1 TITLE PAGE

TITLE OF STUDY:	**Evaluation of the Clinical Safety and Efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model**
INVESTIGATIONAL MATERIALS:	**Manual toothbrush:** ADA reference manual soft-bristled toothbrush **Sonic toothbrush:** AutoBrush® 360° U-Shaped Sonic Toothbrush
Sponsor:	Lander Enterprises, LLC dba AutoBrush® 5700 Biscayne Blvd Apt 822 Miami, Florida 33137
Protocol No.:	AB-GBP-2023-03
Investigator:	Robert T. Nierman, DMD Timber Falls Dental Research 10120 Auburn Park Dr. Fort Wayne, Indiana 46825
Study period:	First Subject First Visit: 11 September 2023 Last Subject Last Visit: 27 October 2023
GCP Statement:	This study was performed in compliance with ICH Good Clinical Practice (GCP) including the archiving of essential documents.
Date of report:	19 December 2023

ABSTRACT

Evaluation of the Clinical Safety and Efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model

Objective: This single-center, randomized, controlled, examiner-blind, 30-day parallel trial assessed safety and efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on plaque and gingivitis, compared to an ADA reference soft manual toothbrush. The extent of gingival abrasion and recession was evaluated.

Methods: 75 subjects, aged 5-64 years, with mild -to-moderate plaque and gingivitis levels were assigned to : 1) twice-daily two-minute brushing with ADA reference manual toothbrush (MTB)/fluoride toothpaste; or 2) twice-daily 30-second brushing with AutoBrush® (AB)/fluoride toothpaste. Subjects refrained from oral hygiene for 12-16 hours before each exam visit at Baseline, Day 15 and Day 30, received oral safety examination, assessed for gingivitis according to Modified Gingival Index (MGI), gingival recession, gingival abrasion and supragingival plaque according to Lobene-Soparkar Modified Turesky Plaque Index (LSPI). Subjects presented with existing mild to moderate gingivitis and no dental prophylaxis was performed. Pre-to-Post-brushing plaque assessments were measured at Day 30. Treatment means and between-treatment means were assessed by the ANCOVA model.

Results: No treatment-related oral adverse events nor differences between groups for gingival recession and abrasion were detected. Significant gingivitis and plaque reductions were observed for AB compared to MTB at Days 15 and 30 ($p<0.0001$). Compared to MTB, AB reduced whole mouth MGI scores by 32.3% and 44.8%, respectively. AB provided significantly greater improvement in gingivitis levels in the hard-to-reach areas (gumline, proximal sites and most distal surfaces) compared to MTB. Whole mouth plaque scores were reduced 32.3% and 10.9% at Days 15 and 30, respectively for AB and compared to the MTB. Improvement in Day 30 Pre-to-Post-brushing plaque scores for AB were significantly better ($p<0.001$) than MTB for whole mouth, gumline, proximal sites and most distal surfaces at 44.8%, 81.8%, 28.8% and 49.7%, respectively.

Conclusion: Thirty-second brushing with AutoBrush® toothbrush was superior to the MTB in reducing gingivitis and plaque at Days 15 and 30, and demonstrated highly significant plaque removal at Day 30 Pre- to Post-brush evaluation. Both toothbrushes were well-tolerated and the safety of the AutoBrush® 360 U-Shaped sonic toothbrush was demonstrated in this 30-day study.

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2 SYNOPSIS REPORT

2.1 OBJECTIVE

The objective of this 30-day, randomized, controlled, examiner-blind, parallel design clinical trial was to assess the safety and efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on plaque and gingivitis, compared to an ADA reference manual toothbrush. Safety was assessed through the evaluation of the extent of gingival abrasion and recession, through oral clinical examinations and interviews to determine soft tissue or oral irritation symptoms, and monitoring of adverse events (AEs) / serious AEs.

2.2 INTRODUCTION

The effective management of dental plaque and gingivitis continues to be a high priority for the dental health of the public. Dental professionals recommend brushing at least twice a day for two minutes to remove plaque and reduce the risk of tooth decay and gum disease.[1] However, the high prevalence of oral diseases worldwide suggests that consumers do not achieve sufficient plaque removal with their toothbrushing routine.

Clinical studies have shown that improvement in mechanical oral hygiene can be achieved through the use of power toothbrushes.[2, 3, 4, 5, 6, 7, 8, 9, 10, 11] In fact, there are systematic reviews and meta-analyses which have demonstrated that power toothbrushes are more effective in removing plaque than manual toothbrushes.[12, 13] Well-designed clinical studies are needed to validate the efficacy of new toothbrush products and claims of improving plaque control and gingival health. A study by Ebel and co-workers[2] assessed the impact of brushing time, brushing techniques, and brushing systematics of young adults (18 years old) on efficiency of plaque removal with a standard manual toothbrush. They found that participants distributed their brushing time across surfaces unevenly which explained the variance of plaque and bleeding results. Brushing technique appeared to be of minor importance. The researchers concluded that the results indicated that establishing systematic interventions or prophylactic programs should emphasize the importance of brushing all surfaces and not neglecting any teeth.

An innovative U-Shaped sonic power toothbrush has been developed by AutoBrush® that is designed with a full two-sided toothbrush head (mouthpiece) with tapered nylon bristles to clean all tooth surfaces at once in a 30-second period. Each U-Shaped brush head contains about 58,000 nylon tapered bristles and is available in six sizes to accommodate a variety of mouth sizes and shapes. Consumers can select the brush head size based on their age: Kids Ages 3 – 5, Kids Ages 6 – 8, Kids Ages 9 – 12, Adult Small, Adult Regular, Adult XL. The handle supplies 30,000 sonic vibrations per minute and features an on/off button for selecting the

"deep clean" brushing mode. Users are directed to insert the brush head into the handle, wet their toothbrush, and apply foam or regular fluoride toothpaste on each side (upper and lower) of the brush head bristles and insert into the mouth. The on/off button initiates the 30-second timer along with a fun musical tune while users gently move the brush in figure 8 motions to clean all tooth surfaces. See Figure 1.

Figure 1. AutoBrush®

The AutoBrush® company's mission is to make brushing simpler, better, and more accessible for kids, adults and individuals with disabilities. A recent independent, single-use, examiner blinded, randomized, two-period, cross-over, clinical study evaluated the safety and plaque removal efficacy in 22 children, 5 to 8 years of age who used the AutoBrush® sonic toothbrush and a marketed children's manual toothbrush. Supragingival plaque levels were assessed according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI). When assigned to the AutoBrush® (AB), subjects used the product for 30 seconds whereas they used the manual toothbrush in their usual manner for 2 minutes. Following single use of the AB, statistically significant reductions were observed for the AB compared to Baseline for whole mouth plaque for 50.6%, gumline levels with 71.2% and proximal levels were reduced by 40.7%. The manual toothbrush provided reductions of 1.9%, 3.5% and 1.1%, respectively. The AB provided 27 times greater whole mouth plaque removal than the manual toothbrush. There were no adverse events in this short-term study and the AutoBrush® was well-tolerated.

Further evidence of the new AutoBrush product's efficacy was demonstrated in a recent 30-day plaque and gingivitis study. Seventy five subjects aged 5-65 years, brushed twice daily with either an ADA reference manual soft toothbrush (MTB) for two minutes or 30 seconds with the

AutoBrush® sonic toothbrush (AB). Compared to the MTB, AB reduced gingivitis by 41% and plaque scores by 27.7% following 30 days of use. There was no adverse effect associated with either toothbrush with respect to gingival recession and abrasion measures. Both toothbrushes were well-tolerated and there were no safety concerns detected during this 30-day study.

This current study design followed the same 30-day study design with the ADA recommended 30-day model to evaluate the safety and efficacy of AutoBrush® compared to an ADA reference manual soft toothbrush on dental plaque and mild to moderate gingivitis. Oral safety was assessed through the examination of the extent of gingival abrasion and recession, as well as oral clinical examinations for soft and hard tissue changes, interviews to determine soft tissue or oral irritation symptoms, and monitoring of subject-reported adverse events (AEs) / serious AEs.

2.3 METHODOLOGY

Prior to the initiation of this study, the protocol, informed consent, assent documents and subject instructions received ethical review and approval from U.S. Investigational Review Board, Inc. The study was conducted in accordance with the International Conference on Harmonization Good Clinical Practice Guideline (ICH-GCP) E6(R2).

This study was a single-center, randomized, controlled, examiner-blind, 30-day parallel study with volunteers aged 5 to 65 years. Based on the assumption that the sonic power toothbrush group improvement would exceed that of the control group by at least 25% at Days 15 and 30, the calculated total sample size of 90 completed subjects (45 per group) provided 90% power to detect a difference of 0.24 with respect to MGI, and 0.4 with respect to PI when compared to the control group, with an effect size (mean/standard deviation) of 0.7, at the Day 30 assessment. These calculations were based on two-sided tests at the 0.05 significance level.

The study consisted of a Screening visit during which potential subjects provided consent to participate in the study, completed health and dental questionnaires and received a clinical oral examination. Adult subjects, ages 18 – 64 years, read and signed an informed consent form and subjects 5 to 17 years of age signed an assent form indicating their willingness to participate in the study and their parents/legal guardians signed the consent form on their behalf. Generally healthy children and adult subjects were eligible and enrolled in this study after meeting the inclusion criteria.

The Screening visit included assessments in the following order:

- Oral safety to evaluate oral soft and hard tissues (OSHT), and the presence or absence of gingival abrasion, recession or other abnormalities;
- Visual examination for qualifying gingivitis levels according to the Modified Gingival Index (MGI).[14]

To qualify for the study, individuals with an adult dentition needed to have at least 18 natural teeth with scorable facial and lingual surfaces. Those under the age of 12 needed to have at least 12 fully erupted primary or permanent teeth. Partially erupted permanent teeth and primary teeth in process of exfoliation were not included in the tooth count. Teeth that were grossly carious, fully crowned, or extensively restored, orthodontically banded, exhibited general cervical abrasion and/or enamel abrasion, > 2 mm gingival recession were not included in the tooth count. All qualified subjects had a mean gingival index ≥ 1.75, according to the MGI, a mean plaque index ≥ 1.95 according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI).[15,16] Subjects were excluded if they had significant oral soft tissue pathology; severe periodontal disease or concurrent periodontal treatment; peri/oral piercings or removable partial dentures; self-reported serious medical conditions; under treatment for a heart condition requiring use of a pacemaker; required antibiotic premedication prior to dental procedures; use tobacco products, had antibiotic, anti-inflammatory, anti-coagulant medication or chemotherapeutic antiplaque/antigingivitis therapy within 30 days of screening; or participated in any study involving oral care products concurrently or within 30 days of screening. This study population evaluated the effect of the two toothbrushes in subjects with primary/mixed dentition and adult dentition. Each toothbrush group contained at least 10 subjects with primary and mixed dentitions.

Following the Screening Visit, qualified subjects participated in a 7- to 14-day Washout period prior to Baseline so that subjects avoided use of anti-plaque and anti-gingivitis mouth rinses, dentifrices or other dental products that can interfere with their plaque or gingivitis status.. Subjects used an ADA Accepted fluoride toothpaste (Crest® Cavity Protection, Procter and Gamble Co., Cincinnati, OH, USA) and an ADA reference standard soft bristle manual toothbrush as their only oral hygiene regimen during the washout period.

All subjects who enrolled in the study agreed to refrain from dental treatment during the course of the study, except on an emergency basis, and to discontinue the use of other oral hygiene products for the duration of the study. Prior to each exam visit, subjects refrained from oral hygiene for 12 to 16 hours and were instructed to avoid eating or drinking 30 minutes prior to the visit. Sipping water was permitted prior to each exam visit. At Baseline, Day 15 and Day 30, subjects confirmed their consent and assent to continue their participation in the study and received clinical assessments in the following order:

- Oral safety (soft and hard tissue examination for evidence of irritation or other abnormalities);
- Gingivitis according to the MGI;
- Gingival recession, measured as the visible distance from the cemento-enamel junction (CEJ) to the gingival margin;
- Gingival Abrasion as described by Danser[17], Rosema[18] and Van der Weijden[19].
- Supragingival plaque levels according to LSPI.

Subjects meeting baseline inclusion criteria were stratified by age: pediatric dentition group (≥ 5 and < 12) and adult dentition group (≥ 12 and ≤ 65). Eligible subjects were randomly assigned to one of two toothbrush groups, such that each group contains at least 10 pediatric subjects, hence, this study population included subjects with primary/mixed dentition and adult dentition.

2.3.1 Study Materials Assignment and Procedures

Qualified subjects were randomly assigned to one of two treatment groups:

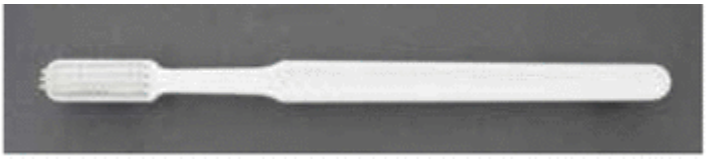
1) **Control Group (Manual Toothbrush)**:Twice daily brushing for two minutes with an ADA reference standard manual soft toothbrush and Crest® Cavity Protection with 0.24% sodium fluoride toothpaste (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).
2) **Sonic Toothbrush (AutoBrush® 360° U-Shaped Sonic Toothbrush)**: Twice daily brushing for 30 seconds with AutoBrush® Sonic Toothbrush and Crest® Cavity Protection with 0.24% sodium fluoride toothpaste (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).

Subjects were provided verbal and written instructions on the use of their assigned toothbrush and maintained a daily diary to document compliance. For the first use, all subjects brushed with their assigned toothbrush under the supervision of study personnel and twice daily subsequent uses were performed at home unsupervised. Participants between 5 and 8 years of age conducted their toothbrush procedures under the supervision of their parent or guardian. Subjects assigned to the AB group were dispensed the AB base handle and the two-sided toothbrush head (mouthpiece) with nylon bristles, appropriate for their mouth size, ranging from: Ages 3-5, 6-8, 9-12, Adult Small, Adult Regular, and Adult XL. A registered dental hygienist dispensed the test products and ensured that the selected mouthpiece provided adequate coverage over all teeth. The AB has a 30-second cycle time which simulates a full 2-minute brushing for all quadrants of the mouth and was set for “deep clean” mode. Figure 2 displays the product features which are the same for adult devices. Each AB package included the charging base with the charging cord, two-sided brush head (mouthpiece) and the base handle. If assigned to the ADA reference MTB (See Figure 3), subjects brushed their teeth twice daily in

their usual manner for 2 minutes. Irrespective of the toothbrush assignment, the fluoride toothpaste volume was dispensed on the brush heads based on acceptable safety standards. Juvenile subjects, age 5 to 8 years, dispensed a smear of toothpaste (~0.25 grams onto the brush head and subjects ≥ 9 years of age used a full ribbon (~1.5 grams).

Figure 2. AutoBrush® Package

Figure 3. ADA Reference Standard Manual Toothbrush

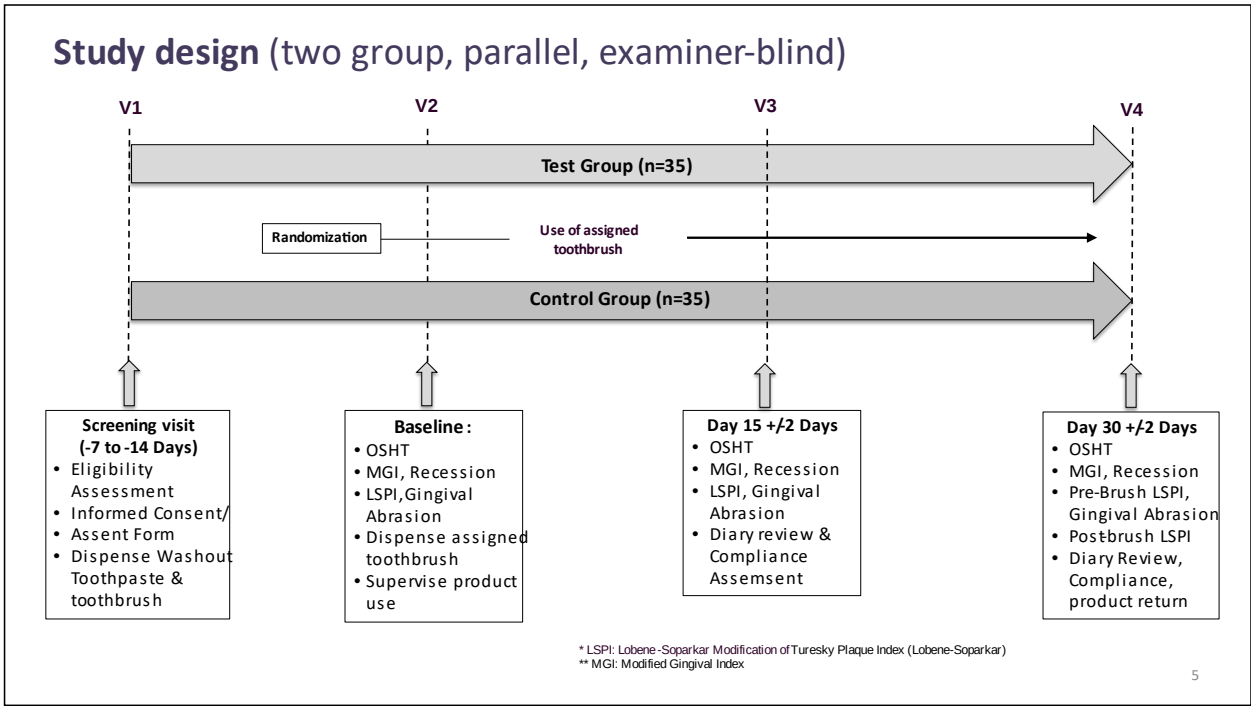


Toothbrush Group assignment process, subsequent product distribution and supervised brushing procedures were conducted in a protected area that ensured blinding of the clinical examiner and the data recorders to subjects' assignments to their toothbrush. Following the Baseline exams, subjects returned at Days 15 and 30 for the same assessments for oral safety, gingival health and plaque. At the Day 30 visit only, subjects received a pre-brushing plaque exam followed by a post-brushing plaque exam to assess the immediate plaque removal with the assigned toothbrush.

Throughout the study, subjects refrained from using any oral care products other than the toothbrush or toothpaste provided to them and avoided the use of other toothbrushes, toothpaste, mouthwashes, chewing gum, breath film, mints, floss or interdental cleaning aids, or other oral care cleaning aids for the duration of this research study. Subjects who routinely use interdental aids were permitted to continue use throughout the study.

Detailed Description of the study design is provided in Figure 4.

Figure 4.



2.3.2 Safety parameters

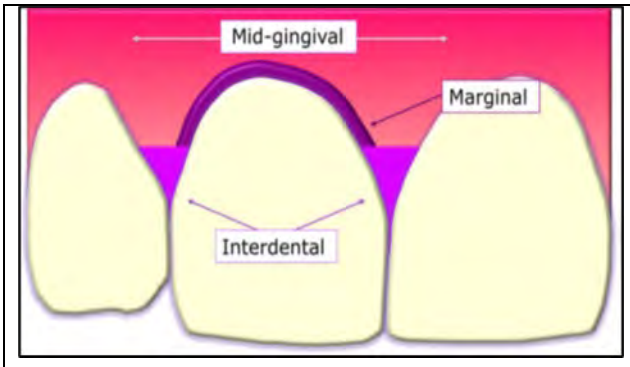
Safety was assessed with respect to AEs and OSHT abnormalities (oral tolerability). Adverse events (AEs) spontaneously reported by the subjects or observed by the site staff were monitored and recorded from the time of the first test product use until the End of Study (or early termination).

Additional safety measures included:

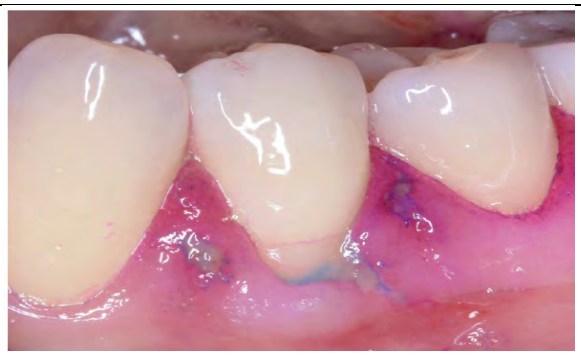
- Change in gingival recession scores at Day 15 and Day 30. Gingival recession was evaluated at Baseline (Visit 2), Day 15 (Visit 3) and Day 30 (Visit 4) using a manual probe (Hu-Friedy® Michigan-0 with William's markings at 1,2,3,5,7,8,10 mm), at six sites per tooth (mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual, and distolingual). Recession was measured as the visible distance from the cemento-enamel junction (CEJ) to the gingival margin. Only positive measurements indicating recession were recorded.

- Change in number of gingival abrasion values for each of the 3 categories, small (≤2 mm), medium (3–5 mm) and large (>5 mm) Day 15 and Day 30. The development of abraded gingival tissue was evaluated on both the facial and lingual gingival surfaces of each tooth at Baseline, Day 15 and Day 30. The gingival tissues of each tooth were divided into 3 areas on both the facial and lingual surfaces: marginal (cervical free gingiva), interdental (papillary free gingiva) and mid-gingival (attached gingiva). Young-2-Tone® disclosing solution was used to help visualize abraded areas of the oral epithelium for each tooth as described by Danser[17] , Rosema[18] and Van der Weijden[19] as illustrated in Figure 5.

Figure 5. Gingival Abrasion Assessment



(From Rosema et al 2014)[18]



(From Faus-Damiá 2015)[20]

2.3.3 Efficacy Parameters

Clinical efficacy assessments were performed by a single examiner at Baseline, Days 15 and 30 in the following sequence: MGI and LSPI.

The primary efficacy variables were the mean change from Baseline in Whole Mouth MGI scores at Day 30 and the mean change in Whole Mouth LSPI scores at Day 30, immediate post-brushing (Pre-brushing to Post-brushing scores).

Gingivitis: Gingival inflammation was assessed at Screening, Baseline, Days 15 and 30, according to the Modified Gingival Index (MGI),[14] and was scored in six areas (distobuccal, midbuccal and mesiobuccal, distolingual, midlingual and mesiolingual) of all scorable teeth using a scale of 0 – 4. Whole mouth MGI scores were calculated by summing all scores and dividing by the number of scorable sites examined. For more details, see Protocol Section 9.3.1 in Appendix 5.1.1.

Supragingival dental plaque: Plaque was measured at Screening, Baseline, Days 15 and 30 (Pre- and Post-Brushing), according to the Turesky Modification of the Quigley-Hein Plaque Index[15], as further modified by Lobene and Soparkar (LSPI).[16] Plaque was disclosed using Young-2-

Tone® disclosing solution and each tooth was scored in six areas (distobuccal, midbuccal and mesiobuccal, distolingual, midlingual and mesiolingual), according to a 0 to 5 scale.

2.4 STATISTICAL METHODS

With 35 completed subjects per treatment group, the study had 80% power to detect a difference between treatments of 0.42 units in MGI and 0.26 units in LSPI after 30 days of treatment, assuming a standard deviation of 0.62 for MGI and 0.38 for LSPI, with a 0.05 two-sided significance level.

All eligible subjects who were randomized into the study and performed at least one use of the study product were included in the safety analysis (e.g., the Safety Population). The Per-protocol (PP) population included subjects who did not have any major protocol violations. Data for safety analysis included all subjects who were randomized and received one of the assigned test products.

2.4.1 Demographic and Baseline Characteristics:

Demographic variables (age, gender, race, and ethnicity) and Baseline characteristics (mean MGI and LSPI) were summarized by treatment group and overall. Demographic and Baseline characteristics were summarized for age, gender, race, mean MGI, and LSPI. Comparisons between the treatment groups were performed using chi-squared tests for categorical variables, and t-tests for all continuous variables.

All tests were two-sided and conducted at the 0.05 significance level. No adjustments were made for multiple comparisons or multiple testing.

2.4.2 Safety Analysis

Clinical safety endpoints included AEs and SAEs and gingival recession and gingival abrasion scores. OSHT abnormalities were included as AEs if they appeared or worsened after the initial assessment. All findings regarding OSHT observations, AEs, SAEs, gingival recession, and gingival abrasion were presented in listings. The number and percentage of subjects experiencing adverse events, tabulated by treatment group was planned.

For gingival recession scores, cross tabulations were prepared for each toothbrush group to illustrate findings from visits to subsequent follow up visits (Baseline vs. Day 15, Baseline vs. Day 30, and Day 15 vs. Day 30. The cross tabulations presented the number of measured sites that exhibited each score transition. In addition, the percentage of transitioned scores from an earlier visit are presented. A table was prepared that presented, for each study visit, a summary of the subject-wise mean recession scores for each treatment, and the number and percentage of subjects in each treatment group that presented at least one measured site with

recession of 1mm or higher; and that presented at least one measured site with recession of 2mm or higher.

For gingival abrasion, change in number of gingival abrasion values in two of the three defined categories was provided at Day 15 and Day 30: small (≤2 mm), medium (3–5 mm). (It is noted that no subject presented with large lesions [>5 mm] at any timepoint.) Summaries of the subject-wise mean abrasion scores by treatment group and visit included:

- A summary of the scores at the visit, and for post-baseline visits, a summary of the changes from baseline at the visit;
- For each post-baseline visit, based on an analysis of covariance (ANCOVA) model that employed the treatment group as a fixed effect, and that included the corresponding baseline value as a covariate: an estimate of the change from baseline that included the Least-squares mean (LS mean) and its standard error; a 95% confidence interval for the LS mean; and the p-value for the comparison of the LS mean change versus zero; results of a comparison of the AB group versus the MTB control group with respect to the changes from baseline, including the difference between the LS means for the treatments, and its standard error; a 95% confidence interval for the difference; and p-value from the between-treatment comparison;
- Cross tabulations were prepared as described for the gingival recession scores. These cross tabulations were prepared separately for transitions of abrasion scores; and also for transitions of assigned abrasion category scores (as described above). Sites that did not present abrasion were assigned a category score of zero. Two additional summary tables were prepared for the gingival abrasion data:
    - A summary indicating, for each treatment and study visit, a categorical distribution of subjects according to the number of measured sites that presented any abrasion (0 sites; between 1 and 4 sites; between 5 and 8 sites; and 9 or more sites);
    - the number of measured sites that presented Category 1 lesions (0 sites; between 1 and 4 sites; between 5 and 8 sites; and 9 or more sites);
    - the number of measured sites that presented Category 2 lesions (0 sites; between 1 and 4 sites; between 5 and 8 sites; and 9 or more sites);
    - The number and percentage of subjects with at least 1 site presenting an abrasion lesion of 1mm or higher; presenting an abrasion lesion of 2mm or higher; and presenting an abrasion lesion of 3mm or higher.

Further details are presented in the Statistical Report, Appendix 5.2.

2.4.3 Efficacy Analysis

For each efficacy variable, a summary of the subject-wise mean scores by treatment group and visit was provided, presenting the same content as described above for the analysis of subject-wise mean gingival abrasion scores.

Data listings were provided for all efficacy variables.

The primary efficacy variables were:

- Whole mouth mean change in MGI scores at Day 30.
- Whole mouth mean change in LSPI scores at Day 30, immediate post-brushing (Pre- to Post-Brushing scores).

Secondary Efficacy Variables:

- Mean MGI change from Baseline at Day 15:
  - Whole mouth;
  - Gumline (marginal);
  - Proximal;
  - Distal score of the last posterior tooth in each quadrant.
- Mean MGI change from Baseline at Day 30:
  - Gumline;
  - Proximal;
  - Distal score of the last posterior tooth in each quadrant.
- Mean LSPI change from Baseline at Day 15:
  - Whole mouth;
  - Gumline;
  - Proximal;
  - Distal score of the last posterior tooth in each quadrant.
- Mean LSPI change from Baseline at Day 30:
  - Pre- and Post- brushing Gumline;
  - Pre- and Post- brushing Proximal;
  - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.

Analyses were performed at Days 15 and 30 for each efficacy variable, using the ANCOVA model with treatment as a factor and the corresponding baseline value as a covariate. The comparisons were made at the 0.05 level, 2-sided. Differences between the means, simultaneous 95% confidence intervals and test results were presented.

2.4.3.1 Changes in Conduct of Planned Analysis

Any changes in the planned analyses that were described in Section 11 of the Protocol (Appendix 5.1.1) and described in the Statistical Report (Appendix 5.2) are summarized here.

- Demographics data comparisons between the toothbrush groups were performed using chi-squared tests for categorical variables, and t-tests for all continuous variables instead of the Fisher's Exact Test.
- Summary tables of site-wise assessment of gingival recession transition of scores (mm) for each toothbrush from Baseline to Day 15 Visit, Baseline to Day 30 Visit, Day 15 to Day 30. The protocol did not stipulate any summary of site-wise scores. Cross-tabulations were added to present a clear picture of changes in site-wise recession findings over the course of the study.
- Analysis methodology for subject-wise mean recession scores was not mentioned in the protocol but the analysis employed an ANCOVA model.
- For gingival recession, the number and percentage of subjects in each treatment group at each study visit with at least one measured site with recession of 1mm or higher; and one measured site with recession of 2mm or higher was added to the analysis to enhance the understanding of the possible impact of the toothbrushes on gingival recession.
- For gingival abrasion, data summaries are presented for cross-tabulations of site-wise score transitions between pairs of visits and cross-tabulations of site-wise abrasion category transitions between pairs of visits. The protocol did not mention this methodology but these cross-tabulations help to present a clear picture of changes in site-wise gingival abrasion findings over the course of the study.
- The protocol proposed analysis of mean change in gingival abrasion scores for each of the 3 categories was replaced by the cross-tabulations described above. The cross-tabulations provide a clearer picture of the possible changes in gingival abrasion that could occur within each treatment group over the course of the study.
- Not described in the protocol, categorical distributions were presented of subjects according to numbers of sites with specific abrasion findings by treatment and visit since this analysis is a useful adjunct to the other data analyses on gingival abrasion scores.
- Although not described in the protocol, analysis of subject-wise mean abrasion scores employed an ANCOVA model as a useful adjunct to the other data analyses on gingival abrasion scores.
- Analysis of subject-wise mean abrasion scores employing an ANCOVA model.
- The protocol had mentioned Dunnett's test for the post-ANCOVA pairwise treatment comparisons; however, that methodology was not applicable to this two-treatment study.

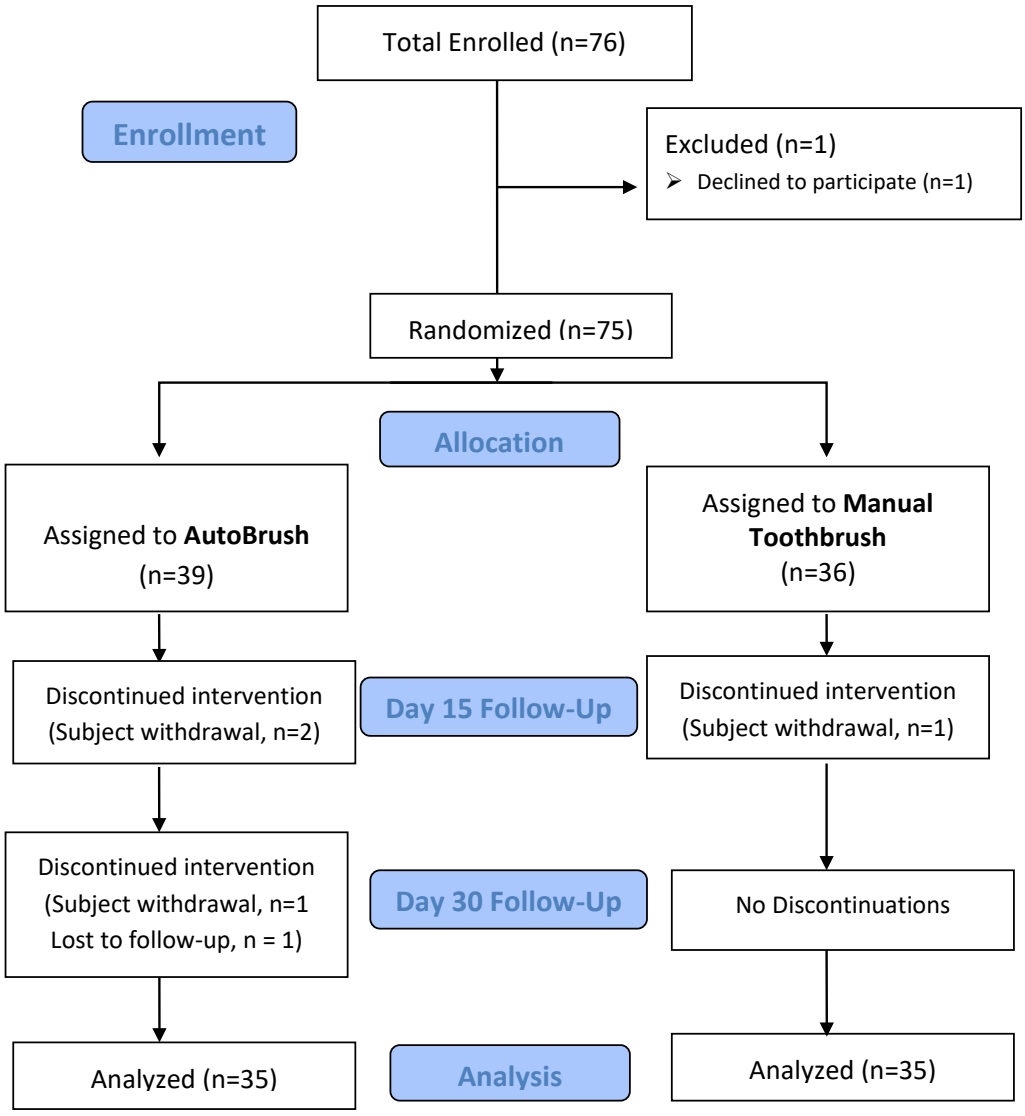
- No analyses were performed on AEs since only one subject was present with an AE so there was no need for statistical analysis.

A detailed description of the changes in statistical analysis methods is provided in the Statistical Report in Appendix 5.2.

3 SUMMARY RESULTS AND CONCLUSIONS

Subject recruitment and screening commenced September 11, 2023, and the study was completed October 27, 2023. Subject flow through the study is presented in Figure 6. Of the 76 subjects screened, 75 subjects met the study entrance criteria and were randomized to one of the two treatment groups. Two subjects randomized to the AB group withdrew from the study prior to Day 15, two subjects withdrew from the study prior to Day 30; one subject randomized to the MTB group withdrew prior to Day 30 and 70 subjects completed all study visits. A summary of subject disposition is provided in Table 4.1.

Figure 6. Flow Diagram



Source: Table 4.1, Listing 5.3.2

Demographics characteristics for the 70 subjects who completed the study are provided in **Table 1** and Table 4.2. Subjects ranged in age from 5 to 64. Although the mean age was slightly higher in the Control group, this difference was not statistically significant. The AB toothbrush group consisted of 48.6% males and 51.4% females; the MTB group consisted of 25.7% males and 74.3% females. Both toothbrush groups comprised predominately of White subjects and fewer than % of the subjects in the study were Hispanic/Latino. The whole mouth MGI and LSPI at baseline were comparable in both groups.

