

# A Manual Bristleless Toothbrush Demonstrates Slight Improvement in Gingival Recession Compared to a Conventional Soft Manual Brush

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**Purpose:** This randomized clinical trial tested whether a novel bristleless toothbrush design is more effective in preventing gingival recession in adults receiving periodontal maintenance than is a soft toothbrush with nylon bristles.

**Materials and Methods:** Twenty-three subjects with gingival recession were recruited who received regular periodontal maintenance care at Western University of Health Sciences Dental Center, and who did not exhibit signs of acute dental or systemic disease, occlusal discrepancies or parafunctional habits. These subjects were randomly assigned to two groups, one using a soft nylon-bristled toothbrush, and the other using the experimental toothbrush that contains a brush head with short, soft, rubbery cones. Both groups received regular periodontal maintenance and periodontal exams by blinded examiners every 3–4 months, measuring probing depth, bleeding on probing, and plaque indices. Gingival recession was assessed clinically and through use of a stent on diagnostic casts obtained at each visit.

**Results:** Average probing depths, plaque levels, and the number of sites with bleeding on probing did not change over at least 9 months. After 9 months, there was a small but statistically significant improvement in gingival recession (0.4 mm,  $p < 0.01$ ) at sites with gingival recession in the experimental toothbrush group compared to the control group.

**Conclusion:** In periodontal maintenance patients, the bristleless toothbrush used in this study was as effective in plaque removal and prevention of gingival inflammation than a conventional toothbrush with soft nylon bristles, while increasing the possibility of gingival tissue rebound over denuded root surfaces.

**Key words:** gingival recession, oral hygiene, toothbrushing

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Gingival recession can be the result of tissue destruction caused by periodontal diseases, anatomic factors or physical injury.<sup>12</sup> Gingival recession can cause tooth sensitivity and expose tooth root surfaces, increasing caries risk. Gingival recession also tends worsen if untreated, and may result in tooth loss.<sup>14</sup> Correction of gingival recession de-

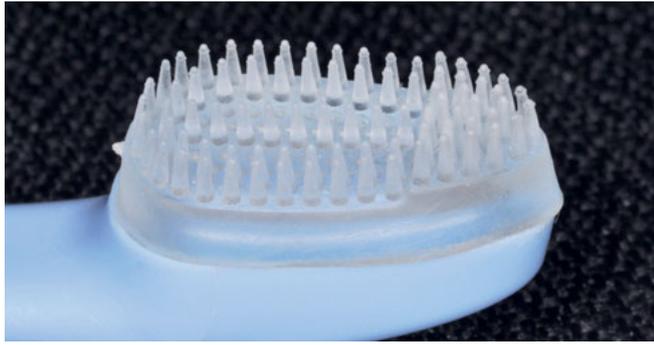
fects typically involves soft tissue grafting which can cause significant postoperative pain and other complications. Given the morbidity associated with surgical correction of gingival recession, the key to preventing and managing gingival recession is to control contributing factors. Aggressive brushing techniques using a hard toothbrush are generally considered to be a contributing factor to gingival recession,<sup>8,9,11,16</sup> although the evidence for this relationship is limited.<sup>18</sup> It is possible that toothbrush hardness matters more than the brushing technique in the development of gingival recession, as a 5-year study found that gingival recession progressed despite introduction of a gentle brushing technique 7.

Several possible explanations exist for the development of gingival recession associated with hard toothbrushes. It is possible that using a hard brush leads to more abrasion of cervical enamel after exposure to acidic beverages.<sup>4</sup> This creates a local tooth surface defect that is harder to clean, leading to locally increased plaque accumulation, gingival inflammation, attachment loss and gingival recession. It is

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**Fig 1** Novel toothbrush head featuring soft, short rubbery cones instead of bristles on a soft base.

also possible that hard brushes cause more direct tissue damage, as studies show increased gingival abrasion and more inflammation after use of a hard toothbrush in humans<sup>24</sup> and monkeys.<sup>10</sup> Inflammation likely destroys the connective tissue supporting the gingival margin, leading to gingival recession.<sup>20</sup>

