Comparative Efficacy of a Soft Toothbrush with Tapered-tip Bristles and an ADA Reference Toothbrush on Established Gingivitis and Supragingival Plaque over a 12-Week Period

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Abstract

• **Objective:** Evaluation of the efficacy of a soft toothbrush with tapered-tip bristles (Test Toothbrush) and an ADA reference soft toothbrush (ADA Toothbrush) on established gingivitis and supragingival plaque over a 12-week period.

• **Methods:** This randomized, single-center, examiner-blind, two-cell, parallel clinical research study assessed plaque removal by the comparison of pre- to post-brushing after a single use, and again after six- and 12-weeks’ use, using the Quigley-Hein Plaque Index, Turesky Modification. The study also assessed gingivitis after six weeks and 12 weeks using the Löe & Silness Gingival Index. Adult male and female subjects from the Central New Jersey, USA area refrained from all oral hygiene procedures for 24 hours. They reported to the study site after refraining from eating, drinking, and smoking for four hours. Subjects had the study procedure explained to them both orally and by written instructions. Subjects then gave written consent to participate before entry into the study. Following an examination for plaque (pre-brushing) and gingivitis (baseline), the subjects were randomized into two balanced groups, each group assigned to one of the two study toothbrushes. Subjects were instructed to brush their teeth for one minute under supervision with their assigned toothbrush and a commercially available fluoride toothpaste (Colgate® Cavity Protection Toothpaste), after which they were again evaluated for plaque (post-brushing). Subjects were dismissed from the study site with their assigned toothbrush and toothpaste, and instructed to brush twice daily at home for the next 12 weeks. The subjects were instructed to brush for one minute during each tooth brushing. The subjects reported to the study site after six weeks and 12 weeks of product use, at which time they were evaluated for plaque and gingivitis.

• **Results:** Seventy-one (71) subjects complied with the protocol and completed the clinical study. Compared to the ADA Toothbrush, the Test Toothbrush provided statistically significantly (p < 0.05) greater reductions of 71.1% in whole mouth plaque index scores, 43.8% in plaque severity index scores, and 81.3% in interproximal sites plaque scores after a single tooth brushing. After six weeks’ use, the Test Toothbrush provided statistically significantly (p < 0.05) greater reductions of 700% in whole mouth gingival index scores, 700% in gingivitis severity index scores, and 400% in interproximal sites gingival scores compared to the ADA Toothbrush. Also after six weeks’ use, the Test Toothbrush provided statistically significantly (p < 0.05) greater reductions of 188.9% in whole mouth plaque index scores, 165% in plaque severity index scores, and 203% in interproximal sites plaque scores compared to the ADA Toothbrush. After 12 weeks’ use, the Test Toothbrush provided statistically significantly (p < 0.05) greater reductions of 266.7% in whole mouth gingival index scores, 300% in gingivitis severity index scores, and 250% in interproximal sites gingival scores compared to the ADA Toothbrush. Also after 12 weeks’ use, the Test Toothbrush provided statistically significantly (p < 0.05) greater reductions of 158.1% in whole mouth plaque index scores, 143.5% in plaque severity index scores, and 145.4% in interproximal sites plaque scores compared to the ADA Toothbrush.

• **Conclusion:** This study demonstrated that a soft toothbrush with tapered-tip bristles provided a significantly greater reduction in supragingival plaque after a single tooth brushing, as well as after six and 12 weeks of twice-daily use, compared to the ADA Toothbrush. After six and 12 weeks of twice-daily use, it also provided a significantly greater reduction in gingivitis as compared to the ADA Toothbrush.

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Introduction

One clinical postulate established as early as the mid-1900s remains true today – that one of the keys to controlling periodontal disease is the effective control of plaque. Biofilm bacteria, also known as dental plaque, begin a chain reaction in the gingival tissues that eventually leads to inflammation and possibly periodontitis. Therefore, controlling biofilm bacteria is essential to controlling dental disease. While self-cleaning mechanisms that exist in the oral cavity, such as saliva, can eliminate food debris, the mechanisms cannot adequately control dental plaque. The most widely used tool for controlling plaque is the toothbrush.

The first bristle toothbrush originated in China around 1000 A.D. Throughout the centuries, toothbrush bristles evolved from animal bristles (hogs, boars) to synthetic fiber bristles (nylon) and mostly remained standard as to bristle placement, length, and strength. It was not until the 1980s that a toothbrush was introduced that offered an angled head with longer and multi-size diameter bristles. Since then, many toothbrushes have been marketed claiming unique design features and are intended to be more effective than a basic toothbrush with regard to the removal of plaque and the reduction in gingivitis. The perception of the importance of tooth brushing was confirmed in 2003 when the “toothbrush” was selected as the number one invention by both teens and adults that they could not live without.