Table 1: Demographic and Baseline Characteristic (Per-Protocol Population*)

Parameters	AutoBrush® (AB) (n=35)	Manual Toothbrush (MTB) (n=3)	Total (N=75)
Age, mean (SD), years	**33.89 (22.13)**	**35.26 (19.95)**	**34.57 (20.93)**
Range	5.0, 64.0	6.0, 63.0	5.0, 64.0
			p=0.7862**
Gender			
Male, n (%)	17 (48.6%)	9 (25.7%)	26 (37.1%)
Female, n (%)	18 (51.4%)	26 (74.3%)	44 (62.9%)
			p=0.0478†
Race, n (%)			
American Indian /Alaskan Native	0	0	0
Black or African American	3 (8.6%)	6 (17.1%)	9 (12.9%)
White	30 (85.7%)	28 (80.0%)	58 (82.9%)
Native Hawaiian or other Pacific Islander	0	0	0
Asian	2 (5.7%)	1 (2.9%)	3 (4.3%)
Other	0	0	0
			p=0.4960†
Ethnicity, n (%)			
Hispanic/Latino	1 (2.9%)	2 (5.7%)	3 (4.3%)
Non-Hispanic/Non-Latino	34 (97.1%)	33 (94.3%)	67 (95.7%)
			p=0.5551†
Baseline whole mouth MGI, mean (SD)	**2.67 (0.23)**	**2.60 (0.30)**	**2.63 (0.27)**
			0.3211**
Baseline whole mouth LSPI, mean (SD)	**3.27 (0.45)**	**3.31 (0.49)**	**3.29 (0.47)**
			p=0.6894**

Source: Table 4.2, Table 4.3.1, Table 4.4.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

** For age, MGI, and LSPI, p-values from two-sided t-tests are presented;

† For gender, race, and ethnicity, p-values from chi-squared tests are presented.

Compliance: Based on review of completed diaries and interviews with subjects, all 70 subjects were compliant with their twice daily use of their assigned toothbrush. All subjects attended study visits as scheduled with the exception of 10 subjects who did not present for the Baseline visit within the 7- to 14-day window of the Screening visit (all 10 attended the Baseline visit 6

days following the Screening visit). This deviation was considered minor and is documented in the Protocol Deviation Log (Appendix 5.3.3).

All subjects, study staff and investigators were compliant with the clinical trial protocol and Good Clinical Practice (GCP) requirements.

3.1 SAFETY RESULTS

3.1.1 Adverse Events

There were no treatment-related oral adverse events observed or reported during the study demonstrating that all treatment materials were well tolerated in this study.

3.1.2 Gingival recession

Participation in this study was restricted to subjects with gingival recession levels ≤ 2 mm. The pre-existing gingival recession measurements (mm) averaged 0.041mm and 0.038mm for the AB and MTB, and remained unchanged at Day 15 and Day 30 (Table 4.5.8). At the Baseline visit, 20 subjects (57.1%) in the AB group presented with at least 1 site with 1mm gingival recession or higher and only 11 subjects (31.4%) had recession levels of 2mm. In the MTB group, 22 subjects (62.9%) had recession levels of 1 mm and 9 subjects (25.7%) had recession level of 2mm. No site presented a recession score greater than 2mm at any follow up visit (see Listing 5.3.6.1). The mean recession scores (mm) over all examined sites are summarized in Table 4.5.8. At each post-baseline visit, except for a handful of instances, each measured site presented the same recession score as noted at the Baseline. Detailed information of recession scores at each visit is presented in Tables 4.5.1-4.5.6 and includes the total number of sites examined and the number of examined sites that presented scores of 0mm, 1mm, and 2mm.

3.1.3 Gingival Abrasion

Categorical summary: At Baseline, the percentage of subjects presenting at least one site with gingival abrasion was 77.1% in the AB group, and 74.3% for the MTB group (Table 4.6.13). The percentage of subjects presenting any level of gingival abrasion at follow up visits tended to be numerically higher in the MTB group. At Day 15, 60.0% of subjects in the AB group presented at least one gingival site with abrasion while there were 82.8% of subjects in the MTB group. By Day 30, the percentage of subjects with at least one abrasion site decreased to 48.6% for AB group and 68.6% for the MTB group. At the Baseline visit, a very small number of subjects had at least one site with a Category 2 abrasion lesion (3mm or higher), AB group = 1 and MTB group = 4. At Day 15 and Day 30, the AB group did not experience any Category 2 lesions, while the MTB group had 2 and 3 subjects at Day 15 and Day 30, respectively.

Analysis of mean abrasion scores: Statistically significant reductions from Baseline were observed for the AutoBrush group only, (Table 4.6.14) for Day 15 and Day 30 follow up visits, $p=0.0002$ and $p<0.0001$. The Baseline mean scores were low for each group, 0.023 for the AB

group and 0.026 for the MTB group. At Day 15, the mean scores were lower for the AB group (0.010) compared to the MTB group (0.030). At Day 30, means scores for AB (0.007) and the MTB group (0.023). At Days 15 and 30, the AB group provided significantly greater reductions in abrasion compared to the MTB group, p<0.002.

Site-wise score transitions: For each of the toothbrushes with sites presenting with no gingival abrasion at Baseline, over 98% presented no abrasion at the Day 15 and Day 30 follow up visits. See Tables 4.6.1 – 4.6.6. For sites that presented any abrasion at Baseline, most sites transitioned to lower abrasion levels at the follow up exams.

Site-wise transitions of Category scores**:** Examined sites that did not present gingival abrasion were assigned to abrasion Category 0, Category 1 represented sites with small (≤2 mm) abrasions, and Category 2 represented sites with medium (3–5 mm) abrasions. Category score transitions was similar to the site scores previously described.

3.2 EFFICACY RESULTS

3.2.1 Primary Efficacy Endpoints

Participants who enrolled in this study presented with mild-to-moderate gingivitis (Baseline MGI score of 1.9 to 3.0). Summary data for the primary efficacy variables is provided in Table 2 and Figure 7 for mean changes in whole mouth MGI scores at Day 30 and the mean changes in whole mouth LSPI scores at Day 30, immediate post-brushing (Day 30 Pre- to Post-brushing).

3.2.1.1 Day 30 Gingivitis Efficacy

At Baseline, there was no significant difference between the groups for whole mouth MGI, with mean scores of 2.67 and 2.60 for the AutoBrush and Manual Toothbrush groups, respectively (p=0.321). See Table 1. Brushing for 30 days resulted in statistically significant improvement in MGI levels relative to the Baseline scores for both toothbrush groups, p<0.0001. Compared to the MTB control group, the AB group provided significantly greater whole mouth mean MGI reductions of 44.7%, p<0.0001. See Table 2 and Figure 7. The magnitude of improvement in gingivitis for the AB was 5 times greater than the MTB group at Day 30.

3.2.1.2 Day 30 Plaque Removal Efficacy After Single Brushing

Subjects in each group presented with appreciable levels of supragingival plaque at Baseline with mean whole mouth mean LSPI scores of 2.67 and 2.60 for the AB and MTB groups, respectively, which did not differ significantly (p=0.689); see Table 1. Following the single brushing at Day 30 (Pre-Brushing to Post-Brushing), both toothbrushes significantly reduced whole mouth LSPI, 1.279 for the AB group and 0.253 for the MTB group, p<0.0001. The mean difference between the two groups was 1.395; compared to the MTB group, AB yielded 44.88% greater whole mouth plaque removal (p<0.0001), see Table 2. The difference in post-brushing scores reflect a 5.1 times greater plaque removal effect for the AB group.

Results are illustrated in Figure 7 and greater details of MGI and LSPI results are provided in Tables 4.3.1 and 4.4.1, respectively.

Table 2. Summary for Primary Efficacy Variables: Day 30 Whole Mouth MGI, Day 30 Pre- to Post-Brush Whole Mouth LSPI

	Summary of Scores at Visit			Summary of Changes from Baseline			
MGI	**n**	**Mean (S.D.)**	**% Diff. vs. Control ‡**	**n**	**Mean (S.D.)**	**p-value vs. Baseline***	**p-value vs. Control†**
AutoBrush® Group							
Baseline	35	2.666 (0.228)	--				
Day 30	35	1.286 (0.428)	44.76%	35	-1.379 (0.361)	<0.0001	<0.0001
Manual Toothbrush Group							
Baseline	35	2.602 (0.298)	n/a				
Day 30	35	2.328 (0.452)	n/a	35	-0.274 (0.356)	<0.0001	n/a

	Summary of Scores at Visit			Summary of Changes from Pre-Brushing			
LSPI	**n**	**Mean (S.D.)**	**% Diff. vs. Control ‡**	**n**	**Mean (S.D.)**	**p-value vs. Pre-Brushing$^{\Omega}$**	**p-value vs. Control$^{\Upsilon}$**
AutoBrush® Group							
Day 30 Pre-Brushing	35	2.992 (0.351)					
Day 30 Post-Brushing	35	1.713 (0.288)	44.9%	35	-1.279 (0.201)	<0.0001	<0.0001
Manual Toothbrush Group							
Day 30 Pre-Brushing	35	3.361 (0.389)	n/a				
Day 30 Post-Brushing	35	3.108 (0.371)	n/a	35	-0.253 (0.119)	<0.0001	n/a

‡ Percentage difference between the mean follow-up visit score and the corresponding mean score for the Control group. A positive value of % difference reflects a lower score for the Test group being summarized.

* within-group p-value comparing the mean score at the follow-up visit versus the mean score at baseline.

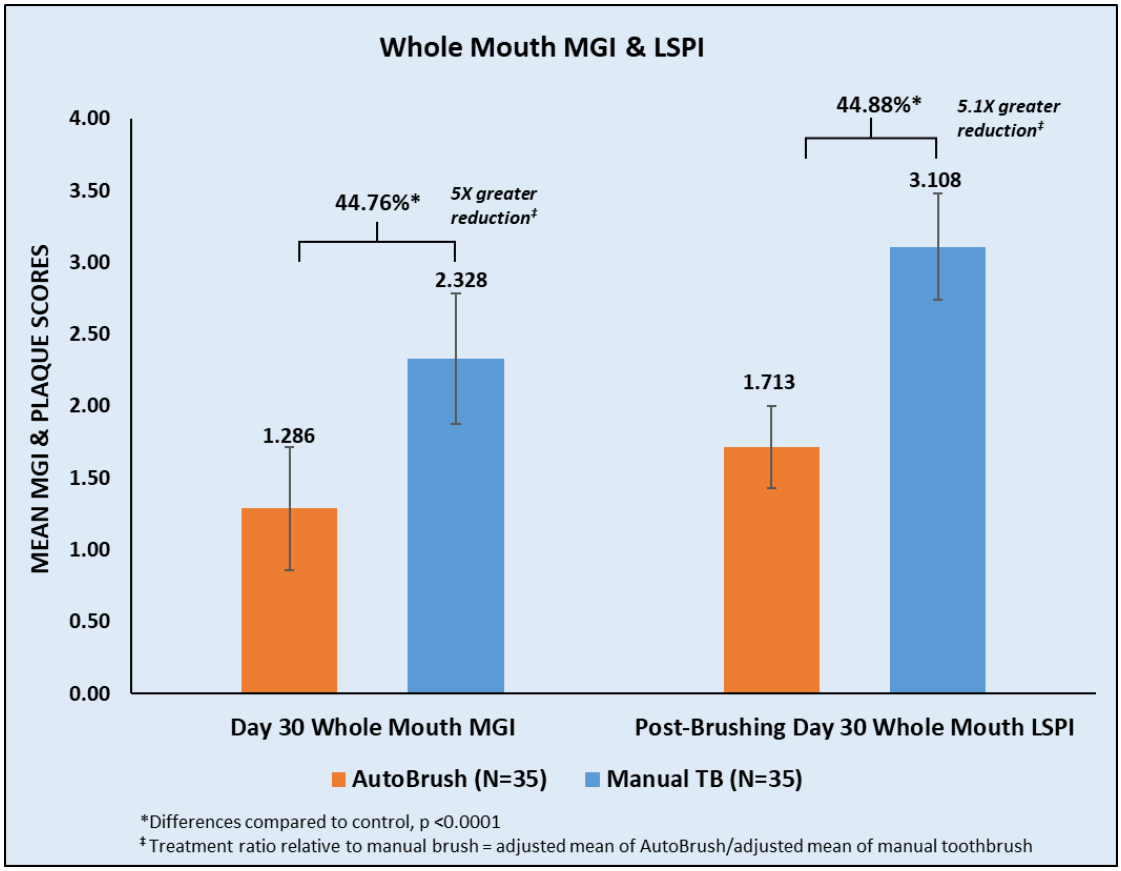
†between-group p-value comparing the mean change from baseline for the indicated test group versus the corresponding change for the Control group

$^{\Omega}$ within-group p-value comparing the mean score at the post-brushing visit versus the Pre-brushing mean score at Day 30

$^{\Upsilon}$ between-group p-value comparing the mean change from Pre-Brushing for the indicated test group versus the corresponding change for the Control group

Source: Table 4.3.1, Table 4.4.1

Figure 7. Day 30 Whole Mouth MGI and Pre- to Post-Brush Whole Mouth LSPI Results



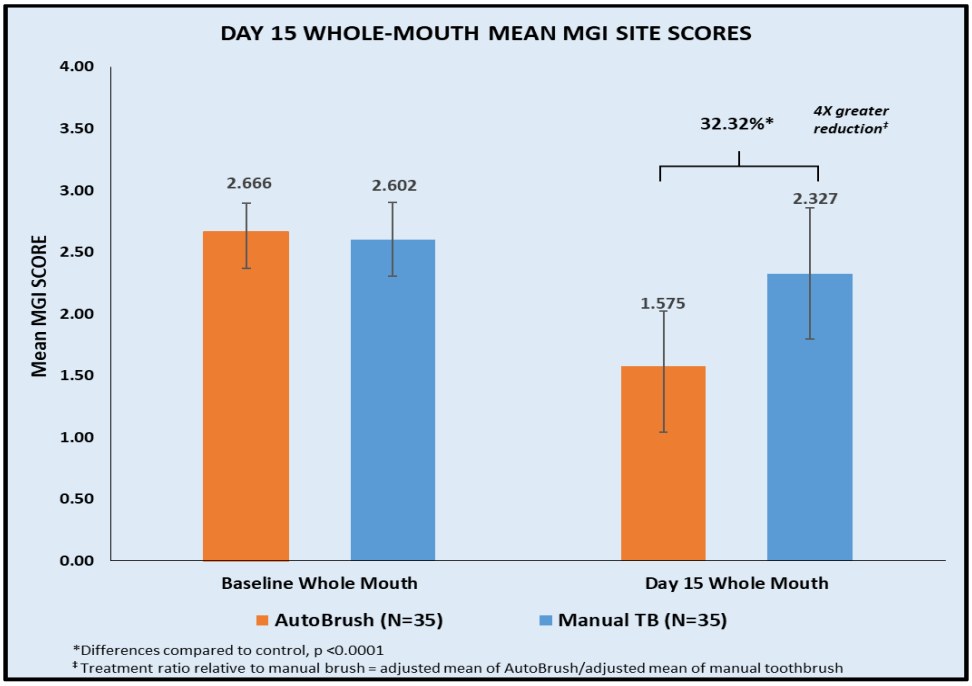
Source: Table 4.3.1, Table 4.4.1

3.2.2 Secondary Efficacy Variables

3.2.2.1 Gingivitis

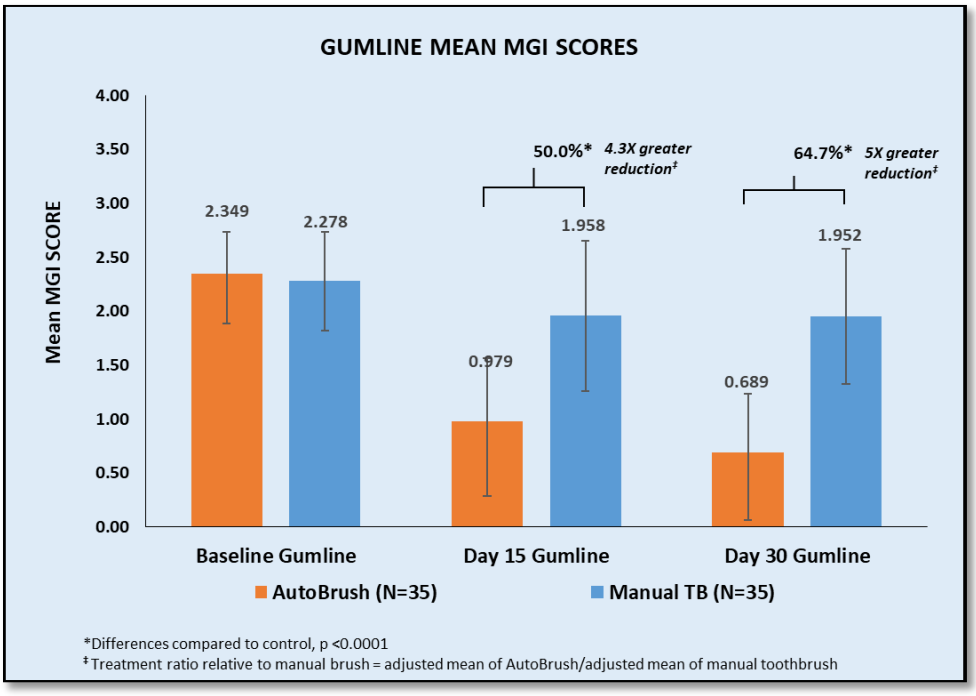
After 15 days of brushing with the assigned toothbrushes, statistically significant improvement in whole mouth MGI levels relative to the Baseline scores were seen for both toothbrush groups (p<0.0001). Between group comparisons were favorable for the AB group compared to the MTB with 32.3% greater improvement in whole mouth MGI, p<0.0001 (Table 4.3.1; Figure 8). Analysis of the hard-to-reach areas (gumline, proximal, and most distal surfaces) are provided in Tables 4.3.2, 4.3.3 and 4.3.4 and described in Figure 9, Figure 10 and Figure 11. At Days 15 and 30, statistically significant improvement from Baseline was observed for all hard-to-reach areas for all toothbrush groups, p<0.001. Compared to the MTB at Days 15, the AB provided greater reductions in gingivitis of 50.0%, 25.4% and 37.4% (p<0.0001), respectively, for gumline, proximal and most distal areas. The magnitude of MGI reductions at Day 15 favored the AB group with up to 4 times greater improvement in hard-to-reach areas over the MTB group. Similar results were observed for Day 30 with the AB product reducing gingivitis levels for the three hard-to-reach areas by 64.7%, 37.0% and 53.5%, respectively, p<0.0001, compared to the MTB and up to a 5 fold greater difference in gingivitis improvement.

Figure 8. MGI Results for Whole Mouth at Day 15



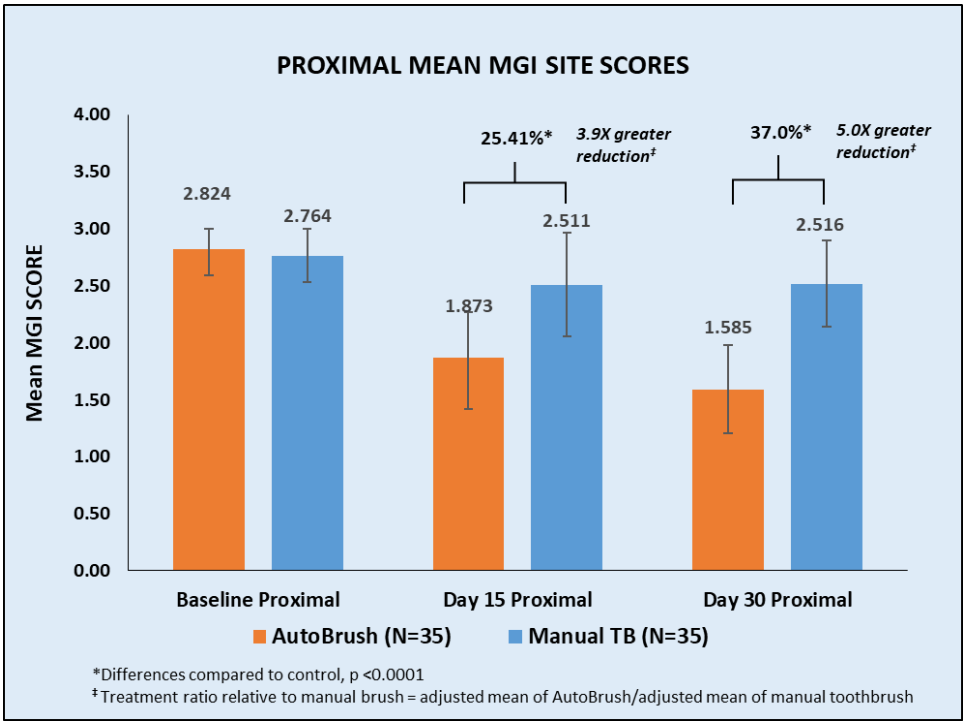
Source: Table 4.3.1

Figure 9. MGI Results for Gumline Sites



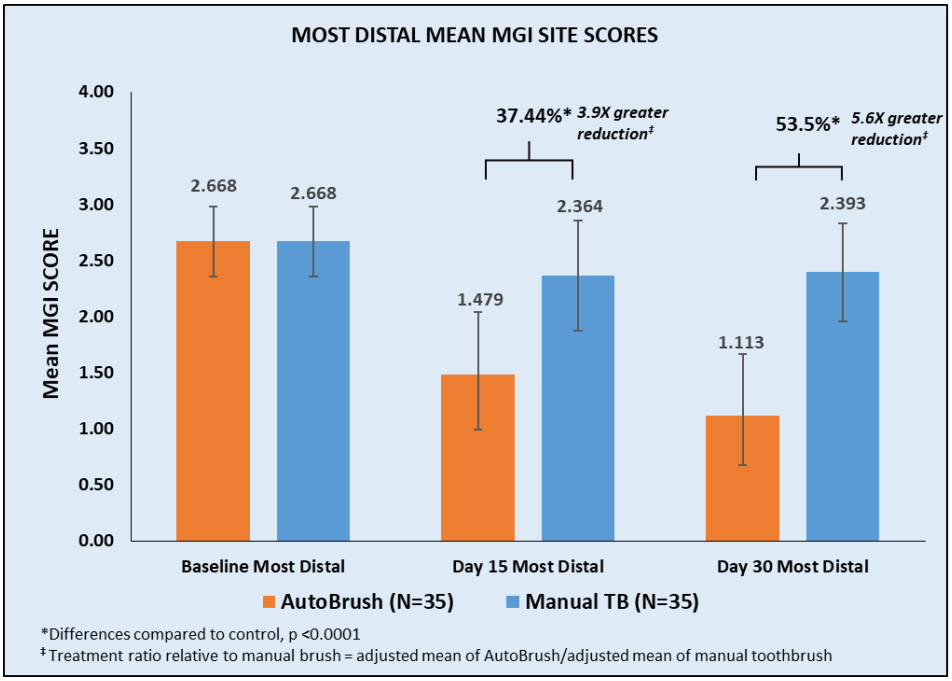
Source: Table 4.3.2

Figure 10. MGI Results for Proximal Sites



Source: Table 4.3.3

Figure 11. MGI Results for Most Distal Sites



Source: Table 4.3.4

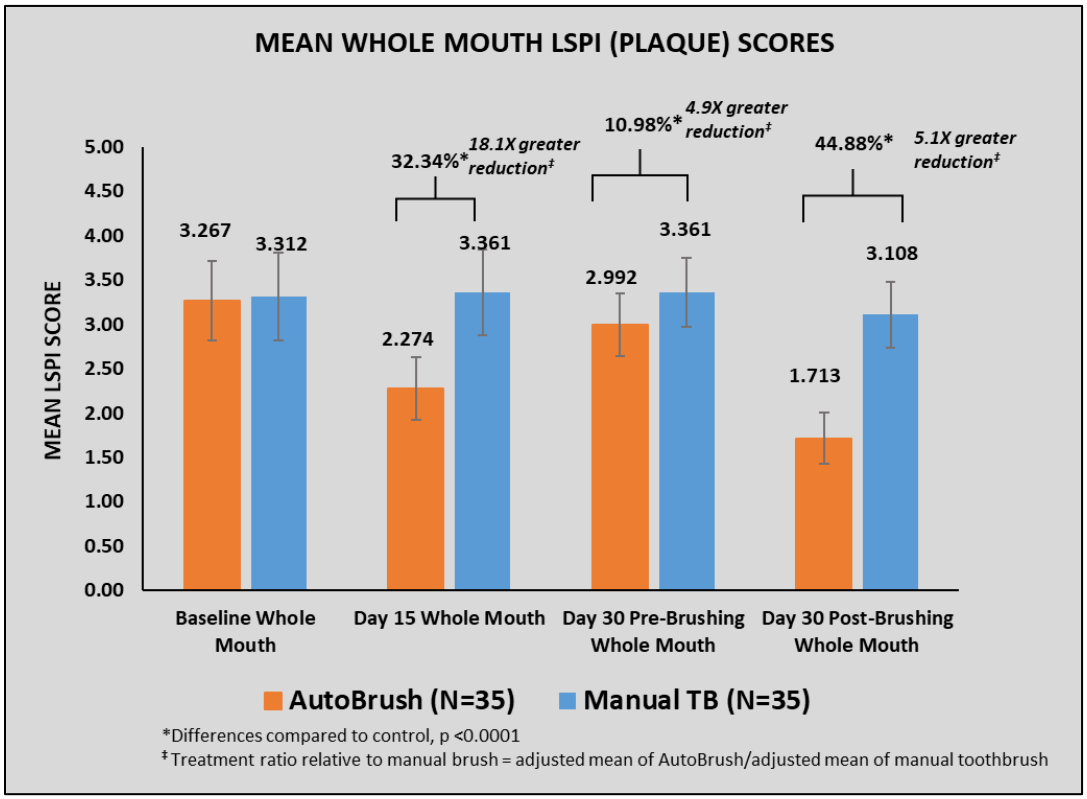
3.2.2.2 Supragingival Plaque Removal

At Baseline, there were no differences between the two groups with respect to whole mouth mean LSPI scores of 3.27 and 3.31, respectively, for AB and MTB (p=0.6894; Table 1). Only the AB group showed significant (P< 0.001) reductions from Baseline in whole mouth, gingival margin, proximal and the most distal area plaque scores at Day 15 and Day 30 (p<0.0001). The AB group significantly reduced more plaque than MTB at Day 15 for whole mouth mean scores as well as at Day 15 and Day 30 for gumline, proximal and most distal surfaces (p<0.0001). After 15 days of brushing, the AB was found to have significantly greater plaque removal for whole mouth scores (32.3%), gumline areas (54.1%), proximal (22.5%), and most distal surface sites (18.2%). Compared to the MTB group at Day 30, significantly greater reductions continued for the whole mouth scores with 10.9% greater removal for the AB group and in the hard-to-reach areas (gumline, proximal and most distal areas) with reductions of 15.7%, 8.8% and 10.8%, in the hard-to-reach areas, respectively. Details of LSPI results (whole mouth, gumline, proximal, and most distal regions) are provided in Table 4.4.1, 4.4.2, 4.4.3, and 4.4.4 and are illustrated in Figure 12, Figure 13, Figure 14 and Figure 15.

3.2.2.3 Plaque Removal After Day 30 Single Brushing

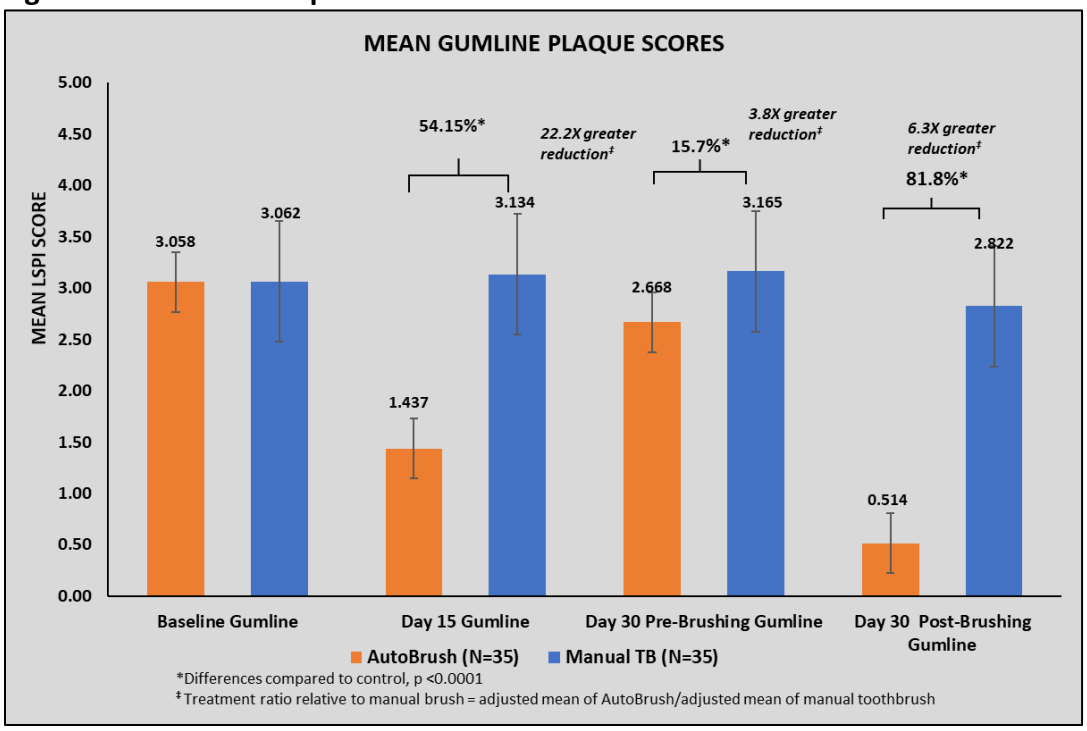
Following the single brushing at Day 30 (Pre-Brushing to Post-Brushing), both toothbrushes significantly reduced LSPI mean whole mouth scores and in the hard-to-reach-areas (gumline, proximal and most distal areas), p<0.01. Compared to the MTB group, the AutoBrush® provided 44.9%, 81.8%, 28.8% and 49.7% greater plaque removal following the Day 30 single brushing, for whole mouth and the gumline, proximal and most distal regions, respectively (p<0.0001). The magnitude of plaque reduction for the AB was 5.1, 6.3, 4.1 and 8.2 times greater than the MTB for whole mouth and the hard-to-reach areas. See Figures 12 - 15.

Figure 12. Whole Mouth Plaque Scores at Each Visit



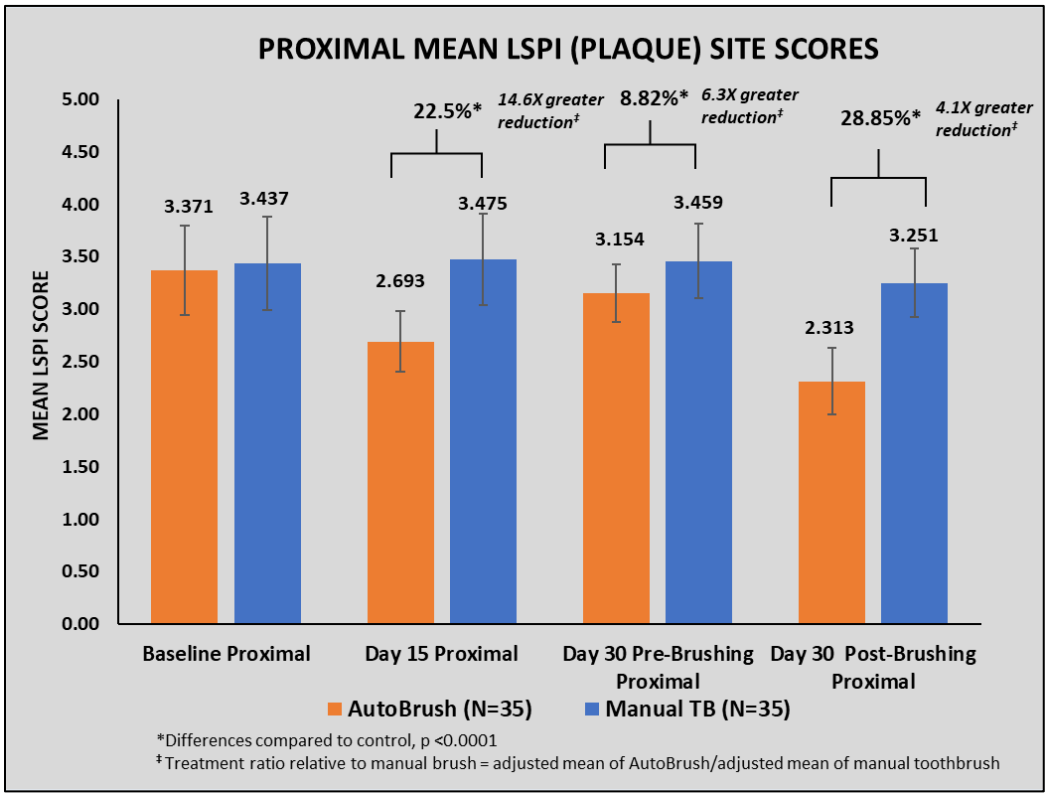
Source: Table 4.4.1

Figure 13. Gumline Plaque Scores at Each Visit



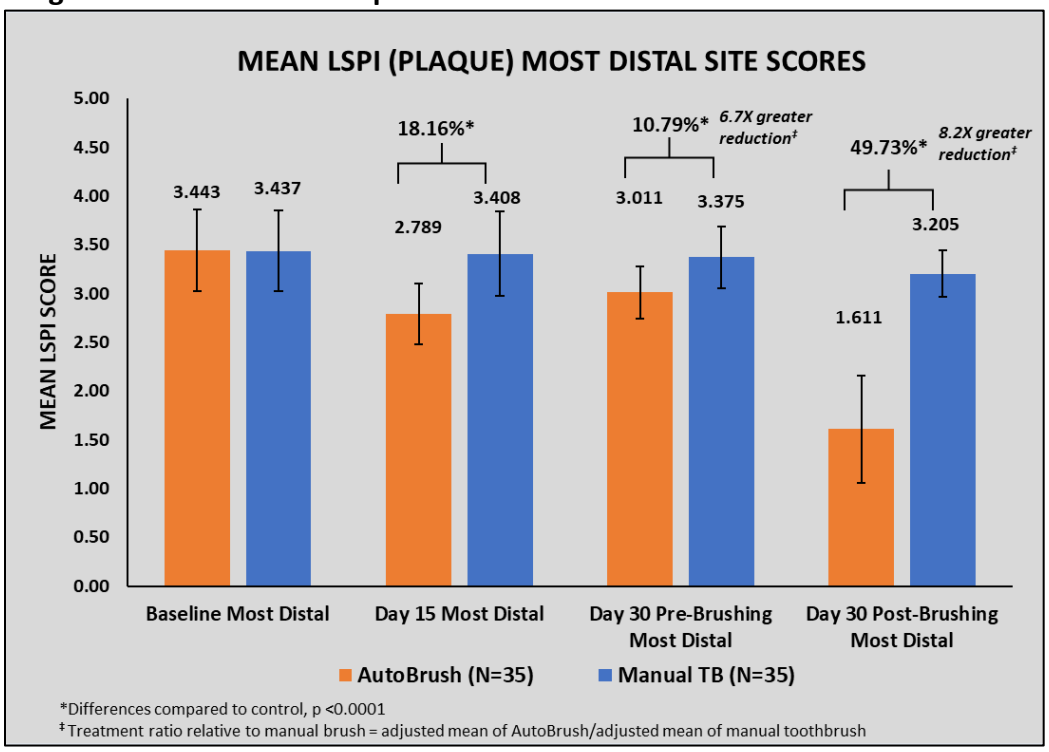
Source: Table 4.4.2

Figure 14. Proximal Plaque Scores at Each Visit



Source: Table 4.4.3

Figure 15. Most Distal Plaque Scores at Each Visit



Source: Table 4.4.4

3.3 DISCUSSION

The prevalence of dental caries and periodontal disease continue to be significant global health problems. Recently, community dental health experts have proposed that global oral health services should be focused and reoriented toward preventive interventions. [22] Efficient and effective oral hygiene is essential to prevention in the management of dental caries and periodontal diseases in children and adults. Systematic reviews have demonstrated that power toothbrushes are more effective than manual toothbrushes at reducing plaque and gingivitis in children and adult populations.[12, 23] Manufacturers have been committed to the research and development of novel and innovative power toothbrush designs that will motivate and assist the consumer in their proficient oral home care strategies. The makers of AutoBrush® market an innovative U-Shaped sonic power toothbrush that is designed with a full two-sided toothbrush head (mouthpiece) with tapered nylon bristles to clean all tooth surfaces at once in a 30-second period.

