Prevention of gingival trauma
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The effects of different levels of brush end-rounding on gingival abrasion: a double-blind randomized clinical trial

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Abstract

Objective
The objective of this study was to evaluate the effect of different levels of filament end-rounding on gingival abrasions (GAs).

Methods
The study was a crossover, split-mouth, contralateral, double-blinded, randomized design using professional brushing. Three manual toothbrushes, with 0%, 40–50% and >90% end-rounded filaments, were investigated. Participants refrained from all oral hygiene procedures for 48 h prior to each of the three visits. Prior to brushing, oral soft tissue (OST) and GAs were assessed. Based on the randomization, during every visit contra-lateral quadrants were brushed with one of the three test brushes. After brushing, GAs were re-assessed. The means of the GAs pre-brushing and post-brushing and differences per brush were calculated. Subanalyses were performed based on the size of the abrasion and its location.

Results
A total of 46 generally healthy participants without periodontitis completed the study and provided a full data set. All brushes had statistically significant increases of abrasions following their use (P < 0.001). Non-end-rounded brushes provided significantly more GAs than did the 40–50% and the >90% brushes (P ≥ 0.001). A subanalysis showed that significantly more small-sized (P ≥ 0.002) abrasions located at the gingival margin (P < 0.001) occurred when a non-end-rounded brush was used. No significant differences were found between the 40–50% and >90% end-rounded brushes in any of the analyses. OST deviations were not observed.

Conclusions
Based on the results of this experiment involving professional brushing, it can be concluded that 40–50% or greater end-rounded filaments can provide a significant reduction in gingival abrasions compared to non-end-rounded filaments.
Introduction

Oral health is an integral part of general health, and a toothbrush is the most common device used for the mechanical removal of dental plaque. When used efficiently, tooth brushing can prevent dental caries and periodontal diseases and improve the oral health of individuals. However, the simple act of cleaning one’s teeth may cause trauma to soft and hard oral tissues.

As early as 1948, it was reported that gingival abrasions (GAs) were related to sharp filament tips. The definition of a GA is a reversible, localized, epithelial lesion. These can be superficial lesions of the keratinized epithelial layer, puncture wounds or mechanical erosion of the epithelium, which may extend into the submucosa and expose the connective tissue. Terms such as soft tissue or gingival abrasion, damage, injury, laceration, lesion, recession and ulceration are used interchangeably. The depth of epithelial lesions caused by tooth brushing is influenced by the quality of the filament end-rounding.

While a direct correlation between gingival abrasion and gingival recession has not been established, Breitenmoser et al. (1979) have demonstrated that the incidence of gingival recession increases by 30% with the use of sharp, non-rounded bristle ends. Studies by Klima and Rossiwall (1976) and Silverstone and Featherstone (1988) also showed that rounded ends are superior, as they produce fewer gingival lesions when compared to non-rounded bristles. End rounding removes the roughness caused by bristle trimming during the manufacturing process. An additional factor implicated in gingival abrasion is bristle stiffness. Soft nylon filaments with rounded ends are less traumatic to the tissue than medium or hard bristles, and they can be directed into the gingival sulcus, minimizing pain, lacerations or gingival or cervical abrasions. The risk of tissue damage is reported to be two times higher with medium–hard than with soft toothbrushes.

The American Dental Association (ADA) recommends that the toothbrush bristle ends be ‘free of sharp or jagged edges and endpoints’ to minimize gingival and dental abrasions. The degree of filament end-rounding found in commercially available manual toothbrushes shows great variation in bristle-end morphology, ranging from rounded to sharp edged. The percentage of acceptable bristle ends varies considerably among different brands, with a range of acceptable filaments observed between 22 and 88%. Although there is evidence of the importance of end-rounded toothbrushes, a large percentage of toothbrushes on the retail market do not meet acceptable quality criteria. As new brushes are developed, it is important to evaluate their safety, which is of concern to both consumers and dental care professionals. The characteristics of
safe and effective toothbrushes are the prime functional properties of the bristles\textsuperscript{23}. Although information on the stiffness of the bristles is generally provided by manufacturers, many products still do not contain information on their bristle end-rounding properties. Each toothbrush may have a different level of filament end-rounding. The effect of various levels of filament end-rounding of manual toothbrushes on GAs has not been investigated before\textsuperscript{24}, although the percentage of filament end-rounding was not measured. The primary objective of this study was therefore to assess the effect of different levels of filament end-rounding on GAs. In addition, the size of the abrasions and their location were evaluated.

