A randomized clinical trial evaluating gingivitis and plaque reduction of an oscillating-rotating power brush with a new brush head with angled bristles versus a marketed sonic brush with self-adjusting technology

MALGORZATA KLUKOWSKA, DDS, PhD, JULIE M. GRENDER, PhD, ERINN CONDE, BS, RENZO ALBERTO CCAHUANA-VASQUEZ, DDS, PhD & C. RAM GOYAL, DDS

ABSTRACT: Purpose: To compare the efficacy of an oscillating-rotating power toothbrush with a novel brush head incorporating angled CrissCross bristles (Oral-B Pro 7000 SmartSeries and Oral-B CrossAction brush head) versus a marketed sonic toothbrush (Colgate ProClinical A1500 with the Triple Clean brush head) in the reduction of gingivitis and plaque over a 6-week period. Methods: This was a single center, randomized, open label, examiner-blind, 2-treatment, parallel group study. Study participants who met the entrance criteria were enrolled in the study and randomly assigned to one of the two toothbrush groups. Study participants brushed with their assigned toothbrush and a marketed fluoride dentifrice for 2 minutes twice daily at home for 6 weeks. Gingivitis and plaque were evaluated at baseline and Week 6. Gingivitis was assessed using the Modified Gingival Index (MGI) and Gingival Bleeding Index (GBI) and plaque was assessed using the Rustogi Modified Navy Plaque Index (RMNPI). Data was analyzed using the ANCOVA with baseline as the covariate. Results: In total, 130 study participants were randomized to treatment resulting in 64 study participants per group completing the study. Both brushes produced statistically significant (P<0.001) reductions in gingivitis and plaque measures relative to baseline. The oscillating-rotating brush with the novel brush head demonstrated statistically significantly (P<0.05) greater reductions in all gingivitis measures, as well as whole mouth and interproximal plaque measures, compared to the sonic toothbrush. The benefit for the oscillating-rotating brush over the sonic brush was 21.3% for gingivitis, 35.7% for gingival bleeding, 34.7% for number of bleeding sites, 17.4% for whole mouth plaque, and 21.2% for interproximal plaque. There were no adverse events reported or observed for either brush. (Am J Dent 2014;27:179-184).

CLINICAL SIGNIFICANCE: The oscillating-rotating toothbrush with a novel brush head design incorporating angled CrissCross bristles was significantly better than a sonic power toothbrush for plaque and gingivitis reduction, particularly at hard-to-reach interproximal sites. Therefore patients needing improved gingival health should consider incorporating the oscillating-rotating brush and the new brush head with angled bristles in their home care routine.

Introduction

Patients are motivated to perform oral hygiene for a variety of therapeutic and cosmetic reasons that range from oral disease prevention to reducing extrinsic stain. While these goals may result from different social and/or health concerns, ultimately they all depend on effective plaque removal. Saliva provides a natural self-cleansing mechanism, but it is not adequate to remove all the dental plaque that builds up in the oral cavity during the course of a day. Regular removal of dental plaque by mechanical means is therefore needed to prevent plaque from accumulating on the teeth and gingiva.1

The most widespread means of removing plaque mechanically from the tooth surface is toothbrushing. Manual toothbrushing remains the most common method of oral hygiene and it can be quite effective when correctly performed for a 2-minute brushing time twice daily.2 However, it appears most dental patients are unable to achieve adequate plaque removal. A systematic review3 concluded that in adults with gingivitis the quality of self-performed mechanical plaque removal with a manual toothbrush was not sufficiently effective and should be improved.

Electric (power) toothbrushes were introduced in the 1960’s and have continued to evolve in both performance and design. Many of the current toothbrushes on the market incorporate a timer to help with 2-minute brushing compliance and to promote adequate plaque removal. A variety of clinical studies have demonstrated that power toothbrushes deliver superior plaque removal compared to a manual toothbrush, increasing their acceptance in the dental community as well as among patients.4-10 In addition, two separate systematic reviews conducted by the Cochrane Collaboration in 200511 and 201012 concluded that oscillating-rotating power toothbrushes were superior to manual brushes and more effective than power brushes working with a side-to-side movement (sonic) for both plaque and gingivitis reduction.

