Research Article

A 6-month randomized controlled trial evaluating a novel smart-connected oscillating-rotating toothbrush versus a smart-connected sonic toothbrush for the reduction of plaque and gingivitis

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Abstract: Purpose: This 6-month study compared the effects of a smart-connected oscillating-rotating (O-R) electric rechargeable toothbrush with micro-vibrations with those of a marketed smart-connected sonic rechargeable toothbrush for the reduction of gingivitis and plaque. **Methods:** In this single-center, examiner-blind, two-treatment, open-label, parallel-group, randomized study, 110 adult subjects with evidence of gingivitis and plaque were randomized to use either the O-R brush (Oral-B iO) or the sonic brush (Philips Sonicare DiamondClean). Both groups were instructed to brush twice daily with a standard sodium fluoride dentifrice. Gingivitis and plaque were assessed at baseline, week 1, and week 24 using the Modified Gingival Index (MGI), Gingival Bleeding Index (GBI), and the Rustogi Modification of the Navy Plaque Index (RMNPI). Designation of gingivitis case status as "healthy" or "not healthy" was made according to the World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions. **Results:** A significantly greater percentage of subjects in the O-R brush group versus the sonic brush group transitioned from "not healthy" to "healthy" gingivitis case status at week 24 (96.4% vs. 81.8%; P= 0.029). The O-R toothbrush produced a significantly greater reduction in adjusted mean MGI score, adjusted mean GBI score, and adjusted mean number of bleeding sites than did the sonic brush (week 24, by 32.6% for MGI score, by 23.7% for GBI score, and by 26.1% for number of bleeding sites, P< 0.001). After a single use on day 1, plaque removal was statistically significantly greater for the O-R brush compared to the sonic brush (P< 0.001); by week 24, the O-R brush demonstrated greater reductions in whole mouth plaque (24.6%), gingival margin plaque (61.9%) and approximal region plaque 25.8% (P≤ 0.007 for all) compared to the sonic brush. (*Am J Dent* 2021;34:54-60).

Clinical significance: This 6-month study provides evidence supporting use of a smart-connected O-R electric toothbrush with micro-vibrations for plaque removal and gingivitis reductions, resulting in transitions to a healthy gingival state.

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Introduction

Periodontal disease is a widespread global health concern.[1] As the average age of the population increases,[2] periodontal disease poses a growing public health threat. People today retain more teeth over the course of their lives than did previous generations,[3,4] yet their retained teeth exhibit more periodontitis as they age.[4,5] Reversing periodontal disease early, at the gingivitis stage, can avert potential permanent consequences of periodontitis.[3,6,7]

Periodontal disease is an inflammatory condition triggered by the bacteria found in dental plaque.[8] A mainstay of plaque removal, toothbrushing, can prevent and reverse gingivitis.[9-11] In particular, growing evidence demonstrates that electric toothbrushes remove plaque and reduce gingivitis better than manual brushes.[12-16] Currently, the most popular electric toothbrushes feature either oscillating-rotating (O-R) or side-to-side (sonic) movement. Multiple studies have shown O-R brushes provide advantages over sonic brushes for plaque removal and gingivitis reduction.[12,16,17]

A novel O-R toothbrush (Oral-B iO[a]) was recently introduced incorporating micro-vibrations. The handle features a linear magnetic drive, different from other O-R brushes that have a gear-based motor. The new drive minimizes intrinsic energy loss, directing energy at the bristles.[18,19] It also produces less noise, which has been shown in research to be preferred by some users.[20] When using the toothbrush at a target pressure range of 0.8-2.5 N the production of micro-vibrations is facilitated at the site of plaque removal.[18,19] In two 8-week studies, the Oral-B iO removed more plaque and reduced gingivitis significantly better than a manual and advanced sonic toothbrush.[21,22] This 6-month study compared the performance of the smart-connected O-R brush with that of the advanced smart-connected sonic toothbrush over a longer time period than examined in the previous study, providing an assessment of the sustained gingival health effects when the brushes are used with interactive features.

Materials and Methods

Study objective - The objective of this 6-month, single-center, examiner-blind, two-treatment, open-label, randomized, parallel-group study was to compare the effects of a smart-connected O-R electric rechargeable toothbrush with micro-vibrations, with those of a marketed smart-connected sonic electric rechargeable toothbrush for the reduction of gingivitis and plaque in adults with baseline evidence of gingivitis and plaque. 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 were obtained (Veritas IRB Inc, Ref: 16457-10:58:3029-10-2019). All participants provided written, informed consent.

