Comparative Plaque Removal Efficacy of Two New Powered Toothbrushes and a Manual Toothbrush

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Abstract

- **Objective:** The purpose of this study was to determine the plaque-reducing effectiveness of two new powered toothbrushes and compare them to a manual toothbrush control.
- **Methods:** This examiner-blind, randomized study used a crossover design. Sixty-five qualifying male and female subjects were randomly assigned one of the two test powered brushes (Spinbrush™ Truly Radiant™ Deep Clean [TRDC] or Spinbrush™ Truly Radiant™ Extra Whitening [TREW], Church & Dwight Co., Inc., Princeton, NJ, USA) or an ADA standard manual toothbrush (MT; American Dental Association, Chicago, IL, USA) according to one of three computer-generated sequences. Following instruction in the use of their assigned toothbrush, subjects brushed at home with a standard fluoride toothpaste twice daily for two minutes during a one-week familiarization period. At the end of this period, the subjects returned to the study site after refraining from oral hygiene for 12–16 hours, and from eating, drinking, and smoking for four hours. Plaque was scored using the Rustogi Modification of the Navy Plaque Index. Subjects brushed under supervision with their assigned toothbrush for two minutes, and plaque was rescored. They were then given one of the alternate toothbrushes according to their assigned sequence, and the familiarization routine and evaluation processes were repeated until each of the subjects used each of the three brushes.
- **Results:** Within-group analyses showed that all three toothbrushes produced statistically significant reductions from the pre-brushing baseline in whole mouth and regional plaque scores ($p < 0.001$), with respective whole mouth reductions of 17.9%, 42.3%, and 38.1% for MT, TRDC, and TREW. Between-group analyses showed that TRDC and TREW were each significantly more effective ($p < 0.001$) than MT, as each showed at least twice as much of a reduction in whole mouth scores. Both of the powered brushes also produced statistically significantly greater reductions than the manual brush at each of the twelve subsets of sites examined, with the greatest differences at interpoximal sites and sites presenting access difficulty, such as those in the lingual posterior region. Additionally, TRDC produced a statistically significant 11.5% greater reduction than TREW ($p = 0.001$) in whole mouth plaque scores, and statistically significantly greater reductions in two of the subsets evaluated.
- **Conclusion:** Both of the powered brushes tested proved to be safe and significantly more effective than the standard manual control brush in reducing plaque. While the finding that the TRDC was significantly more effective than the TREW in reducing whole mouth plaque and plaque in two subsets demonstrates that small differences in toothbrush design may impact performance, longer-term studies would be needed to assess the extent to which this translates to meaningful clinical outcomes.

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Introduction

The control of dental plaque accumulation by mechanical means is the most commonly employed method for the maintenance of oral health, with the toothbrush the most frequently used implement for this purpose. Although there is evidence for the existence of toothbrushes dating back to antiquity, the "modern age" of the toothbrush is thought to have begun in 1938, the year that nylon bristles were used to replace boar's hair, with the subsequent introduction of the electric-powered toothbrush in 1960 providing additional choices for consumers.[1] In the intervening years, the introduction of new materials and manufacturing processes have led to numerous design modifications in an attempt to enhance the plaque removal efficiency of the toothbrush, as well as encourage compliance with a daily oral hygiene regimen.[2] These involved a variety of factors, such as handle design, bristle configuration, and bristle materials in the hope that small changes might produce significant improvements in effectiveness. The interest in toothbrush design is evidenced by a review of the U.S. Patent and Trademark Office's website, which indicates that from 1976 through 2013, there have been more than 4,000 toothbrush-related patents issued in the United States.[3]

There have been numerous studies and systematic reviews to determine the plaque removal effectiveness and safety of powered toothbrushes, and to compare them with manual toothbrushes. Short- and long-term studies have shown powered toothbrushes, especially those with counter-rotational and oscillating-rotating actions, to be as safe as, and generally more effective than manual brushes with respect to plaque reduction,[4-8] as well as reduction of periodontal disease-related parameters.[9,10] Specifically, the Spinbrush™, a powered brush that incorporates a rotating-oscillating head, has been shown in its various iterations to be safe and significantly more effective than manual

toothbrushes in reducing plaque.[11-14]

