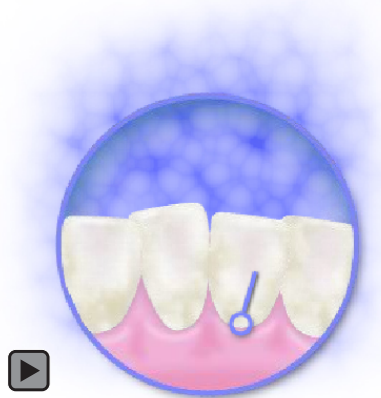# Improved Plaque Removal Efficacy with a New Manual Toothbrush

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Abstract

Aim: To compare the safety and efficacy of two manual toothbrushes, Oral-B Exceed and Asian Colgate 360°, in removing plaque.

Methods and Materials: The study used an examiner-blind, two-treatment, randomized, four-period (visits) crossover design. At the first visit, subjects received a baseline plaque examination; plaque was scored using the Rustogi et al. Modified Navy Plaque Index (RMNPI) and the Turesky et al. Modified Quigley-Hein Plaque Index (TQHPI). Subjects used their assigned toothbrush for one minute. Post-brushing plaque was assessed. The following three visits were separated by an interval of two to six days. At each visit, subjects were assigned brushes according to their treatment sequence and plaque was scored per the first visit.

Results: Forty-eight subjects were enrolled in the study; 47 were included in the analysis. Both brushes were found to be safe and both significantly reduced plaque after a single brushing. The Oral-B Exceed was significantly ($p<0.001$) better than the Asian Colgate 360° at removing whole mouth plaque (18.1% using TQHPI; 9% using RMNPI). The Oral-B Exceed was also significantly better at removing marginal ($p=0.001$) and approximal ($p=0.022$) plaque.

Conclusion: The Oral-B Exceed brush removed significantly more whole mouth, approximal, and gingival margin plaque than the Asian Colgate 360° in a four-period crossover clinical comparison.

Keywords: Dental plaque, clinical trial, manual toothbrush, oral hygiene

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Introduction

Good oral hygiene is essential for preventing dental caries and gingivitis, the most common periodontal disease, and it is well acknowledged effective daily removal of plaque biofilm plays a central role in maintaining oral health.[1-7] Of all the oral hygiene methods available, toothbrushing is the most commonly used. Some people use no other means of plaque removal.
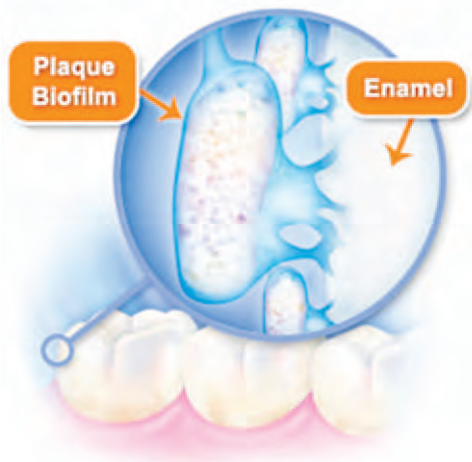
Numerous short- and long-term comparative studies have explored the relative benefits of manual versus powered toothbrushes for the effective mechanical removal of plaque. Despite evidence that certain powered models, namely those with rotation-oscillation action, are consistently more effective than manual brushes in reducing plaque and gingivitis,[8-9] the manual toothbrush is likely to remain in common use. Manual toothbrush manufacturers continue to address the need for improved cleaning efficiency by developing new models with design modifications aimed at achieving improved plaque removal, regardless of the variations and inconsistencies in brushing technique seen in manual toothbrush users in the general population.[10,11]

Clinical studies are crucial for establishing the relative merits of various models as they become available. Typically, both single-use and long-term studies are conducted to examine the proposed superiority of a new toothbrush, as seen for example with the introduction of the manual Oral-B® CrossAction® (Procter & Gamble, Cincinnati, OH, USA) design.[12-15] Ideally, clinical data should be periodically reviewed to determine whether the advantages continue to be robust when further comparisons are made with both existing models and new designs as they appear on the market.[16]

A new Oral-B manual toothbrush, Exceed, incorporates modifications to an existing toothbrush design. These include a crisscross bristle pattern with angulated bristle tufts and a power tip. Another recent approach to manual toothbrush design is the Asian Colgate® 360°® (Colgate-Palmolive, New York, NY, USA). Features include multifunctional bristles, polishing cups, and a tongue cleaner.