Assessments and outcomes - Gingivitis was assessed using the Modified Gingival Index (MGI)[23] and the Gingival Bleeding Index (GBI).[24] MGI scores were assigned to six areas (disto-

buccal, buccal, mesiobuccal, distolingual, lingual, and mesiolingual) on each scorable tooth using a scale ranging from 0 (normal) to 4 (severe inflammation). Scorable teeth refers to all teeth except third molars, teeth with crowns, bridges, or implants, teeth with large restorations, or teeth with orthodontic appliances. GBI scores were obtained by standardized probing of buccal, mesial/distal, and lingual gingival areas of scorable teeth using scores of 0 (absence of bleeding after 30 seconds), 1 (bleeding observed after 30 seconds) or 2 (immediate bleeding observed). Whole-mouth MGI and GBI scores were calculated by dividing the total MGI or GBI score by the number of scorable sites examined.

The Rustogi Modification of the Navy Plaque Index (RMNPI) was used to assess plaque.[25] Plaque was scored as absent (0) or present (1) on the buccal and lingual surfaces of each scorable tooth, for a total of 18 sites per tooth (nine sites per surface). The plaque status of the whole mouth, gingival region, and approximal region was reflected in three separate mean plaque indices (MPI). Each MPI was calculated by dividing the total number of sites with plaque by the total number of sites scored.

Investigational products - This study compared two electric, rechargeable, smart-connected toothbrushes: the Oral-B iO toothbrush coupled with the Ultimate Clean[a] brush head (M7/OR015), and the Sonicare DiamondClean[b] toothbrush coupled with the Premium Plaque Control[b] brush head (HX9903/11). All subjects were provided with standard 0.243% sodium fluoride dentifrice (Crest Cavity Protection[a]).

Eligibility criteria - Subjects were recruited by All Sum Research Center Ltd. in Mississauga, Ontario, Canada. All included subjects were adults in good general health with at least 16 natural, scorable teeth and a habit of typically using a manual toothbrush at home. Eligible subjects had a baseline whole-mouth MGI score of at least 1.75 and not exceeding 2.5, and at least 20 but not more than 90 bleeding sites at baseline, with "bleeding" defined as a GBI score of 1 or 2. Eligible subjects also had a baseline pre-brushing whole-mouth RMPNI score greater than 0.5. Exclusion criteria included a need for antibiotic treatment before dental procedures; oral or periodontal surgery within the previous 2 months; use of an antibiotic or chlorhexidine mouth rinse within the previous 2 weeks; grossly carious, fully crowned, or extensively restored teeth; severe periodontal disease; active treatment for periodontitis, cancer, or a seizure disorder; presence of orthodontic appliances, removeable partial dentures, or peri/oral piercings; presence of a pacemaker or other implanted devices; or current or anticipated pregnancy or nursing. During the study, enrolled subjects were required to refrain from use of any non-study oral hygiene products or to have a dental prophylaxis or any elective dentistry.

Study design - At the baseline visit, subjects gave written informed consent and provided medical history and demographic information. Inclusion/exclusion criteria were reviewed and documented. Subjects were required to refrain from eating, drinking, chewing gum, or using tobacco for 4 hours prior to each visit and to avoid any oral hygiene procedure for 12 hours prior to each visit. An experienced examiner[26-28] conducted an oral exam followed by MGI and GBI evaluations. The same examiner, also experienced in the RMNPI,[26-28] then conducted a plaque assessment after plaque was disclosed with Chrom-O-Red[c] erythrosine FD&C red 3 disclosing solution.

Subjects were stratified according to tobacco use (present or absent), number of bleeding sites (≤ 28 vs. > 28) and scores for MGI (≤ 2.1 vs. > 2.1) and RMNPI (≤ 0.62 vs. > 0.62). Within strata, subjects were randomly assigned to one of two treatment groups in approximately equal numbers. Group assignment and material distribution occurred in a protected area that ensured the examiner would remain blind to which product each subject received. Subjects followed the same procedures in all aspects of the trial except for the brush assigned and the respective usage instructions, which followed each manufacturer's recommendations.

