A randomized clinical trial comparing plaque removal efficacy of an oscillating–rotating power toothbrush to a manual toothbrush by multiple examiners

Abstract: Objective: To determine whether multiple examiners can demonstrate consistent plaque removal advantages for an oscillating–rotating power toothbrush versus a manual toothbrush. Methods: This was a replicate-use, single brushing, examiner-blind, randomized, two-treatment, four-period crossover clinical trial involving four examiners. Subjects were randomized to one of four treatment sequences involving two toothbrushes: an oscillating–rotating power toothbrush or a manual toothbrush. At each of the four visits, subjects arrived having abstained from oral hygiene for 24 h prior, and brushed with their assigned toothbrush and a marketed fluoride dentifrice under supervision unaided by a mirror. Plaque was assessed by each examiner using the Turesky-Modified Quigley–Hein Plaque Index at each study period before and after brushing. Data was analysed separately for each examiner using the analysis of covariance for crossover design. Results: Ninety-five subjects between the ages of 18 and 70 met the entrance criteria and were enrolled in the study. Eighty-seven subjects completed all four periods of the study. Both brushes delivered a significant plaque reduction when compared to baseline. Significant treatment differences were observed for all four examiners—ranging from 0.10 to 0.16—in favor of the oscillating–rotating brush ($P < 0.001$). There were no adverse events reported or observed for either brush. Conclusions: All four examiners demonstrated the power toothbrush removed significantly more plaque after a single brushing than the standard manual toothbrush. Both brushes were well tolerated.

Key words: electric; manual; plaque; toothbrushes

Introduction

Dental caries and periodontal diseases, such as gingivitis, have historically been considered important global oral health burdens. In industrialized countries, dental caries affects 60–90% of school children and the majority of adults while plaque-induced gingivitis can be found in most children worldwide and is also highly prevalent in the adult population (1). Controlling dental plaque accumulation on teeth and gingival tissues is an important step in reducing the incidence of gingivitis as well as controlling the acids produced by plaque bacteria that increase the
occurrence of enamel and root caries. The most popular oral hygiene home care product for plaque control is a toothbrush. During the past several decades, various toothbrush designs, including manual and power, have been introduced to offer patients more effective options to remove plaque.

Randomized controlled clinical trials offer important evidence for clinicians to determine the effectiveness of toothbrushes relative to various controls for the reduction of plaque. Since the first introduction of oscillating-rotating toothbrushes in the 1990s, many well-designed clinical trials have been undertaken to investigate plaque removal versus various manual toothbrushes. Specifically, the entry-level oscillating-rotating brush (D12) evaluated in this trial is used around the world and has been generally accepted as a safe and effective oral hygiene device. Results of numerous studies demonstrate a statistically significantly greater reduction in full-mouth plaque levels for the oscillating-rotating power brush when compared to a manual toothbrush control (2-8). More recently, the plaque removal efficacy of oscillating-rotating power toothbrushes on different surfaces of the teeth was evaluated and results were presented in a review by Grender, et al. (9). Collective results of six clinical trials demonstrated that oscillating-rotating brushes produced significantly greater post-brushing plaque removal in the lingual, approximal and gingival regions of the mouth versus comparator sonic power and manual control brushes.

The majority of clinical trials evaluating the efficacy of oscillating-rotating brushes compared to a manual control toothbrush utilize one examiner administering the plaque assessment. This trial was conducted to determine whether multiple examiners can demonstrate consistent plaque removal advantages for an oscillating-rotating power toothbrush versus a manual toothbrush utilizing the Turesky-Modified Quigley-Hein Plaque Index (TMQHPI) (10, 11).

**Methods/Study population**

This was a single-use, examiner-blind, randomized, two-treatment, four-period crossover, multiple-examiner clinical trial (Fig. 1). The study was approved by an Institutional Ethics Board (Universitätsklinikum Jena – Ethik Kommission, #2578-06/09) and conducted at University of Jena, Germany, between August 2009 and January 2010. At the screening visit, subjects were asked to read and sign a written informed consent and personal medical history and demographics information was obtained.