**Materials and methods**

This study is reported following the Consolidated Standards of Reporting Trials\textsuperscript{25} and the Template for Intervention Description and Replication (TIDieR) checklist\textsuperscript{26}. CONSORT Group. The CONSORT statement 2010. Available at: http://www.consort-statement.org/ (accessed 15 February 2016).

**Ethical aspects**

The study was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and approximate Good Clinical Practice guidelines. Medical ethics approval was obtained prior to the start of the study (MEC NL40530.018.12). The study was registered with the Dutch Trial Register (NTR 3451). The clinical study was conducted following Good Clinical Practice (GCP) as laid out in the International Conference on Harmonization (ICH). The study took place at the Department of Periodontology of the Academic Centre for Dentistry Amsterdam (ACTA), the Netherlands, in June 2012. Participation in this study was voluntary. Participants were informed about the study in a recruitment letter sent by e-mail. After the participants were selected, the purpose, procedures and duration of the study were explained. Subsequently, participants had time to consider whether they wished to be involved and undergo screening. Participants who were eligible and willing to participate in this study signed an informed consent form. Participants could leave the study at any time for any reason without any consequences. To compensate for the inconvenience of participating in this study, participants received financial compensation only on completion of the entire protocol at the end of the study. During the course of the trial, the clinical site was monitored by an external study monitor provided by the sponsor to ensure compliance with the protocol, regulations and guidelines; adequacy of the equipment and facilities; and satisfactory data collection.
Design
This was a three-treatment, crossover, contra-lateral, split-mouth, double-blind, randomized study with professional brushing. A double randomization (DES) was performed a priori for the three different test products and professional brushing in two contra-lateral quadrants (1st and 3rd quadrants OR 2nd and 4th quadrants). The randomization resulted in 12 sequences (block size = 4 9 12 and allocation ratio = 1:1) (for details see; appendix S1), in which every product was tested at two visits (out of three), once in the 1st and 3rd quadrants and once in the 2nd and 4th quadrants. Participants were randomized to one of the 12 sequences. Randomization was performed using true random numbers, which were generated by sampling and processing a source of entropy outside the computer. The source was atmospheric noise, which was sampled and fed into a computer, avoiding any buffering mechanisms in the operating system (www.random.org). Every participant received a unique identification number. No further stratification was applied. The randomization code was kept in a sealed envelope in the investigator site file and was not accessible to the examiner. The clinical research coordinator (NLHH) was responsible for allocation concealment. The examiner and the participant were blind to the treatment randomization, and the records of earlier examinations were not available at each re-examination. All brushing took place in an area separated from the examination area so that the examiner was not aware of the test products and location used by the hygienist.

Participants
Non-dental students were recruited and screened based on the following eligibility criteria: ≥18 years of age, in good general physical and oral health, minimum of 5 evaluable teeth per quadrant excluding teeth with porcelain crowns, no carious lesions requiring immediate treatment, no orthodontic appliances or removable partial dentures, and no periodontitis or active treatment for periodontal disease (by investigator description, anyone presenting a probing depth ≥ 5 mm with bleeding on probing and attachment loss ≥ 2 mm). Participants were considered systemically healthy through assessment with a medical questionnaire. Use of any antibiotics with in the 2 weeks prior to study initiation, anticipation of taking any antibiotics during the course of the study, and self-reported pregnancy or nursing were prohibited. Participants received SMS (Short Message Service) reminders before screening and 48 h before each appointment to stop all oral hygiene procedures.

Sample size
Sample size calculations, with an alpha of 0.01, a difference of 15.1 in the GA increase, and 80% power, based on a SD of 12.78 as derived from a previous study, supported a sample size of 42 participants. Taking possible dropouts into account because of the
duration and number of visits during the trial, it was decided to increase enrolment by 10% and include 46 participants in the study.

