8-week evaluation of anti-plaque and anti-gingivitis benefits of a unique multi-directional power toothbrush versus a sonic control toothbrush

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ABSTRACT: Purpose: To assess the ability of a novel multi-directional power toothbrush to control plaque and gingivitis when compared to a marketed sonic power toothbrush control. **Methods:** This was a randomized and controlled, examiner-blinded, parallel group, 8-week study at a single center, in adult subjects with mild-to-moderate gingivitis. Pre-treatment gingivitis levels and plaque coverage were evaluated at baseline using the Lobene Modified Gingival Index (MGI), the Gingival Bleeding Index (GBI), and the Rustogi Modified Navy Plaque Index (RMNPI). Qualified subjects were randomly assigned to either a novel multi-directional power toothbrush with a wireless display (Oral-B Professional Deep Sweep + SmartGuide TRICLEAN 5000, also marketed as Oral-B TriZone) or the marketed control sonic toothbrush (Philips Sonicare FlexCare). After a supervised brushing at the clinical site at baseline, subjects brushed unsupervised at home twice daily according to manufacturer instructions with the assigned test brush and standard sodium fluoride dentifrice. After 8 weeks, subjects were recalled to assess toothbrush efficacy via the MGI and GBI gingivitis and RMNPI plaque evaluations. **Results:** A total of 128 evaluable subjects completed the study. After 8 weeks of brushing, both test toothbrushes provided statistically significant reductions compared to baseline in mean whole mouth MGI and GBI, and in RMNPI whole mouth and interproximal (approximal) sites ($P< 0.001$). The novel multi-directional power brush consistently produced significantly superior anti-gingivitis and anti-plaque reductions relative to pre-treatment versus the sonic control brush: the Week 8 adjusted mean relative reductions were 30% and 29% greater for whole mouth MGI and GBI, respectively ($P< 0.001$); and were 44% and 77% greater for the RMNPI whole mouth and interproximal regions, respectively ($P\leq 0.003$). Both toothbrushes were well-tolerated. (*Am J Dent* 2012;25 Sp Is A:27A-32A).

CLINICAL SIGNIFICANCE: Brushing for an 8-week period with a novel multi-directional power toothbrush with wireless display provided superior gingivitis and plaque reductions relative to a marketed sonic control toothbrush.

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Introduction

Plaque-induced gingivitis is one of the most common, yet preventable, afflictions worldwide, with epidemiologic surveys estimating that up to four-fifths of adults may be impacted.[1,2] While the edematous papillae and gingival margins along with bleeding upon provocation that are characteristic of gingivitis are readily apparent to the examining clinician, patients may be unaware of these signs of infection or their significance. Others recognize that gingivitis is undesirable, yet fail to achieve optimal gingival health using their routine oral hygiene habits.[3]

In fact, research[4-11] has demonstrated that a majority of adults do not floss regularly, and do not brush efficiently and/or long enough to thoroughly remove the dental plaque that is associated with gingival inflammation, and when left untreated, results in potentially periodontitis and systemic sequelae. A lack of plaque removal in the interproximal and other difficult to clean oral regions is of particular concern, given that periodontal lesions and dental caries are more prevalent where cleaning is not satisfactory.[12,13] While many adults' home care regimens may be substandard, it is clear that at a minimum, almost all use a toothbrush.[14] Changing long-standing habits can prove difficult and time-consuming,[4] but incorporating a technologically-advanced power toothbrush with enhanced plaque-removal efficiency into the daily routine is a simple strategy that can yield substantial gum health benefits and blunt the impact of inadequate manual brushing technique mastery and/or lack of interproximal debridement. Several decades after their introduction, it is now well-established that power toothbrushes are safe and effective.[15-17]

Sonic toothbrushes represent one type of power brush technology. One of the more recently introduced sonic brushes, the Sonicare FlexCare[a] with ProResults[a] brush head, uses side-to-side action and was designed with a longer shaft and modified radial configuration to, according to the manufacturer, provide more consistent cleaning with lesser dependence on brushing technique, and to better clean the harder-to-access posterior regions.[18] In a 4-week randomized clinical trial, Holt et al[19] reported that Sonicare FlexCare provided statistically significant reductions in plaque and gingivitis versus baseline. At Week 4, FlexCare also demonstrated significant advantages versus the manual toothbrush control for reducing bleeding and plaque, including plaque in posterior and interproximal sub-regions. Milleman et al[20] demonstrated that Sonicare FlexCare produced significant reductions in plaque versus the Sonicare Elite 9000,[a] with the greatest effects seen on anterior teeth and interproximal surfaces, in a randomized, crossover study.