The clinical effectiveness of tooth brushing depends on a number of factors. In addition to toothbrush design, brushing methods, brushing time, as well as frequency of brushing also play a role in determining effective tooth brushing. Mechanical removal of plaque by tooth brushing depends on the skills, perseverance, and motivation of the individual. Thus, plaque removal can be highly variable and inconsistent within the general population. Therefore, toothbrush manufacturers aim for design innovations that will help the user compensate for non-ideal tooth brushing techniques and inadequate brushing time.

One change from the standard toothbrush design involves the hardness of the bristles. The hardness or softness of the bristles is influenced by their physical characteristics, including diameter, length, and material. For example, a larger bristle diameter will cause the bristles to be harder and less flexible. Hard bristles allow for minimal flexibility during brushing and have the potential to transmit enough force to the gums to cause damage. Conversely, bristles must be minimally stiff enough to remove plaque.

Up until the late 1900s, the majority of toothbrushes manufactured and purchased were hard-bristle brushes. However, a shift to soft-bristle brushes occurred when the dental community accepted that dental plaque and its prevention, not calculus, was the main etiologic factor in periodontal disease. The change from hard bristles to soft bristles became prevalent to avoid causing trauma to the gingival areas. The advanced toothbrushes, with softer bristles and a variety of bristle designs, in theory, can remove greater amounts of plaque, especially from the gum lines and approximal surfaces. Even though there have been conflicting results on which toothbrush designs are more capable of effective plaque control, as new toothbrush designs come to life it is important to evaluate their safety and efficacy in removing plaque and improving gingival health.

This clinical study evaluated plaque removal and reduction in gingival inflammation of a new manual soft toothbrush with tapered-tip bristles as compared to a manual ADA reference toothbrush. The protocol for this study was reviewed and approved by an independent Institutional Review Board.

Materials and Methods

This independent clinical study employed an examiner-blind, two-treatment, randomized parallel design. The following criteria were used to enroll adult male and female subjects from the Central New Jersey, USA area into the study:

1. Subjects had to be between the ages of 18 and 70, inclusive, in generally good health, possess a minimum of 20 uncrowned permanent natural teeth (excluding third molars), needed to be available for the duration of the study, and needed to sign an informed consent form.

2. At their initial examination, subjects were required to present with a mean score of 1.5 or greater using the Quigley-Hein Plaque Index, Turesky Modification, and a score of at least 1.0 using the Loe and Silness Gingival Index.

3. Presence of any of the following led to the exclusion of subjects from the study: orthodontic appliances, removable prostheses or partial dentures, tumors of the soft or hard tissues of the oral cavity, advanced periodontal disease, or five or more carious lesions requiring restorative treatment.

4. Subjects were excluded if they had received a dental prophylaxis or if they had received antibiotic therapy within one month prior to entering the study. Pregnant or lactating women were also excluded.

5. Subjects were excluded if they had a history of allergies to oral care products, personal care consumer products or their ingredients, or if they had any medical condition that would preclude them from not eating or drinking for four hours prior to their examinations.

Subjects refrained from all oral hygiene procedures for 24 hours prior to reporting to the study site. In addition, subjects were not allowed to eat, drink, or smoke for the four hours prior to their visit. Following an examination for gingivitis (baseline) and supragingival plaque (pre-brushing), qualified subjects were randomized into two balanced groups. Groups were assigned one of the two study toothbrushes:

1. Test Toothbrush (Colgate® Slimsoft™ Toothbrush, Colgate-Palmolive Company, New York, NY, USA; Figures 1 and 2); or

2. ADA reference soft-bristle toothbrush (American Dental Association, Chicago, IL, USA).

Subjects were instructed to brush their teeth for one minute, under supervision, with their assigned toothbrush and a commercially available fluoride toothpaste (Colgate® Cavity Protection Toothpaste, Colgate-Palmolive Company, New York, NY, USA), after which they were again evaluated for plaque (post-brushing). Subjects were dismissed from the study site with their assigned toothbrush and toothpaste, and instructed to brush twice daily at home for the next 12 weeks. The subjects were instructed to brush for one minute during each tooth brushing. The subjects reported to the study site after six weeks and 12 weeks of product use, at which time they were evaluated for plaque and gingivitis. Prior to their six- and 12-week visits, subjects refrained from all oral hygiene procedures for 24 hours, and from eating, drinking, and smoking for four hours.
Clinical Scoring Procedures

Whole mouth gingivitis was scored according to the Löe-Silness Gingival Index. Each tooth was scored in six areas: mesiofacial, midfacial, distofacial, mesiolingual, midlingual and distolingual as follows:

- 0 = Absence of inflammation
- 1 = Mild inflammation: slight change in color and little change in texture
- 2 = Moderate inflammation: moderate glazing, redness, edema, hypertrophy
- 3 = Severe inflammation: marked redness and hypertrophy; tendency to bleed spontaneously

Any teeth with cervical restorations or prosthetic crowns, as well as any third molars were excluded from the scoring procedure. Values from all scoreable tooth surfaces were averaged to determine whole mouth mean scores.

