional at-home plaque removal with a manual toothbrush. Population-based research also shows long-term oral health benefits for electric toothbrush users compared to their manual counterparts.[9] Among electric toothbrushes, those with an oscillating-rotating (OR) motion have demonstrated greater plaque removal and gingivitis control versus other electric (sonic) toothbrushes and manual toothbrushes.[10-15] Not only have OR toothbrushes been shown to be more clinically effective, but a recent meta-analysis shows they are preferred over sonic toothbrushes.[13]

In 2020, Procter & Gamble introduced an innovation in OR toothbrush technology with the Oral-B iO,[a] the most advanced OR model featuring a linear magnetic drive that produces an OR motion plus microvibrations.[16] In a recent meta-analysis, the Oral-B iO was shown to provide statistically significantly greater plaque control, bleeding site reduction, and the ability to transition users from a state of gingivitis (≥ 10% bleeding sites) to a state of gingival health (< 10% bleeding sites) compared to manual, sonic, and traditional OR toothbrushes.[11]

Most recently, a new iO model has been designed to appeal to users who habitually use a manual toothbrush but need improved plaque control. This new, entry-tier OR toothbrush has many features that could facilitate a comfortable transition from manual to an electric toothbrush, including a quieter sound than other electric models, one simple button that controls power and brushing mode, and three brushing modes. In the present study, this new OR brush was compared with an advanced sonic toothbrush to assess relative efficacy in gingivitis and plaque reduction over 4 weeks of use and plaque reduction after a single use.

Materials and Methods

Design summary and ethics statement - This was a single-center, examiner-blind, two-treatment, parallel-group, randomized study conducted over 6 weeks (May-June 2023), including 4 weeks of investigational product use, at Procter & Gamble Oral Health Science Center, Mason, Ohio, USA. The study protocol was reviewed and approved by Advarra IRB (Pro 00069023). The study is registered at ISRCTN13370721. The

Fig. 1. Test toothbrushes: Oral-B iO2 oscillating-rotating electric toothbrush (left) and usmile sonic toothbrush (right).

study was conducted following the US Code of Federal Regulations. All participants provided written informed consent.

Participants - Participants were healthy adults who had at least 16 scorable teeth and who mainly used a manual toothbrush for their daily oral care routine. All participants had gingivitis at baseline [a whole mouth Modified Gingival Index (MGI)[17] score of 1.75-2.5 and 10%-70% of scorable sites with a Gingival Bleeding Index (GBI)[18] score of 1 or 2] and a baseline Rustogi Modification of the Navy Plaque Index (RMNPI)[19] (plaque) score greater than 0.5. Inclusion in the study required that participants refrain from enrolling in any other oral care study, having elective dentistry, and using no study oral hygiene products (except regular flossers who were allowed to continue using dental floss) during the trial. Participants agreed also to refrain from at-home oral hygiene procedures for 12 hours before all study visits and to refrain from eating, drinking, or using medicated lozenges, breath mints, tobacco, or chewing gum for 4 hours before all study visits (except small sips of water allowed for up to 45 minutes before the study visit).

No participants were permitted who required prophylactic antibiotics or who were currently receiving treatment for periodontitis, cancer, or a seizure disorder. Participants were excluded if they had diabetes, severe periodontal disease, any carious lesions in need of restoration, orthodontic appliances, removable partial dentures, perioral piercings, or a pacemaker or other implanted device. Participants were also excluded if they had taken anti-inflammatory, anticoagulant, or antibiotic medication within the previous 2 weeks; if they had used chlorhexidine mouthrinse within the previous 2 weeks; if they had received dental prophylaxis within the previous 4 weeks; if they had received oral or gum surgery within the previous 2 months; or if they were pregnant or nursing.

Study procedures - At the screening visit, all participants provided written informed consent and medical history and demographic information. Following this, an experienced dental examiner[20,21] conducted a gingival health examination, and participants were then provided with instructions for continuing participation, including that they should maintain their current at-home oral care regimen without making any changes until the baseline of the study.

At the baseline visit, participants who met continuance criteria received an oral/perioral examination of hard and soft tissues, followed by pre-brushing MGI and GBI assessments, in that order. Next, participants' plaque was disclosed with TRACE disclosing solution[b]: participants rinsed for 15 seconds with 20 drops of disclosing solution diluted in 10 ml of water. A plaque assessment was performed after plaque disclosure.