Oral-B[b] has a long history of producing technologically-advanced power brushes with clinically-proven superior anti-plaque and anti-gingivitis benefits compared to power and manual toothbrush controls.[21,22] The newest entry in the Oral-B power brush family, marketed as Oral-B Professional Deep Sweep + SmartGuide TRICLEAN 5000[b] in the United States

Figure. **A.** New multi-directional power toothbrush with wireless display. **B.** Sonic toothbrush control.

and Oral-B TriZone[b] in Europe, has multi-directional 3-D, triple-zone cleaning action designed to disrupt and sweep away plaque, even reaching the interdental spaces; all while providing an experience familiar to manual brush users. The model is also available with a wireless display (SmartGuide) to help guide patients' brushing time and technique, and is described in greater detail in the introductory article of this special issue.[23]

This randomized and controlled 8-week clinical trial evaluated the anti-plaque and anti-gingivitis efficacy of this innovative brush with wireless display when compared to Sonicare FlexCare, a sonic power control toothbrush.

Materials and Methods

A randomized two-treatment, parallel group, examiner-blinded, single center study design was utilized for this 8-week clinical investigation. Following review and approval of the study protocol and subject consent form by the Institutional review board, the trial commenced with recruitment of adult volunteers. In order to participate, prospective subjects were required to be at least 18 years of age and in good general health. Enrollees further needed a minimum of 16 natural, scorable teeth, evidence of gingivitis (at least 10 sites with a score of '1' or '2' via the Gingival Bleeding Index[24] and a baseline Modified Gingival Index[25] score between 1.75 and 2.3); and a baseline plaque score of at least 0.50 using the Rustogi Modified Navy Plaque Index[26] for qualification. Where any of the following conditions were present at screening, potential subjects were excluded from participation: severe periodontal disease or active periodontitis treatment; grossly carious and/or extensively restored teeth; the need for antibiotic pre-medication prior to dental procedures; orthodontics or removable appliances; antibiotic or chlorhexidine usage within 2 weeks of study inception; pregnancy or lactation; or any other diseases or conditions which could interfere with study participation. Once enrolled, subjects additionally were mandated to follow pre-visit instructions pertaining to food/drink/oral hygiene restrictions and abstain from elective dentistry (including prophylaxes) and chlorhexidine, or any other non-assigned oral care products. Violators of the continuing eligibility requirements or subjects who were treated with antibiotics during the trial, were to be excluded from the data analyses or further study participation.

Study participants were directed to cease all oral hygiene 12 hours prior to the baseline visit, and to discontinue eating, chewing gum, drinking, and using tobacco 4 hours in advance of the visit. Subjects complying with the pre-study restrictions and providing written informed consent received a baseline examination of the oral hard and soft tissues, followed by two separate evaluations of gingivitis status: the Modified Gingival Index (MGI)[25] and the Gingival Bleeding Index (GBI).[24] A disclosed plaque examination – the Rustogi Modification of the Navy Plaque Index (RMNPI)[26] was then conducted to assess pre-treatment plaque levels. Qualifying subjects were stratified based on tobacco use, typical toothbrush used pre-study (manual or power), MGI gingivitis scores (≤0.20 versus >2.0), and whole mouth mean RMNPI scores (≤0.65 versus >0.65). Next, using a computer balance and assignment program, subjects were randomly assigned to one of the two toothbrush test groups (Figure):

1. Multi-directional rechargeable power toothbrush: Oral-B Professional Deep Sweep + SmartGuide TRICLEAN 5000 (D34/EB30[b]) in the United States (marketed as Oral-B TriZone in other regions), with the SmartGuide demonstration mode deactivated; or
2. Marketed sonic power toothbrush control: Philips Sonicare FlexCare with ProResults brush head (HX6911[a]), with the EasyStart feature deactivated.

Subjects in both the experimental and control brush groups were directed to brush according to the manufacturers' instructions twice daily for 2 minutes each brushing, after applying the supplied Crest Cavity Protection[b] dentifrice (0.243% sodium fluoride) to their brush head. The randomization and subject brushing was carried out in a protected area separate from that of the study evaluations for assurance of examiner- and data recorder-blinding. The first brushing at the baseline visit was supervised by clinic personnel in front of a mirror to ensure understanding of the verbal and written usage instructions. All other toothbrushing over the ensuing study period was unsupervised in the home setting.

