American Journal of Dentistry, Vol. 25, Special Issue A, September, 2012

AMERICAN JOURNAL OF DENTISTRY

Volume 25, Special Issue A, September, 2012 - p. 1A - 32A

A Novel Power Toothbrush with Triple Zone Cleaning Technology

AMERICAN JOURNAL OF DENTISTRY

Published By Mosher & Linder, Inc.

Volume 25, Special Issue A, September, 2012 - p. 1A - 32A

www.amjdent.com

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A new power toothbrush with multi-directional movement

While research has consistently shown superior plaque removal benefits for certain power toothbrush technologies versus their manual counterparts, a segment of the population continues to prefer their manual-like brush experience. Unfortunately, the high prevalence of oral diseases worldwide indicates many patients fail to achieve adequate plaque removal with their manual toothbrushing routine. Dental professionals continue to emphasize the importance of improving brushing habits with patients, but research shows behavior modification is challenging.

Another approach to achieve better cleaning performance can be obtained through advances in toothbrush design, which allow for maximizing plaque removal while providing a brushing experience some patients prefer. Oral-B recently introduced a novel multi-directional power tooth-brush, marketed as Oral-B TriZone or Oral-B Deep Sweep/Triclean models in the United States, as an alternative for patients who could benefit from improved plaque removal but prefer the traditional size and shape of a manual toothbrush head and a unique manual brushing technique. This novel brush is characterized by its unique, multi-directional movement derived from the three distinct brush zones: power tip, manual-like stationary bristles, and wide sweeping-pulsating bristles.

This issue summarizes the technology and features of the novel power toothbrush as well as results from four clinical trials evaluating its efficacy relative to various control toothbrushes. The research shows the new multi-directional power toothbrush outperformed manual and sonic controls in reducing plaque and gingivitis. This toothbrush offers an effective option dental professionals should consider for patients who prefer a manual-like brush experience but need the benefits of improved cleaning.

Franklin Garcia-Godoy, DDS, MS, PhD
Editor

The **American Journal of Dentistry** (ISSN 0894-8275) is published six times a year in the months of February, April, June, August, October and December by **Mosher & Linder, Inc.,** 1138 N. Germantown Pkwy., #360, Cordova, TN 38016, U.S.A.

Subscription rates for one year: Individual or institution in the United States: $90.00 (surface mail); Canada and Mexico: US$125.00 (airmail); all other countries: US$145.00 (airmail); single copies: U.S.A. $20.00; Canada and Mexico: US$24.00 (airmail); all other countries: US$27.00 (airmail). Journal issues prior to the current volume, when available, may be ordered at current single copy price. All subscriptions and single copy orders are prepaid and payable in U.S. currency and are subject to change without notice. Remittance should be made by check or money order payable to **American Journal of Dentistry**. Subscriptions can begin at any time. Subscribers requiring an address change should submit an old mailing label with the new address including the zip code, giving 60-day notice.

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Postmaster: Send change of address or undeliverable copies to the American Journal of Dentistry, Subscription Department, 1138 N. Germantown Parkway #360, Cordova, TN 38016, U.S.A.

Printed in the United States of America.

A novel power toothbrush with multi-directional, triple zone cleaning technology

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ABSTRACT: Purpose: Numerous laboratory and clinical studies have proven that certain power toothbrush technologies are more effective in removal of dental plaque and reduction of gingivitis than regular manual toothbrushes. Regardless of this evidence, there is still a large group of individuals who prefer the experience of a manual-like toothbrush. Recently a novel multi-directional power brush has been developed as an alternative for those people who favor the traditional size and shape of a manual toothbrush and prefer the manual brushing technique, but would benefit from the greater cleaning efficiency of the power brush. **Methods:** This unique multi-directional power toothbrush with triple-zone cleaning technology has been tested in multiple clinical trials. This special issue introduces the technical features of the brush and presents four clinical investigations conducted with this power toothbrush versus manual and sonic controls. **Results:** The studies described in this issue demonstrate the superior efficacy of the multi-directional brush in plaque and gingivitis reduction relative to control brushes, even in the hard-to-reach interdental spaces and marginal areas. (*Am J Dent* 2012;25 Sp Is A:3A-9A).

CLINICAL SIGNIFICANCE: Dental professionals should consider this novel multi-directional power brush for patients who prefer a manual toothbrush experience but need improved plaque control and gingival health.

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Introduction

Fifty years ago, electric ('power') toothbrushes were novel and not widely available. Users were in the minority, and many found the toothbrush models to be bulky, inefficient and technically unreliable. For these reasons many consumers returned to their manual toothbrush and dental professionals did not routinely recommend or endorse power toothbrushes for general use. Several decades later, however, the power toothbrush has evolved dramatically in appearance, functionality, and efficiency and has firmly established a prominent position in mainstream consumer oral products. A 2011 industry analysis estimated that at least one-third of all toothbrush expenditures were on power toothbrushes in the United States, underscoring their burgeoning popularity.[1] Both consumers and clinicians are increasingly choosing and recommending power toothbrushes for their thorough cleaning ability, ease of use, and – with some brushes – enhanced compliance due to features such as built-in timers and pressure sensors.

An impressive body of scientific evidence supports the perception that some power toothbrushes control plaque and gingivitis better than their manual counterparts. Numerous independent, peer-reviewed in vitro and clinical investigations have confirmed that certain power toothbrush technologies are indeed more efficacious in removing dental plaque as well as reversing and controlling gingivitis, compared to their manual counterpart.[2-6] A widely-cited 2004 report,[7] updated in 2011,[8] from the independent Cochrane Collaboration concluded that among all types of marketed power brushes, only those with an oscillating-rotating mode of action reduced plaque and gingivitis more effectively than a manual toothbrush. This conclusion was derived from their systematic review and meta-analysis of 42 studies involving approximately 3,800 subjects in both short and longer-term trials. The long-known association between suboptimal dental plaque removal and periodontal disease, coupled with newer research linking periodontal disease to adverse systemic outcomes, validates the importance of offering consumers superior plaque removal tools to aid in their quest for both oral and whole-body health.[9-13]

In spite of the benefits, consumer research has shown that a segment of adults has not taken advantage of the proven cleaning efficacy of power brushes because some favor the larger head size and feel of their customary manual toothbrush. Additionally, many value their manual brushing 'experience': a predisposition to the amount of toothpaste customarily applied, the ability to brush several teeth at once, and a manual brushing stroke not consistent with most power toothbrushes. In 2000, Beals et al[14] reported that the use of a simple horizontal stroke predominated (69%) in two observational brushing studies of videotaped adults, confirming other research.[15,16] Furthermore, it has been estimated that over 90% of adults employ their personal brushing method, which is generally a "scrub" method.[17,18] Unfortunately, inadequate brushing technique, insufficient brushing duration, and lack of interproximal cleaning have been found in many investigations to be the norm for a majority of manual toothbrush users.[19-25] High global levels of gingivitis, periodontitis, and interproximal caries testify to the fact that many consumers are lacking the skill and/or motivation to adequately and consistently remove or disrupt enough pathogenic plaque (particularly in the hard-to-clean regions) to stave off dental/oral disease using solely a standard, flat-trimmed toothbrush and their usual brushing method.[26-29] While clinicians often prescribe twice daily, 2-minute oral hygiene sessions that include flossing, research reveals that participants regularly skip interproximal cleaning, overestimate brushing durations, and fail to achieve plaque-free tooth surfaces through their normal efforts.[20,21,30-34] Longer and

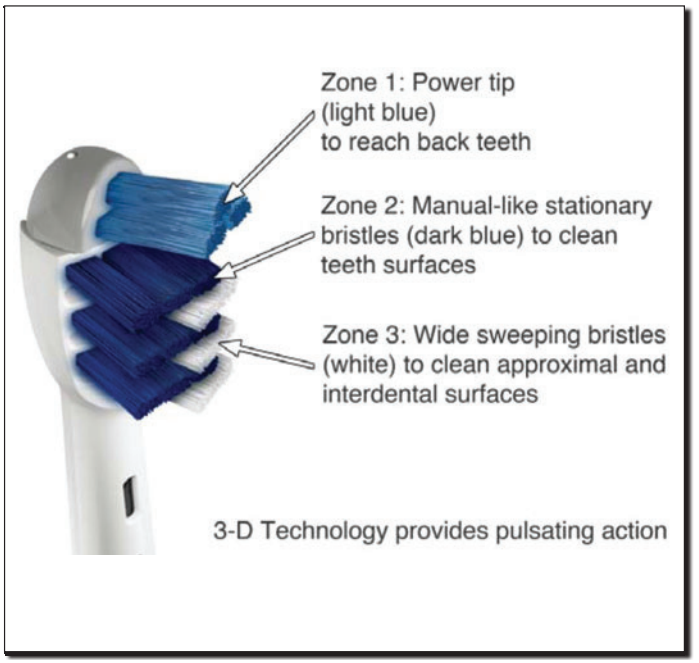

Fig. 1. TriZone multi-directional cleaning technology.

more skilled brushing still remains the ideal, but behavioral modification with respect to changing manual toothbrushing habits is notoriously hard to achieve and sustain.[20,23] A more realistic strategy for enacting better cleaning may be found through advances in toothbrush design to maximize plaque removal, allowing the individual to achieve oral health improvements without having to significantly alter their existing routines such as their personal brushing technique.