Qualified participants were then stratified concerning toothbrush used at home (exclusively manual toothbrush vs. mixed manual and electric toothbrush), baseline MGI, pre-brushing RMNPI, number of bleeding sites, and tobacco use and randomly assigned to one of the two treatment groups based on a sponsor-provided, encoded assignment program. Group assignment and product distribution were conducted in a protected area to ensure the blinding of the examiner. Products were packaged in blind-labeled kit boxes. After receiving their study products, participants received written and verbal usage instructions, including the instruction to brush for 2 minutes twice daily according to each manufacturer's instructions for the duration of the study, and then performed their first brushing under supervision at the study site. After this first product use, participants received a post-brushing plaque examination according to the same protocol used for the pre-brushing examination.

At the week 4 visit, continuance criteria were reviewed, and participants received an oral exam and a final set of pre-brushing gingivitis and plaque examinations using the same study protocol. Participants returned their study products, and participants were dismissed from the study.

Treatments groups - A novel, entry-tier OR electric toothbrush [Oral-B iO2 (OP030) used with the Oral-B iO Ultimate Clean Brush Head[a] (OR015)] to operate in Daily Clean mode. This was compared with the usmile sonic electric toothbrush[c] [Marble-Art (U2S)] used with the usmile Advanced Whitening[c] brush head (Fig. 1). Sonic toothbrush users were instructed to use the brush in the "Clean" mode and at the "High" intensity level. All participants used regular fluoridated toothpaste (Crest Cavity Protection,[a] 0.243% sodium fluoride). Toothbrushes and toothpaste tubes were visually inspected upon product return for compliance monitoring.

Clinical assessments - At each visit, gingivitis was assessed first by MGI[17] and then by the number of bleeding sites (determined according to the standards of the GBI[18]). For the MGI score, six sites per tooth were assigned a score from 0 (no inflammation) to 4 (severe inflammation). These scores were

Table 1. Baseline demographics.

Demographic	Sonic brush (n=38)	OR brush (n=37)	Overall (n=75)	P-value
Age (Years)				
Mean (SD)	41.4 (15.44)	40.6 (14.23)	41.0 (14.76)	0.811[a]
Range	18 - 76	19 - 71	18 - 76	
Sex				
Female[b]	31 (81.6%)	26 (70.3%)	57 (76.0%)	0.289[c]
Male[b]	7 (18.4%)	11 (29.7%)	18 (24.0%)	
Race				
Black or African American[b]	10 (26.3%)	14 (37.8%)	24 (32.0%)	0.441[c]
Multiracial[b]	1 (2.6%)	2 (5.4%)	3 (4.0%)	
White/Caucasian[b]	27 (71.1%)	21 (56.8%)	48 (64.0%)	
Tobacco				
No[b]	35 (92.1%)	36 (97.3%)	71 (94.7%)	0.615[c]
Yes[b]	3 (7.9%)	1 (2.7%)	4 (5.3%)	

Abbreviations: OR, oscillating-rotating; SD, standard deviation.
[a] Two-sided ANOVA P-value for the treatment comparison.
[b] Data are presented as the number (percent) of participants in each category.
[c] Two-sided Fisher's exact test P-value for the treatment comparison.

Table 2. Baseline clinical measurements.

Clinical measurement	Sonic brush[a]	OR brush[b]	Overall	P-value
Mean (SD) MGI (whole mouth)	2.160 (0.1329)	2.166 (0.1097)	2.163 (0.1213)	0.839
Mean (SD) number of bleeding sites (whole mouth)	33.95 (20.283)	33.68 (15.783)	33.81 (18.081)	0.949
Mean (SD) RMNPI				
Whole mouth	0.666 (0.0565)	0.659 (0.0491)	0.663 (0.0527)	0.621
Interproximal	0.992 (0.0463)	1.000 (0.0000)	0.996 (0.0332)	0.334
Gingival margin	0.999 (0.0039)	1.000 (0.0000)	1.000 (0.0028)	NA

Abbreviations: MGI, Modified Gingival Index; NA, not applicable; RMNPI, Rustogi Modification of the Navy Plaque Index; SD, standard deviation.
[a] n = 38.
[b] n = 36 for MGI and RMNPI; n = 37 for number of bleeding sites.

summed and divided by the number of scorable sites to derive the whole mouth MGI score. For the GBI, six sites per tooth were probed and assigned a score from 0 (no bleeding after 30 seconds) to 2 (immediate bleeding). Sites with a score of 1 or 2 were counted as "bleeding sites." Scorable teeth were those without crowns, restorations that covered 50% or more of the tooth surface, and excluded bridges and third molars.

