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Original Article

EFFICACY OF PLAQUE REMOVAL BY A NEW POWER BRUSH TO A ADA REFERENCE MANUAL TOOTHBRUSH: A RANDOMIZED CLINICAL TRIAL

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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, double 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 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.

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 ($P = 0.003$).

Conclusion: 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.

Key words: Power toothbrush, plaque, manual 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 inter-vention.[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 tooth brushing 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, 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.

MATERIAL AND METHODS:

In this randomized, replicate use, single-brushing, 36 completed subjects in this two-treatment, four-period crossover

study 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 of Jaipur Dental College, Jaipur assessed and approved the subject consent form and study protocol prior to study inception. Subject recruitment was limited to generally healthy adults at least 18 years of age with no less than 16 natural teeth with facial and lingual surfaces present. 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 TriZonea or Oral-B Vitality Deep Sweep, a D12/ EB30), and Crest Cavity Protectiona dentifrice for use in the subsequent 3 days acclimation phase, which was incorpo-rated 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. 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 as-signed sequence with an American Dental Association (ADA) reference soft manual brush. Following randomization, subjects next disclosed their dental plaque by swishing with red disclosing solution 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]. 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 dis-closing agent for 1 minute to redisclose 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 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), 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 random-ized study population ranged from 25-60 years, with a mean of 45.6 years (Table 1).

	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%

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).

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[CD]
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.

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 treat-ment 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 carry-over 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 RustogiModified 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]

CONCLUSION:

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.

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