Power toothbrush design features aimed at greater plaque removal efficiency include an increase in brush stroke frequency with modifications to filament patterns and configuration. The advanced Oral-B oscillating-rotating power toothbrush models8 incorporate 8,800 oscillations and 40,000 pulsations per minute to increase brush stroke frequency. The other fundamental property of the brush head is ensuring the bristles are designed to optimize plaque removal on all tooth surfaces. Vertical brush filaments remove plaque from flat, accessible surfaces effectively but are less effective in the interproximal hard-to-clean areas of the teeth.13

Toothbrush manufacturers realize the importance of an optimally designed toothbrush, particularly one engineered for
maximum plaque removal in hard-to-clean areas since use of interdental aids by patients is low. Recently, the 16° angle inclined bristle filament technology designed for optimal shear forces has been applied to the oscillating-rotating power brush head available in the Cross-Action™ manual toothbrush, a brush that has demonstrated consistent, significant advantages with respect to interproximal penetration and cleaning effectiveness.13 The idea behind it was to combine the angled bristles with short movements with a high number of turning points of direction at high frequency provided by oscillation-rotation technology to optimize the plaque removal. The outer and inner rings of the brush head have angles of +16° and -16°, respectively, for the oscillation’s forward and backward directions. The inner part of the brush head, designed with straight filaments to provide stability of the filament design, has only minor movement.

A recent entry in the sonic toothbrush market is the Colgate ProClinical A1500. The ProClinical brush is described as employing a unique cleaning action that combines both up-down (pulsation-like) and side-to-side strokes in one brushing mode (“Sonic Wave”), with up to 32,500 strokes per minute. The brush is marketed with the Triple Clean brush head, which is reported to help remove surface stains in laboratory studies, deep clean along the gingival margin and remove plaque.15,16

This study evaluated and compared the effectiveness of a clinically proven oscillating-rotating power toothbrush with the novel brush head with angled CrissCross bristles to the newly marketed sonic toothbrush with the TripleClean® brush head in the reduction of gingivitis and plaque in adults with mild-to-moderate gingivitis over a 6-week period.

**Materials and Methods**

This was a randomized, 2-treatment, examiner-blind, parallel group study involving 65 study participants per group. Clinical evaluations were completed at baseline and Week 6. The study protocol was approved by the Institutional Review Board (BRCL, #70032013LV). One hundred and thirty-four study participants were enrolled and asked to sign a written informed consent prior to their participation in the study. At the baseline visit, study participants’ medical history and demographics were obtained and those study participants that satisfied the study inclusion/exclusion criteria were randomized.

To qualify for the study, participants were required to have a whole mouth mean baseline plaque score greater than 0.5 using the Rustogi Modified Navy Plaque Index® (RMNPI), a baseline whole mouth mean Modified Gingival Index18 (MGI) score of at least 1.75 but not greater than 2.3, and a minimum of 10 bleeding sites employing the Gingival Bleeding Index19 (GBI). In addition, study participants had to be at least 18 years of age, be in good general health as determined by the investigator after review of the study participant’s medical history, and have a minimum of 16 natural teeth with facial and lingual valid surfaces. Study participants were not allowed to take part in any other oral care research for the duration of this trial and they had to agree to delay any elective dentistry, including a prophylaxis, until study completion.

Study participants also agreed to refrain from the following: the use of non-study oral hygiene products for the duration of the study; brushing their teeth and performing any other oral hygiene procedures for 12 hours prior to each visit; and eating, chewing gum, drinking and tobacco use for 4 hours prior to each visit, except for small sips of water up until 45 minutes prior to each visit. Study participants were advised that they would be excluded from the study if there was evidence of existing poor oral hygiene (e.g., severe periodontal disease, grossly carious or extensively restored teeth), or if antibiotics or chlorhexidine mouth rinse had been used within 2 weeks prior to the start of the study. Study participants were also excluded if there was evidence of any disease or condition that may interfere with study procedures.

The study test products included (Fig. 1):

1. The oscillating-rotating toothbrush with the novel brush head incorporating angled CrissCross bristles (Oral-B Pro 7000 SmartSeries with SmartGuide with Oral-B CrossAction brush head, D34/EB50).
2. The marketed sonic toothbrush (Colgate ProClinical A1500) fitted with the Triple Clean brush head.

Study participants in both groups used a standard 0.243% sodium fluoride dentifrice (Crest Cavity Protection®) with their test brush.

At the baseline visit, eligible study participants were given an oral soft tissue examination followed by assessment of the gingiva using MGI and number of bleeding sites (GBI). Study participants then rinsed with 2.5 ml of Chrom-O-Red® erythro-
sine FD&C red 3 disclosing solution (for 10 seconds followed by a water rinse for 10 seconds) to stain the plaque present on their teeth. A plaque assessment (RMNPI) was then conducted. The same experienced examiner carried out both the safety assessment as well as the clinical assessments for each study participant.20,21

Study participants were then stratified based on their baseline whole mouth MGI score (< 2, ≥2), bleeding score (GBI), whole mouth mean RMNPI score (≤ 0.65, > 0.65), tobacco use, and typical toothbrush used at home (manual brush or power brush), and then randomly assigned to one of the two treatment groups: oscillating-rotating or sonic.