Besides toothbrush hardness, the effect of other aspects of toothbrush design are unclear, as dentifrice abrasiveness may also influence recession development.<sup>2</sup> Changing the bristle pattern on a manual toothbrush with nylon bristles did not have any effect.<sup>6</sup> Similarly, changing the shape of the individual nylon bristles did not have any effect.<sup>5</sup> More important than shape or arrangement may be the material used for the brush, as nylon bristles were found in a canine model to cause more tissue damage compared to bristles made from other materials.<sup>3</sup> Most relevant, in patients who had previously received root coverage procedures, an electric toothbrush was more effective in preventing recession than a manual brush.<sup>1</sup>

Given these studies and that gingiva can recover after injury,<sup>23</sup> a gentler toothbrush design should prevent tissue abrasion and promote regrowth of damaged gingiva. Recently, case reports of spontaneous reversal of gingival recession after using a novel toothbrush containing short rubbery cones instead of nylon bristles came to the authors's attention, and we hypothesized that this novel toothbrush design may have a beneficial effect on gingival margin position. Therefore, the aim of this study was to determine if progression of gingival recession in periodontal maintenance patients with pre-existing gingival recession differs between users of a soft nylon brush and those using the novel toothbrush.

## MATERIALS AND METHODS

### Trial Design

This was a single-blinded, randomized, parallel-group clinical trial. Data are reported following the CONSORT (Consolidated Standards of Reporting Trials) guidelines.<sup>19</sup> Subjects were assigned to two groups with a 1:1 allocation ratio. Eli-

gibility criteria and method were not changed during the trial. The study was approved by the Institutional Review Board at Western University of Health Sciences (Approval number 14-IRB-054) and conducted in accordance with the declaration of Helsinki. This study has been registered at ClinicalTrials.gov (Identifier: NCT02951065).

### Participants

Twenty-three subjects were recruited who received regular periodontal treatment at the Western University of Health Sciences Dental Center, and who had facial gingival recession with at least 1 mm clinical attachment loss in the anterior dentition and were between 18 and 80 years of age. Patients were excluded who could not provide consent, had severe uncontrolled medical conditions resulting in an American Society of Anesthesiologist's Physical Status Class greater than III, had acute pain or infection, caries near the gingival margin, restorations covering the gingival recession defect, presence of Miller Class III or IV defects,<sup>15</sup> severe or aggressive periodontitis, were missing more than one anterior tooth, had severe malocclusion, presence of occlusal trauma requiring more than limited adjustment, tobacco use, ongoing or planned orthodontic treatment, oral piercings, or a history of bruxism, clenching, nail biting, holding pins with teeth, or gum scratching habits. Subjects were also excluded who preferred to use an electric toothbrush over a manual brush. Subjects were enrolled between March 2015 and September 2015, and the study has been ongoing as of October 2016.

### Intervention

Subjects were randomly assigned to a test or control group through block assignment in blocks of 4 subjects at a time. At each visit, subjects received a comprehensive periodontal exam, personalized oral hygiene instructions demonstrating the modified Stillman technique for the soft brush or scrubbing technique for the bristleless brush. Subjects received a low-abrasivity toothpaste (Complete Care Plus Enamel Strengthening, Arm & Hammer; York, PA, USA) and either a regular soft brush (Indicator Contour Clean Toothbrush, Oral-B; Iowa City, IA, USA) or a special brush (Peri-Clean, Great Neck, NY, USA; Fig 1). Subjects were instructed to brush twice a day with the provided brush and toothpaste, and use waxed dental floss (REACH Mint waxed floss, Johnson&Johnson; New Brunswick, NJ, USA) twice daily. After oral hygiene instruction, subjects received periodontal maintenance. None of the subjects received occlusal adjustments, as none of the teeth with recession defects had interference contacts at the onset of the study. For record keeping and future analysis, diagnostic casts were made using polyvinylsiloxane impressions. To ensure compliance with the oral hygiene regimen and monitor for unexpected problems associated with the brushes, subjects were contacted by phone to answer questions and concerns from the subjects about using the toothbrush. Periodontal exam, oral hygiene instruction and periodontal maintenance were repeated every 3-4 months for at least 9 months during the course of this study.