Recognizing that small differences in design can produce measurable differences in brushing effectiveness, the Spinbrush product line has recently been expanded with the development of two variants, Truly Radiant™ Deep Clean and Truly Radiant™ Extra Whitening. Compared to existing versions, both brushes have rotating-oscillating heads, up and down translational motion plates, and elongated bristles for deeper access to interproximal regions. The Deep Clean brush also has more elongated rubber bristles intended to clean all areas of the mouth effectively, and the Extra Whitening brush has whitening bristles that form a "whitening cup" to help keep dentifrice on the tooth surface.

The purpose of this study was to determine the safety and relative plaque-reducing effectiveness of each of these new brushes and compare them to a manual toothbrush control.

Materials and Methods

Study Design

This was a randomized, examiner-blind, crossover design clinical trial to investigate the plaque reduction effectiveness of two newly designed powered toothbrushes, and compare these to that of a standard manual toothbrush with a single use. The study protocol was reviewed and approved by the U.S. Investigational Research Board, Inc., Miami, FL, USA. Informed consent was obtained before subjects were entered into the study.

The two powered brushes tested were the Spinbrush Truly Radiant Deep Clean (TRDC) and Spinbrush Truly Radiant Extra Whitening (TREW), both products of Church & Dwight Co., Inc., Princeton, NJ, USA, while the manual brush was the ADA Standard Manual Toothbrush (MT; American Dental Association, Chicago, IL, USA). Following a screening examination, qualifying subjects were assigned to one of three test product sequences (ABC, BCA, CAB) based on a computer-generated randomization scheme. Prior to each of the three test sessions, there was a one-week acclimation period in which subjects were provided with the type of brush to be tested as determined by the assigned sequence, a standard fluoride toothpaste (Crest® Cavity Protection Regular Toothpaste, Procter & Gamble Co., Cincinnati, OH, USA), a timer, and a diary in which to record the time of each tooth brushing. Subjects were instructed on the proper use of their respective toothbrush and performed their first brushing at the study site under supervision. They were then instructed to brush at home for two minutes twice daily for one week to allow them to become familiar with using the assigned brush. They were also instructed to refrain from using any oral hygiene products other than those provided during this time.

Following each acclimation period, the subjects returned to the study site having refrained from all oral hygiene procedures (including gum chewing) for the previous 12–16 hours, and from eating, drinking, and smoking for four hours. They received an oral soft and hard tissue examination and a baseline plaque scoring (pre-brushing plaque exam). They then went into a separate room, out of view of the dental examiner, where they brushed under supervision with their assigned toothbrush and a standard amount (1.5 g) of fluoride toothpaste for a timed two minutes. After brushing, the subjects returned to the examination room, rinsed once again with the disclosing solution (G.U.M.® Dental Disclosing Solution, Red Cote, Sunstar Americas Inc, Chicago, IL, USA), and plaque was re-scored (post-brushing plaque exam). The acclimation period and test sessions were repeated until each subject used each of the three brushes.

Study Population

Sixty-seven males and females were recruited and enrolled into the study. Subjects were required to be between the ages of 18 and 69 years, in good general health, regularly use either a manual or a powered toothbrush (approximately 50% of each), have at least eighteen natural teeth, have a mean full mouth Modified Navy Plaque Index (MNPI)[7] ≥ 0.60, and be willing to adhere to the study procedures. Subjects were excluded from the study if they had evidence of neglected dental health and need of prompt professional attention, an amount of extrinsic stain and/or calculus deposits that would interfere with a plaque assessment, evidence of major oral hard or soft tissue lesions at baseline, a history of a significant adverse event, allergy, or irritation that was due to oral hygiene products, fixed or removable orthodontic appliances, or a serious medical condition or transmittable disease.

Clinical Assessments

All the clinical assessments were made by a single experienced dental examiner who was blinded to the randomized toothbrush assignments.

