Special Issue Article

A 4-week clinical comparison of a novel multi-directional power brush to a manual toothbrush in the reduction of gingivitis and plaque

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ABSTRACT: **Purpose:** To evaluate the efficacy of a novel multi-directional power toothbrush in reducing plaque and gingivitis relative to a standard manual toothbrush control. **Methods:** This 4-week, randomized and controlled, single-center, parallel group, examiner-blinded clinical study enrolled adults with mild-to-moderate gingivitis. At baseline, pre-treatment gingivitis and plaque levels were assessed via the Lobene Modified Gingival Index (MGI), the Gingival Bleeding Index (GBI), and the Rustogi Modified Navy Plaque Index (RMNPI). Subjects qualifying were assigned randomly to one of two toothbrush groups: a novel multi-directional power toothbrush (Oral-B Professional Deep Sweep TRICLEAN 1000, also marketed as Oral-B TriZone) or a standard soft manual control toothbrush. Aside from a supervised brushing at baseline on-site, subjects brushed at home twice daily with their assigned test brush. After 1 week, subjects returned for RMNPI plaque evaluations. At Week 4, subjects were again recalled to evaluate toothbrush efficacy, and received MGI and GBI gingivitis and RMNPI plaque evaluations. **Results:** 119 evaluable subjects completed the study. Both the novel power and manual control toothbrushes yielded statistically significant ($P< 0.001$) mean plaque reductions compared to baseline at Weeks 1 and 4 (except Week 1 manual brush gingival margin) and significant mean MGI and GBI gingivitis reductions ($P< 0.001$). Comparing the relative effectiveness of the test brushes, the novel multi-directional power brush produced significantly superior anti-gingivitis and anti-plaque reductions compared to pre-treatment relative to the manual control brush in every analysis at both time points. The Week 4 adjusted mean relative reductions favoring the multi-directional power brush were 3 and 1.49 times greater for whole mouth MGI and GBI, respectively ($P< 0.001$); and were 2.1, 4.7 and 2 times greater for the RMNPI whole mouth, gingival margin and interproximal regions, respectively ($P< 0.001$). Both toothbrushes were well-tolerated. (*Am J Dent* 2012;25 Sp Is A:14A-20A).

CLINICAL SIGNIFICANCE: A novel multi-directional power toothbrush provided superior gingivitis and plaque reductions relative to a manual control toothbrush over a 4-week period.

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Introduction

Power toothbrushes have evolved and grown technologically more sophisticated in recent years with increased acceptance by consumers. Still, there remains a sizable segment of consumers who continue to use a conventional manual toothbrush, with some preferring the size and feel of the manual brush head and/or the manual brushing technique. While optimal gingival health is certainly possible with use of a manual toothbrush, research has shown that many adults find it formidable to fully comply with professional advice to mechanically remove all dental plaque daily, instead defaulting to what is typically the standard home regimen: manual toothbrushing less than the suggested 2 minutes twice daily, without adjunctive interdental plaque removal aids.[1-4] Several investigators have noted that individuals often overestimate their brushing times, do not brush effectively, and seldom consistently use dental floss.[5-8]

The high prevalence of gingivitis on a global basis bears witness to the likelihood that the "average" home oral hygiene routine solely involving manual toothbrushing with varying skill levels is generally not rigorous enough to prevent gingival disease.[9,10] The classic experiments of Löe et al[11,12] are widely cited as evidence of the ability of the bacterial byproducts harbored in undisturbed plaque to rapidly generate gingival inflammation and bleeding, with such effects being reversible with subsequent thorough debridement. However, when inefficient manual brushing coupled with a lack of interdental cleaning is chronic, oral disease including dental caries and gingivitis is probable and particularly concerning the interproximal regions, where outcomes can be more pronounced, and can progress to periodontitis.[13-15]

Surfaces beneath the contact point of teeth are hard-to-reach with a regular manual or power toothbrush. With plaque accumulation in this area, approximal surfaces are predominantly at risk for caries demineralization. The detection of white spot lesions – the reversible stage of caries – on these surfaces is still problematic for clinicians; so often the problem is developed in this phase of cavitation. Inadequate plaque removal also has additional consequences. Inappropriate oral hygiene increases the probability of staining or halitosis, and could have a major impact on general health. Therefore, optimal plaque control procedures and tools should be recommended.