The present study compared plaque removal following a single brushing with these two commercially available manual brushes in order to establish their relative advantages and used a four-period repeated single use crossover design to control for residual (carryover) effects. Two indices commonly used for assessing plaque removal are the Rustogi et al. Modified Navy Plaque Index (RMNPI)[17] and the Turesky et al. Modified Quigley-Hein Plaque Index (TQHPI).[18,19] Although these indices score plaque in different ways, there are strong positive correlations between them.[20] If there is a real clinical advantage for plaque removal with one of the brushes in the present study, then this should be expressed regardless of which index is used.

Methods and Materials

Study Devices

The two manual toothbrushes used in this study were the Oral-B Exceed and the Asian Colgate 360° (Figure 1). The dentifrice used was Crest Cavity Protection Toothpaste (Procter & Gamble, Cincinnati, OH, USA).

Subjects

For inclusion in each study, subjects were required to be in good general health, between 18 and 70 years of age, and have a minimum of 16 scorable teeth (not including third molars, crowns, and surfaces with cervical restorations). In addition, the subjects had to be willing to refrain from all oral hygiene procedures for at least 23-25 hours prior to each study visit and from eating, drinking, chewing gum, and smoking for four
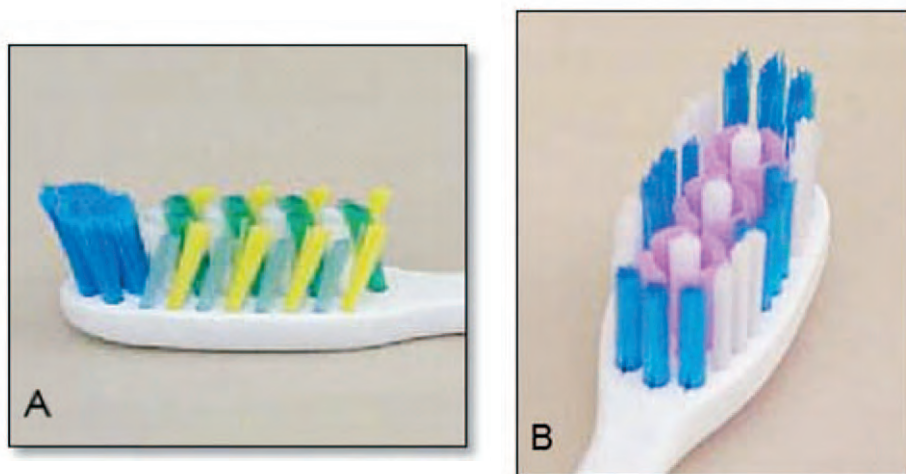
Figure 1. Toothbrushes: (a) Oral-B Exceed (b) Asian Colgate 360°.

hours prior to each study visit. Other reasons for excluding subjects included evidence of neglected dental health and participation in any other clinical study for the duration of this study. All subjects provided written informed consent and completed a health history form prior to study entry.

Study Design
The study evaluated plaque reduction following a single brushing and used an examiner-blind, two-treatment, randomized, four-period (visits), repeated single use crossover design with the following treatment sequences that determined the order in which the two toothbrushes were assigned: ABBA, BAAB, AABB, BBAA. Subjects were assigned in a ratio of 1:1:1:1 to one of the four randomization sequences.

Between the four study visits subjects used their own dental hygiene products at home. At the first study visit, subjects who provided written informed consent and were eligible for the study in terms of the inclusion and exclusion criteria received an oral hard and soft tissue examination. Subjects then swished with red disclosing solution for one minute to disclose any accumulated plaque. They then received a baseline plaque examination.

Plaque was scored first by the primary examiner with the TQHPI (Figure 2).