Oral-B[a]: Recognized leader in toothbrush innovation

Since its inception in 1950 by Dr. Robert Hutson, a California periodontist, Oral-B's unparalleled record of delivering cutting-edge solutions for better oral health has reflected continuing innovation in the product development of high-performing toothbrushes for the most thorough cleaning. In fact, no other manufacturer has a longer history in the design, research, development, and marketing of manual and power brushes. The first multi-tufted, flat-trim toothbrush with end rounded bristles became the standard against which other brushes were compared. The development of "Indicator bristles" helped consumers recognize when to change their toothbrush thus ensuring optimal performance. The introduction in 1999 of a manual toothbrush with "criss cross" bristles was researched and developed to compensate for inadequate brushing technique.[14] It was designed to provide the best possible interproximal cleaning and clean hard-to-access areas while allowing consumers to maintain their preferred brushing habits.

In the early 1990s, the Oral-B Plaque Remover was introduced. This was the first toothbrush to feature the oscillating-rotating mode of action and the prophylaxis-inspired small round brush head, now confirmed in over 90 clinical studies to provide superior cleaning efficacy.[35] Over the years, a series of advances including the addition of a visible 2-minute timer, high frequency pulsating movement (Oral-B 3D Plaque Remover, 1998) and later increased oscillations and pulsating frequencies culminated in the premium Oral-B Professional Care Smart Series with SmartGuide class of brushes. Recognizing that motivation and compliance for tooth brushing is critical, the SmartGuide wireless display technology encourages the consumer to become more involved in their brushing experience. Oral-B's commercially-available family of power brushes now encompasses numerous distinct power brush offerings to meet the unique needs and wants of individual consumers with differing preferences.

Why a new power toothbrush?

The 'best' toothbrush is the one the individual will regularly use and enjoy. With this in mind, researchers at Oral-B sought to accommodate a segment of individuals who may or may not be proficient brushers but nonetheless are unwilling to part with their manual brush. These consumers like the manual brush head characteristics and want to keep their familiar brushing technique, and have not adapted to the small brush head and tooth-specific focused cleaning mechanism of most marketed power brushes. Oral-B undertook an extensive research and development program to develop a new power brush that would deliver the brush head and brushing experience this segment of consumers prefer without sacrificing efficacy. A review of exclusive attributes of this recently launched power brush, along with a summary of the supporting pre-clinical and clinical research establishing its effectiveness and consumer acceptance, is outlined below.

NOVEL MULTI-DIRECTIONAL POWER BRUSH

This novel brush, marketed as Oral-B TriZone[a] or Oral-B Deep Sweep/TRICLEAN[a] models in the United States, is characterized by its unique, multi-directional movement derived from the three distinct brush zones, which collectively contain over 2,000 bristles. Each zone collaboratively helps to provide improved plaque removal in three different intraoral regions (Figs. 1, 2).

Zone 1: The power tip for hard-to-reach back teeth - Designed to reach the posterior teeth and anterior lingual surfaces, this moving "toe" features dynamic forward-angled bristles in a multi-tuft design that sweep wide to allow more bristle action for additional access to the interproximal areas. The light blue bristles of the power tip are Indicator filaments which fade over time to signal to the user that it is time to replace the brush head (Fig. 1).

Zone 2: The manual-like stationary bristles for thorough cleaning of the tooth surface - These dark blue bristles are positioned in alternating rows with the white moving interdental rows. Their movement is directed by the manual action of the user, as is the case with a manual toothbrush, allowing the user to control the brushing motion. With the 3-D model, these bristles have an additional pulsating action (Fig. 1).

Zone 3: The wide sweeping-pulsating bristles for interdental cleaning - Moving interdental tufts (white, Fig. 1) work synergistically with the stationary bristles. The result is that the alternating tuft pattern and length places filaments in the critical approximal regions, and bristles sweep perpendicular to manual brushing motion, enabling interdental spaces to be cleaned thoroughly.

The Oral-B power brush is notably distinct as the only power brush to feature the triple-zone cleaning technology. Its

Fig. 2. Oral-B TriZone or Oral-B Professional Deep Sweep + SmartGuide TRICLEAN 5000 (United States).

brush head resembles a manual toothbrush but has multi-directional movement for enhanced plaque removal. Its inventive multi-directional movements are delivered by 7,600-8,800 direction changes per minute, depending on the model, creating shearing forces that combat the tenacity and stickiness of plaque biofilm for excellent cleaning efficacy. Enhancing the effect of premium models is the simultaneous 3-D action provided by 40,000 pulsations to disrupt dental plaque as a precursor to the sweeping action. Integrating these two technologies in the novel multi-directional power brush in a model that would be embraced by manual brush devotees was the result of extensive design modifications and robust laboratory testing, and further, drew inspiration from the documented plaque removal effectiveness of certain other power brush technologies with combined movements. The Oral-B Triumph brush, for example, which employs the oscillating-rotating mode of action in tandem with 3-D pulsating movement, has been consistently shown in independent clinical testing to provide superior plaque removal benefits versus both sonic and manual control toothbrushes.[36-42] The new Oral-B multi-directional power brush presented in this special issue shares the same drive system as Oral-B's popular oscillating-rotating brushes, but the bristle configuration and movement are markedly different.

The unique brush head is patterned after a manual counterpart in appearance i.e. the brush head size, brush head shape

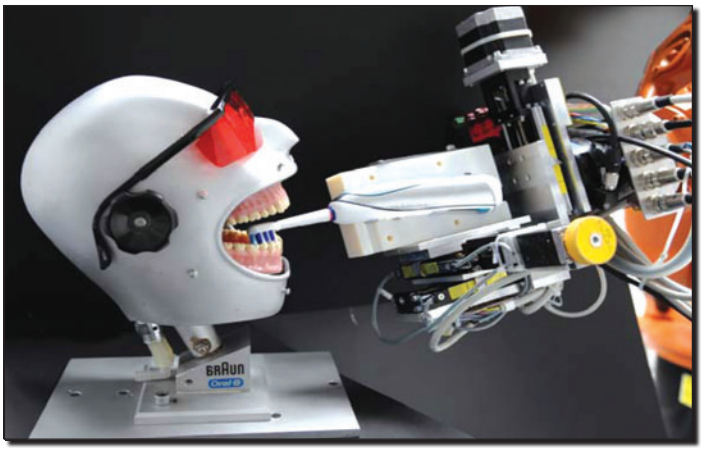

Fig. 3. Robot testing simulates consumer toothbrushing while controlling variables.

and brush head topography, but is smaller to provide good posterior access while allowing paste consumption comparable to manual brushes. It also covers an area 43% wider than an ADA manual toothbrush head during toothbrushing via its wide sweeping bristles. Like the Oral-B Professional Smart Series, the novel multi-directional brush is available with Oral-B's proprietary wireless SmartGuide technology to provide real-time feedback for monitoring brushing pressure, brushing time, charging status, and more.

Evidence of effectiveness: From Prototype to Launch

Laboratory testing

Oral-B's comprehensive consumer research phase demonstrating the unmet need marked the beginning of the vision for an innovative brush with unique specifications. The next stage of development involved the exploration of copious design routes in the development of the most efficacious yet 'manual user-friendly' forerunners. Winning prototype models were then subjected to rigorous laboratory testing before promoting the final forerunners to consumer and clinical evaluations. Oral-B incorporates in vitro robot testing in its investigation of the cleaning performance of new products early in the product development process prior to brush scale up for human assessment (Fig. 3). The robot system is programmed to simulate consumer use of manual or power toothbrushes under standardized and controlled conditions for objectivity, and control of potentially confounding variables such as brushing technique, time, and the 'novelty effect'. The robot test method employed by Oral-B has been clinically evaluated and published, and results show the method can be of value with respect to predicting clinical outcomes.[43,44]

Clinical effectiveness testing

In light of the knowledge that currently marketed power toothbrushes possess wide-ranging modes of action, brush head topographies, filament configurations, etc., the need for sound clinical testing to establish relative cleaning profiles to guide professional recommendations and consumer purchasing is paramount. To evaluate the ability of the new power toothbrush detailed in this special issue to reduce plaque and gingivitis relative to controls, a series of comparative randomized,

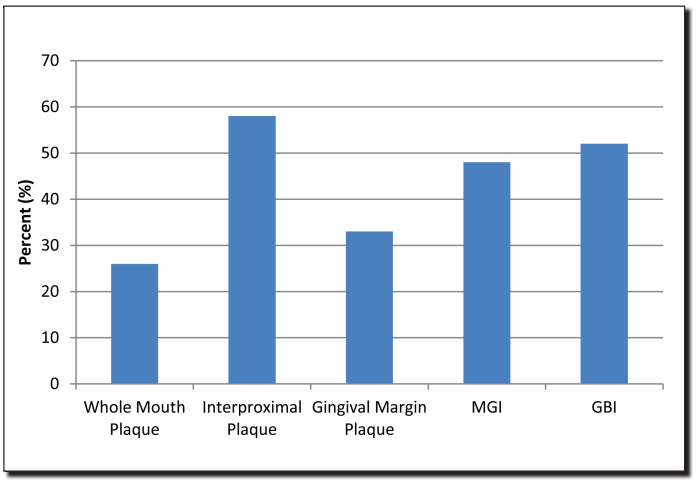

Fig. 4. Percent benefit for multi-directional power toothbrush relative to sonic control for Plaque, Modified Gingival Index (MGI) and Gingival Bleeding Index (GBI) at Week 4.[51]

examiner-blinded clinical trials of varying length, design, and subject populations were fielded.