To qualify for the study, subjects had to be between 18 and 70 years of age, in good general health and possess a minimum of 16 natural teeth with facial and lingual scorable surfaces. Subjects were not allowed to participate in any other oral care study for the duration of this study and they had to agree to delay any elective dentistry, including a prophylaxis, until study completion.

Subjects also consented to refrain from brushing their teeth and performing any other oral hygiene procedures for 24 h prior to each visit and refrain from eating, drinking and smoking for 4 h prior to each visit, except for small sips of water. Subjects were excluded from the study if there was evidence of existing poor oral hygiene (e.g., severe periodontal disease, active treatment for periodontal disease, five or more carious lesions requiring restorative treatment) or if they had active orthodontic therapy or a removable prosthesis. Subjects were also excluded if there was evidence of any disease or condition that may interfere with study procedures.

The study test products (Fig. 2) included:

1. Oscillating-rotating toothbrush [Oral-B Vitality (D12; The Procter & Gamble Company, Cincinnati, OH, USA) with timer and Oral-B Precision Clean brush head (EB17; The Procter & Gamble Company)].

![Fig. 1. Study design.](image-url)
Subjects used the oscillating–rotating toothbrush for 2 min per brushing, per manufacturer’s instructions. Subjects brushed with the manual toothbrush in their customary manner for a timed 1-min brushing, which was based on habits and practices data showing the average brushing time for an adult manual toothbrush user is 46 s (12). At the beginning of each period (1–4) visit, continuance criteria were assessed for each eligible subject and an oral soft tissue examination was completed. Subjects were then asked to swish their mouth with red disclosing solution and each examiner independently conducted a pre-brushing plaque examination (TMQHPI) (10, 11). At the Period 1 visit, subjects were randomized to one of the following four treatment sequences determined by a computer-generated plan prepared before the study: ABBA, BAAB, AABB or BBAA with approximately 24 subjects in each treatment sequence. Subjects were then instructed to brush with their assigned toothbrush and marketed toothpaste under supervision unaided by a mirror. Brushing was conducted in a protected area that ensured blinding of the examiners to the identity of the test products. After brushing their teeth, subjects swished with disclosing solution again and received a post-brushing plaque examination by all plaque examiners independently. The examiners had been previously trained on the method, but no calibration was performed among the group. These same procedures were followed for all four (4) periods. At Period 4, subject accountability was documented.

Statistical analyses

Sample size was determined based on previous plaque removal data from a similarly designed crossover study. Using an estimate of variability from this study (mean squared error = 0.057), 100 subjects in a 2-treatment, 4-period crossover study should give two-tailed alpha = 0.05 with 80% power to detect a true difference in Turesky plaque removal scores (from baseline) of about 0.068 between the two treatment brushes. Statistical analysis for plaque removal efficacy was performed separately for each examiner (EX1, EX2a, EX2b and EX3). During the course of the study, Ex2a left the university for personal reasons and Examiner 2b continued the study, so a separate analysis was conducted for EX2a and EX2b. The plaque scores were averaged on a per-subject basis, so that each subject had a single whole-mouth average score at baseline and another whole-mouth average score following brushing. The difference (baseline minus post-brushing) in average scores was calculated for each subject in each treatment period. The difference scores were analysed for treatment group differences using a mixed model analysis of covariance for a crossover design with factors in the model for subjects (random), period, treatment, carryover and baseline whole-mouth average score as the covariate. If carryover was not significant at the 10% level, then it was deleted from the final statistical model. The carryover effect was not significant for two of the examiners and was removed, while for the other two examiners carryover was significant at the 10% level and was retained in the final model. Because of the switch in examiner 2 (2a and 2b), a subset analysis (n = 32) was also carried out for the evaluable subjects who were examined by EX2b, to compare the magnitude of the plaque removal of the two brushes under EX1 and EX3’s grading to EX2b’s plaque evaluation.

In addition, a supplemental analysis was conducted to look at intraclass correlation (ICC) measures for plaque using the 32 subjects who had all three examiners’ evaluations (EX1, 2b and 3). This set of examiners provided the most complete subset of subjects that had both treatments evaluated. The ICC measures the degree of consistency or reliability among the three examiners on the subjects’ average pre-brushing and post-brushing scores. As each subject used each brush twice in this crossover study, the ICC was evaluated on the average of the two scores from each brush at each assessment.