After 8 weeks following the baseline visit, subjects were recalled to the clinical site for plaque and gingivitis evaluations. Previous to the visit, subjects were reminded to follow the previous pre-visit hygiene and food restrictions. Oral hard and soft tissue evaluations were performed to evaluate any adverse events. The MGI evaluation was conducted, followed by the GBI. Plaque levels were then determined via the RMNPI examination.

Clinical outcome parameters - All clinical safety and efficacy

Table 1. Baseline subject demographics. Randomized subjects.

Characteristic	Oral-B multi-directional power brush N=65	Sonic control brush N=65	Total N=130
Mean age (SD)[A]	43.7 (10.6)	42.8 (11.5)	43.3 (11.0)
Age range	18-69	18-69	18-69
Female (N, %)[B]	42 (64.6%)	45 (69.2%)	87 (66.9%)
Male (N, %)[B]	23 (35.4%)	20 (30.8%)	43 (33.1%)
Smoker (N, %)[C]			
Yes	13 (20.0%)	11 (16.9%)	24 (18.5%)
No	52 (80.0%)	54 (83.1%)	106 (81.5%)
Brush type[B]			
Manual	56 (86.1%)	54 (83.1%)	110 (84.6%)
Power	9 (13.9%)	11 (16.9%)	20 (15.4%)

SD = standard deviation; N= number of subjects.
[A] Two sample t-test was used to compare mean age between the two groups (P=0.647).
[B,C] Chi-Square test was used to assess balance between the two groups for gender (P= 0.576), smoking status (P= 0.651), and pre-study brush type (P= 0.627).

evaluations were performed by a single grader highly experienced in each of the respective methods.

Assessment of the oral soft tissues was accomplished via a visual examination of the oral cavity and perioral region using a standard dental light and mirror and gauze, and 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 potentially product-related and not noted at the baseline evaluation or worsening since treatment were documented.

The initial gingivitis evaluation (MGI) was scored by the examiner on six gingival areas (distobuccal, buccal, mesiobuccal, mesiolingual, lingual and distolingual) of all scorable teeth, using 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. Whole mouth MGI scores were computed by summing all scores and dividing by the number of scorable sites examined.

With the second assessment of gingival health, GBI, 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 run gently around the tooth at an angle of approximately 60 degrees 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 six gingival areas (distobuccal, buccal, mesiobuccal, mesiolingual, lingual and distolingual) of the scorable teeth were probed in a likewise manner, waiting approximately 30 seconds before recording the number of gingival units which 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 calculated by totaling all scores and dividing by the number of scorable sites examined.

Table 2. Baseline MGI, GBI and RMNPI results.

	N	Baseline mean (SD)	P-value*
Modified Gingival Index			
Oral-B multi-directional power brush	65	2.066 (0.0880)	0.820
Sonic control brush	65	2.070 (0.0853)	
Gingival Bleeding Index			
Oral-B multi-directional power brush	65	0.114 (0.0615)	0.238
Sonic control brush	65	0.103 (0.0471)	
RMNPI – Whole Mouth			
Oral-B multi-directional power brush	65	0.601 (0.0436)	0.979
Sonic control brush	65	0.601 (0.0419)	
RMNPI – Interproximal			
Oral-B multi-directional power brush	65	0.965 (0.0627)	0.528
Sonic control brush	65	0.958 (0.0703)	

SD = standard deviation; N = number of subjects.
*T-test P-value for treatment group comparison at study baseline.

Following both gingivitis evaluations, subjects rinsed with 2.5 milliliters of Chroma-O-Red[c] erythrosine FD&C, red #3 disclosing solution for 10 seconds to stain all tooth surfaces for the presence of dental plaque. The examiner then performed the RMNPI plaque examination as follows: disclosed plaque was quantified on nine sites per facial and lingual tooth surface for a maximum of 504 total sites (excluding third molars, crowns, and surfaces with cervical restorations). Plaque coverage was scored as 0= Absent or 1= Present. A mean plaque index (MPI) was calculated for each subject on a whole mouth basis (areas A-I) and separately for the interproximal (approximal) regions (areas D, F).

Statistical analyses - Assuming a sample size of 65 completing subjects per brush test group and variability of 0.054 whole mouth mean MGI, the resulting 90% power was expected to detect a mean MGI difference between groups (using two-sided testing with a 5% significance level) as small as 0.035 units. With similar assumptions for RMNPI plaque and an assumed variability of 0.038, a mean between-group plaque difference as small as 0.022 units could be detected.

