

A 12-Week Clinical Comparison of an Oscillating-Rotating Power Brush Versus a Marketed Sonic Brush with Self-Adjusting Technology In Reducing Plaque and Gingivitis

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Abstract

- **Objective:** The aim of this investigation was to assess the comparative gingivitis and plaque reduction efficacy of a leading oscillating-rotating power toothbrush and a recently introduced sonic toothbrush in adults with gingivitis.
- **Methods:** This was a 12-week, randomized and controlled, parallel group, examiner-blind, single-center clinical study of 130 adults with pre-existing gingivitis and plaque. At baseline, the Modified Gingival Index (MGI), Gingival Bleeding Index (GBI), and total number of bleeding sites were assessed, along with plaque levels (whole mouth, gingival margin, and interproximal) via the Rustogi Modified Navy Plaque Index (RMNPI). Qualified subjects were randomly assigned to one of two power toothbrush test groups: the Oral-B® Triumph with SmartGuide™ (marketed in the United States as the Oral-B® Professional Care SmartSeries 5000 [D34]) oscillating-rotating brush, or the Colgate® ProClinical™ A1500 (also marketed as elmex® ProClinical®) sonic brush. Subjects brushed at home for two minutes twice daily with their assigned power toothbrush and a marketed sodium fluoride dentifrice, and were re-evaluated for gingivitis at Week 4 and Week 12 via the MGI, GBI, and total number of bleeding sites, and for plaque reduction via the RMNPI.
- **Results:** Ninety-seven percent (97%) of the 130 enrolled subjects completed the trial and 62 and 65 subjects in the oscillating-rotating and sonic brush groups, respectively, had evaluable data for analysis. Statistically significant mean reductions in all three gingivitis parameters and plaque relative to baseline were seen at both Weeks 4 and 12 with unsupervised use of both test toothbrushes ($p < 0.001$). The oscillating-rotating power brush provided statistically significantly superior reductions compared to the sonic brush in mean adjusted MGI (31% and 29% at Weeks 4 and 12, respectively; $p < 0.001$), GBI (17% at Week 12; $p = 0.047$), and total number of bleeding sites (48% and 30% at Weeks 4 and 12, respectively; $p = 0.002$), and produced statistically significantly greater relative mean adjusted plaque reductions for RMNPI whole mouth plaque (38% and 24% at Weeks 4 and 12, respectively; $p < 0.001$), gingival margin plaque (36% at Week 4; $p = 0.004$), and interproximal plaque (39% and 26% at Weeks 4 and 12, respectively; $p < 0.001$). Both power toothbrushes were well-tolerated.
- **Conclusion:** An advanced oscillating-rotating power toothbrush produced substantial, statistically superior reductions in plaque and gingivitis via multiple outcome measures compared to a new sonic toothbrush after both four weeks and 12 weeks of tooth brushing.

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Introduction

Bleeding associated with oral hygiene might appear to be an obvious signal that something is amiss, yet numerous investigations have shown a significant percentage of surveyed adults did not attribute their bleeding upon tooth brushing to gingivitis, or did not realize that gingivitis is an inflammatory disease with a potential progression to periodontitis and even systemic sequelae without intervention.¹⁻⁶ The prevalence statistics for gingivitis and periodontal disease are concerning; data recently released from the CDC's 2009-2010 NHANES full-mouth periodontal assessment survey found that about one in two (47.2%) American adults 30 years of age and above has periodontal disease, with the percentage rising to 70% in adults 65 years of age and above.⁷ Further, it has been suggested that previous prevalence estimates in the United States may have been significantly underestimated, given that earlier NHANES

surveys employed only partial mouth examinations.⁷ On a worldwide basis, the FDI World Dental Federation has estimated roughly 75% of adults may be afflicted with gingivitis.⁸