## Outcomes

At each visit, a full-mouth periodontal exam was conducted that measured probing depths, bleeding on probing, plaque levels and gingival recession. Measurements were recorded by the subject's primary operator (a 3rd or 4th year dental student), and verified by a team of calibrated faculty (1 periodontist, 1 general dentist, 1 dental hygienist) on a virtually random basis. Neither students nor the verifying faculty were aware of the subject assignment.

Periodontal probing was performed using light probing force and by gently walking the probe through the entire sulcus, recording the worst probing depths in the distobuccal, mid-buccal, mesio-buccal, distolingual, midlingual and mesiolingual area of each tooth.

For each area, bleeding on probing was recorded if a drop of blood appeared immediately after probing, and the percentage of sites with bleeding on probing were calculated.

Plaque levels were assessed visually for the facial and lingual half of each tooth using the Turesky-modified Quigley-Hein plaque index:<sup>21</sup> facial and lingual tooth surfaces were scored as '0' if no plaque was present, '1' if specks of plaque were present and '2' if a thin (< 1 mm) continuous band of plaque was present. A '3' indicated a thick band of plaque between 1 mm and 1/3 of the tooth surface, '4' meant that 1/3 to 2/3 of the tooth surface was covered in plaque, and '5' was reserved for heavy plaque accumulation covering more than 2/3 of the crown.

Gingival recession was measured clinically at any site where the cemento-enamel junction was exposed, and measurements were taken for these sites at the mesiofacial line angle, mid-facial center of tooth, disto-facial line angle, mesiolingual line angle, mid-lingual center of tooth and distolingual line angle from the cemento-enamel junction to the gingival margin. All measurements were carried out using a UNC-15 periodontal probe (Hu-Friedy; Chicago, IL, USA), and the measurement method was not changed during the trial. As a second method for monitoring changes in gingival recession, polyvinylsiloxane impressions were made at the initial and 6-month visit, and a stent was fabricated for measuring recession relative to the stent (Fig 2). Relative recession was determined based on defined measurements paths on 4 sites per tooth on the facial gingiva from the gingival margin to the stent edge. Brush use was monitored not only by asking subjects, but also by checking the brushes for signs of wear (the subjects' used toothbrushes were collected at every visit).

## Examiner Calibration

For examiner calibration, additional volunteers were recruited who had gingival recession, but did not participate in the toothbrush trial. Here, the principal investigator (TKB) measured and recorded gingival recession, probing depths and plaque levels per quadrant. Then, another examiner measured and recorded these values independently, and discussed measurements afterwards. This process was repeated until at least 90% of recorded values were no more than 1 mm or 1 category different. Inter- and intra-reproducibility values were then calculated from the last calibration session.



**Fig 2** Measuring stent created using thermoplastic vacuformed material. For each facial surface, the position from the stent margin to the gingival margin was measured with a UNC-15 periodontal probe along the angulation and at the site indicated by the markings.

## Sample Size, Randomization, Blinding

The focus was on detecting a clinically significant effect of 0.5 mm difference in gingival recession as the primary clinical outcome, and assumed a standard deviation of 0.7 mm (based on research comparing electric vs manual brushes<sup>13</sup>), yielding a minimum number of 31 sites with recession needed per group. Assumptions for sample size calculation were: type I error of 5% and power 80%. Subjects in sets of four were assigned randomly to allocation blocks by a series of coin tosses. Allocation of subjects and enrollment was performed by this study's principal investigator (TKB), and verifying faculty were not informed of the subject allocation to either control or test brush. To increase the degree of concealment, students were not informed about the specific expected effect of the toothbrushes.