Subjects received kit boxes containing assigned treatment products (either the O-R toothbrush or the sonic toothbrush, plus standard sodium fluoride dentifrice) and were given written and verbal instructions on product use. The O-R brush was to be used in Daily Clean mode, while the sonic brush was to be used in Clean mode with intensity level 3 (high). Subjects were aided in downloading the toothbrush app (either the Oral-B app or the Sonicare app, depending on their randomization) to their mobile device and were instructed to connect their toothbrush to the app when brushing for the duration of the study. Both apps track and provide guidance to users on brushing behaviors, such as brushing time, location, and pressure; the Oral-B app provides camera-free position detection via Artificial Intelligence algorithms. Subjects were asked to use the products under observation in front of a mirror and were instructed to use the products at home twice daily (including the app) for the duration of the study.

After this first use of the electric toothbrush, each subject repeated the disclosing procedure and received a second oral exam and RMNPI plaque assessment from the examiner.

At the week 1 visit (±2 days), subjects returned to the site at approximately the same time as their baseline appointment. Continuance criteria were assessed and recorded. The examiner administered a pre-brushing oral exam followed by MGI and GBI assessments for each subject. Subjects then repeated the plaque disclosing procedure and the examiner administered an RMNPI assessment.

At Week 12, subjects were resupplied with a new brush head and dentifrice and reminded about usage instructions, including use of the app, for their assigned toothbrush.

At the week 24 visit (±10 days), subjects returned to the site at approximately the same time as their baseline and week 1 appointments. Subjects brought their test materials to the site and continuance criteria were assessed and recorded. The examiner administered a final pre-brushing oral exam, MGI assessment, GBI assessment, plaque disclosure, and RMNPI assessment. (Fig. 1)

Safety - Oral soft tissue was assessed by visual examination of the oral cavity and perioral area. Oral hard tissue was assessed by visual examination of the dentition and restorations. Abnormal findings were recorded and categorized by location. An Adverse Event was recorded if a new abnormal finding was noted after product distribution or any previously noted abnormal finding increased in severity during the treatment

Fig. 1. Study design.

Table 1. Baseline demographics.

Demographic/Clinical measurement		Sonic brush (n=55)	O-R brush (n=55)	Overall (n=110)	P-value
Age (Years)	Mean (SD)	46.4 (13.52)	46.1 (12.78)	46.2 (13.09)	0.891
	Min.- Max.	21- 71	18 - 64	18 - 71	
Sex	Female	39 (70.9%)	37 (67.3)	76 (69.1%)	0.837
	Male	16 (29.1%)	18 (32.7%)	34 (30.9%)	
Race	American Indian or Alaskan Native	1 (1.8%)	3 (5.5%)	4 (3.6%)	0.678
	Asian	4 (7.3%)	5 (9.1%)	9 (8.2%)	
	Black or African American	15 (27.3)	12 (21.8%)	27 (24.5%)	
	Multiracial	3 (5.5%)	1 (1.8%)	4 (3.6%)	
	White/Caucasian	32 (58.2%)	34 (61.8%)	66 (60.0%)	
Smoker	No	52 (94.5%)	55 (100.0%)	107 (97.3%)	0.243
	Yes	3 (5.5%)	0 (0.0%)	3 (2.7%)	

period. All self-reported Adverse Events were recorded. Whole body Adverse Events were collected only if potentially related to product use.

Statistical analysis - Power analyses were conducted with $\alpha = 0.05$, using a two-sided test and a sample size of 55 subjects per group, using data from a similarly designed study.[22] Assuming the variability of whole-mouth MGI is 0.124, a sample size of 55 subjects per group should provide at least 90% power to detect a difference in mean MGI scores of at least 0.077 units between treatments. Similarly, for plaque, assuming the variability of whole-mouth RMNPI is 0.049, a sample size of 55 subjects per group should provide at least 90% power to detect a difference in mean RMNPI scores of at least 0.031 units between treatments.

For each treatment group, demographic data and baseline variables were summarized and tested for treatment differences to assess balance at baseline (t-test for continuous variables and Fisher's exact test for categorical variables), and any adverse events reported or noted during the study were documented.

The percentage of subjects whose gingivitis case status was classified as "not healthy" (≥ 10% bleeding sites) or "healthy" (< 10% bleeding sites), as defined by the World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions of the American Academy of Periodontology and the European Federation of Periodontology,[6,29] was computed at each week and compared between treatment groups using a Fisher's Exact test. The odds ratio of changing from "not healthy" to "healthy" was also computed for each week.