**Investigational products**
The home-use products were distributed in labelled kit boxes for a duration of approximately four weeks by the clinical research coordinator (and dental hygienist) (NLHH) at the screening visit. The kit boxes contained a manual toothbrush and two tubes of Blend-a-med Classic 75 ml dentifrice (NaF containing 1450 ppm F) (http://www.oralblendamed.de/de-de/produkte/blend-a-med-classic-original-zahnpasta). The soft manual toothbrush was an Oral-B® Indicator 40 (>90% end-rounded filaments) (http://www.oralb.com/products/indicator-toothbrush/) and is accepted by the American Dental Association (ADA). The home-use dentifrices were weighed before distribution at the screening and after collection at visit 3. Participants were instructed to use these home-use study products twice daily (morning and evening) in their customary manner for the duration of the study.

The test products used for the professional brushing exercise were Oral-B Indicator 40 Soft manual toothbrushes with 0% end-rounded filaments (prototype), 40–50% end-rounded filaments (prototype) and >90% end-rounded filaments (commercially available). The percentages refer to degrees of end-rounding, which is a gradual process that ranges from blunt cut filaments with no end-rounding (0%) to those that have a perfect, dome-shaped tip (100%). Figure 1 a–c shows scanning electron microscopy (SEM) images of the test products.

**Study Procedures**

**Screening**
At the screening, the eligibility (inclusion/exclusion) criteria were reviewed. A comprehensive oral soft tissue examination (OST) was conducted to evaluate the oral and perioral regions, including hard and soft tissues. Assessment of the oral soft tissue was conducted via a visual examination of the oral cavity and perioral area utilizing a standard dental light, dental mirror and gauze. The structures examined included the gingiva (free and attached), hard and soft palates, oropharynx/uvula, buccal mucosa, tongue, floor of the mouth, labial mucosa, mucobuccal/mucolabial folds, lips and perioral area.
A. 0% end-rounded filaments.

B. 40–50% end-rounded filaments.

C. >90% end-rounded filaments.

FIGURE 1. Scanning electron microscopy (SEM) images (200 lm) derived from and provided by Procter & Gamble (Kronberg, Germany).
Visit 1

Participants visited the clinic after refraining from all oral hygiene procedures for approximately 48 h prior to visit 1. Pre-brushing OST was performed as described previously. The pre-brushing GAs were assessed after the gingiva was stained with Mira-2-Ton disclosing solution (Mira-2-Ton, Hager & Werken GmbH & Co. KG., Duisburg, Germany) for better visualization of the areas where the surface of the oral epithelium had been abraded. The staining procedure was performed as follows: the gingiva was dried with an air blast and stained. Undiluted dye was applied by the examiner (EVDS) with a fully saturated cotton swab starting from the lingual surfaces of the lower jaw, followed by the buccal surfaces of the lower jaw and the palatal and buccal surfaces of the upper jaw (up to 1.5 cm from the gum line). After staining, participants were instructed to rinse their mouths with water (one sip only) and expectorate carefully. Prior to the GA assessment, the gingiva was dried with an air blast. Abrasions were recorded in each buccal and lingual quadrant of the incisor and canine, premolar and molar regions. Marginal (cervical-free gingiva), interdental (papillary-free gingiva) and midgingival (attached gingiva) aspects of the gingiva were assessed for small (Ø ≤ 2.5 mm), medium (Ø > 2.5 mm, but ≤ 5 mm) and large (Ø > 5 mm) GAs (for the standard operational procedure of scoring Gingival abrasions, see: appendix S2). A lesion in the interdental area between two teeth was assigned to the closest tooth area. The midgingival area comprised the gingival tissues up to the muco-gingival junction. In the upper jaw, this area comprised the whole palate. A PQ-William’s periodontal probe (Hu-Friedy Mfg. Co., Inc., Chicago, IL, USA), placed across the long axis of the lesions, was used to measure the size of the abrasions. The greatest diameter of the abrasion lesion determined the size. Loosely attached discolorations were excluded from evaluation. When plaque or abrasions at the gingival margin were difficult to assess, the examiner carefully tried to remove the staining. Staining that could not be removed was assessed as an abrasion. The number and site location of the GAs were recorded on the case record form, with the exclusion of the third molars and central incisors. The rationale for not including the central incisors was to avoid results from overlapping brushing of adjacent quadrants.