## Data Analysis

Group characteristics such as mean age, recession, and probing depths were compared using Student's t-test, and proportions of gender and ethnicity/race were compared using the chi-squared analysis. Normality of data such as the recession measurements were confirmed using the Shapiro-Wilk test. Recession was analyzed by calculating the difference in measurement for each recession site at the initial visit and each follow-up visit (3 months, 6 months, 9 months), averaging recession changes for each group and comparing these using the Welch two-sample t-test. Plaque levels, probing depths and percent bleeding sites were also averaged for all subjects, and the two averages were compared for each clinical parameter using the Welch's two-sample t-test. All analyses were performed using the R statistical package (Vienna, Austria) and data were plotted using the ggplot2 package.<sup>22</sup>

## RESULTS

Seventy-one subjects were approached for possible inclusion in this study, and 23 were accepted from March to

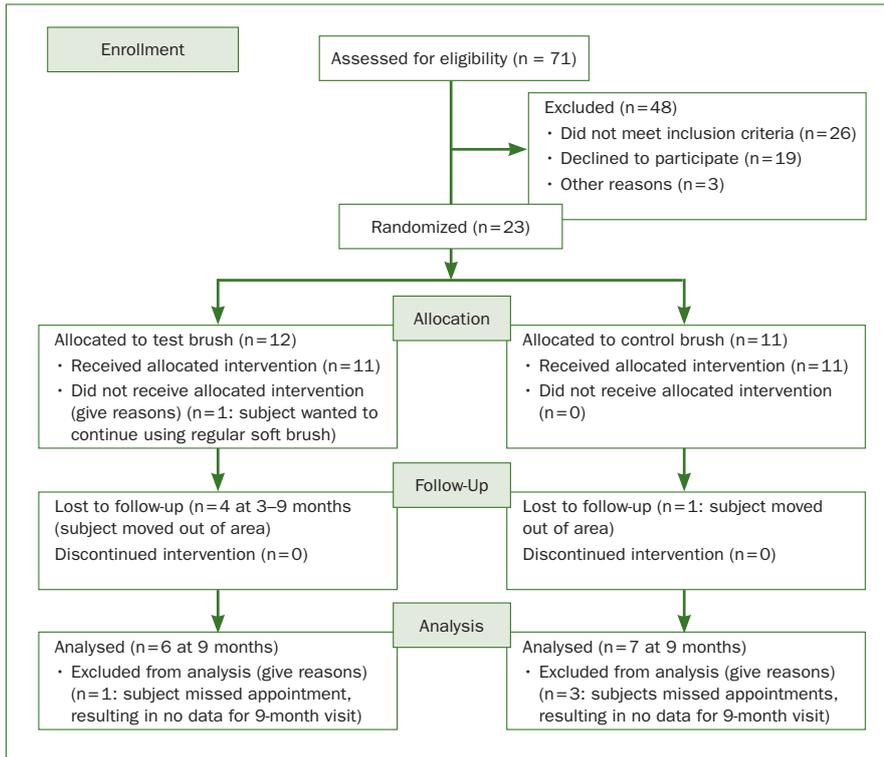
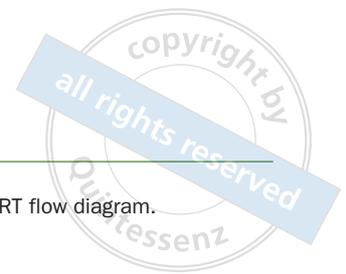


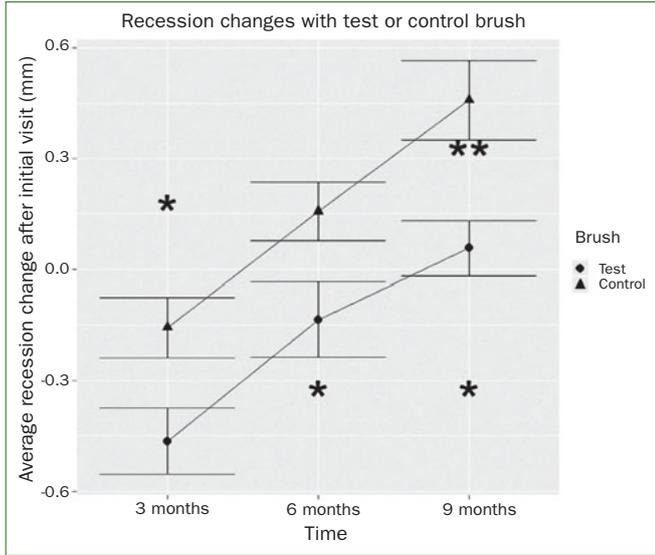
Fig 3 CONSORT flow diagram.

