# The effects of oscillating-rotating electric toothbrushes on plaque and gingival health: A meta-analysis

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ABSTRACT: Purpose: To compare the effects of oscillating-rotating (O-R), sonic (side-to-side), and manual toothbrushes on plaque and gingival health after multiple uses in studies up to 3 months. Methods: A meta-analysis was conducted on randomized clinical trials (RCTs) up to 3 months in duration to evaluate O-R electric toothbrush effectiveness regarding gingivitis reduction and plaque removal versus sonic and/or manual toothbrushes. To ensure access to subject-level data, this meta-analysis was limited to RCTs involving O-R toothbrushes from a single manufacturer conducted from 2007 to 2017 for which subject-level data were available and that satisfied criteria of duration, parallel design, examiner-graded, etc. For gingivitis studies, a one-step individual subject meta-analysis was used to assess direct and indirect treatment differences and to identify any subject-level covariates modifying treatment effects. In the two-step meta-analysis, individual participant data were first analyzed in each study independently using the last timepoint (up to 3 months), producing aggregate data for each study. Then forest plots were produced using these aggregate data with random-effects models. For plaque studies, the efficacy variables were standardized so direct comparisons could be generated using the 2-step meta-analysis. Network meta-analysis was performed to assess the indirect plaque comparisons. Results: 16 parallel group RCTs with 2,145 subjects were identified assessing gingivitis via number of bleeding sites. In five and 11 gingivitis studies assessing O-R brushes versus manual and sonic brushes, respectively, a change in the average number of bleeding sites of -8.9 (95% CI: -15.9, -1.9) and -3.1 (95% CI: -3.8, -2.4) was observed ( $P \le 0.008$ ). These reductions equate to a 50% and 28% bleeding benefit for O-R technology versus the respective controls. The sonic brush bleeding change versus manual was -5.9 (P= 0.062), a 34% bleeding benefit. Utilizing individual bleeding scores, subjects with localized or generalized gingivitis ( $\geq 10\%$  bleeding sites) had 7.4 times better odds of transitioning to generally healthy (< 10% bleeding sites) after using an O-R brush versus manual. 20 parallel design RCTs with 2,551 subjects assessed plaque (TMQHI, RMNPI). In eight and 12 plaque RCTs assessing an O-R brush versus manual and sonic brushes, respectively, standardized changes in average plaque scores of -1.51(95% CI: -2.17, -0.85) and -0.55 (95% CI: -0.82, -0.28) were observed (P< 0.001). These plaque reductions by O-R equate to a relative 20% and 4% greater benefit, respectively. The change for sonic versus manual was -0.93 (95% CI: -1.48, -0.38); (P< 0.001) which equates to a 12% plaque benefit. (Am J Dent 2020;33:3-11).

**CLINICAL SIGNIFICANCE:** This subject-level meta-analysis of studies up to 3 months provides sound evidence supporting recommendations for patients with various degrees of gingival bleeding to use oscillating-rotating electric toothbrushes over manual and sonic toothbrushes to improve plaque control and gingival health.

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## Introduction

A notable development in the history of toothbrushing was the 1960s debut of the electric (i.e. power) toothbrush. This mechanized brush promised more efficient plaque removal with less user effort than a manual toothbrush. Later-generation, more streamlined electric toothbrushes with differing brush head movement modalities, speeds, and filament arrangements were subsequently introduced (e.g., side-to-side, circular in onedirection, ionic, oscillating-rotating).<sup>1</sup> Via continued research and development, many modern electric toothbrush models also offer advanced safety and efficiency features like pressure sensors, timers, brushing modes, and need-specific bristle designs.