Baseline subject demographic data were compared between the test groups using a two-sample t-test for age, and a Chi-Square test for gender, smoking status, and pre-study brush type. The within-treatment Week 8 differences from baseline for MGI, GBI and RMNPI were tested versus zero using an ANCOVA with the respective baseline scores as covariate. In comparing post-treatment results between test groups, the Week 8 gingivitis (MGI, GBI) and RMNPI plaque reductions compared to pre-treatment were analyzed separately using an ANCOVA with baseline whole mouth scores as covariate. Confidence intervals were additionally generated based on the treatment difference of the change from baseline scores. Similar analyses were conducted for the interproximal (approximal) regions of the RMNPI. All comparisons were two-sided at the 0.05 level of significance.

Results

At study baseline, 130 subjects (65 per group) were randomly assigned to one of the two test toothbrushes. Two subjects, one in each toothbrush group, withdrew from the

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Table 3. Week 8 results for MGI, GBI, and RMNPI.

	N	Adjusted mean change from baseline (SE)[A]	Percent change from baseline[B]	Between treatment difference (SE) 95% CI	Percent Oral-B greater reduction versus Control[C,D]
MGI					
Oral-B multi-directional power brush	64	0.299 (0.0059)	14.5%	0.069 (0.0083)	30.0%
Sonic control brush	64	0.230 (0.0059)	11.1%	(0.052, 0.085)	(P< 0.001)
GBI					
Oral-B multi-directional power brush	64	0.063 (0.0024)	55.3%	0.014 (0.0034)	28.6%
Sonic control brush	64	0.049 (0.0024)	47.6%	(0.007, 0.021)	(P< 0.001)
Whole Mouth RMNPI					
Oral-B multi-directional power brush	64	0.074 (0.0053)	12.3%	0.023 (0.0075)	44.2%
Sonic control brush	64	0.052 (0.0053)	8.7%	(0.008, 0.038)	(P= 0.003)
Interproximal RMNPI					
Oral-B multi-directional power brush	64	0.237 (0.0191)	24.6%	0.103 (0.0270)	76.9%
Sonic control brush	64	0.134 (0.0191)	14.0%	(0.049, 0.156)	(P< 0.001)

MGI = Modified Gingival Index; GBI = Gingival Bleeding Index; RMNPI = Rustogi Modified Navy Plaque Index.
SE = standard error; CI = confidence interval; N = number of subjects.

[A] Within-brush difference from baseline was tested versus zero via ANCOVA. For both MGI and GBI, no significant interactions (P= 0.414 and P= 0.220, respectively) were detected between baseline covariate and treatment and were removed from the models. The MGI covariate was non-significant (P= 0.648), and the GBI covariate was significant (P< 0.001). For RMNPI, borderline significant interaction (P= 0.045) was detected between baseline covariate and treatment and was retained in the model.

[B] Change from Baseline = 100% (Adjusted mean change divided by Baseline mean). P< 0.001 for both comparisons.

[C] Oral-B adjusted mean reduction – Sonicare adjusted mean reduction)/Sonicare adjusted mean reduction.

[D] Two-sided P-value for treatment comparisons of Week 8 MGI, GBI, and RMNPI reduction via ANCOVA with baseline as covariate.

trial after the baseline visit, resulting in 128 subjects (98%) completing the 8-week study, all with fully evaluable data. As shown in Table 1, the randomized study population averaged 43.3 years, with a range of 18 to 69 years. Sixty-seven percent (67%) of study participants were female, a majority (82%) were non-smokers, and 85% of all subjects were manual toothbrush users prior to study entrance. The test groups were well-balanced with respect to these demographic variables (P≥ 0.576).

Modified Gingival Index (MGI) - Pre-treatment subjects' gingival health as evaluated by the MGI did not differ significantly between brush groups, with baseline mean MGI scores of 2.066 for the multi-directional power brush group and 2.070 for the sonic brush control group (P= 0.820) (Table 2). After 8 weeks of brushing, compared to baseline, subjects in both toothbrush groups saw an improvement in gingivitis as evidenced by a statistically significant (P< 0.001) lower adjusted mean MGI score, with reductions versus baseline of 0.299 (14.5%) and 0.230 (11.1%) for the multi-directional power brush and sonic brush control groups, respectively (Table 3). Comparing the post-treatment gingivitis reductions between the two toothbrush groups revealed a treatment difference of 0.069, representing a 30% statistically superior (P< 0.001) mean gingivitis reduction for the multi-directional power brush versus the sonic brush control.