This 30-day, examiner-blind clinical trial was designed to assess the safety of AutoBrush®, and its efficacy for the control of plaque and gingivitis, compared to an ADA reference soft manual toothbrush. A reasonable concern for new toothbrush designs, manual or power, is the potential to cause soft tissue damage in the form of gingival abrasion or gingival recession. Analysis of recession measurements in this study revealed no change from Baseline at any subsequent timepoint, Day 15 or Day 30. The initial levels of recession were extremely small, which makes sense considering this study recruited a gingivitis population with an initial level of recession less than 2 mm. Site-wise score cross-tabulations indicated that increases in site-wise recession scores were exceedingly rare. Thus, there was no obvious negative impact on gingival recession associated with either study toothbrush. Similar to recession, the initial levels of gingival abrasion were quite small and the Baseline levels reflect any potential damage caused by the ADA reference toothbrush that subjects used during the 7 to 14 day washout period. Up to 168 sites were assessed for gingival abrasion in a mouth will a full complement of 28 teeth. The extremely low mean abrasion scores at Baseline and all subsequent timepoints represent a remarkably low level of toothbrush trauma initially and throughout the study. The greatest change in abrasion lesions actually reduced from Baseline for the AB group. The majority of the gingival abrasion lesions were small in size and appeared to be superficial and reversible.

Any potential safety signal was addressed through the evaluation of the extent of gingival abrasion and recession, as well as through oral clinical examinations and interviews to determine soft tissue or oral irritation symptoms. There were no observed or reported Adverse Events or Serious Adverse Events during the study. Both toothbrushes were well-tolerated and did not contribute to any toothbrush trauma such as gingival abrasion and gingival recession.

A revealing measure of the efficacy of a toothbrush is the improvement in plaque-induced gingivitis. In a diverse population of participants aged 5-65 years, results of this study reflect the ability of the innovative AutoBrush® toothbrush to improve gingival health and provide a corresponding level of plaque reduction compared to an ADA reference standard MTB. After 15 and 30 days of brushing, the AutoBrush® surpassed the ADA reference MTB with respect to improvement in whole mouth gingivitis scores. Similar results were seen in the hard-to-reach areas (gumline, proximal and most distal surfaces). This study assessed gingivitis and plaque levels on the distal surfaces of the most distal tooth in each quadrant of the mouth. Considering the population included individuals with adult dentition, and primary or mixed dentition, the most distal tooth in each mouth could be a primary molar, or 6-year or 12-year permanent molar. Gingivitis reductions for the most distal and posterior surfaces in the mouth demonstrate the reach of the AutoBrush® in the most posterior parts of the mouth to remove plaque and thereby reduced gingival inflammation.

Plaque removal efficacy mirrored the gingivitis reduction with significant improvements for the AutoBrush® compared to the MTB at all timepoints. The cumulative benefit in plaque reduction that was observed at Days 15 and 30 when assessing the pre-brushing LSPI scores suggests that the AutoBrush® effectively disrupted dental plaque colonies, helping to minimize further accumulation of plaque bacteria and thereby reduced and inhibited gingival inflammation. Compared to the MTB, AutoBrush removed 5 times more plaque and was 5 times more effective in improving gingivitis. The immediate post-brushing assessment following the pre-brushing plaque assessment on Day 30 helps to explain why gingivitis improvements were seen at Day 30 since plaque removal throughout the 30 days was key to preventing and reducing gingivitis. For all areas of the mouth (whole-mouth, gumline, proximal and most distal), the AutoBrush® removed significantly more plaque than the ADA reference MTB, up to 6 times more plaque removal at Day 30.

In a recent, unpublished, single-use clinical study with 22 children, aged 5-8 years, 30 seconds use of the AutoBrush® significantly reduced whole mouth plaque levels compared to a children's MTB, used for two minutes, by 50%. Hard-to-reach areas, such as gumline and proximal, had plaque levels reduced by 69.7% by 40.7%. An earlier 30-day study (AB-2023-002) on the AutoBrush® product was conducted with 75 subjects aged 5-65 years of age evaluating twice daily brushing with either an ADA reference manual soft toothbrush for two minutes or brushing for 30 seconds with AutoBrush®. At the end of 30 days, there were no adverse events nor differences between groups for gingival recession and abrasion were detected. Thirty-second brushing with AutoBrush®360° was superior to the MTB in reducing gingivitis and plaque at Days 15 and 30, and demonstrated highly significant immediate plaque removal at

Day 30 Pre-to-Post-brush evaluation. Both toothbrushes were well-tolerated and there were no safety concerns detected during this 30-day study.

Effective plaque removal in children is a constant challenge since efficiency can be impacted by a child's age and dexterity. A recent systematic review concluded that there was strong evidence that use of an electric toothbrush provided meaningful improvement in plaque levels compared to a manual toothbrush in children as young as 2 years of age up to 17 years.[21] Toothbrushing research in a pediatric population has been limited to assessment of plaque removal efficacy with no substantial assessment on gingivitis. It is noteworthy that the 30-second brushing with the AutoBrush® provided significantly greater improvement in plaque removal and gingivitis compared to a two minute brushing with a manual toothbrush. In a 30-second time period, the unique toothbrush was able to disrupt plaque biofilm and reduce gingivitis, even in hard-to-reach areas. Similar benefits have been seen with power toothbrushes, such as sonic and oscillating-rotating design, which are achieved with two-minute brushing periods. It is well-known that power toothbrushes are more effective than manual toothbrushes in removing plaque and reducing gingivitis.[12–13]

The introduction of the AutoBrush® 360 U-Shaped Sonic Power Toothbrush represents a disruption to the power toothbrush market with plaque and gingivitis benefits achieved with 30-seconds of toothbrushing versus two minutes with a manual toothbrush.

3.4 CONCLUSION

In conclusion, the AutoBrush® 360° U-Shaped Sonic Power Toothbrush demonstrated a superior reduction in plaque and showed a beneficial improvement in gingival health compared with the manual toothbrush. The results of this study demonstrate the benefits of the AutoBrush® in providing clinically measurable improvement in plaque removal and gingival health in a population of children and adults.

There was no significant increase in gingival abrasion and recession observed during the study, and no reported adverse events. Results from this study of the comparative safety and efficacy of the AB® indicate that this new power toothbrush for children and adults is safe and is significantly more effective than an ADA reference soft manual toothbrush.

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4 TABLES, FIGURES, AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

4.1 Disposition of Study Subjects

Table 4.1
Disposition of Study Subjects
(All Randomized Subjects)

	AutoBrush Toothbrush (N = 39)	Manual Toothbrush (N = 36)	Overall (N = 75)
Randomized	39	36	75
Completed Study	35 (89.7%)	35 (97.2%)	70 (93.3%)
Discontinued*	4 (10.3%)	1 (2.8%)	5 (6.7%)
Withdrew from Study	3 (75.0%)	1 (100%)	4 (80.0%)
Lost to Follow-up	1 (25.0%)	0	1 (20.0%)

Source: Listings 5.3.1 and 5.3.2

* Percentages for discontinuation reasons are based on the number of discontinued subjects.

4.2 Demographics and Baseline Characteristics

Table 4.2
Demographics and Baseline Characteristics
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush (N = 35)	Manual Toothbrush (N = 35)	Overall (N = 70)	Between Treatment Comparisons**
Age (years)				
n	35	35	70	
Mean (SD)	33.89 (22.13)	35.26 (19.95)	34.57 (20.93)	0.7862
Median	44.00	38.00	40.00	
Min, Max	(5.0, 64.0)	(6.0, 63.0)	(5.0, 64.0)	
Gender				
Male	17 (48.6%)	9 (25.7%)	26 (37.1%)	0.0478
Female	18 (51.4%)	26 (74.3%)	44 (62.9%)	
Race				
American Indian /Alaskan Native	0	0	0	0.4960
Black or African American	3 (8.6%)	6 (17.1%)	9 (12.9%)	
White	30 (85.7%)	28 (80.0%)	58 (82.9%)	
Native Hawaiian or other Pacific Islander	0	0	0	
Asian	2 (5.7%)	1 (2.9%)	3 (4.3%)	
Other	0	0	0	
Ethnicity				
Hispanic/Latino	1 (2.9%)	2 (5.7%)	3 (4.3%)	0.5551
Non-Hispanic/Non-Latino	34 (97.1%)	33 (94.3%)	67 (95.7%)	

Source: Listings 5.3.1, 5.3.2, 5.3.4, 5.3.5.1, and 5.3.5.5

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

** For age, MGI, and PI, p-values from two-sided t-tests are presented.
For gender, race, and ethnicity, p-values from chi-squared tests are presented.

Table 4.2 (Cont'd)
Demographics and Baseline Characteristics
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush (N = 35)	Manual Toothbrush (N = 35)	Overall (N = 70)	Between Treatment Comparisons**
Whole Mouth MGI at Baseline				
Subjects with Non-Missing Data	35	35	70	
Mean (SD)	2.67 (0.23)	2.60 (0.30)	2.63 (0.27)	0.3211
Median	2.70	2.65	2.67	
Min, Max	(2.3, 3.0)	(1.9, 3.0)	(1.9, 3.0)	
Subjects with Missing Data	0	0	0	
Whole Mouth PI at Baseline				
Subjects with Non-Missing Data	35	35	70	
Mean (SD)	3.27 (0.45)	3.31 (0.49)	3.29 (0.47)	0.6894
Median	3.21	3.15	3.21	
Min, Max	(2.5, 5.0)	(2.7, 5.0)	(2.5, 5.0)	
Subjects with Missing Data	0	0	0	

Source: Listings 5.3.1, 5.3.2, 5.3.4, 5.3.5.1, and 5.3.5.5

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

** For age, MGI, and PI, p-values from two-sided t-tests are presented.
For gender, race, and ethnicity, p-values from chi-squared tests are presented.

4.3 Modified Gingival Index

4.3.1 Modified Gingival Index Whole Mouth Findings

Table 4.3.1
Analysis of Whole Mouth Modified Gingival Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	2.666 (0.2278)	2.602 (0.2980)
Median	2.702	2.652
Min, Max	2.27, 3.00	1.86, 3.00
Subjects with Missing Data	0	0

Source: Listings 5.3.1, 5.3.2, and 5.3.5.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.3.1
Analysis of Whole Mouth Modified Gingival Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	1.575 (0.4446)	2.327 (0.5316)
Median	1.562	2.424
Min, Max	0.77, 2.31	0.90, 3.00
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-1.090 (0.3936)	-0.276 (0.3585)
Median	-1.148	-0.208
Min, Max	-1.74, -0.01	-1.45, 0.21
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.097 (0.0637)	-0.269 (0.0637)
95% CI	(-1.224, -0.970)	(-0.396, -0.142)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.828 (0.0904)	n/a
95% CI	(-1.008, -0.647)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.3.5.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.3.1
Analysis of Whole Mouth Modified Gingival Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	1.286 (0.4286)	2.328 (0.4519)
Median	1.210	2.360
Min, Max	0.63, 2.26	1.16, 3.00
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-1.379 (0.3613)	-0.274 (0.3564)
Median	-1.421	-0.225
Min, Max	-1.99, -0.40	-1.20, 0.25
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.378 (0.0613)	-0.275 (0.0613)
95% CI	(-1.501, -1.256)	(-0.397, -0.153)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.103 (0.0870)	n/a
95% CI	(-1.277, -0.929)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.3.5.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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4.3.2 Modified Gingival Index Gumline Surfaces

Table 4.3.2
Analysis of Modified Gingival Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	2.349 (0.3885)	2.278 (0.4592)
Median	2.268	2.393
Min, Max	1.59, 3.00	1.34, 3.00
Subjects with Missing Data	0	0

Source: Listings 5.3.1, 5.3.2, and 5.3.5.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.3.2
Analysis of Modified Gingival Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	0.979 (0.5884)	1.958 (0.6949)
Median	1.000	2.040
Min, Max	0.03, 2.04	0.19, 3.00
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-1.371 (0.4908)	-0.320 (0.4391)
Median	-1.393	-0.271
Min, Max	-2.08, -0.07	-1.69, 0.38
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.372 (0.0794)	-0.319 (0.0794)
95% CI	(-1.531, -1.214)	(-0.477, -0.160)
p-value comparing LS Mean versus 0	<.0001	0.0002
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.053 (0.1124)	n/a
95% CI	(-1.278, -0.829)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.3.5.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.3.2
Analysis of Modified Gingival Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	0.689 (0.5431)	1.952 (0.6273)
Median	0.477	1.926
Min, Max	0.04, 2.03	0.19, 3.00
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-1.661 (0.4324)	-0.326 (0.4863)
Median	-1.739	-0.185
Min, Max	-2.36, -0.45	-1.69, 0.30
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.656 (0.0779)	-0.331 (0.0779)
95% CI	(-1.812, -1.501)	(-0.486, -0.175)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.325 (0.1104)	n/a
95% CI	(-1.545, -1.105)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.3.5.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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4.3.3 Modified Gingival Index Proximal Surfaces

Table 4.3.3
Analysis of Modified Gingival Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	2.824 (0.1777)	2.764 (0.2319)
Median	2.875	2.823
Min, Max	2.45, 3.00	2.13, 3.00
Subjects with Missing Data	0	0

Source: Listings 5.3.1, 5.3.2, and 5.3.5.3

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.3.3
Analysis of Modified Gingival Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	1.873 (0.3931)	2.511 (0.4561)
Median	1.838	2.630
Min, Max	1.14, 2.64	1.25, 3.00
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.950 (0.3632)	-0.253 (0.3360)
Median	-1.011	-0.205
Min, Max	-1.58, 0.01	-1.33, 0.18
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.956 (0.0595)	-0.247 (0.0595)
95% CI	(-1.075, -0.837)	(-0.366, -0.129)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.709 (0.0846)	n/a
95% CI	(-0.877, -0.540)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.3.5.3

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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Table 4.3.3
Analysis of Modified Gingival Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	1.585 (0.3922)	2.516 (0.3784)
Median	1.554	2.595
Min, Max	0.92, 2.52	1.64, 3.00
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-1.239 (0.3491)	-0.248 (0.3056)
Median	-1.222	-0.238
Min, Max	-1.88, -0.38	-0.99, 0.23
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.238 (0.0562)	-0.248 (0.0562)
95% CI	(-1.350, -1.126)	(-0.361, -0.136)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.990 (0.0798)	n/a
95% CI	(-1.149, -0.830)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.3.5.3

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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4.3.4 Modified Gingival Index Most Distal Surfaces

Table 4.3.4
Analysis of Modified Gingival Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	2.668 (0.3106)	2.668 (0.3091)
Median	2.750	2.750
Min, Max	1.88, 3.00	1.88, 3.00
Subjects with Missing Data	0	0

Source: Listings 5.3.1, 5.3.2, and 5.3.5.4

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.3.4
Analysis of Modified Gingival Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	1.479 (0.5569)	2.364 (0.4873)
Median	1.500	2.375
Min, Max	0.50, 2.50	1.38, 3.13
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-1.189 (0.4710)	-0.304 (0.3704)
Median	-1.125	-0.250
Min, Max	-2.25, -0.25	-1.25, 0.25
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.189 (0.0722)	-0.304 (0.0722)
95% CI	(-1.333, -1.045)	(-0.448, -0.160)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.886 (0.1020)	n/a
95% CI	(-1.089, -0.682)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.3.5.4

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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Table 4.3.4
Analysis of Modified Gingival Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	1.113 (0.5484)	2.393 (0.4363)
Median	1.000	2.375
Min, Max	0.38, 2.25	1.38, 3.00
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-1.555 (0.4733)	-0.275 (0.3951)
Median	-1.625	-0.250
Min, Max	-2.38, -0.38	-1.13, 0.50
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.555 (0.0734)	-0.275 (0.0734)
95% CI	(-1.701, -1.408)	(-0.422, -0.128)
p-value comparing LS Mean versus 0	<.0001	0.0004
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.280 (0.1038)	n/a
95% CI	(-1.487, -1.072)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.3.5.4

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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4.4 Analysis of Plaque Index Findings

4.4.1 Whole Mouth Plaque Index

Table 4.4.1
Analysis of Whole Mouth Plaque Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	3.267 (0.4515)	3.312 (0.4900)
Median	3.213	3.154
Min, Max	2.48, 5.00	2.70, 5.00
Subjects with Missing Data	0	0

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.5

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.4.1
Analysis of Whole Mouth Plaque Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	2.274 (0.3568)	3.361 (0.4846)
Median	2.193	3.262
Min, Max	1.61, 3.45	2.67, 4.93
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.992 (0.3152)	0.049 (0.1910)
Median	-1.025	0.042
Min, Max	-1.64, -0.49	-0.41, 0.42
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.998 (0.0398)	0.055 (0.0398)
95% CI	(-1.077, -0.918)	(-0.024, 0.134)
p-value comparing LS Mean versus 0	<.0001	0.1714
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.053 (0.0563)	n/a
95% CI	(-1.165, -0.941)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.5

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.4.1
Analysis of Whole Mouth Plaque Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	2.992 (0.3508)	3.361 (0.3886)
Median	2.946	3.268
Min, Max	2.19, 3.68	2.72, 4.54
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.275 (0.3630)	0.049 (0.2550)
Median	-0.250	0.104
Min, Max	-1.32, 0.32	-0.46, 0.43
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.284 (0.0419)	0.058 (0.0419)
95% CI	(-0.368, -0.200)	(-0.026, 0.142)
p-value comparing LS Mean versus 0	<.0001	0.1703
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.342 (0.0593)	n/a
95% CI	(-0.460, -0.224)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.5

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.4.1
Analysis of Whole Mouth Plaque Index Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	1.713 (0.2879)	3.108 (0.3715)
Median	1.763	3.023
Min, Max	1.25, 2.33	2.49, 4.21
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Change from Pre- to Post-Brushing (CFPre)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-1.279 (0.2014)	-0.253 (0.1193)
Median	-1.265	-0.232
Min, Max	-1.66, -0.85	-0.54, -0.03
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFPre		
LS Mean (SE)	-1.280 (0.0276)	-0.251 (0.0276)
95% CI	(-1.335, -1.225)	(-0.306, -0.196)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.029 (0.0390)	
95% CI	(-1.107, -0.951)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.5

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

4.4.2 Gumline Plaque Index

Table 4.4.2
Analysis of Plaque Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	3.058 (0.5171)	3.062 (0.5871)
Median	3.022	2.909
Min, Max	2.16, 5.00	2.28, 5.00
Subjects with Missing Data	0	0

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.6

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.4.2
Analysis of Plaque Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	1.437 (0.5950)	3.134 (0.5884)
Median	1.380	3.143
Min, Max	0.23, 3.32	2.28, 4.93
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-1.621 (0.4971)	0.072 (0.2590)
Median	-1.750	0.054
Min, Max	-2.50, -0.73	-0.55, 0.55
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-1.622 (0.0652)	0.073 (0.0652)
95% CI	(-1.752, -1.492)	(-0.058, 0.203)
p-value comparing LS Mean versus 0	<.0001	0.2698
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.694 (0.0922)	n/a
95% CI	(-1.878, -1.510)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.6

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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Table 4.4.2
Analysis of Plaque Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	2.668 (0.5287)	3.165 (0.4734)
Median	2.554	3.060
Min, Max	1.24, 3.64	2.35, 4.50
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.390 (0.4394)	0.103 (0.3196)
Median	-0.421	0.104
Min, Max	-1.36, 0.30	-0.50, 0.61
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.390 (0.0576)	0.103 (0.0576)
95% CI	(-0.505, -0.276)	(-0.012, 0.218)
p-value comparing LS Mean versus 0	<.0001	0.0773
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.494 (0.0814)	n/a
95% CI	(-0.656, -0.331)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.6

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.4.2
Analysis of Plaque Index Findings on Gumline Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	0.514 (0.2909)	2.822 (0.4752)
Median	0.474	2.696
Min, Max	0.05, 1.25	2.16, 4.18
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Change from Pre- to Post-Brushing (CFPre)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-2.154 (0.3687)	-0.343 (0.1718)
Median	-2.056	-0.318
Min, Max	-2.86, -0.98	-0.77, -0.07
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFPre		
LS Mean (SE)	-2.155 (0.0469)	-0.342 (0.0469)
95% CI	(-2.248, -2.061)	(-0.436, -0.249)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.812 (0.0664)	
95% CI	(-1.945, -1.680)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.6

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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4.4.3 Proximal Plaque Index

Table 4.4.3
Analysis of Plaque Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	3.371 (0.4262)	3.437 (0.4472)
Median	3.316	3.333
Min, Max	2.64, 5.00	2.90, 5.00
Subjects with Missing Data	0	0

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.7

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.4.3
Analysis of Plaque Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	2.693 (0.2930)	3.475 (0.4379)
Median	2.684	3.411
Min, Max	2.17, 3.52	2.84, 4.93
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.678 (0.2896)	0.038 (0.1682)
Median	-0.704	0.043
Min, Max	-1.48, -0.22	-0.38, 0.36
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.687 (0.0344)	0.047 (0.0344)
95% CI	(-0.756, -0.618)	(-0.021, 0.116)
p-value comparing LS Mean versus 0	<.0001	0.1726
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.735 (0.0488)	n/a
95% CI	(-0.832, -0.637)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.7

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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Table 4.4.3
Analysis of Plaque Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	3.154 (0.2728)	3.459 (0.3574)
Median	3.141	3.385
Min, Max	2.66, 3.70	2.85, 4.56
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.217 (0.3428)	0.022 (0.2373)
Median	-0.219	0.071
Min, Max	-1.30, 0.34	-0.45, 0.42
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.232 (0.0366)	0.037 (0.0366)
95% CI	(-0.305, -0.159)	(-0.036, 0.110)
p-value comparing LS Mean versus 0	<.0001	0.3145
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.269 (0.0518)	n/a
95% CI	(-0.373, -0.166)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.7

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.4.3
Analysis of Plaque Index Findings on Proximal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	2.313 (0.3194)	3.251 (0.3279)
Median	2.326	3.205
Min, Max	1.75, 2.89	2.65, 4.23
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Change from Pre- to Post-Brushing (CFPre)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.841 (0.2198)	-0.208 (0.1134)
Median	-0.842	-0.202
Min, Max	-1.25, -0.30	-0.49, 0.01
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFPre		
LS Mean (SE)	-0.842 (0.0297)	-0.207 (0.0297)
95% CI	(-0.901, -0.783)	(-0.266, -0.147)
p-value comparing LS Mean versus 0	<.0001	<.0001
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.635 (0.0420)	
95% CI	(-0.719, -0.552)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.7

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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4.4.4 Most Distal Surface

Table 4.4.4
Analysis of Plaque Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	3.443 (0.4194)	3.437 (0.4141)
Median	3.375	3.375
Min, Max	2.75, 5.00	2.88, 5.00
Subjects with Missing Data	0	0

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.8

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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Table 4.4.4
Analysis of Plaque Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	2.789 (0.3133)	3.408 (0.4326)
Median	2.875	3.250
Min, Max	1.75, 3.38	2.88, 4.88
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.654 (0.3848)	-0.029 (0.2146)
Median	-0.500	0.000
Min, Max	-1.63, 0.00	-0.50, 0.50
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.652 (0.0461)	-0.030 (0.0461)
95% CI	(-0.745, -0.560)	(-0.122, 0.062)
p-value comparing LS Mean versus 0	<.0001	0.5225
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.623 (0.0653)	n/a
95% CI	(-0.753, -0.493)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.8

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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Table 4.4.4
Analysis of Plaque Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	3.011 (0.2684)	3.375 (0.3165)
Median	3.125	3.250
Min, Max	2.50, 3.50	2.88, 4.50
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - PRE-BRUSHING		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.432 (0.3742)	-0.062 (0.2630)
Median	-0.375	-0.125
Min, Max	-1.50, 0.25	-0.63, 0.38
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.430 (0.0386)	-0.064 (0.0386)
95% CI	(-0.508, -0.353)	(-0.141, 0.014)
p-value comparing LS Mean versus 0	<.0001	0.1046
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.367 (0.0546)	n/a
95% CI	(-0.476, -0.258)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.8

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.4.4
Analysis of Plaque Index Findings on Most Distal Surfaces
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	1.611 (0.5489)	3.205 (0.2347)
Median	1.500	3.125
Min, Max	0.63, 2.63	2.88, 4.00
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4) - POST-BRUSHING		
Summary of Change from Pre- to Post-Brushing (CFPre)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-1.400 (0.5188)	-0.170 (0.1564)
Median	-1.500	-0.125
Min, Max	-2.50, -0.38	-0.50, 0.13
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFPre		
LS Mean (SE)	-1.400 (0.0652)	-0.170 (0.0652)
95% CI	(-1.530, -1.270)	(-0.300, -0.040)
p-value comparing LS Mean versus 0	<.0001	0.0110
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-1.229 (0.0921)	
95% CI	(-1.413, -1.046)	
Between-treatment p-value	<.0001	

Source: Listings 5.3.1, 5.3.2, and 5.5.3.5.8

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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4.5 Clinical Safety Findings: Gingival Recession

4.5.1 Site-wise Gingival Recession Score (mm) Transitions Between Baseline and the Day 15 Visit - AutoBrush

Table 4.5.1

Sitewise Gingival Recession Score (mm) Transitions Between Baseline and the Day 15 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score3

score2(Baseline Score)	score3(Day 15 Score)			
Frequency Row Pct	0	1	2	Total
0	4757 99.98	1 0.02	0 0.00	4758
1	2 1.47	134 98.53	0 0.00	136
2	1 2.63	0 0.00	37 97.37	38
Total	4760	135	37	4932

Source: Listings 5.3.1, 5.3.2, and 5.3.6.1
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 15 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.5.2 Site-wise Gingival Recession Score (mm) Transitions Between Baseline and the Day 15 Visit – Manual Toothbrush

Table 4.5.2

Sitewise Gingival Recession Score (mm) Transitions Between Baseline and the Day 15 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score3

score2(Baseline Score)	score3(Day 15 Score)			
Frequency Row Pct	0	1	2	Total
0	4915 100.00	0 0.00	0 0.00	4915
1	9 7.96	104 92.04	0 0.00	113
2	0 0.00	0 0.00	36 100.00	36
Total	4924	104	36	5064

Source: Listings 5.3.1, 5.3.2, and 5.3.6.1
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 15 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.5.3 Site-wise Gingival Recession Score (mm) Transitions-Baseline and Day 30 – AutoBrush

Table 4.5.3

Sitewise Gingival Recession Score (mm) Transitions Between Baseline and the Day 30 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score4

score2(Baseline Score)	score4(Day 30 Score)			
Frequency Row Pct	0	1	2	Total
0	4757 99.98	1 0.02	0 0.00	4758
1	3 2.21	133 97.79	0 0.00	136
2	1 2.63	0 0.00	37 97.37	38
Total	4761	134	37	4932

Source: Listings 5.3.1, 5.3.2, and 5.3.6.1
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.5.4 Site-wise Gingival Recession Score (mm) Transitions-Baseline and Day 30 - Manual Toothbrush

Table 4.5.4

Sitewise Gingival Recession Score (mm) Transitions Between Baseline and the Day 30 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score4

score2(Baseline Score)	score4(Day 30 Score)			
Frequency Row Pct	0	1	2	Total
0	4915 100.00	0 0.00	0 0.00	4915
1	10 8.85	103 91.15	0 0.00	113
2	0 0.00	0 0.00	36 100.00	36
Total	4925	103	36	5064

Source: Listings 5.3.1, 5.3.2, and 5.3.6.1
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.5.5 Site-wise Gingival Recession Score (mm) Transitions-Day 15 - Day 30 - AutoBrush

Table 4.5.5

Sitewise Gingival Recession Score (mm) Transitions Between the Day 15 Visit and the Day 30 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score3 by score4

score3(Day 15 Score)	score4(Day 30 Score)			
Frequency Row Pct	0	1	2	Total
0	4760 100.00	0 0.00	0 0.00	4760
1	1 0.74	134 99.26	0 0.00	135
2	0 0.00	0 0.00	37 100.00	37
Total	4761	134	37	4932

Source: Listings 5.3.1, 5.3.2, and 5.3.6.1
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Day 15 visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.5.6 Site-wise Gingival Recession Score (mm) Transitions-Day 15 - Day 30 - Manual Toothbrush

Table 4.5.6

Sitewise Gingival Recession Score (mm) Transitions Between the Day 15 Visit and the Day 30 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score3 by score4

score3(Day 15 Score)	score4(Day 30 Score)			
Frequency Row Pct	0	1	2	Total
0	4924 100.00	0 0.00	0 0.00	4924
1	1 0.96	103 99.04	0 0.00	104
2	0 0.00	0 0.00	36 100.00	36
Total	4925	103	36	5064

Source: Listings 5.3.1, 5.3.2, and 5.3.6.1
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Day 15 visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.5.7 Percentage of Subjects Presenting Gingival Recession

Table 4.5.7
Percentage of Subjects Presenting Gingival Recession at Each Study Visit
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Number of Subjects With at Least 1 Site:		
Presenting Recession 1mm or Higher	20 (57.1%)	22 (62.9%)
Presenting Recession 2mm	11 (31.4%)	9 (25.7%)
Day 15 Visit (Visit 3)		
Number of Subjects With at Least 1 Site:		
Presenting Recession 1mm or Higher	20 (57.1%)	21 (60.0%)
Presenting Recession 2mm	11 (31.4%)	9 (25.7%)
Day 30 Visit (Visit 4)		
Number of Subjects With at Least 1 Site:		
Presenting Recession 1mm or Higher	20 (57.1%)	21 (60.0%)
Presenting Recession 2mm	11 (31.4%)	9 (25.7%)

Source: Listings 5.3.1, 5.3.2, and 5.3.6.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

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Table 4.5.7
Summary of Gingival Recession Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	0.041 (0.0495)	0.037 (0.0565)
Median	0.030	0.024
Min, Max	0.00, 0.19	0.00, 0.30
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.001 (0.0028)	-0.002 (0.0091)
Median	0.000	0.000
Min, Max	-0.02, 0.00	-0.05, 0.00
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.001 (0.0011)	-0.002 (0.0011)
95% CI	(-0.003, 0.002)	(-0.004, 0.001)
p-value comparing LS Mean versus 0	0.5857	0.1778
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	0.001 (0.0016)	n/a
95% CI	(-0.002, 0.004)	
Between-treatment p-value	0.5668	

Source: Listings 5.3.1, 5.3.2, and 5.3.6.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.5.7
Summary of Gingival Recession Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	0.040 (0.0495)	0.037 (0.0561)
Median	0.030	0.024
Min, Max	0.00, 0.19	0.00, 0.30
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.001 (0.0030)	-0.002 (0.0091)
Median	0.000	0.000
Min, Max	-0.02, 0.00	-0.05, 0.00
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.001 (0.0012)	-0.002 (0.0012)
95% CI	(-0.003, 0.001)	(-0.004, 0.000)
p-value comparing LS Mean versus 0	0.4714	0.1213
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	0.001 (0.0016)	n/a
95% CI	(-0.002, 0.004)	
Between-treatment p-value	0.5523	

Source: Listings 5.3.1, 5.3.2, and 5.3.6.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

4.5.8 Summary of Gingival Recession Findings

Table 4.5.8
Summary of Gingival Recession Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	0.041 (0.0503)	0.038 (0.0562)
Median	0.030	0.025
Min, Max	0.00, 0.19	0.00, 0.30
Subjects with Missing Data	0	0

Source: Listings 5.3.1, 5.3.2, and 5.3.6.1

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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4.6 Clinical Safety Findings; Gingival Abrasion

4.6.1 Site-wise Abrasion Score (mm) Transitions Baseline - Day 15 - AutoBrush

Table 4.6.1

Sitewise Abrasion Score (mm) Transitions Between Baseline and the Day 15 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score3

score2(Baseline Score)	score3(Day 15 Score)			
Frequency Row Pct	0	1	2	Total
0	5216 99.24	31 0.59	9 0.17	5256
1	45 95.74	2 4.26	0 0.00	47
2	36 94.74	1 2.63	1 2.63	38
3	1 100.00	0 0.00	0 0.00	1
Total	5298	34	10	5342

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 15 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.6.2 Site-wise Abrasion Score (mm) Transitions Baseline - Day 15 - Manual Toothbrush

Table 4.6.2

Sitewise Abrasion Score (mm) Transitions Between Baseline and the Day 15 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score3

score2(Baseline Score)	score3(Day 15 Score)				
Frequency Row Pct	0	1	2	3	Total
0	5258 98.02	56 1.04	48 0.89	2 0.04	5364
1	47 94.00	3 6.00	0 0.00	0 0.00	50
2	39 95.12	2 4.88	0 0.00	0 0.00	41
3	4 100.00	0 0.00	0 0.00	0 0.00	4
Total	5348	61	48	2	5459

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 15 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.6.3 Site-wise Abrasion Score (mm) Transitions Baseline - Day 30 -AutoBrush

Table 4.6.3

Sitewise Abrasion Score (mm) Transitions Between Baseline and the Day 30 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score4

score2(Baseline Score)	score4(Day 30 Score)			
Frequency Row Pct	0	1	2	Total
0	5230 99.51	16 0.30	10 0.19	5256
1	45 95.74	1 2.13	1 2.13	47
2	37 97.37	1 2.63	0 0.00	38
3	1 100.00	0 0.00	0 0.00	1
Total	5313	18	11	5342

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.6.4 Site-wise Abrasion Score (mm) Transitions Baseline - Day 30 - Manual Toothbrush

Table 4.6.4

Sitewise Abrasion Score (mm) Transitions Between Baseline and the Day 30 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score2 by score4

score2(Baseline Score)	score4(Day 30 Score)				
Frequency Row Pct	0	1	2	3	Total
0	5281 98.49	45 0.84	31 0.58	5 0.09	5362
1	48 96.00	0 0.00	1 2.00	1 2.00	50
2	39 95.12	2 4.88	0 0.00	0 0.00	41
3	4 100.00	0 0.00	0 0.00	0 0.00	4
Total	5372	47	32	6	5457

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.6.5 Site-wise Abrasion Score (mm) Transitions - Day 15 - Day 30 - AutoBrush

Table 4.6.5

Sitewise Abrasion Score (mm) Transitions Between the Day 15 Visit and the Day 30 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score3 by score4

score3(Day 15 Score)	score4(Day 30 Score)			
Frequency Row Pct	0	1	2	Total
0	5271 99.49	18 0.34	9 0.17	5298
1	33 97.06	0 0.00	1 2.94	34
2	9 90.00	0 0.00	1 10.00	10
Total	5313	18	11	5342

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Day 15 visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.6.6 Site-wise Abrasion Score (mm) Transitions - Day 15 - Day 30 - Manual Toothbrush

Table 4.6.6

Sitewise Abrasion Score (mm) Transitions Between the Day 15 Visit and the Day 30 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of score3 by score4

score3(Day 15 Score)	score4(Day 30 Score)				
Frequency Row Pct	0	1	2	3	Total
0	5271 98.58	45 0.84	27 0.50	4 0.07	5347
1	58 95.08	2 3.28	1 1.64	0 0.00	61
2	43 89.58	0 0.00	4 8.33	1 2.08	48
3	1 50.00	0 0.00	0 0.00	1 50.00	2
Total	5373	47	32	6	5458

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: The numerical row labels to the left of the grid above represent all the scores that were recorded at the Day 15 visit.
The numerical column labels above the grid represent all the scores that were recorded at the Day 30 visit.
Each cell in the grid represents a score transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated score transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column score.