Despite the high global incidence of gingivitis/periodontitis, research has shown that this common chronic disease is not inevitable and there are readily modifiable risk factors, including appropriate oral hygiene.^{9,10} It has been widely accepted for many decades that the etiology of gingivitis is associated with the formation of bacterial pathogens formed within undisturbed dental plaque, leading to the characteristic inflammation and bleeding.^{11,12} Readily reversible in its earliest stages with effective oral hygiene, neglected gingivitis can lead to periodontal disease, with attendant gingival recession, loss of attachment, and potential tooth loss.^{13,14} Meticulous and frequent mechanical plaque removal via technically proficient manual tooth brushing along with interproximal cleaning has been understood to be

necessary for the prevention of gingivitis, yet a fairly small population segment appears able to achieve this, as indicated by oral hygiene regimen surveys and gingivitis prevalence data.¹⁵⁻¹⁸ Fortunately, most individuals attempt at least some form of plaque removal on a daily basis, and cosmetic concerns (*e.g.*, desire for whiter teeth, fresh breath) drive consumers to use, at a minimum, the mainstay of personal oral hygiene: the toothbrush.¹⁹ This underscores the value of using the most highly effective and clinically validated plaque-removing toothbrushes.

Toothbrush manufacturers like Oral-B have long recognized the importance of an optimally designed toothbrush, engineered for maximum plaque removal throughout the dentition and in the hard-to-clean areas, in assisting individuals to achieve better oral health without requiring difficult-to-achieve changes to their existing home care regimen. Ongoing technological innovation for superior plaque, gingivitis, and stain removal, validated through extensive clinical research, has culminated in the current family of Oral-B's rechargeable power toothbrushes featuring oscillating-rotating technology.²⁰ The oscillating-rotating mode of action has been shown in the Cochrane Collaboration's meta-analysis and systematic review of greater than 40 clinical trials to be the only type of power toothbrush with proven statistically significant superiority in plaque and gingivitis reduction versus a manual toothbrush.^{21,22} The Oral-B® Triumph (Procter & Gamble, Cincinnati, OH, USA; marketed as Oral-B® Professional Care SmartSeries 5000 in the United States) not only provides 8,800 oscillations each minute, but also simultaneously supplies 40,000 pulsations per minute; it has five unique cleaning modes and several interchangeable brush head selections, each designed for specific user needs and preferences.²³ Additionally, the remote wireless display (SmartGuide™) increases patient compliance, including extending brushing time and improving brushing technique through real-time visual feedback.^{23,24} Numerous published trials have demonstrated the plaque- and gingivitis-fighting superiority of Oral-B's advanced oscillating-rotating power toothbrushes when clinically tested head-to-head against leading sonic power brushes.²⁵⁻³⁰

A recent entry in the sonic toothbrush commercial market is the Colgate® ProClinical™ A1500, (Colgate-Palmolive, New York, NY, USA; also marketed as elmex® ProClinical®), sold by Colgate and manufactured by Omron Healthcare Co. Ltd., Japan. The ProClinical A1500 is reported by Colgate to be the first power brush in the UK with automatically adjusting "smart sensors" for different cleaning actions and speeds based on positioning, resulting in "...a superior clean for both teeth & gums."³¹ The ProClinical is described as employing a unique cleaning action that combines both up-down (pulsation-like) and side-to-side strokes in one brushing mode ("Sonic Wave"), with up to 32,500 strokes per minute, and using either of two available brush head types.³¹

Counter to a large body of literature showing oscillating-rotating brushes to be superior to sonic brushes in plaque and gingivitis control,^{25-30,32-35} a recently published report found greater plaque reduction for the sonic Colgate ProClinical A1500 compared to the Oral-B Triumph and another sonic brush in a four-week clinical trial.³⁶ The objective of the present investigation was to compare the effectiveness of a clinically proven Oral-B

oscillating-rotating power toothbrush versus the newly marketed sonic Colgate toothbrush in reducing plaque and gingivitis in a longer-term, well-controlled clinical trial with multiple efficacy parameters, in adults with confirmed gingivitis and plaque.

Materials and Methods

This clinical trial spanning 12 weeks was a controlled and randomized, examiner-blind, two-treatment, parallel group study at a single center, investigating the comparative plaque- and gingivitis-fighting efficacy of a marketed oscillating-rotating power toothbrush, the Oral-B Triumph with SmartGuide fitted with the Floss Action EB25 brush head (Procter & Gamble, Cincinnati, OH, USA), relative to a recently introduced sonic power toothbrush, the Colgate ProClinical A1500 with the Triple Clean brush head (Colgate-Palmolive, New York, NY, USA; Figure 1).