A mean Gingivitis Severity Index score was also calculated for each subject by dividing the total number of whole mouth gingival sites that were scored as a 2 or 3 by the total number of tooth sites scored in the mouth. This index allows the gingival sites that received scores of 2 and 3 to be compared during the study.

A gingivitis interproximal sites score was calculated for each subject by adding the mesiofacial, distofacial, mesiolingual, and distolingual scores of each tooth and dividing the sum by the total number of those sites scored.

Whole mouth dental plaque was scored using the Quigley-Hein Plaque Index as modified by Turesky. Supragingival plaque on the facial and lingual surfaces of each tooth was disclosed using the Mirascored in six areas: mesiofacial, midfacial, distofacial, mesiolingual, midlingual and distolingual as follows:

- 0 = No plaque
- 1 = Isolated flecks of plaque at the gingival margin
- 2 = A continuous band of plaque up to 1 mm at the gingival margin
- 3 = Plaque greater than 1 mm in width and covering up to one third of the tooth surface
- 4 = Plaque covering from one third to two thirds of the tooth surface
- 5 = Plaque covering more than two thirds of the tooth surface

A mean Plaque Severity Index score was also calculated for each subject by dividing the total number of whole mouth plaque sites that received scores of 3, 4, or 5 by the total number of tooth sites scored in the mouth. This index allows the plaque sites that received scores of 3, 4, and 5 to be compared during the study.

A plaque interproximal sites score was calculated for each subject by adding the mesiofacial, distofacial, mesiolingual, and distolingual Quigley-Hein Plaque Index (Turesky Modification) scores of each tooth and dividing the sum by the total number of those sites scored.

Dental Examiner

The same dental examiner performed all dental examinations in the study. The examiner had been trained, calibrated, and was highly experienced in the clinical scoring procedures used in this study.

Oral Soft Tissue Assessment

The dental examiner visually examined the oral cavity and peri-oral area using a dental light and dental mirror at each visit. These examinations included evaluation of the soft and hard palate, gingival mucosa, buccal mucosa, mucogingival fold areas, tongue, sublingual and submandibular areas, salivary glands, and the tonsilar and pharyngeal areas.

Oral Cavity Abrasion from Tooth Brushing

The dental examiner visually examined the oral cavity for abrasion as a result of tooth brushing. The results are reported in a separate publication.

Statistical Methods

Statistical analyses were performed separately for the gingivitis assessments and for the plaque assessments. Comparison of the treatment groups with respect to baseline gingival index scores and pre-brushing plaque index scores were performed using an analysis of variance (ANOVA). Within-treatment comparison of the follow-up examinations to the baseline gingivitis and pre-brushing plaque index scores were performed using paired t-tests. Comparisons of the treatment groups with respect to baseline-adjusted gingival and pre-brushing adjusted plaque scores at the follow-up examinations were performed using analyses of covariance (ANCOVA).

The response used for the between-product plaque and gingivitis analyses were the six-week and 12-week endpoint mean values. The response for the within-product plaque analyses was the difference between pre- and post-brushing, six-week, and 12-week mean values. The response for the within-product gingivitis analyses was the difference between the baseline and six-week and 12-week mean values. All statistical tests of hypotheses were two sided and employed a level of significance of $\alpha = 0.05$.

Results

Seventy-five (75) subjects were assessed for eligibility and randomized into the study (Figure 3). A total of seventy-one (71) subjects complied with the protocol and completed the 12-week clinical study. The gender and age of the subjects who completed...
the study are presented in Table I. Two subjects using the Test Toothbrush experienced a non-serious adverse event. One of the adverse events was noted as unrelated to product usage, while the other adverse event was related to product usage. Both subjects discontinued use of the Test Toothbrush as requested by the clinical study site.

### Table I
<table>
<thead>
<tr>
<th></th>
<th>Number of Subjects</th>
<th>Agea</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
<td>Totalb</td>
<td>Mean</td>
</tr>
<tr>
<td>Test Toothbrush</td>
<td>10</td>
<td>24</td>
<td>34</td>
<td>45.5</td>
</tr>
<tr>
<td>ADA Toothbrush</td>
<td>7</td>
<td>30</td>
<td>37</td>
<td>53.0</td>
</tr>
</tbody>
</table>

*aNo statistically significant (p > 0.05) difference was indicated between the two toothbrush groups with respect to either gender or age.

