

Relative Plaque Removal of Three Toothbrushes in a Nine-Period Crossover Study

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Background: This study measured the ability of three toothbrushes to remove plaque following three single brushing episodes with each toothbrush.

Methods: This was a randomized, controlled, examiner-blind, nine-period crossover study conducted in 72 adult subjects over a 3-month period that examined plaque removal with a rechargeable power toothbrush and two manual toothbrushes. During the course of this study, subjects brushed three times with each of the toothbrushes. Plaque was scored before and after brushing using the Rustogi Modification of the Navy Plaque Index.

Results: Average baseline plaque scores were between 0.373 and 0.376 for the three treatment groups. The power toothbrush delivered an adjusted (via analysis of covariance) mean difference between baseline and post-brushing plaque scores of 0.270, whereas the manual toothbrushes delivered adjusted mean differences of 0.211 (control ADA manual toothbrush) and 0.190 (experimental manual toothbrush). The power toothbrush demonstrated a statistically significantly greater reduction in plaque than the ADA reference manual toothbrush ($P < 0.001$), which in turn had a statistically significantly greater reduction in plaque than the experimental manual toothbrush ($P < 0.001$). The powered toothbrush group had, on average, 42.4% and 28.2% greater plaque removal scores than the experimental manual toothbrush and ADA reference manual toothbrush groups, respectively. Results for the interproximal and gingival regions also demonstrated statistically significantly ($P < 0.001$) greater plaque removal for the powered toothbrush relative to the control manual toothbrushes.

Conclusion: The powered toothbrush was found to deliver greater plaque removal by 42.4% and 28.2% compared to the control manual toothbrushes. *J Periodontol* 2005;76:2230-2235.

KEY WORDS

Crossover study; manual toothbrushes; plaque removal; power toothbrushes.

The contribution of dental plaque to the etiology of gingivitis is well established.¹ Increased plaque levels resulting from inadequate plaque control, in turn, result in an evolution to a more pathogenic microflora. This transition in microflora composition induces a well-characterized host inflammatory response of the marginal gingiva known as gingivitis, which is characterized by redness, gingival bleeding, edema, and gingival tenderness. In some cases, gingivitis is the precursor to a more destructive disease of the supporting periodontium known as periodontitis.^{2,3}

The primary intervention for the removal of plaque and concomitant prevention of gingivitis for most people is routine oral hygiene as delivered through toothbrushing. Although many toothbrushes (if used properly) can provide effective plaque control, clinical studies have consistently demonstrated that powered toothbrushes deliver superior plaque removal compared to manual toothbrushes.⁴⁻²¹ The results from a recent independent and systematic meta-analysis of 29 clinical studies showed that powered toothbrushes with rotation-oscillation action removed more plaque and reduced gingivitis more effectively than manual toothbrushes, whereas powered toothbrushes without rotation-oscillation action were not consistently found to be superior to manual toothbrushes.²² Collectively, the literature supports the general effectiveness of powered toothbrushes relative to manual toothbrushes for plaque removal and reduction of gingivitis.

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A rechargeable version of a battery-powered toothbrush[‡] that incorporates a dual moving head design with one rotation-oscillation head and one translational head moving back and forth has recently been developed. The two AA batteries have been replaced by a rechargeable battery, resulting in both a thinner brush head and brush handle design. The current study was designed to assess the plaque removal efficacy of this experimental powered toothbrush compared to two manual toothbrushes, the American Dental Association (ADA) reference manual toothbrush and the experimental manual toothbrush,[§] following repeated single brushings.