Table 1 Subject composition

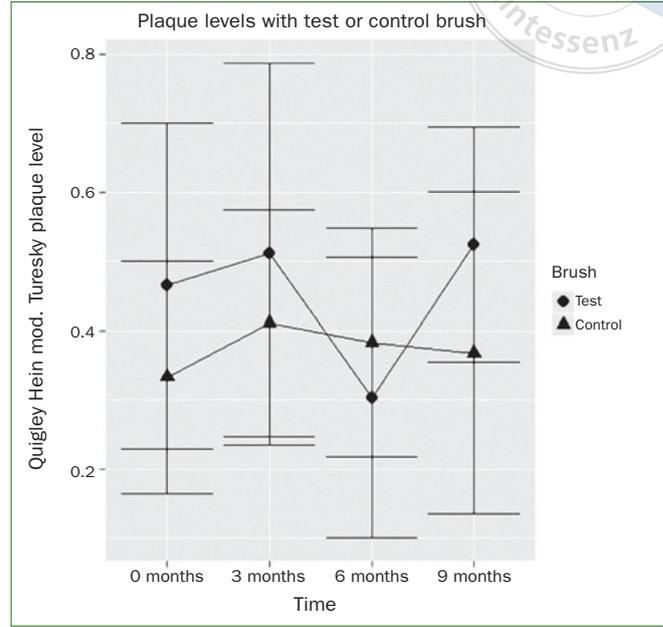
Characteristic	Test	Control
Number	11	11
Female	55%	60%
Mean age	49	49
Tobacco users	0	0
Parafunction history	0	0
Teeth exhibiting fremitus	0	0
Ethnicity		
Caucasian	4	3
Hispanic	2	6
Other	5	1
Average probing depth	2.4 mm	2.6 mm*
Average % BOP sites	6	8
Average plaque level	0.3	0.4
Average recession	0.5 mm	0.4 mm
Number of sites with recession	228	289
Randomization produced experimental groups quite similar to each other, with no statistically significant differences in demographics, initial number of sites with bleeding on probing, plaque level or amount of gingival recession. *The control group initially had a slightly higher, statistically significant (p < 0.05) average probing depth.		

September 2015. While many potential subjects were not interested in participating in this study, we noticed a high preponderance of bruxism history (20 out of 26 patients meeting exclusion criteria) in patients with slight gingival recession. The 23 accepted subjects were distributed to the test and control group as described above. In the test group, four subjects dropped out over the course of the trial, but did not report a reason. One subject in the test group did not want to continue using the test brush, but preferred a conventional soft brush. The control group had a lower drop-out rate with only one subject dropping out because of relocation, but three subjects did not attend the 3-month follow-up visit (Fig 3).

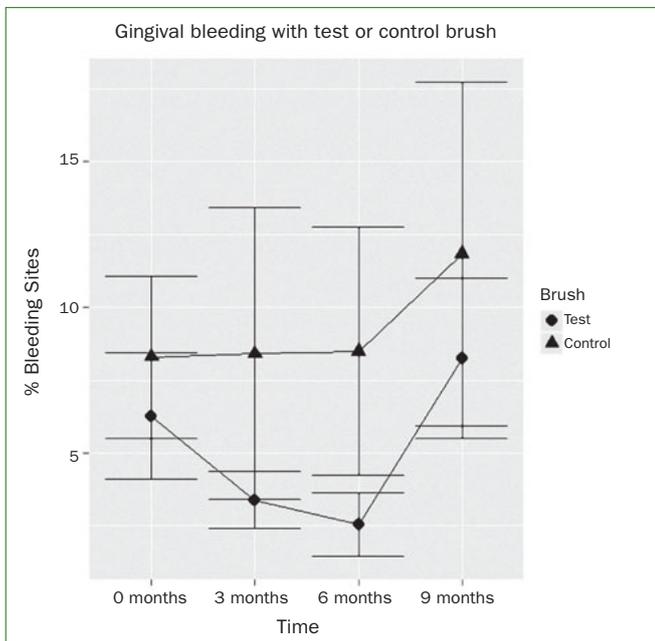
Randomization was largely successful with both groups not statistically significantly different in age, gender and ethnicity. Subjects generally had small degrees of gingival recession (0.4-0.5 mm on average) on the facial surfaces of anterior teeth, mostly with very little interproximal gingival recession at the onset of the study. Subjects were all periodontally well maintained at the onset and throughout the study, with minimal probing depths (2.4-2.6 mm; the control group had a slightly higher initial probing depth), few sites exhibiting bleeding on probing (6-8%) and low facial/lingual plaque levels (0.3-0.4 Quigley-Hein index as modified by Turesky).<sup>21</sup> Overall, patients had a history of generalized mild chronic periodontitis or gingivitis as indicated in their dental records and based on past clinical attachment readings (Table 1).