Toothbrush designs to maximize cleaning are based on the precept that dental plaque is the predominant driver of gingival bleeding and disease.<sup>2,3</sup> In the absence of plaque control, a localized inflammatory response manifests in gingival bleeding, edema, and erythema.<sup>4-7</sup> Without intervention, chronic inflammation ensues in susceptible individuals and can culminate in periodontitis with tissue destruction and potential bone and subsequent tooth loss.<sup>8,9</sup>

In addition to regular dental prophylaxes and professional care, toothbrushing for mechanical plaque biofilm disruption and removal continues to be the core component of the oral hygiene regimen. Realistically, a majority of individuals do not accomplish thorough brushing with a basic manual brush<sup>10-12</sup> and therefore gingivitis prevalence rates are high globally.<sup>13</sup> Electric toothbrushes and brush head configurations have been designed to provide greater disruption of plaque and to access regions that harbor plaque and are associated with greater bleeding and disease. Physical plaque removal is accomplished by different mechanisms depending on the electric toothbrush type.

The Oral-B oscillating-rotating (O-R) electric toothbrush uses a small round brush head to contour to the shape of the tooth, emulating the cleaning generated by a professional prophylaxis handpiece. The filaments rotate in one direction and then another in a continuous succession for plaque biofilm disruption and removal, which has been supported by clinical and safety data.<sup>1,14-16</sup> Toothbrushes frequently termed 'sonic' typically have more traditionally-shaped brush heads that vibrate side-to-side at a high rate of speed and are characterized

by a singular, harmonic tone. The plaque removal effectiveness of manual, O-R and/or sonic toothbrushes has been evaluated in systematic reviews and meta-analyses,<sup>17-22</sup> however they were conducted without the benefit of access to the included studies' individual raw subject data which precluded exploration of an important criteria: the effect of baseline gingival disease levels (i.e., individual subject bleeding scores) on posttreatment response. Further, additional clinical studies have been conducted following the publication of the earlier metaanalyses assessing the anti-plaque and anti-gingivitis efficacy of O-R electric toothbrushes when compared to sonic and manual controls, underscoring the utility of a supplemental, updated review.

In response, this new meta-analysis evaluates randomized clinical trials (RCTs) supported by a single manufacturer (Procter & Gamble) from 2007 to 2017 and selected for inclusion due to access to the raw subject data for the purposes of a novel investigation of baseline disease severity with respect to treatment outcomes and to estimate the percentage of subjects transitioning to generally healthy status. The PICO model was utilized for this review as follows: Patient: adults with at least mild gingivitis as classified at the time of the investigation; Intervention: O-R toothbrush; Comparator: sonic or manual toothbrush; Outcomes: number of bleeding sites from Gingival Bleeding Index (GBI),<sup>23</sup> Löe-Silness Gingival Index (LSGI),<sup>24</sup> Papillary Bleeding Index (GBI),<sup>25</sup> Mazza Gingival Index (GI),<sup>26</sup> and plaque score using Turesky's Modification of Quigley-Hein index (TMQHI)<sup>27,28</sup> and Rustogi Modified Navy Plaque Index (RMNPI).<sup>29</sup> The purpose of this review was to estimate the effects on plaque and gingivitis of O-R toothbrush technology compared to sonic toothbrush technology and manual toothbrushing, when utilized for up to 3 months (PICO question).

# **Materials and Methods**

The meta-analysis was conducted in agreement with the principles of the PRISMA statement,<sup>30</sup> and has been posted on clinicaltrials.gov.<sup>31</sup>

*Search process* - The authors undertook a search in the Procter & Gamble Oral Care Clinical archive for the identification of RCTs from 2007 to 2017. Relevant trials were reviewed for determination of eligibility for inclusion in this meta-analysis.

*Eligibility criteria* - Data were included from human subjects from RCTs: (1) of up to 3 months in length that were randomized and controlled, parallel group, and examiner blinded; (2) reporting the effects on plaque and/or gingivitis following an intervention with comparator control group(s); and (3) that were examiner-based (e.g. no digital imaging studies).