Figure 1. The Oral-B Triumph with SmartGuide and Floss Action brush head (marketed in the US as the Oral-B Professional Care SmartSeries 5000 [D34]) oscillating-rotating brush, and the Colgate ProClinical A1500 sonic brush with Triple Clean brush head.

Following independent Institutional Review Board review and approval of the subject consent form and study protocol, adult volunteers providing written informed consent were screened at the baseline visit via a detailed medical/dental history and intraoral clinical soft tissue evaluations for evidence of pre-existing plaque and gingivitis and other study qualification criteria. Specifically, participants were required to be at least 18 years of age and in generally good health, with a baseline Modified Gingival Index³⁷(MGI) score between 1.75 and 2.3, at least 10 bleeding sites as determined by the Gingival Bleeding Index³⁸ (GBI), and a baseline plaque (Rustogi Modification of the Navy Plaque Index³⁹ [RMNPI]) score exceeding 0.50. Eligible subjects needed a minimum of 16

natural teeth with facial and lingual scorable surfaces. Oral/dental conditions disqualifying participants included severe periodontal disease and/or active periodontitis treatment, grossly carious, fully crowned, or extensively restored teeth, orthodontic appliances or removable partial dentures, and perioral piercings. Additionally, to preclude confounding data, volunteers could not have used antibiotics or a chlorhexidine mouthrinse within the previous two weeks nor have a requirement for antibiotic premedication prior to dental procedures. Females self-reporting pregnancy or lactation were not enrolled. Prospective subjects were ineligible if they did not agree to delay elective dentistry (including prophylaxis), refrain from use of non-study oral products, or forgo participation in other oral care clinical studies for the duration of the investigation. At the baseline evaluations, any volunteers who had not followed pre-study directives to refrain from tooth brushing and all other oral hygiene procedures for the preceding 12 hours, and to cease eating, drinking, tobacco use, and gum chewing for at least the preceding four hours (except small water sips up to 45 minutes prior) were disqualified from study enrollment.

At baseline and the subsequent clinical visits, the initial subject evaluation was the oral soft tissue evaluation, followed by the MGI and GBI gingival health assessments, and lastly, following disclosing of dental plaque, the RMNPI. All clinical evaluations were performed by a single, highly experienced clinical grader. Descriptions of these safety and/or clinical efficacy assessments follow.

Oral Soft Tissue

In order to evaluate test product safety, assessment of the oral soft tissues via a visual examination of the oral cavity and perioral area was made, utilizing a standard dental light, dental mirror, and gauze. The structures examined included the gingiva (free and attached), hard and soft palate, oropharynx/uvula, buccal mucosa, tongue, floor of the mouth, labial mucosa, mucobuccal/mucolabial folds, lips, and perioral area. Any abnormal findings noted after product assignment (not present at baseline) and potentially test product-related were documented.

Modified Gingival Index (MGI)³⁷

Gingival inflammation was scored on the buccal and lingual marginal gingival and interdental papilla of all scorable teeth, employing a scale of 0–4 as follows: 0 = normal (absence of inflammation); 1 = mild inflammation (slight change of color, little change in texture) of any portion of, but not the entire marginal or papillary gingival unit; 2 = mild inflammation of the entire gingival unit; 3 = moderate inflammation (moderate glazing, redness, edema and/or hypertrophy) of the marginal or papillary gingival unit; and 4 = severe inflammation (marked redness and edema/hypertrophy, spontaneous bleeding or ulceration) of the marginal or papillary gingival unit. An MGI whole mouth score was calculated by summing the scores and then dividing by the number of examined gradable sites.

Gingival Bleeding Index (GBI)³⁸

Following the method described by Saxton and van der Ouderaa,³⁸ the gingiva was lightly air-dried and a periodontal

probe with a 0.5 mm diameter tip was inserted into the gingival crevice to a depth of 2 mm or until slight resistance was felt. The probe was then gently moved around the tooth at an angle of approximately 60° and in contact with the sulcular epithelium. Minimum axial force was used to avoid undue penetration into the tissue, and the probe was moved around the crevice, gently stretching the epithelium. Each of three gingival areas of the scorable teeth (buccal, mesial/distal, and lingual) was probed in this fashion, waiting approximately 30 seconds before recording the number of gingival units that bled, according to the following scale: 0 = absence of bleeding after 30 seconds; 1 = bleeding observed after 30 seconds; and 2 = immediate bleeding observed. The GBI whole mouth score was computed by totaling the scores and then dividing by the number of scorable sites examined.