Plaque removal benefits

Plaque biofilm proliferates rapidly in the absence of skilled oral hygiene, and its bacterial byproducts have been implicated in the inflammation and bleeding on probing seen commonly with plaque-induced gingivitis in a plethora of research over decades.[9-12,45,46] The acid production of undisturbed dental plaque as a contributor to dental caries, particularly in the more difficult to access posterior and interproximal dental surfaces, constitutes another challenge when oral hygiene is not optimal, as is often the case with the typical standard manual toothbrush user.[47]

The potential of the new Oral-B multi-directional power toothbrush to remove dental plaque (both whole mouth and in hard-to-access sub-regions) when compared to both a standard manual reference toothbrush and marketed power brush controls was assessed in four independent single-center clinical trials. The first clinical report in this special issue by Klukowska et al[48] describes a two-treatment, replicate use, single-brushing crossover study in a cohort of generally healthy adults. Following an acclimation period, the novel multi-directional power brush prototype (the only brush in the four reported clinical trials to utilize a 2-D, rather than 3-D, Oral-B brush handle) was compared to an American Dental Association (ADA) manual reference brush[d] for plaque removal efficacy over the four study periods. The results showed that the novel multi-directional power brush yielded a significantly superior mean whole mouth plaque reduction as compared to the ADA manual brush control ($P= 0.003$).

The second clinical investigation of the anti-plaque efficacy of the novel multi-directional power brush relative to a standard manual toothbrush presented in this special issue was conducted as a randomized, parallel group trial over a period of 4 weeks in a population exhibiting mild-to-moderate gingivitis.[49] Subjects brushed twice daily in the home setting, and the test brushes (novel multi-directional power or the ADA manual reference control brush) were assessed for plaque removal effectiveness at Weeks 1 and 4. Use of the Rustogi Modified Navy Plaque Index (RMPNI)[50] allowed for additional sub-analyses of challenging-to-clean intraoral regions. Week 4 study results revealed that the multi-directional power brush was significantly ($P< 0.001$) more efficacious than the manual control brush, with 2.1 times greater whole mouth plaque removal, and 4.7 and 2 times superior plaque benefits for the gingival margin and interproximal regions, respectively.

As described by Goyal et al[51] in the third special issue report, the plaque removal benefits of the new Oral-B multi-directional brush were compared to a commercially available sonic power brush control marketed as cleaning "deep between teeth and along the gumline"[52] (Sonicare Essence[e]) in a 4-week, randomized, parallel group clinical trial in volunteers with evidence of pre-existing gingivitis. Brushing was unsupervised twice daily and plaque was evaluated via RMNPI. In all regions analyzed, at 4 weeks the novel multi-directional power brush statistically significantly ($P\leq 0.001$) outperformed the Sonicare Essence control brush in whole mouth plaque removal (26% better) gingival margin plaque removal (58% superior), and approximal plaque removal (33% better) (Fig. 4).

Another commercially-available sonic toothbrush control, Sonicare's premium-positioned FlexCare with ProResults brush head,[e] was compared head-to-head with the novel multi-directional power brush in a randomized, parallel group clinical study of 8 weeks duration in mild-to-moderate gingivitis sufferers. Klukowska et al[53] detail the methodology and results of this trial as the final clinical report in this special issue. Following twice daily at home brushing with the test brushes, participants assigned to the novel multi-directional power brush experienced 44% significantly greater whole mouth and 77% superior interproximal RMNPI plaque removal ($P\leq 0.003$) at Week 8 compared to subjects using the Sonicare FlexCare control brush.

Collectively, the results of the four clinical investigations corroborate the successful design and functionality of the Oral-B novel multi-directional, targeted triple-zone cleaning technology in reducing all-over plaque and biofilm accumulation in both the harder-to-clean gingival margin and interdental spaces.

Gingivitis reduction benefits

Abundant evidence of the relationship between plaque accumulation and gingivitis has been published. The consequences of neglected plaque in the interdental regions may be the most concerning, with research linking it to attachment loss in such regions as the mandibular molar interproximal sites.[54,55] Periodontal disease and even systemic complications are possible outcomes of chronic gingivitis, accentuating the value of high-performing toothbrushes that compensate for any user skill deficiencies, that penetrate well interproximally, and that can boost compliance.

Three of the four clinical trials presented in this special issue incorporated a parallel group, multi-week design, providing sufficient duration for the evaluation of the gingivitis-reducing effect of the novel multi-directional power brush compared with control brushes. Each utilized two measures of gingival health assessment, the Lobene Modified Gingival Index (MGI)[56] and the Gingival Bleeding Index (GBI),[57] to determine the impact of plaque reduction on pre-existing gingivitis. With previous clinical research generally showing a

corresponding reduction in gingival inflammation and bleeding with clinically meaningful plaque reduction, it was expected there would be a similar gingivitis benefit in the three trials in this special issue where the tested brushes provided significant decreases in plaque versus baseline.

Not surprisingly, in each of the three studies gingivitis reductions were seen in both the Oral-B novel multi-directional power brush and manual or sonic control brush groups, as all brushes provided a statistically significant plaque reduction benefit compared with baseline. The magnitude of the gingivitis benefit, however, was consistently significantly greater for subjects brushing with the new multi-directional power brush across both measured gingivitis clinical outcome parameters. Sharma et al[49] reported subjects brushing for 4 weeks with the multi-directional power brush saw significantly superior reductions in gingivitis compared to manual brushers: 3 times and 1.49 times greater for MGI and GBI, respectively ($P< 0.001$).

When the multi-directional power brush was assessed versus a marketed sonic brush control, the results similarly showed the new brush to produce superior gingivitis reduction. Goyal et al[51] reported in this special issue on a 4-week investigation wherein the novel multi-directional power brush significantly decreased baseline gingivitis 48% better than Sonicare Essence as measured by MGI, and 52% better as quantified by GBI ($P\leq 0.001$). Finally the 8-week results detailed in the final clinical report by Klukowska et al[53] revealed that gingivitis reduction was 30% and 29% greater via whole mouth MGI and GBI, respectively, ($P< 0.001$) for subjects brushing with the Oral-B novel multi-directional power brush than for those assigned to the Sonicare FlexCare with Pro Results brush head.

Safety

The new Oral-B multi-directional power brush has been shown to be safe and well-tolerated, as evidenced by laboratory testing, in-depth consumer research and the results of the four reported clinical trials in this issue, where there were no adverse events associated with use of the new power brush.

Consumer acceptance

The clinical effectiveness and safety of the Oral-B novel multi-directional power brush, summarized previously and described in more depth throughout this special issue, were unequivocally established preceding product launch through extensive research. Recognizing that brush effectiveness is irrelevant if the consumer does not use the product, a salient question was investigated through additional consumer analysis: does the new multi-directional power brush succeed in providing those consumers with a preference for a manual toothbrush (regardless of their current ability to remove sufficient plaque to prevent gingivitis) a familiar, manual brushing-like feel and experience while delivering superior cleaning? Two key characteristics raised frequently by the segment with a bias towards manual brushing – brush head attributes and brushing experience – were thoroughly explored.

Qualitative research and product in-use testing demonstrated that consumers typically brushing with a manual toothbrush preferred the novel multi-directional power brush over their usual manual brush as they were able to clearly feel its superior cleaning efficacy. Surveyed consumers valued the multi-directional bristle field as it allowed them to focus less on individual teeth and more on all-over cleaning, similar to manual brushing. Consumers also were enthusiastic about the brush head size for the opportunity to apply their desired amount of toothpaste, in keeping with the volume they are accustomed to using with a manual brush. The ability to use the multi-directional brush like their regular manual brush, including whatever brushing action they were in the habit of performing, made the new power brush fit easily into their typical oral hygiene routine.

In short, feedback showed that consumers found the novel multi-directional power brush both looked and felt more like a manual brush than other power brushes they had used. They valued the 'overall clean' they experienced without sacrificing the familiarity of their manual toothbrush. And in one clinical study,[58] 95% of those participants who had used a manual brush before and were now using the Oral-B novel multi-directional brush did not want to relinquish it at the end of the trial, saying they preferred it to their usual manual brush.