Power toothbrushes can serve as a solution to many of the drawbacks connected to a manual toothbrush by delivering more enhanced plaque removal due to the mode of action, increased brushing time, better compliance and/or, correcting poor brushing technique. Additionally, some power brushes are designed to penetrate further into the approximal tooth regions for greater plaque removal in hard-to-reach places. Power brushes are widely considered safe and highly effective, with a large meta-analysis[16] published by the independent Cochrane Collaboration revealing that oscillating-rotating power toothbrushes were significantly more advantageous in plaque and

Table 1. Study eligibility criteria.

Inclusion criteria

- Generally healthy adults at least 18 years of age;
- A minimum of 16 natural teeth with facial and lingual scorable surfaces;
- Gingivitis, as evidenced by a pre-treatment Modified Gingival Index[18] score between 1.75 and 2.3, and at least 10 bleeding sites as determined by the Gingival Bleeding Index;[19]
- Plaque, as evidenced by a pre-treatment Rustogi Modified Navy Plaque Index[20] score of at least 0.50;
- Willingness to delay elective dentistry (including prophylaxis);
- Willingness to refrain from all oral hygiene 12 hours prior to each study visit, and discontinue eating, drinking, and smoking 4 hours prior to each study visit.

Exclusion criteria

- Self-reported pregnant or lactating females;
- Severe periodontal disease, or active treatment for periodontal disease;
- Requirement for antibiotic pre-medication prior to dental procedures;
- Grossly carious, fully crowned, or extensively restored teeth;
- Use of chlorhexidine or antibiotics within 2 weeks of the baseline visit;
- Orthodontic appliances, peri/oral piercing, or removable partial dentures;
- Any disease or conditions that could be expected to interfere with examination; procedures or the subject safely completing the study;
- Use of non-study assigned products.

gingivitis control in both short and longer-term investigations compared to manual toothbrushes, and a recent systematic review[17] confirming their safety relative to manual brushes.

To meet the need of those preferring a manual toothbrushing experience but desiring more effective cleaning, Oral-B[a] has developed a novel multi-directional power toothbrush with a brush head reminiscent of a manual brush in size and feel, and with movement approximating the motions of standard manual brushing techniques. This unique new power brush provides a 'triple zone' cleaning action that features both pulsating sweeping and stationary bristles together with a dynamic angled power tip. Importantly, the new multi-directional brush is designed to provide effective shearing forces to disturb and sweep away plaque without requiring undue dexterity or skill from the user. Additionally, the bristle design allows for deep penetration into the approximal tooth spaces. In the current 4-week clinical study reported herein, this novel power brush was compared to the brush type most commonly used worldwide – a standard, manual toothbrush – for its ability to remove plaque throughout the whole mouth as well as in more difficult to clean areas, and its effectiveness in reducing gingivitis and gingival bleeding.

Materials and Methods

The study design employed in this 4-week investigation of the anti-plaque and anti-gingivitis effectiveness of a novel multi-directional power toothbrush when compared with a standard reference manual toothbrush control was a single-center, randomized, examiner-blinded, parallel group clinical trial in generally healthy adult volunteers. Study enrollees were required to be at least 18 years of age, have a minimum of 16 natural and scorable teeth, and show evidence of existing plaque formation and gingivitis. Table 1 summarizes the study entrance criteria.

Following approval of the study protocol and subject consent form by an institutional review board, prospective study participants presented to the clinical site for the baseline visit. Subjects were instructed to refrain from all forms of oral

Fig. 1. **A.** Novel Oral-B Multi-directional power toothbrush. **B.** ADA Manual toothbrush control.