A trained dental hygienist (SCS) brushed the 1st and 3rd quadrants with the assigned toothbrush according to the randomization sequence. Brushing was performed using the modified Bass method. No dentifrice was used. A timer was used to assess the duration of a one-minute brushing procedure per toothbrush and a 15-second procedure per buccal/lingual aspect of one quadrant. This process was repeated for the 2nd and 4th quadrants with the alternate toothbrush. Following brushing, OST was re-assessed and the gums and the teeth were restained for post-brushing GAs. Throughout the study, all examinations were performed by the same examiner (EVDS) under the same conditions.
Visits 2 and 3
Participants visited the clinic for visits 2 and 3. To minimize carry-over effects, the minimum time between visits was approximately 7 days. Visits 2 and 3 comprised the same procedures as visit 1 and described previously: pre-brushing measurements, professional brushing exercise and post-brushing measurements.

Data analysis
The statistical analysis was performed by a researcher who was blinded to the randomization (JG). The adjusted mean with standard errors (SE) for the overall abrasions in all regions and incremental differences of all pre- and post-brushing GAs were calculated for brushes with 0%, 40–50% and >90% end-rounded filaments. As a subanalysis, the subsequent adjusted mean and SE regarding the number of lesions of small, medium and large sizes were calculated separately for the different levels of filament end-rounding. Similarly, means were calculated related to the region. The primary analysis was a comparison of the different levels of filament end-rounding pre- and post-brushing and of the change in incidence of GAs (pre-brushing minus post-brushing). An F-test was used for testing the overall brush effect. The ANOVA model for the pre-brushing number of abrasions included brush, period and region as fixed effects. The ANCOVA model for the post-brushing number of abrasions and for the change in the number of abrasions included pre-brushing number of abrasions, brush, period and region as fixed effects, while subject and subject by period were as modelled as random effects. A two-sided P-value from the ANCOVA t-test was used for testing the change in the number of abrasions relative to zero and for brushes based on the adjusted mean change in the number of abrasions. Analyses were performed by ‘intention to treat’, and P-values <0.05 were accepted as significant.

Results
Participants
In total, 56 participants were screened and six participants were excluded. Thus, 50 participants were enrolled in the study, and of those, four dropped out before visit one. In total, 46 participants, 14 males (30%) and 32 females (70%) with a mean age of 22.5 (SD 2.51) years, and a range of 18–31 years, completed the study and were included in the analyses (Figure 2). Based on the pre- and post-brushing OST, no deviations were observed.
Chapter 2

Recruitment

Informed consent procedure and medical questionnaire

Assessment for eligibility N=56

Excluded N=6
• Carious lesions N=5
• Periodontitis N=1

Included N=50

Distribution home-use products and instructions

Drop out N=4
• Illness N=2
• Schedule conflict N=2

Randomization N=46

Visit 1
• Pre-brushing OST & GAs
• Professional brushing according randomization
• Post-brushing OST & GAs

Visit 2
• Pre-brushing OST & GAs
• Professional brushing according randomization
• Post-brushing OST & GAs

Visit 3
• Pre-brushing OST & GAs
• Professional brushing according randomization
• Post-brushing OST & GAs

Collection home-use products

N=46

Analysis

FIGURE 2. Flow chart depicting subject enrolment and measurements.
Data analysis

With regard to overall GAs, the 0% end-rounded brush showed an increase of 10.38, while the 40–50% brush had an adjusted mean increase of 8.56 abrasions and the >90% brush had an increase of 8.80 abrasions. The difference between the pre- and post-brushing adjusted mean scores differed significantly (P < 0.001) for the 0%, 40–50% and >90% end-rounded brushes. The average pre-brushing scores were comparable (P = 0.713) for the three brushes. All brushes showed a significant (P = 0.002) increase in the total numbers of abrasions post-brushing. The 0% brush differed significantly from the 40–50% brush (P = 0.001) and the >90% brush (P = 0.005) regarding abrasion increase (pre- to post-brushing). There was no statistically significant difference between the 40–50% and the >90% brushes (P = 0.671) (Table 1). Subanalyses relevant to the size of the GAs showed a statistically significant increase from pre-brushing for small- and medium-sized abrasions for all brushes. For small-sized abrasions, the 0% brush had a significantly higher increase in abrasions compared to the 40–50% brush (P = 0.002) and the >90% brush (P = 0.008) (Table 2). Table 3 shows small-sized GAs in the marginal, interdental and mid-gingival areas. Analysing the data relative to the regions’ marginal abrasions showed a significant difference between the 0% brush compared to both the 40–50% brush (P=<0.001) and the >90% brush (P=<0.001). All participants who completed the study showed signs of compliance. The average weight of the dentifrice used was 33 (SD 16) grams in the period from the initial screening to visit 3 (n = 46). There was one participant reporting a mild, non-serious adverse event, which was probably related to study procedures/products that mentioned tooth hypersensitivity.