Pre-Brushing Scores for Plaque and Baseline Scores for Gingivitis

As shown in Tables II and III, the whole mouth plaque, plaque severity, and plaque interproximal scores were 2.87, 0.78, and 3.03, respectively, for subjects in the Test Toothbrush group. The whole mouth plaque, plaque severity, and plaque interproximal scores were 2.86, 0.78, and 3.03, respectively, for the ADA Toothbrush group. The whole mouth gingivitis, gingivitis severity, and gingivitis interproximal scores were 1.38, 0.38, and 1.49, respectively, for subjects in the Test Toothbrush group. The whole mouth gingivitis, gingivitis severity, and gingivitis interproximal scores were 1.38, 0.38, and 1.49, respectively, for the ADA Toothbrush group. There was no statistically significant (p > 0.05) difference between subjects in the Test Toothbrush group and in the ADA Toothbrush group for any of the six plaque and gingivitis measurements.

Removal of Supragingival Plaque after a Single Tooth Brushing (Table II)

The mean whole mouth post-brushing plaque index score observed for subjects in the Test Toothbrush group was 1.33, which represented a 53.7% statistically significant (p < 0.05) reduction in whole mouth plaque index scores relative to the whole mouth pre-brushing plaque index scores. The mean whole mouth post-brushing plaque
index score observed for subjects in the ADA Toothbrush group was 1.96, which represented a 31.5% statistically significant (p < 0.05) reduction in whole mouth plaque index scores relative to the whole mouth pre-brushing plaque index scores. Relative to the whole mouth plaque index scores for subjects in the ADA Toothbrush group, subjects in the Test Toothbrush group exhibited a 71.1% statistically significantly (p < 0.05) greater reduction in whole mouth plaque index scores.

The mean post-brushing plaque severity index score observed for subjects in the Test Toothbrush group was 0.09, which represented an 88.5% statistically significant (p < 0.05) reduction in plaque severity index scores relative to the pre-brushing plaque severity index scores. The mean post-brushing plaque severity index score observed for subjects in the ADA Toothbrush group was 0.30, which represented a 61.5% statistically significant (p < 0.05) reduction in plaque severity index scores relative to the pre-brushing plaque severity index scores. Relative to plaque severity index scores for subjects in the ADA Toothbrush group, subjects in the Test Toothbrush group exhibited a 43.8% statistically significantly (p < 0.05) greater reduction in plaque severity index scores.

Reduction of Gingivitis after Six Weeks (Table III)

The mean six-week whole mouth gingival index score observed for subjects in the Test Toothbrush group was 1.22, which represented an 11.6% statistically significant (p < 0.05) reduction in whole mouth gingival index scores relative to baseline whole mouth

### Table II
Summary of the Pre- and Post-brushing Plaque Index Scores for Subjects Who Completed the Clinical Study

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Toothbrush</th>
<th>n</th>
<th>Mean ± SD</th>
<th>Mean ± SD</th>
<th>Mean ± SD</th>
<th>% Reduction</th>
<th>% Difference</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Pre-brushing Scores</td>
<td></td>
<td>Post-brushing Scores</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole Mouth Plaque</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>2.87 ± 0.21</td>
<td>1.33 ± 0.29</td>
<td>1.54 ± 0.24</td>
<td>53.7%</td>
<td>71.1%</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>ADA Toothbrush</td>
<td>37</td>
<td>2.86 ± 0.21</td>
<td>1.96 ± 0.30</td>
<td>0.90 ± 0.25</td>
<td>31.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plaque Severity</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>0.78 ± 0.17</td>
<td>0.09 ± 0.07</td>
<td>0.69 ± 0.16</td>
<td>85.5%</td>
<td>43.8%</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>ADA Toothbrush</td>
<td>37</td>
<td>0.78 ± 0.14</td>
<td>0.30 ± 0.15</td>
<td>0.48 ± 0.12</td>
<td>65.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plaque Interproximal</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>3.03 ± 0.17</td>
<td>1.58 ± 0.29</td>
<td>1.45 ± 0.27</td>
<td>47.9%</td>
<td>81.3%</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>ADA Toothbrush</td>
<td>37</td>
<td>3.03 ± 0.19</td>
<td>0.80 ± 0.29</td>
<td>0.80 ± 0.26</td>
<td>26.4%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Statistically significant reduction from pre- to post-brushing measurements.

1Reduction between the pre- and post-brushing index scores, expressed as a percentage of the pre-brushing score. A positive value indicates a lower index score at the post-brushing examination than at the pre-brushing examination.