*Study selection and data collection* - The authors of this paper and knowledgeable toothbrush team members, assessed the eligibility of all studies from the archives run between 2007 and 2017. From the studies included in the final analysis, we extracted the following data: study name and year; country; study design; participants' age and gender; intervention; follow-up visit; and values of outcome measurements (subject-level data, sample size, means and standard deviations). If the study had more than one follow-up visit, we used the final assessment up to and including the 3-month visit for data extraction. Statistical analysis - For gingival bleeding, both one-step and two-step meta-analysis approaches were used. The one-step individual subject meta-analysis using mixed model was used to assess direct and indirect treatment differences with corresponding P values and to identify patient-level covariates modifying treatment effects. Study and treatment were included as random effects, allowing for different treatment-effect sizes by study. Baseline bleeding and separate interactions with study and treatment were also modeled to allow the relationship between baseline and end-of-treatment bleeding to differ by study and treatment. The model also permitted the residual variance to vary for each study (Equation  $9^{32}$ ). In the two-step meta-analysis, the individual participant data were first analyzed in each separate study independently, which produced aggregate data for each study. Then forest plots were produced using these aggregate data, which were synthesized in the second step using the generic inverse variance method with random-effects models.

For plaque studies, the efficacy variables (TMQHI: eight studies and RMNPI: 12 studies) were standardized by dividing the mean treatment difference in each study by that study's standard deviation, which was then used to generate direct comparisons across studies<sup>33</sup> using two-step meta-analysis. Three assumptions for network meta-analysis (homogeneity, transitivity, and treatment rank credibility) were evaluated and satisfied. Network meta-analysis was performed using multivariate random effects meta-analysis<sup>34</sup> to assess indirect comparisons between positive and negative controls.

The estimated mean differences and the 95% confidence intervals (CIs) are presented in forest plots. Percent change from control was calculated by the weighted percent change from the control from different studies where the weights were calculated from the random effects model. Network meta-analysis provided treatment difference with 95% confidence interval and P-scores based on the point estimates and standard errors of the frequentist network meta-analysis estimates. P-scores were calculated as means of one-sided P-values, which provided the ranking of the treatments by measuring the mean extent of certainty that a treatment is better than the competing treatments.<sup>35</sup> Smaller P-scores indicates better anti-plaque efficacy in our case.

The current Gingivitis Case Definitions from the 2017 World Workshop in Periodontology<sup>36</sup> were followed to classify subject-level gingival bleeding at baseline and the final visit used in the analysis as: Generally Healthy (<10% bleeding sites), Localized Gingivitis (10%-30% bleeding sites), or Generalized Gingivitis (>30% bleeding sites). Transition rates by treatment were then calculated and used to generate odds ratios with 95% confidence intervals.

The summary-level meta-analyses were conducted using the "metafor" and "netmeta" package in R version 3.2.3.<sup>37,38</sup> All subject-level analyses were conducted using SAS 9.4.<sup>a</sup>

## Results

*Clinical trials overview* - In the gingivitis meta-analysis, 16 parallel group design RCTs with a total of 2145 subjects in three different countries were included. Of these, five trials assessed O-R electric toothbrushes compared to manual toothbrushes and 11 studies were comparisons of O-R electric tooth-

O-R = Oscillating-rotating toothbrush.

Subjects

824

1727

2551

Countries

represented

USA, Canada, Germany

#### Table 1a. Studies included in the gingivitis meta-analysis.

Study type	Number of studies	Subjects	Countries represented
O-R vs. Manual	5	586	
O-R vs. Sonic	11	1559	
All	16	2145	USA, Canada, China