The primary examiner had previously participated in a calibration study where the examiner differentiated therapeutic rinses from placebo
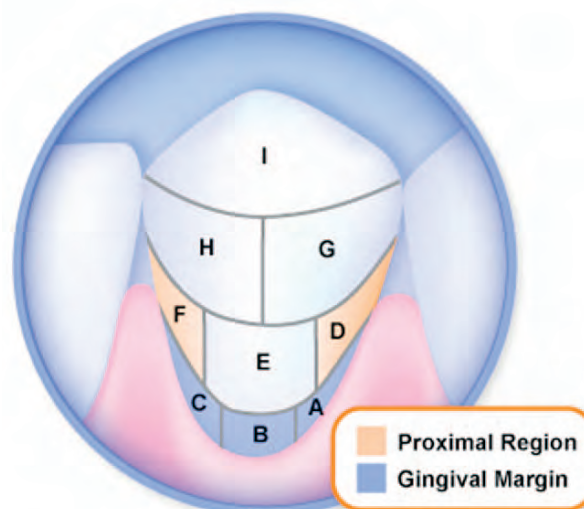

Figure 2. Rustogi et al. Modification of the Navy Plaque Index.[17] Disclosed plaque is scored in each tooth area as present (scored as 1) or absent (scored as 0) and recorded for both buccal and lingual surfaces. Whole mouth = areas A, B, C, D, E, F, G, H and I; Marginal (gumline) = areas A, B and C; Interproximal (approximal) = areas D and F

controls with respect to plaque scores. With the TQHPI, buccal and lingual aspects on all teeth were scored (i.e., for 28 teeth there was a total of 56 sites). Scoring was as follows:

0 = no plaque/debris
1 = separate flecks of plaque at the cervical margin of the tooth
2 = a thin continuous band of plaque (up to 1 mm) at the cervical margin of the tooth
3 = a band of plaque wider than 1 mm but covering less than one third of the crown of the tooth

4 = plaque covering at least one third but less than two thirds of the crown of the tooth

5 = plaque covering two thirds or more of the crown of the tooth

This was followed by a secondary examiner, who was newly trained, using the RMNPI. With the RMNPI, plaque was evaluated on each of the nine areas of the buccal and lingual tooth surfaces (i.e., for 28 teeth there was a total of 504 sites). Plaque was scored as either present (score = 1) or absent (score = 0). Whole mouth, marginal, and approximal areas were defined as shown in Figure 3.

Subjects were then instructed to brush for one minute with their assigned toothbrush and the toothpaste. Brushing was supervised but was unaided by access to a mirror. After brushing, the subjects again swished with red disclosing solution in order to disclose any remaining plaque. A post-brushing plaque examination was then performed by the primary examiner which was followed by a plaque examination by the trainee examiner. Each of the following three visits occurred in turn separated by an interval of two to six days, and subjects were assigned brushes according to their treatment sequence. The same disclosing, brushing, and plaque grading procedures were followed at each visit.

Data Analysis
A sample size of 45 completed subjects was estimated for this study based on plaque removal data from the primary examiner to ensure an 80% (power = $1-\beta$) or greater chance of detecting a group treatment difference of about 0.05 as measured by the TQHPI.

Average whole mouth TQHPI scores obtained for each subject were scored at baseline and following brushing the differences (baseline minus postbrushing) were calculated. Analysis of covariance (ANCOVA) for a crossover design was applied to the differences, with baseline scores as covariates, to assess treatment effects. The RMNPI scores were analyzed using ANCOVA separately for average whole-mouth scores, average gingival margin scores, and average interproximal scores with the appropriate scores as the covariate. For each variable, an initial ANCOVA model with terms for subject, treatment,

Figure 3. Tooth areas graded by the Turesky et al. Modified Quigley Hein Plaque Index.[18,19]

period, and residual (carryover) effects was performed. If the carryover term had p>0.1, then this term was dropped from the model and a final ANCOVA was performed to test for treatment differences. All treatment comparisons were two-sided and used a significance level of $\alpha=0.05$.

Results
A total of 48 subjects were enrolled in the study. One of these subjects missed the second and third visit and was withdrawn from the study prior to visit four. Of the 47 subjects whose data were analyzed, 38 subjects had data for all four visits and nine subjects each missed one visit. No subject withdrew from either study because of adverse effects related to treatment. Table 1 shows the demographic data for the subjects included in the analyses.