MATERIALS AND METHODS

This was a randomized, controlled, examiner-blind, nine-period crossover study conducted over a 3-month period that examined plaque removal with a new power toothbrush and two manual toothbrushes. During the course of this study, subjects brushed three times with each toothbrush. The study protocol was approved by an institutional review board for human subjects. Study participation was on a voluntary basis following written informed consent from the subjects. A population of 72 healthy adults with a minimum of 16 gradable teeth, between the ages of 18 and 70 years, was recruited. Prospective subjects were excluded from the study for the following reasons: obvious periodontal disease, orthodontic appliances or removable prosthesis, carious lesions requiring treatment, pregnancy, or inability to comply with the study protocol. Subjects were randomly assigned to one of six treatment sequences (ABC, ACB, BAC, BCA, CAB, and CBA) over the first three study visits, over the second three study visits, and over the final three study visits. Each subject used each of the following brushes three times during the course of the study: the experimental powered toothbrush and the control and experimental manual toothbrushes. Randomization and treatment assignment were performed by a member of the study staff who was not involved in collecting the efficacy data. Subjects were recruited from the general population of employees and patients at the University of Texas Health Science Center at San Antonio with enrollment from April 2004 to June 2004.

Subjects refrained from all oral hygiene procedures and chewing gum for 12 hours prior to their appointment. In addition, the subjects did not eat, drink, or smoke the morning of their appointment. All subjects were appointed between 7:30 am and 12:30 pm to facilitate compliance with the study requirements and were queried regarding compliance with instructions prior to each study visit. As subjects reported to the clinical facility, they were randomly assigned to one of the treatment sequences. Subjects were disclosed

with disclosing solution^{||} as directed by the manufacturer in a dedicated supervised brushing room to maintain blinding. They were then moved to a separate clinical operatory where they were examined by a blinded examiner for baseline overnight plaque using the Rustogi Modified Navy Plaque Index²³ (Fig. 1). Subjects were examined by a single examiner at each appointment. The plaque examination was scored on the buccal and lingual surfaces of all teeth with the exception of the third molars. The maximal number of teeth was 28 with 504 scorable sites, whereas the minimal number of teeth was 16 with 288 scorable sites. Subjects returned to the brushing room where they were instructed to brush their teeth with their assigned toothbrush following their normal regimen for 1 minute in the presence of a supervisor. Subjects were disclosed with disclosing solution and reported to the separate clinical operatory where they were reexamined by the blinded examiner. Following a washout period averaging 7 to 8 days, subjects returned to the clinical facility to evaluate the next toothbrush in their assigned sequence.

For statistical comparison, the plaque scores were averaged on a per-subject basis. Each subject had a single whole-mouth average score for baseline and for the exam following a 1-minute brushing with their assigned toothbrush. The difference (baseline minus post-brushing) in average scores was calculated and analyzed using a mixed model analysis of covariance for a crossover design,²⁴ with the baseline whole-mouth average score as the covariate and terms in the model for subjects, periods, treatments, and residual (carryover) effects. This analysis is referred to as the full-model analysis. If the residual (carryover) effects term was not statistically significant ($P > 0.05$), then a reduced model without residual effects was used for the final analysis. For completeness, in addition to the whole-mouth analysis, gingival margin and interproximal plaque scores were also compared (Fig. 1). All statistical tests of hypotheses were two sided and employed a level of significance of $\alpha = 0.05$.

RESULTS

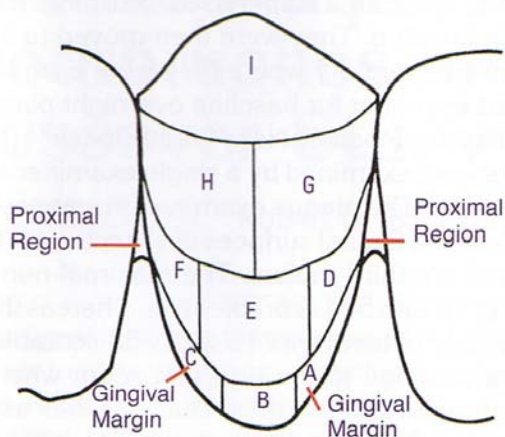
A total of 75 subjects were randomized and enrolled into the nine-period crossover study. During the course of this study, subjects were to brush three times with the experimental powered toothbrush and three times with each manual toothbrush. A total of 72 subjects provided complete data for the nine study periods. Three subjects provided data for either three ($N = 2$) or four ($N = 1$) of the nine study periods: one

[‡] Crest SpinBrush Pro, Procter & Gamble, Cincinnati, OH.

