Comparative Efficacy of a Soft Toothbrush with Tapered-tip Bristles to an ADA Reference Toothbrush on Gingival Abrasion over a 12-Week Period

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Abstract

• **Objective:** Evaluation of the impact of a soft toothbrush with tapered-tip (Test Toothbrush) bristles and an ADA reference toothbrush (ADA Toothbrush) on gingival abrasion over a 12-week period.

• **Methods:** This was a randomized, single-center, examiner-blind, two-cell, parallel clinical research study and used the Danser Gingival Abrasion Index to assess the level of gingival abrasion after a single brushing, as well as after six weeks and 12 weeks of twice-daily brushing. 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. Following a qualifying examination using plaque and gingivitis scores along with a baseline gingival abrasion examination, subjects were randomized into two balanced groups, each group using 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 gingival abrasion. 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 gingival abrasion.

• **Results:** Seventy-one (71) subjects complied with the protocol and completed the clinical study. The results of this study showed that the Test Toothbrush provided statistically significantly (p < 0.05) greater reductions in gingival abrasion scores as compared to the gingival abrasion scores of the ADA Toothbrush after a single tooth brushing, after six weeks, and after 12 weeks of product use (75.0%, 85.5%, 73.9%, respectively).

• **Conclusion:** The soft toothbrush with tapered-tip bristles produced significantly less gingival abrasion after 12 weeks of product use as compared to the ADA reference toothbrush.

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Introduction

Because the toothbrush has always been central in the maintenance of oral health, dentists worldwide have universally promoted the use of tooth brushing with a dentifrice to maintain healthy mouths. However, it has long been known that tooth brushing may have some undesirable effects on the gingiva and tooth surfaces, one of the most common being gingival abrasion. Gingival abrasion is the wearing of the gingival surface caused by friction with a foreign object, as can occur with improper tooth brushing.

The most common condition is the local recession of the gingival margin. Gingival recession can occur when the gumline lowers its position in relationship to the tooth surface and exposes the roots of the tooth. Different theories have evolved as to the cause of gingival recession, with improper tooth brushing techniques and tools being recognized culprits. It has been reported that gingival recession can occur over time when the brushing is too vigorous and forceful, when the brush bristles are too hard, when the brushing is too frequent or is longer than the recommended two minutes, and when too much brushing emphasis is on the gums. It can occur with manual as well as power brushes, and at any age. When a toothbrush enters the mouth it meets the hardest substance in the human body, the tooth enamel, as well as the very soft gums, tongue, etc. Since the teeth are encircled by the soft gums, it is easy to damage those layers of skin. The most vulnerable area to tooth abrasion damage is at the gumline, where the teeth meet
As the gum line recedes, the dentin, which is normally covered by the gums, becomes exposed. Exposure usually begins at the dentin-enamel junction and expands down the root to the tooth tip. As a result of the dentin being exposed, the nerve endings contained within the dentin also become exposed, resulting in tooth sensitivity to cold, sweet, or touch. Frequently, discomfort occurs during tooth brushing as the bristles move across the side of the tooth.\textsuperscript{13,16}

More seriously, the dentin itself can be literally cut away by the toothbrush if a forceful brushing technique is continuously used. Once a receded gum line has exposed enough dentin, the toothbrush can easily start to cut a hole into the tooth. Left untreated, this hole, known as a notch, will trap food and bacteria and lead to tooth decay. Decay that occurs in the dentin notch will quickly destroy the tooth, resulting in the need for dental treatment, such as a root canal. If the notch is deep, the tooth can weaken sufficiently to cause cracking and loss. Even continued rigorous brushing at the gum line without notching will cause more of the tooth to be exposed. Eventually, the tooth becomes unattached and falls out due to insufficient gum around it to hold it in place.\textsuperscript{17}