Statistical analyses for gingivitis efficacy and multiple-brushing plaque efficacy were based on change from baseline score for whole-mouth average MGI, GBI, and number of bleeding sites as well as whole-mouth, approximal and gingival margin RMNPI (baseline minus week 1 and baseline minus week 24; pre-brushing scores were used for RMNPI). ANCOVA were performed for week 1 and week 24 to determine treatment differences in the whole-mouth average gingivitis and plaque reductions with the respective baseline gingivitis and plaque score as the covariate. Treatment by baseline score interaction was included in the models if it was significant at the 10% level. Separate analyses were performed for each gingivitis and plaque endpoint. MGI was the primary endpoint and week 24 was the most important time point. The within-treatment difference from baseline gingivitis scores (MGI, GBI, number of bleeding sites) and difference from baseline (pre-brushing) plaque scores (whole-mouth, approximal and gingival margin RMNPI) were tested versus zero using a paired t-test.

Statistical analyses for single-brushing plaque efficacy assessments (whole mouth, gingival margin and approximal) followed the same approach. They were based on single-brushing plaque reduction (baseline pre-brushing minus baseline post-brushing), with the relevant pre-brushing RMNPI score as the covariate.

Gingivitis and plaque on lingual surfaces were analyzed separately for treatment differences as previously described. All treatment comparisons were considered two-sided with an $\alpha = 0.05$ significance level.

Results

Study population: baseline demographic and clinical characteristics - 112 subjects were screened, 110 qualified and were randomized to treatment, and 110 completed the study. There were 76 females and 34 males with a mean age (SD) of 46.2 (13.09) years (Table 1).

At baseline, there were no significant differences between groups for gingivitis measures (whole mouth or lingual) ($P \geq 0.446$) or RMNPI scores ($P \geq 0.221$; Table 2) and the gingivitis case status for every subject was categorized as "not healthy" (≥ 10% bleeding sites).

Gingivitis case status transitions - At Week 1, 18.2% of subjects in the O-R toothbrush group had transitioned to "healthy"

Table 2. Baseline clinical measurements.

Demographic/Clinical measurement	Sonic brush (n=55)	O-R brush (n=55)	Overall (n=110)	P-value
Gingivitis, whole mouth				
Mean (SD) MGI	2.123 (0.1043)	2.115 (0.0937)	2.119 (0.0988)	0.645
Mean (SD) GBI	0.213 (0.1172)	0.220 (0.1154)	0.217 (0.1158)	0.766
Mean (SD) number of bleeding sites	30.62 (12.863)	31.44 (14.148)	31.03 (13.465)	0.752
Gingivitis, lingual surface				
Mean (SD) MGI	2.147 (0.1109)	2.130 (0.1205)	2.139 (0.1156)	0.446
Mean (SD) GBI	0.237 (0.1293)	0.241 (0.1360)	0.239 (0.1321)	0.875
Mean (SD) number of bleeding sites	17.55 (8.491)	17.76 (8.979)	17.65 (8.699)	0.896
RMNPI, whole mouth (pre-brushing)				
Mean RMNPI (SD)	0.632 (0.0457)	0.637 (0.0506)	0.634 (0.0481)	0.579
Mean RMNPI (SD), approximal region	1.000 (0.0000)	1.000 (0.0000)	1.000 (0.0000)	N/A
Mean RMNPI (SD), gingival margin	1.000 (0.0000)	1.000 (0.0000)	1.000 (0.0000)	N/A
RMNPI, lingual surface (pre-brushing)				
Mean RMNPI (SD)	0.624 (0.0461)	0.634 (0.0455)	0.629 (0.0459)	0.221
Mean RMNPI (SD), gingival margin	1.000 (0.0000)	1.000 (0.0000)	1.000 (0.0000)	N/A
Mean RMNPI (SD), approximal region	1.000 (0.0000)	1.000 (0.000)	1.000 (0.0000)	N/A

(< 10% bleeding sites) status compared to only 5.5% in the sonic group (P= 0.073; Table 3). Subjects in the O-R group had 3.85 times (95% CI, 1.00-14.87) higher odds of transitioning from "not healthy" to "healthy" versus those in the sonic group at week 1. At week 24, significantly more subjects in the O-R toothbrush group than in the sonic toothbrush group transitioned from "not healthy" to "healthy" status (96.4% vs. 81.8%; P= 0.029) with an odds ratio of 5.89 (95%CI, 1.23-28.29).