After the gingivitis assessment, plaque was assessed at 18 sites per tooth by the RMNPI (0 = no plaque; 1 = plaque present).[19] Plaque was assessed before and after brushing at the baseline visit, and before brushing at the week-4 visit. The mean plaque index was calculated by dividing the total number of plaque-containing areas by the total number of scorable sites. Scores were calculated for the whole mouth, the interproximal region, and the gingival margin. Single-brushing efficacy was assessed by comparing the pre-brushing RMNPI score with the post-brushing score at the same visit. Multiple-use efficacy was assessed by comparing the baseline pre-brushing score with the week-4 pre-brushing score. Scorable teeth were those without crowns or cervical restorations and excluded third molars. All assessments were performed by the same blinded examiner.

Safety assessments were conducted via oral examination of hard and soft tissue both before and after product use as well as Adverse Events (AEs) reported by the participant. An AE was recorded if a new abnormal finding was noted after treatment application, or any abnormal finding noted before treatment application increased in severity after treatment was applied.

Statistical analysis - Power analyses were conducted with $\alpha = 0.05$, using a two-sided test and a group size of 40 participants. Based on previous study data,[21,22] it was assumed that the change in the number of bleeding sites would have a variability of 3.05 and the change in whole mouth RMNPI would have a variability of 0.04. A group size of 40 participants was calculated to provide at least 80% power to detect a 1.9-unit between-treatment difference in the number of bleeding sites and a 0.025-unit between-treatment difference in RMNPI score. Demographic and baseline clinical data were analyzed using an analysis of variance (ANOVA) or two-sided Fisher's exact test.

The primary endpoint was the change in the number of bleeding sites from baseline to week 4. Secondary endpoints were the change in MGI from baseline to week 4, the change in pre-brushing whole mouth RMNPI from baseline to week 4, and the change in whole mouth RMNPI after single use. The interproximal region and the gingival margin were also assessed separately for plaque. The null hypothesis was that there would be no between-group difference for any of the gingivitis assessments or plaque assessments after adjusting for baseline values.

An analysis of covariance (ANCOVA), with the baseline score as covariate, was used to determine between-treatment differences in gingivitis reduction from baseline (whole mouth number of bleeding sites and MGI; baseline minus week 4). A

Table 3. Change from baseline results at week 4 for gingival health comparisons.[a]

	Adjusted Mean (SE) change from Baseline	% Treatment difference relative to Sonic[b]	Treatment comparison two-sided P-value
MGI Score (whole mouth)[c]			
Sonic	0.168 (0.0129)	NA	<0.001
OR	0.273 (0.0131)	62.6%	
Number of bleeding sites (whole mouth)[d]			
Sonic	11.47 (0.824)	NA	<0.001
OR	17.49 (0.835)	52.4%	

Abbreviations: MGI, Modified Gingival Index; NA, not applicable; OR oscillating-rotating; SE, standard error.
[a] ANCOVA model included baseline and treatment effects.
[b] Percent treatment difference relative to sonic = -100×(treatment difference/adjusted mean of sonic).
[c] Overall baseline mean = 2.162, error variance = 0.0062.
[d] Overall baseline mean = 33.38, error variance = 25.094.