O-R = Oscillating-rotating toothbrush

Study type

O-R vs. Manual

O-R vs. Sonic

All

Table 1b. Studies Included in the Plaque Meta-Analysis

Number

of studies

8

12

20

Bleeding: Oral-B vs. Manual Brush										
	Baseline		Oral-B		Ма	nual Bru	sh			
Study	Mean	Mean	Sd	n	Mean	Sd	n	Oral-B	- Manual	Brush (95% CI)
Klukowska et al. <sup>39</sup>	7.68	1.24	1.53	57	4.16	2.88	60			-2.92 [ -3.69, -2.15]
Klukowska et al. <sup>40</sup>	14.71	4.32	2.53	49	7.86	3.32	50			-3.54 [ -4.66, -2.41]
Ccahuana-Vasquez et al.	<sup>41</sup> 21.36	10.21	9.08	75	16.32	13.86	75		•	-6.11 [ -7.23, -4.99]
Milleman, 2014	32	8.92	3.89	50	30.97	11.63	47	⊶∎⊶		-22.05 [-25.18, -18.92]
Li et al. <sup>42</sup>	70.9	32.63	19.29	63	43.25	20.75	60	,		-10.62 [-16.91, -4.33]
RE Model								_	_	-8.90 [-15.87, -1.93]
							1		÷	
							-3	-20 -	10 0	
								Mean Differ	ence	

Fig. 1a. Results from clinical trials included in the bleeding sites meta-analysis: Oral-B oscillating-rotating (O-R) toothbrush versus manual toothbrush.

brush technology versus sonic technology (Table 1a).

The plaque meta-analysis incorporated 20 parallel group design RCTs across three countries with 2,551 total subjects: eight RCTs compared O-R electric brushes versus manual toothbrushes, and 12 trials assessed O-R electric brush technology relative to the sonic brush mode of action (Table 1b).

The O-R rechargeable electric toothbrushes in the gingivitis and plaque RCTs included Oral-B<sup>b</sup> D12 models and higher (Vitality, Triumph, Professional Series/Smart Series). The sonic toothbrushes serving as positive controls included Philips Sonicare<sup>c</sup> products (FlexCare, FlexCare Platinum, Diamond-Clean) and Colgate<sup>d</sup> ProClean A1500 and C200. The manual (negative control) comparator toothbrushes in the clinical studies were either ADA reference,<sup>e</sup> Oral-B Indicator,<sup>b</sup> or Lion Dentor Systema<sup>f</sup> toothbrushes.

*Gingivitis* - For the five RCTs assessing O-R electric toothbrushes compared to manual toothbrushes for their effects on gingivitis, O-R brushes produced a reduction (decrease) of 8.9 (95% CI: 1.9, 15.9) in average number of bleeding sites versus manual brushes. These results represent a 50.3% greater bleeding reduction versus the negative control toothbrushes (P= 0.008) (Figs. 1a, 2).

With respect to the 11 gingivitis RCTs comparing O-R electric brushes to sonic brushes, O-R brushes provided a 28% greater bleeding benefit versus sonic brushes: those using O-R brushes had a reduction (decrease) of 3.1 (95% CI: 2.4, 3.8) in average number of bleeding sites compared to sonic brushes (P<0.001) (Figs. 1b, 2).

When the subject level data were evaluated, a -5.9 mean bleeding site difference for sonic brushes versus manual brushes was observed, which approached statistical significance (P= 0.062) (Fig. 2).

In the subject-level meta-analysis model, baseline bleedingby-treatment interaction term was significant (P< 0.001), indicating that the effect of O-R electric brushes compared with that of the control depends on the number of baseline bleeding sites. The specific nature of this relationship is summarized in Fig. 3, which shows that the benefit of O-R brushes increases as baseline bleeding increases across all gingivitis levels.

Specifically for O-R brushers, analysis of the effect of baseline gingivitis status revealed that 73% of the 473 subjects with localized baseline gingivitis (10% to 30% number of bleeding sites) and 20% of the 114 subjects with generalized gingivitis (> 30% bleeding sites) transitioned to generally healthy post-treatment, compared with only 28% and 7% similarly transitioning, respectively, for manual toothbrush users, and 58% and 11%, respectively, for the sonic brush cohort (Table 2).