Plaque Scoring. Pre- and post-brushing plaque was scored using the Rustogi Modified Navy Plaque Index (RMNPI).[15] Subjects swished with 5 ml of disclosing solution for 10 seconds, expectorated, and then rinsed with 10 ml of water for an additional 10 seconds and expectorated. The RMNPI is scored by dividing each of the facial and lingual tooth surfaces into nine predefined areas, and recording plaque as present or absent in each of these. In addition to providing a whole mouth plaque score, the predefined areas allow for the separate assessment of gingival, interproximal, mid-facial (or lingual), and incisal regions of each tooth surface. The mean plaque index for each subject was calculated by dividing the total number of areas with plaque by the total number of areas scored. Separate mean plaque indices were calculated for the whole tooth, and separately for subsets of sites consisting of gingival and interproximal areas.

Oral Soft and Hard Tissues. The buccal, labial, and sublingual mucosae, lips, attached gingiva, mucogingival regions, tongue, hard and soft palates, oropharynx, and cervical regions of all teeth were examined at screening and at each of the test sessions, with particular emphasis on color, texture, soft tissue abrasion, or ulcerations. Any changes in the course of the study were recorded and an assessment made by the examiner as to whether or not they could be attributable to the toothbrush used.

Statistical Analyses

The primary outcome variable was the mean RMNPI score per subject as determined at pre- and post-brushing. The statistical plan included the calculation of whole mouth scores as well as scores for predetermined subsets, including interproximal, facial, lingual, and gingival sites. Within-group comparisons were performed by comparing pre- and post-brushing mean

scores using paired t-tests. Between-group comparisons were performed using an analysis of covariance (ANCOVA) model suitable for a crossover study design, with the pre-brushing scores included as a covariable. Factors incorporated in the ANCOVA model included subject, treatment, period, sequence group, and baseline plaque score. Post-ANCOVA pairwise treatment comparisons of the adjusted means were performed using t-tests. Tukey's method was utilized to control for multiple comparisons. All statistical tests were two-sided and employed a level of significance of $\alpha = 0.05$.

Results

Sixty-seven subjects were enrolled in the study, of which 65 completed the study and constituted the evaluable subject population. The subjects completing the study included 24 males (mean age, 34.5 years) and 41 females (mean age, 45.0 years). The two subjects not completing the study withdrew because of scheduling conflicts. There were no clinically significant findings or product-related adverse events observed during the course of the study.

Within-group whole mouth plaque reduction results are presented in Table I. All three toothbrushes produced statistically significant whole mouth plaque reductions from baseline ($p < 0.001$), with respective reductions of 17.9%, 42.3%, and 38.1% for the manual brush (MT), Truly Radiant Deep Clean Spinbrush (TRDC), and Truly Radiant Extra Whitening Spinbrush (TREW). With the exception of the manual brush in the lingual interproximal and posterior lingual interproximal regions, all three brushes also produced statistically significant plaque reductions at each of the twelve subsets of sites listed in Table II (within-group data not shown). However, reductions produced by the powered brushes were uniformly considerably larger than those produced by the manual brush, especially in more difficult to access sites. For example, for all interproximal sites the respective percent reductions were 3.1, 18.2, and 16.6 for MT, TRDC, and TREW; for posterior interproximal sites respective percent reductions were 2.8, 16.5, and 14.8; and for posterior lingual gingival sites the respective percent reductions were 7.9, 23.2, and 22.3.

Table I
Comparison of Within-Treatment Pre- and Post-Brushing Mean Whole Mouth RMNPI Scores
(N = 65)

Group	Pre-Brush Plaque Score (SD)[1]	Post-Brush Plaque Score (SD)[1]	% Reduction	p-value[2]
MT	0.666 (0.063)	0.547 (0.068)	17.9%	< 0.001
TRDC	0.664 (0.063)	0.383 (0.069)	42.3%	< 0.001
TREW	0.662 (0.058)	0.410 (0.083)	38.1%	< 0.001

[1] Unadjusted mean RNPI Plaque Index score
[2] p-value derived from paired t-test

Between-group plaque reduction results are presented in Tables II–IV. TRDC and TREW were both significantly more effective ($p < 0.001$) than MT, with 139.2% and 114.6% greater reductions in whole mouth plaque scores, respectively. Both powered brushes also produced statistically significantly greater plaque reductions than the manual brush at each of the twelve subsets of sites examined ($p < 0.001$). These findings were consistent with the within-group reductions, and reflected the ability of the powered brushes to more effectively reach all areas of the dentition. In addition, compared to TREW, TRDC produced a statistically significantly greater reduction of 11.5% in whole mouth plaque score ($p = 0.001$) as well as statistically significantly greater reductions in the gingival and facial subsets.