As has been reported, gingival abrasion is an ongoing problem affecting as much as 80\% of the population.\textsuperscript{14} The dental profession continues to recommend brushing with soft bristle toothbrushes to lessen the possibility of gingival abrasion. More recently, different bristle designs have evolved, each aiming to be more effective in eliminating gingival abrasion. One relatively new design is a soft tapered-tip bristle which has been tested for gingival abrasion in a limited number of clinical studies.\textsuperscript{16,19} The objective of this clinical study was to compare a new soft toothbrush with tapered-tip bristles (Test Toothbrush) to a soft ADA reference toothbrush (ADA Toothbrush) on gingival abrasion using the Danzer Gingival Abrasion Index\textsuperscript{21} after a single use, as well as after six and 12-weeks’ use. 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. Adult male and female subjects from the Central New Jersey, USA area were enrolled into the study based on the criteria shown in the companion publication.\textsuperscript{22} Subjects reported to the study site after refraining from any oral hygiene procedures for 24 hours, and from eating, drinking, or smoking for four hours. Following an examination in which both the teeth and gums were stained with Mira-2-Tone disclosing solution (Meradent Hager, Germany) for better visualization and assessment of gingival abrasion (baseline), qualified subjects were randomized into two balanced groups. Groups were assigned one of the two study toothbrushes:

1. Colgate\textsuperscript{®} Slimsoft\textsuperscript{™} Toothbrush; Colgate-Palmolive Company, New York, NY, USA (Figures 1 and 2); or
2. ADA reference soft bristled 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\textsuperscript{®} Cavity Protection Toothpaste, Colgate-Palmolive Company, New York, NY, USA), after which they were again evaluated for gingival abrasion. Subjects were dismissed from the study site with their assigned toothbrush and toothpaste, and instructed to brush for one minute, twice daily at home, for the next 12 weeks. The subjects reported to the study site after six weeks and 12 weeks of product use, at which time they were evaluated for gingival abrasion. 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 Procedure**

The scoring methodology was based on the Danzer Gingival Abrasion Index.\textsuperscript{21} In particular, the gingiva was disclosed by Mira-2-Tone disclosing solution for better visualization of the areas where the oral epithelial surfaces had been abraded. The gingival tissues were divided into three areas: marginal (cervical free gingiva); proximal (papillary free gingiva); and mid-gingival (attached gingiva). The number and site location of any gingival abrasion were then recorded (excluding the third molar and central incisor regions).

**Gingival Abrasion Assessment**

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

For the 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 tonsillar and pharyngeal areas.

**Statistical Methods**

Comparison of the treatment groups with respect to baseline gingival abrasion scores was performed using an analysis of variance (ANOVA). Statistical analyses were performed for gingival abrasion assessments by comparing the treatment groups with respect to mean gingival abrasion scores at each follow-up examination using an ANOVA. The response used for the between-treatment group analyses was the mean post-brushing, six-week, and 12-week values. All statistical tests of hypothesis were two-sided, and employed a level of significance of $\alpha = 0.05$. 

![Figure 1. Colgate Slimsoft Toothbrush.](image1)

![Figure 2. Brush head of Colgate Slimsoft Toothbrush.](image2)
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.

Pre-brushing

Table II presents a summary of the gingival abrasion scores measured at the pre-brushing examinations. The mean pre-brushing gingival abrasion score observed was 0.21 for subjects in the Test Toothbrush group and 0.30 for subjects in the ADA Toothbrush group. There was no significant statistical (p > 0.05) difference between the mean gingival abrasion scores of the two groups pre-brushing.

Post-brushing

Table III summarizes the gingival abrasion scores measured at the post-brushing examination (Baseline). The mean post-brushing gingival abrasion score remained at 0.21 for subjects in the Test Toothbrush group and rose to 0.84 for subjects in the ADA Toothbrush group. Relative to subjects in the ADA Toothbrush group, subjects in the Test Toothbrush group exhibited a statistically significantly (p < 0.05) greater reduction of 75.0% in gingival abrasion scores.

Table I

<table>
<thead>
<tr>
<th>Toothbrush</th>
<th>Number of Subjects</th>
<th>Age¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADA Reference Toothbrush</td>
<td>10     24   34   45.5  19-69</td>
<td></td>
</tr>
<tr>
<td>Test Toothbrush</td>
<td>7      30    37   53.0  21-69</td>
<td></td>
</tr>
</tbody>
</table>

¹No statistically significant (p > 0.05) difference was indicated between the two toothbrush groups with respect to either gender or age.

Figure 3. CONSORT 2010 Flow Diagram.