2Difference between pre- to post-brushing reductions in index, expressed as a percentage of the reduction for the ADA Toothbrush. A positive value indicates greater index reduction for the Test Toothbrush.

3Significance of post-ANOVA comparison of mean pre- to post-brushing reductions in plaque.

### Table III
Summary of the Six-Week Gingivitis Index Scores for Subjects Who Completed the Clinical Study

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Toothbrush</th>
<th>n</th>
<th>Mean ± SD</th>
<th>Mean ± SD</th>
<th>Mean ± SD</th>
<th>% Reduction</th>
<th>% Difference</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline Scores</td>
<td></td>
<td>Six-Week Scores</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole Mouth Gingivitis</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>1.38 ± 0.14</td>
<td>1.22 ± 0.12</td>
<td>0.16 ± 0.07</td>
<td>11.6%</td>
<td>700.0%</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>ADA Toothbrush</td>
<td>37</td>
<td>1.38 ± 0.12</td>
<td>1.36 ± 0.14</td>
<td>0.02 ± 0.08</td>
<td>1.4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gingival Severity</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>0.38 ± 0.14</td>
<td>0.22 ± 0.11</td>
<td>0.16 ± 0.08</td>
<td>42.1%</td>
<td>700.0%</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>ADA Toothbrush</td>
<td>37</td>
<td>0.38 ± 0.12</td>
<td>0.36 ± 0.14</td>
<td>0.02 ± 0.07</td>
<td>5.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gingival Interproximal</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>1.49 ± 0.18</td>
<td>1.29 ± 0.15</td>
<td>0.20 ± 0.09</td>
<td>13.4%</td>
<td>400.0%</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>ADA Toothbrush</td>
<td>37</td>
<td>1.49 ± 0.15</td>
<td>1.45 ± 0.18</td>
<td>0.04 ± 0.10</td>
<td>2.7%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Statistically significant reduction from baseline to six-week measurements.

1Reduction between the baseline and 6-week gingivitis scores, expressed as a percentage of the baseline score. A positive value indicates a lower gingivitis score at the 6-week-brushing examination than at the baseline examination.

2Difference between baseline to 6-week score reductions in gingivitis, expressed as a percentage of the reduction for the ADA Toothbrush. A positive value indicates greater gingivitis reduction for the Test Toothbrush.

3Significance of post-ANCOVA comparison of baseline means to adjusted 6-week score means in gingivitis.
gingival index scores. The mean six-week whole mouth gingival index score observed for subjects in the ADA Toothbrush group was 1.36, which represented a 1.4% non-statistically significant (p > 0.05) reduction in whole mouth gingivitis index scores relative to whole mouth baseline gingival index scores. Relative to whole mouth gingival index scores for subjects in the ADA Toothbrush group, the Test Toothbrush group exhibited a 700.0% statistically significantly (p < 0.05) greater reduction in whole mouth gingival index scores.

The mean six-week gingivitis severity index score observed for subjects in the Test Toothbrush group was 0.22, which represented a 42.1% statistically significant (p < 0.05) reduction in gingivitis severity index scores relative to baseline gingivitis severity index scores. The mean six-week gingivitis severity index score observed for subjects in the ADA Toothbrush group was 0.36, which represented a 5.3% non-statistically significant (p > 0.05) reduction in gingivitis severity index scores relative to baseline gingivitis severity index scores. Relative to gingivitis severity index scores for subjects in the ADA Toothbrush group, the Test Toothbrush group exhibited a 700.0% statistically significantly (p < 0.05) greater reduction in gingivitis severity index scores.

The mean six-week interproximal sites gingivitis score observed for subjects in the Test Toothbrush group was 1.29, which represented a 13.4% statistically significant (p < 0.05) reduction in interproximal sites gingivitis scores relative to the interproximal sites baseline gingivitis scores. The mean six-week interproximal sites gingivitis score observed for subjects in the ADA Toothbrush group was 1.45, which represented a 2.7% non-statistically significant (p > 0.05) reduction in interproximal sites gingivitis scores relative to the interproximal sites baseline gingivitis scores. Relative to interproximal sites gingivitis scores for subjects in the ADA Toothbrush group, the Test Toothbrush group exhibited a 400% statistically significantly (p < 0.05) greater reduction in interproximal sites gingivitis scores.

The mean whole mouth six-week plaque index score observed for subjects in the Test Toothbrush group was 0.25, which represented a 67.9% statistically significant (p < 0.05) reduction in plaque severity index scores relative to baseline plaque severity index scores. The mean six-week plaque index score observed for subjects in the ADA Toothbrush group was 0.58, which represented a 25.6% statistically significant (p < 0.05) reduction in plaque severity index scores relative to baseline plaque severity index scores. Relative to six-week plaque index scores for subjects in the ADA Toothbrush group, the Test Toothbrush group exhibited a 165.0% statistically significantly (p < 0.05) greater reduction in plaque severity index scores.