Summary

Two decades of clinical research and several independent systematic reviews have shown the superiority in both plaque removal and gingivitis control of oscillating-rotating power toothbrushes when compared to a manual toothbrush and other power toothbrushes. However, despite this body of evidence, consumer research identified a need within a segment of the population for a highly effective power toothbrush which more closely resembles the feel and experience of a standard manual toothbrush. Oral-B's novel multi-directional power toothbrush provides the solution, and is the result of an extensive, multi-faceted research and development program. Its unique multi-directional, triple-zone cleaning technology confers a wide-sweeping motion that allows the brush head to cover a significantly wider area than a regular manual toothbrush, ensuring all areas are reached, even far back in the mouth. Additionally, the combination of manual motion and power pulsations give tooth surfaces a thorough clean, which consumers report they can feel. This perception of clean has been validated by the impressive results of laboratory evaluations and multiple clinical trials with varied study designs, durations, and subject populations. As presented in the following pages of this special issue, the novel multi-directional power brush significantly outperformed the standard manual or marketed sonic toothbrush control in plaque reduction, and provided a superior, clear-cut advantage in gingivitis reduction in the three studies assessing gingival health. Significantly greater plaque benefits provided by the new multi-directional brush relative to control brushes were directly demonstrated not only for the whole mouth, but also in the critical hard-to-clean interproximal and gingival margin areas. Importantly, those consumers formerly preferring a manual brush enthusiastically embraced the novel multi-directional power brush in both consumer tests and clinical trials.

a. Procter & Gamble Company, Cincinnati, OH, USA.
b. KUKA Robotics, Augsburg, Germany.

c. Frasaco USA, Greenville, NC, USA.
d. American Dental Association, Chicago, IL, USA.
e. Philips Oral Healthcare, Snoqualmie, WA, USA.

Acknowledgements: To Ms. Shelly Campbell for assistance with manuscript preparation as well as Mr. Dirk Markgraf of the Procter & Gamble Company, Kronberg, Germany for technical support.

Disclosure statement: Dr. Mielczarek declared no conflict of interest. Dr. Klukowska, Dr. Kaiser, Dr. Stoerkel, Dr. Mandl, Ms. Walters, and Dr. Warren are employees of Procter & Gamble.

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Research Article

A single-brushing study to compare plaque removal efficacy of a new power brush to an ADA reference manual toothbrush

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ABSTRACT: Purpose: To determine the effectiveness of a new multi-directional power toothbrush in reducing plaque when compared to a standard manual toothbrush control in a single brushing design. **Methods:** This was a randomized, replicate use, single-brushing, two-treatment, four-period, examiner-blinded crossover clinical trial at a single center. Qualified subjects entered an acclimation phase, after which they were randomly assigned to one of four treatment sequences specifying the order of use of the two test toothbrushes: a novel multi-directional power toothbrush with a 2-D drive (Oral-B Vitality TriZone) and an American Dental Association (ADA) reference soft manual brush. Subjects used each brush twice over the course of the trial. At each of the four period visits, after abstaining from oral hygiene for 24 hours, participants received a baseline (pre-brushing) Turesky Modification of the Quigley-Hein Plaque Index (TMQHPI) examination. They then brushed under supervision with the brush assigned for that period for 2 minutes (multi-directional power brush) or as customary (manual brush control). Subjects were then re-examined for TMQHPI post-brushing to determine the plaque removal efficacy of the respective brushes. A washout phase of 2-5 days separated treatment periods. TMQHPI scores were averaged on a per-subject basis, and analyzed using a mixed model analysis of covariance for a crossover design. **Results:** All 36 randomized subjects completed the study and were fully evaluable. Both the multi-directional power and manual control brushes produced statistically significant mean whole mouth TMQHPI plaque reductions compared to baseline ($P < 0.001$). Comparing the brushes, the power brush provided a 7.9% significantly superior mean whole mouth plaque reduction relative to the manual brush control ($P = 0.003$). Both toothbrushes were well-tolerated. (*Am J Dent* 2012;25 Sp Is A:10A-13A).

CLINICAL SIGNIFICANCE: Single-use, replicate brushing with a novel multi-directional power toothbrush produced superior plaque reduction in comparison to a manual control toothbrush.

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Introduction

A preponderance of research has established that the acidogenic byproducts of dental plaque biofilms are strongly linked to dental caries and plaque-induced gingivitis when not thoroughly removed on a consistent basis.[1-4] The characteristic inflammation and bleeding upon provocation of gingivitis – not noticeable and/or recognized as a concern to all affected patients – in turn may progress to periodontitis without intervention.[2,5,6] The high worldwide rates of gingivitis and periodontal disease[7-9] suggest a majority of adults are not accomplishing sufficient daily plaque removal using their customary oral hygiene regimens, which studies show most typically consist of at least once daily toothbrushing with a manual brush and infrequent or no targeted interdental plaque removal.[10-12]

Power (electric) toothbrushes were largely seen as a niche item mostly suitable for special populations when first introduced, but several decades of innovation and technological improvements have resulted in a new generation of power brushes with greater efficacy and patient-pleasing features that can enhance compliance. In particular, the oscillating-rotating class of power toothbrushes was found in an independent meta-analysis of over 42 clinical trials to show statistically superior anti-plaque and anti-gingivitis abilities versus a manual toothbrush.[13] The popularity of power brushes has soared as consumers have discovered their robust cleaning ability coupled with ease of use.[14] Yet there remains a subset of individuals who have been reticent to trade their familiar manual toothbrush and style of brushing for the somewhat unique brush head feel and modes of action of most marketed power toothbrushes, despite evidence that power brushes have been shown to provide superior plaque reduction.[13,15,16]

With this group in mind, Oral-B[a] has recently developed a unique new multi-directional power toothbrush designed to mimic the experience of brushing with a manual toothbrush, without sacrificing the exceptional cleaning (including in the commonly missed hard-to-reach areas) characteristic of the Oral-B power brush family. Incorporating a proprietary 2-D triple-zone cleaning action to disrupt and sweep away plaque, this novel multi-directional power brush (marketed as Oral-B Vitality TriZone or Oral-B Vitality Deep Sweep, depending on the region) features both stationary and moving tuft fields in tandem with a penetrating moving "toe" to give a consistent all-over clean while approximating the brush head size and typical motions of manual brushing. To assess its ability to reduce plaque relative to a manual toothbrush control and to contribute to the body of clinical research around this innovative new brush using another clinical model, a randomized and controlled crossover comparative clinical trial was conducted.

Materials and Methods

In this randomized, replicate use, single-brushing, two-treatment, four-period, examiner-blinded crossover clinical trial, the plaque removal effectiveness of a multi-directional power toothbrush was evaluated in comparison to that of a standard manual toothbrush control. A human subjects ethics review committee assessed and approved the subject consent form and study protocol prior to study inception. Subject recruit-

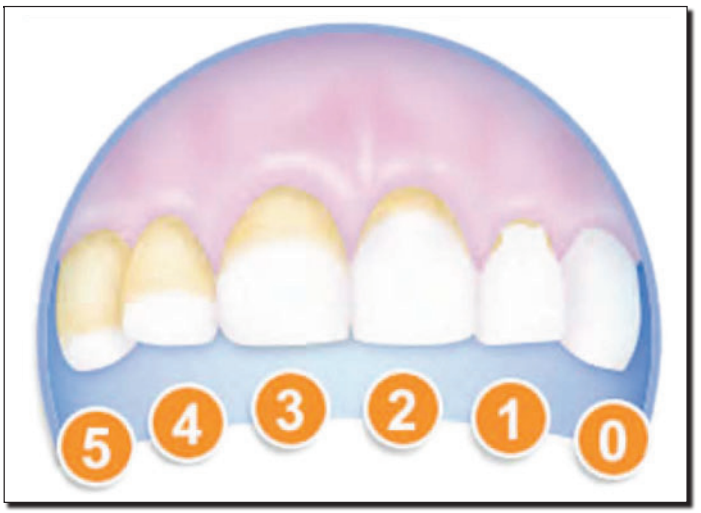

Figure. Procedure for the Turesky Modification of the Quigley-Hein Plaque Index.[17,18] Image originally published in *J Contemp Dent Pract*, 2008;9:4.
Disclosing: To disclose the plaque, subjects swished with red disclosing solution.
Scoring: At each period visit, disclosed plaque was quantified on six sites per tooth (mesiofacial, facial, distofacial, mesiolingual, lingual and distolingual) of all natural teeth except third molars, for a total of 168 potential sites. The area graded on the mesial and distal surfaces was determined by three reference points: the line angles of the tooth to the contact point, both bordered by the gingival margin, allowing a standardized small triangular grading area. Plaque coverage was scored as '0' = No plaque present; '1' = Separate flecks of plaque at the cervical margin; '2' = A thin continuous back of plaque (up to 1 mm) at the cervical margin; '3' = A band of plaque wider than 1 mm but covering less than one-third of the surface; '4' = Plaque covering at least one-third but less than two-thirds of the surface; '5' = Plaque covering more than two-thirds of the surface. An average plaque score was derived for each subject at each examination by summing the individual plaque scores (six per tooth) and dividing that sum by the number of sites graded for that subject.

ment was limited to generally healthy adults at least 18 years of age with no less than 16 natural teeth with facial and lingual scorable surfaces. Prospective participants were ineligible for study enrollment if they: (1) were undergoing periodontal treatment or had severe periodontal disease; (2) had five or more carious lesions requiring restorative treatment; (3) were in active orthodontic therapy or had removable prostheses; or (4) had any other diseases or conditions with a potential to interfere with study participation or compromise their safety.