Each study participant was supplied with their assigned toothbrush and the anti-cavity dentifrice in an area separate from the examination room to ensure the examiner was blinded to treatment assignment since the brushes were used open label. Under supervision by a member of the research staff not associated with the clinical assessments, study participants then received oral hygiene and product usage instructions (per manufacturers’ usage instructions), and brushed in front of a mirror for on-site practice. Study participants were then instructed to brush with their assigned toothbrush and dentifrice (pea size) for 2 minutes twice daily at home for 6 weeks. The oscillating-rotating brush was used in the daily clean mode and the sonic brush was used in auto mode. The on-site supervised brushing at the baseline visit was considered one of the study participant’s twice-daily brushings.

Study participants were scheduled to return to the research center with their study product for their Week 6 (± 2 days) assessment visit. They were reminded prior to this visit that they should refrain from brushing their teeth for 12 hours prior to their appointment time, and that for 4 hours before the visit they were to refrain from eating, chewing gum, drinking or using tobacco products. Continuance criteria were assessed prior to examinations taking place. Once eligibility was determined, study participants received an oral soft tissue examination, MGI, GBI (number of bleeding sites) and RMNPI plaque assessments in the same manner as conducted during the baseline visit.

The safety assessment involved both the hard and soft tissues of the oral cavity. The structures examined included the free and attached gingiva, hard and soft palate, tongue, floor of the mouth, buccal mucosa, labial mucosa, mucobuccal/mucolabial folds, oropharynx/uvula, lips, and perioral area. All non-serious voluntarily reported whole body and oral related adverse events that were product related were documented. In addition, all serious adverse events were documented.

The MGI 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’ = moderate inflammation (moderate glazing, redness, edema and/or hypertrophy) of the marginal or papillary gingiva 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 scored sites examined.

The GBI assessment immediately followed, 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° 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 as described above of the scored teeth was 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. GBI score was characterized as ‘0’, ‘1’ or ‘2’ to determine total number of bleeding sites.

The RMNPI was then used to score plaque on the teeth. This index gives a total of 504 sites for all 28 teeth (excluding third molars, crowns and surfaces with cervical restorations). Mean RMNPI scores (total number of tooth areas with plaque present/total number of tooth areas scored) were calculated for each study participant at both the baseline and Week 6 examinations for the whole mouth, along the gingival margin and for interproximal surfaces (Fig. 2).

Data analyses - Based on previous clinical research with a similar design, power analyses were calculated with α = 0.05, using a 2-sided test and a sample size of 65 study participants per group. A sample size of 65 study participants per group, based on whole mouth MGI variability of 0.737, provides 90% power to detect a difference in MGI mean scores as small as 0.042 units between treatments. Similarly for plaque, assuming the variability of whole mouth RMNPI is 0.0464, a sample size of 65 study participants per group should provide 90% power to detect a difference in RMNPI mean scores of 0.027 units between treatments.

Fig. 2. The Rustogi modification of the Navy Plaque Index. Disclosed plaque is scored on each facial and lingual tooth surface as present ("1") or absent ("0"). The whole mouth is represented by areas A-I: interproximal (approximal) areas are D and F, and the marginal (gingival) areas include A, B and C.
Both groups showed significant (P< 0.001) reductions from baseline in MGI and GBI scores as well as number of bleeding sites. At Week 6, gingivitis reductions at Week 6 versus baseline were 13.5% for the oscillating-rotating brush and 11.1% for the sonic brush assessed by MGI; and 52.5% for oscillating-rotating brush and 38.7% for the sonic brush assessed by GBI. The percent reduction from baseline for the number of bleeding sites was 54.8% for the oscillating-rotating brush and 40.7% for the sonic brush. The oscillating-rotating toothbrush demonstrated statistically significantly (P≤ 0.0006) greater mean reductions in MGI by 21.3%, GBI by 35.7% and number of bleeding sites by 34.7% relative to the sonic toothbrush after 6 weeks of brushing (Table 2).

Plaque scores - There was strong evidence of plaque accumulation at study entry (baseline whole mouth RMNPI score of > 0.60). Table 3 shows the mean baseline Week 6 whole mouth, interproximal, and gingival margin scores for both groups, and mean changes in scores from baseline. Both groups showed significant (P< 0.001) reductions from baseline in whole mouth, gingival margin and interproximal plaque scores at Week 6. Whole mouth plaque percent reductions from baseline were 17.3% for the oscillating-rotating brush and 14.8% for the sonic brush; interproximal plaque was reduced by 22.4% for oscillating-rotating and 18.4% for sonic. The gingival margin percent plaque reduction versus baseline was 4.0% for the oscillating-rotating brush and 3.7% for the sonic brush.