TABLE 1. Mean (SE) of overall sites with gingival abrasions (marginal, interdental, and mid-gingival areas).

<table>
<thead>
<tr>
<th>Brush with % end-rounding N=46</th>
<th>Pre-brushing Adj. Mean (SE)</th>
<th>Post-brushing Adj. Mean (SE)</th>
<th>Difference Adj. Mean (p-value**)</th>
<th>Brush difference (p-value***) 40-50% &gt;90%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>12.31 (0.66)</td>
<td>22.44 (0.50)</td>
<td>10.38 (&lt;0.001)</td>
<td>1.82 (0.001) 1.59 (0.005)</td>
</tr>
<tr>
<td>40-50%</td>
<td>11.87 (0.66)</td>
<td>20.62 (0.50)</td>
<td>8.56 (&lt;0.001)</td>
<td>-0.24 (0.671)</td>
</tr>
<tr>
<td>&gt;90%</td>
<td>12.01 (0.66)</td>
<td>20.86 (0.50)</td>
<td>8.80 (&lt;0.001)</td>
<td></td>
</tr>
<tr>
<td>Overall test p-value*</td>
<td>0.713</td>
<td>0.002</td>
<td>0.002</td>
<td></td>
</tr>
</tbody>
</table>

* One-sided p-value, F-test, for testing overall brush effect. The ANOVA model for the pre-brushing number of abrasions included brush, period and region as fixed effects while subject and subject by period were modeled as random effects. The ANCOVA model for the post-brushing number of abrasions and for the change in the number of abrasions included pre-brushing number of abrasions, brush, period and region as fixed effects, while subject and subject by period were modelled as random effects.

** Two-sided p-value from ANCOVA t-test for testing the change in the number of abrasions relative to zero.

*** Two-sided p-value from ANCOVA t-test for testing brushes based on the adjusted mean change in the number of abrasions.
### TABLE 2. Subanalysis: Mean (SE) of small-, medium- and large-sized gingival abrasions in marginal, interdental, and mid-gingival areas.

<table>
<thead>
<tr>
<th>Size abrasions</th>
<th>Brush with % end-rounding</th>
<th>Pre-brushing Adj. Mean (SE)</th>
<th>Post-brushing Adj. Mean (SE)</th>
<th>Difference Adj. Mean (p-value***)</th>
<th>Brush difference (p-value***)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=46</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0%</td>
<td>11.44 (0.61)</td>
<td>21.32 (0.50)</td>
<td>10.07 (&lt;0.001)</td>
<td>1.78 (0.002)</td>
<td>1.52 (0.008)</td>
</tr>
<tr>
<td>Small 0%</td>
<td>11.04 (0.61)</td>
<td>19.54 (0.50)</td>
<td>8.29 (&lt;0.001)</td>
<td>-0.26 (0.637)</td>
<td></td>
</tr>
<tr>
<td>&gt;90%</td>
<td>11.25 (0.61)</td>
<td>19.80 (0.50)</td>
<td>8.56 (&lt;0.001)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall test p-value*</td>
<td>0.630</td>
<td>0.003</td>
<td>0.003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medium 0%</td>
<td>0.53 (0.10)</td>
<td>0.87 (0.08)</td>
<td>0.32 (&lt;0.001)</td>
<td>0.09 (0.389)</td>
<td>0.10 (0.333)</td>
</tr>
<tr>
<td>&gt;90%</td>
<td>0.56 (0.10)</td>
<td>0.77 (0.08)</td>
<td>0.22 (0.006)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall test p-value*</td>
<td>0.896</td>
<td>0.569</td>
<td>0.569</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Large 0%</td>
<td>0.31 (0.07)</td>
<td>0.26 (0.03)</td>
<td>0.00 (0.998)</td>
<td>-0.02 (0.540)</td>
<td>-0.03 (0.423)</td>
</tr>
<tr>
<td>&gt;90%</td>
<td>0.21 (0.07)</td>
<td>0.30 (0.03)</td>
<td>0.03 (0.268)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall test p-value*</td>
<td>0.464</td>
<td>0.704</td>
<td>0.704</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

See footnote table 1 for the explanation of the symbols.