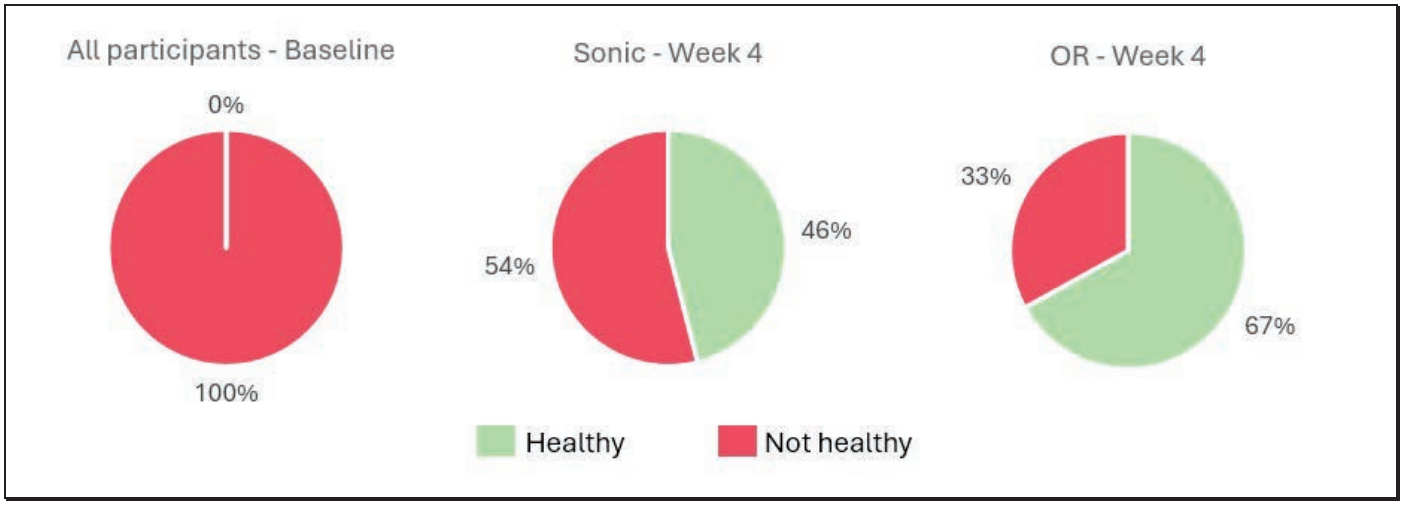

Fig. 2. Participants (%) classified as healthy vs nonhealthy at Baseline (all participants) and Week 4 (by treatment group). OR: oscillating-rotating. "Healthy" = less than 10% bleeding sites. "Not healthy" = 10% or more bleeding sites. P= 0.038 between treatments at Week 4.

paired difference t-test was used to test within-group changes from baseline versus zero.

An ANCOVA was used to assess multiple-brushing efficacy (baseline pre-brushing RMNPI minus week 4 pre-brushing RMNPI) with baseline pre-brushing RMNPI as the covariate. An ANCOVA was used to assess single-brushing efficacy (baseline pre-brushing RMNPI minus baseline post-brushing RMNPI) with pre-brushing RMNPI as the covariate. Multiple-brushing and single-brushing analyses were performed for the whole mouth, the interproximal region, and the gingival margin.

All statistical tests ($\alpha = 0.05$) were two-sided.

Results

The study enrolled 164 participants. Of these, 81 participants were screen failures, eight dropped before baseline, 75 met entrance criteria and were randomized to treatment (38 in the sonic group and 37 in OR group), and one participant dropped after randomization. Seventy-four participants completed the study, and one participant was excluded for noncompliance with study procedures and was not included in the efficacy analyses.

Participants' mean age was 41 years (range 18-76 years), and the female-to-male distribution was 76% to 24%, respectively. Demographic characteristics and clinical measurements at baseline were balanced between the treatment groups (P≥ 0.289) (Tables 1, 2).

Gingivitis reduction - By week 4, both treatment groups demonstrated a statistically significant reduction of adjusted mean whole mouth MGI score and whole mouth number of bleeding sites (P< 0.001 for both). The MGI reduction benefit was 62.6% greater with the OR brush than with the sonic brush (P< 0.001). The bleeding site reduction benefit was 52.4% greater with the OR brush than with the sonic brush (P< 0.001) (Table 3). Additionally, the OR brush group, compared with the sonic brush group, had a statistically significantly greater number of participants transitioning from a baseline "unhealthy" gingival status (≥ 10% bleeding sites) to a "healthy" gingival status (< 10% bleeding sites) by the conclusion of the study (P= 0.038) (Fig. 2).

Plaque reduction - By week 4, both brushes produced a statistically significant reduction in whole mouth and interproximal RMNPI scores relative to baseline (P< 0.001 for both). The OR brush demonstrated statistically significantly greater efficacy versus the sonic brush, producing a 42.1% greater reduction in whole mouth RMNPI and a 159% greater reduction in interproximal RMNPI (P< 0.001 for both) after 4 weeks of use (Table 4).

Both groups produced a statistically significant reduction in whole mouth, interproximal, and gingival margin plaque after a single brushing (P< 0.001 for all). The OR brush demonstrated statistically significantly greater efficacy versus the sonic brush, producing a 19.3% greater reduction in whole mouth RMNPI, a 21.4% greater reduction in interproximal RMNPI, and a 19.6% greater reduction in gingival margin RMNPI (P< 0.001 for all) (Table 4).

Table 4. Change from baseline results for RMNPI plaque efficacy endpoints.