Rustogi Modification of the Navy Plaque Index³⁹

The presence of subject dental plaque was determined by staining all surfaces with Chromo-O-Red erythrosine FD&C, red 3 disclosing solution (Germiphene Corp., Bradford, Ontario, Canada). Disclosed plaque was then quantified on nine sites per facial and lingual tooth surface of all 28 teeth for a maximum 504 sites total (excluding 3rd molars, crowns, and surfaces with cervical restorations) and scored as follows: 0 = absent; and 1 = present. A mean plaque index (MPI) was calculated for each subject by dividing the total number of tooth areas with plaque present by the total number of tooth areas scored on a whole mouth basis (areas A-I), along the gingival margin (areas A, B, C), and interproximally (D, F; Figure 2).

Subjects meeting all study entrance criteria at baseline were stratified based on entry gingivitis (MGI) and whole mouth mean plaque scores, tobacco use, and typical toothbrush used pre-study (manual or power brush), and randomly assigned via an encoded computer program to one of the two test power

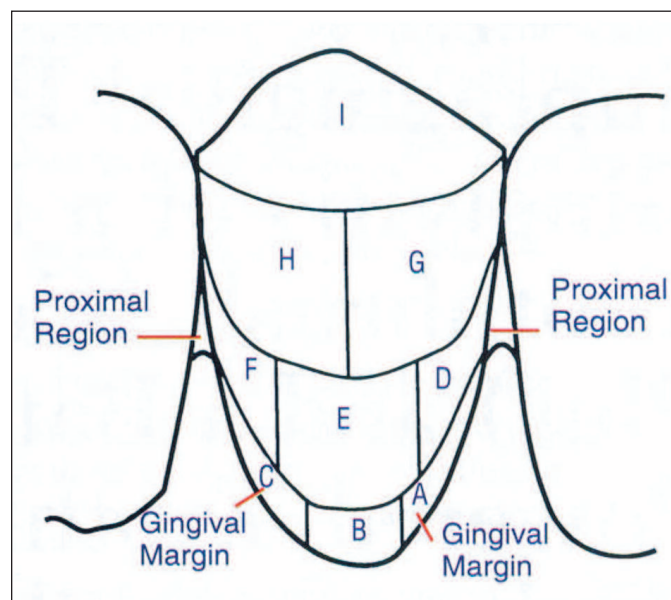


Figure 2. The Rustogi, et al. Modification of the Navy Plaque Index.³⁹ Disclosed plaque is scored in each facial and lingual tooth surface as present ("1") or absent ("0"). The whole mouth is represented by areas A-I; interproximal (approximal) regions are D and F, and the marginal (gingival) area includes A, B, and C.

brush groups. Identically appearing test kit boxes were dispensed to subjects, all containing two tubes of Crest® Cavity Protection (Procter & Gamble, Cincinnati, OH, USA) toothpaste. Kits for subjects assigned to the oscillating-rotating brush group contained a fully charged Oral-B Triumph with SmartGuide (in deactivated “demo” mode) and a charger, while subjects assigned to the sonic brush group received a fully charged Colgate ProClinical A1500 with a charger and adapter. Via both oral and written instructions for home use, subjects were instructed to brush their teeth with their assigned brush and a pea-sized amount of the dentifrice according to manufacturer instructions, for two minutes, twice daily, for the duration of the study. To verify adequate understanding of these instructions, prior to dismissal subjects performed the first brushing at the clinical site in front of a mirror with their assigned products under the supervision of site personnel, and in an area not accessible to the clinical grader for assurance of treatment assignment blinding.