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4.6.7 Site-wise Abrasion Category Transitions Baseline - Day 15 - AutoBrush

Table 4.6.7

Sitewise Abrasion Category Transitions Between Baseline and the Day 15 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of cat2 by cat3

cat2(Baseline Category)	cat3(Day 15 Category)		
Frequency Row Pct	0	1	Total
0	5216 99.24	40 0.76	5256
1	81 95.29	4 4.71	85
2	1 100.00	0 0.00	1
Total	5298	44	5342

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: Examined sites that did not present gingival abrasion were assigned to abrasion category 0.
NOTE: The numerical row labels to the left of the grid above represent all the abrasion categories that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the abrasion categories that were recorded at the Day 15 visit.
Each cell in the grid represents a category transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated category transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column category.

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4.6.8 Site-wise Abrasion Category Transitions Baseline - Day 15 - Manual Toothbrush

Table 4.6.8

Sitewise Abrasion Category Transitions Between Baseline and the Day 15 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of cat2 by cat3

cat2(Baseline Category)	cat3(Day 15 Category)			
Frequency Row Pct	0	1	2	Total
0	5258 98.02	104 1.94	2 0.04	5364
1	86 94.51	5 5.49	0 0.00	91
2	4 100.00	0 0.00	0 0.00	4
Total	5348	109	2	5459

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: Examined sites that did not present gingival abrasion were assigned to abrasion category 0.
NOTE: The numerical row labels to the left of the grid above represent all the abrasion categories that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the abrasion categories that were recorded at the Day 15 visit.
Each cell in the grid represents a category transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated category transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column category.

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4.6.9 Site-wise Abrasion Category Transitions Baseline - Day 30 - AutoBrush

Table 4.6.9

Sitewise Abrasion Category Transitions Between Baseline and the Day 30 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of cat2 by cat4

cat2(Baseline Category)	cat4(Day 30 Category)		
Frequency Row Pct	0	1	Total
0	5230 99.51	26 0.49	5256
1	82 96.47	3 3.53	85
2	1 100.00	0 0.00	1
Total	5313	29	5342

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: Examined sites that did not present gingival abrasion were assigned to abrasion category 0.
NOTE: The numerical row labels to the left of the grid above represent all the abrasion categories that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the abrasion categories that were recorded at the Day 30 visit.
Each cell in the grid represents a category transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated category transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column category.

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4.6.10 Site-wise Abrasion Category Transitions Baseline - Day 30 - Manual Toothbrush

Table 4.6.10

Sitewise Abrasion Category Transitions Between Baseline and the Day 30 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of cat2 by cat4

cat2(Baseline Category)	cat4(Day 30 Category)			
Frequency Row Pct	0	1	2	Total
0	5281 98.49	76 1.42	5 0.09	5362
1	87 95.60	3 3.30	1 1.10	91
2	4 100.00	0 0.00	0 0.00	4
Total	5372	79	6	5457

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: Examined sites that did not present gingival abrasion were assigned to abrasion category 0.
NOTE: The numerical row labels to the left of the grid above represent all the abrasion categories that were recorded at the Baseline visit.
The numerical column labels above the grid represent all the abrasion categories that were recorded at the Day 30 visit.
Each cell in the grid represents a category transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated category transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column category.

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4.6.11 Site-wise Abrasion Category Transitions - Day 15 - Day 30 - AutoBrush

Table 4.6.11

Sitewise Abrasion Category Transitions Between the Day 15 Visit and the Day 30 Visit
For Subjects Using the AutoBrush Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of cat3 by cat4

cat3(Day 15 Category)	cat4(Day 30 Category)		
Frequency Row Pct	0	1	Total
0	5271 99.49	27 0.51	5298
1	42 95.45	2 4.55	44
Total	5313	29	5342

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: Examined sites that did not present gingival abrasion were assigned to abrasion category 0.
NOTE: The numerical row labels to the left of the grid above represent all the abrasion categories that were recorded at the Day 15 visit.
The numerical column labels above the grid represent all the abrasion categories that were recorded at the Day 30 visit.
Each cell in the grid represents a category transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated category transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column category.

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4.6.12 Site-wise Abrasion Category Transitions - Day 15 - Day 30 - Manual Toothbrush

Table 4.6.12

Sitewise Abrasion Category Transitions Between the Day 15 Visit and the Day 30 Visit
For Subjects Using the Manual Toothbrush
(Subjects in the Per-Protocol Population)*

The FREQ Procedure

Table of cat3 by cat4

cat3(Day 15 Category)	cat4(Day 30 Category)			
Frequency Row Pct	0	1	2	Total
0	5271 98.58	72 1.35	4 0.07	5347
1	101 92.66	7 6.42	1 0.92	109
2	1 50.00	0 0.00	1 50.00	2
Total	5373	79	6	5458

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2
** The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations.*
NOTE: Examined sites that did not present gingival abrasion were assigned to abrasion category 0.
NOTE: The numerical row labels to the left of the grid above represent all the abrasion categories that were recorded at the Day 15 visit.
The numerical column labels above the grid represent all the abrasion categories that were recorded at the Day 30 visit.
Each cell in the grid represents a category transition from the ROW value to the COLUMN value.
The top number in a cell represent the number of sites that presented the indicated category transition.
The bottom number in a cell indicates the percentage of sites tabulated in the row that transitioned to each column category.

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4.6.13 Categorical Summary of Gingival Abrasion Findings

Table 4.6.13
Categorical Summary of Gingival Abrasion Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Dist'n of Subjects According to # Sites Presenting Any Abrasion		
0	8 (22.9%)	9 (25.7%)
1 - 4	19 (54.3%)	20 (57.1%)
5 - 8	7 (20.0%)	4 (11.4%)
9 or more	1 (2.9%)	2 (5.7%)
Dist'n of Subjects According to # Sites with Category 1 Lesions		
0	8 (22.9%)	9 (25.7%)
1 - 4	20 (57.1%)	20 (57.1%)
5 - 8	6 (17.1%)	4 (11.4%)
9 or more	1 (2.9%)	2 (5.7%)
Dist'n of Subjects According to # Sites with Category 2 Lesions		
0	34 (97.1%)	31 (88.6%)
1 - 4	1 (2.9%)	4 (11.4%)
5 or more	0	0
Number (%) of Subjects With at Least 1 Site:		
Presenting Abrasion 1mm or Higher	27 (77.1%)	26 (74.3%)
Presenting Abrasion 2mm or Higher	19 (54.3%)	20 (57.1%)
Presenting Abrasion 3mm or Higher	1 (2.9%)	4 (11.4%)

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: Category 1 lesions are 1mm - 2mm in length; Category 2 lesions are 3mm – 5mm in length. It is noted that no subject presented any lesions greater than 5mm in length at any study visit.

Table 4.6.13
Categorical Summary of Gingival Abrasion Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Dist'n of Subjects According to # Sites Presenting Any Abrasion		
0	14 (40.0%)	6 (17.1%)
1 - 4	19 (54.3%)	21 (60.0%)
5 - 8	2 (5.7%)	6 (17.1%)
9 or more	0	2 (5.7%)
Dist'n of Subjects According to # Sites with Category 1 Lesions		
0	14 (40.0%)	6 (17.1%)
1 - 4	19 (54.3%)	21 (60.0%)
5 - 8	2 (5.7%)	6 (17.1%)
9 or more	0	2 (5.7%)
Dist'n of Subjects According to # Sites with Category 2 Lesions		
0	35 (100%)	33 (94.3%)
1 - 4	0	2 (5.7%)
5 or more	0	0
Number (%) of Subjects With at Least 1 Site:		
Presenting Abrasion 1mm or Higher	21 (60.0%)	29 (82.9%)
Presenting Abrasion 2mm or Higher	9 (25.7%)	18 (51.4%)
Presenting Abrasion 3mm or Higher	0	2 (5.7%)

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: Category 1 lesions are 1mm - 2mm in length; Category 2 lesions are 3mm – 5mm in length. It is noted that no subject presented any lesions greater than 5mm in length at any study visit.

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Table 4.6.13
Categorical Summary of Gingival Abrasion Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Dist'n of Subjects According to # Sites Presenting Any Abrasion		
0	18 (51.4%)	11 (31.4%)
1 - 4	17 (48.6%)	19 (54.3%)
5 - 8	0	4 (11.4%)
9 or more	0	1 (2.9%)
Dist'n of Subjects According to # Sites with Category 1 Lesions		
0	18 (51.4%)	11 (31.4%)
1 - 4	17 (48.6%)	20 (57.1%)
5 - 8	0	3 (8.6%)
9 or more	0	1 (2.9%)
Dist'n of Subjects According to # Sites with Category 2 Lesions		
0	35 (100%)	32 (91.4%)
1 - 4	0	3 (8.6%)
5 or more	0	0
Number (%) of Subjects With at Least 1 Site:		
Presenting Abrasion 1mm or Higher	17 (48.6%)	24 (68.6%)
Presenting Abrasion 2mm or Higher	7 (20.0%)	17 (48.6%)
Presenting Abrasion 3mm or Higher	0	3 (8.6%)

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: Category 1 lesions are 1mm - 2mm in length; Category 2 lesions are 3mm – 5mm in length. It is noted that no subject presented any lesions greater than 5mm in length at any study visit.

4.6.14 Analysis of Gingival Abrasion Findings

Table 4.6.14
Analysis of Gingival Abrasion Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Baseline Visit (Visit 2)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	0.023 (0.0222)	0.026 (0.0294)
Median	0.018	0.018
Min, Max	0.00, 0.08	0.00, 0.13
Subjects with Missing Data	0	0

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

Table 4.6.14
Analysis of Gingival Abrasion Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 15 Visit (Visit 3)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	0.010 (0.0118)	0.030 (0.0280)
Median	0.006	0.024
Min, Max	0.00, 0.04	0.00, 0.10
Subjects with Missing Data	0	0
Day 15 Visit (Visit 3)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.013 (0.0258)	0.004 (0.0398)
Median	-0.008	0.006
Min, Max	-0.08, 0.04	-0.11, 0.07
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.015 (0.0037)	0.005 (0.0037)
95% CI	(-0.022, -0.007)	(-0.002, 0.013)
p-value comparing LS Mean versus 0	0.0002	0.1538
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.020 (0.0052)	n/a
95% CI	(-0.030, -0.010)	
Between-treatment p-value	0.0003	

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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Table 4.6.14
Analysis of Gingival Abrasion Findings
(Subjects in the Per-Protocol Population*)

	AutoBrush Toothbrush	Manual Toothbrush
Day 30 Visit (Visit 4)		
Summary of Scores		
Subjects with Non-Missing Data	35	35
Mean (SD)	0.007 (0.0095)	0.023 (0.0276)
Median	0.000	0.013
Min, Max	0.00, 0.04	0.00, 0.12
Subjects with Missing Data	0	0
Day 30 Visit (Visit 4)		
Summary of Change from Baseline (CFB)		
Subjects with Non-Missing Data	35	35
Mean (SD)	-0.016 (0.0226)	-0.003 (0.0416)
Median	-0.007	0.000
Min, Max	-0.08, 0.01	-0.13, 0.10
Subjects with Missing Data	0	0
Within-Treatment LS Means for CFB		
LS Mean (SE)	-0.017 (0.0035)	-0.001 (0.0035)
95% CI	(-0.024, -0.010)	(-0.008, 0.006)
p-value comparing LS Mean versus 0	<.0001	0.7743
Between-Treatment Comparison vs. Control		
LS Mean for Difference (SE)	-0.016 (0.0050)	n/a
95% CI	(-0.026, -0.006)	
Between-treatment p-value	0.0019	

Source: Listings 5.3.1, 5.3.2, and 5.3.6.2

* The per-protocol population consists of those subjects who completed the study without experiencing any major protocol violations that could have altered the study results.

NOTE: The analysis of the changes from baseline employed an analysis of covariance model with treatment as a factor and the corresponding baseline value as a covariate.

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5 APPENDICES

5.1 Study Information

5.1.1 Study Protocol and Amendments

AUT0BRUSH

Clinical Evaluation of the Safety and Efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model

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Clinical Protocol

Protocol No. AB-GBP-2023-03

FINAL
28 August 2023

STATEMENT OF COMPLIANCE

This trial will be conducted in compliance with the protocol and in accordance with Good Clinical Practice (GCP) as required by the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).
- International Council for Harmonisation; Good Clinical Practice E6(R2) (ICH-GCP); U.S. Food and Drug Administration (FDA) March 2018. International E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry, Current Step 4 version dated 9 November 2016.
- Clinical Investigations of Medical Devices for Human Subjects – Good Clinical Practice, ISO 14155:2020, consistent with FDA Guidance, "Acceptance of Clinical Data to Support Medical Device Applications and Submissions: Frequently Asked Questions; Guidance for Industry and Food and Drug Administration Staff (February 21, 2018).

All study personnel will be trained on study procedures and will be knowledgeable in GCP guidelines on protection of subject interests, health and confidentiality.

SIGNATURE PAGE

The signature below constitutes the approval of this protocol, its attachments and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and ICH guidelines.

Principal Investigator:

Signed: _____ Date: _____

Robert T. Nierman, DMD, MS
Timber Falls Dental Research
10120 Auburn Park Dr.
Fort Wayne, IN 46825
(260) 426-8061

Sponsor Representative:

Signed: _____ Date: _____

Chris Lander
Lander Enterprises, LLC dba AutoBrush
5700 Biscayne Blvd Apt 822
Miami, Florida 33137

TABLE OF CONTENTS

List of Abbreviations

AE	Adverse Event/Adverse Experience
ADA	American Dental Association
ANOVA	Analysis of Variance
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CRF	Case Report Form
DCF	Data Clarification Form
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IRB	Institutional Review Board
LSPI	Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index
MGI	Modified Gingival Index
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience

1 PROTOCOL SUMMARY

TITLE: Clinical Evaluation of the Safety and Efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model

Protocol Number: AB-GBP-2023-03

Study Duration: Each subject will participate in a 30-day clinical trial.

Description of Test Agents:

1) Control group: American Dental Association (ADA) reference standard manual soft bristle toothbrush with Crest Cavity Protection toothpaste used twice daily for 2 minutes (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).
2) AutoBrush® 360° U-shaped Sonic Toothbrush with Crest Cavity Protection toothpaste used twice daily for 30 seconds (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).

Objective:

The objective of this 30 day, randomized, two group, parallel, examiner-blind clinical trial is to assess the safety and efficacy of AutoBrush® 360° U-shaped Sonic Toothbrush on plaque and gingivitis, compared to an ADA reference standard manual toothbrush. The extent of gingival abrasion and recession will be evaluated.

Study population: Approximately 80 healthy volunteers, 5 - 65 years of age will be enrolled so that 70 subjects (35 per group) complete the study; at least 20 subjects aged 5-12 years old so that 10 pediatric subjects are randomized to each group; ~40 subjects aged 5 – 65 will be randomized to each group.

Sponsor:

Chris Lander
Lander Enterprises, LLC dba AutoBrush
5700 Biscayne Blvd, Apt 822
Miami, Florida 33137

Key Inclusion Criteria:

1) Generally healthy males and females at least 5 – 65 years of age.
2) Volunteers must read and sign an informed consent form. If under the age of 18, volunteer must provide assent to participate, and consent must be obtained from a parent or legal guardian prior to being enrolled into the study.
3) Regular manual toothbrush user and able to brush their own teeth daily.
4) A minimum of 18 natural teeth, in the adult dentition, with scorable facial and lingual surfaces.

a) If under the age of 12, must have at least 12 fully erupted teeth, primary or permanent teeth. NOTE: Partially erupted permanent teeth and primary teeth that are loose or in process of exfoliation will **not** be included in the tooth count.
b) Teeth that are grossly carious, orthodontically banded, exhibiting general cervical abrasion and/or enamel abrasion, > 2 mm gingival recession will not be included in the tooth count.

5) A plaque index score ≥ 1.80 according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI), following 12 to 16 hours plaque accumulation period at Baseline.
6) A gingival index score ≥ 1.75 according to the Modified Gingival Index at Baseline.
7) Willingness to abstain from all other oral hygiene procedures for the 30-day trial period.
8) No current active orthodontic treatment (e.g., orthodontic banding or appliances).
9) No evidence of major hard or soft tissue lesions or trauma.
10) Not currently using any form of tobacco products.

Study Design:

This single-center, randomized, controlled, double-blind, 30-day, parallel study will include an oral screening examination visit consisting of assessments in the following order:

- Oral soft and hard tissue exam will be assessed through soft and hard tissue, presence or absence of gingival abrasion, recession or other abnormalities.
- Gingivitis according to the Modified Gingival Index (MGI).

At Baseline, Day 15 and Day 30, the following exams will be performed in the following order:

- Oral soft and hard tissue exam will be assessed through soft and hard tissue examination for irritation, gingival abrasion, recession or other abnormalities.
- Gingivitis according to the Modified Gingival Index (MGI).
- Gingival recession, measured as the visible distance from the cemento-enamel junction (CEJ) to the gingival margin. Only positive measurements indicating recession will be recorded.
- Gingival Abrasion: Young-2-Tone® disclosing solution will be used to help visualize abraded areas of the oral epithelium. If abrasion is present, the site will be measured and recorded in millimeters. If no abrasion is present, the site will be recorded as “0”.
- Supragingival plaque levels, determined according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI). Plaque will be disclosed using the Young-2-Tone® disclosing solution and each tooth will be scored in six areas (distobuccal, midbuccal and mesiobuccal, distolingual, midlingual and mesiolingual).

- At Day 30, a post-brushing plaque assessment will be performed to assess plaque removal immediately following the use of the assigned toothbrush.

Prior to each exam visit, subjects will refrain from oral hygiene for 12 to 16 hours and will not eat or drink 30 minutes prior to the visit, except for small sips of water. Following informed consent and assent procedures (subjects aged 5 to 17) and collection of baseline demographics, qualified subjects will receive an oral examination and assessment for MGI, gingival recession, gingival abrasion and LSPI. Subjects will be enrolled into the study with existing mild to moderate gingivitis and there will be no dental prophylaxis performed during the study.

Subjects meeting study entrance criteria will be randomly assigned to one of two treatment groups:

1) Twice daily brushing for two minutes with an ADA reference standard manual soft toothbrush with Crest Cavity Protection 0.24% sodium fluoride toothpaste (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).
2) Twice daily brushing for 30 seconds with AutoBrush® 360° U-shaped Sonic Toothbrush and Crest Cavity Protection 0.24% sodium fluoride toothpaste (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 years of age).

Subjects will be provided verbal and written instructions on the use of their assigned oral care brushing. The first product use will be performed at the clinical site under the supervision of study personnel. Subjects assigned to the AutoBrush® 360° U-shaped Sonic Toothbrush will brush their teeth for 30 seconds with Crest Cavity Protection toothpaste. Subjects aged 5 to 8 years will dispense a pea-sized amount (~ 0.25 grams) or smear the paste into the two-sided brush head (mouthpiece). Subjects aged 9 to 65 years of age will dispense a ribbon of paste (~ 1.5 grams) into the two-sided brush head. Subjects using the manual toothbrush will be instructed to brush in their usual manner for two minutes. Subjects aged 5 to 8 years old will dispense/smear a pea-size amount of paste (~0.25 grams) on to the toothbrush bristles and subjects 9 to 65 years of age will dispense a full ribbon (~1.5 grams) of toothpaste. All subjects will maintain a daily diary to document compliance with the use of their assigned.

The use of a Washout period prior to Baseline will be included in this design so that subjects avoid use of antimicrobial mouth rinses, dentifrices or other dental products that might affect a subject's plaque or gingivitis status. Subjects will be asked to use the provided marketed fluoride toothpaste, e.g., Crest Cavity Protection toothpaste and ADA reference standard soft bristle toothbrush as their only oral hygiene regimen during the washout period. A 7 to 14-day washout period is appropriate to allow subjects to comply

with study and lifestyle restrictions prior to the Baseline Visit. Following the Baseline exams, subjects will return at Day 15 and Day 30 for the same assessments for oral safety, gingival inflammation, gingival recession, gingival abrasion and supragingival plaque. During the study, subjects will refrain from using any oral care products other than the toothbrush and toothpaste products provided to them and will avoid the use of chewing gums and mints. Individuals who use an interdental daily cleaning device will be allowed to continue and will document use on their daily diary.

Safety:

Safety will be assessed through oral clinical examinations and interviews to determine soft tissue or oral irritation symptoms. Lips, gingiva, buccal, labial, and sublingual mucosae, tongue, hard and soft palate, uvula and oropharynx will be examined for signs of reddening and inflammation, ulceration, soft tissue abrasion and recession, white patches and desquamation/sloughing of mucosal tissues and findings will be recorded on the Oral Exam CRF, with determination of severity (mild, moderate, or severe). Oral soft tissue findings will be tabulated and summarized by treatment group for each exam visit. The number and percentage of subjects experiencing adverse events will be tabulated by treatment. Adverse events will be summarized according to relationship to study material and according to severity. The development or advancement of gingival recession and abrasion will be evaluated for safety purposes.

Efficacy Endpoints:

Primary Efficacy variables:

- Whole mouth mean change in MGI scores at Day 30.
- Whole mouth mean change in LSPI scores at Day 30, immediate post-brushing.

Secondary Efficacy Variables:

- MGI at Day 15:
  - Whole mouth mean change.
  - Gumline (marginal).
  - Proximal (marginal).
  - Mean distal score of the last posterior tooth in each quadrant.
- LSPI at Day 15:
  - Pre- and Post- brushing Whole mouth.
  - Pre- and Post- brushing Gumline.
  - Pre- and Post- brushing Proximal.
  - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.
- MGI at Day 30
  - Gumline.

- Proximal.
- Distal score of the last posterior tooth in each quadrant.

- LSPI scores at Day 30
  - Pre- and Post- brushing Gumline.
  - Pre- and Post- brushing Proximal.
  - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.

Safety Endpoints:

- Mean change in gingival recession at Day 15 and Day 30.
- Mean change in gingival abrasion values.
- Number of gingival abrasion lesions on Day 15 and Day 30 in each of the 3 abrasion categories: small (≤2 mm), medium (3–5 mm) and large (>5 mm).
- Number of sites evaluated for gingival abrasion exhibiting each transition in measured lesion size between Baseline and Day 15; between Baseline and Day 30; and between Day 15 and Day 30.
- Number and percentage of subjects experiencing adverse events will be tabulated by treatment group.

Statistical Analyses:

Based on published studies comparing a sonic toothbrush to a manual toothbrush, sufficient subjects will be screened so that 80 will be randomized to treatment to ensure a total of 70 subjects (35 per treatment group) complete the Day 30 assessments. With 35 subjects per treatment group the study is calculated to have 80% power to detect a difference between treatments of 0.42 units in MGI and 0.26 units in LSPI after 30 days of treatment, assuming a standard deviation of 0.62 for MGI and 0.38 for LSPI, with a 0.05 two-sided significance level. These calculations are based on two-sided tests at the 0.05 significance level.

For each efficacy variable, summary statistics using appropriate descriptive statistics (mean, standard deviation, median, minimum, maximum) by treatment group will be provided at each visit.

Comparisons between the treatment groups for each efficacy variable will be performed for Day 15 and Day 30 utilizing an analysis of covariance (ANCOVA) model that includes treatment group as a fixed effect, and the corresponding baseline value as a covariate. Tables comparing treatment groups will provide differences in the least squares mean, the standard error of the differences, the 95% confidence interval for the difference, and the p-value.

All hypothesis tests employed to compare the treatments will be 2-sided, and will be

performed at the 0.05 level of significance.

2 KEY ROLES

Principle Investigator:	Robert T. Nierman, DMD, MS Timber Falls Dental Research 10120 Auburn Park Dr. Fort Wayne, IN 46825 (260) 426-8061 Email: rtnierman@gmail.com
Clinical Examiner:	Jeffery Milleman, DDS, MP Kaylie Wills, BSDH
Others (study coordinator):	Trista Eads, BSDH Tristaeads@yahoo.com
Sponsor:	Chris Lander Lander Enterprises, LLC dba AutoBrush 5700 Biscayne Blvd, Apt 822 Miami, Florida 33137
Monitor:	Sylvia L. Santos, RDH, MS or designee SLS Clinical Research Consulting, LLC Phone: 201-572-9223 sersantos@verizon.net
Study site:	Timber Falls Dental Research 10120 Auburn Park Dr. Fort Wayne, IN 46825 (260) 426-8061
Statistician:	Howard M. Proskin, PhD Howard M. Proskin and Associates, Inc. 35 Sleepy Hollow Ln Rochester, NY 14618

3 BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

The effective management of dental plaque and gingivitis continues to be a high priority for the dental health of the public. Dental professionals recommend brushing at least twice a day to remove plaque and reduce the risk of tooth decay and gum disease.[1] However, the high prevalence of oral diseases worldwide suggests that consumers do not achieve sufficient plaque removal with their manual toothbrushing routine.

Clinical studies have shown that improvement in mechanical oral hygiene can be achieved through the use of power toothbrushes.[2, 3, 4, 5, 6, 7, 8, 9, 10, 11] In fact, there are systematic reviews and meta-analyses which have demonstrated that power toothbrushes are more effective in removing plaque than manual toothbrushes.[12, 13] Well-designed clinical studies are needed to validate the efficacy of new toothbrush products and claims in improving plaque control and gingival health.

An innovative U-Shaped sonic power toothbrush has been developed by AutoBrush® that is designed with a full mouthpiece (double sided) with tapered nylon bristles to clean all surface areas of the teeth at once in a 30 second period. The company's mission is to make brushing simpler, better, and more accessible for kids, adults and individuals with disabilities. A recent independent, single-use, examiner blinded, randomized, two-period, cross-over, clinical study evaluated the safety and plaque removal efficacy of AutoBrush® 360° U-shaped Sonic Toothbrush, compared to a marketed children's manual toothbrush. Twenty-two children, 5 to 8 years of age, were randomized to receive each toothbrush product and completed all phases of the study. Supragingival plaque levels were assessed according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI). When assigned to the AutoBrush, subjects used the product for 30 seconds whereas they used the manual toothbrush in their usual manner for 2 minutes. Following single use of the AutoBrush, statistically significant reductions were observed for the AutoBrush compared to Baseline for whole mouth plaque for 50.6%, gumline levels with 71.2% and proximal levels were reduced by 40.7%. The manual toothbrush provided reductions of 1.9%, 3.5% and 1.1%, respectively. The AutoBrush provided up to 27 times greater plaque removal than the manual toothbrush.

This 30-day study is designed to compare the safety and efficacy of AutoBrush® 360° U-shaped Sonic Toothbrush to an ADA reference standard manual soft toothbrush on plaque and gingivitis in a 30-day clinical study.

4 OBJECTIVE

The objective of this 30 day, randomized, two group, parallel, examiner-blind clinical trial is to assess the safety and efficacy of AutoBrush® 360° U-shaped Sonic Toothbrush on plaque and gingivitis, compared to an ADA reference standard manual toothbrush. The extent of gingival abrasion and recession will be evaluated.

4.1 Endpoints

4.1.1 Safety

Safety will be assessed through oral clinical examinations and interviews to determine soft tissue or oral irritation symptoms. Soft tissue exams will focus on the potential impact on gingival recession and gingival abrasion.

Safety endpoints include:

- Mean change in gingival recession at Day 15 and Day 30.
- Mean change in number of gingival abrasion values for each of the 3 categories, small (≤2 mm), medium (3–5 mm) and large (>5 mm) Day 15 and Day 30.
- Number and percentage of subjects experiencing adverse events, tabulated by treatment group.

4.1.2 Efficacy

Efficacy endpoints will be:

- Primary Efficacy variables:
  - Whole mouth mean change in MGI scores at Day 30.
  - Whole mouth mean change in LSPI scores at Day 30, immediate post-brushing.
- Secondary Efficacy Variables:
  - Whole mouth mean change in MGI scores at Day 15.
  - Mean change in distal score of the last posterior tooth in each quadrant.
  - Mean change in LSPI scores at Day 15 and Day 30 (immediate post-brushing) for:
    - Gumline LSPI scores (marginal)
    - Proximal LSPI scores (mesial and distal).
    - Mean change in distal score of the last posterior tooth in each quadrant.
  - Mean change in LSPI scores at Day 15 and Day 30 (Pre-brushing) for:
    - Gumline LSPI scores (marginal)
    - Proximal LSPI scores (mesial and distal).

5 STUDY DESIGN

This single-center, randomized, controlled, examiner-blind, 30-day parallel study will consist of a Screening/Baseline visit during which potential subjects (age 5-65 years) will read and sign an informed consent form, complete health and dental questionnaires and a receive a clinical oral examination. For subjects 5 to 17 years of age, subjects' parents/legal guardians will read and sign the consent form and subjects will sign an assent form.

Screening visit will include assessments in the following order:

- Oral safety will be assessed through soft and hard tissue examination (OSHT), presence or absence of gingival abrasion, recession or other abnormalities.
- Visual examination for qualifying gingivitis levels according to the Modified Gingival Index (MGI);[14]

Qualified subjects will participate in a 7 to 14-day Washout period prior to Baseline so that subjects avoid use of antimicrobial mouth rinses, dentifrices or other dental products that might affect a subject's plaque or gingivitis status. Subjects will be asked to use the provided marketed fluoride toothpaste, e.g., Crest Cavity Protection toothpaste and ADA reference standard soft bristle toothbrush as their only oral hygiene regimen during the washout period. A 7 to 14-day washout period is appropriate to allow subjects to comply with study and lifestyle restrictions prior to the Baseline Visit.

Prior to each exam visit, subjects will refrain from oral hygiene for 12 to 16 hours and will not eat or drink 30 minutes prior to the visit. Sipping water will be permitted prior to each exam visit. The Baseline visit will include confirmation of consent and assent to participate in the study, review of inclusion and exclusion criteria, and exams in the following order:

- OSHT
- MGI
- Gingival recession, measured as the visible distance from the cemento-enamel junction (CEJ) to the gingival margin.
- Gingival Abrasion as described by Danser[15] , Rosema[16] and Van der Weijden[17].
- Supragingival plaque levels, determined according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI).[18, 19]

Subjects meeting study entrance criteria will be stratified by age: pediatric dentition group (≥ 5 and < 12) and adult dentition group (≥ 12 and ≤ 65), randomly assigned to one of two treatment groups, such that at least each group contains at least 10 pediatric subjects:

1) Control group: ADA reference standard manual soft bristle toothbrush with Crest Cavity Protection toothpaste used twice daily for 2 minutes (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 and ≤ 65 years of age).
2) AutoBrush® 360° U-shaped Sonic Toothbrush with Crest Cavity Protection toothpaste used twice daily for 30 seconds (~0.25 grams for subjects aged 5-8 years old, ~1.5 grams for subjects ≥ 9 and ≤ 65 years of age).

Subjects will be provided verbal and written instructions on the use of their assigned toothbrush. The first assigned brushing will be performed at the clinical site under the supervision of study personnel. All subjects will maintain a daily diary to document compliance with the use of their assigned toothbrush product.

Following the Baseline exams, subjects will return at Days 15 and 30 for the same assessments for oral safety, gingival health and plaque. At the Day 30 visit only, subjects will receive a pre-brushing plaque exam followed by a post-brushing plaque exam to assess the immediate effect of plaque removal with the assigned toothbrush.

During the study, subjects will refrain from using any oral care products other than the toothbrush or toothpaste provided to them and will avoid the use of other toothbrushes, toothpaste, mouthwashes, chewing gum, breath film, mints, floss or interdental cleaning aids, or other oral care cleaning aids for the duration of this research study. Subjects who routinely use interdental aids will be permitted to continue use throughout the study.

6 STUDY POPULATION

Approximately 80 healthy male and female volunteers, 5 - 65 years of age, will be enrolled so that 70 subjects (35 per group) complete the study. At least 20 subjects aged 5-12 years old will be enrolled so that 10 pediatric subjects are randomized to each group. To participate in this study, all subjects will fulfill the inclusion and exclusion criteria as outlined in sections 6.1 and 6.2.

6.1 Inclusion Criteria

To be eligible for study participation, subjects must meet the following criteria:

1) Be generally healthy males and females at least 5 to 65 years of age.
2) If under age 18, willing to provide assent to participate and consent from a parent or legal guardian prior to being entered into the study.
3) If 18 years of age or older, is able to read, sign and receive a copy of the signed informed consent form.
4) Be regular manual toothbrush users and able to brush their own teeth on a daily basis.
5) Be in good health based on medical history review by the investigator.
6) Be willing to refrain from all oral hygiene for approximately 12-16 hours prior to each study visit and discontinue eating and drinking for approximately 30 minutes prior to each study visit, with the exception of sips of water.
7) Have a minimum of 18 natural teeth, in the adult dentition, with scorable facial and lingual surfaces. If under the age of 12, must have at least 12 fully erupted teeth, primary or permanent teeth. **NOTE**: Partially erupted permanent teeth and primary teeth that are loose or in process of exfoliation will not be included in the tooth count. Teeth that are grossly carious, orthodontically banded, exhibiting general cervical abrasion and/or enamel abrasion, > 2 mm gingival recession will not be included in the tooth count.
8) Present with a gingival index score ≥ 1.75 according to the Modified Gingival Index at Baseline.
9) Present with a plaque index score $\geq$ 1.80 according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index, following a 12 to 16-hour plaque accumulation period at Baseline.
10) Be willing and able to refrain from dental treatment during the course of the study, except on an emergency basis.

6.2 Exclusion Criteria

Subjects presenting with any of the following will not be included in the study:

1) A history of adverse effects, oral soft or hard tissue sensitivity, to any ingredient in the test materials.
2) Self-reported serious medical conditions.
3) Self-reported as pregnant or nursing.
4) Under treatment for a heart condition requiring use of pacemaker.
5) Have any condition, in the opinion of the investigator, that would place the subject at increased risk or preclude the subject's full compliance with or completion of the study?
6) Require antibiotic premedication prior to dental procedures.
7) Have had antibiotic, anti-inflammatory, anti-coagulant medication or chemotherapeutic antiplaque/antigingivitis therapy within 30 days of screening exams.
8) Have participated in any study involving oral care products, concurrently or within the 30 days of screening exams.
9) Unwilling to discontinue use of other oral hygiene products for the duration of the study.
10) Present use of any tobacco products.
11) Presence of severe periodontal disease or being actively treated for periodontal disease.
12) Have grossly carious, fully crowned, or extensively restored teeth.
13) Have orthodontic appliances, peri/oral piercings, or removable partial dentures.
14) Have significant oral soft tissue pathology based on a visual examination.