### TABLE 3. Subanalysis: Mean (SE) of small-sized gingival abrasions in marginal, interdental, and mid-gingival areas.

<table>
<thead>
<tr>
<th>Region</th>
<th>Brush with % end-rounding</th>
<th>Pre-brushing Adj. Mean (SE)</th>
<th>Post-brushing Adj. Mean (SE)</th>
<th>Difference Adj. Mean (p-value***)</th>
<th>Brush difference (p-value*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=26</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0%</td>
<td>4.04 (0.29)</td>
<td>11.00 (0.35)</td>
<td>6.85 (&lt;0.001)</td>
<td>1.96 (&lt;0.001)</td>
<td>1.97 (&lt;0.001)</td>
</tr>
<tr>
<td>Marginal</td>
<td>4.33 (0.29)</td>
<td>9.04 (0.35)</td>
<td>4.89 (&lt;0.001)</td>
<td>0.01 (0.979)</td>
<td></td>
</tr>
<tr>
<td>&gt;90%</td>
<td>4.10 (0.29)</td>
<td>9.03 (0.35)</td>
<td>4.88 (&lt;0.001)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall test p-value*</td>
<td>0.618</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0%</td>
<td>7.30 (0.50)</td>
<td>9.40 (0.28)</td>
<td>2.50 (&lt;0.001)</td>
<td>-0.21 (0.551)</td>
<td>-0.47 (0.173)</td>
</tr>
<tr>
<td>Mid-gingival</td>
<td>6.44 (0.50)</td>
<td>9.60 (0.28)</td>
<td>2.71 (&lt;0.001)</td>
<td>-0.27 (0.444)</td>
<td></td>
</tr>
<tr>
<td>&gt;90%</td>
<td>6.95 (0.50)</td>
<td>9.87 (0.28)</td>
<td>2.97 (&lt;0.001)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall test p-value*</td>
<td>0.169</td>
<td>0.392</td>
<td>0.392</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0%</td>
<td>0.11 (0.05)</td>
<td>0.89 (0.10)</td>
<td>0.70 (&lt;0.001)</td>
<td>0.02 (0.861)</td>
<td>-0.07 (0.589)</td>
</tr>
<tr>
<td>Interdental</td>
<td>0.23 (0.05)</td>
<td>0.86 (0.10)</td>
<td>0.68 (&lt;0.001)</td>
<td>-0.09 (0.472)</td>
<td></td>
</tr>
<tr>
<td>&gt;90%</td>
<td>0.23 (0.05)</td>
<td>0.96 (0.10)</td>
<td>0.77 (&lt;0.001)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall test p-value*</td>
<td>0.115</td>
<td>0.755</td>
<td>0.755</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

See footnote table 1 for the explanation of the symbols.
Discussion

Toothbrushing is effective in reducing levels of dental plaque and, generally, can be considered safe for the teeth and their surrounding tissues. The efficacy of manual toothbrushes in plaque removal following a brushing exercise is indicated by a reduction in the baseline plaque score of 42% on average, with a range of 30–53% dependent on the plaque index used. The available evidence indicates that the bristle tuft arrangement (flat trim, multilevel, angled) and brushing duration are factors that contribute to the variation in observed efficacy. In the literature, several factors related to gingival abrasions (GAs) have been suggested, such as abusive toothbrush use, manual or electric tooth brushing, toothbrush grip, brush head shape, stiffness of bristles, end-rounding of the toothbrush bristles, daily toothbrush frequency, bristle material, hardness and tip morphology.

Filaments must have a degree of stiffness for sufficient abrasion to dislodge plaque deposits. This stiffness has to be balanced against potential detrimental effects to dental hard and soft tissues. Designing a short-term clinical study to assess the incidence of GAs caused by tooth brushing is complicated because many factors, such as brushing technique, force, time, brushing skills of the participants and compliance with the study’s brushing instructions, influence the results. Therefore, a professional brushing model was employed and procedures were standardized to minimize the effect of differential variables as interfering factors. This design has been used previously by other investigators in the evaluation of different brushing techniques, brushing force and manual/electric toothbrushes. The mean increase of GAs in this study, where participants’ teeth were brushed by a professional, was lower than that observed by Rosema et al. (2014) where the panellists brushed their own teeth with their own toothbrushes, although scoring was performed by the same examiner. Versteeg et al. (2005) showed that there was no difference in GAs between participants who brushed their own teeth (with their own sensory perception feedback) and those whose teeth were brushed by a professional brusher. The most probable explanation for the effect size difference between the present study and Rosema et al. may therefore be differences in toothbrush brands and brushing technique (e.g. self-brushing versus professional brushing).