Those subjects who met all entrance criteria were further required to comply with pre-visit restrictions regarding oral hygiene, eating, drinking, and smoking. In addition, throughout the course of the study they were not allowed to receive elective dentistry (including prophylaxis), use oral hygiene products other than those assigned except as directed during acclimation and washout phases, or participate in any other oral/dental clinical studies. Subjects violating any of these continuing eligibility requirements would be removed from study participation or excluded from the data analyses.

At the initial study visit, volunteers who provided written informed consent were screened for study qualification based on the aforementioned criteria. Enrolled subjects were provided with the multi-directional power toothbrush (marketed as Oral-B Vitality TriZone[a] or Oral-B Vitality Deep Sweep,[a] D12/EB30), and Crest Cavity Protection[a] dentifrice for use in the subsequent 2- to 3-day acclimation phase, which was incorporated to familiarize them with the power brush. Subjects' first brushing was done at the clinical site to ensure understanding of the manufacturer's usage instructions. Subjects were then dismissed and told to brush for 2 minutes twice daily according to manufacturer's instructions for the acclimation phase. At least 48 hours in advance of the Period I visit, subjects were directed to revert back to use of their usual, pre-study toothbrush, and to continue using that brush along with the supplied Crest Cavity Protection toothpaste for the duration of the investigation during at-home (non-supervised) use periods.

Table 1. Baseline subject demographics – Randomized subjects.

	Mean	Minimum - Maximum
Age (SD)	45.6 (8.63)	25-60
Gender	Frequency	Percentage
Female	31	86.1%
Male	5	13.9%
Race	Frequency	Percentage
Black	2	5.6%
Caucasian	34	94.4%

SD = standard deviation.

Clinical site personnel reminded all study participants to discontinue all oral hygiene 24 hours prior to the Period I visit, and to cease eating, drinking, chewing gum, and using tobacco within 4 hours of their appointment. Subjects presented to the visit with the multi-directional power brush provided for the acclimation phase. Those participants with continuing study eligibility were then randomized with a computer-generated randomization schema to one of the four treatment sequences specifying the order of use of the two study test toothbrushes; each subject would use each of the brushes twice over the course of the trial. In addition to the multi-directional power toothbrush, subjects also brushed when dictated by their assigned sequence with an American Dental Association (ADA) reference soft manual brush.[b] Following randomization, subjects next disclosed their dental plaque by swishing with red disclosing solution[c] for 1 minute. A qualified examiner then performed a baseline, pre-brushing plaque examination using the Turesky Modification of the Quigley-Hein Plaque Index (TMQHPI)[17,18] (Figure). Subjects were then relocated to a brushing room not accessible to the clinical examiner for blinding purposes, where they brushed under the watch of the brushing supervisor to ensure correct technique was used and unaided by a mirror with the first toothbrush in their assigned treatment sequence. If this brush was the multi-directional power toothbrush, subjects brushed for 2 minutes according to the manufacturer's instructions with the fully charged brush. When the first assigned brush was the manual toothbrush control, subjects brushed in their customary manner. Pre-measured dentifrice was supplied on a tongue depressor for consistency. After brushing, subjects then swished with disclosing agent for 1 minute to re-disclose their teeth. Finally, the clinical examiner conducted a post-brushing TMQHPI evaluation to determine the effectiveness of the respective brushes in removing plaque during the single brushing.

Following Period I, subjects entered a 2- to 5-day washout period wherein they brushed with their pre-study toothbrush and the supplied Crest Cavity Protection toothpaste in their customary fashion. Prior to each of the remaining three period visits, they were reminded of the pre-visit restrictions around oral hygiene and eating, drinking, and smoking. At Periods II, III, and IV, subjects were again required to confirm ongoing eligibility. Plaque was disclosed, subjects received a pre-brushing TMQHPI evaluation, and then brushed under supervision with their next

Table 2. Turesky Modification of the Quigley-Hein Plaque Index Plaque Reduction results.

Test brush	N	Baseline mean[A]	Adjusted mean plaque reduction (SE)[B]	Between treatment difference (SE) 95% CI	% greater reduction of Oral B vs control[C,D]
Oral-B multi-directional power brush	36	2.146	1.046 (0.0422)	0.076 (0.0254)	7.9%
Manual control brush	36	2.169	0.969 (0.0422)	(0.026, 0.127)	(P= 0.003)

SE = standard error; % = percentage; CI = confidence interval; N = number of subjects.
Between subject variance = 0.05251; Mean Standard Error = 0.02306.
[A] Brushes didn't differ with respect to their baseline (pre-brushing) plaque level (P= 0.366).
[B] Carryover effect was not significant (P= 0.148) and was removed. The final analysis of co-variance (ANCOVA) model included baseline plaque, treatment and period as fixed effects and subject as random effect. Baseline plaque was a positive and significant covariate (P< 0.001). Both brushes delivered a significant (P< 0.001) plaque reduction when compared to zero.
[C] (Oral-B adjusted mean reduction – manual brush control adjusted mean reduction)/manual brush control adjusted mean reduction.
[D] Two-sided P-value for testing treatment difference based on the adjusted mean plaque reduction.

assigned test toothbrush (multi-directional power or manual control). A post-brushing TMQHPI examination was performed, and subjects then began the next washout phase (Periods II and III) or were dismissed from the clinical trial (Period IV).

Statistical analyses - Based on previous plaque removal data generated by the TMQHPI examiner (root mean squared error = 0.154), 36 completed subjects in this two-treatment, four-period crossover study with a two-tailed alpha = 0.05 and beta = 0.01 should be able to detect a true difference in whole mouth TMQHPI of about 0.086 between treatment groups.

Baseline subject demographic data were summarized. The TMQHPI scores were averaged on a per-subject basis, so that each subject had a single whole mouth average score prior to brushing (baseline), and another whole mouth average score following brushing in each of the four treatment periods. The difference (baseline minus post-brushing) in average scores was calculated for each subject for each period. The difference scores were analyzed for treatment group differences using a mixed model analysis of covariance (ANCOVA) for a crossover design with terms in the model for subjects (random factor), treatment, period, carryover effects, and the pre-brushing (baseline) whole mouth average score as the covariate. The adjusted mean plaque removal scores for each treatment were analyzed for statistical significance from zero using a t-test on the adjusted treatment mean score differences from ANCOVA.

Results

A total of 36 subjects were enrolled in the study and randomized to a treatment sequence, and all (100%) completed the trial with fully evaluable data. Subject age in the randomized study population ranged from 25-60 years, with a mean of 45.6 years (Table 1). Females comprised 86% of the study population, and a majority (94%) was Caucasian.

As shown in Table 2, there were no significant differences in the baseline (pre-brushing) TMQHPI scores between the multi-directional power brush and manual brush control, where the plaque means were 2.146 and 2.169, respectively (P= 0.366). After single-use brushing, both the multi-directional power brush and the manual brush control provided significant (P< 0.001) mean whole mouth TMQHPI plaque reductions (baseline minus post-brushing): the power brush produced a 48.7% reduction, while the manual brush control yielded a mean 44.7% reduction (Table 2). Comparing brushes, use of the multi-directional power brush resulted in a 7.9% significantly greater whole mouth plaque reduction on average versus the manual brush (P= 0.003).

One subject reported a mouth ulcer during the acclimation phase, which was deemed mild and not toothbrush-related; the event resolved by study end. Both toothbrushes were well-tolerated.

Discussion

New toothbrushes with technological advances or design modifications regularly arrive on drugstore shelves, necessitating the need for well-controlled clinical research to clarify the relative effectiveness of these introductions compared to currently marketed or reference brushes. Ideally, both short-term (single use) and longer-term trials are fielded collectively, using multiple measures of clinical efficacy to establish the plaque removal and anti-gingivitis potential of a toothbrush. In the study reported herein, a single-use, four-period crossover design evaluating whole mouth plaque removal using the treatment sequences ABBA, BAAB, AABB, and BBAA and including washout phases between study periods was employed; this is an ideal model for the estimation of carryover and treatment effects.[19] While there was no statistically significant carryover effect in this trial, the selected model ensures the validity of the test results in the event of a significant carryover effect outcome. Lang et al[20] reported that short-term, single-use trials are useful in controlling confounding variables, e.g. subject compliance.