[§] Lion Dentor Systema, Lion, Tokyo, Japan.

^{||} Red-Cote, John O. Butler, Chicago, IL.

Rustogi Modification of the Navy Plaque Index

**Figure 1.**

Rustogi Modification of the Navy Plaque Index. Plaque is assessed for each tooth area (A through I) and is scored using the following scale: 0 = absent and 1 = present. Facial and lingual surfaces of all gradable teeth are scored, and a mean plaque index (MPI) is calculated for each subject at each examination ($MPI = \text{total number of tooth areas with plaque present} / \text{total number of tooth areas scored}$). Subjects' MPI scores were calculated for the whole mouth (areas A through I), interproximal areas (D and F), and along the gingival margin (areas A, B, and C).

subject changed jobs and could not continue, one left town and could not keep appointments, and one withdrew voluntarily to have elective surgery. The data supplied by the 72 subjects represent the primary efficacy analyses. Subjects ranged in age from 23 to 62 years, with a mean age of 43 years. Subjects were predominantly female (52 of 72). No adverse events were reported during the conduct of this study, which is consistent with the previously reported safety profiles of these toothbrushes.

A summary of the whole-mouth plaque data for all surfaces is reported in Table 1. Average baseline plaque scores were from 0.373 to 0.376 for the three treatment groups. In the full-model analysis of all surfaces examined, the residual (carryover) effects were statistically significant ($P = 0.012$). Thus, the residual term was retained, and the full model was used for the final analysis. The experimental power toothbrush delivered an adjusted (via analysis of covariance) mean difference between baseline and post-brushing plaque scores of 0.270, whereas the ADA reference manual and experimental toothbrushes delivered adjusted mean differences of 0.211 and 0.190, respectively. All three toothbrushes demonstrated highly statistically significant reductions in post-brushing plaque scores versus baseline (all $P < 0.001$). The toothbrushes delivered from 51% to 72% reductions in whole-mouth plaque scores. The experimental powered toothbrush group had,

on average, 42.4% and 28.2% greater plaque removal scores compared to the manual toothbrush groups, experimental manual and ADA reference manual toothbrushes, respectively. These results were statistically significant ($P < 0.001$). In addition, the ADA reference manual group had on average 11.1% greater plaque removal scores compared to the experimental manual group. This result was also statistically significant ($P < 0.001$).

For the interproximal region (Table 1), average baseline scores for each group were from 0.190 to 0.195. In the full-model analysis of interproximal surfaces, the residual (carryover) effects were statistically significant ($P = 0.011$). Thus, the residual term was retained and the full model was used for the final analysis. The experimental powered toothbrush delivered an adjusted (via analysis of covariance) mean difference between baseline and post-brushing plaque scores of 0.171, whereas the experimental manual and ADA reference manual toothbrushes delivered adjusted mean differences of 0.100 and 0.126, respectively. All three toothbrushes demonstrated highly statistically significant reductions in post-brushing plaque scores versus baseline (all $P < 0.001$). The toothbrushes delivered from 53% to 88% reductions in interproximal plaque scores. The experimental powered toothbrush group had, on average, 70.7% and 35.4% greater plaque removal scores than manual toothbrush groups, experimental manual and ADA reference manual, respectively. These results were statistically significant ($P < 0.001$). In addition, the ADA reference manual group had 26.1% higher plaque removal scores than the experimental manual group. This result was also statistically significant ($P < 0.001$).