Utilizing individual subject bleeding scores, the analysis showed that those subjects with baseline localized or generalized gingivitis ( $\geq 10\%$  bleeding sites) had 7.4 times better odds of transitioning to generally healthy status (< 10% bleeding sites) post-intervention with use of an O-R electric toothbrush versus a manual toothbrush (95% CI: 4.9, 11.3), P< 0.05, and 1.8 times greater odds transitioning compared to sonic toothbrushing (95% CI: 1.4, 2.3), P< 0.05 (Table 3).

Compared to both the negative (manual brushes) and posi-

	Baseline		Oral-B		Po	sitive Cont	rol		
Study	Mean	Mean	Sd	n	Mean	Sd	n Or	al-B - Positiv	e Control (95% Cl
Goyal et al.43	10.99	6.61	6.96	85	9.25	11.27	88		-2.64 [-4.45, -0.83]
Klukowska et al.44	17.47	7.55	4.79	64	9.93	7.18	64	-	-2.38 [-3.35, -1.42]
Klukowska et al.45	18.28	3.7	3.1	65	7.47	7.57	65	-	-3.77 [-4.85, -2.68]
Klukowska et al.46	18.77	6.58	7.97	62	9.1	10.9	65		-2.52 [-4.39, -0.66]
Ccahuana-Vasquez et al.47	20.26	7.41	5.3	74	11.25	9.38	74	-	-3.84 [-4.98, -2.70]
Klukowska et al.48	20.81	6.47	7.03	63	7.46	7.57	64		-0.98 [-2.15, 0.18]
Klukowska et al. <sup>49</sup>	20.88	9.44	9.68	64	12.38	9.17	64	- <b>-</b>	-2.95 [-4.08, -1.81]
Ccahuana-Vasquez et al. <sup>50</sup>	22.73	8.04	8.37	75	11.94	9.05	73	H	-3.90 [-5.19, -2.61]
Goyal, 2015	27.12	13.33	7.72	50	17.93	9.41	47	H	-4.61 [-5.81, -3.41]
Putt, 2007	28.44	12.49	15.18	97	14.25	16.33	91		+1.76 [-5.36, 1.84]
Williams et al. <sup>51</sup>	28.98	23.93	16.51	81	28.52	19.37	84		-4.59 [-8.65, -0.53]
RE Model								+	-3.09 [-3.79, -2.38]
								( TTT TTT	7
								-10 -4 0	

Fig. 1b. Results from clinical trials included in the bleeding sites meta-analysis: Oral-B oscillating-rotating (O-R) toothbrush versus side-to-side (sonic) toothbrush.



Fig. 2. Differences in adjusted number of bleeding sites between groups using one-step meta-analysis on subject-level data.

Table 2. Movement from Baseline: % Baseline Bleeding vs. % Post Baseline Bleeding (All studies).

Treatment			Pos		
	Baseline	Total	<10%	10%-30%	>30%
Oral-B O-R	<10%	487	479 (98%)	8 (2%)	0 (0%)
	10%-30%	473	358 (73%)	113 (24%)	2 (1%)
	>30%	114	23 (20%)	69 (61%)	22 (19%)
Negative Control	<10%	132	132 (100%)	0 (0%)	0 (0%)
	10%-30%	100	28 (28%)	69 (69%)	3 (3%)
	>30%	60	4 (7%)	30 (50%)	26 (43%)
Positive Control	<10%	344	321 (93%)	23 (7%)	0 (0%)
	10%-30%	369	214 (58%)	147 (40%)	8 (2%)
	>30%	66	7 (11%)	41 (62%)	18 (27%)

tive (sonic brushes) controls, the O-R electric toothbrushes demonstrated gingivitis reductions across the whole baseline disease spectrum. This includes generalized, localized and generally periodontally healthy case types with isolated gingival inflammation sites (Fig. 4).



Fig. 3. Gingival bleeding response versus baseline bleeding levels: Oral-B O-R versus negative control and positive control.

Table 3. Percentage of subjects and odds ratio of moving to healthy.