Gingival Bleeding Index (GBI) - The baseline GBI mean scores of 0.114 and 0.103 for the multi-directional power and sonic brush groups, respectively, were not significantly different (P= 0.238) (Table 2). With twice daily brushing for 8 weeks, the adjusted mean GBI scores were significantly (P< 0.001) reduced compared to baseline by 55.3% (0.063 reduction) for the multi-directional power brush group, and 47.6% (0.049 reduction) for the sonic brush control group (Table 3). The reduction in gingival bleeding relative to pre-treatment was 28.6% greater (0.014 adjusted mean between-group difference) for the multi-directional power brush group versus the sonic brush control group (P< 0.001) (Table 3).

Rustogi Modified Navy Plaque Index (RMNPI) - Pre-treatment plaque levels at baseline did not differ between brush groups, where the RMNPI whole mouth mean scores were 0.601 for each brush group (P= 0.979) (Table 2). As shown in Table 3, both groups realized significant plaque reductions after 8 weeks, with an adjusted whole mouth mean reduction and percentage improvement versus baseline of 0.074 and 12.3%, respectively, for the multi-directional power brush group, and 0.052 and 8.7%, respectively, for the sonic brush control group (P< 0.001). A comparison of the Week 8 plaque reduction between the brush groups showed that the multi-directional power brush produced a 44.2% significantly superior reduction (P= 0.003) in mean whole mouth RMPNI with a difference of 0.023 (Table 3).

As depicted in Table 2, at baseline, the mean RMNPI interproximal (approximal) region scores were similar between the multi-directional power (0.965) and sonic control (0.958) brush groups (P= 0.528). By Week 8, post-treatment adjusted mean interproximal RMNPI scores were significantly (P< 0.001) lower compared with pre-treatment in both brush groups, with mean reductions of 0.237 for the novel multi-directional power brush and 0.134 for the sonic brush control; this translated to reductions versus baseline of 24.6% and 14%, respectively (Table 3). Brushing for 8 weeks with the novel multi-directional power brush produced a 76.9% significantly greater reduction in interproximal plaque (P< 0.001), whereas the between-brush reduction difference was 0.103 (Table 3).

There were no reported product-related adverse events, indicating both toothbrushes were well-tolerated.

Discussion

A common frustration of dental professionals providing in-office oral hygiene instruction is the apparent lack of full compliance in an undesirably large number of individuals.

Research reveals that when the patient returns for a recall visit, the inflamed and bleeding gingival and/or interproximal regions laden with plaque or calculus are still present despite previous brushing and flossing directions, proving the challenge in establishing consistent interproximal cleaning and sufficiently rigorous manual toothbrushing.[27] Certain power toothbrushes with strategically-formulated bristle design, to penetrate the more difficult to clean interdental regions while requiring minimal user effort, can therefore be a welcome addition to the patient's home care regimen.

The Sonicare Flexcare sonic power toothbrush is widely available, and when used with the ProResults brush head, is stated by the manufacturer to produce greater tooth coverage and superior cleaning to manual and power toothbrush controls, including in the areas most challenging to access.[18] Previous clinical research[19,28,29] has shown that brushing with the Sonicare brush with the ProResults brush head gave significant mean plaque and gingivitis reductions versus baseline. Based on these results, this brush was employed as a positive control in the anti-plaque and anti-gingivitis assessment of the novel Oral-B multi-directional power brush in the clinical trial reported herein.

The results of this controlled and examiner-blinded 8-week trial demonstrated that while both toothbrushes provided statistically significant reductions in gingivitis and plaque versus baseline, the new multi-directional power brush uniformly yielded highly significantly greater reductions compared to the Sonicare Flexcare control across every clinical outcome parameter. For whole mouth plaque, subjects brushing with the multi-directional power brush saw a 44% greater mean RMNPI plaque reduction at Week 8 than those using the sonic brush control. The between-brush benefit in the interproximal (approximal) RMNPI regions favoring the new power brush versus the sonic brush control was even more dramatic, with a 77% significantly superior mean plaque reduction, validating the effectiveness of the distinct multi-directional, pulsating and sweeping action to displace plaque where interdental aids are often suggested. Consistent with research showing that significant decreases in plaque via power toothbrushing have been associated with improvements in gingival health,[17,21] it is not surprising that the multi-directional power brush-assigned group experienced gingivitis reductions. The magnitude of these benefits, 30% and 29% significantly superior mean reductions in gingivitis (MGI) and gingival bleeding (GBI), respectively, compared with the sonic brush control is substantial. Using the variability computed from this study and a sample size of 64 per group, a difference in MGI reductions between brushes of 0.024 could be detected with 80% power.

In conclusion, brushing for an 8-week period with a novel multi-directional power toothbrush consistently provided superior gingivitis and plaque reductions relative to a marketed sonic control toothbrush.

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