For the gingival region (Table 1), average baseline scores for each group were from 0.933 to 0.943. In the full-model analysis of gingival areas, the residual (carryover) effects were not statistically significant ($P = 0.093$). Thus, the residual term was dropped, and the reduced model was used for the final analysis. The experimental powered toothbrush delivered an adjusted (via analysis of covariance) mean difference between baseline and post-brushing plaque scores of 0.635, whereas the experimental manual and ADA reference manual toothbrushes delivered adjusted mean differences of 0.460 and 0.495, respectively. All three toothbrushes demonstrated highly statistically significant reductions in post-brushing plaque scores versus baseline (all $P < 0.001$). The toothbrushes delivered from 49% to 68% reductions in gingival region plaque scores. The experimental powered toothbrush had, on average, 37.9% and 28.3% greater plaque removal scores compared to the manual toothbrush groups, experimental manual and ADA reference manual, respectively. These results were statistically significant ($P < 0.001$). In addition,

Table 1.

Plaque Results: All Regions, Interproximal Region, and Gingival Margin Region

| Toothbrush Treatment Group | N* | Baseline Score (mean \pm SD) | Baseline Minus Post-Brushing Difference (adjusted mean \pm SE) [†] | % Plaque Removal Versus Baseline [‡] | % Greater Plaque Removal Score [§] |
|----------------------------|-----|--------------------------------|-------------------------------------------------------------------------------|-----------------------------------------------|---------------------------------------------|
| All regions | | | | | |
| Experimental powered | 216 | 0.374 \pm 0.101 | 0.270 \pm 0.005 | 72% | 42.4% |
| ADA reference manual | 216 | 0.376 \pm 0.093 | 0.211 \pm 0.005 | 56% | 11.1% |
| Experimental manual | 216 | 0.373 \pm 0.087 | 0.190 \pm 0.005 | 51% | — |
| Interproximal region | | | | | |
| Experimental powered | 216 | 0.195 \pm 0.170 | 0.171 \pm 0.006 | 88% | 70.7% |
| ADA reference manual | 216 | 0.195 \pm 0.149 | 0.126 \pm 0.006 | 65% | 26.1% |
| Experimental manual | 216 | 0.190 \pm 0.155 | 0.100 \pm 0.006 | 53% | — |
| Gingival margin region | | | | | |
| Experimental powered | 216 | 0.933 \pm 0.193 | 0.635 \pm 0.013 | 68% | 37.9% |
| ADA reference manual | 216 | 0.938 \pm 0.181 | 0.495 \pm 0.013 | 53% | 7.5% |
| Experimental manual | 216 | 0.943 \pm 0.166 | 0.460 \pm 0.013 | 49% | — |

The differences between adjusted means between the groups are statistically significant ($P < 0.001$; experimental powered toothbrush > ADA reference manual > experimental manual).

* The 216 values for each brush head represent triplicate measurements for each of the 72 subjects and were appropriately considered in the analysis of covariance model.

[†] Adjusted means and standard errors from analysis of covariance with baseline score as the covariate. All adjusted mean differences were statistically significantly greater than zero ($P < 0.001$).

[‡] % plaque removal versus baseline = $100\% \times (\text{baseline minus post-brushing difference}/\text{baseline score})$.

[§] % greater plaque removal score = $100\% \times (\text{brush mean} - \text{experimental manual mean})/\text{experimental manual mean}$.

the ADA reference manual group had 7.5% greater plaque removal scores compared to the experimental manual group. This result was also statistically significant ($P < 0.001$).

DISCUSSION

Reports in the literature have consistently demonstrated that powered toothbrushes with rotation-oscillation mechanisms deliver superior plaque removal compared to manual toothbrushes.⁴⁻²¹ The results of a Cochrane Collaboration systematic meta-analysis review of 29 clinical trials involving 2,547 subjects found that brushes with rotation-oscillation action removed statistically significantly more plaque and reduced gingivitis more effectively than manual toothbrushes.²² In contrast, all other types of power toothbrushes were not found to be more effective than manual toothbrushes. Importantly, the benefits of rotation-oscillation toothbrushes appear to be generalizable to the population, because one of the findings from a large practice-based study examining 16,903 patients was that dental professionals reported that 80.5% of their patients had noticeable benefits with respect to plaque removal and gingival condition.²⁵ There are at least a dozen power toothbrushes that are directly based on this clinically proven rotation-oscillation technology in the marketplace today, which demonstrates the robustness of the technology.