hygiene 12 hours in advance of the visit and discontinue drinking, eating, chewing gum, and tobacco use for 4 hours prior to the visit. At the visit, subjects signed an inform consent and an oral hard and soft tissue examination similar to that described by the American Dental Association was performed and any pre-existing abnormalities or unique anatomical structures were recorded. To assess pre-treatment gingival health, the Lobene Modified Gingival Index (MGI)[18] as well as the Gingival Bleeding Index (GBI)[19] were next conducted by an experienced examiner. Baseline plaque levels were subsequently quantified by this examiner using the Rustogi Modification of the Navy Plaque Index (RMNPI)[20] evaluation. Subjects who fulfilled all the study entrance criteria (Table 1) were then stratified by virtue of gender, tobacco use, MGI gingivitis scores ($\leq$ 0.20 versus > 2.0), and whole mouth mean RMNPI scores ($\leq$ 0.65 versus > 0.65), and randomly assigned by a computerized balance and assignment program to one of the two test toothbrush groups (Fig. 1):

- Experimental multi-directional rechargeable power toothbrush: Oral-B Professional Deep Sweep TRICLEAN 1000 (D16u/EB30) or Oral-B 'TriZone'[a] in other regions.
- Manual toothbrush control: American Dental Association (ADA) reference soft manual brush.[b]

The first subject brushing procedure with the assigned toothbrush was performed at the clinical site under the supervision of the site personnel to ensure that participants were in full understanding of the brush use instructions, which were provided both orally and in writing. This one-time supervised brushing was conducted in an area not accessible to the clinical examiner and data recorder(s) to maintain blinding to the subjects' toothbrush assignments. Those assigned to the multi-directional power brush were instructed to brush for 2 minutes per the manufacturer's instructions, while those using the manual

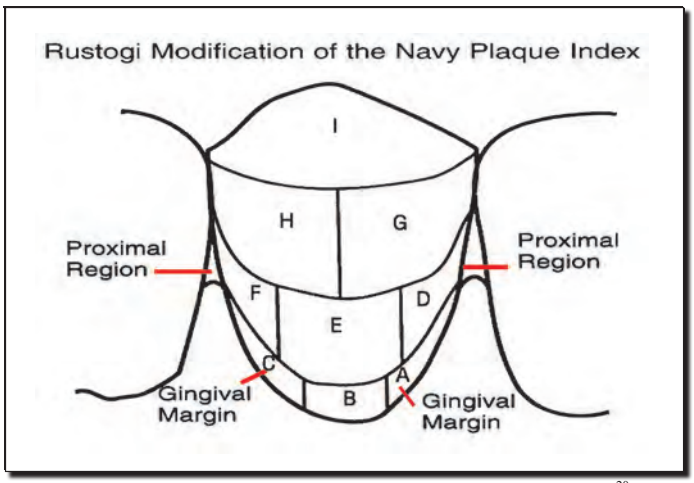

Fig. 2. Procedure for the Rustogi Modification of the Navy Plaque Index.[20]
Disclosing: To disclose the plaque, subjects swished for 10 seconds with 2.5 ml of Chroma-O-Red erythrosine FD&C, red #3 disclosing solution.
Scoring: At Week 1 and Week 4, disclosed plaque was quantified on nine sites per facial 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 gingival margin (areas A, B, C) and interproximal (approximal) regions (areas D, F).

toothbrush were told to brush in their customary fashion. Subjects from both groups used Crest Cavity Protection[a] dentifrice (0.243% sodium fluoride) throughout the study. Over the course of the ensuing 4-week study period, subjects were instructed to continue brushing at home, twice daily, as directed at the baseline visit.

Following 1 week of home usage, subjects were recalled to the clinical site, having been directed to discontinue for 4 hours all food and drink, tobacco use and chewing gum, and all oral hygiene for 12 hours before this visit. Continuance requirements (abstaining from all elective dentistry, including prophylaxes, as well as chlorhexidine, antibiotics, and any non-study oral care products) were verified, and any subjects who were non-compliant were to be excluded from the data analyses or withdrawn from the trial. To assess the presence of any potentially treatment-related adverse effects, an oral hard and soft tissue evaluation was performed, and any abnormal findings that were not noted at the baseline evaluation or that had worsened since treatment use began were documented. The relative plaque control abilities of the test toothbrushes were next evaluated via the RMNPI examination.