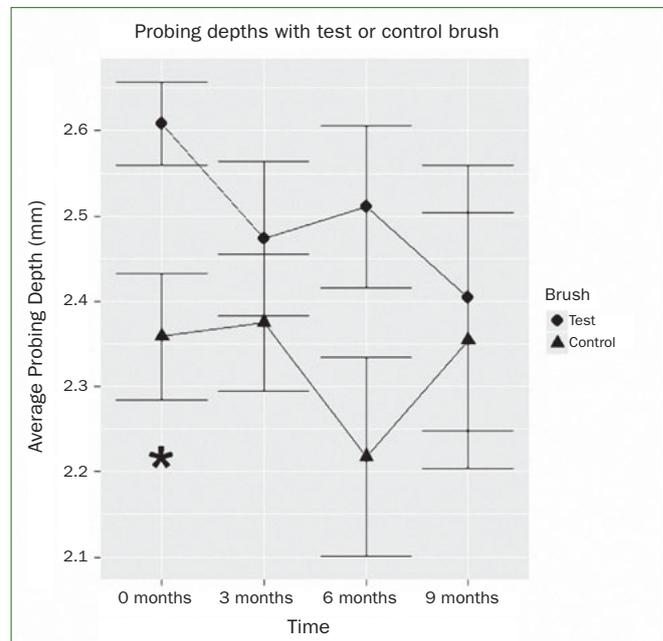
**Fig 4** Recession changes with test or control brush. When comparing changes in recession after the initial visit, the group using the bristleless brush (PeriClean) had statistically significantly less worsening of gingival recession over time (\* $p < 0.01$ ), and actually a small, but statistically significant regrowth of gingival tissue after 9 months (\*\* $p < 0.01$ ).



**Fig 5** Plaque levels with test or control brush. Although some patients reported that the bristleless brush felt less effective in cleaning, there was no statistically significant difference and change in plaque levels for each type of brush. In general, plaque levels were very low.



**Fig 6** Gingival bleeding with test or control brush. We also did not observe any statistically significant difference in gingival inflammation as evidenced by the percentage of bleeding sites with the two different brushes.



**Fig 7** Probing depths with test or control brush. Although the subjects assigned to using a soft nylon brush initially had slightly higher probing depths (\* $p < 0.05$ ), during the course of the study we did not observe any differences or worsening of probing depths within the subjects.



**Fig 8a** Subject 8 of the test brush group at beginning of trial. Note multiple areas of broad, shallow recession on maxillary anterior teeth and U-shaped gingival architecture, but little if any visible plaque.



**Fig 8b** Subject 8 of the test brush group 6 months into trial. Note continued good plaque control, but less inflammation than seen before. Traces of impression material are seen on the cusp tip of no. 3 and 4.