Approximately four weeks after the baseline visit (Week 4), subjects were recalled for safety and efficacy clinical evaluations. All participants who were still in compliance with the study entrance criteria and who had abstained in the preceding 12 hours from tooth brushing and all other oral hygiene procedures, as well as ceased eating, drinking, tobacco use, and gum chewing for a minimum of four hours previously, were eligible to continue in the clinical trial. In the same manner as at the baseline visit, oral soft tissue, MGI and GBI gingivitis and bleeding, and disclosed RMNPI plaque evaluations were performed (in that order) to assess post-treatment test brush safety and effectiveness responses.

Subjects continued twice-daily assigned home test brush usage before returning to the clinical site about 12 weeks post-baseline for the final evaluations (Week 12) for those with confirmed continuing eligibility. All procedures and evaluations were identical to those at the Week 4 visit.

Statistical Analyses

Pre-study sizing was accomplished using power analyses with $\alpha = 0.05$, using a two-sided test and a sample size of 65 subjects per group (130 subjects total). Assuming the variability of whole mouth MGI was 0.0737, a 65-subject/group sample size was expected to provide 90% power to detect a difference in MGI mean reductions as small as 0.042 units between brush treatments. Similarly for plaque, assuming the variability of whole mouth RMNPI was 0.0464, a sample size of 65 subjects per group was expected to provide 90% power to detect a difference in RMNPI mean reductions of 0.027 units between test brushes.

Between-group baseline subject demographic data were assessed for balance using a two sample t-test for age, chi-square test for gender, smoking status, and brush type, and Fisher’s Exact test for race. Statistical analyses for gingivitis efficacy were based on whole mouth average MGI, GBI, or number of bleeding sites change from baseline scores (baseline minus Week 4 or 12). An analysis of covariance (ANCOVA) was performed to determine treatment differences on the whole mouth average

gingivitis reduction with the respective baseline gingivitis score as the covariate. Additionally, confidence intervals were generated on the treatment difference for the change from baseline scores. Separate analyses were performed for each gingivitis endpoint with MGI as the primary gingivitis endpoint.

Statistical analyses for plaque efficacy were based on average whole mouth RMNPI change from baseline score (baseline minus Week 4 or 12). The four- and 12-week plaque reductions were analyzed separately for treatment differences using an ANCOVA with baseline whole mouth RMNPI score as the covariate. Similar analysis was carried out for gingival margin and interproximal RMNPI, but with whole mouth RMNPI as the primary interest. Additionally, confidence intervals were generated on the treatment difference of the change from baseline scores.

Within-treatment differences from baseline for the gingivitis scores and RMNPI scores were tested versus zero for both visits using an ANCOVA model with the respective baseline score as the covariate.

All treatment comparisons were considered two-sided with an $\alpha = 0.05$ significance level.

Results

At baseline, 130 subjects were enrolled in the trial and randomized to a power brush test group: 65 in the Oral-B oscillating-rotating group and 65 in the Colgate sonic group. One-hundred twenty-six subjects (97%) completed the study and were evaluable at Week 12. Three subjects in the oscillating-rotating group were lost to follow-up after the baseline visit, and one additional subject in this group was lost to follow-up after Week 4. As shown in Table I, the randomized study population had an age range of 18 to 83 years, with a mean age of 36.2

Table I
Baseline Subject Demographics – Randomized Subjects

	Oscillating- Rotating	Sonic	Overall
Characteristic	n = 65	n = 65	n = 130
Mean Age (SD) ^a	35.9 (10.55)	36.5 (13.4)	36.2 (12.02)
Age Range	18–63	18–83	18–83
Female (n, %) ^b	43 (66%)	49 (75%)	92 (71%)
Male (n, %) ^b	22 (34%)	16 (25%)	38 (29%)
Race			
Caucasian ^c	33 (51%)	35 (54%)	68 (52%)
Black ^c	17 (26%)	17 (26%)	34 (26%)
All Other Ethnicities ^c	15 (23%)	13 (20%)	28 (22%)
Tobacco Users ^b	9 (14%)	12 (19%)	21 (16%)
Manual Brushers ^b	57 (88%)	56 (86%)	113 (87%)
Power Brushers ^b	8 (12%)	9 (14%)	17 (13%)

n = number of subjects; SD = standard deviation

^aTwo-sample t-test was used to compare between-group mean age (p = 0.788).