The mean interproximal sites six-week plaque index score observed for subjects in the Test Toothbrush group was 0.25, which represented a 42.7% statistically significant (p < 0.05) reduction in interproximal sites plaque scores relative to baseline interproximal sites plaque scores. The mean interproximal sites six-week plaque index score observed for subjects in the ADA Toothbrush group was 1.16, which represented a 15.9% statistically significant (p < 0.05) reduction in interproximal sites plaque scores. Relative to six-week plaque index scores for subjects in the ADA Toothbrush group, the Test Toothbrush group exhibited a 188.9% statistically significantly (p < 0.05) greater reduction in interproximal sites plaque scores.

**Table IV**

Summary of the Six-Week Plaque Index Scores for Subjects Who Completed the Clinical Study

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Toothbrush</th>
<th>n</th>
<th>Pre-Brushing Scores</th>
<th>Six-Week Scores</th>
<th>Pre-Brushing to Six-Week Score Reduction in Plaque Index Difference Within Toothbrushes</th>
<th>Between-Toothbrush Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Mouth Plaque</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>2.87 ± 0.21</td>
<td>1.83 ± 0.36</td>
<td>1.04 ± 0.31 % Reduction</td>
<td>188.9% p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>ADA Toothbrush</td>
<td>37</td>
<td>2.86 ± 0.21</td>
<td>2.50 ± 0.34</td>
<td>0.36 ± 0.28 % Reduction</td>
<td>12.6%</td>
</tr>
<tr>
<td>Plaque Severity</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>0.78 ± 0.17</td>
<td>0.25 ± 0.15</td>
<td>0.53 ± 0.15 % Reduction</td>
<td>67.9% p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>ADA Toothbrush</td>
<td>37</td>
<td>0.78 ± 0.14</td>
<td>0.58 ± 0.20</td>
<td>0.20 ± 0.18 % Reduction</td>
<td>25.6%</td>
</tr>
<tr>
<td>Plaque Interproximal</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>3.03 ± 0.17</td>
<td>2.04 ± 0.36</td>
<td>1.00 ± 0.33 % Reduction</td>
<td>33.0% p &lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>ADA Toothbrush</td>
<td>37</td>
<td>3.03 ± 0.19</td>
<td>2.70 ± 0.27</td>
<td>0.33 ± 0.27 % Reduction</td>
<td>10.9%</td>
</tr>
</tbody>
</table>

* Statistically significant reduction from pre-brushing to 6-week measurements.

1Reduction between the pre-brushing and 6-week index scores, expressed as a percentage of the pre-brushing score. A positive value indicates a lower index score at the 6-week brushing examination than at the pre-brushing examination.

2Difference between pre-brushing to 6-week index scores, expressed as a percentage of the reduction for the ADA Toothbrush. A positive value indicates greater index reduction for the Test Toothbrush.

3Significance of post-ANCOVA comparison of pre-brushing means to adjusted 6-week score means in plaque.

**Removal of Supragingival Plaque after Six Weeks (Table IV)**

The mean whole mouth six-week plaque index score observed for subjects in the Test Toothbrush group was 1.83, which represented a 36.2% statistically significant (p < 0.05) reduction in whole mouth plaque index scores relative to whole mouth baseline plaque index scores. The mean whole mouth six-week plaque index score observed for subjects in the ADA Toothbrush group was 2.50, which represented a 12.6% statistically significant (p < 0.05) reduction in whole mouth plaque index scores relative to the whole mouth pre-brush plaque scores. Relative to whole mouth plaque index scores for subjects in the ADA Toothbrush group, the Test Toothbrush group exhibited a 188.9% statistically significantly (p < 0.05) greater reduction in whole mouth plaque index scores.

**Reduction of Gingivitis after 12 Weeks (Table V)**

The mean whole mouth 12-week gingival index score observed for subjects in the Test Toothbrush group was 1.16, which represented a 15.9% statistically significant (p < 0.05) reduction in whole mouth gingivitis index scores relative to the mean whole mouth baseline gingivitis index scores.
The mean whole mouth 12-week gingival index score observed for subjects in the ADA Toothbrush group was 1.32, which represented a 4.3% statistically significant (p < 0.05) reduction in whole mouth gingival index scores relative to the mean whole mouth baseline gingival scores. Relative to whole mouth gingival index scores for subjects in the ADA Toothbrush group, the Test Toothbrush group exhibited a 266.7% statistically significantly (p < 0.05) greater reduction in whole mouth gingival index scores.