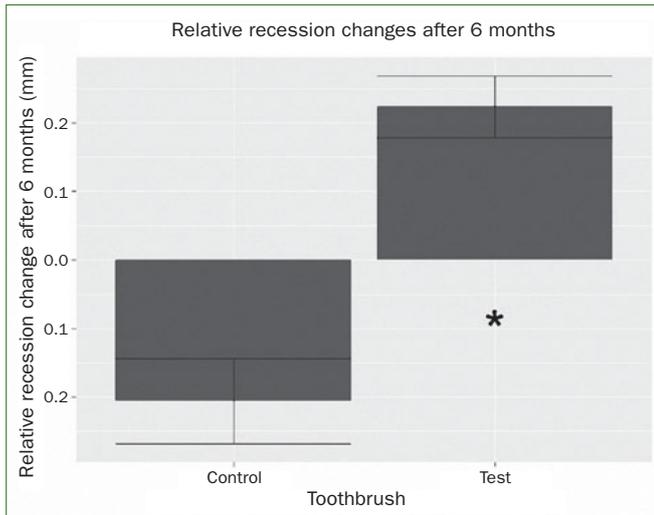
**Fig 8c** Subject 8 of the test brush group at end of trial. Note continued good plaque control and low level of inflammation. While deeper areas of recession did not resolve, gingival architecture did improve slightly with more parabolic gingival architecture, thickened gingival contour at tooth line angles, and slight coronal creep of the gingival margin (white arrows) at some teeth.

Interexaminer reproducibility between the principal investigator (TKB) and verifying faculty for probing depths and recession measurements within 1 mm was about 96% (unweighted kappa scores ranged from 0.65 to 0.86). For plaque scores, the interexaminer reproducibility for plaque scores ranged between 80 to 100% (kappa score not determinable). Intraexaminer reproducibility for relative recession measurements was 92% (unweighted kappa 0.72).

Subjects had obviously used the toothbrushes, as the returned brushes exhibited typical wear patterns associated with toothbrush use. Phone follow-up was done, and no problems with the toothbrushes were reported.

The primary outcome variable of this study was gingival recession as measured from the exposed cemento-enamel junction to the gingival margin. Actual statistical power ranged from 61% at 6 months and 79% at both 3 and 9 months. Following recession changes over time, it was

found that although both groups initially seemed to have increased gingival recession after 3 months, it was not statistically significant for the test toothbrush ( $p > 0.05$ , 95% confidence interval [CI]: 0.0044 mm improved recession to 0.32 mm increased recession). In contrast, the control group using a regular soft brush and the modified Stillman method exhibited slight, but statistically significant worsening of recession ( $p < 0.001$ , 95% CI: 0.27 to 0.64 mm increased recession at sites with recession). This changed over time, and the gingiva recovered to its initial position in the control group. In contrast, the test group maintained gingival margin position better than the control group at all visits ( $p < 0.05$ , about 0.4 mm difference; 179 test vs 115 control sites at 3 month, 153 test sites vs 156 control sites at 6 months, 97 test sites vs 156 control sites at 9 months; numbers vary due to the three dropouts in the test group, and the 3 control subjects who missed their



**Fig 9** Relative recession changes after 6 months. We also determined if the clinical appearance of improved gingival contours is reflected in relative recession measurements of facial gingiva using a stent with defined measuring paths after 6 months of toothbrush use, and there is a statistically significant difference in relative recession. Control brush users lost slightly gingiva, whereas the test brush users gained gingiva. The difference matches the clinically observed difference in gingival recession.

3-month recall appointment). Unlike the control brush, gingival margin position did not change statistically significantly at first with the test brush, and there was a slight, but statistically significant reduction in gingival recession after 9 months ( $p < 0.001$ , 95% CI: 0.24 to 0.67 mm improved recession for sites with recession) (Fig 4).

Plaque removal efficiency was determined using the Quigley-Hein method modified by Turesky.<sup>21</sup> No statistically significant differences were found in plaque levels for either group ( $p > 0.05$ ) (Fig 5).

To rule out inflammation as a source of gingival swelling and seemingly improved recession, bleeding sites and probing depths were determined. No statistically significant difference was noted in the number of sites with gingival bleeding ( $p > 0.05$ , Fig 6), and although the groups initially had slightly different probing depths, there was no statistically significant difference in mean probing depths between the groups ( $p > 0.05$ , Fig 7).

Diagnostic casts and clinical photographs were examined to see if there were clinically noticeable changes. In both groups, there were no major changes in gingival color or shape, and plaque levels remained low. For the test group, a slight improvement was noticed in gingival architecture that produced slightly narrower recession defects, more parabolic gingival margin scallop and less visible erythema and edema. At some sites, a slight coronal creep of the gingival margin was observed (Fig 8). The study was uneventful, and no subjects suffered adverse events from

either toothbrush used. Control brush users expressed no comment or concerns about the brush or study, while test brush users felt either very satisfied with the brush or that the brush was not aggressive enough in plaque removal. It was observed that all subjects who had concerns about the brush's effectiveness also had crowded teeth.