Ifthe subject reports taking medication, a history of allergy, and/or a chronic disease which in the opinion of investigator will not affect the clinical parameter(s) being assessed or the safety of the subject, the subject may be enrolled in the study and the conditions will be noted on the Subject's source document.

6.3 Subject Identification, Screening and Enrollment

Subjects will be recruited from the local population utilizing the recruitment materials approved by the IRB. Subject screening, enrollment, product assignments, and dental assessments will be conducted at the clinic site. The investigator will maintain a screening and enrollment log of all subjects who sign an ICF for this study and for all children who signed assent form and a parent/legal guardian signed ICF for this study. The log will include unique subject identification numbers/screening numbers (1001-1080) and dates of subject screening, enrollment and completion (or early termination). Once a number has been assigned to a subject, it cannot be reassigned to another subject. For subjects who fail screening, the reason(s) for non-participation will be recorded on the log. The Investigator will also maintain a confidential identification list containing each enrolled subject's name and corresponding unique subject number, to enable records to be identified.

6.4 Treatment Assignment Procedures

Up to 80 qualified subjects will be randomly assigned to one of two treatment groups. Qualified subjects will be stratified by age: pediatric dentition group (≥ 5 and ≤ 12) and adult dentition group (>12 and ≤ 65), such that at least 20 pediatric subjects will be enrolled, and 10 pediatric subjects are randomized to each group. Upon qualification, each enrolled subject will be sequentially issued a unique subject randomization number (001-080), which determines the treatment assignments according to a randomization scheme prepared by the Sponsor. Subjects will be randomized to one of two treatment groups:

1) Control Group: Twice daily brushing with an ADA reference standard manual soft toothbrush (age-appropriate) and Crest® Cavity Protection dentifrice.
2) Sonic Toothbrush Group: Twice daily brushing with AutoBrush® 360° U-shaped Sonic Toothbrush (age-appropriate) and Crest® Cavity Protection dentifrice.

Subjects assigned to the AutoBrush group will be dispensed a toothbrush head appropriate for their mouth size, ranging from: Ages 3-5, 6-8, 9-12, Adult Small, Adult Regular, and Adult XL. For subjects assigned to the manual toothbrush group: subjects will receive the ADA reference standard manual soft toothbrush. The Investigator or designee will maintain randomization worksheets documenting the subject assignment to treatment groups.

6.4.1 Withdrawal

Every effort will be made within the bounds of safety and subject choice to have each subject complete the study. A discontinuation occurs when an enrolled subject ceases participation in the study, regardless of the circumstances, prior to completion of the protocol. The reason for a subject discontinuation from the study will be reported in the case report form. The investigators must attempt to determine the primary reason for discontinuation. A study subject will be discontinued from participation in the study if:

- Any clinical adverse event (AE), intercurrent illness, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the subject.
- The subject meets any exclusion criteria (either newly developed or not previously recognized).

Subjects are free to withdraw from participation in the study at any time upon request. A discontinuation must be immediately reported to the sponsor's clinical monitor or the designated representative if it is due to a serious adverse event. The final evaluation required by the protocol will be performed at the time of study discontinuation.

6.4.2 Termination of Study

This study may be prematurely terminated if, in the opinion of the investigator or the sponsor, there is sufficient reasonable cause. Written notification, documenting the reason for study termination, will be provided to the investigator or sponsor by the terminating party.

Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to subjects.
- Insufficient adherence to protocol requirements.
- Plans to modify, suspend or discontinue the development of the experimental test article.

If the study is prematurely terminated or suspended, the sponsor will promptly inform the investigators/institutions, of the termination or suspension and the reason(s) for the termination or suspension. The IRB will also be informed promptly and provided with the reason(s) for the termination or suspension by the investigator/institution.

7 INVESTIGATIONAL PRODUCT

7.1 Study Material Description

7.1.1 ADA Reference Standard Soft Manual Toothbrush

Juvenile subjects, age 5 to 8 years, assigned to the manual toothbrush group will be dispensed the ADA reference standard adult's manual soft toothbrush. Subjects who are ≥ 9 and ≤ 65 years of age will be dispensed the ADA reference standard adult's soft manual toothbrush. Subjects assigned to the manual toothbrush will brush their teeth twice daily in their usual manner for 2 minutes. Only the first product use in the office will be supervised by a Timber Falls Research staff member.

Manual Toothbrush Control:	**ADA Reference Standard Soft Manual Toothbrushes**
Kids Ages 5-8 years	ADA reference standard Adult's Soft Toothbrush
Kids and adults ≥ 9 and ≤ 65 years	ADA reference standard Adult's Soft Toothbrush
Packaging	Single packaging

7.1.2 AutoBrush® 360° U-shaped Sonic Toothbrush

Subjects assigned to the AutoBrush group will be dispensed the AutoBrush base and the two-sided toothbrush head (mouthpiece) with nylon bristles, appropriate for their mouth size, ranging from: Ages 3-5, 6-8, 9-12, Adult Small, Adult Regular, and Adult XL. The brush has a 30 seconds cycle time which simulates a full 2-minute brushing for all quadrants of the mouth.

Only the first product use in the office will be supervised by a Timber Falls Dental Research staff member. The figure below displays the product features which are the same for adult devices.

Sonic Toothbrush:	**Sonic Rechargeable Toothbrush**
Trade name for Kids Ages 5-8	AutoBrush® 360° U-shaped Sonic Toothbrush
	
Trade name for kids and adults ≥ 9 and ≤ 65 years	AutoBrush® 360° U-shaped Sonic Toothbrush 
Manufacturer	Lander Enterprises, LLC dba AutoBrush
Packaging	Single packaging

Ancillary supplies for the 30-day phase of the include a single tube of Crest® Cavity Protection dentifrice (0.243% sodium fluoride, Procter & Gamble, Cincinnati, OH, USA), at least 4.6 oz. tube. For the 7 to 14-day washout period, subjects will receive the ADA reference standard soft manual toothbrush and a tube of the Crest Cavity Protection toothpaste for use twice daily for two minutes.

7.2 Packaging, Labeling and Storage

All products must be stored by the clinical site at room temperature. Manual toothbrushes, AutoBrush® 360° U-shaped Sonic Toothbrushes and Crest® Cavity Protection toothpaste will be supplied in the original marketed packages with no overwrap. Each subject will receive a carrying bag that will contain the label noting the relevant randomization number and instructions for use.

7.2.1 Manual toothbrush control group

Label for subjects 5-8 years old with instructions to dispense approximately 0.25 grams of toothpaste on to the bristles:

Protocol: AB-GBP-2023-03 **Subject Randomization#:_____**
INSTRUCTIONS FOR USE for Ages 5 – 8 years old **UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION:**
1) Wet your toothbrush and dispense a smear of toothpaste onto the brush head. 2) Brush in your usual manner with your assigned toothbrush for two minutes 3) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing. 4) Rinse brush head after use.
Warnings: Keep all test materials out of reach of children under 12 years of age. **For Investigational Use Only – Not for Sale**
If you have questions, contact the Timber Falls Dental Research Emergency number: (260) 426-8061

For subjects ≥ 9 and ≤ 65 years to dispense approximately 1.5 grams (full ribbon) of toothpaste on to the bristles:

Protocol: AB-GBP-2023-03 **Subject Randomization#:_____**
INSTRUCTIONS FOR USE, FOR CHILDREN ≥ 9 and < 18 years **(UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION) AND ADULTS (≥ 18 years):**
1) Wet your toothbrush and dispense a full ribbon of toothpaste onto the brush head. 2) Brush in your usual manner with your assigned toothbrush for two minutes 3) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing. 4) Rinse brush head after use.
Warnings: Keep all test materials out of reach of children under 12 years of age. **For Investigational Use Only – Not for Sale**
If you have questions, contact the Timber Falls Dental Research Emergency number: (260) 426-8061

7.2.2 AutoBrush® 360° U-shaped Sonic Toothbrush group

Instructions for use will be similar for all age groups with the exception of the amount of toothpaste used for the 5- to 8-year-old subjects.

The following label for subjects 5-8 years old to dispense approximately 0.25 grams of toothpaste on to the bristles:

Protocol: AB-GBP-2023-03 **Subject Randomization#:_____**
INSTRUCTIONS FOR USE for Ages 5 – 8 years old. **UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION:**
1) Follow package instructions for charging the AutoBrush base device. 2) To assemble the AutoBrush, firmly attach the nylon brush head onto the AutoBrush base. 3) Wet your toothbrush and dispense a smear of paste onto each side of the brush head. 4) Place the brush into your mouth, press the on/off button (the circle in the middle of the AutoBrush base). *** **DO NOT PRESS ANY OTHER BUTTONS EXCEPT FOR THE POWER BUTTON** 5) Hold the base and use biting figure 8 motions while alternating directions for the full 30 seconds. 6) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing. 7) Remove the brush head from the base, rinse and air dry after use.
Warnings: Keep all test materials out of reach of children under 12 years of age. For Investigational Use Only – Not for Sale
If you have questions, contact the Timber Falls Dental Research Emergency number: (260) 426-8061

For subjects ≥ 9 and ≤ 65 years to dispense approximately 1.5 grams (full ribbon) of toothpaste on to the bristles:

Protocol: AB-GBP-2023-03 **Subject Randomization#:_____**

INSTRUCTIONS FOR USE, FOR CHILDREN ≥ 9 <18 years
(UNDER PARENT/LEGAL GUARDIAN'S SUPERVISION) AND ADULTS (≥ 18 years):

1) Follow package instructions for charging the AutoBrush base device.
2) To assemble the AutoBrush, press the nylon brush head firmly onto the AutoBrush base.
3) Wet your toothbrush and dispense a ribbon of toothpaste onto each side of the brush head.
4) Place the brush into your mouth, press the on/off button (the circle in the middle of the AutoBrush base).

*** **DO NOT PRESS ANY OTHER BUTTONS EXCEPT FOR THE POWER BUTTON**

5) Hold the base and use biting figure 8 motions while alternating directions for the full 30 seconds.
6) Thoroughly rinse your mouth out with water. Do not swallow toothpaste while brushing.
7) Remove the brush head from the base, rinse and air dry after use.

Warnings: Keep all test materials out of reach of children under 12 years of age.
For Investigational Use Only – Not for Sale
If you have questions, contact the Timber Falls Dental Research Emergency number: (260) 426-8061

7.3 Dosage, Preparation and Administration of Investigational Product

At Screening visit, all subjects will receive regular fluoride toothpaste and an ADA accepted age-appropriate size toothbrush for use during the 7 to 14-Day Washout Period.

Following Baseline exam procedures, subjects will be instructed to use their assigned toothbrush twice daily as detailed in their instructions attached to their daily diary.

7.4 Accountability Procedures for the Investigational Product(s)

Lander Enterprises, LLC will provide the investigator with sufficient amounts of the study test materials. The investigator must ensure that deliveries of investigational product from the sponsor are received by the responsible person, that all receipts are recorded in writing and that the product is stored in a secure area under recommended storage conditions. It is also the responsibility of the investigator to ensure that the integrity of packaged study product not be jeopardized prior to dispensing. The investigator will dispense the test material only to subjects included in this study following the procedures specified in the study protocol. Each subject will be administered only the test material carrying his/her randomization number.

All dispensing will be documented. The investigator is responsible for ensuring all full, partially full, and empty test material containers are disposed at the end of the study. The investigator must maintain accurate and adequate records including dates of receipt and return of test material shipments, and quantities received/returned from/to Lander Enterprises, LLC as well as, dates and amounts dispensed to the study subjects.

7.5 Assessment of Subject Compliance with Investigational Product

Compliance will be assessed at the Days 15 and 30 visits through review of the subjects' daily diaries. Subjects will be required to maintain a daily diary to record the time of completion of their assigned morning and evening toothbrushing. Toothpaste will be weighed prior to being dispensed at Visit 2 and once it is returned at Visit 4.

7.6 Concomitant Medications/Non-Drug Therapy

Any medication the subject takes during the study is considered concomitant medication. All concomitant medications and non-drug therapy (e.g., tooth extraction, endodontic treatment, etc.) must be recorded in the subject's medical source document.

8 STUDY PROCEDURES, EVALUATION AND SCHEDULE

The schedule of observations and assessments is provided in Sec. 16, Table 1, Study Flow Chart.

8.1 Screening (Visit 1)

Prior to randomization to treatment groups, the following procedures will be performed:

- Parent or legal guardian will read and sign the informed consent form prior to enrollment of juvenile subjects.
- Juvenile subject will provide assent to participate.
- Informed consent for adult subjects.
- Collection of medical and dental history.
- Inclusion/Exclusion Criteria checklist.
- Clinical exams:
  - OSHT
  - Tooth Charting
  - Visual screening for qualifying levels of gingivitis.
  - Visual screen for gingival abrasion and recession.
- Dispense Washout toothpaste and toothbrush.
- Study staff review and dispense daily diary and home use written instructions.
- Appoint subjects for next visit.

8.2 Baseline (Visit 2)

- Confirm continuing Informed consent and assent.
- Query to update medical and oral health and record adverse events and concomitant medications.
- Review and update Inclusion/Exclusion Criteria checklist.
- Clinical exams:
  - OSHT.
  - Modified Gingival Index (MGI).
  - Gingival recession, measured as the visible distance from the cemento-enamel junction (CEJ) to the gingival margin.
  - Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI).
  - Gingival Abrasion evaluation using Young-2-Tone® disclosing solution will be used to help visualize abraded areas of the oral epithelium.
  - Identify subjects with qualifying levels of gingivitis and plaque: MGI ≥ 1.75, LSPI ≥ 1.80.

If subject meets entry criteria, the following procedures will be performed:

- Randomization to test groups.
- Dispense assigned test materials.
- Supervise initial use of assigned test products.
- Study staff review and dispense daily diary and home use written instructions.
- Appoint subjects for next visit.

8.3 Day 15 (± 2 days) – Midpoint Exams (Visit 3)

- Query to update medical and oral health and record adverse events and concomitant medications.
- Assess compliance with study instructions and use of test materials.
- Oral soft and hard tissue examination for safety.
- Clinical exams:
  - OSHT.
  - MGI.
  - Gingival Recession evaluation.
  - LSPI.
  - Gingival Abrasion Assessment.
- Appoint subjects for next visit.

8.4 Day 30 (± 2 days) – Final Exams (Visit 4)

- Query to update medical and oral health and record adverse events and concomitant medications.
- Assess compliance with study instructions and use of test materials.
- Oral soft and hard tissue examination for safety.
- Clinical exams:
  - OSHT.
  - MGI.
  - Gingival Recession evaluation.
  - Pre-Brushing LSPI.
  - Gingival Abrasion Assessment.
  - Subjects perform last brushing with their assigned toothbrush.
  - Post-Brushing LSPI.
- Discharge subject and provide final instructions for follow-up of ongoing adverse events, as applicable.

During the study, subjects will follow their usual dietary habits, but will be instructed to refrain from using any oral care products other than the test materials provided to them.

8.5 Early Termination Visit

If a subject discontinues from the study for any reason prior to the final visit, the following procedures should be conducted:

- Record adverse events and concomitant medications.
- Oral soft and hard tissue examination.
- Schedule follow-up visit for any ongoing adverse events.

9 STUDY PROCEDURES/EVALUATIONS

9.1 Demographics

Demographic information will be collected at the Screening/Baseline Visit and will include the subject's race, gender, age and tobacco use.

9.2 Safety Assessments

9.2.1 Oral Examinations

An oral examination will be conducted to monitor the changes to the soft and hard tissues. Examination of the oral hard tissues (teeth), all facial, lingual/palatal, mesial/distal and occlusal surfaces, will be completed by direct observation, using retraction aids as appropriate.

Oral soft tissue examination will be accomplished throughout the study by direct observation and palpation with retraction aids, as appropriate. The examination will include evaluation of the labial mucosa (including lips), buccal mucosa, mucogingival folds, gingival mucosa, hard palate, soft palate, uvula, tonsillar area, pharyngeal area, tongue, sublingual area, submandibular area and salivary glands. Results of the examination will be documented with details of any abnormalities. Any abnormality or worsening of a pre-existing condition observed by the clinical examiner or reported by the subject following the Visit 1 OSHT examination will be recorded as an AE.

Observations such as reddening/inflammation, ulceration, white patches and desquamation/sloughing of mucosal tissues will be documented, with determination of severity (mild, moderate or severe):

Mild:	The oral condition is easily tolerated and does not interfere with daily activity
Moderate:	The oral condition causes enough discomfort to interfere with daily activity.
Severe:	The oral condition results in an incapacity to work or do usual activity and requires medical/dental intervention.

Clinically significant findings will be recorded as adverse events and an assessment will be made regarding the relationship to test materials.

9.2.2 Gingival Recession

Gingival recession will be evaluated at Baseline (Visit 2), Day 15 (Visit 3) and Day 30 (Visit 4). Gingival recession is marked by the apical migration of the gingival margin away from the cemento-enamel junction (CEJ). The clinical recession measurements will be conducted at six sites per tooth (mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual, and distolingual). Recession will be measured as the visible distance from the cemento-enamel junction (CEJ) to the gingival margin. Only positive measurements indicating recession will be recorded.

9.2.3 Gingival Abrasion

Gingival Abrasion as described by Danser[15] , Rosema[16] and Van der Weijden[17]. Young-2-Tone® disclosing solution will be used to help visualize abraded areas of the oral epithelium. The gingival tissues of each tooth, present or not present, will be divided into 3 areas on both the facial and lingual surfaces, as illustrated in Fig. 1: marginal (cervical free gingiva), interdental (papillary free gingiva) and mid-gingival (attached gingiva). If abrasion is present, the site will be measured and recorded in millimeters. If no abrasion is present, the site will be recorded as “0”.

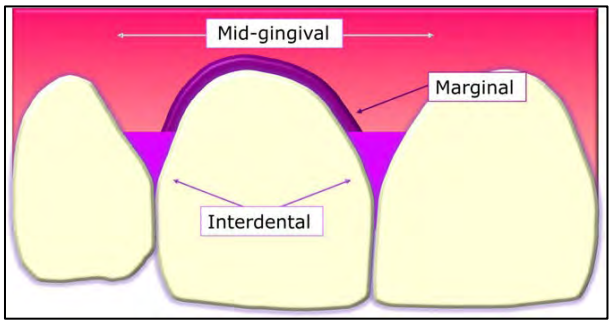

Figure 1. (From Rosema et al 2014)

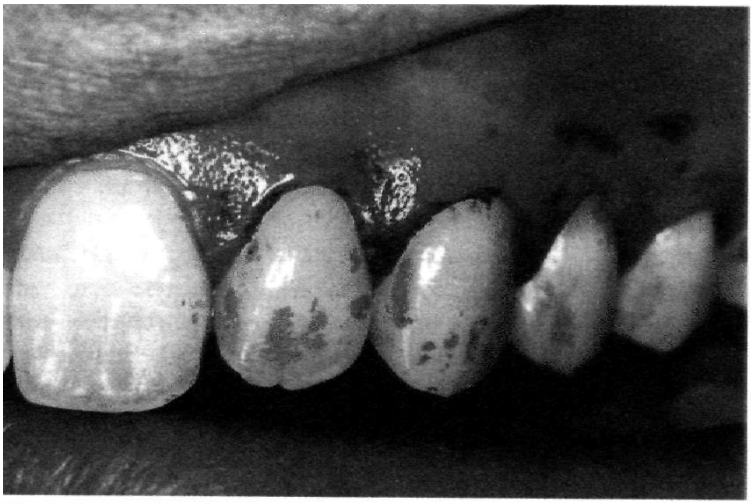

Figure 2. (from Danser et al, 1998a)

9.3 Efficacy Assessments

Clinical efficacy assessments will be performed by a single examiner at Baseline, Days 15 and 30 in the following sequence: MGI and LSPI.

9.3.1 Gingival Inflammation

Gingival inflammation will be assessed at Screening, Baseline, Days 15 and 30, according to the Modified Gingival Index (MGI),[14] and will be scored in six areas (distobuccal, midbuccal and mesiobuccal, distolingual, midlingual and mesiolingual) of all scorable teeth using a scale of 0 – 4 as noted below:

0 = Normal (absence of inflammation).
1 = Mild inflammation (slight change in color, little change in texture) of any portion of the entire gingival unit.
2 = Mild inflammation of the entire gingival unit.
3 = Moderate inflammation (moderate glazing, redness, edema, and/or hypertrophy) of the gingival unit.
4 = Severe inflammation (marked redness and edema/hypertrophy, spontaneous bleeding, or ulceration) of the gingival unit.

Whole mouth MGI scores will be calculated by summing all scores and dividing by the number of scorable sites examined.

9.3.2 Plaque Index

Supragingival dental plaque will be assessed according to the Turesky Modification of the Quigley-Hein Plaque Index as further modified by Lobene and Soparkar (LSPI).[18,19] Plaque will be disclosed using a red disclosing solution and each tooth will be scored in six areas

(distobuccal, midbuccal and mesiobuccal, distolingual, midlingual and mesiolingual), according to the criteria noted below:

0 = No plaque.
1 = Separate flecks or discontinuous band of plaque at the gingival (cervical) margin.
2 = Thin (up to 1 mm), continuous band of plaque at the gingival margin.
3 = Band of plaque wider than 1 mm but less than 1/3 of tooth surface area.
4 = Plaque covering 1/3 or more, but less than 2/3 of tooth surface area.
5 = Plaque covering 2/3 or more of tooth surface area.

At Day 30 visit only, subjects will brush with their assigned toothbrush at the clinical test site and will be re-disclosed for a second plaque assessment (post-treatment).

A whole mouth plaque index will be calculated for each subject by adding all the individual scores and dividing this sum by the number of measurements. To understand the plaque removal efficacy of each toothbrush in hard-to-reach areas, separate subsets of the plaque index will be calculated for gingival margin (gumline) and the proximal surfaces. Gumline LSPI scores will be calculated by summing the number of gingival margin (buccal and lingual) scores and dividing by the number of measurements. Proximal LSPI scores (mesial and distal) will be calculated by summing the number of proximal site scores (distobuccal, mesiobuccal, distolingual and mesiolingual) and dividing by the number of measurements.

9.4 Examiner Repeatability Exercises

A single trained dental examiner will perform the oral examinations and MGI and LSPI assessments. Prior to Baseline exams, at least 10 subjects will be assessed for gingival inflammation and plaque levels, according to the MGI and LSPI with at least 10 minutes between repeat examinations. Repeatability will be evaluated through the demonstration of at least 80% frequency of agreement of assessments. Re-training and/or recalibration (followed by a repeat of the exercise) will be performed if the evaluated level of reliability is judged to be low.

NOTE: Repeatability exercises will not be needed if the examiner has used MGI and LSPI in a clinical trial within two months prior to the start of this study.

10 ADVERSE EVENT REPORTING AND DOCUMENTATION

Adverse events will be determined by visual examination of the oral cavity by the dental examiner. In addition, clinical research center personnel will ask subjects about the occurrence of any adverse events during their participation in this study. All observed or volunteered adverse events, regardless of treatment group or suspected causal relationship to study product, will be recorded on the adverse event page(s) of the case report form.

10.1 Adverse Events

An adverse event (AE) is any untoward medical occurrence in a clinical study subject administered an investigational product and that does not necessarily have a causal relationship with the study product. An AE is therefore any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease (new or exacerbated) temporally associated with the use of a study product, whether or not related to that study product.

An unexpected AE is one of a type not identified in nature, severity, or frequency in the investigational product safety summary or of greater severity or frequency than expected based on the information in the study product safety summary.

The Investigator will probe, via discussion with the subject, for the occurrence of AEs during each subject visit and record the information in the site's source documents. Adverse events will be recorded in the subject CRF. Adverse events will be described by duration (start and stop dates), severity, outcome, treatment and relation to study product, or if unrelated, the cause.

Pre-existing conditions will not be regarded as AEs if the condition follows a normal course of recovery unless it worsens after exposure to the study product.

10.2 Definition of a Serious Adverse Event (SAE)

The Investigator or other study personnel must immediately (within 24 hours) inform the Sponsor of all Serious Adverse Events (SAEs) that occur in study subjects.

An SAE is any untoward medical occurrence that at any dose:

- Results in death.
- Is life-threatening.
- Requires hospitalization, or prolongation of existing hospitalization.
- Results in persistent or significant disability/incapacity.
- Is a congenital anomaly or birth defect.

Important medical event/experience that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

Note: Classification of an AE as 'serious' is based on the outcome of the event and is a factor in determining reporting requirements.

10.3 Medical Device Incidents

Medical devices are being provided by the Sponsor for use in this study; the medical devices in this study include the plaque disclosing solution (Class I medical device), the standard ADA manual toothbrush and the AutoBrush® 360° U-shaped sonic toothbrush (Class I medical device).

A medical device incident is any malfunction or deterioration in the characteristics and/or performance of a device as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a subject/user/other person or to a serious deterioration in his/her state of health.

Not all incidents lead to death or serious deterioration in health. The nonoccurrence of such a result might have been due to other fortunate circumstances or to the intervention of health care personnel.

Medical device incidents, including those resulting from malfunctions of the devices, must be detected, documented, and reported by the investigator on the Incident Report Form.

10.4 Unanticipated adverse device effect (UADE)

An unanticipated adverse device effect is any serious adverse effect on health or safety, or any life-threatening problem or death caused by, or associated with, a device, if that effect problem, or death was not previously identified in nature, severity, or degree of incidence in the study plan, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

10.5 Recording an Adverse Event

All serious adverse events will be recorded and reported immediately to the Study Sponsor. An AE shall be documented when a subject reports an untoward event or when subjects are asked directly about concurrent illnesses and concomitant medication or from answers on subject-completed diary forms. When an AE is discovered or reported, the PI or designee shall complete the AE/SAE Case Report Form. The Principal Investigator shall review all AEs/SAEs and determine the severity, relationship (of the AE/SAE to the test article/investigational product), and outcome. The PI also will determine whether the subject will remain in the study.

Severity, relationship and outcome will be defined as follows:

Severity	Description
Mild	Awareness of signs or symptoms, but easily tolerated.
Moderate	Discomfort to a degree that the AE/SAE causes interference with normal daily life activities and/or requires medication.
Severe	Incapacity with regard to work or usual daily life activities. Requires medical attention/intervention.

Relationship	Description
Unrelated	Clearly evident relationship to other etiologies such as concomitant medications or conditions or subject's known clinical state.
Possible	Uncertain association. Other etiologies are also possible.
Probable	Causal relationship cannot be ruled out.
Definite	AE/SAE with a clear-cut temporal association

Outcome	Description
Not recovered/Not resolved	AE/SAE had not resolved by end of study. (Does not mean AE/SAE was not followed until resolution.)
Resolved without sequelae	AE/SAE completely resolved by end of study (or ongoing yet unrelated to study, therefore resolved for purposes of study).
Resolved with sequelae	AE/SAE resolved by end of study, but aftereffect or disease or injury is present. e.g., a stroke that resulted in partial paralysis; the stroke resolved, but residual paralysis.
Death	

10.6 Follow-up

Study-related adverse events will be monitored to resolution by the Investigator for at least 30 days following study completion or discontinuing use of the study product.

Serious Adverse Events/Experiences will be followed to resolution to the extent possible (e.g., medical attention by subject's primary care physician).

10.6.1 Follow-up of Incidents

During the study:

- All incidents will be followed until resolution of the event, until the condition stabilizes, until the condition is otherwise explained, or until the subject is lost to follow-up. This applies to all subjects, including those withdrawn prematurely. The investigator is responsible for ensuring that follow-up includes any supplemental investigations as may be indicated to elucidate as completely as practical the nature of the incident.
- New or updated information will be recorded on the originally completed form with all changes signed and dated by the investigator.

After the study:

- Investigators are not obligated to actively seek reports of incidents in former subjects. However, if the investigator learns of any incident at any time after a subject has been discharged from the study, and such incident is reasonably related to a medical device provided for the study, the investigator will promptly notify the Study Manager and Sponsor.

10.7 Reporting Adverse Events

The Investigator will report all serious adverse events immediately to the Sponsor monitor, Sylvia L. Santos, RDH, MS at 201-572-9223, and will complete a Serious Adverse Event Form within the following timelines:

- All deaths and immediately life-threatening events, whether related or unrelated, will be recorded on the Serious Adverse Event Form and sent by email within 24 hours of site awareness to the attention of Sylvia L. Santos at sersantos@verizon.net.
- Serious adverse events other than death and immediately life-threatening events, regardless of relationship, will be reported by email within 72 hours of site awareness to the attention of Sylvia L. Santos at sersantos@verizon.net.

The Sponsor's representative or monitor will be notified within the time frame specified above, after any adverse event has been reported to the Investigator or Investigator's staff.

10.8 Reporting of Medical Device Incidents and Malfunctions

10.8.1 Incident reporting:

- All incidents must be reported to the Sponsor monitor within 24 hours (or sooner if possible) of the investigator or designee becoming aware of the situation.

- Any medical device incident occurring during the study will be documented in the subject's medical records, in accordance with the investigator's normal clinical practice, and on the appropriate Incident Report Form. In addition, for incidents fulfilling the definition of an AE or an SAE, the appropriate AE CRF page or SAE form will be completed and reported as per the AE and SAE reporting sections.
- The Incident Report Form will be completed as thoroughly as possible and signed by the investigator before transmittal to the Sponsor. It is very important that the investigator describes any corrective or remedial actions taken to prevent recurrence of the incident.
- The completed Incident Report Form should be scanned and emailed to the Study Monitor as soon as possible, but not later than 24 hours after study site personnel learn of the event. If there is an SAE, the completed SAE pages should be sent together with this report form. However, if a copy of the SAE report is sent with this form, this does not replace the procedure to report an SAE. The original Incident Report Form will remain with the subject’s records.
- The Study Monitor should be notified of the situation by telephone or email.
- The Study Monitor will be responsible for forwarding the Incident Report Form to the Sponsor.
- The initial report will be followed up with more information as relevant, or as requested by the Sponsor.

10.8.2 Malfunction reporting:

The investigator will follow the following directions regarding device failure (malfunction):

- Notify the Study Monitor immediately.
- Schedule the subject to return to the site promptly to return the failed device.
- Record any incidents on the CRF and Incident Report Form following instructions given in the section above.
- Return the failed device to the Sponsor as soon as possible, including documentation of the details of the failure.

10.8.3 Regulatory and Ethics Reporting Requirements for Incidents

- The investigator will promptly report all incidents occurring with any medical device provided for use in the study within 24 hours. The Sponsor has a legal responsibility to notify appropriate regulatory bodies and other entities about certain safety information relating to medical devices being used in clinical studies. Prompt notification of incidents by the investigator to the Sponsor is essential in order to meet legal obligations and ethical responsibility towards the safety of subjects.

- The investigator, or responsible person according to local requirements, will comply with the applicable local regulatory requirements relating to the reporting of incidents to the IRB.

10.9 Reporting Unanticipated Adverse Device Effects

Investigators are required to submit a report of a UADE to the Sponsor and the reviewing IRB as soon as possible, but in no event later than 10 working days after the Investigator first learns of the event.

Sponsors must immediately conduct an evaluation of a UADE and must report the results of the evaluation to FDA, all reviewing IRBs, and participating Investigators within 10 working days after the Sponsor first receives notice of the effect.

11 STATISTICAL CONSIDERATIONS

This section outlines the basic statistical approach for the study.

Data will be electronically and/or manually recorded on Case Report Forms (CRFs). Timber Falls Dental Research will be responsible for data entry, and statistical analysis of the data will be performed by Howard M. Proskin & Associates.

11.1 Data Sets Analyzed

All eligible subjects who are randomized into the study and perform at least one use of the study product will be included in the safety analysis (e.g., the Safety Population). The Per-protocol (PP) population will include subjects who do not have major protocol violations possibly altering the study outcome (e.g., low compliance, visit window violations etc.). Subjects will be classified into analysis sets prior to opening of the product code.

No accounting of missing data will be made. The Sponsor will be informed of dropouts in the final study report. Data for discontinued subjects will be included in the safety analysis. Subjects discontinued due to an adverse event will be included in the safety analysis.

11.1.1 Exclusion of Data from Analysis

Any of the following will be considered a protocol violation and will be exclude from analysis:

- Violation of inclusion or exclusion criteria that can affect efficacy.
- Medical history which impacts efficacy.
- Use of prohibited treatment or medication before or during the study, which can affect the assessment of efficacy. The assessments affected will be determined prior to database lock.

- Not receiving randomized treatment.
- Noncompliance with randomized treatment.

11.2 Sample Size Considerations

Based on published studies comparing a sonic toothbrush to a manual toothbrush,[5, 6, 8, 9, 10, 11] sufficient subjects will be screened so that 80 will be randomized to treatment to ensure a total of 70 subjects (35 per treatment group) complete the Day 30 assessments. With 35 subjects per treatment group the study is calculated to have 80% power to detect a difference between treatments of 0.42 units in MGI and 0.26 units in LSPI after 30 days of treatment, assuming a standard deviation of 0.62 for MGI and 0.38 for LSPI, with a 0.05 two-sided significance level. These calculations are based on two-sided tests at the 0.05 significance level. Assuming an estimated attrition rate of 5%, 80 subjects will be screened and randomized.

11.3 Safety Review

Oral soft tissue findings will be tabulated and summarized by treatment group for each exam visit. The number and percentage of subjects experiencing adverse events will be tabulated by treatment. Adverse events will be summarized according to relationship to study material and according to severity.

Safety endpoints include:

- Mean change in gingival recession at Day 15 and Day 30.
- Mean change in gingival abrasion values.
- Number of gingival abrasion lesions on Day 15 and Day 30 in each of the 3 abrasion categories: small (≤2 mm), medium (3–5 mm) and large (>5 mm).
- Number of sites evaluated for gingival abrasion exhibiting each transition in measured lesion size between Baseline and Day 15; between Baseline and Day 30; and between Day 15 and Day 30.
- Number and percentage of subjects experiencing adverse events, tabulated by treatment group.

11.4 Demographic and Baseline Characteristics

Demographic and Baseline characteristics will be summarized for age, gender, race, mean MGI, and LSPI. Data will be summarized using appropriate descriptive statistics (mean, standard deviation, median, minimum, maximum) by treatment group and overall. Categorical demographic and baseline data will be evaluated using Fisher's Exactness Test and continuous demographic and baseline data will be evaluated using ANOVA. All tests will be two-sided and

conducted at the 0.05 significance level. No adjustments for multiple comparisons or multiple testing will be made.

11.5 Efficacy Review

11.5.1 Primary Efficacy Endpoint

The primary efficacy endpoint:

- Mean change in Whole Mouth MGI scores at Day 30.
- Mean change in Whole Mouth LSPI scores at Day 30, immediate post-brushing.

11.5.2 Secondary Efficacy Endpoint

- MGI at Day 15:
    - Whole mouth.
    - Gumline (marginal).
    - Proximal (marginal).
    - Mean distal score of the last posterior tooth in each quadrant.
- LSPI at Day 15:
    - Pre- and Post- brushing Whole mouth
    - Pre- and Post- brushing Gumline.
    - Pre- and Post- brushing Proximal.
    - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.
- MGI at Day 30
    - Gumline.
    - Proximal.
    - Distal score of the last posterior tooth in each quadrant.
- LSPI scores at Day 30
    - Pre- and Post- brushing Gumline.
    - Pre- and Post- brushing Proximal.
    - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.

For each efficacy variable summary statistics using appropriate descriptive statistics (mean, median, minimum, maximum) by treatment group and overall will be provided at each visit.