While both the Oral-B multi-directional power brush and the ADA manual reference brush control significantly reduced whole mouth TMQPHI plaque after a single brushing versus baseline, the multi-directional power brush proved superior and removed a significantly greater percentage (7.9%) relative to the manual control. The TMQPHI is a well-established plaque index used frequently in toothbrush clinical trials, and as depicted in the Figure, quantifies the amount of plaque coverage on the crown of each scored tooth. While highly statistically significant, the percentage of superior relative plaque removal benefit of the multi-directional power brush differed in magnitude from that seen in the other manual brush clinical trial reported separately in this Special Issue.[21-23] This is likely due to the difference in the brush handle. The power brush handle in this trial employed 2-D technology (oscillating-rotating), whereas the brush handle in the other three clinical trials used 3-D technology (oscillating-rotating-pulsating). Other contributing factors may have included the respective subject populations' pre-study skill in manual brushing proficiency and the clinical plaque measurement used in the trials. The Rustogi

Modified Navy Plaque Index[24] used in the other three trials is particularly well-suited to analyses of difficult to clean surfaces, such as the gingival margin and approximal areas. The full extent of the plaque removal benefits of the new multi-directional power brush's unique triple zone brush head design for maximum penetration of marginal and interproximal areas in the current study may thus be understated when these hard-to-clean areas so integral to optimal gingival health are not separately analyzed.

Many clinical trials involving various designs and different populations have shown Oral-B power toothbrushes to be superior to manual toothbrushes in plaque reduction,[13,16,25-28] and the results of this investigation proved consistent. The significant 7.9% relatively greater mean plaque removal benefit produced by the novel multi-directional power brush compared to the manual control could additionally be expected to confer improvements in gingival health in a longer-term model, as research has demonstrated a correlation between reductions in TMPQHI scores and gingivitis levels, as well as a link between the outcomes of single-use clinical models and longer-term results.[29,30] Thus for those patients desiring both a recognizable manual-like brushing experience and robust cleaning, the new multi-directional power toothbrush supplies the requested familiarity combined with significantly better plaque removal efficacy for improved gingival health.

a. Procter & Gamble Company, Cincinnati, OH, USA.
b. American Dental Association, Chicago, IL, USA.
c. Sunstar Americas, Inc., Chicago, IL, USA.

Acknowledgements: To Shelly Campbell for assistance with manuscript preparation.

Disclosure statement: Drs. Klukowska, Grender and Timm are employees of Procter & Gamble. The study was supported by Procter & Gamble.

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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 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 (≤ 0.20 versus > 2.0), and whole mouth mean RMNPI scores (≤ 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):

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

- 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

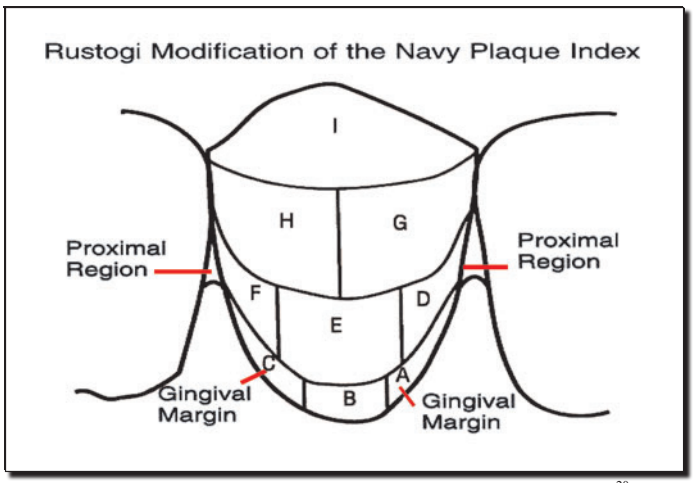

Fig. 2. Procedure for the Rustogi Modification of the Navy Plaque Index.[20]
Disclosing: To disclose the plaque, subjects swished for 10 seconds with 2.5 ml of Chroma-O-Red erythrosine FD&C, red #3 disclosing solution.
Scoring: At Week 1 and Week 4, disclosed plaque was quantified on nine sites per facial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

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.

a. Procter & Gamble Company, Cincinnati, OH, USA.
b. Philips Oral Healthcare, Snoqualmie, WA, USA.
c. Germiphene Corporation, Bradford, Ontario, Canada.

Acknowledgements: To Shelly Campbell for assistance in manuscript preparation.

Disclosure statement: Dr. Sharma, Dr. Mielczarek, and Mr. Qaqish declared no conflict of interest. Drs. Klukowska and Grender are employees of Procter & Gamble. The study was supported by Procter & Gamble.

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Evaluation of a new multi-directional power toothbrush versus a marketed sonic toothbrush on plaque and gingivitis efficacy

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ABSTRACT: Purpose: To evaluate the plaque- and gingivitis-reducing efficacy of a newly developed multi-directional power toothbrush in comparison to a commercially-available sonic power toothbrush. **Methods:** Adult subjects with mild-to-moderate gingivitis were eligible for this 4-week, randomized and controlled, single-center, examiner-blinded, parallel group study. At baseline, plaque and gingivitis status was assessed with the Rustogi Modified Navy Plaque Index (RMNPI), Lobene Modified Gingival Index (MGI), and Gingival Bleeding Index (GBI). Subjects meeting all eligibility criteria were randomly assigned to one of two power toothbrushes: a novel multi-directional power toothbrush (Oral-B Professional Deep Sweep TRICLEAN 1000 also marketed as Oral-B TriZone) or the marketed sonic control toothbrush (Philips Sonicare Essence 5500). A single supervised brushing occurred onsite at baseline; thereafter toothbrushing was conducted twice daily at home in accordance with manufacturer instructions using the assigned power brush. At 4 weeks post-baseline, subjects returned for MGI, GBI, and RMNPI evaluations to determine the plaque and gingivitis efficacy of the respective brushes. **Results:** All 130 subjects completing the trial were evaluable. Both the novel multi-directional power and sonic control brushes produced significant mean reductions in gingivitis, gingival bleeding and plaque (whole mouth and region-specific) at Week 4 in comparison to baseline ($P < 0.001$). The new multi-directional power brush performed statistically significantly better ($P \leq 0.001$) in all efficacy measures after 4 weeks of brushing, providing superior adjusted mean relative reduction benefits versus the sonic control brush of 48% for MGI, 52% for GBI, 26% for whole mouth RMNPI, 58% for gingival margin RMNPI plaque, and 33% for interproximal (approximal) RMNPI plaque. Both toothbrushes were well-tolerated. (*Am J Dent* 2012;25 Sp Is A:21A-26A).

CLINICAL SIGNIFICANCE: A novel multi-directional power toothbrush produced significantly greater plaque and gingivitis reduction efficacy compared to a marketed sonic control brush over a 4-week period.

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Introduction

Patients presenting for a preventive oral examination and prophylaxis generally receive instruction in proper tooth-brushing and interdental plaque removal techniques, either as a new patient or by way of reminder. Ideally, all patients would then follow through with a consistent and rigorous home care regimen between professional cleanings and re-instruction. The high worldwide prevalence of gingivitis, however, indicates that an undesirably large number of adults struggle to regularly remove sufficient plaque to avoid gingival inflammation and/or bleeding.[1-3] Numerous investigations have shown that adults overestimate their toothbrushing duration and effectiveness, and frequent flossing is not an ingrained habit for many.[4-7]

Without intervention, pathogenic microbes in undisturbed plaque have been shown to rapidly lead to gingivitis, and with chronic neglect, potentially to periodontitis.[8-10] Increasingly, poor periodontal health is also being linked to systemic disease.[11,12] Researchers and clinicians have concurred that the best approach in achieving gingival health is daily, conscientious plaque removal, with particular attention to the more difficult to access regions (e.g., approximal) where undisrupted plaque can otherwise proliferate and precipitate adverse periodontal and/or caries processes.[13-15] Where plaque removal is not optimal with use of a manual toothbrush due to ineffective technique, many have found greater success using a power toothbrush.

Sonic power toothbrush technology is now common, and Philips[a] produces a line of toothbrushes utilizing a patented sonic technology said to provide "better plaque removal than a manual toothbrush."[16] According to its manufacturer, the Sonicare Essence[a] power brush reaches "deep between teeth and along the gumline" and incorporates a uniquely angled brush neck to better reach back teeth.[16] In a 4-week randomized clinical trial reported by Farrell et al,[17] subjects brushing with Sonicare Essence saw significant reductions in gingivitis and bleeding sites compared with baseline.

Another popular power brush employs an oscillating-rotating technology pioneered by Oral-B.[b] A large independent meta-analysis[18] of over 42 clinical trials found that oscillating-rotating power toothbrushes were significantly more effective in plaque- and gingivitis-fighting performance than manual toothbrushes. Through continuing research Oral-B has developed a novel power brush with the aim of combining plaque removal effectiveness and design features particularly appealing to manual brush users. This new brush, marketed as Oral-B Professional Deep Sweep TRICLEAN 1000 in the United States and Oral-B TriZone in Europe, has a 3-D, multi-directional brush head specifically fashioned to penetrate the hard to clean dental spaces, while simultaneously providing a brushing experience that will feel familiar to former manual toothbrush users via a larger brush head size and triple-zone cleaning action. Additional design specifications are outlined in the introductory article in this Special Issue.[19] To determine the anti-plaque and anti-gingivitis performance of this unique new Oral-B power brush, it was compared to a marketed sonic power toothbrush control in a randomized and controlled 4-week clinical trial.