Gingivitis reduction efficacy - At week 1 and week 24, both groups showed significant reductions from baseline in all gingivitis measurements (P< 0.001 for all). Between-group ANCOVA comparisons at week 1 and week 24 showed that the O-R brush group had significantly greater reductions in all adjusted mean gingivitis measurements than did the sonic brush group (week 24, by 32.6% for MGI, by 23.7% for GBI, and by 26.1% for number of bleeding sites; P< 0.001 for all) (Table 4).

Table 3. Between-group comparison of "healthy" vs. "not healthy" gingivitis case status at week 1 and week 24*.

	Not healthy n (%)	Healthy n (%)	P-value OR brush vs sonic brush
Week 1			
Sonic brush	52 (94.85%)	3 (5.5%)	P=0.073
O-R brush	45 (81.8%)	10 (18.2%)	
Week 24			
Sonic brush	10 (18.2%)	45 (81.8%)	P=0.029
O-R brush	2 (3.6%)	53 (96.4%)	

*All subjects had a "not healthy" gingivitis case status (approximately 20 or more bleeding sites) at baseline.

Table 4. Change from baseline results for whole-mouth gingivitis efficacy endpoints, ANCOVA summary.

			Adjusted mean (SE) change from baseline	Percent treatment difference relative to sonic	Two-sided P-value
MGI score	Week 1	Sonic brush	0.090 (0.0076)	--	P= 0.002
		O-R brush	0.124 (0.0076)	37.6%	
	Week 24	Sonic brush	0.425 (0.0200)	--	P< 0.001
		O-R brush	0.564 (0.0200)	32.6%	
GBI score	Week 1	Sonic brush	0.039 (0.0026)	--	P< 0.001
		O-R brush	0.054 (0.0026)	41.1%	
	Week 24	Sonic brush	0.141 (0.0031)	--	P< 0.001
		O-R brush	0.174 (0.0031)	23.7%	
Number of bleeding sites	Week 1	Sonic brush	5.09 (0.370)	--	P< 0.001
		O-R brush	7.38 (0.370)	44.9%	
	Week 24	Sonic brush	19.43 (0.485)	--	P< 0.001
		O-R brush	24.50 (0.485)	26.1%	

Percent treatment difference relative to sonic = -100*(treatment difference/adjusted mean of sonic brush).

Plaque reduction efficacy - After a single brushing, the O-R brush group showed significantly greater reductions for whole mouth, gingival margin and approximal RMNPI scores (P< 0.001 for all) compared to the sonic brush, with a plaque removal benefit ranging from 12.3% to 17.8%. At week 1 and week 24, both groups showed significant reductions from baseline in whole mouth, gingival margin, and approximal region RMNPI (P≤ 0.014). Between-group ANCOVA comparisons at week 1 and week 24 showed that the O-R brush group had significantly greater reductions in adjusted mean whole mouth, gingival margin, and approximal region RMNPI (week 24, by 24.6% for whole mouth RMNPI, by 61.9% for gingival margin RMNPI, and by 25.8% for approximal region RMNPI; P≤ 0.007 for all) (Table 5). A similar benefit was seen for the O-R brush over the sonic brush for whole mouth lingual surfaces, with a 23.6% greater reduction at week 24 (P= 0.014; Table 6).

Safety - Both treatments were well tolerated. One non-serious adverse event was observed (mild herpetic lesion) not related to product use.

Table 5. Change from baseline results for whole-mouth plaque efficacy endpoints, ANCOVA summary.