Analyses will be performed at Days 15 and 30 for each efficacy variable, analyses will be performed using the ANCOVA model with treatment as a factor and the corresponding baseline value as a covariate. The comparisons will be made at the 0.05 level, 2-sided. Tables comparing treatment groups will provide differences in the least squares mean, the standard error of the differences, the confidence interval for the difference, and the p-value.

12 DATA HANDLING AND RECORD KEEPING

Data that is manually recorded on CRFs or source documents will be entered into an Excel spreadsheet and transmitted to the statistician for statistical analysis. The investigator site will be responsible for data entry into an Excel spreadsheet as well as transmission of the data to the statistician for statistical analysis. The investigator's study coordinator and consultant statistician will agree on data entry format. The data entry personnel will perform a 100% QC of data entered into the Excel Spreadsheet against the paper CRFs. Following data entry verification and prior to statistical analysis, the spreadsheet will be transmitted to the AutoBrush study manager and study monitor for review to detect data entry issues/errors, logical data inconsistencies, missing data, protocol deviations, outliers and develop any necessary data queries. Following the satisfaction completion of data queries, the data entry file will be supplied to the statistician under password protection. A follow-up email will be provided to the statistician revealing the password.

The investigator will prepare and maintain adequate and accurate source documents designed to record all observations and other pertinent data for each subject participating in the study. Data captured in source documents includes subject information, original records of clinical findings, observations, medical histories, prior and concomitant medication records, inclusion/exclusion eligibility checklist, records of subject visits and phone calls, progress notes, subjects' diaries or evaluation checklists, test product dispensing and accountability records.

A Case Report Form (CRF) will be completed for each subject enrolled in the study and will include documenting subject demographics and subject's study completion status. All information recorded on the CRFs for this study must be consistent with the subject's source documentation records. The Investigator or designee must review all entries for completeness and correctness.

The Investigator or designee agrees to make all CRFs and source documents available to the Sponsor's Study Monitor for full inspection. After resolution of the monitor's queries, a copy of the final CRF will be placed in the investigator's study file and the original will be taken by the site monitor and provided to the Sponsor.

The sponsor will review the CRFs and additional source documents for completeness and adherence to the protocol.

12.1 Study Records Retention

Study documents should be retained for a minimum of 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal

discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the Sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

12.2 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, Good Clinical Practice (GCP) requirements. The noncompliance may be either on the part of the subject, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the site to use continuous vigilance to identify and report deviations within 5 working days of identification of the protocol deviation, or within 5 working days of the scheduled protocol-required activity. All deviations must be promptly reported to the Sponsor and must be addressed in study subject source documents. In addition, protocol deviations must be sent to the local IRB per their guidelines. The site PI/study staff are responsible for knowing and adhering to their IRB requirements.

13 ETHICS

13.1 Institutional Review Board

This study will be reviewed byVeritas Investigational Review Board, Inc. which is an appropriately constituted Institutional Review Board (IRB) as outlined in 21 CFR Part 56 and is registered with the US Department of Health and Human Services (DHHS) as #IRB00003814, #IRB00005916, #IRB00005917. The IRB will review the protocol, any amendments, the informed consent form (ICF), the assent form, subject instructions and questionnaires, safety information, Investigator’s curriculum vitae (CV) and advertisements.

Approval by the Board must be obtained prior to the initiation of the study. Approval by the Board must be obtained prior to the initiation of the study.

13.2 Ethical Conduct of the Study

This study will be conducted in accordance with 21 Code of Federal Regulations (CFR) Parts 50 and 56. The study will be conducted in accordance with the Principles of Good Clinical Practice.

Lander Enterprises, LLC is responsible for the ongoing safety evaluation of the investigational products and will promptly notify participating Investigators and regulatory authorities of findings that could adversely affect the safety of subjects, impact the conduct of the study, or alter the IRB’s approval to continue the study. Lander Enterprises, LLC will promptly report all adverse reactions related to the test articles that are both serious and unexpected to the

appropriate regulatory authorities and to all Investigators and IRBs currently involved in studies of this test article.

13.3 Subject Information, Consent and Assent

The clinical investigation, including the consent form and assent form, will be reviewed by an IRB in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Informed consent will be obtained from the parent or legal guardian of each subject prior to participation in any study procedures as required by the Food and Drug Administration (FDA) GCP guidelines. Information will be given in both oral and written form and subjects' parents/legal guardian must be given ample opportunity to inquire about details of the study prior to signing and dating the consent form. Assent will be obtained from all children and consent from a parent or legal guardian. An exact copy of the signed consent and assent forms will be given to the parent/legal guardian of the subject and the original will be maintained with the subject's records.

13.4 Authorization to Disclose Protected Health Information

Subjects will be informed of the following information: The purpose of the protected health information (PHI) being collected, the possibility the PHI may be re-disclosed, the duration of the authorization, the right to revoke the authorization, and the right to refuse signature and limit access to PHI during and following the conduct of the trial. As applicable, written authorization to disclose PHI will be incorporated into the informed consent process and will be obtained prior to the subject entering the study. Each subject will be provided with a signed copy of the authorization and the original will be retained on file at the study center.

Subject confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participating subjects.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study, or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor or other authorized representatives of the sponsor may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the subjects in this study. The clinical study site will permit access to such records.

14 MONITORING

A Sponsor representative may meet with the Investigator and his/her staff prior to the entrance of the first subject to review the procedures to be followed in conducting the study. After the enrollment of the first subject, the Investigator will permit the Sponsor to monitor the progress of the trial on site periodically. The Investigator will make available the source documents as well as the subjects' records and signed consent forms.

15 AMENDMENTS/MODIFICATION OF THIS PROTOCOL

No amendment to the protocol will be permitted without approval from the study Sponsor, Investigator, and IRB. Such changes will be documented in writing. Approval by the IRB must be obtained prior to initiation of the amendment.

16 SCHEDULE OF ACTIVITIES

Procedures:	Visit 1 Screening/ Washout (7-14 days prior to Baseline)	Visit 2 Baseline (7-14 days from Screening)	Visit 3 Day 15 ± 2 days	Visit 4 Day 30 ± 2 days
Informed Consent/Assent	X			
Confirm continuing informed consent/assent		X	X	X
Medical/Dental History	X			
Record Concomitant Medications	X	X	X	X
Review Inclusion and Exclusion Criteria	X	X		
Update Medical/Dental History		X	X	X
Confirm Continuing Inclusion/Exclusion		X	X	X
Query Subjects and record Adverse Events		X	X	X
Clinical Exams:				
Intraoral Exam	X	X	X	X
MGI		X	X	X
Gingival Recession, Gingival Abrasion		X	X	X
Pre-brushing LSPI		X	X	X
Post-brushing LSPI				X
Randomization		X		
Dispense washout toothpaste and toothbrush	X			
Washout Products and Diary Review/Return		X		
Supervised use of toothpaste & assigned toothbrush		X		X
Dispense toothpaste & assigned toothbrush		X		
Schedule appointment for next visit	X	X	X	
Test Article and Diary Review/Return			X	X
Study Conclusion and Exit				X

17 REFERENCES

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Electronic Record and Signature Disclosure: Accepted: 8/28/2023 11:03:00 AM ID: 7775d9e7-066a-4060-b704-0132b9bfb936		

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Notary Events	Signature	Timestamp

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Completed	Security Checked	8/28/2023 11:08:56 AM

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

5.1.2 Case Report Forms

Sample Case Report Forms available on request

5.1.3 Ethics Committees and Subject Information

Veritas Investigational Review Board Services, Inc.
3551 St. Charles Blvd., Suite 501
Kirkland, Quebec
H9H 3C4
Telephone: 514-337-0442
Toll Free: 1-866-384-4221

5.1.4 Investigators and Study Personnel

Principle Investigator:	Robert T. Nierman, DMD, MS Timber Falls Dental Research 10120 Auburn Park Dr. Fort Wayne, IN 46825 (260) 426-8061 Email: rtnierman@gmail.com
Others (study coordinator):	Trista Eads, BSDH Tristaeads@yahoo.com
Sponsor:	Chris Lander Lander Enterprises, LLC dba AutoBrush 5700 Biscayne Blvd, Apt 822 Miami, Florida 33137
Monitor:	Sylvia L. Santos, RDH, MS or designee SLS Clinical Research Consulting, LLC Phone: 201-572-9223 sersantos@verizon.net
Study site:	Timber Falls Dental Research 10120 Auburn Park Dr. Fort Wayne, IN 46825 (260) 426-8061
Statistician:	Howard M. Proskin, PhD Howard M. Proskin and Associates, Inc. 35 Sleepy Hollow Ln Rochester, NY 14618

1-Page Curricula Vitae and Licenses for Dr. Robert Nierman are attached.

ROBERT NIERMAN

RTNIERMAN@GMAIL.COM | (260) 415-5919
12178 Fazio Drive | Fort Wayne, IN 46818

EDUCATION

Midwestern University — **Downers Grove, IL**
Doctor of Dental Medicine (4.0 GPA, 1/130) — May 2022
Master of Science in Biomedical Sciences (3.998 GPA) — Sept 2017 – Oct 2022

Loyola University — **Chicago, IL**
Postbaccalaureate Course Work — May – Aug 2017

Indiana University — **Bloomington, IN**
Bachelor of Science in Kinesiology, Minor in Coaching — May 2014

RESEARCH

Nodal and Cripto-1 Expression in 4NQO Induced OSCC — **March 2018 – Oct 2022**

- Experimental mouse model utilizing 4-Nitroquinoline-1-oxide as a carcinogen to induce oral squamous cell carcinoma in C57Bl/6 mice
- Quantified a significant increase in relative expression of Cripto-1 in the 4NQO mice on a high-fat diet when compared to a low-fat diet, leading to a potential correlation with chronic inflammation
- Determined the effects of chronic inflammation and OSCC on the oral microbiome via a 16S-rRNA bacterial analysis of saliva samples taken pre- and post-treatment

Chicago Dental Society Midwinter Meeting — **Feb 2020**
Student Research Poster Presenter — Chicago, IL

- Designed and presented a poster on Cripto and Nodal research at the expo
- Presented my research findings and fielded questions for an entire day at the Midwinter Meeting

Midwestern University CDMI Student Research Group — **Aug 2019 – Aug 2020**
President — Downers Grove, IL

- Working to build a research-based mindset at CDMI through evidence-based dentistry
- Started a lecture series with Dr. John Mitchell, Ph.D. the Associate Dean of Research on how to transform a research idea into a grant proposal, publication, and presentation at a national conference
- Learning how the field of research plays a vital role academic dentistry and the beneficence of the patient

Midwestern University Research Extravaganza — **April 2019**
1st Place Presenter — Downers Grove, IL

- Presented on preliminary data on the effects of chronic inflammation and oral cancer on Nodal and Cripto expression
- Ten-minute oral presentation followed by a Q&A session

Salus Research, Inc. — **Jan – May 2017**
Research Assistant — Fort Wayne, IN

- Patient interaction via consenting, protocol instruction, and patient accountability visits
- Recorded data for research provider
- Assembled and organized research data for study results
- Systematically organized medical records of past studies

PRESENTATIONS AND PUBLICATIONS

- Abstract and poster accepted for 2020 Chicago Dental Society Midwinter Meeting
- 2019 Midwestern University CDMI Research Extravaganza; 1st Place Presenter

EXPERIENCE

Timber Falls Family Dentistry/Dental Research — **Aug 2023 – Present**
Owner Dentist/Principal Investigator — Fort Wayne, IN

- Responsible for the care and well-being of our patients
- Ensure the office and myself maintain a high standard of care
- Oversee staff and business management.

Luarde Dental Care **May 2022 – Sept 2023**
Associate Dentist Fort Wayne, IN

- Proficient in all aspects of clinical dentistry; including restorations, crowns, bridges, molar endo and retreats, surgical extractions, removable prostheses, and all-on-4 prostheses
- Transitioning to take over all orthodontic straight wire cases while taking continuing education in orthodontics via USDI courses
- Trained in digital dentistry with Planmeca E4D CAD/CAM and diode lasers
- $273,735.00 in production during the subsequent two quarters post-graduation

Oral & Maxillofacial Surgery Associates **Nov 2016 – May 2022**
Dr. Steve Schimmele, DDS, FACS Observation Fort Wayne, IN

- Observed third molar extractions, implants, partial glossectomy, unilateral sagittal split osteotomy with neuroplasty, BSSO, and scar excision with split thickness skin graft and coronoidectomy
- Learned the value of building relationships with patients, ensuring they feel well cared for

Parkview Regional Medical Center **Oct 2016 – Jan 2017**
O.R. Inventory Coordinator Fort Wayne, IN

- Collaborated with leadership and sales representatives to ensure adequate provisions to meet the OR demand
- Responsible for stocking specialized products in the Orthopedic, General, Neuro, Cardiovascular, and Robotic departments
- Accountable for ordering and tracking all biological products, including heart valves and grafts

Team Indiana Elite **Feb 2015 – Sept 2016**
Professional Distance Runner Bloomington, IN

- Following a collegiate career-ending knee injury, came back to chase an Olympic Qualifying Standard
- Trained on a seven-day regimen, averaging 100-110 miles per week, while working 25 hours a week

ATI Physical Therapy **Sept 2014 – July 2015**
Rehab Technician Bloomington, IN

- Responsible for instructing patients through their exercise programs

Indiana University Cross Country and Track & Field **June 2010- June 2014**
Team Member and Captain Bloomington, IN

- Led the team on race day, ensuring everyone was warmed up and ready on time
- Responsible for organizing optional practices along with morning runs while on trips

SKILLS

- Excellent at building and maintaining relationships
- Comfortable with speaking to large groups
- Strong leadership skills and team oriented
- Hard working and extremely disciplined
- Strong written and verbal communication skills
- Attention to detail and strives for excellence
- Organized and excellent time management
- Lab skills: pipetting, handling mRNA samples, qPCR protocol, protein isolation
- Profound problem-solving skills

AWARDS AND ACCOMPLISHMENTS

- 2022 MWU CDMI Dean's Recognition Award
- 2022 MWU CDMI Award of Excellence
- 2014 Big Ten Runner-Up Indoor Mile
- 2013 & 2014 Big Ten Runner-Up Steeplechase
- 2013 – '14 Big Ten Distinguished Scholar Recipient
- 2013 NCAA 2nd Team All-American Steeplechase
- 2013 Big Ten Cross Country Champions
- 2012 Indoor Track and Field Big Ten Champions
- 2006 Eagle Scout Award

PROFESSIONAL ASSOCIATIONS

- American Assoc. of Dental Research 2019 – '21
- American Dental Association 2018 – Present
- Indiana Dental Society 2018 – Present
- Academy of General Dentistry 2018 – Present

5.1.5 Sponsor and Investigator Signatures

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Principal Investigator:

Signed:  Date: 12-19-2023

Robert T. Nierman, DMD, MS
Timber Falls Dental Research
10120 Auburn Park Dr.
Fort Wayne, IN 46825
(260) 426-8061

Sponsor Representative:

Signed:  Date: 12/20/2023

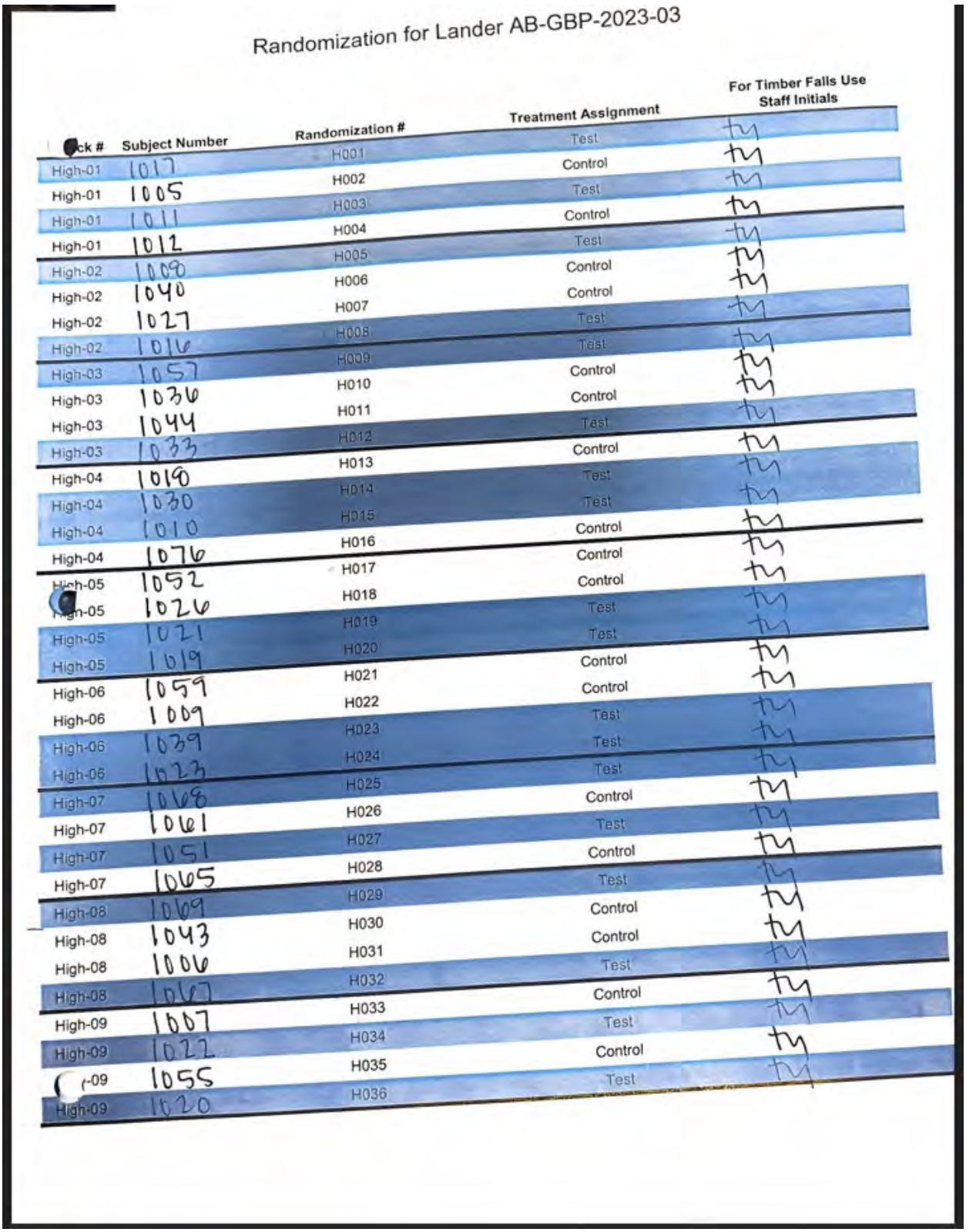
Chris Lander
Lander Enterprises, LLC dba AutoBrush®
5700 Biscayne Blvd Apt 822
Miami, Florida 33137

5.1.6 List of Study Products

Manual toothbrush: ADA reference manual soft-bristled toothbrush

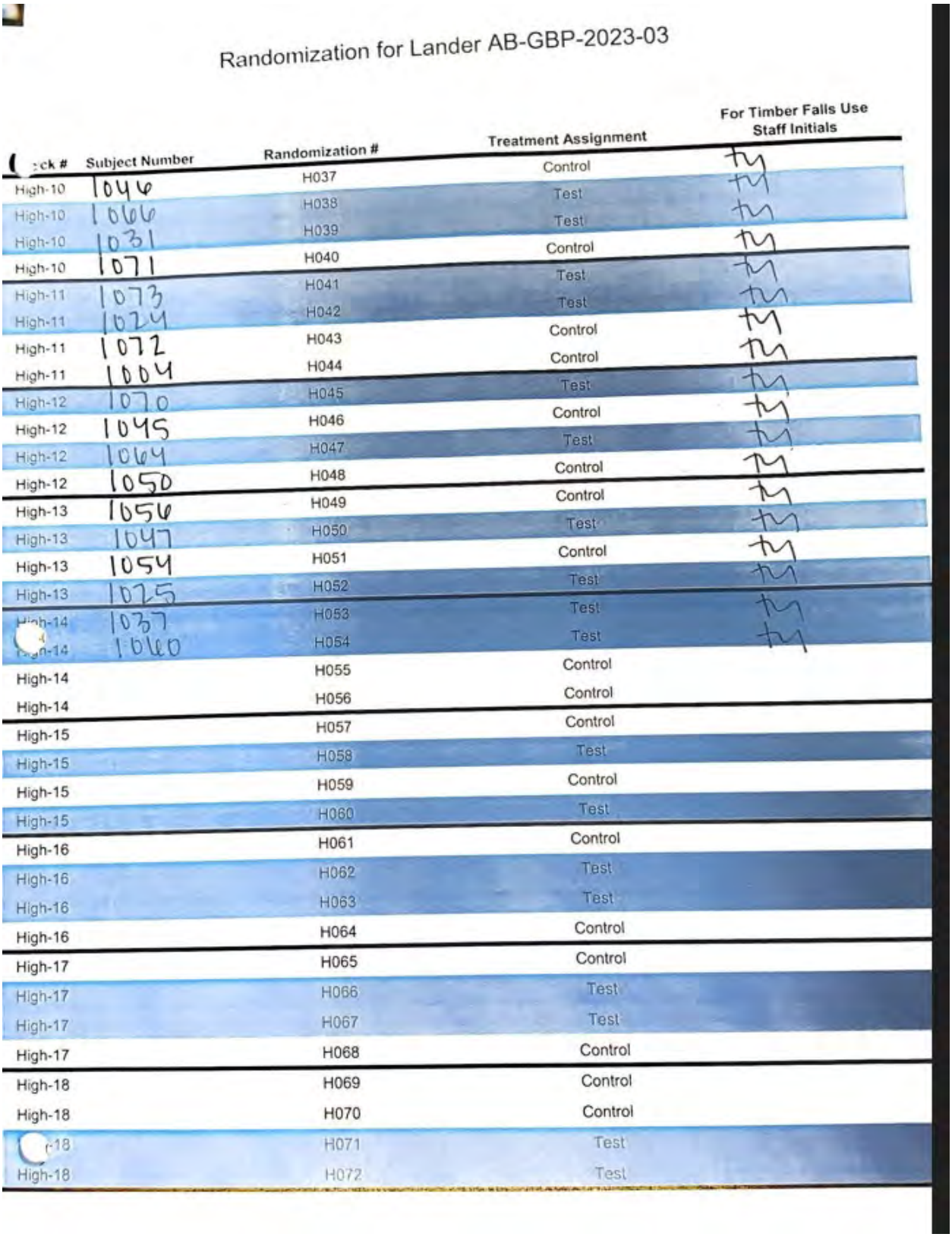
Sonic toothbrush: AutoBrush® 360° U-Shaped Sonic Toothbrush

5.1.7 Randomization Scheme and Codes



Randomization for Lander AB-GBP-2023-03

Block #	Subject Number	Randomization #	Treatment Assignment	For Timber Falls Use Staff Initials
High-01	1017	H001	Test	ty
High-01	1005	H002	Control	ty
High-01	1011	H003	Test	ty
High-01	1012	H004	Control	ty
High-02	1009	H005	Test	ty
High-02	1040	H006	Control	ty
High-02	1027	H007	Control	ty
High-02	1016	H008	Test	ty
High-03	1057	H009	Test	ty
High-03	1036	H010	Control	ty
High-03	1044	H011	Control	ty
High-03	1033	H012	Test	ty
High-04	1019	H013	Control	ty
High-04	1030	H014	Test	ty
High-04	1010	H015	Test	ty
High-04	1076	H016	Control	ty
High-05	1052	H017	Control	ty
High-05	1026	H018	Control	ty
High-05	1021	H019	Test	ty
High-05	1019	H020	Test	ty
High-06	1059	H021	Control	ty
High-06	1009	H022	Control	ty
High-06	1039	H023	Test	ty
High-06	1023	H024	Test	ty
High-07	1068	H025	Test	ty
High-07	1061	H026	Control	ty
High-07	1051	H027	Test	ty
High-07	1065	H028	Control	ty
High-08	1069	H029	Test	ty
High-08	1043	H030	Control	ty
High-08	1006	H031	Control	ty
High-08	1067	H032	Test	ty
High-09	1007	H033	Control	ty
High-09	1022	H034	Test	ty
High-09	1055	H035	Control	ty
High-09	1020	H036	Test	ty



Randomization for Lander AB-GBP-2023-03

Block #	Subject Number	Randomization #	Treatment Assignment	For Timber Falls Use Staff Initials
High-10	1046	H037	Control	TM
High-10	1066	H038	Test	TM
High-10	1031	H039	Test	TM
High-10	1071	H040	Control	TM
High-11	1073	H041	Test	TM
High-11	1024	H042	Test	TM
High-11	1072	H043	Control	TM
High-11	1004	H044	Control	TM
High-12	1070	H045	Test	TM
High-12	1045	H046	Control	TM
High-12	1064	H047	Test	TM
High-12	1050	H048	Control	TM
High-13	1056	H049	Control	TM
High-13	1047	H050	Test	TM
High-13	1054	H051	Control	TM
High-13	1025	H052	Test	TM
High-14	1037	H053	Test	TM
High-14	1060	H054	Test	TM
High-14		H055	Control	
High-14		H056	Control	
High-15		H057	Control	
High-15		H058	Test	
High-15		H059	Control	
High-15		H060	Test	
High-16		H061	Control	
High-16		H062	Test	
High-16		H063	Test	
High-16		H064	Control	
High-17		H065	Control	
High-17		H066	Test	
High-17		H067	Test	
High-17		H068	Control	
High-18		H069	Control	
High-18		H070	Control	
High-18		H071	Test	
High-18		H072	Test	

Randomization for Lander AB-GBP-2023-03

Block #	Subject Number	Randomization #	Treatment Assignment	For Timber Falls Use Staff Initials
Low-01	1062	L001	Test	TM
Low-01	1015	L002	Control	TM
Low-01	1035	L003	Test	TM
Low-01	1074	L004	Control	TM
Low-02	1075	L005	Test	TM
Low-02	1029	L006	Control	TM
Low-02	1028	L007	Test	TM
Low-02	1038	L008	Control	TM
Low-03	1001	L009	Test	TM
Low-03	1003	L010	Test	TM
Low-03	1063	L011	Control	TM
Low-03	1053	L012	Control	TM
Low-04	1049	L013	Test	TM
Low-04	1048	L014	Test	TM
Low-04	1013	L015	Control	TM
Low-04	1014	L016	Control	TM
Low-05	1058	L017	Test	TM
Low-05	1002	L018	Test	TM
Low-05	1042	L019	Control	TM
Low-05	1032	L020	Control	TM
Low-06	1034	L021	Test	TM
Low-06		L022	Control	
Low-06		L023	Control	
Low-06		L024	Test	
Low-07		L025	Control	
Low-07		L026	Control	
Low-07		L027	Test	
Low-07		L028	Test	
Low-08		L029	Test	
Low-08		L030	Control	
Low-08		L031	Control	
Low-08		L032	Test	
Low-09		L033	Control	
Low-09		L034	Test	
Low-09		L035	Test	
09		L036	Control	
Low-10		L037	Control	

5.1.8 Publications Referenced in the Report

Please refer to the reference list in Section 3.5 of this report.

5.2 Statistical Narrative Report

Protocol No. AB-GBP-2023-03

Clinical Safety and Efficacy of AutoBrush® 360° U-Shaped Sonic Toothbrush on Plaque and Gingivitis in a 30-Day Model

Final Statistical Report

10 November 2023

Report Prepared by:

Howard M. Proskin, Ph.D.

Howard M. Proskin & Associates, Inc.
35 Sleepy Hollow Ln.
Rochester, NY 14618

Objective:

The objective of this 30 day, randomized, two group, parallel, examiner-blind clinical trial was to assess the safety and efficacy of AutoBrush® 360° U-shaped Sonic Toothbrush on plaque and gingivitis, compared to an ADA Accepted manual toothbrush. The extent of gingival abrasion and recession was evaluated.

Study Design:

This single-center, randomized, controlled, and double-blind study was conducted according parallel-groups design. Following a screening examination at which subject eligibility was determined and informed consent and assent was obtained, enrolled subjects reported to the study site for three subsequent visits: Baseline, Day 15, and Day 30. At the Baseline visit, subjects were randomized to one of the two study toothbrushes, and were instructed to use their assigned toothbrush twice daily over the course of the study according to instructions provided.

At Baseline and at each follow-up study visit, whole mouth oral examinations were performed according to the Modified Gingival Index (MGI); the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (LSPI); gingival abrasion; and gingival recession. An oral soft and hard tissue (OSHT) examination was also performed at each visit. At the Day 30 visit, subjects brushed their teeth with the assigned product while in the dental clinic, and were reexamined for LSPI and OSHT following brushing (to enable an assessment of pre- to post-brushing changes). OSHT was also performed at the Screening visit. Information regarding Adverse Events was obtained at Baseline and at all follow-up study visits. Additional details concerning the conduct of the study are provided in the study protocol.

Study Populations:

The Safety Population consisted of all eligible subjects who were randomized into the study and performed at least one use of the study product. The Per-protocol (PP) population included subjects who completed all study visits without any major protocol violations.

Study Endpoints:

Safety endpoints included:

- Mean change in gingival recession at Day 15 and Day 30.
- Mean change in number of gingival abrasion values for each of the 3 categories, small (≤2 mm), medium (3–5 mm) and large (>5 mm) Day 15 and Day 30.
- Number and percentage of subjects experiencing adverse events, tabulated by treatment group.

Efficacy Endpoints were as follows:

Primary Efficacy variables:

- Whole mouth mean change in MGI scores at Day 30.
- Whole mouth mean change in LSPI scores at Day 30, immediate post-brushing.

Secondary Efficacy Variables:

- MGI at Day 15:
  - Whole mouth mean change.
  - Gumline (marginal).
  - Proximal (marginal).
  - Mean distal score of the last posterior tooth in each quadrant.
- LSPI at Day 15:
  - Pre- and Post- brushing Whole mouth.
  - Pre- and Post- brushing Gumline.
  - Pre- and Post- brushing Proximal.
  - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.
- MGI at Day 30
  - Gumline.
  - Proximal.
  - Distal score of the last posterior tooth in each quadrant.
- LSPI scores at Day 30
  - Pre- and Post- brushing Gumline.
  - Pre- and Post- brushing Proximal.
  - Pre- and Post- brushing distal score of the last posterior tooth in each quadrant.

Statistical Analyses:

All analyses for safety were performed on the Safety population. Analyses for efficacy were performed on the PP population. All hypothesis tests performed for treatment comparisons were two-sided, and employed a 0.05 level of significance.

Changes from Methodology described in the protocol are presented in the Appendix below.

Safety Review:

All findings regarding OSHT observations, gingival recession, and gingival abrasion were presented in listings.

For gingival recession, for each study treatment, cross tabulations of pre versus post visit scores were prepared for each pair of study visits (Baseline vs. Day 15, Baseline vs. Day 30, and Day 15 vs. Day 30) that illustrate the number of measured sites that exhibited each score transition. Each of these cross tabulations also presented, for those sites which presented each score at the earlier visit, the percentage that transitioned to each of the scores seen at the later visit. Two additional summary tables were prepared for the gingival recession data:

1. A summary indicating, for each treatment and study visit, the number and percentage of subjects that presented at least one measured site with gingival recession of 1mm or higher; and that presented at least one measured site with gingival recession of 2mm or higher.

2. Summaries of the subject-wise mean gingival recession scores by treatment group and visit that included:
    a. A summary of the scores at the visit, and for post-baseline visits, a summary of the changes from baseline at the visit;
    b. For each post-baseline visit, based on an analysis of covariance (ANCOVA) model that employed the treatment group as a fixed effect, and that included the corresponding baseline value as a covariate,
        i. An estimate of the change from baseline that included the Least-squares mean (LS mean) and its standard error; a 95% confidence interval for the LS mean; and the p-value for the comparison of the LS mean change versus zero.
        ii. The results of a comparison of the Test treatment versus the Control with respect to the changes from baseline, including the difference between the LS means for the treatments, and its standard error; a 95% confidence interval for the difference; and p-value from the between-treatment comparison.

For gingival abrasion, cross tabulations were prepared as described above for the gingival recession scores. These cross tabulations were prepared separately for transitions of abrasion scores; and also for transitions of assigned abrasion category scores (as described above). In the latter, those sites that presented abrasion scores of 0 (*i.e.*, no abrasion) were assigned a category score of zero. Two additional summary tables were prepared for the gingival abrasion data:

1. A summary indicating, for each treatment and study visit,
    a. A categorical distribution of subjects according to:
        i. the number of measured sites that presented any abrasion (0 sites; between 1 and 4 sites; between 5 and 8 sites; and 9 or more sites)
        ii. the number of measured sites that presented Category 1 lesions (0 sites; between 1 and 4 sites; between 5 and 8 sites; and 9 or more sites)
        iii. the number of measured sites that presented Category 2 lesions (0 sites; between 1 and 4 sites; between 5 and 8 sites; and 9 or more sites)
    b. The number and percentage of subjects with at least 1 site:
        i. Presenting an abrasion lesion of 1mm or higher
        ii. Presenting an abrasion lesion of 2mm or higher
        iii. Presenting an abrasion lesion of 3mm or higher.
2. Summaries of the subject-wise mean abrasion scores by treatment group and visit that included:
    a. A summary of the scores at the visit, and for post-baseline visits, a summary of the changes from baseline at the visit;
    b. For each post-baseline visit, based on an analysis of covariance (ANCOVA) model that employed the treatment group as a fixed effect, and that included the corresponding baseline value as a covariate,
        i. An estimate of the change from baseline that included the Least-squares mean (LS mean) and its standard error; a 95% confidence interval for the LS mean; and the p-value for the comparison of the LS mean change versus zero.

ii. The results of a comparison of the Test treatment versus the Control with respect to the changes from baseline, including the difference between the LS means for the treatments, and its standard error; a 95% confidence interval for the difference; and p-value from the between-treatment comparison.

Demographic and Baseline Characteristics:
Demographic variables (age, gender, race, and ethnicity) and Baseline characteristics (mean MGI and LSPI) were summarized by treatment group and overall. Comparisons between the treatment groups were performed using chi-squared tests for categorical variables, and t-tests for all continuous variables.

Efficacy:
For each efficacy variable, a summary of the subject-wise mean scores by treatment group and visit was provided, presenting the same content as described above for the analysis of subject-wise mean gingival abrasion scores.

Data listings were provided for all efficacy variables.

RESULTS

A total of 75 subjects were randomized to a study treatment, of whom 72 participated in post-Baseline (follow-up) study visits, and 70 completed the study. All results are provided in the sets of tables and listings that accompany this report. Except for the disposition table (Table 1), all tables are based on the PP population.

Demographics (Table 4.2):

Subjects ranged in age from 5 to 64. Although the mean age was slightly larger in the Control group, this difference was not statistically significant. The proportion of males was significantly greater in the Test group than in the Control group (48.6% vs. 25.7%; p=0.0478). Both treatment groups consisted predominately of White subjects. Fewer than 5% of the subjects in the study were Hispanic/Latino. The treatment groups were comparable with respect to both the mean whole mouth MGI and the mean whole mouth LSPI at baseline.

SAFETY

GINGIVAL RECESSION: (Tables 4.5.1 – 4.5.8)

In the Test group, at Baseline and both post-Baseline visits, 57.1% of subjects presented at least one site with gingival recession. In the Control group, the corresponding percentages were 62.9% at Baseline, and 60.0% at both post-Baseline visits. Site-wise score cross-tabulations indicated that that increases in site-wise recession scores were exceedingly rare. Thus, there was no apparent impact on gingival recession associated with either study toothbrush.