In the present study, following a single brushing exercise, the 0% end-rounded soft toothbrush caused significantly more GAs compared to the 40–50% and the >90% end-rounded brushes. One to two more gingival abrasions were observed on average when brushing with a 0% end-rounded toothbrush as compared to those with 40–50% or greater end-rounding. Post-brushing small abrasions were more prevalent than medium- and large- sized abrasions. The increase of GAs differed predominantly between the three types of toothbrushes in the marginal region. The pre- and post-brushing ex-
Exercises were performed by a professional brusher according to the Bass method. The Bass method is widely accepted as an effective method for bacterial plaque removal in the crevicular area adjacent to and directly beneath the gingival margin. The use of this method may explain the higher incidence of ‘marginal’ abrasions. The subanalysis (Table 3) showed a significant increase of GAs in the marginal area, although GAs in the mid-gingival area were higher prebrushing. Additional longer term studies should clarify the effect of bristle tip shape on gingival integrity.

The simple act of removing deposits from teeth requires that the toothbrush–dentifrice combination possess some level of abrasiveness. It had been suggested in the past that the combination of a dentifrice and toothbrush filaments can cause damage to oral tissues. However, Versteeg et al. (2005) observed that the use of a dentifrice, with its abrasive ingredients and detergents, did not induce additional abrasions. This observation was in agreement with earlier work by Alexander et al. (1977). Subsequently, in the present study, the toothbrushes were used without any dentifrice to improve visibility for the professional brusher. Adding dentifrice to the experiment could introduce another intervention which was not intended to investigate in this clinical trial. A limitation is that brushing without dentifrice does not reflect the reality. Different abrasives could influence wear and morphology of toothbrush bristle tips during use or the dentifrice could protect the gingiva as a lubrication film.

The present study showed no difference between 40–50% and >90% end-rounding. Danser et al. (1998) evaluated different types of end-rounding, such as the ‘roman’-shaped and ‘gothic’-shaped filaments that can be produced by different end-rounding machines. The ‘roman’ form represents a more-or-less flat end of the filament with rounded edges. The form designated ‘gothic’ represents a filament that has a rounded but more pointed end. The incidence of abrasions was higher with the ‘gothic’ style of end-rounding. Therefore, for the present study, the ‘roman’ style of end-rounding was used. A roman-shaped bristle tip is one potential target shape for production. If production lots contain brushes that including bristles with the ‘gothic’ style of end-rounding, counter-measures should be initiated to improve brush quality.

GA is difficult to score because visible GAs are not a common finding. For the present study, a method was used that was first described by Breitenmoser et al. (1979) and further refined by Danser et al. (1998) to assess abrasions on the cervical, interdental and mid-gingival areas of the gingiva in the incisor and canine, premolar and molar regions. In addition, the size of the lesions was taken into account by differentiating between small (≤ 5 mm) and large (> 5 mm) abrasions. In 2004, Van der Weijden et al. suggested adding a medium-sized abrasion to the GA score to increase the sensitivity of the scoring. The score now encompasses small (Ø ≤ 2 mm), medium (Ø ≥ 3, but ≤5 mm) and large (Ø > 5 mm) abrasions. Scoring is performed according to the nearest millimetre mark on the periodontal probe. As noted in the studies by Van der Weijden...
(2004)29 and Rosema et al. (2014)27, the presence and incidence of medium- and large-sized abrasion is an uncommon finding. The present data confirm that small lesions are the ones most often found. Pre-brushing scores show that, despite 48 h of abstaining from oral hygiene procedures, GAs at baseline are a normal finding. This could be the result of consuming hard and hot foods. Tooth-related soft tissues were28 traditionally divided into three areas: cervical, interdental and mid-gingival. Van der Weijden et al. (2004)29 replaced the term ‘cervical’ with ‘marginal’ to prevent confusion between cervical abrasions, which are related to the hard tissue of the teeth, and marginal GAs. In the present study, the term ‘approximal’ is used instead of the term ‘interdental’ because interdental (or inter-dental/interproximal) areas refer to the area beneath and related to the contact point, and approximal (proximal) areas are the visual spaces between teeth, which are not under the contact area52.