			Adjusted mean (SE) change from baseline	Percent treatment difference relative to sonic	Two-sided P-value
Whole-mouth RMNPI	Day 1 - Single brushing				
		Sonic brush	0.454 (0.0062)	--	P< 0.001
		O-R brush	0.520 (0.0062)	14.6%	
	Week 1	Sonic brush	0.063 (0.0035)	--	P= 0.001
		O-R brush	0.079 (0.0035)	25.6%	
	Week 24	Sonic brush	0.153 (0.0072)	--	P< 0.001
		O-R brush	0.191 (0.0072)	24.6%	
Gingival margin RMNPI	Day 1 - Single brushing				
		Sonic brush	0.625 (0.0136)	--	P< 0.001
		O-R brush	0.736 (0.136)	17.8%	
	Week 1	Sonic brush	0.002 (0.0013)	--	P= 0.008
		O-R brush	0.007 (0.0013)	238.6%	
	Week 24	Sonic brush	0.039 (0.0054)	--	P= 0.002
		O-R brush	0.063 (0.0054)	61.9%	
Approximal region RMNPI	Day 1 - Single brushing				
		Sonic brush	0.794 (0.0101)	--	P< 0.001
		O-R brush	0.891 (0.0101)	12.3%	
	Week 1	Sonic brush	0.063 (0.0126)	--	P= 0.003
		O-R brush	0.116 (0.0126)	84.5%	
	Week 24	Sonic brush	0.371 (0.0247)	--	P= 0.007
		O-R brush	0.467 (0.0247)	25.8%	

Percent treatment difference relative to sonic = -100*(treatment difference/adjusted mean of sonic brush).

Table 6. Change from baseline results for whole-mouth lingual plaque efficacy endpoints, analysis of covariance summary.

		Adjusted mean (SE) change from baseline	Percent treatment difference relative to sonic	Two-sided P-value
Day 1 - Single brushing	Sonic brush	0.390 (0.0087)	--	P< 0.001
	O-R brush	0.471 (0.0087)	20.8%	
Week 1	Sonic brush	0.047 (0.0051)	--	P= 0.022
	O-R brush	0.064 (0.0051)	35.6%	
Week 24	Sonic brush	0.134 (0.0090)	--	P= 0.014
	O-R brush	0.166 (0.0090)	23.6%	

Percent treatment difference relative to sonic = -100*(treatment difference/adjusted mean of sonic brush).

Discussion

Toothbrushing is an established, effective way to remove plaque and reverse gingivitis.[9-11] Systematic reviews and meta-analyses indicate that O-R toothbrushes offer plaque and gingivitis reduction advantages over sonic toothbrushes.[16,17,30] In a recent study, a novel O-R toothbrush with micro-vibrations achieved these important oral health endpoints significantly better than a sonic brush.[22] In the current 6-month study which employed smart connectivity, the novel O-R brush confirmed these results and provided consistent benefits over a longer period than previously evaluated.

In addition to comparing traditional plaque and gingivitis endpoints, this study also evaluated the number of subjects transitioning from "not healthy" to "healthy" gingivitis case status in each group. This is a particularly relevant assessment to clinicians as it is a subject-level indication of gingival health improvement. In prior studies not exceeding 3 months, users of an O-R brush had 1.8 times higher odds than that of sonic brush users of transitioning from "not healthy" to "healthy" gingivitis case status.[16] In a separate 8-week study, the novel O-R brush conferred 4.75 times greater odds of transitioning to health than did a sonic brush.[22] The current study tracked gingivitis case status for 6 months and showed even greater odds of transitioning to "healthy" for O-R brush users relative to sonic brush users (5.89 times) at the study's end, by which time a significantly larger percentage of the O-R brush group (96.4%) than the sonic brush group (81.8%) had transitioned to a state of gingival health.

Users of the novel O-R brush experienced immediate as well as long-term benefits over 6 months, a timeframe that importantly reflects the typical period between dental visits. Prior research also indicated that the novel O-R brush removed significantly more plaque than a sonic brush after a single use.[22] In the current study, significant plaque reductions by the O-R brush relative to the sonic brush were again observed as early as the first use and reductions were maintained at statistically significant levels through week 24, ranging from 24.6% to 61.9% across regions. Significant gingivitis reductions by the O-R brush relative to the sonic brush were also maintained from week 1 through week 24 (23.7% to 32.6%), again consistent with the earlier, shorter-term study.[22]

The lingual surfaces of teeth are an important target for plaque removal and gingivitis prevention. Lingual surfaces are prone to develop plaque because of their proximity to salivary glands,[31] and lingual surfaces tend not to be brushed as thoroughly as other tooth surfaces.[32] The O-R brush tested in this study has already been shown to significantly reduce lingual plaque versus a sonic toothbrush.[33] Current results conform to this trend: the O-R brush provided a significant