The ANCOVA revealed no statistically significant carryover effects (p>0.1), and this term was dropped from the final analysis for treatment group differences. Mean TQHPI and RMNPI scores for pre-brushing and for post-brushing plaque reduction are shown for both groups in Table 2 together with p-values for group differences. The advantage to Oral-B Exceed was significant (p<0.001) for the whole mouth according to TQHPI and for whole mouth (p<0.001), marginal (p=0.001), and approximal (p=0.022) scores according to RMNPI.

For TQHPI, Oral-B Exceed had an adjusted mean reduction in whole mouth plaque scores that was 18.1% greater than the Asian Colgate 360° toothbrush. For RMNPI, the superiority of Oral-B Exceed over Asian Colgate 360° is illustrated in

Table 1. Demographic Characteristics.

Patients (n)	47
Age (years)	
Mean (S.D.)	44.0 (6.6)
Minimum-maximum	27 – 56
Gender (n)	
Males	10
Females	37

Table 2. Pre-brushing and post-brushing plaque reduction.

		Pre-brushing (Mean ± SD)	Post-brushing Plaque Reduction (Adjusted mean ± SE)	Difference in Plaque Removal[a] (p-value)
TQHPI (N = 47)				
Whole mouth	Oral-B Exceed	2.247±0.315	0.632±0.013	0.097 (<0.001)
	Asian Colgate 360°	2.235±0.322	0.535±0.013	
RMNPI (N = 47)				
Whole mouth	Oral-B Exceed	0.439±0.075	0.175±0.003	0.015 (<0.001)
	Asian Colgate 360°	0.440±0.064	0.161±0.003	
Gingival margin	Oral-B Exceed	0.893±0.095	0.309±0.005	0.025 (0.001)
	Asian Colgate 360°	0.896±0.084	0.283±0.005	
Approximal	Oral-B Exceed	0.554±0.175	0.274±0.006	0.019 (0.022)
	Asian Colgate 360°	0.563±0.143	0.255±0.006	

[a] In favor of Oral-B Exceed
SD standard deviation
SE standard error from crossover ANOVA
TQHPI Turesky *et al* Modified Quigley Hein Plaque Index
RMNPI Rustogi *et al* Modification of the Navy Plaque Index
Note: All post-brushing plaque reductions were statistically significantly greater than zero (p<0.001)
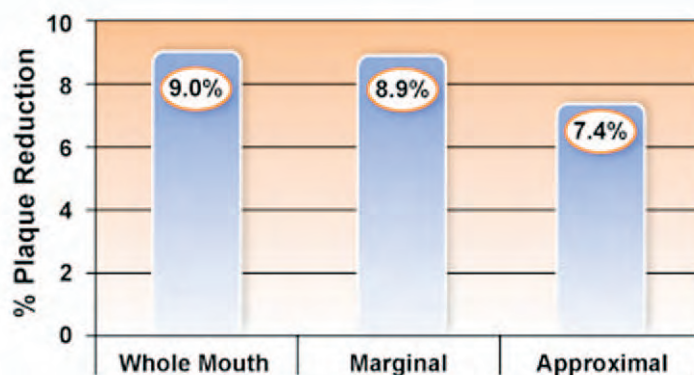
Figure 4. Percent plaque reduction superiority for Oral-B Exceed over Asian Colgate 360° using RMNPI.

Figure 4 for whole mouth (9%), marginal (8.9%), and approximal (7.4%) sites.

Oral safety examinations were normal, and there were no reports of any treatment related adverse effects.

Discussion

Toothbrush manufacturers need to consider many different aspects when designing new models to meet the challenge of enhancing plaque biofilm removal through improved toothbrushing effectiveness. The size and shape of the brush head, filament material and configuration, and brush handle design all have the potential to influence the user and the efficiency of the brush as a whole.[10,11] Research into these design aspects has led to novel ergonomic and technological advances aimed at improving clinical efficacy as well as maximizing user comfort and acceptability to foster user


compliance with recommended brushing time and frequency during normal home use.[21-24]

Comparative clinical studies are crucial for assessing the relative effectiveness of different brushes. Single-use clinical studies are widely used to assess the efficacy of new toothbrushes and in fact plaque removal results obtained in these studies have been shown in several cases to be in agreement with plaque reduction levels and improvements in gingival health over time.[12,14,15,25,26]

In order to ensure valid treatment comparisons would result from this crossover study, a four-period design with sequences AABB, BBAA, ABBA, and BAAB was chosen. This is the optimal four period design for estimating treatment effects and carryover effects.[27] No statistically significant carryover effects existed but even if they had, the treatment comparisons would have been valid.