Results

A total of 95 subjects were enrolled in the study and randomized to a treatment sequence, and 87 subjects completed all
The mean baseline TMQHI scores for both brushes ranged from 2.172 to 2.336 and did not differ significantly for the four examiners ($P \geq 0.369$). Both brushes showed a significant ($P < 0.001$) plaque reduction when compared to zero. Treatment differences observed by the four examiners were 0.147 (EX1), 0.150 (EX3), 0.095 (EX2a), 0.159 (EX2b) all in favor of the oscillating–rotating brush ($P < 0.001$) (Table 2).

Results for the subset analysis (for the evaluable subjects examined by EX2b) showed similar results. The mean Baseline TMQHI scores for both brushes ranged from 2.172 to 2.342 and did not differ significantly ($P \geq 0.218$). Both brushes delivered a significant ($P < 0.001$) plaque reduction when compared to zero. Treatment differences observed for plaque reduction were 0.194 for EX1, 0.183 for EX3 and 0.159 for EX2b, all in favor of the oscillating–rotating brush ($P < 0.001$). Both brushes were well tolerated with no AEs observed or reported (Table 3).

### Table 1. Demographic characteristics of all subjects

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Mean</th>
<th>Min–Max</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>30.2</td>
<td>18–67</td>
<td>11.87</td>
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</table>

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Gender</td>
<td></td>
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<tr>
<td>Female</td>
<td>54</td>
</tr>
<tr>
<td>Male</td>
<td>41</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>95</td>
</tr>
</tbody>
</table>

### Table 2. Treatment comparisons of mean TMQHPI reduction by examiner*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Baseline mean</th>
<th>Adjusted mean plaque reduction (SE)</th>
<th>Treatment difference</th>
<th>$P$-value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>EX1 (90 subjects, 356 obs.)</td>
<td></td>
<td></td>
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<tr>
<td>Oscillating–rotating brush</td>
<td>2.336</td>
<td>0.717 (0.0255)</td>
<td>0.147</td>
<td>&lt;0.001</td>
<td>(0.108, 0.185)</td>
</tr>
<tr>
<td>Manual brush</td>
<td>2.306</td>
<td>0.570 (0.0255)</td>
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<td></td>
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<tr>
<td>EX3 (90 subjects, 356 obs.)</td>
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<tr>
<td>Oscillating–rotating brush</td>
<td>2.276</td>
<td>0.749 (0.0234)</td>
<td>0.150</td>
<td>&lt;0.001</td>
<td>(0.113, 0.186)</td>
</tr>
<tr>
<td>Manual brush</td>
<td>2.271</td>
<td>0.600 (0.0234)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EX2a (60 subjects, 226 obs.)</td>
<td></td>
<td></td>
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<tr>
<td>Oscillating–rotating brush</td>
<td>2.333</td>
<td>0.810 (0.0300)</td>
<td>0.095</td>
<td>&lt;0.001</td>
<td>(0.045, 0.145)</td>
</tr>
<tr>
<td>Manual brush</td>
<td>2.318</td>
<td>0.715 (0.0300)</td>
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<tr>
<td>EX2b (32 subjects, 116 obs.)</td>
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<tr>
<td>Oscillating–rotating brush</td>
<td>2.214</td>
<td>0.652 (0.0369)</td>
<td>0.159</td>
<td>&lt;0.001</td>
<td>(0.102, 0.216)</td>
</tr>
<tr>
<td>Manual brush</td>
<td>2.172</td>
<td>0.493 (0.0368)</td>
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</table>

*Based on analysis of covariance for crossover design.

The supplemental ICC analysis showed a high degree of consistency among the three examiners (EX1, 2b and 3). The ICC for the oscillating–rotating brush was 0.938 pre-brushing and 0.943 post-brushing. The ICC for the control brush was 0.956 pre-brushing and 0.953 post-brushing. These results indicate a high degree of consistency or reliability among the three examiners (Table 4).