Table II

<table>
<thead>
<tr>
<th>Pre-brushing Examination</th>
<th>ADA Toothbrush</th>
<th>Test Toothbrush</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of Subjects</td>
<td>Number of Subjects</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>Test Toothbrush</td>
<td>10</td>
<td>24</td>
</tr>
<tr>
<td>ADA Reference Toothbrush</td>
<td>7</td>
<td>30</td>
</tr>
</tbody>
</table>
Six Weeks

Table IV presents a summary of the gingival abrasion scores measured at the six-week examination. The mean six-week gingival abrasion score observed was 0.09 for subjects in the Test Toothbrush group and 0.62 for subjects in the ADA Toothbrush group. Relative to subjects in the ADA Toothbrush group, subjects in the Test Toothbrush group exhibited a statistically significantly (p < 0.05) greater reduction of 85.5% in gingival abrasion scores.

12 Weeks

Table V summarizes the gingival abrasion scores measured at the 12-week examination. The mean 12-week gingival abrasion score observed was 0.12 for subjects in the Test Toothbrush group and 0.46 for subjects in the ADA Toothbrush group. Relative to subjects in the ADA Toothbrush group, subjects in the Test Toothbrush group exhibited a statistically significantly (p < 0.05) greater reduction of 73.9% in gingival abrasion scores.

Discussion

Numerous toothbrushes of various designs and specifications are available today for the removal of bacterial plaque and food debris, and with proper use most toothbrushes achieve the goal of providing a clean mouth.23 However, due to the enormous variation in the brushes and brushing techniques, gingival abrasion remains prevalent.

The scientific literature supports, to a certain degree, the theory that the toothbrush or tooth brushing is a contributing factor for gingival abrasion. One clinical study reported a significant relationship between bristle hardness and the degree of gingival abrasion.24 Other studies reported that manual toothbrushes with hard bristles may cause more soft tissue trauma compared to toothbrushes with softer bristles, while others reported that gingival recession is a problem both esthetically and functionally and may be related to traumatic tooth brushing.17,25-27 Variables such as the frequency and force of brushing and also the exact criteria for the observations do not permit definite conclusions to be drawn.

The cleaning performance of a toothbrush can be influenced by bristle hardness. However, toothbrush bristles should not be too hard as to damage the gums. It has been shown that the harder the toothbrush bristles, the greater the gingival abrasion, potentially destroying the protective keratin layer.1 Another study determined that there was a trend toward less abrasion with the use of a tapered filament toothbrush, which achieved statistical significance against the ADA reference toothbrush at two weeks but not

Table II
Summary of the Pre-brushing Gingival Abrasion Scores for Subjects Who Completed the Clinical Study

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Toothbrush</th>
<th>n</th>
<th>Pre-brushing Summary1</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gingival Abrasion</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>0.21 ± 0.64</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>ADA Reference Toothbrush</td>
<td>37</td>
<td>0.30 ± 0.66</td>
<td></td>
</tr>
</tbody>
</table>

1No statistically significant (p > 0.05) difference was indicated between the two toothbrush groups with respect to pre-brushing abrasion scores.

Table III
Summary of the Post-brushing Gingival Abrasion Scores for Subjects Who Completed the Clinical Study

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Toothbrush</th>
<th>n</th>
<th>Post-brushing Scores</th>
<th>Post-brushing Scores in Gingival Abrasion Between-Toothbrush Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mean ± SD</td>
<td>% Difference1</td>
</tr>
<tr>
<td>Gingival Abrasion</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>0.21 ± 0.64</td>
<td>75.0%</td>
</tr>
<tr>
<td></td>
<td>ADA Reference Toothbrush</td>
<td>37</td>
<td>0.84 ± 0.87</td>
<td></td>
</tr>
</tbody>
</table>

1Difference between the mean post-brushing gingival abrasion scores, expressed as a percentage of the post-brushing score for the ADA Toothbrush. A positive value indicates less gingival abrasion for the Test Toothbrush.

2Significance of ANOVA comparison of the mean post-brushing scores in gingival abrasion.

Table IV
Summary of the Six-Week Mean Gingival Abrasion Scores for Subjects Who Completed the Clinical Study

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Toothbrush</th>
<th>n</th>
<th>Six-Week Scores</th>
<th>Six-Week Scores in Gingival Abrasion Between-Toothbrush Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mean ± SD</td>
<td>% Difference1</td>
</tr>
<tr>
<td>Gingival Abrasion</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>0.09 ± 0.29</td>
<td>85.5%</td>
</tr>
<tr>
<td></td>
<td>ADA Reference Toothbrush</td>
<td>37</td>
<td>0.62 ± 0.95</td>
<td></td>
</tr>
</tbody>
</table>

1Difference between the mean 6-week gingival abrasion scores, expressed as a percentage of the six-week score for the ADA Toothbrush. A positive value indicates less gingival abrasion for the Test Toothbrush.