Treatment			Post Baseline		
	Baseline	Total	<10%	≥10%	
Oral-B O-R	<10%	487	479 (98%)	8 (2%)	
	≥10%	587	381 (65%)	206 (35%)	
Negative Control	<10%	132	132 (100%)	0 (0%)	
	≥10%	160	32 (20%)	128 (80%)	
Positive Control	<10%	344	321 (93%)	23 (7%)	
	≥10%	435	221 (51%)	214 (49%)	

Localized or generalized gingivitis subjects have 7.4 (4.9, 11.3) times better odds of transitioning to generally healthy (<10% bleeding) on Oral-B O-R vs. negative control and 1.8 (1.4, 2.3) times better odds versus a positive control (based on all data).

*Plaque* - In eight RCTs evaluating the plaque reduction benefits of O-R electric toothbrushes relative to manual toothbrushes, a difference in average standardized plaque scores generated by O-R brushes versus manual brushes of -1.51 (95% CI: -2.17, -0.85) was observed (P< 0.001), equating to a 20% greater benefit (Fig. 5a).



Fig. 4. % Baseline Bleeding vs. Change from Baseline (only GBI & LSGI studies, N=14).



Fig. 5a. Results from clinical trials included in the plaque meta-analysis: Oral-B O-R toothbrush versus manual toothbrush.

When O-R electric brushes were compared to sonic brushes in 12 RCTs, there was a -0.55 (95% CI: -0.82, -0.28) standardized mean plaque score difference, which corresponds to a 4% greater benefit for the O-R brushes (P < 0.001) (Fig. 5b).

Network meta-analysis allowed comparison between all treatments, including sonic brushes versus manual brushes. The mean difference (MD) in standardized plaque scores between sonic brushes versus manual brushes was -0.93 (95% CI: -1.48, -0.38); (P< 0.001), equating to a 12% greater benefit of sonic compared to manual brushes. The ranking of the treatments according to P-score results from network meta-analysis was as follows: (1) O-R electric toothbrushes (1.00); (2) sonic brushes (0.50); (3) manual toothbrushes (0.00) (Fig. 6).

### Discussion

The outcomes from this plaque and gingivitis meta-analysis

provide yet more evidence for the greater gingivitis and plaque reduction benefits of O-R electric brushes over sonic and manual brushes, given the magnitude of the number and diversity of trials and subject populations. These findings are generally consistent with other meta-analyses in the literature. In a global updated systematic review and meta-analysis report evaluating the plaque- and gingivitis-reducing effects of various electric toothbrush types versus manual brushing, which included 56 trials and more than 5,000 subjects, the independent, internationally known Cochrane Collaboration stated, "The greatest body of evidence was for rotation oscillation brushes which demonstrated a statistically significant reduction in plaque and gingivitis at both time points."<sup>17</sup> Van der Weijden et al<sup>19</sup> published a meta review of "published and eligible" systematic reviews relating to mechanical plaque removal for managing gingivitis. The portion of the analysis



Fig. 5b. Results from clinical trials included in the plaque meta-analysis: Oral-B O-R toothbrush versus sonic toothbrush.



Fig. 6. Results from network meta-analysis on standardized plaque score

focused on electric toothbrushes included the aforementioned Cochrane review along with an electric versus manual toothbrush review<sup>20</sup> and a 2016 comparative review of electric toothbrush efficacy.<sup>21</sup> The authors concluded that there was strong evidence for the efficacy of electric brushes in reducing greater plaque and gingivitis compared to manual brushes, with some evidence for the superiority of O-R brushes over sonic toothbrushes in short-term trials.<sup>19</sup> A 2017 metaanalysis<sup>22</sup> of sonic toothbrushes versus manual toothbrushes by de Jager et al<sup>22</sup> reported that in the 18 included short-term (less than 3 months) clinical trials, the sonic brushes produced greater plaque and gingivitis reduction than the manual control toothbrushes, with standardized mean differences of -0.89 and -0.67 (representing 10-20% relative benefits), respectively. In contrast to earlier reports and findings reported in this paper, the de Jager et al<sup>22</sup> review did not find statistically significant differences between O-R and sonic for plaque removal effect or gingivitis reduction (P= 0.10 and P= 0.41, respectively).