The results of the analysis of group differences are also shown in Table 3. The oscillating-rotating toothbrush demonstrated significantly (P< 0.05) greater mean reductions in whole mouth plaque by 17.4% and interproximal plaque by 21.2%
after 6 weeks of brushing compared to the marketed sonic toothbrush.

No product related adverse events or safety concerns were observed or reported in either group.

Discussion

Results of the current study support the efficacy of the novel oscillating-rotating brush head with 16°-angled CrissCross filaments in removing greater whole mouth plaque and plaque in hard-to-clean interproximal areas compared to the sonic test brush with Triple Clean brush head. Furthermore, the oscillating-rotating brush with the novel brush head demonstrated a significantly greater reduction in the number of bleeding sites and overall bleeding scores compared to the sonic brush. In addition, the MGI reductions were statistically significantly greater for the oscillating-rotating brush compared to the sonic brush.

These results are consistent with a separate clinical investigation comparing the same oscillating-rotating brush with the novel brush head incorporating angled bristles versus the FlexCare DiamondClean. In that 6-week randomized, examiner-blind, comparative clinical study, the oscillating-rotating toothbrush was significantly better than the advanced sonic power toothbrush in reducing gingival inflammation and bleeding as well as reducing whole mouth plaque, plaque along the gingival margin and in the approximal regions. That trial also showed users of the oscillating-rotating brush with the new brush head rated it better than those using the sonic brush for overall use experience and key attributes related to cleaning, gentleness, and brush head shape/size.

The literature has consistently demonstrated that power toothbrushes with oscillating-rotating technology deliver superior plaque removal compared to manual and sonic toothbrushes. In fact, a 2013 report compared an oscillating-rotating brush with FlossAction brush head (EB25) versus the Colgate ProClinical A1500 brush tested in this trial. Clinical assessments were made after 4 and 12 weeks of product use. Consistent with the literature, the oscillating-rotating power toothbrush showed statistically significantly greater benefits versus the Colgate sonic brush for gingival health and plaque measures. One contrasting report in the literature tested the Colgate ProClinical A1500 brush versus an oscillating-rotating brush (Oral-B Triumph with SmartGuide) and another sonic power brush (Sonicare Flexcare). The authors concluded the Colgate ProClinical sonic brush resulted in significantly greater plaque reductions relative to both comparator brushes after a single use as well as after 4 weeks use. However, the ProClinical brush did not provide a significant reduction in gingivitis compared to the Oral-B power brush, even though there was a reported difference in plaque reduction. Plaque findings from this trial also deviate from the literature in that the oscillating-rotating brush did not provide statistically greater plaque removal than Sonicare Flexcare. Contrary to the Ayad et al study, a recent review of six clinical trials demonstrated that oscillating-rotating brushes were significantly superior to comparator sonic and manual control brushes in post-brushing plaque removal performance in hard-to-clean lingual, interproximal and gingival margin areas. The cleaning benefits in hard-to-clean areas are particularly important for the prevention of caries and periodontal disease.

The design of the oscillating-rotating brush head evaluated in this study is based on the superior cleaning performance of the CrossAction manual toothbrush, which incorporated filaments inclined at 16° angles. Since its creation, the CrossAction manual toothbrush has proven to maximize plaque removal specifically in hard-to-reach areas. A recent systematic review of manual toothbrush effectiveness highlighted the efficacy of the brush design incorporating angled bristles. After evaluating 59 papers with 212 brushing exercises, the authors found a 12-15% (depending on plaque index) improvement in efficacy can be achieved with an angled bristle tuft design as compared to a flat-trimmed design. The authors noted that “angulation appears to be an efficient novelty of brush head design, which is substantiated based on the results of the present review.” In the novel power brush head, the angled bristles cover a broad area of the tooth surface as they fan open in a controlled manner and are designed to maximize interproximal penetration.

In conclusion, combining an effective power toothbrush handle with a brush head design that enables efficient removal of plaque in hard-to-reach areas is a win/win for oral health care professionals and their patients who are better able to maintain optimal oral health.

Discussion statement: Dr. Klukowska, Dr. Grender, Ms. Conde and Dr. Cahuana-Vasquez are employees of Procter & Gamble. Dr. Goyal had no conflict of interest. The study was supported by the Procter & Gamble Company.

Dr. Klukowska is a Principal Scientist, Dr. Grender is a Research Fellow, and Ms. Conde is a Clinical Trial Manager at the Procter & Gamble Company, Mason, Ohio, USA. Dr. Cahuana-Vasquez is a Clinical Scientist at the Procter & Gamble Company, Kronberg, Germany. Dr. Goyal is Principal Investigator at Bio-Sci Research, Las Vegas, Nevada, USA.

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