Discussion

This study showed that each of the two powered toothbrushes, TRDC and TREW, was significantly more effective than the manual brush in whole mouth plaque reduction, as well as reductions at specific sites. These findings are consistent with those of studies on previous Spinbrush models,[12-14] and indicate that the powered brushes may be particularly effective in reaching hard to access areas and therefore offer clear advantages for individ-

Table II
Comparison of Between-Treatment RMNPI Reductions: TRDC versus MT[1]

Sites	MT	TRDC	Difference[2]	95% CI	p-value[3]	% & Ratio Difference[4]
Whole Mouth	0.117	0.281	-0.163	(-0.182,- 0.144)	< 0.001	139.2%; 2.39X
Interproximal	0.031	0.183	-0.152	(-0.184,-0.121)	< 0.001	497.9%; 5.98X
Gingival	0.189	0.489	-0.300	(-0.339,- 0.261)	< 0.001	159.1%; 2.59X
Facial	0.151	0.363	-0.212	(-0.242,-0.182)	< 0.001	140.3%; 2.40X
Lingual	0.083	0.198	-0.115	(-0.138,-0.092)	< 0.001	138.7%; 2.39X
Lingual Interproximal	0.007	0.078	-0.070	(-0.100, -0.041)	< 0.001	960.8%; 10.61X
Lingual Gingival	0.127	0.349	-0.222	(-0.267, -0.177)	< 0.001	174.5%; 2.75X
Posterior Interproximal	0.027	0.165	-0.138	(-0.172,-0.103)	< 0.001	502.5%; 6.02X
Posterior Facial Interproximal	0.050	0.275	-0.225	(-0.288,-0.162)	< 0.001	451.7%; 5.52X
Posterior Lingual Interproximal	0.004	0.056	-0.052	(-0.083,-0.021)	< 0.001	1301.6%; 14.02X
Posterior Gingival	0.140	0.385	-0.245	(-0.284,-0.206)	< 0.001	174.5%; 2.75X
Posterior Facial Gingival	0.205	0.542	-0.337	(-0.396, -0.278)	< 0.001	164.8%; 2.65X
Posterior Lingual Gingival	0.077	0.229	-0.151	(-0.199, -0.104)	< 0.001	195.4%; 2.95X

[1] Calculations based on baseline-adjusted ANCOVA
[2] Calculated as MT reduction minus TRDC reduction (A positive number means MT had a greater reduction than TRDC, while a negative number means that TRDC had a greater reduction than MT.
[3] p-value from Tukey-adjusted post-ANCOVA t-test
[4] Calculated as [(TRDC reduction – MT reduction)/MT reduction]

Table III
Comparison of Between-Treatment RMNPI Reductions: TREW versus MT[1]