In the present short-term study with a four-period crossover design both toothbrushes removed plaque from the whole mouth, gingival margins, and approximal surfaces and both brushes were safe (i.e., did not cause any trauma to hard or soft tissue). Oral-B Exceed was found to be significantly more effective than the Asian Colgate 360° at removing whole mouth plaque when measured with either the TQHPI ($p<0.001$) or the RMNPI ($p<0.001$). The Oral-B Exceed was found to be 18.1% more effective than the Asian Colgate 360° at whole mouth plaque removal when assessed using the TQHPI and 9% more effective when assessed using the RMNPI.

The superior plaque removal demonstrated by Exceed is likely related to brush design. The Asian
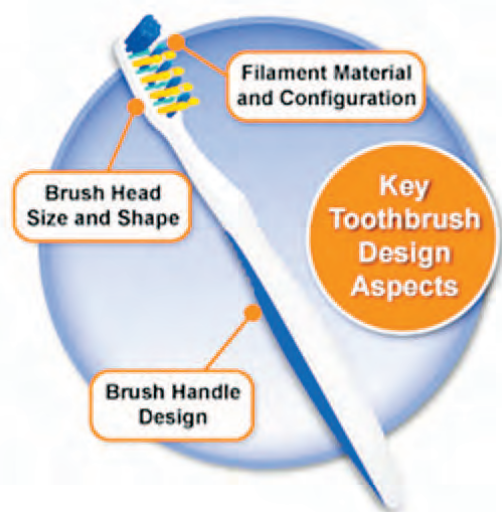
Colgate 360° is an advanced design manual toothbrush which includes the following bristle features: cleaning tips on the heel and toe of the brush for cleaning in hard to reach areas; polishing cups to hold toothpaste against the teeth; and vertical tapered bristles for interdental cleaning. The Oral-B Exceed toothbrush has a criss-cross configuration of the bristles angled in opposite directions to enhance penetration and cleaning between teeth relative to toothbrushes with the vertical bristle configuration.

Strong correlations have been demonstrated between the TQHPI and RMNPI in assessments of toothbrush effectiveness.[20] The demonstration of superiority using both indices in the present study was an indication of the robust nature of this finding. Numerically different levels of superiority were seen with these two indices, but this may have been because the two indices were applied by different examiners. The RMNPI is a valuable index for assessing plaque removal on hard to reach surfaces (e.g., gingival margins and approximal surfaces) where plaque readily accumulates.[21,23] It is important for clinical outcome evaluation that long-term studies be included in assessments of plaque removal in these regions. This same index has also been successfully employed

with the single-use crossover design to reveal a consistent difference (in favor of the CrossAction Vitalizer) in plaque removal efficacy at gingival margins and approximal surfaces across a series of comparisons between different manual toothbrushes.[28] Using this index in the present short-term study, the Oral-B Exceed was found to be significantly more effective than the Asian Colgate 360° at removing both gingival plaque (p=0.001) and approximal plaque (p=0.022). At the gingival margin, the Oral-B Exceed was 8.9% more effective at removing plaque than the Asian Colgate 360° and on approximal surfaces the Oral-B Exceed was 7.4% more effective.

Conclusions

Improving plaque removal is fundamental to preventing dental disease, given the known effect of the bacterial plaque biofilm on caries initiation and periodontal health. This study shows the Oral-B Exceed is a manual toothbrush offering significant plaque removal advantages over the Asian Colgate 360º. The significant advantage for the Oral-B Exceed was shown not only for whole mouth plaque removal but for crucial plaque removal in hard to reach areas at the approximal surfaces and along the gingival margins which can be difficult to access using normal brushing techniques.

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