^bChi-square test was used to compare between-group gender, smoking status, and brush type balance (p = 0.247, p = 0.475, p = 0.795, respectively)

^cTwo-sided Fisher’s Exact Test was used to compare between-group ethnicity balance (p = 0.980)

years. Female subjects were more prevalent than males (70.8%). Caucasian subjects comprised 52.3% of the participants, and the majority of enrollees (83.9%) were non-smokers. Most participants entered the trial as manual toothbrush users (86.9%). In comparing all baseline demographic variables, the test groups were well-balanced with no statistically significant differences ($p \geq 0.247$).

Table II displays the results of the gingivitis parameter outcomes. Per the study entrance criteria, enrolling subjects had mild to moderate gingivitis: baseline whole mouth MGI means for the oscillating-rotating and sonic groups were 2.076 and 2.077, respectively ($p = 0.965$). Twice-daily use of both power brushes produced statistically significant mean reductions in gingivitis at Weeks 4 and 12 ($p < 0.001$). Compared to the sonic brush, the oscillating-rotating brush provided a 31.3% statistically significantly superior gingivitis-reducing benefit at Week 4 ($p < 0.001$), with mean adjusted MGI changes from baseline of 0.273 and 0.208, respectively. The oscillating-rotating brush also produced significantly greater MGI reductions at Week 12; the 28.9% superior relative gingivitis reduction favoring the Oral-B brush reflected an 0.089 adjusted mean MGI between-treatment difference ($p < 0.001$).

Gingivitis as measured by whole mouth GBI, and the number of bleeding sites did not differ significantly between power brush groups at baseline prior to treatment ($p \geq 0.358$), where the sonic group had a mean GBI of 0.142 and mean of 19.2 bleeding sites, and the oscillating-rotating group had GBI and bleeding site means of 0.128 and 18.3, respectively. Following

twice-daily unsupervised brushing, both brushes provided significant improvements in whole mouth GBI at both subject visits ($p < 0.001$), with the oscillating-rotating brush producing a 26% greater (non-significant) reduction benefit versus the sonic brush ($p = 0.062$) at Week 4, and a 17.1% statistically superior reduction in GBI compared to the sonic brush at Week 12 ($p = 0.047$). Subjects in each of the brush groups similarly saw significant reductions in the whole mouth total number of bleeding sites at both Week 4 and Week 12 ($p < 0.001$), but the changes were markedly greater with use of the oscillating-rotating brush: at Week 4, the Oral-B group had 47.5% significantly fewer mean bleeding sites compared to the sonic brush group ($p = 0.002$), and 29.9% relatively fewer mean bleeding sites at Week 12 ($p = 0.002$; Table II).

Table III summarizes the plaque reduction results. Enrolling subjects required evidence of plaque accumulation, and the respective whole mouth, gingival region, and interproximal area mean RMNPI scores for the sonic and oscillating-rotating brush groups did not differ meaningfully ($p \geq 0.286$). Both brushes significantly reduced whole mouth plaque across the 12-week study duration ($p \leq 0.001$ at both Weeks 4 and 12), however the whole mouth adjusted mean RMNPI plaque reduction produced by the oscillating-rotating brush was 37.5% statistically superior to the sonic brush at Week 4 ($p < 0.001$), and 24.2% significantly greater at Week 12 ($p < 0.001$).

Table II

Comparisons of Gingivitis Reductions From Baseline: Modified Gingival Index, Gingival Bleeding Index, and Number of Bleeding Sites Results