Sites	MT	TREW	Difference[2]	95% CI	p-value[3]	% Difference[4]
Whole Mouth	0.117	0.252	-0.134	(-0.154, -0.115)	< 0.001	114.6%
Interproximal	0.031	0.163	-0.132	(-0.164, -0.100)	< 0.001	431.2%
Gingival	0.189	0.434	-0.245	(-0.283, -0.207)	< 0.001	130.0%
Facial	0.151	0.318	-0.167	(-0.197, -0.137)	< 0.001	110.4%
Lingual	0.083	0.186	-0.103	(-0.125, -0.080)	< 0.001	123.4%
Lingual Interproximal	0.007	0.070	-0.063	(-0.093, -0.033)	< 0.001	861.2%
Lingual Gingival	0.127	0.316	-0.189	(-0.233, -0.145)	< 0.001	148.4%
Posterior Interproximal	0.027	0.146	-0.118	(-0.153, -0.084)	< 0.001	432.3%
Posterior Facial Interproximal	0.050	0.231	-0.182	(-0.244, -0.119)	< 0.001	364.4%
Posterior Lingual Interproximal	0.004	0.060	-0.056	(-0.087, -0.025)	< 0.001	1398.2%
Posterior Gingival	0.140	0.353	-0.212	(-0.251, -0.173)	< 0.001	151.1%
Posterior Facial Gingival	0.205	0.484	-0.280	(-0.339, -0.220)	< 0.001	136.7%
Posterior Lingual Gingival	0.077	0.220	-0.143	(-0.190, -0.096)	< 0.001	184.5%

[1] Calculations based on baseline-adjusted ANCOVA
[2] Calculated as MT reduction minus TREW reduction (A positive number means MT had a greater reduction than TREW, while a negative number means that TREW had a greater reduction than MT.
[3] p-value from Tukey-adjusted post-ANCOVA t-test
[4] Calculated as [(TREW reduction – MT reduction)/MT reduction]

Table IV
Comparison of Between-treatment RMNPI Reductions: TRDC versus TREW[1]

Sites	TRDC	TREW	Difference[2]	95% CI	p-value[3]	% Difference[4]
Whole Mouth	0.281	0.252	0.029	(0.010, 0.048)	0.001	11.5%
Interproximal	0.183	0.163	0.020	(-0.011, 0.052)	0.282	12.6%
Gingival	0.489	0.434	0.055	(0.017, 0.093)	0.003	12.7%
Facial	0.363	0.318	0.045	(0.015, 0.075)	0.002	14.2%
Lingual	0.198	0.186	0.013	(-0.010, 0.035)	0.392	6.8%
Lingual Interproximal	0.078	0.070	0.007	(-0.023, 0.037)	0.832	10.4%
Lingual Gingival	0.349	0.316	0.033	(-0.011, 0.078)	0.185	10.5%
Posterior Interproximal	0.165	0.146	0.019	(-0.015, 0.054)	0.387	13.2%
Posterior Facial Interproximal	0.275	0.231	0.043	(-0.019, 0.106)	0.230	18.8%
Posterior Lingual Interproximal	0.056	0.060	-0.004	(-0.035, 0.027)	0.954	-6.5%
Posterior Gingival	0.385	0.353	0.033	(-0.006, 0.072)	0.115	9.3%
Posterior Facial Gingival	0.542	0.484	0.058	(-0.001, 0.117)	0.057	11.9%
Posterior Lingual Gingival	0.229	0.220	0.009	(-0.038, 0.055)	0.903	3.9%

[1] Calculations based on baseline-adjusted ANCOVA
[2] Calculated as TRDC reduction minus TREW reduction (A positive number means TRDC had a greater reduction than TREW, while a negative number means that TREW had a greater reduction than TRDC.
[3] p-value from Tukey-adjusted post-ANCOVA t-test
[4] Calculated as [(TRDC reduction – TREW reduction)/TREW reduction]

uals having difficulty maintaining an adequate level of oral hygiene. The percent reductions seen in the between-treatment comparisons of the powered and manual brushes, while seemingly quite large in the case of some sites, reflect the within-group findings and result from the relatively small reductions produced by the manual brush at the more inaccessible locations.

This study also showed the TRDC brush to produce statistically significantly higher plaque reductions than the TREW for whole mouth scores and two of the subsets. However, given the relatively small absolute differences between the reductions at these sites, a longer-term study would be needed to determine whether the differences are large enough to translate to meaningful clinical outcomes.

In summary, in this single-use study, both of the powered brushes tested proved to be safe and significantly more effective than the standard manual control brush in reducing plaque. Each of the powered brushes had unique new design features meant to enhance performance. The finding that the TRDC was significantly more effective than the TREW in reducing whole mouth plaque and plaque in two subsets demonstrates that small differences in toothbrush design may demonstrably impact performance.

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