The mean 12-week gingivitis severity index score observed for subjects in the Test Toothbrush group was 0.18, which represented a 52.6% statistically significant (p < 0.05) reduction in gingivitis severity index scores relative to the mean baseline gingivitis severity index scores. The mean 12-week gingivitis severity index score observed for subjects in the ADA Toothbrush group was 0.33, which represented a 13.2% statistically significant (p < 0.05) reduction in gingivitis severity index scores relative to the mean baseline gingivitis severity index scores. Relative to the gingivitis severity index score for subjects in the ADA Toothbrush group, the Test Toothbrush group exhibited a 300.0% statistically significantly (p < 0.001) greater reduction in gingivitis severity index scores.

The mean 12-week interproximal sites gingivitis index score observed for subjects in the Test Toothbrush group was 1.21, which represented an 18.8% statistically significant (p < 0.05) reduction in interproximal sites scores relative to the mean interproximal sites baseline gingivitis scores. The mean 12-week interproximal sites gingivitis score observed for subjects in the ADA Toothbrush group was 1.41, which represented a 5.4% statistically significant (p < 0.05) reduction in interproximal sites gingivitis scores relative to the mean interproximal sites baseline gingivitis scores. Relative to interproximal sites gingivitis scores for subjects in the ADA Toothbrush group, the Test Toothbrush group exhibited an 250.0% statistically significantly (p < 0.001) greater reduction in interproximal sites gingivitis scores.

### Removal of Supragingival Plaque after 12 Weeks (Table VI)

The mean whole mouth 12-week plaque index score observed for subjects in the Test Toothbrush group was 1.76, which represented a

### Table V

#### Summary of the 12-Week Gingivitis Index Scores for Subjects Who Completed the Clinical Study

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Toothbrush</th>
<th></th>
<th></th>
<th></th>
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<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>12-Week</td>
<td>% Reduction</td>
<td>% Difference</td>
<td>Sig.</td>
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<tr>
<td>Whole Mouth Gingivitis</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADA Toothbrush</td>
<td>37</td>
<td>1.38 ± 0.12</td>
<td>1.32 ± 0.17</td>
<td>0.06 ± 0.11</td>
<td>4.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.59 ± 0.32</td>
<td>2.06 ± 0.35</td>
<td>266.7%</td>
<td></td>
<td>p &lt; 0.001</td>
<td></td>
</tr>
<tr>
<td>Test Toothbrush</td>
<td>34</td>
<td>1.16 ± 0.13</td>
<td>0.18 ± 0.12</td>
<td>0.02 ± 0.09</td>
<td>15.9%</td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.90 ± 0.20</td>
<td>0.06 ± 0.15</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Statistically significant reduction from baseline to 12-week measurements.

Reduction between the baseline and 12-week gingivitis scores, expressed as a percentage of the baseline score. A positive value indicates a lower gingivitis score at the 12-week brushing examination than at the baseline examination.

Difference between baseline to 12-week score reductions in gingivitis, expressed as a percentage of the reduction for the ADA Toothbrush. A positive value indicates greater gingivitis reduction for the Test Toothbrush.

Significance of post-ANOVA comparison of baseline means to adjusted 12-week score means in gingivitis.

### Table VI

#### Summary of the 12-Week Plaque Index Scores for Subjects Who Completed the Clinical Study

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Toothbrush</th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-Brushing</td>
<td>12-Week</td>
<td>% Reduction</td>
<td>% Difference</td>
<td>Sig.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole Mouth Plaque</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADA Toothbrush</td>
<td>37</td>
<td>2.86 ± 0.21</td>
<td>2.43 ± 0.39</td>
<td>0.43 ± 0.35</td>
<td>15.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>38.7%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Toothbrush</td>
<td>34</td>
<td>2.87 ± 0.21</td>
<td>2.76 ± 0.39</td>
<td>1.11 ± 0.33</td>
<td>158.1%</td>
<td>p &lt; 0.001</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>38.7%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Statistically significant reduction from pre-brushing to 12-week measurements.

Reduction between the pre-brushing and 12-week plaque scores, expressed as a percentage of the pre-brushing score. A positive value indicates a lower plaque index score at the 12-week brushing examination than at the pre-brushing examination.

Difference between pre-brushing to 12-week index scores, expressed as a percentage of the reduction for the ADA Toothbrush. A positive value indicates greater index reduction for the Test Toothbrush.