GINGIVAL ABRASION: (Tables 4.6.1 – 4.6.14)

Site-wise score transitions: For both study toothbrushes, among sites presenting no abrasion at the earlier visit, over 98% presented no abrasion at the later visit. Among sites presenting any positive level of abrasion at the earlier visit, most tended to present reduced levels of abrasion at the later visit.

Site-wise transitions of Category scores: The results for Category score transitions parallel those for score transitions as described above.

Categorical summary: At Baseline, the percentage of subjects presenting any level of gingival abrasion was 77.1% in the Test group, and 74.3% for the Control group. For subsequent study visits, the percentage presenting any level of gingival abrasion tended to be numerically higher in the Control group.

Analysis of Subject-wise mean abrasion scores: For subjects in the Test group, statistically significant reductions from baseline were presented at Day 15 and Day 30. Subjects in the Control group presented a slight numerical increase at Day 15, and a slight numerical decrease at Day 30, neither of which was statistically significant. The changes from baseline for the Test group differed significantly from those for the Control group at both post-Baseline visits.

EFFICACY

MGI: (Tables 4.3.1 – 4.3.4):

Test: For all subsets, significant reductions from baseline were presented at Day 15 and Day 30; with significantly greater reductions than for Control at both visits.

Control: for all subsets, significant reductions from baseline were presented at Day 15 and Day 30.

LSPI: (Tables 4.4.1 – 4.4.4):

Test: For all subsets, significant reductions from baseline were presented at Day 15 and Day 30 pre-brushing; and significant reductions from pre-brushing at Day 30 post-brushing. Significantly greater reductions than for Control were presented in all instances.

Control: for all subsets, small non-statistically significant changes from baseline (increases for all subsets except for most distal surfaces) were presented at Day 15 and Day 30 pre-brushing; and statistically significant reductions from pre-brushing were presented at day 30 post-brushing.

APPENDIX: Changes in Statistical Methodology from that described in the study protocol.

The following methods represent changes from the statistical methodologies that had been described in the study protocol.

Study Parameter: Demographics
Statistical Methodology Employed: Comparisons between the treatment groups were performed using chi-squared tests for categorical variables, and t-tests for all continuous variables.
Statistical Methodology Described in the Study Protocol: Categorical demographic and baseline data will be evaluated using Fisher's Exactness Test and continuous demographic and baseline data will be evaluated using ANOVA.
Rationale for the change: ANOVA is the same as a t-test when comparing two groups. Chi-squared tests are the method typically used by the statistician for demographics tables, and are appropriate for the task.

Study Parameter: Gingival Recession
Statistical Methodology Employed: Cross-tabulations of site-wise score transitions between pairs of visits.
Statistical Methodology Described in the Study Protocol: No summary of site-wise scores was mentioned in the study protocol.
Rationale for the change: Cross-tabulations were added in order to present a clear picture of changes in site-wise recession findings over the course of the study.

Study Parameter: Gingival Recession
Statistical Methodology Employed: Analysis of subject-wise mean recession scores employing an ANCOVA model.
Statistical Methodology Described in the Study Protocol: Mean change in gingival recession at Day 15 and Day 30 is mentioned as a study endpoint, but the analysis methodology is not explicitly described.
Rationale for the change: The description of the ANCOVA methodology in this report represents more of a clarification, as opposed to a change.

Study Parameter: Gingival Recession
Statistical Methodology Employed: For each treatment group at each study visit, the number and percentage of subjects in each treatment group that presented at least one measured site with recession of 1mm or higher; and that presented at least one measured site with recession of 2mm or higher.
Statistical Methodology Described in the Study Protocol: (Not presented)
Rationale for the change: It is felt that the addition of this summary adds to the understanding of the possible impact of the study treatments on gingival recession.

Study Parameter: Gingival Abrasion
Statistical Methodology Employed: Cross-tabulations of site-wise score transitions between pairs of visits; cross-tabulations of site-wise abrasion Category transitions between pairs of visits
Statistical Methodology Described in the Study Protocol: No summary of site-wise scores or categories was mentioned in the study protocol.
Rationale for the change: These cross-tabulations were added in order to present a clear picture of changes in site-wise gingival abrasion findings over the course of the study.

Study Parameter: Gingival Abrasion
Statistical Methodology Employed: (none)
Statistical Methodology Described in the Study Protocol: Mean change in number of gingival abrasion values for each of the 3 categories, small (≤2 mm), medium (3–5 mm) and large (>5 mm) Day 15 and Day 30.
Rationale for the change: This protocol-proposed analysis was replaced by the cross-tabulations described above. It is felt that the cross-tabulations provided a clearer picture of the possible changes in gingival abrasion that could occur within each treatment group over the course of the study.

Study Parameter: Gingival Abrasion
Statistical Methodology Employed: Categorical distributions of subjects according to numbers of sites with specific abrasion findings by treatment and visit.
Statistical Methodology Described in the Study Protocol: (No corresponding analysis was mentioned in the study protocol.)
Rationale for the change: It is felt that this analysis is a useful adjunct to the other data analyses on gingival abrasion scores.

Study Parameter: Gingival Abrasion
Statistical Methodology Employed: Analysis of subject-wise mean abrasion scores employing an ANCOVA model.
Statistical Methodology Described in the Study Protocol: (No corresponding analysis on subject-wise mean abrasion scores was mentioned in the study protocol.)
Rationale for the change: It is felt that this analysis is a useful adjunct to the other data analyses on gingival abrasion scores.

Study Parameter: Efficacy parameters
Statistical Methodology Employed: Analysis of subject-wise mean abrasion scores employing an ANCOVA model. Dunnett's test was not employed.
Statistical Methodology Described in the Study Protocol: Methodology described in the protocol included mention of Dunnett's test.
Rationale for the change: Since there are only two study treatments, there is not need to employ Dunnett's test for this study.

Study Parameter: Adverse Events
Statistical Methodology Employed: (No analyses were performed)
Statistical Methodology Described in the Study Protocol: The number and percentage of subjects experiencing adverse events will be tabulated by treatment. Adverse events will be summarized according to relationship to study material and according to severity.
Rationale for the change: No adverse event data was provided for statistical analysis.

5.3 Subject Data Listings

5.3.1 Randomization

Listing 5.3.1
Treatment Randomization
(All Randomized Subjects)

Subject	Randomization Number	Treatment Assignment
1001	L009	Test
1002	L018	Test
1003	L010	Test
1004	H044	Control
1005	H002	Control
1006	H031	Control
1007	H033	Control
1008	H005	Test
1009	H022	Control
1010	H015	Test
1011	H003	Test
1012	H004	Control
1013	L015	Control
1014	L016	Control
1015	L002	Control
1016	H008	Test
1017	H001	Test
1018	H013	Control
1019	H020	Test
1020	H036	Test
1021	H019	Test
1022	H034	Test
1023	H024	Test
1024	H042	Test
1025	H052	Test
1026	H018	Control

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Listing 5.3.1 (Cont'd)
Treatment Randomization
(All Randomized Subjects)

Subject	Randomization Number	Treatment Assignment
1027	H007	Control
1028	L007	Test
1029	L006	Control
1030	H014	Test
1031	H039	Test
1032	L020	Control
1033	H012	Test
1034	L021	Test
1035	L003	Test
1036	H010	Control
1037	H053	Test
1038	L008	Control
1039	H023	Test
1040	H006	Control
1042	L019	Control
1043	H030	Control
1044	H011	Control
1045	H046	Control
1046	H037	Control
1047	H050	Test
1048	L014	Test
1049	L013	Test
1050	H048	Control
1051	H027	Test
1052	H017	Control
1053	L012	Control

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Listing 5.3.1 (Cont'd)
Treatment Randomization
(All Randomized Subjects)

Subject	Randomization Number	Treatment Assignment
1054	H051	Control
1055	H035	Control
1056	H049	Control
1057	H009	Test
1058	L017	Test
1059	H021	Control
1060	H054	Test
1061	H026	Control
1062	L001	Test
1063	L011	Control
1064	H047	Test
1065	H028	Control
1066	H038	Test
1067	H032	Test
1068	H025	Test
1069	H029	Test
1070	H045	Test
1071	H040	Control
1072	H043	Control
1073	H041	Test
1074	L004	Control
1075	L005	Test
1076	H016	Control

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5.3.2 Subject Disposition (All Randomized Subjects)

Listing 5.3.2
Subject Disposition
(All Enrolled Subjects)

Treatment Group: (Not Randomized)

					Discontinued Subjects Only	
Subject	Informed Consent Date	Any Adverse Events?	Completed Study?	Completion/ Discontinuation Date	Reason for Discontinuation	Last Study Visit
1041	09/21/2023	No	No	09/29/2023	Subject withdrew from study	Screening Visit

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Listing 5.3.2 (Cont'd)
Subject Disposition
(All Enrolled Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

					Discontinued Subjects Only	
Subject	Informed Consent Date	Any Adverse Events?	Completed Study?	Completion/ Discontinuation Date	Reason for Discontinuation	Last Study Visit
1001	09/21/2023	No	Yes	10/26/2023		
1002	09/21/2023	No	Yes	10/26/2023		
1003	09/21/2023	No	Yes	10/26/2023		
1008	09/21/2023	No	Yes	10/26/2023		
1010	09/21/2023	No	Yes	10/26/2023		
1011	09/21/2023	No	Yes	10/25/2023		
1016	09/21/2023	No	Yes	10/25/2023		
1017	09/21/2023	No	Yes	10/26/2023		
1019	09/21/2023	No	Yes	10/27/2023		
1020	09/21/2023	No	No	10/04/2023	Subject withdrew from study	Baseline Visit
1021	09/21/2023	No	Yes	10/26/2023		
1022	09/21/2023	No	Yes	10/26/2023		
1023	09/21/2023	No	Yes	10/25/2023		
1024	09/21/2023	No	No	10/27/2023	Subject lost to follow-up	Day 15 Visit
1025	09/21/2023	No	Yes	10/26/2023		
1028	09/21/2023	No	Yes	10/25/2023		
1030	09/21/2023	No	Yes	10/25/2023		
1031	09/21/2023	No	No	10/13/2023	Subject withdrew from study	Baseline Visit
1033	09/21/2023	No	Yes	10/26/2023		
1034	09/21/2023	No	Yes	10/27/2023		

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Listing 5.3.2 (Cont'd)
Subject Disposition
(All Enrolled Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

					Discontinued Subjects Only	
Subject	Informed Consent Date	Any Adverse Events?	Completed Study?	Completion/ Discontinuation Date	Reason for Discontinuation	Last Study Visit
1035	09/21/2023	No	Yes	10/27/2023		
1037	09/21/2023	No	Yes	10/27/2023		
1039	09/21/2023	No	Yes	10/27/2023		
1047	09/22/2023	No	Yes	10/27/2023		
1048	09/22/2023	No	Yes	10/27/2023		
1049	09/22/2023	No	Yes	10/27/2023		
1051	09/22/2023	No	Yes	10/26/2023		
1057	09/22/2023	No	Yes	10/25/2023		
1058	09/22/2023	No	Yes	10/25/2023		
1060	09/22/2023	No	Yes	10/27/2023		
1062	09/22/2023	No	Yes	10/27/2023		
1064	09/22/2023	No	Yes	10/27/2023		
1066	09/22/2023	No	Yes	10/27/2023		
1067	09/22/2023	No	Yes	10/27/2023		
1068	09/22/2023	No	No	10/27/2023	Subject withdrew from study	Day 15 Visit
1069	09/22/2023	No	Yes	10/25/2023		
1070	09/22/2023	No	Yes	10/25/2023		
1073	09/22/2023	No	Yes	10/27/2023		
1075	09/22/2023	No	Yes	10/26/2023		

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Listing 5.3.2 (Cont'd)
Subject Disposition
(All Enrolled Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

					Discontinued Subjects Only	
Subject	Informed Consent Date	Any Adverse Events?	Completed Study?	Completion/ Discontinuation Date	Reason for Discontinuation	Last Study Visit
1004	09/21/2023	No	Yes	10/26/2023		
1005	09/21/2023	No	Yes	10/26/2023		
1006	09/21/2023	No	Yes	10/26/2023		
1007	09/21/2023	No	Yes	10/27/2023		
1009	09/21/2023	No	Yes	10/27/2023		
1012	09/21/2023	No	Yes	10/25/2023		
1013	09/21/2023	No	Yes	10/25/2023		
1014	09/21/2023	No	Yes	10/25/2023		
1015	09/21/2023	No	Yes	10/25/2023		
1018	09/21/2023	No	Yes	10/26/2023		
1026	09/21/2023	No	Yes	10/25/2023		
1027	09/21/2023	No	Yes	10/25/2023		
1029	09/21/2023	No	Yes	10/25/2023		
1032	09/21/2023	No	Yes	10/27/2023		
1036	09/21/2023	No	Yes	10/27/2023		
1038	09/21/2023	No	Yes	10/26/2023		
1040	09/21/2023	No	Yes	10/26/2023		
1042	09/21/2023	No	Yes	10/25/2023		
1043	09/21/2023	No	Yes	10/26/2023		
1044	09/21/2023	No	Yes	10/25/2023		

L_DISP.SAS, 07NOV2023: 10:54

Listing 5.3.2 (Cont'd)
Subject Disposition
(All Enrolled Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

					Discontinued Subjects Only	
Subject	Informed Consent Date	Any Adverse Events?	Completed Study?	Completion/ Discontinuation Date	Reason for Discontinuation	Last Study Visit
1045	09/21/2023	No	Yes	10/25/2023		
1046	09/22/2023	No	Yes	10/25/2023		
1050	09/22/2023	No	Yes	10/25/2023		
1052	09/22/2023	No	Yes	10/26/2023		
1053	09/22/2023	No	Yes	10/25/2023		
1054	09/22/2023	No	No	10/11/2023	Subject withdrew from study	Baseline Visit
1055	09/22/2023	No	Yes	10/25/2023		
1056	09/22/2023	No	Yes	10/25/2023		
1059	09/22/2023	No	Yes	10/25/2023		
1061	09/22/2023	No	Yes	10/27/2023		
1063	09/22/2023	No	Yes	10/27/2023		
1065	09/22/2023	No	Yes	10/26/2023		
1071	09/22/2023	No	Yes	10/26/2023		
1072	09/22/2023	No	Yes	10/25/2023		
1074	09/22/2023	No	Yes	10/26/2023		
1076	09/22/2023	No	Yes	10/26/2023		

L_DISP.SAS, 07NOV2023: 10:54

5.3.3 Protocol Deviations

PROTOCOL DEVIATION LOG

PROTOCOL ID: AB-GBP-2023-03 (Island Time)
PI NAME: Dr. Robert T. Nierman DMD, MS

MONITOR		
Monitor Name	**From Date**	**To Date**
Sylvia L. Santos	**11-Sep-23**	27-Oct-23

Protocol Deviation Code List:

1. Inclusion/Exclusion
2. Investigational Product
3. ConMeds
4. Lab
5. Visit Schedule
6. Procedures/Tests
7. Randomization
8. Safety Reporting
9. Protocol Specific Discontinuation Criteria
10. Non-Compliance
11. Other

Action Taken Code List:

1. No action taken - minor deviation
2. Subject discontinued
3. Subject discontinued and replaced
4. No action taken - subject completed the study
5. Site re-trained
6. Other, specify: _____

PROTOCOL DEVIATIONS

Subject ID	Rand Number (if applicable)	Visit Number	Protocol Deviation Code *(see list)*	Description of Deviations	Action Taken Code *(see list)*	Comments
1057	H009	2	5	Out of visit window	1	9/22 - 9/28
1074	L004	2	5	Out of visit window	1	9/22-9/28
1075	L005	2	5	Out of visit window	1	9/22-9/28
1076	H016	2	5	Out of visit window	1	9/22-9/28
1052	H017	2	5	Out of visit window	1	9/22 9/28
1061	H026	2	5	Out of visit window	1	9/22 - 9/28

PROTOCOL DEVIATION LOG

PROTOCOL ID: AB-GBP-2023-03 (Island Time)
PI NAME: Dr. Robert T. Nierman DMD, MS

1068	H025	2	5	Out of visit window	1	9/22 - 9/28
1051	H027	2	5	Out of visit window	1	9/22 -9/28
1069	H029	2	5	Out of visit window	1	9/22 - 9/28
1065	H028	2	5	Out of visit window	1	9/22 - 9/28

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5.3.4 Demographic Data

Listing 5.3.4
Subject Demographic Data

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Age (Years)	Gender	Race	Ethnicity
1001	5	Male	White	Non-Hispanic/Non-Latino
1002	9	Female	White	Non-Hispanic/Non-Latino
1003	7	Female	White	Non-Hispanic/Non-Latino
1008	57	Female	White	Non-Hispanic/Non-Latino
1010	50	Female	White	Non-Hispanic/Non-Latino
1011	12	Female	White	Non-Hispanic/Non-Latino
1016	37	Female	White	Non-Hispanic/Non-Latino
1017	53	Male	Black or African American	Non-Hispanic/Non-Latino
1019	61	Male	Black or African American	Non-Hispanic/Non-Latino
1020	61	Female	White	Non-Hispanic/Non-Latino
1021	53	Female	White	Non-Hispanic/Non-Latino
1022	28	Female	White	Non-Hispanic/Non-Latino
1023	58	Female	White	Non-Hispanic/Non-Latino
1024	45	Female	White	Non-Hispanic/Non-Latino
1025	47	Female	White	Hispanic/Latino
1028	5	Male	White	Non-Hispanic/Non-Latino
1030	64	Male	White	Non-Hispanic/Non-Latino
1031	34	Male	Black or African American	Non-Hispanic/Non-Latino
1033	54	Female	White	Non-Hispanic/Non-Latino
1034	10	Male	White	Non-Hispanic/Non-Latino
1035	6	Male	White	Non-Hispanic/Non-Latino
1037	40	Male	White	Non-Hispanic/Non-Latino

L_DEMOG.SAS, 07NOV2023: 10:54

Listing 5.3.4 (Cont'd)
Subject Demographic Data

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Age (Years)	Gender	Race	Ethnicity
1039	12	Male	White	Non-Hispanic/Non-Latino
1047	56	Male	White	Non-Hispanic/Non-Latino
1048	11	Male	Asian	Non-Hispanic/Non-Latino
1049	6	Female	Asian	Non-Hispanic/Non-Latino
1051	12	Male	White	Non-Hispanic/Non-Latino
1057	44	Male	White	Non-Hispanic/Non-Latino
1058	9	Male	White	Non-Hispanic/Non-Latino
1060	62	Female	White	Non-Hispanic/Non-Latino
1062	8	Male	White	Non-Hispanic/Non-Latino
1064	44	Female	White	Non-Hispanic/Non-Latino
1066	51	Female	White	Non-Hispanic/Non-Latino
1067	56	Male	White	Non-Hispanic/Non-Latino
1068	59	Female	White	Non-Hispanic/Non-Latino
1069	59	Female	White	Non-Hispanic/Non-Latino
1070	47	Female	White	Non-Hispanic/Non-Latino
1073	45	Female	White	Non-Hispanic/Non-Latino
1075	8	Male	Black or African American	Non-Hispanic/Non-Latino

Listing 5.3.4 (Cont'd)
Subject Demographic Data

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Age (Years)	Gender	Race	Ethnicity
1004	31	Female	White	Non-Hispanic/Non-Latino
1005	54	Female	Black or African American	Non-Hispanic/Non-Latino
1006	60	Female	White	Non-Hispanic/Non-Latino
1007	58	Female	Asian	Non-Hispanic/Non-Latino
1009	50	Female	White	Non-Hispanic/Non-Latino
1012	40	Female	Black or African American	Non-Hispanic/Non-Latino
1013	11	Male	White	Non-Hispanic/Non-Latino
1014	10	Female	White	Non-Hispanic/Non-Latino
1015	6	Female	White	Non-Hispanic/Non-Latino
1018	37	Male	White	Non-Hispanic/Non-Latino
1026	52	Female	White	Non-Hispanic/Non-Latino
1027	62	Female	White	Non-Hispanic/Non-Latino
1029	7	Female	White	Non-Hispanic/Non-Latino
1032	9	Male	White	Non-Hispanic/Non-Latino
1036	45	Female	White	Non-Hispanic/Non-Latino
1038	7	Female	White	Non-Hispanic/Non-Latino
1040	42	Female	White	Non-Hispanic/Non-Latino
1042	10	Male	White	Non-Hispanic/Non-Latino
1043	59	Female	White	Non-Hispanic/Non-Latino
1044	58	Male	White	Non-Hispanic/Non-Latino
1045	38	Male	White	Non-Hispanic/Non-Latino
1046	32	Female	White	Hispanic/Latino

Listing 5.3.4 (Cont'd)
Subject Demographic Data

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Age (Years)	Gender	Race	Ethnicity
1050	30	Female	White	Non-Hispanic/Non-Latino
1052	37	Female	White	Non-Hispanic/Non-Latino
1053	7	Male	Black or African American	Non-Hispanic/Non-Latino
1054	40	Female	Black or African American	Non-Hispanic/Non-Latino
1055	47	Male	White	Non-Hispanic/Non-Latino
1056	44	Female	White	Non-Hispanic/Non-Latino
1059	43	Female	White	Non-Hispanic/Non-Latino
1061	63	Female	White	Non-Hispanic/Non-Latino
1063	10	Male	White	Non-Hispanic/Non-Latino
1065	27	Female	White	Hispanic/Latino
1071	52	Female	White	Non-Hispanic/Non-Latino
1072	63	Female	Black or African American	Non-Hispanic/Non-Latino
1074	6	Female	Black or African American	Non-Hispanic/Non-Latino
1076	27	Female	Black or African American	Non-Hispanic/Non-Latino

5.3.5 Individual Efficacy Response Data

Listing 5.3.5.1
Whole Mouth Mean Modified Gingival Index by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1001	2.50	1.63	0.77
1002	3.00	1.51	1.57
1003	3.00	1.79	1.58
1008	2.30	2.28	1.36
1010	2.42	1.59	1.33
1011	2.27	0.89	0.63
1016	2.66	1.17	2.26
1017	2.54	1.43	1.34
1019	2.87	2.17	0.88
1020	2.64	.	.
1021	2.71	1.49	1.09
1022	2.33	1.56	1.20
1023	2.70	1.31	0.99
1024	1.99	1.29	.
1025	2.62	1.30	1.27
1028	3.00	1.72	2.25
1030	2.76	1.02	1.03
1031	2.96	.	.
1033	2.91	1.75	1.67
1034	2.70	1.58	1.41
1035	2.83	2.18	1.79
1037	3.00	2.25	1.41

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

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Listing 5.3.5.1 (Cont'd)
Whole Mouth Mean Modified Gingival Index by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1039	2.71	1.01	1.02
1047	2.91	2.25	1.80
1048	2.68	1.35	0.72
1049	2.70	1.57	0.82
1051	2.83	1.17	1.09
1057	2.59	2.27	0.96
1058	2.40	0.84	1.24
1060	2.29	1.10	0.89
1062	2.32	0.77	0.86
1064	2.74	1.59	1.30
1066	2.48	1.40	0.94
1067	2.84	1.95	2.19
1068	2.33	1.17	.
1069	2.65	2.03	1.09
1070	2.50	1.56	1.21
1073	2.51	1.36	1.17
1075	3.00	2.31	1.89

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

L_MGI.SAS, 07NOV2023: 10:54

Listing 5.3.5.1 (Cont'd)
Whole Mouth Mean Modified Gingival Index by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1004	2.69	2.70	1.49
1005	2.65	2.36	2.36
1006	2.22	1.62	2.30
1007	1.96	1.07	1.68
1009	2.42	2.22	1.91
1012	2.65	2.77	2.14
1013	2.64	2.73	1.90
1014	2.71	2.93	2.44
1015	2.72	2.42	2.16
1018	1.86	1.65	1.69
1026	2.06	1.85	2.01
1027	2.35	0.90	1.16
1029	3.00	2.93	3.00
1032	2.68	2.13	2.46
1036	2.98	2.83	2.97
1038	2.19	1.97	2.44
1040	2.67	2.13	2.34
1042	2.79	2.78	2.91
1043	2.60	2.11	2.01
1044	2.98	2.70	2.58
1045	2.85	2.71	2.83
1046	2.57	1.88	2.31

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

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Listing 5.3.5.1 (Cont'd)
Whole Mouth Mean Modified Gingival Index by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1050	2.92	2.52	2.74
1052	2.94	2.84	2.91
1053	2.54	2.51	2.55
1054	2.86	.	.
1055	2.57	2.15	2.64
1056	2.82	2.43	1.88
1059	2.26	2.37	2.38
1061	2.84	2.91	2.56
1063	2.81	2.00	2.19
1065	2.38	2.09	2.15
1071	2.75	2.88	2.83
1072	2.37	1.58	1.97
1074	3.00	3.00	3.00
1076	2.63	2.75	2.59

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

L_MGI.SAS, 07NOV2023: 10:54

Listing 5.3.5.2

Mean Modified Gingival Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1001	2.25	1.20	0.28
1002	3.00	1.07	1.09
1003	3.00	1.36	1.00
1008	1.91	1.85	0.96
1010	2.19	1.02	0.65
1011	1.88	0.08	0.04
1016	2.18	0.45	1.73
1017	2.12	0.88	0.86
1019	2.61	1.89	0.25
1020	2.30	.	.
1021	2.27	0.70	0.29
1022	1.95	1.00	0.55
1023	2.21	0.36	0.14
1024	1.41	0.55	.
1025	2.18	0.63	0.58
1028	3.00	1.26	2.03
1030	2.39	0.33	0.36
1031	2.89	.	.
1033	2.76	1.22	1.18
1034	2.46	1.28	0.76
1035	2.65	1.88	1.30
1037	3.00	1.76	0.83

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

L_MGI.SAS, 07NOV2023: 10:54

Listing 5.3.5.2 (Cont'd)
Mean Modified Gingival Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1039	2.29	0.21	0.29
1047	2.73	1.63	1.21
1048	2.40	0.73	0.27
1049	2.47	1.21	0.42
1051	2.57	0.57	0.48
1057	2.16	1.52	0.28
1058	2.04	0.15	0.79
1060	1.59	0.20	0.23
1062	2.05	0.03	0.24
1064	2.43	0.72	0.37
1066	1.92	0.56	0.21
1067	2.77	1.68	1.95
1068	1.71	0.48	.
1069	1.96	1.57	0.22
1070	1.80	0.65	0.37
1073	2.04	0.61	0.22
1075	3.00	2.04	1.68

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

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Listing 5.3.5.2 (Cont'd)
Mean Modified Gingival Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1004	2.39	2.38	0.77
1005	2.36	2.04	2.10
1006	1.52	0.96	1.46
1007	1.50	0.29	1.18
1009	1.89	2.03	1.61
1012	2.48	2.45	1.86
1013	2.44	2.38	1.46
1014	2.48	2.86	2.14
1015	2.50	2.13	1.88
1018	1.34	1.18	1.25
1026	1.50	1.23	1.50
1027	1.89	0.19	0.19
1029	3.00	2.84	3.00
1032	2.46	1.87	2.28
1036	2.93	2.60	2.90
1038	1.80	1.55	2.09
1040	2.17	1.52	1.80
1042	2.54	2.60	2.81
1043	2.13	1.61	1.48
1044	2.93	2.41	2.27
1045	2.63	2.36	2.63
1046	2.11	1.39	1.93

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

L_MGI.SAS, 07NOV2023: 10:54

Listing 5.3.5.2 (Cont'd)
Mean Modified Gingival Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1050	2.77	2.14	2.39
1052	2.82	2.63	2.73
1053	2.37	2.28	2.26
1054	2.75	.	.
1055	2.07	1.69	2.19
1056	2.66	1.92	1.26
1059	1.66	1.84	1.88
1061	2.52	2.74	2.21
1063	2.54	1.54	1.85
1065	2.02	1.63	1.73
1071	2.39	2.68	2.61
1072	1.73	1.12	1.56
1074	3.00	3.00	3.00
1076	2.21	2.48	2.07

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

L_MGI.SAS, 07NOV2023: 10:54

Listing 5.3.5.3

Mean Modified Gingival Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1001	2.63	1.84	1.01
1002	3.00	1.73	1.80
1003	3.00	2.00	1.87
1008	2.49	2.50	1.55
1010	2.54	1.87	1.67
1011	2.47	1.29	0.92
1016	2.90	1.54	2.52
1017	2.75	1.70	1.58
1019	3.00	2.31	1.19
1020	2.81	.	.
1021	2.94	1.89	1.49
1022	2.53	1.84	1.52
1023	2.95	1.79	1.42
1024	2.28	1.66	.
1025	2.84	1.63	1.62
1028	3.00	1.95	2.36
1030	2.94	1.36	1.36
1031	3.00	.	.
1033	2.99	2.02	1.91
1034	2.83	1.73	1.74
1035	2.93	2.33	2.04
1037	3.00	2.49	1.70

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

L_MGI.SAS, 07NOV2023: 10:54

Listing 5.3.5.3 (Cont'd)
Mean Modified Gingival Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1039	2.91	1.41	1.38
1047	3.00	2.56	2.09
1048	2.82	1.66	0.95
1049	2.82	1.75	1.03
1051	2.97	1.48	1.40
1057	2.81	2.64	1.30
1058	2.57	1.19	1.47
1060	2.64	1.55	1.22
1062	2.45	1.14	1.17
1064	2.90	2.03	1.77
1066	2.76	1.83	1.30
1067	2.88	2.08	2.31
1068	2.64	1.52	.
1069	3.00	2.26	1.53
1070	2.85	2.02	1.63
1073	2.74	1.73	1.65
1075	3.00	2.45	2.00

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

L_MGI.SAS, 07NOV2023: 10:54

Listing 5.3.5.3 (Cont'd)
Mean Modified Gingival Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1004	2.84	2.86	1.85
1005	2.79	2.52	2.49
1006	2.58	1.95	2.72
1007	2.20	1.46	1.92
1009	2.68	2.32	2.07
1012	2.74	2.92	2.27
1013	2.74	2.90	2.12
1014	2.83	2.96	2.60
1015	2.82	2.57	2.30
1018	2.13	1.89	1.91
1026	2.33	2.17	2.27
1027	2.58	1.25	1.64
1029	3.00	2.98	3.00
1032	2.79	2.26	2.54
1036	3.00	2.94	3.00
1038	2.39	2.18	2.61
1040	2.92	2.44	2.61
1042	2.92	2.86	2.96
1043	2.84	2.36	2.28
1044	3.00	2.85	2.74
1045	2.96	2.88	2.93
1046	2.81	2.12	2.50

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

L_MGI.SAS, 07NOV2023: 10:54

Listing 5.3.5.3 (Cont'd)
Mean Modified Gingival Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1050	3.00	2.71	2.91
1052	3.00	2.95	3.00
1053	2.63	2.63	2.70
1054	2.92	.	.
1055	2.81	2.39	2.86
1056	2.90	2.68	2.19
1059	2.56	2.63	2.63
1061	3.00	3.00	2.74
1063	2.95	2.23	2.36
1065	2.55	2.32	2.37
1071	2.93	2.98	2.95
1072	2.68	1.82	2.18
1074	3.00	3.00	3.00
1076	2.83	2.89	2.85

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

Listing 5.3.5.4

Mean Modified Gingival Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1001	2.25	1.13	0.63
1002	3.00	1.00	1.00
1003	3.00	2.00	1.25
1008	2.50	2.13	1.13
1010	2.50	1.13	0.75
1011	2.13	0.88	0.63
1016	2.63	1.25	2.25
1017	2.38	1.13	1.00
1019	3.00	2.50	1.50
1020	2.50	.	.
1021	2.63	1.00	0.38
1022	1.88	1.00	0.50
1023	2.75	0.50	0.38
1024	1.88	1.00	.
1025	3.00	2.00	1.38
1028	3.00	1.88	2.13
1030	2.75	0.75	0.88
1031	3.00	.	.
1033	2.88	1.50	1.63
1034	2.75	1.63	1.25
1035	3.00	2.00	2.00
1037	3.00	2.38	1.75

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

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Listing 5.3.5.4 (Cont'd)
Mean Modified Gingival Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1039	2.88	0.88	0.75
1047	3.00	1.50	1.13
1048	2.50	1.63	0.38
1049	2.50	1.63	0.71
1051	3.00	1.38	0.88
1057	2.63	2.00	1.25
1058	2.13	0.50	0.88
1060	2.25	1.25	0.88
1062	2.38	0.75	0.75
1064	2.63	1.38	0.88
1066	2.38	1.25	0.38
1067	2.63	1.63	1.88
1068	1.75	0.50	.
1069	3.00	1.88	0.75
1070	2.75	2.50	2.00
1073	2.75	1.50	1.13
1075	3.00	2.38	2.00

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

Listing 5.3.5.4 (Cont'd)
Mean Modified Gingival Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1004	2.50	2.25	1.38
1005	2.88	2.50	2.25
1006	1.88	1.63	2.38
1007	2.38	1.63	2.38
1009	2.38	2.13	1.88
1012	2.63	2.88	2.00
1013	2.63	2.50	2.00
1014	2.75	2.88	2.25
1015	2.75	2.25	2.13
1018	2.00	1.50	1.75
1026	2.25	1.88	2.25
1027	2.63	1.38	1.75
1029	3.00	2.75	3.00
1032	2.88	2.25	2.50
1036	3.00	2.88	3.00
1038	2.25	2.13	2.50
1040	2.63	2.00	2.00
1042	2.75	2.38	2.75
1043	2.88	2.88	2.25
1044	3.00	2.63	2.63
1045	2.75	2.63	3.00
1046	2.88	1.88	2.50

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

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Listing 5.3.5.4 (Cont'd)
Mean Modified Gingival Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4
1050	3.00	2.25	2.50
1052	3.00	3.00	3.00
1053	2.75	2.75	2.75
1054	3.00	.	.
1055	2.75	2.50	2.88
1056	3.00	2.38	2.00
1059	2.13	2.13	2.13
1061	3.00	3.00	2.75
1063	2.63	2.00	2.13
1065	2.25	2.25	2.38
1071	2.75	3.00	3.00
1072	2.63	1.63	1.88
1074	3.00	3.00	3.00
1076	2.88	3.13	2.88

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

Listing 5.3.5.5

Whole Mouth Mean Plaque Index by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1001	3.29	1.83	2.78	1.55
1002	4.14	2.49	3.16	1.94
1003	3.50	2.30	2.93	1.87
1008	2.54	2.04	2.68	1.77
1010	3.11	2.31	2.75	1.41
1011	3.03	2.06	2.67	1.27
1016	3.16	1.98	2.77	1.35
1017	2.78	2.19	2.19	1.33
1019	2.48	1.61	2.47	1.35
1020	3.15	.	.	.
1021	2.73	2.13	2.71	1.87
1022	3.05	2.41	3.18	2.04
1023	2.96	2.38	2.95	1.57
1024	3.11	2.48	.	.
1025	3.18	1.91	2.46	1.25
1028	3.60	2.19	2.98	1.76
1030	2.85	1.74	2.65	1.26
1031	3.05	.	.	.
1033	3.29	2.58	2.94	1.83
1034	3.36	2.64	3.64	2.00
1035	3.45	2.43	3.61	1.95
1037	3.60	2.36	2.81	1.43

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

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Listing 5.3.5.5 (Cont'd)
Whole Mouth Mean Plaque Index by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1039	2.99	2.19	3.24	1.95
1047	3.51	2.38	3.26	1.88
1048	3.15	2.60	3.19	1.57
1049	2.97	2.10	3.30	1.82
1051	3.21	2.28	2.96	1.95
1057	3.21	2.16	3.11	1.65
1058	3.45	2.63	3.29	2.09
1060	3.65	3.10	3.44	2.03
1062	3.54	1.99	3.12	1.87
1064	3.55	2.52	3.10	1.67
1066	3.26	2.17	2.73	1.48
1067	3.50	2.36	3.52	2.33
1068	3.47	3.16	.	.
1069	3.09	2.01	2.79	1.67
1070	2.95	2.16	2.73	1.47
1073	3.22	1.93	2.92	1.56
1075	5.00	3.45	3.68	2.19

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

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Listing 5.3.5.5 (Cont'd)
Whole Mouth Mean Plaque Index by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1004	2.99	2.83	2.72	2.49
1005	3.12	3.01	3.39	2.97
1006	3.03	3.03	3.07	2.83
1007	3.27	3.49	3.34	3.04
1009	2.81	2.80	3.04	2.64
1012	3.11	3.42	3.28	3.23
1013	3.85	4.04	3.97	3.47
1014	4.09	4.39	4.33	3.98
1015	4.06	4.04	3.65	3.56
1018	3.03	3.26	3.18	2.91
1026	2.79	2.94	3.19	2.78
1027	2.87	2.78	2.83	2.73
1029	5.00	4.93	4.54	4.21
1032	3.36	3.25	3.71	3.34
1036	3.28	3.38	3.38	3.24
1038	2.95	3.10	3.38	3.02
1040	3.05	3.15	3.10	2.92
1042	3.58	3.44	3.68	3.49
1043	2.70	2.88	2.88	2.67
1044	3.06	3.24	3.24	2.90
1045	3.46	3.54	3.54	3.40
1046	2.81	3.04	3.00	2.74

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

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Listing 5.3.5.5 (Cont'd)
Whole Mouth Mean Plaque Index by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1050	3.40	3.01	3.14	3.11
1052	3.48	3.52	3.27	3.02
1053	4.00	4.01	3.84	3.62
1054	3.63	.	.	.
1055	3.15	3.00	3.12	2.75
1056	2.75	2.67	3.07	2.91
1059	3.10	3.52	3.52	2.98
1061	3.08	3.29	3.35	3.14
1063	3.43	3.45	3.22	3.00
1065	3.38	3.74	3.15	2.99
1071	3.23	3.14	3.35	3.11
1072	3.53	3.49	3.16	2.98
1074	2.99	3.10	3.26	3.08
1076	4.14	3.73	3.73	3.50

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The whole-mouth mean is the average value of the scores obtained on all tooth surfaces in the mouth.

