Study Protocol

Evaluation of Toothbrush Bristles in Reduction of Plaque, Inflammation, Bleeding, and Abrasion: A Comparative Study of Tapered vs. End-Rounded Bristles

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Sponsor : Sunstar Americas, Inc.

I. INTRODUCTION

Toothbrushes with tapered bristles were designed to clean plaque accumulated interdental area effectively. *In vitro* studies showed that the effectiveness in artificial plaque reduction is greater than that of the conventional toothbrushes with end rounded bristles. However, clinical studies in dental plaque and gingivitis have not showed consistent results in the superiority compared to conventional toothbrushes[1)-3)]. The purpose of this randomized, examiner blind, parallel controlled clinical research is to evaluate the cleaning efficacy of toothbrushes tufted with tapered bristles and end rounded bristles in removal of interdental plaque using three clinical endpoints, Plaque Index (PI), Bleeding on Probing index (BOP) Periodontal Probing Depth (PPD), Clinical Attachment Loss (CAL), and Gingival Abrasion Score. This study will demonstrate the influence of a type of processing bristles on removal of interdental plaque and reduction of inflammation and determine an agreement between the different evaluation methods.

II. STUDY OBJECTIVES

The objective of this study is to evaluate and compare toothbrushes with two different bristle types in the reduction of plaque index (PI), inflammation, Bleeding on Probing index (BOP), Periodontal Probing Depth (PPD), Clinical Attachment Loss (CAL), and Gingival Abrasion Score for interdental area.

III. STUDY GROUPS

Two different bristles will be tufted into the same tuft pattern. All toothbrush head and handle are identical. The study samples will be provided by a sponsor. The bristle dimensions (height, base diameter of filament) will be same. The difference between the two toothbrushes is the type of processing bristles.

Product A: Double Tapered J-hook bristles (GUM® Technique® Deep Clean Toothbrush, 525 TPA1)
Product B: End rounded bristles: The same handle/head design as the Product A

Table 1. Physical characteristics of the bristles in all test groups

	Product A	Product B
Name	Double tapered J-hook (DTJ)	End rounded (Control)
Individual filament heights in all tufts	10 and 13 mm	10 and 10 mm
Tall filament end	Chemically tapered	Rounded
Short filament end	Chemically tapered	Rounded
Filament's base diameter, milli inch (mm)	7 (0.18)	7 (0.18)
Filament material	PBT	Nylon

IV. SUBJECT INFORMATION AND CONSENT

The clinical investigation, including the consent form, will be reviewed by an IRB in accordance with Title 21 of the Code of Federal Regulations, Parts 50 and 56. Subject consent will be obtained prior to participation in any study procedures as required by the Food and Drug Administration (FDA) GCP guidelines. Subjects will be given ample opportunity to read the consent form and have all questions about study conduct answered before signing and dating the consent form. Each subject will be provided with an exact copy of the informed consent form to retain for his or her records.

Informed consent means the knowing consent of an individual, so situated so as to exercise free power of choice without undue inducement or constraint or coercion. The elements of information necessary for such consent include: a statement that the study involves research; an explanation of the procedures to be followed and their purpose; identification of any procedures that are experimental; any expected discomforts, risks or benefits; approximate number of subjects involved in the study; any appropriate alternative procedures or treatments; description of the confidentiality of subject records; name and phone number of the individual to contact with inquiries concerning the research; explanation of compensation or free medical treatment available for research-related injury; statement that the subject is free to withdraw consent and to discontinue participation at any time; statement that participation is voluntary; indication of any additional costs to the subject; assurance that the subject will be notified of new findings relevant to the subject's participation; statement that it is within the Principal Investigator's discretion to drop the subject from participation at any time.

In addition, the agreement entered into by the subject should include no exculpatory language by which the subject is made to waive, or appear to waive, any of his/her legal rights or to release the institution from liability or negligence.

V. SUBJECT POPULATION

Sample Size Calculation

The sample size was calculated to detect a 10% difference between the study groups, assuming mean baselines of 0.45 units in plaque scores and a standard deviation (SD) of 0.06. With a significance level (α) of 0.05 and a power of 80%, the estimated sample size is 29 participants per group. To account for an estimated dropout rate of 15%, the adjusted sample size is 35 participants per group, and a total sample size of 70 participants.

Volunteers must read and sign the Informed Consent Form after the nature of the study has been fully explained.

Inclusion Criteria

Individuals may be included in the study provided they meet all of the following inclusion criteria:

- Must have read, understood and signed an informed consent prior to being entered into the study.
- Must be 18 to 70 years of age, male or female.
- Have at least 20 natural or restored teeth, not including implants.
- Must have average Plaque Index of Rustogi Modification teeth greater than 2 (Navy PI) at screening.
- Must have more than 20% of pockets with bleeding on probing at screening.
- Agree not to have a dental prophylaxis or any other elective, non-emergency dental procedures (other than those provided during the study) any time during the study.
- Agree to refrain from regular oral hygiene regimen for 24 hours and eating for 4 hours before the appointment in the study.
- Agree to abstain from the use of any dental products other than those provided in the study.
- Agree to comply with the conditions and schedule of the study.