Significance of post-ANOVA comparison of pre-brushing means to adjusted 12-week score means in plaque.
38.7% statistically significant (p < 0.05) reduction in whole mouth plaque index scores relative to the mean whole mouth pre-brush plaque index scores. The mean whole mouth 12-week plaque index score observed for subjects in the ADA Toothbrush group was 2.43, which represented a 15.0% statistically significant (p < 0.05) reduction in whole mouth plaque index scores relative to the mean whole mouth pre-brushing plaque scores. Relative to whole mouth plaque index scores for subjects in the ADA Toothbrush group, the Test Toothbrush group exhibited a 158.1% statistically significantly (p < 0.05) greater reduction in whole mouth plaque index scores.

The mean 12-week plaque severity index score observed for subjects in the Test Toothbrush group was 0.22, which represented a 71.8% statistically significant (p < 0.05) reduction in plaque severity index scores relative to the pre-brushing plaque severity index scores. The mean 12-week plaque severity index score observed for subjects in the ADA Toothbrush group was 0.55, which represented a 29.5% statistically significant (p < 0.05) reduction in plaque severity index scores relative to the pre-brushing plaque severity scores. Relative to 12-week plaque index severity scores for subjects in the ADA Toothbrush group, the Test Toothbrush group exhibited a 143.5% statistically significantly (p < 0.05) greater reduction in plaque severity index scores.

The mean 12-week interproximal sites plaque score observed for subjects in the Test Toothbrush group was 1.95, which represented a 35.6% statistically significant (p < 0.05) reduction in interproximal sites plaque scores relative to the mean interproximal sites pre-brushing plaque scores. The mean 12-week interproximal sites plaque score observed for subjects in the ADA Toothbrush group was 2.59, which represented a 14.5% statistically significant (p < 0.05) reduction in interproximal sites plaque scores relative to the mean interproximal sites pre-brushing plaque scores. Relative to 12-week interproximal sites plaque scores for subjects in the ADA Toothbrush group, the Test Toothbrush group exhibited a 145.4% statistically significantly (p < 0.001) greater reduction in interproximal sites plaque scores.

Discussion

Tooth brushing remains one of the most common procedures to remove plaque, with an estimated 90% of the population of developed countries using a toothbrush once or twice a day.2,3,8 Brushing effectively is essential to prevent the initiation and proliferation of pathogenic biofilm bacteria and gingivitis.9,30 There are a number of laboratory methodologies available to evaluate the cleaning efficacy of new toothbrush designs.10-13 Tapered bristles have been shown in these studies to be more effective in reaching the interproximal areas of teeth along the gingival margin and under the gum line where plaque accumulates when compared to an end-rounded bristle, flat-trimmed toothbrush.1,2,3 It has also been reported that tapered bristles have an advantage for reaching into the fissure as compared to end-rounded bristles.17

In the current investigation, seventy-one (71) subjects complied with the protocol and completed the clinical study. The results showed that the Test Toothbrush (Colgate Slimsoft Toothbrush) provided significant reductions of 53.7% in whole mouth plaque index scores, 88.5% in plaque severity index scores, and 47.9% in interproximal sites plaque scores relative to the pre-brushing plaque index scores after a single brushing. Compared to the ADA Toothbrush, the Test Toothbrush provided significantly greater reductions in whole mouth plaque index scores by 71.1%, in plaque severity index scores (43.8%), and in interproximal sites plaque scores (81.3%) after a single tooth brushing. After six weeks, the Test Toothbrush provided significantly greater reductions in whole mouth gingival index scores (700.0%), in gingivitis severity index scores (700.0%), and in interproximal sites gingivitis scores (400.0%) compared to the ADA Toothbrush. Also after six weeks use, the Test Toothbrush provided significantly greater reductions in whole mouth plaque index scores (188.9%), in plaque severity index scores (165.0%), and in interproximal sites plaque scores (203.0%) as compared to the ADA Toothbrush. After 12 weeks’ use, the Test Toothbrush provided significantly greater reductions in whole mouth gingival index scores (266.7%), in gingivitis severity index scores (300.0%), and in interproximal sites gingival scores (250.0%) as compared to the ADA Toothbrush. Also after 12 weeks, the Test Toothbrush provided significantly greater reductions in whole mouth plaque index scores (158.1%), in plaque severity index scores (143.5%), and in interproximal sites plaque scores (145.4%) as compared to the ADA Toothbrush.

It can be concluded that the new soft toothbrush with tapered-tip bristles provides significantly greater dental plaque removal after a single tooth brushing, and significantly greater reductions in plaque and gingivitis after six and 12-weeks’ use when compared to an ADA reference manual toothbrush.

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Conflict of Interest: John Gallob, Dolores M. Petrone, and Luis R. Mateo declare no conflict of interest and received funds from the Colgate-Palmolive Company to conduct the study and analyze the data. Patricia Chaknis, Boyce M. Morrison, Jr., Malcolm Williams, and Foti Panagakos were employees of the Colgate-Palmolive Company at the time of the clinical study.

References