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Listing 5.3.5.6

Mean Plaque Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1001	3.25	0.78	2.53	0.25
1002	4.09	1.59	3.00	0.63
1003	3.36	1.36	2.55	0.74
1008	2.24	1.20	2.35	0.39
1010	2.81	1.61	2.22	0.15
1011	2.72	1.28	2.10	0.16
1016	2.91	0.95	2.29	0.52
1017	2.36	1.38	1.24	0.26
1019	2.16	0.23	2.05	0.07
1020	2.85	.	.	.
1021	2.43	1.52	2.25	0.32
1022	2.63	1.43	2.84	0.59
1023	2.73	1.64	2.55	0.39
1024	2.82	1.55	.	.
1025	2.89	0.61	1.82	0.05
1028	3.34	1.21	2.74	0.76
1030	2.64	0.89	2.19	0.28
1031	2.71	.	.	.
1033	3.10	2.08	2.46	0.42
1034	3.24	2.02	3.54	0.89
1035	3.25	1.35	3.50	0.83
1037	3.50	1.22	2.48	0.30

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

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Listing 5.3.5.6 (Cont'd)
Mean Plaque Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1039	2.88	1.90	3.04	0.83
1047	3.19	1.29	3.10	0.48
1048	3.10	1.96	3.13	0.29
1049	2.95	1.50	3.24	0.47
1051	3.14	1.93	2.84	0.95
1057	2.94	1.12	2.76	0.54
1058	3.27	2.17	3.23	0.75
1060	3.41	2.68	3.29	0.89
1062	3.42	1.47	3.00	0.95
1064	3.35	1.69	2.76	0.41
1066	2.85	1.06	2.25	0.25
1067	3.30	1.41	3.27	1.25
1068	3.17	2.81	.	.
1069	2.87	0.91	2.37	0.35
1070	2.70	0.83	2.31	0.26
1073	3.02	0.72	2.48	0.54
1075	5.00	3.32	3.64	0.79

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

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Listing 5.3.5.6 (Cont'd)
Mean Plaque Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1004	2.73	2.48	2.46	2.16
1005	2.70	2.66	3.06	2.56
1006	2.73	2.71	2.69	2.37
1007	2.92	3.18	3.08	2.68
1009	2.39	2.29	3.00	2.34
1012	2.73	3.23	3.11	3.02
1013	3.73	4.00	3.96	3.44
1014	3.98	4.38	4.29	3.90
1015	3.90	3.94	3.54	3.46
1018	2.77	2.96	3.00	2.64
1026	2.35	2.65	2.96	2.31
1027	2.53	2.28	2.50	2.22
1029	5.00	4.93	4.50	4.18
1032	3.20	3.15	3.59	3.13
1036	3.05	3.15	3.03	2.95
1038	2.91	2.93	3.36	2.77
1040	2.81	2.93	2.76	2.50
1042	3.46	3.35	3.56	3.23
1043	2.28	2.50	2.35	2.22
1044	2.73	2.88	2.93	2.54
1045	3.29	3.38	3.38	3.16
1046	2.43	2.89	2.94	2.46

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

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Listing 5.3.5.6 (Cont'd)
Mean Plaque Index on Gumline Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1050	3.25	2.70	2.96	2.86
1052	3.27	3.32	3.11	2.66
1053	4.00	3.93	3.80	3.50
1054	3.41	.	.	.
1055	2.80	2.67	2.81	2.37
1056	2.44	2.32	3.02	2.80
1059	2.80	3.36	3.29	2.52
1061	2.69	3.14	3.07	2.98
1063	3.15	3.23	2.90	2.65
1065	3.09	3.52	2.91	2.70
1071	2.93	2.80	3.16	2.88
1072	3.17	3.21	2.79	2.48
1074	2.88	3.04	3.23	2.92
1076	4.10	3.62	3.67	3.21

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Gumline surfaces is the average value of the scores obtained on gingival margin surfaces in the mouth.

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Listing 5.3.5.7

Mean Plaque Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1001	3.31	2.36	2.91	2.20
1002	4.16	2.95	3.24	2.60
1003	3.57	2.77	3.12	2.43
1008	2.68	2.47	2.85	2.46
1010	3.26	2.66	3.01	2.04
1011	3.18	2.45	2.96	1.82
1016	3.29	2.50	3.01	1.76
1017	2.99	2.60	2.66	1.87
1019	2.64	2.30	2.68	1.99
1020	3.31	.	.	.
1021	2.88	2.43	2.95	2.64
1022	3.27	2.90	3.35	2.77
1023	3.08	2.74	3.14	2.16
1024	3.26	2.94	.	.
1025	3.32	2.57	2.79	1.84
1028	3.72	2.68	3.11	2.26
1030	2.96	2.17	2.88	1.75
1031	3.22	.	.	.
1033	3.38	2.83	3.18	2.54
1034	3.41	2.95	3.68	2.55
1035	3.55	2.96	3.66	2.51
1037	3.65	2.93	2.97	2.00

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

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Listing 5.3.5.7 (Cont'd)
Mean Plaque Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1039	3.04	2.33	3.35	2.51
1047	3.67	2.93	3.33	2.58
1048	3.17	2.93	3.22	2.21
1049	2.99	2.39	3.33	2.50
1051	3.25	2.45	3.02	2.44
1057	3.35	2.68	3.29	2.21
1058	3.54	2.85	3.32	2.76
1060	3.77	3.30	3.52	2.60
1062	3.59	2.25	3.18	2.33
1064	3.65	2.94	3.28	2.30
1066	3.47	2.72	2.97	2.10
1067	3.60	2.83	3.65	2.88
1068	3.62	3.33	.	.
1069	3.20	2.55	3.00	2.33
1070	3.07	2.82	2.94	2.07
1073	3.33	2.54	3.14	2.07
1075	5.00	3.52	3.70	2.89

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

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Listing 5.3.5.7 (Cont'd)
Mean Plaque Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1004	3.12	3.00	2.85	2.65
1005	3.33	3.19	3.55	3.18
1006	3.17	3.19	3.26	3.06
1007	3.45	3.64	3.47	3.22
1009	3.01	3.05	3.05	2.79
1012	3.31	3.51	3.36	3.33
1013	3.90	4.07	3.97	3.48
1014	4.14	4.39	4.36	4.02
1015	4.15	4.09	3.70	3.61
1018	3.16	3.41	3.28	3.04
1026	3.01	3.08	3.31	3.02
1027	3.04	3.03	3.00	2.99
1029	5.00	4.93	4.56	4.23
1032	3.43	3.29	3.77	3.45
1036	3.40	3.49	3.56	3.39
1038	2.97	3.18	3.39	3.15
1040	3.17	3.27	3.28	3.13
1042	3.64	3.49	3.74	3.61
1043	2.91	3.07	3.14	2.90
1044	3.22	3.42	3.39	3.08
1045	3.54	3.63	3.63	3.52
1046	3.01	3.11	3.03	2.88

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

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Listing 5.3.5.7 (Cont'd)
Mean Plaque Index on Proximal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1050	3.48	3.16	3.23	3.24
1052	3.59	3.63	3.35	3.21
1053	4.00	4.04	3.86	3.68
1054	3.74	.	.	.
1055	3.33	3.17	3.27	2.94
1056	2.90	2.84	3.09	2.96
1059	3.25	3.61	3.63	3.21
1061	3.27	3.37	3.49	3.23
1063	3.57	3.56	3.39	3.18
1065	3.52	3.85	3.28	3.14
1071	3.38	3.31	3.45	3.22
1072	3.70	3.63	3.35	3.23
1074	3.04	3.13	3.27	3.15
1076	4.17	3.79	3.76	3.64

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Proximal surfaces is the average value of the scores obtained on mesial and distal surfaces in the mouth.

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Listing 5.3.5.8

Mean Plaque Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1001	3.38	2.38	3.13	1.00
1002	4.00	3.00	3.38	2.00
1003	4.00	2.88	3.13	1.50
1008	2.88	2.63	2.88	1.25
1010	3.38	2.88	3.00	1.38
1011	4.00	2.50	3.00	2.38
1016	3.50	2.75	3.00	1.75
1017	3.13	2.63	2.50	2.13
1019	2.75	2.38	2.50	1.25
1020	3.63	.	.	.
1021	3.25	2.50	2.63	1.00
1022	3.38	2.88	3.00	1.38
1023	3.38	3.00	2.75	1.25
1024	3.38	3.13	.	.
1025	3.63	2.88	2.63	0.63
1028	3.38	2.63	3.13	1.75
1030	3.00	1.75	2.75	1.38
1031	3.13	.	.	.
1033	3.50	3.13	2.88	0.75
1034	3.38	3.00	3.13	1.88
1035	3.25	2.88	3.13	1.88
1037	3.13	3.00	3.13	1.00

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

L_PI.SAS, 07NOV2023: 10:54

Listing 5.3.5.8 (Cont'd)
Mean Plaque Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1039	2.88	2.50	3.13	2.38
1047	3.25	3.00	3.13	1.38
1048	3.38	3.00	3.25	0.75
1049	3.13	2.50	3.25	1.75
1051	3.50	2.75	2.88	1.75
1057	3.50	2.38	3.13	2.00
1058	3.25	3.00	3.25	2.63
1060	4.25	3.13	3.25	1.50
1062	3.50	2.50	3.13	2.25
1064	3.38	2.88	3.25	1.25
1066	3.38	2.88	2.50	0.88
1067	3.63	3.00	3.50	2.00
1068	3.75	3.38	.	.
1069	3.38	3.00	2.75	2.00
1070	3.25	3.25	2.75	2.38
1073	3.63	2.88	3.13	1.38
1075	5.00	3.38	3.50	2.63

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

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Listing 5.3.5.8 (Cont'd)
Mean Plaque Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1004	3.38	3.00	3.13	2.88
1005	2.88	3.13	3.25	3.13
1006	3.25	3.00	3.25	2.88
1007	3.75	3.88	3.50	3.38
1009	2.88	2.88	3.13	3.00
1012	3.50	3.25	3.25	3.25
1013	4.13	4.38	4.13	3.75
1014	3.75	3.75	3.75	3.50
1015	3.50	3.88	3.25	3.25
1018	3.13	3.38	3.13	3.13
1026	3.00	3.25	3.38	3.13
1027	3.00	3.00	3.00	3.00
1029	5.00	4.88	4.50	4.00
1032	3.38	3.25	3.63	3.25
1036	3.13	3.13	3.25	3.25
1038	3.00	3.00	3.25	3.00
1040	3.63	3.38	3.38	3.38
1042	3.38	3.25	3.50	3.38
1043	3.13	3.13	3.13	3.00
1044	3.25	3.38	3.38	3.13
1045	3.50	3.50	3.25	3.25
1046	3.13	3.25	3.00	3.00

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

L_PI.SAS, 07NOV2023: 10:54

Listing 5.3.5.8 (Cont'd)
Mean Plaque Index on Most Distal Surfaces by Treatment and Study Visit

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit 2	Visit 3	Visit 4 (Pre-Brushing)	Visit 4 (Post-Brushing)
1050	3.13	3.00	2.88	3.00
1052	3.75	3.75	3.63	3.50
1053	3.75	3.75	3.63	3.38
1054	3.88	.	.	.
1055	3.25	3.13	3.13	3.00
1056	3.38	2.88	3.13	3.00
1059	3.50	4.00	3.75	3.25
1061	3.50	3.25	3.25	3.13
1063	3.50	3.38	3.38	3.13
1065	3.63	3.50	3.38	3.13
1071	3.25	3.25	3.50	3.13
1072	3.88	3.75	3.25	3.13
1074	3.17	3.17	3.50	3.17
1076	4.00	3.63	3.38	3.38

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

The mean score over Most Distal surfaces is the average value of the scores obtained on the distal surfaces of the last posterior tooth in each quadrant.

5.3.6 Individual Safety Data

Listing 5.3.6.1
Gingival Recession Data

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

	Visit 2					Visit 3					Visit 4				
Subject	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2
1001	120	0.000	120	0	0	120	0.000	120	0	0	120	0.000	120	0	0
1002	138	0.000	138	0	0	138	0.000	138	0	0	138	0.000	138	0	0
1003	126	0.000	126	0	0	126	0.000	126	0	0	126	0.000	126	0	0
1008	138	0.109	125	11	2	138	0.101	126	10	2	138	0.101	126	10	2
1010	162	0.049	154	8	0	162	0.049	154	8	0	162	0.049	154	8	0
1011	150	0.000	150	0	0	150	0.000	150	0	0	150	0.000	150	0	0
1016	168	0.030	163	5	0	168	0.030	163	5	0	168	0.030	163	5	0
1017	150	0.147	136	6	8	150	0.147	136	6	8	150	0.147	136	6	8
1019	132	0.038	128	3	1	132	0.038	128	3	1	132	0.030	129	2	1
1020	162	0.302	130	15	17		(No visit)					(No visit)			
1021	168	0.042	163	3	2	168	0.042	163	3	2	168	0.042	163	3	2
1022	168	0.018	165	3	0	168	0.018	165	3	0	168	0.018	165	3	0
1023	168	0.036	162	6	0	168	0.036	162	6	0	168	0.036	162	6	0
1024	168	0.042	163	3	2	168	0.042	163	3	2		(No visit)			
1025	114	0.053	108	6	0	114	0.053	108	6	0	114	0.053	108	6	0
1028	114	0.000	114	0	0	114	0.000	114	0	0	114	0.000	114	0	0
1030	108	0.046	104	3	1	108	0.046	104	3	1	108	0.046	104	3	1
1031	168	0.006	167	1	0		(No visit)					(No visit)			

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean recession score (mm) over all examined sites, and the number of examined sites presenting scores of 0mm, 1mm, and 2mm at the visit. It is noted that no site presented a recession score greater than 2mm at any visit.

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Listing 5.3.6.1 (Cont'd)
Gingival Recession Data

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

	Visit 2					Visit 3					Visit 4				
Subject	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2
1033	150	0.107	136	12	2	150	0.107	136	12	2	150	0.107	136	12	2
1034	138	0.000	138	0	0	138	0.000	138	0	0	138	0.000	138	0	0
1035	120	0.000	120	0	0	120	0.000	120	0	0	120	0.000	120	0	0
1037	162	0.062	152	10	0	162	0.062	152	10	0	162	0.062	152	10	0
1039	156	0.000	156	0	0	156	0.000	156	0	0	156	0.000	156	0	0
1047	144	0.132	129	11	4	144	0.132	129	11	4	144	0.132	129	11	4
1048	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1049	114	0.000	114	0	0	114	0.000	114	0	0	114	0.000	114	0	0
1051	132	0.000	132	0	0	132	0.000	132	0	0	132	0.000	132	0	0
1057	150	0.193	129	13	8	150	0.193	129	13	8	150	0.193	129	13	8
1058	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1060	168	0.036	162	6	0	168	0.036	162	6	0	168	0.036	162	6	0
1062	114	0.000	114	0	0	114	0.000	114	0	0	114	0.000	114	0	0
1064	162	0.000	162	0	0	162	0.000	162	0	0	162	0.000	162	0	0
1066	156	0.083	146	7	3	156	0.083	146	7	3	156	0.083	146	7	3
1067	132	0.106	123	4	5	132	0.091	124	4	4	132	0.091	124	4	4
1068	126	0.056	119	7	0	126	0.056	119	7	0		(No visit)			
1069	138	0.080	129	7	2	138	0.080	129	7	2	138	0.080	129	7	2

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean recession score (mm) over all examined sites, and the number of examined sites presenting scores of 0mm, 1mm, and 2mm at the visit. It is noted that no site presented a recession score greater than 2mm at any visit.

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Listing 5.3.6.1 (Cont'd)
Gingival Recession Data

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

	Visit 2					Visit 3					Visit 4				
Subject	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2
1070	162	0.049	154	8	0	162	0.049	154	8	0	162	0.049	154	8	0
1073	138	0.029	134	4	0	138	0.029	134	4	0	138	0.029	134	4	0
1075	84	0.000	84	0	0	84	0.000	84	0	0	84	0.000	84	0	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean recession score (mm) over all examined sites, and the number of examined sites presenting scores of 0mm, 1mm, and 2mm at the visit. It is noted that no site presented a recession score greater than 2mm at any visit.

Listing 5.3.6.1 (Cont'd)
Gingival Recession Data

Treatment Group: ADA Accepted Soft Manual Toothbrush

	Visit 2					Visit 3					Visit 4				
Subject	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2
1004	168	0.054	159	9	0	168	0.000	168	0	0	168	0.000	168	0	0
1005	150	0.053	144	4	2	150	0.053	144	4	2	150	0.053	144	4	2
1006	156	0.051	148	8	0	156	0.051	148	8	0	156	0.051	148	8	0
1007	114	0.132	104	5	5	114	0.132	104	5	5	114	0.123	105	4	5
1009	114	0.026	111	3	0	114	0.026	111	3	0	114	0.026	111	3	0
1012	132	0.076	122	10	0	132	0.076	122	10	0	132	0.076	122	10	0
1013	156	0.000	156	0	0	156	0.000	156	0	0	156	0.000	156	0	0
1014	126	0.000	126	0	0	126	0.000	126	0	0	126	0.000	126	0	0
1015	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1018	168	0.000	168	0	0	168	0.000	168	0	0	168	0.000	168	0	0
1026	144	0.028	140	4	0	144	0.028	140	4	0	144	0.028	140	4	0
1027	108	0.296	90	4	14	108	0.296	90	4	14	108	0.296	90	4	14
1029	132	0.000	132	0	0	132	0.000	132	0	0	132	0.000	132	0	0
1032	141	0.000	141	0	0	138	0.000	138	0	0	138	0.000	138	0	0
1036	120	0.100	110	8	2	120	0.100	110	8	2	120	0.100	110	8	2
1038	132	0.000	132	0	0	132	0.000	132	0	0	132	0.000	132	0	0
1040	162	0.037	156	6	0	162	0.037	156	6	0	162	0.037	156	6	0
1042	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean recession score (mm) over all examined sites, and the number of examined sites presenting scores of 0mm, 1mm, and 2mm at the visit. It is noted that no site presented a recession score greater than 2mm at any visit.

Listing 5.3.6.1 (Cont'd)
Gingival Recession Data

Treatment Group: ADA Accepted Soft Manual Toothbrush

	Visit 2					Visit 3					Visit 4				
Subject	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2	Total Sites	Mean Score	=0	=1	=2
1043	138	0.022	135	3	0	138	0.022	135	3	0	138	0.022	135	3	0
1044	168	0.036	162	6	0	168	0.036	162	6	0	168	0.036	162	6	0
1045	168	0.065	157	11	0	168	0.065	157	11	0	168	0.065	157	11	0
1046	162	0.006	161	1	0	162	0.006	161	1	0	162	0.006	161	1	0
1050	168	0.054	161	5	2	168	0.054	161	5	2	168	0.054	161	5	2
1052	168	0.000	168	0	0	168	0.000	168	0	0	168	0.000	168	0	0
1053	138	0.000	138	0	0	138	0.000	138	0	0	138	0.000	138	0	0
1054	132	0.038	127	5	0		(No visit)					(No visit)			
1055	162	0.025	158	4	0	162	0.025	158	4	0	162	0.025	158	4	0
1056	150	0.073	142	5	3	150	0.073	142	5	3	150	0.073	142	5	3
1059	168	0.030	163	5	0	168	0.030	163	5	0	168	0.030	163	5	0
1061	126	0.024	124	1	1	126	0.024	124	1	1	126	0.024	124	1	1
1063	144	0.000	144	0	0	144	0.000	144	0	0	144	0.000	144	0	0
1065	168	0.012	166	2	0	168	0.012	166	2	0	168	0.012	166	2	0
1071	168	0.077	158	7	3	168	0.077	158	7	3	168	0.077	158	7	3
1072	156	0.064	150	2	4	156	0.064	150	2	4	156	0.064	150	2	4
1074	78	0.000	78	0	0	78	0.000	78	0	0	78	0.000	78	0	0
1076	126	0.000	126	0	0	126	0.000	126	0	0	126	0.000	126	0	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean recession score (mm) over all examined sites, and the number of examined sites presenting scores of 0mm, 1mm, and 2mm at the visit. It is noted that no site presented a recession score greater than 2mm at any visit.

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Listing 5.3.6.2
Gingival Abrasion Data at All Sites in the Mouth

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

	Visit 2				Visit 3				Visit 4			
Subject	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites
1001	120	0.050	5	0	120	0.000	0	0	120	0.000	0	0
1002	144	0.000	0	0	144	0.007	1	0	144	0.000	0	0
1003	138	0.007	1	0	138	0.000	0	0	138	0.000	0	0
1008	164	0.049	5	0	164	0.024	4	0	164	0.006	1	0
1010	164	0.018	2	0	164	0.030	3	0	164	0.024	2	0
1011	154	0.058	5	0	154	0.000	0	0	154	0.013	2	0
1016	164	0.030	4	0	164	0.043	6	0	164	0.037	3	0
1017	164	0.049	4	0	164	0.012	2	0	164	0.006	1	0
1019	164	0.024	3	0	164	0.006	1	0	164	0.012	1	0
1020	164	0.018	2	0		(No visit)				(No visit)		
1021	164	0.006	1	0	164	0.018	2	0	164	0.018	2	0
1022	164	0.049	4	0	164	0.000	0	0	164	0.018	3	0
1023	164	0.049	6	0	164	0.012	2	0	164	0.024	2	0
1024	164	0.043	7	0	164	0.030	4	0		(No visit)		
1025	164	0.006	1	0	164	0.000	0	0	164	0.000	0	0
1028	120	0.008	1	0	120	0.000	0	0	120	0.000	0	0
1030	164	0.030	3	0	164	0.006	1	0	164	0.006	1	0
1031	164	0.024	4	0		(No visit)				(No visit)		
1033	164	0.030	5	0	164	0.006	1	0	164	0.018	2	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean abrasion score (mm) over all examined sites, the number of sites presenting abrasion scores in Category 1 (1 - 2mm), and the number of sites presenting abrasion scores in Category 2 (3 - 5mm). It is noted that no sites presented scores that were in Category 3 (>5mm) at any visit. Sites presenting no abrasion were assigned a score of 0mm.

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Listing 5.3.6.2 (Cont'd)
Gingival Abrasion Data at All Sites in the Mouth

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

	Visit 2				Visit 3				Visit 4			
Subject	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites
1034	144	0.000	0	0	144	0.014	1	0	144	0.000	0	0
1035	132	0.000	0	0	132	0.000	0	0	132	0.000	0	0
1037	164	0.024	3	0	164	0.012	1	0	164	0.000	0	0
1039	154	0.000	0	0	154	0.000	0	0	154	0.013	2	0
1047	164	0.079	10	0	164	0.000	0	0	164	0.000	0	0
1048	144	0.007	1	0	144	0.000	0	0	144	0.007	1	0
1049	120	0.000	0	0	120	0.008	1	0	120	0.000	0	0
1051	144	0.014	1	0	144	0.021	2	0	144	0.007	1	0
1057	164	0.000	0	0	164	0.012	1	0	164	0.012	2	0
1058	144	0.007	1	0	144	0.007	1	0	144	0.007	1	0
1060	164	0.006	1	0	164	0.043	7	0	164	0.000	0	0
1062	144	0.028	2	0	144	0.000	0	0	144	0.021	2	0
1064	164	0.055	7	0	164	0.000	0	0	164	0.000	0	0
1066	164	0.018	2	0	164	0.006	1	0	164	0.000	0	0
1067	140	0.014	1	0	140	0.000	0	0	140	0.000	0	0
1068	164	0.000	0	0	164	0.000	0	0		(No visit)		
1069	164	0.018	2	0	164	0.006	1	0	164	0.000	0	0
1070	164	0.061	4	1	164	0.018	2	0	164	0.000	0	0
1073	164	0.000	0	0	164	0.024	3	0	164	0.000	0	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean abrasion score (mm) over all examined sites, the number of sites presenting abrasion scores in Category 1 (1 - 2mm), and the number of sites presenting abrasion scores in Category 2 (3 - 5mm). It is noted that no sites presented scores that were in Category 3 (>5mm) at any visit. Sites presenting no abrasion were assigned a score of 0mm.

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Listing 5.3.6.2 (Cont'd)
Gingival Abrasion Data at All Sites in the Mouth

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

	Visit 2				Visit 3				Visit 4			
Subject	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites
1075	120	0.000	0	0	120	0.000	0	0	120	0.000	0	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean abrasion score (mm) over all examined sites, the number of sites presenting abrasion scores in Category 1 (1 - 2mm), and the number of sites presenting abrasion scores in Category 2 (3 - 5mm). It is noted that no sites presented scores that were in Category 3 (>5mm) at any visit. Sites presenting no abrasion were assigned a score of 0mm.

Listing 5.3.6.2 (Cont'd)
Gingival Abrasion Data at All Sites in the Mouth

Treatment Group: ADA Accepted Soft Manual Toothbrush

	Visit 2				Visit 3				Visit 4			
Subject	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites
1004	164	0.043	6	0	164	0.104	9	0	164	0.012	1	0
1005	164	0.024	3	0	164	0.006	1	0	164	0.012	2	0
1006	164	0.043	3	1	164	0.018	3	0	164	0.006	1	0
1007	158	0.013	1	0	158	0.013	2	0	158	0.000	0	0
1009	164	0.134	13	0	164	0.024	4	0	164	0.000	0	0
1012	164	0.012	1	0	164	0.024	1	1	164	0.030	1	1
1013	154	0.078	8	0	154	0.026	3	0	154	0.013	1	0
1014	144	0.056	6	0	144	0.000	0	0	144	0.021	2	0
1015	144	0.000	0	0	144	0.049	4	0	144	0.000	0	0
1018	164	0.012	2	0	164	0.055	7	0	164	0.000	0	0
1026	164	0.000	0	0	164	0.006	1	0	164	0.030	4	0
1027	146	0.000	0	0	146	0.000	0	0	146	0.021	3	0
1029	138	0.000	0	0	138	0.022	3	0	138	0.007	1	0
1032	144	0.028	2	0	144	0.035	3	0	144	0.035	4	0
1036	164	0.024	3	0	164	0.037	3	0	164	0.030	3	0
1038	144	0.000	0	0	144	0.000	0	0	144	0.000	0	0
1040	164	0.049	5	0	164	0.055	7	0	164	0.067	9	0
1042	144	0.049	2	1	144	0.056	7	0	144	0.000	0	0
1043	140	0.007	1	0	140	0.007	1	0	140	0.043	3	1

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean abrasion score (mm) over all examined sites, the number of sites presenting abrasion scores in Category 1 (1 - 2mm), and the number of sites presenting abrasion scores in Category 2 (3 - 5mm). It is noted that no sites presented scores that were in Category 3 (>5mm) at any visit. Sites presenting no abrasion were assigned a score of 0mm.

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Listing 5.3.6.2 (Cont'd)
Gingival Abrasion Data at All Sites in the Mouth

Treatment Group: ADA Accepted Soft Manual Toothbrush

	Visit 2				Visit 3				Visit 4			
Subject	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites	Total Sites	Mean Score	Cat1 Sites	Cat2 Sites
1044	164	0.012	2	0	164	0.049	4	0	164	0.043	4	0
1045	164	0.018	2	0	164	0.000	0	0	164	0.037	4	0
1046	164	0.091	9	1	164	0.012	1	0	164	0.000	0	0
1050	164	0.018	2	0	164	0.085	11	0	164	0.006	1	0
1052	164	0.006	1	0	164	0.012	2	0	164	0.018	3	0
1053	144	0.000	0	0	144	0.014	1	0	144	0.000	0	0
1054	164	0.037	6	0		(No visit)				(No visit)		
1055	164	0.030	2	1	164	0.030	5	0	164	0.000	0	0
1056	164	0.037	3	0	164	0.000	0	0	164	0.073	8	0
1059	164	0.024	2	0	164	0.030	3	0	164	0.030	3	0
1061	164	0.037	4	0	164	0.006	1	0	164	0.055	5	0
1063	144	0.000	0	0	144	0.069	6	0	144	0.069	8	0
1065	164	0.024	4	0	164	0.098	7	1	164	0.122	4	4
1071	164	0.024	3	0	164	0.037	4	0	164	0.018	3	0
1072	152	0.007	1	0	152	0.039	3	0	152	0.013	1	0
1074	120	0.000	0	0	120	0.017	2	0	120	0.000	0	0
1076	163	0.000	0	0	164	0.000	0	0	164	0.000	0	0

Note: Visit 2 = Baseline Visit Visit 3 = Day 15 Visit Visit 4 = Day 30 Visit

Note: For each visit, the information presented is the total number of sites examined, the mean abrasion score (mm) over all examined sites, the number of sites presenting abrasion scores in Category 1 (1 - 2mm), and the number of sites presenting abrasion scores in Category 2 (3 - 5mm). It is noted that no sites presented scores that were in Category 3 (>5mm) at any visit. Sites presenting no abrasion were assigned a score of 0mm.

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Listing 5.3.6.3
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1001	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1002	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1003	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1008	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1010	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1011	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1016	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1017	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1019	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	(none)
1020	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(No Visit)	(No Visit)	(No Visit)
	Day 30 Visit - PRE-BRUSHING	(No Visit)	(No Visit)	(No Visit)
	Day 30 Visit - POST-BRUSHING	(No Visit)	(No Visit)	(No Visit)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

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Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1021	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1022	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1023	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1024	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(No Visit)	(No Visit)	(No Visit)
	Day 30 Visit - POST-BRUSHING	(No Visit)	(No Visit)	(No Visit)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1025	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1028	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1030	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1031	Screening Visit	Bilateral linea alba due to cheek biting, moderate	(none)	(none)
	Baseline Visit	Bilateral linea alba due to cheek bite, moderate	(none)	(none)
	Day 15 Visit	(No Visit)	(No Visit)	(No Visit)
	Day 30 Visit - PRE-BRUSHING	(No Visit)	(No Visit)	(No Visit)
	Day 30 Visit - POST-BRUSHING	(No Visit)	(No Visit)	(No Visit)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

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Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1033	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1034	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1035	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1037	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1039	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1047	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Genrealized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Genrealized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Genrealized Moderate	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

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Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1048	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1049	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1051	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1057	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1058	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1060	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1062	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1064	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1066	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1067	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1068	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(No Visit)	(No Visit)	(No Visit)
	Day 30 Visit - POST-BRUSHING	(No Visit)	(No Visit)	(No Visit)
1069	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

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Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1070	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1073	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: AutoBrush 360° U-shaped Sonic Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1075	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

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Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1004	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1005	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Mild	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Mild	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

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Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1006	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	(none)
1007	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

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Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1009	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1012	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1013	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1014	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1015	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1018	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

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Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1026	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1027	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1029	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1032	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1036	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1038	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1040	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1042	Screening Visit	(none)	Coating Generalized Moderate	Distal Buccal Cusp Fracrure on K
	Baseline Visit	(none)	Coating Generalized Moderate	Distal Buccal Cusp Fracture on K
	Day 15 Visit	(none)	Coating Generalized Moderate	Distal Buccal Cusp Fracture on K
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	Distal Buccal Cusp Fracture on K
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	Distal Buccal Cusp Fracture on K

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

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Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1043	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1044	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1045	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Genrealized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Genrealized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Genrealized Moderate	(none)
1046	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Genrealized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Genrealized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Genrealized Moderate	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

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Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1050	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1052	Screening Visit	(none)	Coating Generalized Mild	(none)
	Baseline Visit	(none)	Coating Generalized Mild	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1053	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1054	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(No Visit)	(No Visit)	(No Visit)
	Day 30 Visit - PRE-BRUSHING	(No Visit)	(No Visit)	(No Visit)
	Day 30 Visit - POST-BRUSHING	(No Visit)	(No Visit)	(No Visit)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1055	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1056	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1059	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1061	Screening Visit	(none)	Coating Generalied Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

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Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1063	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1065	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1071	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1072	Screening Visit	(none)	Coating Generalized Moderate	(none)
	Baseline Visit	(none)	Coating Generalized Moderate	(none)
	Day 15 Visit	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	Coating Generalized Moderate	(none)
	Day 30 Visit - POST-BRUSHING	(none)	Coating Generalized Moderate	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

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Listing 5.3.6.3 (Cont'd)
Abnormal Oral Soft and Hard Tissue Findings
(All Randomized Subjects)

Treatment Group: ADA Accepted Soft Manual Toothbrush

Subject	Visit	Mucosa (including lips)	Tongue	Teeth
1074	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)
1076	Screening Visit	(none)	(none)	(none)
	Baseline Visit	(none)	(none)	(none)
	Day 15 Visit	(none)	(none)	(none)
	Day 30 Visit - PRE-BRUSHING	(none)	(none)	(none)
	Day 30 Visit - POST-BRUSHING	(none)	(none)	(none)

Note: '(none)' indicates that no abnormality was noted. Asterisk (*) indicates that the abnormal findings were classified as an adverse event.

No abnormal findings were noted at any study vist for the following tissue types: Gingival Mucosa; Hard Palate; Soft Palate; Mucogingival Folds; Sublingual Area; Submandibular Area; Salivary Glands; Tonsilar Area; Pharyngeal.

5.3.7 Adverse Event Listings (Each Subject)

There were no SAEs/AEs during this study.