Exclusion Criteria

Individuals are not eligible for participation in this study if any of the following are noted:

- Physical limitations or restrictions that might preclude normal tooth brushing.
- Evidence of gross oral pathology
- Periodontal probing pocket depths (PPD) ≥ 5mm.
- Evidence of major soft tissue lesions or trauma at the baseline visit as determined by the Investigator/Examiner.
- Chronic disease with concomitant oral manifestations
- Subjects who are currently undergoing, or require, extensive dental work, orthodontic treatment or periodontal surgery or orthodontic treatment in the preceding 3 months
- Currently using bleaching trays
- Eating disorders
- Recent history of substance abuse
- Smoking >10 cigarettes/day
- Participation in other clinical studies within 14 days of screening
- Pregnancy

VI. STUDY DESIGN OVERVIEW

This parallel group, examiner blinded, randomized, single center study will enroll 70 subjects to target 58 subjects completing the study. Subjects will visit the clinical site 4 times including a screening visit, and if eligible, 3 additional study visits. Subjects will be instructed to refrain from regular oral hygiene regimen for 24 hours and from eating for four hours before each appointment. The study examiner and staff will screen for subjects that meet the enrollment criteria. Eligible subjects will be randomly assigned to one of two treatment groups.

- Group 1: Product A – 35 participants
- Group 2: Product B – 35 participants

After distribution of an assigned test toothbrush, subjects will receive a basic brushing instruction for Bass method by a study staff but without actual brushing. Subjects will perform toothbrushing

using the assigned product for 2 minutes under supervision. Plaque Index (Navy PI), Bleeding on Probing (BOP Index), Periodontal Probing Depth, Clinical Attachment Loss, and Gingival Abrasion Score will be taken before/after the one-time brushing. Photos will be taken before and after brushing.

Subjects will use the assigned toothbrush for the whole study. Subjects will be evaluated for their Gingival Abrasion Score, BOP, and PI, PPD and CAL every study visit. The study schedule is shown in Table 2. Adverse experiences will be noted and recorded during the study.

Patients who are fully compliant to the clinical trial protocol should enter the primary analysis.

Table 2. Summary of Study Visits

Events	Visit 1 Eligibility Screening	Visit 2 Week 0	Visit 3 Week 2	Visit 4 Week 4
Informed consent, demographics, Inclusion/Exclusion criteria, medical history, concurrent meds	X			
Update of Inclusion/Exclusion criteria		X	X	X
Photos (3 front, left, and right side of mouth)		X		X
Clinical Measurements for inclusion/ exclusion (PD, BOP, PI)	X			
Clinical endpoints (Gingival Abrasion, BOP, PI, PPD and CAL)		X	X	X
Repeat clinical endpoints and photos before and after brushing		X		X
Test product distribution		X		
Instruction of brushing		X		
Reminder call/text		X	X	X
Compliance check			X	X
Adverse events		X	X	X

VII. CLINICAL SUPPLIES

Test Materials

The sponsor will provide the following items to the study site:

- 2 test toothbrushes with different types of bristles (A, B)
- Toothpaste throughout the study period

Packaging and Labeling

The toothbrushes will be recognized as a different type.

Delivery and Inventory:

Immediately upon receipt of study supplies at the clinical site, study personnel will account for all products. The study staff is responsible for maintaining the inventory log.

Storage:

Study supplies will be maintained under secure conditions, until assignment to subjects.

Return of Study Supplies:

At the conclusion of the study, all unused products will be returned to the Sponsor.
Used products will also be returned to the Sponsor.

VIII. TREATMENT REGIMEN

Qualified subjects meeting all inclusion and exclusion criteria will be provided with their assigned toothbrush (A or B) at Visit 2. Subjects will be instructed to brush their teeth as instructed with their assigned toothbrush 2 times daily (after breakfast, before going to bed) for 2 minutes, using only the provided toothpaste at Visit 2.

The same fluoride toothpaste will be used throughout the whole study period. Subjects will refrain from using other oral hygiene products such as interdental brush, floss, or antimicrobial mouthwash throughout the study period.

IX. PRODUCT USE COMPLIANCE

Product compliance will be monitored by phone calls and/or text messages to the participants to remind them to use the product following the instructions given.

X. RESTRICTIONS

Subjects will be advised of the following restrictions during the study period:

- To avoid using other oral hygiene products such as interdental brush, floss, or antimicrobial mouthwash throughout the study period.
- To avoid starting or changing treatments, medications including OTC drugs and supplements that potentially modify plaque accumulation for the duration of the study.
- To refrain from starting or changing habits (e.g. eating chewing gum) to potentially modify subject's plaque accumulation condition for the duration of the study.