American Journal of Dentistry, Vol. 25, Special Issue A, September, 2012

Materials and Methods

A parallel group study design was utilized in this 4-week randomized and examiner-blinded single-center clinical investigation of the anti-plaque and anti-gingivitis efficacy of a newly developed multi-directional rechargeable power toothbrush, the Oral-B Professional Deep Sweep TRICLEAN 1000 (D16u/EB30) in the U.S. (and Oral-B TriZone in other regions), compared to a marketed sonic power toothbrush control: Philips Sonicare Essence 5500 with e-series standard brush head (Figure).

Potential study participants were screened for inclusion at the clinical site following the review and acceptance of the study protocol and subject consent form by an institutional review board. To qualify for enrollment, adult volunteers were required to be at least 18 years of age and in good general health, possess at least 16 natural and scorable teeth, and have baseline intraoral conditions indicative of existing gingivitis and plaque: a Modified Gingival Index[20] score of 1.75 to 2.3; a minimum of 10 sites with a 1 or 2 score using the Gingival Bleeding Index;[21] and a minimum Rustogi Modified Navy Plaque Index[22] plaque score of 0.50. If potential subjects had grossly carious and/or extensively restored dentition, severe periodontal disease, removable appliances or orthodontics, or were pregnant or lactating, they were excluded from participation. Additionally, if volunteers were under active periodontitis treatment, required antibiotic pre-medication in advance of dental treatment, had used chlorhexidine or antibiotics within 2 weeks of the study start, or reported any other diseases or conditions which might compromise clinical trial participation or the integrity of the study data, they were not permitted to enroll.

At the baseline visit, subjects who provided written informed consent and had followed pre-visit instructions (discontinued all forms of oral hygiene 12 hours prior to the appointment, as well as eating, drinking, chewing gum, and using tobacco 4 hours prior to the visit) were examined for baseline oral hard and soft tissues status. To assess pre-treatment gingival health, both the Modified Gingival Index (MGI)[20] and the Gingival Bleeding Index (GBI)[21] were subsequently performed. Next, the Rustogi Modification of the Navy Plaque Index (RMNPI)[22] plaque evaluation was conducted. Those subjects meeting all study inclusion and exclusion criteria were then stratified according to MGI gingivitis scores ($\leq$ 0.20 versus > 2.0), whole mouth mean RMNPI scores ($\leq$ 0.65 versus > 0.65), tobacco usage, and by the customary toothbrush used before study enrollment (power or manual), and were randomly assigned via a computer-generated balance and assignment program to either the new multi-directional power or sonic control toothbrush test group.

So that clinical site personnel could confirm subjects' understanding of the oral and written toothbrushing instructions, the initial brushing was performed under the watch of the on-site brushing supervisor in an area not visible to the clinical examiner or data recorder(s) to ensure their blinding to subject treatment assignments. The supplied test brushes were fully charged, with the sonic control brush 'Easy Start' feature deactivated. Subjects in both groups were instructed to apply Crest Cavity Protection[b] 0.243% sodium fluoride dentifrice to their assigned toothbrush head, and then brush for 2 minutes per the manufacturer's instructions. Subjects were directed to brush in a likewise manner twice daily at home for the duration of the 4-week study test period.

Figure. Test toothbrushes. **A.** Novel multi-directional power toothbrush. **B.** Sonic control toothbrush.

After approximately 1 month of use, subjects returned to the clinical site, having discontinued for 4 hours all food and drink, tobacco use and chewing gum, and all oral hygiene for 12 hours before this visit. An oral hard and soft tissue evaluation was first conducted to assess any treatment-associated adverse events. Gingivitis and gingival bleeding were next evaluated via the MGI and GBI evaluations, respectively. Finally, an RMNPI examination was performed for the quantification of plaque coverage.

Clinical efficacy evaluation - An experienced clinical grader conducted all clinical safety and efficacy evaluations at both study visits. The safety examination of the oral soft tissues involved visual examination of the oral cavity and perioral region with 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. The examiner noted any abnormal findings potentially product-related and (1) not documented at the baseline evaluation; or (2) worsening since assigned brush use.

The MGI evaluation was performed using scoring of the Lobene Modified Gingival Index[20] as follows:

At baseline and Week 4, gingivitis inflammation 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 calculated by summing all scores and dividing by the number of examined scorable sites.

Immediately following the MGI evaluation, the examiner assessed gingival bleeding using the GBI. With this method, 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 computed by totaling all scores and dividing by the number of examined scorable sites.

When both gingival health evaluations were complete, dental plaque was disclosed. Subjects swished with 2.5 milliliters of Chroma-O-Red[c] erythrosine FD&C, red #3 disclosing solution for 10 seconds to stain all tooth surfaces. The RMNPI plaque examination was conducted in the following manner: disclosed plaque was quantified on nine sites per facial and lingual tooth surface for a maximum 504 sites total (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 regions (areas A, B, C) and interproximal (approximal) regions (areas D, F).

Statistical analyses - An assumption of a sample size of 65 completing subjects per toothbrush test group 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 0.061 between groups (using two-sided testing with a 5% significance level). Using analogous assumptions with an assumed variability of 0.093 for RMNPI plaque, it was estimated a mean between-group plaque difference as small as 0.053 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 4 difference 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. Similar analyses were conducted for the gingival margin and interproximal (approximal) regions of the RMNPI. All comparisons were two-sided at the 0.05 level of significance.

Table 1. Baseline subject demographics. Randomized subjects.

Characteristic	Oral-B multi-directional power brush	Sonic control brush	Total
	N=65	N=65	N=130
Mean age (SD)[A]	42.8 (10.9)	41.5 (11.7)	42.1 (11.2)
Age range	18-69	18-63	18-69
Female (N, %)[B]	44 (67.7%)	42 (64.6%)	86 (66.1%)
Male (N, %)[B]	21 (32.3%)	23 (35.4%)	44 (33.9%)
Smoker (N, %)[C]			
Yes	7 (10.8)	6 (9.2%)	13 (10.0%)
No	58 (89.2%)	59 (90.8%)	117 (90.0%)
Brush type[B]			
Manual	54 (83.1%)	57 (87.7%)	111 (85.4%)
Power	11 (16.9%)	8 (12.3%)	19 (14.6%)

SD = standard deviation; N= number of subjects.
[A] Two sample t-test was used to compare mean age between the two groups (P= 0.519).
[B,C] Chi-Sqaure test was used to assess balance between the two groups for gender (P= 0.711), smoking status (P= 0.770), and pre-study brush type (P= 0.456).

Table 2. Baseline MGI, GBI and RMNPI results.

	N	Baseline Mean (SD)	P-value*
Modified Gingival Index			
Oral-B multi-directional power brush	65	2.061 (0.0884)	0.313
Sonic control brush	65	2.047 (0.0641)	
Gingival Bleeding Index			
Oral-B multi-directional power brush	65	0.115 (0.0669)	0.266
Sonic control brush	65	0.104 (0.0449)	
RMNPI – Whole mouth			
Oral-B multi-directional power brush	65	0.598 (0.0398)	0.512
Sonic control brush	65	0.602 (0.0429)	
RMNPI – Gingival margin			
Oral-B multi-directional power brush	65	1.00 (0.000)	NA
Sonic control brush	65	1.00 (0.000)	
RMNPI – Interproximal			
Oral-B multi-directional power brush	65	0.960 (0.0741)	0.896
Sonic control brush	65	0.958 (0.0641)	

SD = standard deviation; N = number of subjects.
*T-test P-value for treatment group comparison at study baseline.
NA = Not applicable.

Results

A total of 130 subjects (65 per group) were randomly assigned to a test toothbrush group at baseline. All subjects completed the trial and were fully evaluable for the Week 4 analyses. The mean age of the randomized study population was 42.1 years (Table 1) and ranged from 18 to 69 years. With respect to gender, 66% of the subjects were female. Most (90%) of study participants were non-smokers, and most (85%) were typical manual toothbrush users prior to study enrollment. There were no significant between-group differences in any of these baseline demographic parameters (P≥ 0.456) (Table 1).

Modified Gingival Index (MGI) - As shown in Table 2, pre-treatment, baseline average MGI scores were not significantly

Table 3. Week 4 results for MGI, GBI, and RMNPI.