	Adjusted Mean (SE) change from Baseline	% Treatment difference relative to Sonic[a]	Treatment comparison two-sided P-value
Whole mouth RMNPI score[b]			
Single brushing[c]			
Sonic	0.436 (0.0128)	NA	<0.001
OR	0.520 (0.0131)	19.3%	
Week 4[d]			
Sonic	0.089 (0.0044)	NA	<0.001
OR	0.127 (0.0045)	42.1%	
Interproximal RMNPI Score[e]			
Single brushing[f]			
Sonic	0.706 (0.0201)	NA	<0.001
OR	0.856 (0.0206)	21.4%	
Week 4[g]			
Sonic	0.081 (0.0181)	NA	<0.001
OR	0.210 (0.0184)	159.0%	
Gingival Margin RMNPI Score[e]			
Single brushing[h]			
Sonic	0.593 (0.0212)	NA	<0.001
OR	0.709 (0.0218)	19.6%	

Abbreviations: NA, not applicable; OR, oscillating-rotating; RMNPI, Rustogi Modification of the Navy Plaque Index; SE, standard error.
[a] Percent treatment difference relative to sonic = -100×(treatment difference/adjusted mean of sonic).
[b] ANCOVA model included baseline and treatment effects.
[c] Overall baseline mean = 0.663, error variance = 0.0062.
[d] Overall baseline mean = 0.661, error variance = 0.0007.
[e] ANOVA model included treatment effect.
[f] Overall baseline mean = 0.996, error variance = 0.0153.
[g] Overall baseline mean = 0.996, error variance = 0.0121.
[h] Overall baseline mean = 1.000, error variance = 0.0171.

Safety - Both treatments were well tolerated. One AE, mild and not related to treatment, was recorded during this study.

Discussion

After 4 weeks of use, the novel OR brush produced a statistically significantly greater reduction in gingivitis, as measured by MGI and number of bleeding sites, than did the comparator sonic brush (P< 0.001). Consistent with these results, statistically significantly more users of the OR brush than of the sonic brush transitioned from a baseline "unhealthy" gingival state to a state of gingival health (P= 0.038). Additionally, the OR brush, relative to the sonic brush, produced a statistically significantly greater reduction in whole mouth, interproximal, and gingival margin plaque after a single use; significant whole mouth and interproximal benefits persisted over 4 weeks of use (P< 0.001). Both treatments were well tolerated.

To our knowledge, this comparative study represents the first published clinical evaluation of the usmile sonic toothbrush and supports the conclusions of previous studies showing superior performance for OR brushes versus sonic brushes for plaque and gingivitis reduction.[12-15] A recent meta-analysis[11] has confirmed the consistent performance of OR brushes, revealing statistically significantly greater bleeding site reduc-tions, plaque reductions, and rates of transitioning to gingival health for OR-brush versus sonic-brush users (P< 0.001).

Among OR brushes, Oral-B iO technology has consistently demonstrated better performance relative to its comparators.[11] The Oral-B iO has shown significantly superior gingivitis and plaque efficacy relative to a manual brush with as little as a single use and throughout 12 weeks of use.[21,23] The iO technology has also demonstrated significant gingivitis- and plaque-reduction benefits versus a sonic brush over 6 months of use.[20] The efficacy advantage may be attributed to the round head of the iO, which is designed to conform to a tooth better than the traditional, rectangular shape favored by manual and sonic brushes (Fig. 1). The iO Ultimate Clean brush head has enhanced bristle density and 'Tuft-in-Tuft' technology. Design features of the brush head maximize tooth surface coverage and plaque removal.[16]

Though this study only assessed gingivitis reduction at a single (4-week) time point, OR brushes have elsewhere shown gingivitis control benefits as soon as 1 week after beginning use and for as long as 6 months.[20,23] Therefore, it can reasonably be expected that the clinical benefits observed here would prove similarly swift and durable, and this should be explored in future studies, along with comparisons with various brush models. The current results, derived from established assessment techniques[17-19] implemented by an experienced, blinded examiner[20,21] in the context of a randomized, controlled study, should be integrated into future meta-analyses.

These findings have practical implications for patients who use a manual toothbrush and present with gingivitis and other plaque-related conditions. The evidence is clear that OR electric toothbrushes provide superior cleaning and gingival health compared to manual toothbrushes,[10,11,14] but some patients who are unfamiliar with electric technology may be hesitant to change. The Oral-B iO2 evaluated in this trial offers a simple 3-mode design and a quieter drive mechanism, all designed to ease the transition to an electric brush for first-time users.[24]

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