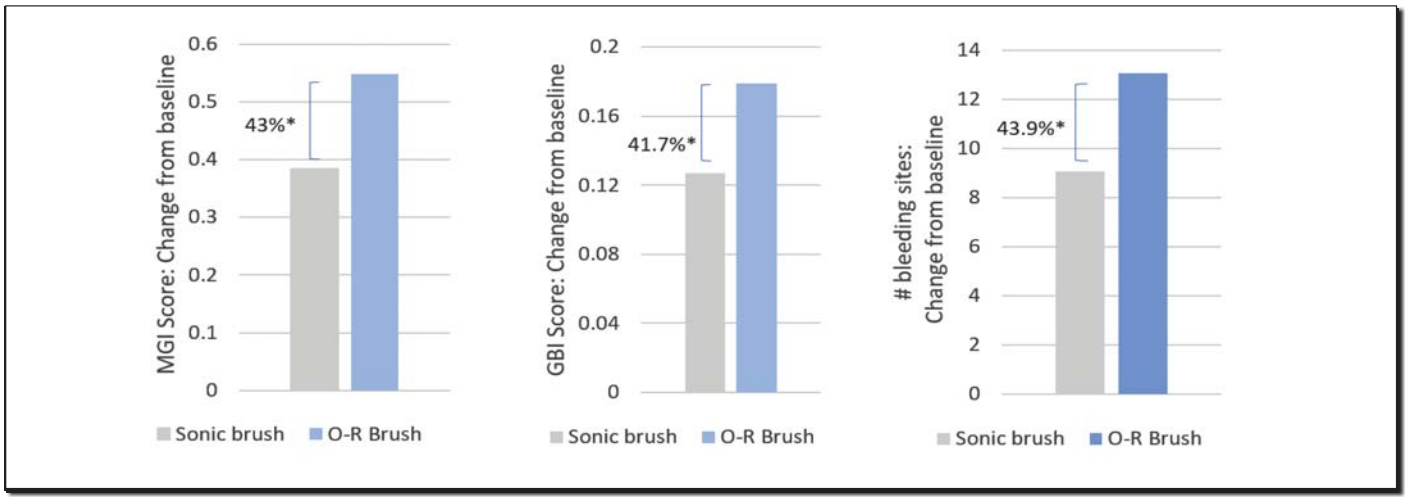

Fig. 2. Adjusted mean change from baseline scores for lingual gingivitis efficacy endpoints at week 24. A. Lingual surface MGI scores. B. Lingual surface GBI scores. C. Lingual surface # bleeding sites.
* Statistically significant difference between treatments based on ANCOVA, P< 0.001

advantage versus the sonic brush in reducing adjusted mean whole-mouth lingual plaque from day 1 through week 24. The current study also demonstrated that by week 24 the O-R brush was significantly more effective than the sonic brush in reducing lingual area gingivitis, by 43.0% for adjusted mean MGI, by 41.7% for adjusted mean GBI, and by 43.9% for adjusted mean number of bleeding sites (Fig. 2). The disproportionate effectiveness in lingual areas provided by the O-R brush can be attributed in part to the round Oral-B brush head, which optimizes access and cleaning efficiency in the hard-to-clean lingual areas.[34] Moreover, the app for the O-R brush provides coaching via active position detection to help achieve more even coverage across the entire dentition.

Assessing the impact of the interactive elements of the O-R brush tested in this trial, both on compliance and effectiveness, is an opportunity for future research since we cannot draw conclusions about the benefit of the app versus the brush in this trial. With the current study design it was not possible to access app usage data for the sonic brush, so we did not control app usage in either group to ensure a balanced assessment; however, both groups were encouraged to use the app upon enrollment and at the 12-week resupply contact. Studies have demonstrated that interactive, Bluetooth-connected O-R toothbrushes can increase the time that users spend brushing, improve brushing thoroughness and enhance plaque removal outcomes versus manual toothbrush controls.[35,36] Studies among pediatric and adolescent patients have also shown a benefit on oral health outcomes when an educational/coaching app was added to a usual care routine.[37-39] Moreover, a recent pilot study also showed an observed association between self-reported bleeding on brushing using the O-R app and clinically assessed bleeding on probing, indicating the app may provide value as a self-assessment tool.[40] While other research has not shown a significant improvement in oral health outcomes when an app was added to an electric toothbrushing routine, the authors note that the app may be a helpful tool for patient motivation and engagement.[41,42] Additional research is ongoing to assess benefits and opportunities for interactivity using the app under different usage scenarios with different patient populations and endpoints.

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