At 4 weeks following baseline, subjects returned to the clinical site for the final study assessments. As previously, verification that subjects had followed pre-appointment food/drink/smoking/oral hygiene restrictions and continued to meet all study eligibility requirements was obtained. Safety examinations were conducted. MGI and GBI gingivitis, and RMNPI plaque evaluations were performed in like manner as at baseline, and as described below.

Clinical efficacy evaluations - The clinical grader conducting the MGI gingivitis evaluation scored inflammation 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.

Immediately thereafter using the 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.

The final efficacy evaluation was the RMNPI to quantify dental plaque; with the description and procedure as shown in Fig. 2.

Statistical analyses - Prior to study inception, a sample size assumption of 60 subjects per toothbrush test group completing the trial and whole mouth MGI variability of 0.107 was used to determine that 90% power would be expected to detect a mean MGI difference of 0.064 units between groups (using two-sided testing with a 5% significance level). With analogous assumptions with an assumed variability of 0.116 for RMNPI plaque, it was expected that a mean between-group plaque difference as small as 0.069 units would be detected.

Baseline subject demographic data were compared between the test groups using a two-sample t-test for age, a Chi-Square test for gender, and a Fischer's Exact test for smoking status between-group balance. The within-treatment Week 4 difference from baseline for MGI and GBI, and Weeks 1 and 4 differences from baseline for whole mouth RMNPI, were tested versus zero using an ANCOVA with the respective baseline scores as covariate. To compare the test brushes post-treatment, the Week 4 gingivitis (MGI, GBI) and Weeks 1 and 4 RMNPI plaque reductions versus baseline were analyzed separately using an ANCOVA, with baseline whole mouth scores as covariate. Similar analyses were conducted for the gingival margin and interproximal (approximal) regions of the RMNPI at both time points. All comparisons were two-sided at the 0.05 level of significance.

Results

In total, 120 subjects (60 per group) were randomly assigned at baseline to one of the two test toothbrushes. One

Table 2. Baseline subject demographics. Randomized subjects.

	Oral-B multi-directional power brush	ADA manual control	Total
Characteristic	N=60	N=60	N=120
Mean Age (SD)[A]	41.8 (10.39)	41.7 (11.07)	41.8 (10.69)
Age Range	18-64	18-65	18-65
Female (n, %)[B]	42 (70.0%)	40 (66.7%)	82 (68.3%)
Male (n, %)[b]	18 (30.0%)	20 (33.3%)	38 (31.7%)
Smoker (n, %)[C]			
Yes	8 (86.7%)	5 (8.3%)	13 (10.8%)
No	52 (13.3%)	55 (91.7%)	107 (89.2%)

SD = standard deviation; N= number of subjects.

[A] Two sample t-test was used to compare mean age between the two groups (P= 0.939).

[B] Chi-Sqaure test was used to assess balance between the two groups for gender (P= 0.695).

[C] Fisher's Exact test was used to assess balance between the two groups for smoking status (P= 0.559).

Table 3. Baseline MGI, GBI and RMNPI results.

	N	Baseline mean (SD)	P-value*
Modified Gingival Index			
Oral-B multi-directional power brush	60	2.038 (0.0687)	0.508
ADA manual control brush	60	2.030 (0.0688)	
Gingival Bleeding Index			
Oral-B multi-directional power brush	60	0.090 (0.0200)	0.077
ADA manual control brush	60	0.085 (0.0153)	
RMNPI – Whole Mouth			
Oral-B multi-directional power brush	60	0.634 (0.0360)	0.952
ADA manual control brush	60	0.634 (0.0344)	
RMNPI – Gingival Margin			
Oral-B multi-directional power brush	60	1.000 (0.000)	NA
ADA manual control brush	60	1.000 (0.000)	
RMNPI – Interproximal			
Oral-B multi-directional power brush	60	1.000 (0.000)	NA
ADA manual control brush	60	1.000 (0.000)	

MGI = Modified Gingival Index; GBI = Gingival Bleeding Index; RMNPI = Rustogi Modified Navy Plaque Index.
SD = standard deviation; N = number of subjects.
* T-test P-value for treatment group comparison at study baseline.

Table 4. Week 4 results for Modified Gingival Index (MGI) and Gingival Bleeding Index (GBI).