### Discussion

All four examiners in this plaque removal clinical trial found a significant treatment difference ($P < 0.001$) in favor of the oscillating–rotating brush after a single-use brushing experience. The D12 model evaluated in this trial is an entry-level brush, indicating the examiners had excellent sensitivity to detect differences between the brushes. While both manual and oscillating–rotating brushes were effective at plaque removal, the oscillating–rotating brush was significantly more effective. The treatment differences support the use of the oscillating–rotating technology over a standard manual toothbrush.

While these data are based on replicate-use single brushing exercises rather than a long-term usage study, results determined by all four examiners are consistent with findings reported in the literature, including a systematic review of longer-term studies (e.g. 4 weeks or longer) by the Cochrane Collaboration first published in 2003 and subsequently updated comparing manual and power toothbrush effectiveness (13–15). Beginning in 2003, the Cochrane Collaboration Oral Health group published a systematic review examining more than 30 years of published studies and oscillating–rotating toothbrushes consistently demonstrated a statistically significant benefit over manual toothbrushes (13). Similar findings were reported in a 2005 update after reviewing 42 clinical trials, involving 3855 participants (14). Conclusions from this independent research group were ‘brushes with a rotation–oscillation action removed plaque and reduced gingivitis more effectively than manual brushes in the short-term and reduced gingivitis scores in studies over 3 months’. Once again, a new
systematic review was conducted and published in 2014 by the Cochrane Oral Health group reviewing evidence (56 studies) to assess the effects of using a power toothbrush compared with using a manual toothbrush for maintaining oral health and similar findings were obtained (15). Thirteen trials, involving 979 total participants, utilized the Quigley–Hein (Turesky) index to assess plaque removal of oscillating–rotating and manual toothbrushes in the 2014 review. There was excellent reproducibility across the trials showing superior plaque removal for the oscillating–rotating technology. In addition to the evidence demonstrating the benefits of using an oscillating–rotating powered toothbrush versus a manual toothbrush, studies also show plaque removal advantages relative to other power toothbrush technologies (9, 16).

Brushing time in this trial was set to mimic ‘real-world’ experience, and therefore, the time differed between the power (2 min) and manual toothbrush (1 min). However, the superior plaque removal benefits exhibited by the power brush cannot be attributed to differences in brushing time alone. Previous reports have evaluated oscillating–rotating brushes and standard manual toothbrushes when both brushes were used for a 2-min period. Research was carried out with a generally healthy population as well as an orthodontic population. (17, 18) The power brush removed statistically significantly more plaque ($P < 0.05$) than the manual brush when brushing time was constant across groups at 2 min. A separate 4-week study among periodontal patients using an oscillating–rotating handle also showed the power brush provided significantly greater plaque removal than a manual brush when subjects in both groups reported similar brushing time. (19).

The consequences of inefficient plaque removal are most concerning because of the potential for destructive loss of attachment, which could lead to tooth loss and/or an increase in susceptibility to caries jeopardizing the overall oral health of the patient. Oral health research has also linked systemic health complications as a possible outcome of chronic plaque build-up, gingivitis and periodontitis (20). Evidence from this study and other clinical trials conducted over the past 40 years supports the basis for recommending brushes that use oscillating–rotating technology to improve oral hygiene and reduce the incidence of plaque-related oral diseases.

**Conclusion**

In this replicate-use, single brushing, examiner-blind, randomized, four-period crossover clinical trial, four examiners demonstrated significantly greater plaque removal for an oscillating–rotating power toothbrush than a standard manual toothbrush.

**Clinical Relevance**

**Scientific Rationale for study**

The majority of studies evaluating the efficacy of oscillating–rotating brushes versus a manual control toothbrush utilize one plaque examiner. This trial was conducted to determine the ability of multiple examiners in the same study environment to detect plaque removal differences between an oscillating–rotating power toothbrush and a manual toothbrush.

**Principal Findings**

The oscillating–rotating toothbrush removed significantly more plaque after a single brushing than a regular manual toothbrush, a finding confirmed by four independent examiners.

**Practical Implications**

These results support recommending an oscillating–rotating power toothbrush to patients who use a manual toothbrush, but need improved plaque control.
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Conflict of interest and Sources of funding

Ms. Kurtz, Dr. Reise and Prof. Dr. Sigusch report no conflict of interests. Drs. Klukowska, Grender and Timm are employees of Procter & Gamble. The study was funded by Procter & Gamble.

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