	Baseline Mean (SD)	Adjusted Mean Reduction from Baseline (SE)	% Difference Between Brushes ^a	p-value ^b
Modified Gingival Index				
<u>Week 4</u>				
Oscillating-Rotating (n = 62)	2.076 (0.079)	0.273 (0.012)	31.3%	< 0.001
Sonic (n = 65)	2.077 (0.086)	0.208 (0.012)		
<u>Week 12</u>				
Oscillating-Rotating (n = 61)	2.076 (0.079)	0.397 (0.017)	28.9%	< 0.001
Sonic (n=65)	2.077 (0.086)	0.308 (0.017)		
Gingival Bleeding Index				
<u>Week 4</u>				
Oscillating-Rotating (n = 62)	0.128 (0.081)	0.063 (0.005)	26.0%	0.062
Sonic (n = 65)	0.142 (0.093)	0.050 (0.005)		
<u>Week 12</u>				
Oscillating-Rotating (n = 61)	0.128 (0.081)	0.089 (0.005)	17.1%	0.047
Sonic (n = 65)	0.142 (0.093)	0.076 (0.004)		
Number of Bleeding Sites				
<u>Week 4</u>				
Oscillating-Rotating (n = 62)	18.3 (10.55)	9.0 (0.65)	47.5%	0.002
Sonic (n = 65)	19.2 (11.14)	6.1 (0.63)		
<u>Week 12</u>				
Oscillating-Rotating (n = 61)	18.3 (10.55)	12.6 (0.66)	29.9%	0.002
Sonic (n = 65)	19.2 (11.14)	9.7 (0.64)		

SD = standard deviation; SE = standard error; % = percentage
^aIn favor of oscillating-rotating over sonic
^bComparison versus baseline using a two-sided analysis of covariance (ANCOVA)

Table III

Comparisons of Plaque Reductions From Baseline: Rustogi Modified Navy Plaque Index Results

	Baseline Mean (SD)	Adjusted Mean Reduction from Baseline (SE)	% Difference Between Brushes ^a	p-value ^b
Whole Mouth RMNPI				
<u>Week 4</u>				
Oscillating-Rotating (n = 62)	0.608 (0.051)	0.110 (0.005)	37.5%	< 0.001 ^c
Sonic (n = 65)	0.602 (0.047)	0.080 (0.005)		
<u>Week 12</u>				
Oscillating-Rotating (n = 61)	0.608 (0.051)	0.153 (0.005)	24.2%	< 0.001 ^c
Sonic (n=65)	0.602 (0.047)	0.124 (0.005)		
Gingival Margin RMNPI				
<u>Week 4</u>				
Oscillating-Rotating (n = 62)	0.998 (0.012)	0.060 (0.004)	36.4%	0.004 ^c
Sonic (n = 65)	0.997 (0.008)	0.044 (0.004)		
<u>Week 12</u>				
Oscillating-Rotating (n = 61)	0.998 (0.012)	0.090 (0.006)	12.5%	0.194 ^c
Sonic (n = 65)	0.997 (0.008)	0.080 (0.006)		
Interproximal RMNPI				
<u>Week 4</u>				
Oscillating-Rotating (n = 62)	0.993 (0.025)	0.275 (0.014)	38.9%	< 0.001 ^c
Sonic (n = 65)	0.985 (0.054)	0.198 (0.014)		
<u>Week 12</u>				
Oscillating-Rotating (n = 61)	0.993 (0.025)	0.407 (0.017)	26.4%	< 0.001 ^c
Sonic (n = 65)	0.985 (0.054)	0.322 (0.016)		

SD = standard deviation; SE = standard error; % = percentage
^aIn favor of oscillating-rotating over sonic
^bComparison versus baseline using a two-sided analysis of covariance (ANCOVA)
^cComparison versus baseline using two-sided analysis of variance (ANOVA) since all subjects but nine had a baseline mean value of one for gingival margin and interproximal RMNPI.

For the gingival margin RMNPI whole mouth analysis, the oscillating-rotating brush significantly outperformed the sonic power brush with 36.4% greater mean adjusted plaque reduction at Week 4 ($p = 0.004$); the brush groups did not differ statistically at Week 12 ($p = 0.194$; Table III). In comparing the brush groups at the interproximal (approximal) region, while each test brush provided significant improvements compared to baseline ($p < 0.001$), the oscillating-rotating group saw 38.9% and 26.4% significantly superior reductions in plaque compared to the sonic group at Weeks 4 and 12, respectively ($p < 0.001$).

Both brushes were well-tolerated, and there were no adverse events reported or observed.

Discussion

Consumer desire for an attractive, healthy-looking smile is at an all-time high, and there is a growing awareness and interest in the latest technologically advanced oral hygiene products such as power toothbrushes. In seeking esthetic benefits, patients may be less aware of the important gingival health advantages afforded by smartly designed brushes that reduce the degree of technical acumen needed to achieve good plaque control; research shows motivation and/or skill for efficient manual tooth brushing is consistently suboptimal to prevent gingival disease in a large percentage of adults.^{7,8,15-18} Toothbrush manufacturers have keyed in on the need for highly effective, yet easy to use, power toothbrushes, with ongoing research and development leading to novel design features, particularly in the most widely used classes of power toothbrushes, the oscillating-rotating and sonic.