	N	Adjusted mean change from baseline[A]	Percent change from baseline[B]	Between treatment difference (SE)	Oral-B greater reduction versus Control[C,D]
MGI					
Oral-B multi-directional power brush	59	0.379	18.6%	0.256 (0.0226)	3 times
ADA manual control	60	0.124	6.1%		(P< 0.001)
GBI					
Oral-B multi-directional power brush	59	0.055	61.1%	0.018 (0.0023)	1.49 times
ADA manual control	60	0.037	43.5%		(P< 0.001)

N = number of subjects.

[A] Within-brush difference from baseline was tested versus zero using ANCOVA. For both MGI and GBI, no significant interactions (P> 0.134 and P= 0.152, respectively) were detected between baseline covariate and treatment.

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

[C] (Oral-B adjusted mean reduction – ADA manual adjusted mean reduction) / ADA manual adjusted mean reduction.

[D] Two-sided P-value for treatment comparisons of Week 4 MGI or GBI reduction using ANCOVA with baseline as covariate.

subject in the multi-directional power brush group voluntarily withdrew following the Week 1 visit, resulting in 119 (99%) fully evaluable subjects completing the 4-week study. Table 2 shows the pre-treatment demographic characteristics of the randomized population. At baseline, study participants averaged 41.8 years, ranging from 18 to 65 years. Female subjects comprised 68% of the study population, and 107 subjects (89%) reported that they were non-smokers. There were no statistically significant differences between test groups with respect to any demographic variable, indicating the groups were well-balanced (P≥ 0.559).

Modified Gingival Index (MGI) - Prior to using the assigned test brushes, the gingivitis level of the subject population was not significantly different between test groups, with baseline mean MGI scores of 2.038 and 2.030 for the multi-directional power brush and manual brush control groups, respectively (P= 0.508; Table 3). Brushing for 4 weeks with the assigned toothbrushes resulted in statistically significant (P< 0.001) gingivitis reductions relative to baseline in both test groups: the adjusted mean MGI reduction was 0.379 (18.6%) for those using the multi-directional power brush, and 0.124 (6.1%) for subjects brushing with the manual brush control (Table 4). The magnitude of the reduction was significantly greater for the multi-directional power brush group compared to the manual brush group, where the adjusted mean reduction of 0.256 represented a three-fold superior relative MGI benefit (P< 0.001).

Gingival Bleeding Index (GBI) - As shown in Table 3, the multi-directional power brush and manual brush control groups were not significantly different in baseline gingival bleeding status prior to test brushing initiation, with mean GBI scores of 0.090 and 0.085, respectively (P= 0.077). Following 4 weeks of brushing, both test groups realized statistically significant improvements in gingival bleeding compared to baseline, with an adjusted mean GBI reduction of 0.055 (61.1%) for those using the multi-directional power brush, and 0.037 (43.5%) for subjects assigned to the manual brush control (P< 0.001; Table 4). The post-treatment adjusted mean gingival bleeding reduction was 1.49 times significantly greater in the multi-directional power brush group versus the manual brush group (P< 0.001) (Table 4).

Rustogi Modified Navy Plaque Index (RMNPI) - There were no differences in baseline plaque levels between the test groups, with RMNPI whole mouth mean scores of 0.634 for each brush group (P= 0.952; Table 3). Following 1 week of at-home brushing, both the multi-directional power brush and manual brush control groups saw significant (P< 0.001) adjusted mean RMNPI reductions: 0.253 (39.9%) and 0.108 (17.0%), respectively (Table 5). Comparing these reductions by test group,

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Table 5. Week 1 and Week 4 results for Rustogi Modified Navy Plaque Index (RMNPI).