While these previously published reviews provide valuable data, a novel feature of this meta-analysis was the access to individual raw subject data. The access to individual data enabled exploration of the relationship between the baseline level of gingival bleeding and the post-brushing outcomes and relative odds ratios of moving from disease to health, or from more diseased to less diseased as an outcome of the three modalities of toothbrushing using the new Gingivitis Case Definitions.<sup>36</sup> Across the 16 gingivitis trials there was a broad spectrum of subject baseline disease levels, ranging from 0% to 78.6% bleeding sites. The minimum study overall baseline bleeding mean across studies was diverse and ranged from 7.68 to 70.9 sites. Subjects with less than 10% bleeding sites at baseline ('generally healthy') comprised 45% of the 2,145 participants, those with localized gingivitis (10%-30%) constituted 44% of all subjects analyzed, and the remaining 11% of the total pooled subject population had incoming generalized gingivitis (> 30% baseline bleeding sites). This vast range likely better represents the general population and heightens applicability of the results, as opposed to trial data sets where entrance is limited predominately to more diseased populations.

Irrespective of the considerable span in entrance gingival disease levels, the O-R electric toothbrushes produced a significant reduction in gingival bleeding sites, and the mean benefits consistently exceeded those for subjects using either the positive control (sonic brushes) or negative control (manual brushes). The trend for optimized gingival health with O-R brushing was seen across the entire therapeutic spectrum of prestudy gingivitis incidence, as evidenced by the shifts in the average number of bleeding sites from study start to end, and the 7.4 and 1.8 greater odds of a shift to generally healthy with O-R technology versus manual and sonic brushes, respectively.

The Procter & Gamble Company sponsored every study in this meta-analysis. While this could be considered a potential source of systematic bias, this across-study risk of bias is mitigated because all studies were randomized, examiner-blinded and controlled. Furthermore, the robust nature and scope of the research supports that the results are valid and reproducible. The individual study analyses were based on the per-protocol population to assess the effect of adhering to intervention. Valid and reliable outcome measures were used in all studies and examiners were not aware of the participants' assigned intervention during the trial. All studies had a pre-specified analysis plan and results were included regardless of outcome.

The majority of the 16 gingivitis trials utilized the standardized Modified Gingival Index (MGI)<sup>24</sup> for quantifying gingival color and inflammation changes. Additionally, many included the Gingival Bleeding Index (GBI).23 This established index assesses bleeding upon stimulation with a periodontal probe and offers utility in gingivitis clinical research as its use both reflects typical real-world gingival health assessment and between-visit tracking in clinical practice. It also acknowledges the proven connection between observable bleeding and health status, thus providing a validated means for identifying shifts from disease to health with use of therapeutic interventions in clinical research.<sup>56</sup> The importance of diagnosing and treating gingival bleeding is underscored by the fact that it has been shown to be predictive of long-term outcomes for periodontitis. In a 26-year longitudinal trial of over 500 Norwegian males,<sup>57</sup> bleeding upon probing was prognostic of future attachment loss: sites that had a Gingival Index score of '2' (bleeding on probing) were found to have had 70% greater attachment loss versus those that had a GI score of '0' (non-inflamed). Notably, there was a 46-times greater risk of tooth loss with teeth adjacent to chronic inflamed tissue relative to teeth that were not in that environment.58 Beyond oral disease, assessing and managing gingival bleeding and inflammation is of importance in light of an emerging body of research that suggests some systemic conditions (in particular diabetes, cardiovascular disease, pre-term birth) may have linkages to periodontal disease.<sup>59-61</sup> For both oral and systemic health, it is therefore essential to control the precursor to periodontal disease (gingivitis) and gingival bleeding is a reliable diagnostic parameter and clinical research endpoint signifying the presence of gingival inflammation and its extent that is associated with health and/or disease progression.62-64