The clinical measurements were verified and changes observed by measuring relative recession as recorded on diagnostic casts obtained at the initial and 6-month visit. As seen in Fig 9, there was a statistically significant difference in the position of the gingiva relative to the fabricated stent ( $p < 0.001$ ). While the control brush users lost a small amount of facial gingiva, the test brush users gained a small amount. The difference observed mirrored what was observed clinically, and validated the clinical observations.

## DISCUSSION

Over 9 months, no lasting major detrimental changes were observed in either the test or control group, and it appears that both the bristleless or conventional brush design can produce consistent plaque and inflammation control in patients on periodontal maintenance. While complete recovery of lost gingiva was not seen at sites with deep gingival recession, development of improved gingival appearance was apparent in the test group, as was slight, but statistically significant improvement of gingival recession in sites with facial or lingual recession. This may be clinically relevant as a soft, bristleless toothbrush may be better at maintaining gingival margin positions in patients with a history of aggressive toothbrushing.

Although it is clinically significant that gingival recession may be able to be reversed slightly with a gentle toothbrush design and technique, this study has several limitations. First, this is a pilot study that tested the brush on relatively few subjects, as most patients with gingival recession defects at the Dental Center did not meet the strict inclusion criteria. The inclusion criteria were kept stringent to avoid known contributing factors to gingival recession such as periodontal disease, smokeless tobacco use and occlusal trauma, which could obscure the effect of toothbrush design on gingival recession. Furthermore, most of the excluded subjects had a history of parafunctional habits and gingival recession. The study also suffered from a significant amount of attrition in both groups, as subjects dropped out or missed recall appointments; this was not related to the study but rather was typical of the patient population served by this clinic. In general, compliance with treatment in a dental school clinic setting seems low, as reported elsewhere.<sup>17</sup> A solution for this problem would be to conduct a larger trial of this brush in a group of private dental practices.

We addressed the possibility of inaccurate clinical measurements by dental students (unweighted kappa was about 0.5-0.6 to a periodontist for recession measurement) by having the measurements verified by calibrated faculty, which improved interexaminer agreement and kappa to the

reported value. In addition, recession changes were independently assessed using a measuring stent on diagnostic casts obtained during the study, which confirmed the clinical measurement results. The observed effect of about 0.4 mm improved recession in this study is similar to that observed by Acunzo's powered vs manual toothbrush study,<sup>1</sup> which suggests that this effect may be obtainable through a variety of methods. It also provides some assurance that a small degree of gingival margin recovery is possible even in the confines and less than ideal clinical setting of a dental school clinic.

Three subjects in the test group reported that 'the brush does not feel like it cleans between teeth', or 'feels not aggressive enough', which suggested low test brush efficacy. However, this was not seen clinically, given the plaque level measured with the Quigley-Hein index modified by Turesky (Fig 5,  $p > 0.05$ ).<sup>21</sup> This index measures facial and lingual plaque accumulation, and it is possible that there may be differences in interproximal plaque accumulation, as the test-brush cones do not reach interproximally. Alternatively, subjects may feel that the test brush is not aggressive enough since the subjects do not feel bristles reaching interproximally. If the test-brush users had worse interproximal cleaning, it should have resulted in greater inflammation and bleeding on probing. However, there was no statistically significant difference in bleeding scores between the groups, and it can be assumed that the complaint was based on the lack of bristle sensation. Since the test brush is not designed to clean interproximally, the current authors recommend that potential patients be advised of the different feel of the brush, and that appropriate interproximal oral hygiene methods such as floss or interproximal brushes be taught to patients using this brush.

## CONCLUSION

Bristleless brushes appear to be a safe alternative to conventional soft brushes in patients with gingival recession. These brushes may more effectively prevent additional gingival recession, as they allow slight coronal expansion of the gingival margin.

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