2Significance of ANOVA comparison of the mean six-week scores in gingival abrasion.

Table V
Summary of the 12-Week Mean Gingival Abrasion Scores for Subjects Who Completed the Clinical Study

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Toothbrush</th>
<th>n</th>
<th>12-Week Scores</th>
<th>12-Week Scores in Gingival Abrasion Between-Toothbrush Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mean ± SD</td>
<td>% Difference1</td>
</tr>
<tr>
<td>Gingival Abrasion</td>
<td>Test Toothbrush</td>
<td>34</td>
<td>0.12 ± 0.33</td>
<td>73.9%</td>
</tr>
<tr>
<td></td>
<td>ADA Reference Toothbrush</td>
<td>37</td>
<td>0.46 ± 0.83</td>
<td></td>
</tr>
</tbody>
</table>

1Difference between the mean 12-week gingival abrasion scores, expressed as a percentage of the 12-week score for the ADA Toothbrush. A positive value indicates less gingival abrasion for the Test Toothbrush.

2Significance of ANOVA comparison of the mean 12-week scores in gingival abrasion.
at four weeks. It is interesting to note that in that four-week study, the ADA reference toothbrush was more effective in the reduction of plaque and bleeding as compared to the tapered filament toothbrush. This stands in contrast to the results of a study in which a soft toothbrush with tapered-tip bristles was more effective than the ADA reference toothbrush in the reduction of plaque and gingivitis during a 12-week clinical study.

Several methods are used to define gingival abrasion. Scanning electron microscopy (SEM) is often used to assess gingival abrasion. A clinical study that used both SEM and visual inspection, and where all subjects were brushed by one dental hygienist using hard and soft manual toothbrushes, reported that brushing may result in moderate to severe abrasion of the gingiva, and that both visual and SEM findings were found to correlate significantly. Another study investigated gingival injury caused by standardized brushing. An examiner scored the visible gingival abrasion, and the consistency of the examiner was shown to be 90% compared to SEM analysis. Another clinical study investigated the use of disclosing agents for identification of gingival abrasion. It showed that by staining the lesions with a commercially obtained plaque solution (very similar to Mira-2-Tone used in the present study), the presence of plaque and bleeding as compared to the ADA reference toothbrush in the reduction of plaque and gingivitis was more effective in the reduction of plaque and bleeding as compared to the tapered filament toothbrush. This stands in contrast to the results of a study in which a soft toothbrush with tapered-tip bristles was more effective than the ADA reference toothbrush in the reduction of plaque and gingivitis during a 12-week clinical study.

In the present study, the Danser Gingival Abrasion Index was used in which the gingiva was disclosed by Mira-2-Tone disclosing solution. The gingival tissues were divided into three areas: marginal (cervical free gingiva); proximal (papillary free gingiva); and mid-gingival (attached gingiva). The number and site location of any gingival abrasion were then recorded (excluding the third molar and central incisor regions). This study demonstrated that the Colgate Slimsoft Toothbrush provided a significantly greater reduction in gingival abrasion scores compared to the gingival abrasion scores of the ADA reference toothbrush following one-time supervised tooth brushing, and after six and 12 weeks of twice-daily use. The Colgate Slimsoft Toothbrush reduced gingival abrasion scores by 75%, 85.5% and 73.9% after one-time use, six, and 12 weeks, respectively, as compared to the ADA reference toothbrush. These results confirm previously reported results that brushing with the same test toothbrush over a period of 12 weeks led to a significantly lower amount of gingival damage compared to that observed with a normal flat-trimmed reference toothbrush.

Thus, it can be concluded that brushing with the Colgate Slimsoft Toothbrush, a soft toothbrush with tapered-tip bristles, resulted in significantly less gingival abrasion after up to 12 weeks, as compared to the ADA reference 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., Foti Panagakos, and Malcolm Williams were employees of the Colgate-Palmolive Company at the time of the clinical study.

References
28. Versteer PA, Piscar M, Rosema TAM, Timmerman MF, Van der Velden U,