In the analyses of whole-mouth and interproximal plaque reduction scores, statistically significant differences in residual or carryover effects between the treatment groups were detected, indicating that the plaque reduction score for a given treatment was influenced by the treatment that came immediately before. Since the average washout period between treatment episodes was 8.6 days (median of 7 days), and the treatment exposure consisted of only a single brushing, it is unlikely that a true physiological carryover effect was operative. Furthermore, the statistical analysis that compared the treatment groups adjusted the estimated treatment group differences for the presence of these carryover effects. In any case, the carryover effects were investigated. For both whole-mouth and interproximal plaque reduction scores, the ADA reference manual toothbrush had a statistically significantly greater ($P \leq 0.037$) carryover effect than the other two toothbrushes, whereas the experimental manual and the experimental powered toothbrush had carryover effects that did not significantly differ ($P \geq 0.409$). The treatments that followed the ADA reference manual toothbrush had higher scores due to the higher carryover effect. To examine the impact of adjusting the estimated treatment differences for the presence of carryover effects, a supplemental statistical analysis was performed that ignored the carryover effects. The same statistically significant pairwise treatment differences reported in Table 1

were also found in this analysis. The differences between the ADA reference manual toothbrush and the other toothbrushes were influenced in a manner consistent with the carryover effect differences. In the supplemental analysis, the percent differences in whole-mouth plaque scores were 42.6%, 30.8%, and 9.0% for the experimental powered toothbrush versus experimental manual toothbrush, experimental powered toothbrush versus ADA reference manual toothbrush, and ADA reference manual toothbrush versus experimental manual toothbrush, respectively. In the original analysis that adjusted for carryover effects, these percentages were 42.4%, 28.2%, and 11.1%, respectively. The experimental powered toothbrush and experimental manual toothbrush had similar carryover effects, and the percent differences from the two analyses are similar (42.6% and 42.4%). These two treatments had their mean scores inflated by the ADA reference manual toothbrush carryover effect in the supplemental analysis, so the advantage for the experimental powered toothbrush over the ADA reference manual toothbrush is larger (30.8% versus 28.2%), and the advantage for the ADA reference manual toothbrush over the experimental manual toothbrush is smaller (9.0% versus 11.1%) than in the original analysis, which adjusted the treatment means for the carryover effect differences. Similar results were found for the analyses of interproximal plaque reduction scores.

In this study, a powered toothbrush was found to deliver superior plaque removal, with 42.4% and 28.2% greater plaque removal scores compared to the experimental manual and ADA reference manual toothbrushes, respectively. This benefit was manifested on both whole-mouth, interproximal, and gingival regions, with statistically significant plaque reductions favoring the experimental powered toothbrush observed for all regions. Previous research has reported that the battery-powered version of this rechargeable toothbrush delivers superior plaque removal scores of 49% and 28% compared to a pair of manual toothbrushes.²⁰ In general, observations of plaque removal efficacy in single-use brushing studies have proven to be relatively consistent with longer-term measures of plaque removal efficacy ranging from 4 to 12 weeks.^{6,7,11-13} The long-term gum health benefits of these brushes were not examined in this study because the repeated single brushing study design is not a reasonable design for addressing gum health endpoints. However, the battery-powered version of the experimental rechargeable powered toothbrush has been shown to reduce gingival inflammation and gingival bleeding scores by 59% when used over a 1-month period.²⁶ In summary, the new experimental rechargeable power group had greater mean plaque removal scores

that were 42.4% and 28.2% greater than those observed in the manual toothbrush groups in this study.

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