	Adjusted mean change from baseline (SE)[A]	Percent change from baseline[B]	Between-treatment difference (SE)	Percent Oral-B greater reduction versus Control[C,D]
MGI				
Oral-B multi-directional power brush (N=65)	0.215 (0.0067)	10.4%	0.070 (0.0095)	48.3%
Sonic control brush (N=65)	0.145 (0.0067)	7.1%		(P< 0.001)
GBI				
Oral-B multi-directional power brush (N=65)	0.050 (0.0018)	43.5%	0.017 (0.0025)	51.5%
Sonic control brush (N=65)	0.033 (0.0018)	31.7%		(P< 0.001)
Whole Mouth RMNPI				
Oral-B multi-directional power brush (N=65)	0.144 (0.0047)	24.1%	0.030 (0.0066)	26.3%
Sonic control brush (N=65)	0.114 (0.0047)	18.9%		(P< 0.001)
Gingival Margin RMNPI				
Oral-B multi-directional power brush (N=65)	0.076 (0.0057)	7.6%	0.028 (0.0081)	58.3%
Sonic control brush (N=65)	0.048 (0.0057)	4.8%		(P= 0.001)
Interproximal RMNPI				
Oral-B multi-directional power brush (N=65)	0.389 (0.0142)	40.5%	0.097 (0.0201)	33.1%
Sonic control brush (N=65)	0.293 (0.0142)	30.6%		(P < 0.001)

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

[A] Within-brush difference from baseline was tested versus zero using ANCOVA. For MGI, RMNPI whole mouth, and RMNPI interproximal regions, no significant interactions (P= 0.095, P= 0.795, and P= 0.703, respectively) were detected between baseline covariate and treatment and were removed from the models. For GBI, the model included interaction term between the baseline covariate and treatment (P= 0.024); brushes were compared at the mean baseline score of 0.11.

[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 4 MGI, GBI, and RMNPI reduction using ANCOVA with baseline as covariate.

different between the multi-directional power and sonic control brush groups, where the means were 2.061 and 2.047, respectively (P= 0.313). Both groups experienced significant (P< 0.001) mean reductions in gingivitis as measured via MGI after 4 weeks of toothbrush use: the adjusted mean reduction versus baseline for the new power brush group was 0.215 (10.4% decrease), while the mean reduction for the sonic control group was 0.145 (7.1% decrease) (Table 3). The extent of the gingivitis reductions relative to baseline following 4 weeks of twice daily toothbrushing was 48.3% significantly greater for the multi-directional power brush group as compared to the sonic control brush group (P< 0.001).

Gingival Bleeding Index (GBI) - At baseline, the measurement of subject gingival bleeding via the GBI revealed no significant between-group differences (P= 0.266), with baseline mean scores of 0.115 for the multi-directional power brush, and 0.104 for the sonic brush control group (Table 2). As depicted in Table 3, gingival bleeding was significantly reduced on average in each brush group after 4 weeks' use of the assigned toothbrush, with an adjusted mean GBI score reduction of 0.050 for the multi-directional power brush and 0.033 for the sonic brush control, representing 43.5% and 31.7% significant decreases in bleeding, respectively (P< 0.001). The difference in mean bleeding reduction was 0.017 between groups, favoring the multi-directional power brush, which provided 51.5% comparatively greater bleeding reduction relative to the sonic control brush (P< 0.001) (Table 3).

Rustogi Modified Navy Plaque Index (RMNPI) - There were no significant differences between the two brush groups at study baseline in either whole mouth, gingival margin region, or interproximal region RMNPI (P≥ 0.512) (Table 2). However, following 4 weeks of brushing with the assigned toothbrush, both the new multi-directional power brush and sonic control brush users experienced significant mean plaque reductions when compared with baseline. For whole mouth RMNPI, the change from pre-treatment was 24.1% (adjusted mean reduction of 0.144) for the multi-directional power brush, and the mean reduction of 0.114 for the sonic control group equated to an 18.9% decrease (P< 0.001) (Table 3). A between-group comparison of these reductions revealed that the multi-directional power brush produced a 26.3% superior whole mouth mean plaque reduction versus the sonic brush control (Table 3).

Similar benefits favoring the multi-directional power brush were seen when analyzing regions of the dentition that can prove challenging to clean. As shown in Table 3, at Week 4, the adjusted mean reduction compared to baseline at the RMNPI gingival margin sites was 0.076 (7.6%) and 0.048 (4.8%) for the multi-directional power brush and sonic brush control groups, respectively (P< 0.001). These results represented a 58.3% greater plaque reduction in the gingival margin region for the multi-directional power brush relative to the sonic brush control (P= 0.001). In the interproximal region, both test brushes provided significant improvement (P< 0.001) in RMNPI plaque scores after 4 weeks of brushing, with the multi-directional power brush group seeing an adjusted mean plaque reduction of 0.389 (40.5%), while the sonic brush control group saw a mean decrease of 0.293 (30.6%) (Table 3). The between-group reduction difference of 0.097 demonstrated that the new multi-directional power brush provided 33.1% significantly greater RMNPI interproximal plaque reduction as compared to the sonic control brush (P< 0.001) (Table 3).

Both toothbrushes were well-tolerated, with no product-associated adverse events.

Discussion

New entries into the burgeoning power toothbrush segment are ongoing, and dental professionals benefit from published reports of well-controlled research contrasting the effectiveness of various brushes with differing modes of action and brush design configurations so they can in turn give evidence-based recommendations when patients inevitably ask for guidance. In this 4-week clinical investigation, a newly developed Oral-B multi-directional power toothbrush featuring a distinctive triple zone cleaning action with pulsating sweeping and stationary bristles was evaluated for efficacy in reducing both plaque and gingivitis in a population of generally healthy adults with confirmed plaque formation and mild to moderate gingivitis. The comparator power toothbrush in this trial, the Sonicare Essence, is marketed as effectively reaching "deep between teeth and along the gumline" and "removing plaque in those hard-to-reach places",[16] thus making it an apt control in this investigation of two brushes developed for maximum plaque removal and user acceptance but with dissimilar cleaning mechanisms.

While plaque reduction is desirable in and of itself for cosmetic purposes, the more salient benefits of plaque control are found in minimizing the risk of dental caries and gingivitis; the latter which may progress in severity to periodontitis without thorough, consistent mechanical removal.[10,23] Power toothbrushes have proven to be a powerful tool in improving both compliance and cleaning efficiency, thus simplifying the path to better gingival health. Single-use toothbrushing study designs cannot evaluate test brushes' anti-gingivitis potential, requiring a longer treatment period duration so that repeated, efficient plaque removal (if present) may show manifestation in decreased gingival inflammation and bleeding. In the current study, subjects brushed in their home setting twice daily for approximately 1 month (4 weeks), allowing adequate time for any improvement in gingival health conferred via better plaque control provided by the test brushes to be observed.

Both the Oral-B novel multi-directional power and Sonicare Essence toothbrushes decreased plaque and improved the gingival health of the assigned subjects at Week 4 relative to baseline, with statistically significant mean reductions in gingivitis (MGI and GBI) and RMNPI whole mouth, gingival margin, and interproximal plaque. This is in accordance with previous research such as that by Goyal et al[24] showing power brushes manufactured by both Oral-B and Sonicare have provided significant plaque and gingivitis reductions when compared with pre-treatment in a similarly-designed multi-week, parallel group clinical trial.

Notably, the novel multi-directional power brush in this investigation provided superior plaque and gingivitis reductions versus baseline compared to the sonic control brush across all five clinical outcome measures which were highly statistically significant. Multi-directional power brush-assigned subjects experienced a 26% greater relative RMNPI mean whole mouth plaque reduction, and when analyzed by region, a 58% superior mean gingival margin reduction and 33% greater interproximal (approximal) region RMNPI plaque reduction, confirming the new power brush's efficacy in disrupting and sweeping away plaque not only in the most accessible intraoral regions, but importantly, in areas known to be difficult for the average adult to clean sufficiently. As a result, the between-brush greater mean comparative reductions for both MGI gingivitis (48%) and gingival bleeding (52%) both favored the multi-directional power brush, as significantly lower plaque levels following 4 weeks of test brushing would be anticipated to positively impact gingival health. Using the variability computed from this study with a sample size of 65 per group, a difference in MGI reductions between brushes of 0.027 could be detected with 80% power.

In summary, a new power toothbrush with a unique multi-directional design consistently produced significantly greater plaque and gingivitis reduction efficacy compared to a marketed sonic control brush over a 4-week period.

a. Philips Oral Healthcare, Snoqualmie, WA, USA.
b. Procter & Gamble Company, Cincinnati, OH, USA.
c. Germiphene Corporation, Bradford, Ontario, Canada.

Acknowledgements: To Shelly Campbell for assistance with manuscript preparation.

Disclosure statement: Dr. Goyal and Mr. Qaqish declared no conflict of interest. Dr. Klukowska, Dr. Grender and Ms. Cunningham are employees of Procter & Gamble. The study was supported by Procter & Gamble.

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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

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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b. Procter & Gamble Company, Cincinnati, OH, USA.
c. Germiphene Corporation, Bradford, Ontario, Canada.

Acknowledgements: To Shelly Campbell for assistance with manuscript preparation.

Disclosure statement: Drs. Klukowska, Grender and Biesbrock are employees of Procter & Gamble. Dr. Goyal and Mr. Qaqish declared no conflict of interest. The study was supported by Procter & Gamble.

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