Bleeding is a central tenet of periodontal case definitions. As a result of the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions, the American Academy of Periodontology (AAP) and the European Federation of Periodontology (EFP) updated and recategorized the former disease classifications from 1999 and presented a new periodontitis staging and grading system, and asserted that definitions of periodontal health are critical in part for epidemiological surveillance as well as in establishing target therapeutic end points for periodontal therapies.<sup>36,65,66</sup> The consortia stated, "While gingival health and gingivitis have many clinical features, case definitions are primarily predicated on presence or absence of bleeding on probing."<sup>65</sup>

This meta-analysis report utilized the new gingival health and disease case definitions as a result of the availability of the subject-level data for individual bleeding scores. Consistent with the AAP and EFP's assessment that sites that progress to attachment loss have chronically greater levels of gingival inflammation and thus gingivitis management is a 'primary prevention strategy for periodontitis',<sup>36</sup> evidence-based determination of interventions which are clinically proven to reduce plaque and gingivitis and thus provide statistically and clinically meaningful odds ratios of transitioning patients toward a generally healthy periodontium with minimal bleeding is essential. In this meta-analysis, the inclusion of odds ratios provided a clear picture of the comparative abilities of the toothbrushes to foster transition from pre-treatment disease categories, and demonstrated that the likelihood of moving to gingival health was substantially in favor of those who were assigned to the O-R toothbrushes.

The 50% and 28% significantly greater bleeding reduction outcomes for O-R brushes versus the negative and positive controls, respectively, compare favorably to other interventions. McClanahan et al<sup>67</sup> found a 40-66% mean gingival bleeding reduction 1 week following a single professional dental prophylaxis, whereas when considering periodic recall interval prophylaxes in the prevention of gingivitis relative to none, a 2018 Cochrane review<sup>68</sup> of over 1,100 subjects did not find a benefit. Regular flossing has been shown to produce relatively greater gingival bleeding reductions of roughly 40% versus non-flossing in a RCT.<sup>69</sup>

While the studies in this meta-analysis were limited to a duration of 3 months or less, recently published multi-year research demonstrates lasting oral health effects of electric toothbrushes in markets for which oscillating-rotating toothbrushes are the most commonly used. An analysis of a large, long-term 11-year observational investigation<sup>70</sup> [Participants of Study of Health in Pomerania (SHIP)] of the longitudinal influence of electric toothbrushes on oral health variables (caries, periodontal health, tooth loss) in 2,819 adults found that the use of electric brushes provided a significant protective effect across time versus manual brushing, reducing clinical attachment loss progression by 21%, periodontal pocket depth progression by 22%, and producing 19.5% greater tooth retention. While the type of electric brush used was not differentiated, Oral-B electric brushes are the category leader in Germany<sup>71</sup> and it can therefore be inferred that a majority of the electric brushes used were O-R. Importantly, the inclusion of long-term periodontal probing, attachment level, and tooth loss data in the SHIP investigation provides for the first time a response to the statement from the 2014 Cochrane review of shorter-term trials: "Empirical data on thresholds for clinically important differences in plaque and gingivitis levels would help to determine whether oral hygiene aids provide important health benefits."17

Due to the unique access to the pooled studies' raw subject data, O-R electric brushes with round brush heads have been shown in the current analyses to provide significantly greater odds relative to sonic and manual brushes of patients transitioning from gingival bleeding and disease to health, the central goal of all sound patient oral care.

Based on the wealth of clinical data supporting the safety and efficacy of O-R toothbrushing technology, as noted in this meta-analysis and corroborated by independent reviews, clinicians can confidently recommend O-R electric toothbrushes to their patients to remove plaque and improve gingival health.

- a. SAS Institute, Cary, NC, USA.
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