Clinicians are frequently asked for opinions on specific products, and it is necessary to stay apprised of the research literature to make well-informed patient product recommendations based on clinically proven, consistent data. Oscillating-rotating power toothbrushes have a lengthy, well-established history of demonstrating clinical superiority to both manual toothbrushes and other modes of power brushes, with a favorable safety profile across myriad subject populations, settings, and independent investigators.^{21,22,25-30,32-35,40-42} The Oral-B Triumph oscillating-rotating brush, for example, has been shown in multiple clinical investigations, short-term and longer-term, both parallel group and crossover design, to produce statistically significantly greater plaque and gingivitis reduction as compared to sonic power brush controls.^{25-30,32-35} The 2010 Cochrane Collaboration review of 17 clinical studies involving roughly 1400 subjects concluded that oscillating-rotating brushes were more efficacious than sonic brushes for plaque and gingivitis benefits over four- to 12-week test periods.⁴³

In contrast, Ayad, *et al.*³⁶ recently published the results of a four-week clinical trial comparing the sonic Colgate ProClinical A1500 to another sonic power brush, Sonicare™ Flexcare (Philips Oral Healthcare, Snoqualmie, WA, USA), and the oscillating-rotating Oral-B Triumph. The report stated that the Colgate ProClinical sonic brush produced significantly more plaque reduction (RMNPI) after a single use and after four weeks than both the oscillating-rotating and Sonicare brushes. No corresponding significantly greater gingivitis-reducing

benefit relative to the comparator Oral-B power brush was found for Colgate ProClinical, despite the reported superior relative plaque reduction. Further, differing markedly from other published research,^{25-30,32-35,43} study results did not show Oral-B Triumph provided statistically greater plaque removal than Sonicare Flexcare and showed only marginal plaque removal efficacy after four weeks in the interproximal areas for both Oral-B Triumph and Sonicare Flexcare brushes. This single report thus is contradictory in scope to a preponderance of published clinical literature to date showing oscillating-rotating technology to be superior to brushes with other modes of action in reducing plaque and improving gingival health.^{21,22,25-30,32-35,40-43}

In the clinical investigation reported here, consistent with the aforementioned body of published literature, the oscillating-rotating power toothbrush was statistically significantly superior to the newly introduced Colgate ProClinical A1500 sonic brush by all three outcome measures of gingival health (MGI, GBI, number of bleeding sites) and at each RMNPI plaque region assessed (whole mouth, gingival margin, interproximal) at both Week 4 and Week 12, with the exception of GBI at Week 4 and gingival margin plaque at Week 12, where the oscillating-rotating brush was directionally, though not statistically, better than the sonic brush. The whole mouth plaque reduction benefits favoring Oral-B Triumph ranged from 24.2%–37.5% over the 12-week test period, and as might be expected based on the relationship between plaque and inflammation,^{11,12} were associated with improvements in gingivitis, with superior MGI reductions from baseline for the oscillating-rotating brush versus the sonic brush of 28.9%–31.3% and 29.9%–47.5% superiority in total number of bleeding sites average reduction. The magnitude of the mean post-treatment gingivitis reductions clearly and substantially favoring the oscillating-rotating brush relative to the sonic brush are in close agreement with those in a recently published 12-week similarly designed trial, where Oral-B Triumph was compared to Sonicare DiamondClean.³⁰ There, MGI and bleeding site improvements were 31.9%–32.3% and 34.9%–43.4% significantly greater, respectively, for the oscillating-rotating brush versus the sonic brush.

Conclusion

Consistent with the literature evaluating oscillating-rotating power toothbrushes with comparator brushes, an advanced oscillating-rotating power toothbrush produced substantial, statistically superior reductions in plaque and gingivitis via multiple outcome measures compared to a new sonic toothbrush, after both four weeks and 12 weeks of tooth brushing.

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