Some authors suggest that bristle ends become more rounded with clinical use 53. There are controversial reports regarding the time needed for wear to occur 8, 54. Little is known about deterioration patterns. Future studies should evaluate the shape of the tip over time and determine if any changes in shape (e.g. a non-end-rounded tip becoming round upon use) are relevant for maintenance of gingival integrity55. In this study, a new toothbrush was used for each brushing exercise. This implies that, for the experiment, a maximum possible abrasive effect for the given shape was scored. Consumers select their toothbrushes based on non-scientific criteria, and usually, the softness of a toothbrush is a determining factor53. In general, package information on end-rounding quality is lacking. Based on the results of this experiment, it can be concluded that 40–50% end-rounding can provide a significant reduction in GAs. If present, GAs are more pronounced as small-sized lesions located at the marginal area.

**Clinical relevance**

**Scientific rationale for the study**

End-rounded filaments of manual toothbrushes are highly desirable for safe tooth brushing. The effect of various levels of filament end-rounding of manual toothbrushes on gingival abrasions has not been investigated before.

**Principle findings**

A 0% end-rounded manual toothbrush is unsafe to use. A 40–50% end-rounded brush provides a significant reduction of gingival abrasions.
Practical implications
A majority of consumers select their toothbrushes based on non-scientific criteria, including brand, cost and even colour or shape. Manufacturers may consider including bristle end-rounding properties in their product information for consumers and dental care professionals.

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Conflict of interest
The authors NLHH, DES, EvdS and GAW declare that they have no conflict of interest. Slot and Van der Weijden have received external advisor fees, lecturer fees or research grants from Procter & Gamble. RA and JG are employees of Procter & Gamble.

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References


23. ADA. Accepted Dental Therapeutics. Chicago, USA: American Dental Association; 1984.


Supporting information

APPENDIX S1. Randomization sequence box.

<table>
<thead>
<tr>
<th>Sequence</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
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Test product: A/B/C with different levels of end-rounding
Contra-lateral brushing per treatment: quadrant 1/3 or 2/4

APPENDIX S2. Standard operational procedure of scoring Gingival abrasions in the marginal, interdental, and mid-gingival areas.

Procedure
Prior to the staining gingiva will be dried with the air blast and stained with Mira-2-Ton. Dye (non diluted) will be applied by the examiner with a fully saturated cotton swab starting from the lingual surfaces of the lower jaw followed by the buccal surfaces of the lower jaw and palatal and buccal surfaces of the upper jaw (up to 1.5 cm from the gum line). For all assessment the same staining sequence will be followed. After staining, subjects will be instructed to rinse out their mouth with water (one sip only) and spit out very carefully.

Assessment
Prior to the assessment, the gingiva will be dried with the air blast. During the measurement the size of each lesion (colored dark blue) will be measured using periodontal probe (assessing the largest width of lesion). Loosely attached discolorations will be excluded from evaluation. If examiner has difficulty with assessment at the gingival margin (plaque or abrasion), she/he will carefully try to remove the staining (not removable staining will be assessed as abrasion). After brushing the gingival will be restained again prior to the 2nd assessment (post brushing).
**Abrasion score**

Abrasions are split into 3 categories
- small, if Ø ≤ 2.5 mm,
- medium, if Ø > 2.5, but ≤ 5 mm,
- large, if Ø > 5 mm

Abrasions are recorded in the following regions (for each quadrant)
- M=molar
- P=premolar
- I=incisors + canin

For each region cervical, approximal and gingival areas are assessed (Figure S2). The lesion in the interdental area in between two teeth (molar, premolar and incisor) is assigned to the closest tooth area. In each quadrant both surfaces (Lingual and Buccal) are assessed. Each subject will be assigned a total number of small, medium and large lesions (separately) across all scorable sites. In addition, an overall total will be computed by adding together the number of small, medium and large lesions.

**FIGURE S2. Regions**

**References**