	N	Adjusted mean change from baseline[A]	Percent change from baseline[B]	Between treatment difference (SE)	Oral-B greater reduction versus Control[C,D]
WEEK 1					
Whole mouth					
Oral-B multi-directional power brush	60	0.253	39.9%	0.146 (0.0170)	2.3 times
ADA manual control	60	0.108	17.0%		(P< 0.001)
Gingival margin					
Oral-B multi-directional power brush	60	0.163	16.3%	0.146 (0.0198)	9.6 times
ADA manual control	60	0.017	1.7% (P=0.230)		(P< 0.001)
Interproximal					
Oral-B multi-directional power brush	60	0.588	58.8%	0.344 (0.0410)	2.4 times
ADA manual control	60	0.244	24.4%		(P< 0.001)
WEEK 4					
Whole mouth					
Oral-B multi-directional power brush	59	0.353	55.7%	0.188 (0.0163)	2.1 times
ADA manual control	60	0.165	26.0%		(P< 0.001)
Gingival margin					
Oral-B multi-directional power brush	59	0.318	31.8%	0.252 (0.0221)	4.7 times
ADA manual control	60	0.067	6.7%		(P< 0.001)
Interproximal					
Oral-B multi-directional power brush	59	0.769	76.9%	0.389 (0.0416)	2 times
ADA manual control	60	0.380	38.0%		(P< 0.001)

N = number of subjects.

[A] Within-brush difference from baseline was tested versus zero using ANOVA for gingival margin and interproximal analyses, and using ANCOVA for whole mouth. With the latter, no significant interaction (P> 0.191) was detected between baseline covariate and treatment.

[B] Change from baseline = 100% (adjusted mean change divided by baseline mean). P< 0.001 for both comparisons unless as specified.

[C] (Oral-B adjusted mean reduction – ADA manual adjusted mean reduction) / ADA manual adjusted mean reduction.

[D] Two-sided P-value for treatment comparisons of Week 1 or 4 RMNPI reduction using ANCOVA with baseline as covariate.

the difference of 0.146 favoring the multi-directional power brush represented a 2.3-fold superior plaque removal benefit compared to the manual brush group at Week 1 (Table 5). After brushing for an additional 3 weeks, at Week 4, the percentage adjusted mean RMNPI reduction from baseline had increased to 55.7% (change of .353) and 26.0% (change of 0.165) for the power brush and manual brush control groups, respectively (P< 0.001) (Table 5). As at Week 1, the reduction in plaque versus baseline for the multi-directional power brush group was significantly superior to that of the manual control brush group at Week 4, with the between-group difference of 0.188 representing a 2.1 times greater mean plaque reduction benefit (Table 5).

When analyzing specifically the gingival margin region of the RMNPI, results showed that both test groups had a baseline mean score of 1.000 (Table 3). After 1 week of brushing, the multi-directional power brush group had a significant (P< 0.001) adjusted mean RMNPI reduction in the gingival margin region of 0.163 (16.3%). Manual brush users saw a mean RMNPI gingival margin plaque reduction of 0.017 (1.7%) but this was not statistically significant (P= 0.230) (Table 5). Comparing brushes, the Week 1 adjusted mean plaque reduction produced by the multi-directional brush was 9.6 times greater than that of the manual brush control (P< 0.001) (Table 5). By Week 4, both test brush groups realized significant gingival margin RMNPI adjusted mean reductions versus baseline, with a change of 0.318 (31.8%) for the power brush group, and 0.067 (6.7%) for the manual brush control group (P< 0.001; Table 5). The magnitude of the reduction was significantly larger in the multi-directional power brush group, where the 0.252 between-group difference at Week 4 represented a 4.7-fold relative superior benefit for the power brush versus the manual brush (P< 0.001).

For the RMNPI interproximal (approximal) region plaque analyses, there were no pre-treatment differences between the brush groups, with means of 1.000 for each (Table 3). After 1 week of brushing, both test brushes provided statistically significant (P< 0.001) plaque removal benefits in the interproximal region, with an adjusted mean change of 0.588 (58.8%) for the multi-directional power brush and 0.244 (24.4%) for the manual brush control (Table 5). The larger Week 1 mean reduction for the power brush group compared to the manual brush group was 2.4 times greater in relative magnitude for the mean adjusted 0.344 between-group treatment difference (P< 0.001) (Table 5). By Week 4, the percentage change from baseline in interproximal RMNPI plaque removal had increased for both brush groups, with a 0.769 (76.9%) and 0.380 (38.0%) significant mean reduction for the multi-directional power and manual brush control groups, respectively (P< 0.001) (Table 5). The Week 4 adjusted mean interproximal plaque removal benefit provided by the multi-directional power brush was 2 times significantly greater than that afforded by the manual brush control (P< 0.001).

Discussion

With an estimated four-fifths or more of all adults worldwide experiencing some degree of gingivitis, it is evident that most do not strictly follow the often professionally-recommended twice daily toothbrushing and flossing regimen.[10,21] Yet surveys have shown that at minimum a daily attempt at oral hygiene (generally via manual toothbrushing), whether for cosmetic, social, or health reasons, is the norm.[5,22] With a very intentional

technique such as that provided via professional toothbrushing or a trained patient under controlled, supervised conditions, reducing plaque to negligible levels with a manual brush is achievable.[23-25] The typical skill level and frequency/duration of use by the average brusher, however, makes it is less likely sufficient plaque will be consistently, meticulously removed to sustain gingival health, especially in the more difficult to clean approximal and gingival margin regions.[4,26] A large investigation by Morris et al[27] revealed that even when adults brushed immediately before an examination, one-third of the teeth still showed visible (non-disclosed) plaque.

While substandard plaque control with use of a manual toothbrush and resulting gingival inflammation and bleeding may be prevalent, some manual brush users are hesitant to trade their conventional toothbrush and brushing technique for a power toothbrush, despite convincing research that power toothbrushes (in particular, oscillating-rotating) have been consistently shown to significantly outperform manual brushes in plaque and gingivitis removal.[16,28,29] These individuals prefer the shape, size, and 'feel' of the manual brush head over the smaller brush head size of many marketed power brushes, along with a more manual-like brushing movement heretofore not available in a power toothbrush. In the current trial, a recently developed Oral-B power brush specifically designed with this group of consumers in mind was evaluated for its ability to fight plaque and gingivitis in a population with evidence of these conditions. The unique multi-directional brush with 3-D 'tri-zone' sweeping and pulsating action combined with stationary bristles provides those who have historically favored a manual toothbrush a similar brushing experience, but with the benefits afforded by a power toothbrush designed for high cleaning efficiency, including penetration into the interproximal spaces. The ADA reference manual toothbrush selected as the control in this trial typifies a manual brush used across diverse geographies. By instructing subjects assigned to the manual brushing test group to brush in their customary fashion, the efficacy results are more likely to mirror actual outcomes for the average manual brusher in the general population, as manual brushes do not incorporate compliance-enhancing features such as timers, wireless displays, etc. as do certain power brushes (e.g., available in the Oral-B Professional Series).

A 4-week, parallel group design was employed to allow sufficient time to assess any gingivitis reductions associated with lower plaque levels, thus only plaque was re-evaluated at Week 1. Each of the two test brushes, the novel multi-directional power toothbrush and the manual control brush, produced reductions compared to baseline in RMNPI mean whole mouth and interproximal plaque first at Week 1, and incrementally more by Week 4; however, only the new power brush significantly reduced plaque at the gingival margin at both time points. With respect to gingival inflammation and bleeding, both test toothbrushes provided statistically significant improvements via the MGI and GBI evaluations after 4 weeks of twice daily brushing.

Using the variability computed from this study and a sample size of 60 per group, a difference in MGI reductions between brushes of 0.063 could be detected with 80% power. In every clinical evaluation at both the Week 1 and Week 4 visits, the novel multi-directional power toothbrush significantly outperformed the manual brush control in the scope of the post-treatment reductions. The between-brush post-treatment relative RMNPI whole mouth plaque reduction favoring the new power brush at Week 4 was 2.1 times greater in magnitude. In less accessible regions key to gingival health, the marginal and approximal areas, the novel multi-directional power brush delivered 4.7 and 2 times greater mean plaque reduction compared to the manual brush, respectively, at Week 4. Undoubtedly, these substantial mean improvements in plaque coverage with use of this new power brush designed to cover a wider area versus a typical manual brush head underpinned the robust reductions in gingival inflammation and gingival bleeding, whereas the between-brush superior relative benefit for the novel power brush with twice daily brushing for 4 weeks was greater by a factor of 3 for mean MGI, and nearly 1.5 times larger for GBI.

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