XI. STUDY PROCEDURES

Pre-Screening Phone Call

As part of the recruitment and screening process, individuals interested in participating in the study will contact the clinical research center. A follow-up phone call will be conducted using a standardized script to:

- Confirm that the participant meets the inclusion and exclusion criteria.
- Schedule the screening visit, and assess participant's availability for the other 3 study visits.
- Provide pre-screening instructions: refrain from toothbrushing for 24 hours and eating for at least 4 hours prior to Visit 1.

Reminder Phone Calls and Text Messages (24-48 hours prior to each visit)

For Visits 1 through 4, participants will receive a reminder phone call and text message 24 to 48 hours before their scheduled appointment. During this call, study staff will:

- Confirm the date and time of the upcoming visit.
- Review any updates or changes in the participant's medical and dental history.
- Remind participants of study instructions, including brushing behavior and adherence to study restrictions.
- Remind participants of the following pre-visit instructions: refrain from toothbrushing for 24 hours and eating for at least 4 hours prior to the visit.

Screening Visit 1

During the screening, Visit 1, the following procedures will be conducted:

1. Obtain written informed consent from all participants.
2. Confirm eligibility by reviewing inclusion and exclusion criteria.
3. Collect baseline data via questionnaires, including demographic information, medical history, dental history, and current medication usage.
4. Take blood pressure measurement.
5. Perform assessments to determine clinical eligibility:
    - Periodontal Probing Depths (PPD)
    - Bleeding on Probing (BOP)

6. Apply plaque disclosing solution to teeth and assess Plaque Index (PI)
7. Record eligibility status based on PI (>2) and BOP (>20%) and PPD (< 4mm).
8. Complete urine pregnancy test for women of childbearing age, if applicable.
9. Confirm availablity for 3 study visits and schedule remaining visits.

Visit 2 (Week 0)

During Visit 2, the following procedures will be conducted:

1. Review and confirm inclusion and exclusion criteria.
2. Update the participant's medical history and current medications
3. Assess and document any adverse events since the last visit.
4. Take blood pressure measurement.
5. Take pre-staining intraoral photographs (frontal, left, right views).
6. Apply plaque disclosing agent to stain hard and soft tissues.
7. Take photographs following plaque disclosure, prior to brushing.
8. Perform whole-mouth clinical assessments and record findings:
    - Plaque Index (PI)
    - Bleeding on Probing (BOP)
    - Gingival Abrasion Score
    - Periodontal Probing Depths (PPD)
    - Clinical Attachment Loss (CAL)
9. Randomize eligible participants to one of two treatment groups using a computer-generated permuted block randomization sequence, ensuring balanced group sizes.
10. Distribute the assigned toothbrush and toothpaste to participants.
11. Provide standardized brushing instructions using the Bass method using a mouth model and regular toothbrush.
12. Supervise a 2-minute brushing session using the assigned toothbrush and a half-inch length of toothpaste.
13. Apply plaque disclosing agent again to stain hard and soft tissues.
14. Take post-brushing intraoral photographs (frontal, left, right views).
15. Repeat clinical assessments (PI, BOP, Gingival Abrasion Score) following brushing to assess immediate effects.
16. Assess and document any adverse events.
17. Confirm the schedule of the next visit within 14 ± 2 days and review pre-visit instructions.

Visit 3 (Week 2)

During Visit 3, the following procedures will be conducted:

1. Review and confirm inclusion and exclusion criteria.
2. Update the participant's medical history and current medications.
3. Compliance check for study instructions, including brushing behavior and adherence to study restrictions.
4. Assess and document any adverse events since the last visit.
5. Take blood pressure measurement.
6. Apply plaque disclosing agent to stain hard and soft tissues.
7. Perform whole-mouth clinical assessments and record findings:
    - Plaque Index (Navy PI)
    - Gingival Abrasion Score
    - Bleeding on Probing (BOP)
    - Periodontal Probing Depths (PPD)
    - Clinical Attachment Loss (CAL)
8. Provide each participant with a new supply of fluoride toothpaste.
9. Confirm the schedule of the next visit within 14 ± 2 days and review pre-visit instructions.

Visit 4 (Week 4)

During the final visit, the following procedures will be conducted:

1. Review and confirm inclusion and exclusion criteria.
2. Update the participant's medical history and current medications.
3. Compliance check for study instructions, including brushing behavior and adherence to study restrictions.
4. Assess and document any adverse events since the last visit.
5. Take blood pressure measurement.
6. Take pre-staining intraoral photographs (frontal, left, right views).
7. Apply plaque disclosing agent to stain hard and soft tissues.
8. Take photographs following plaque disclosure, prior to brushing.
9. Perform whole-mouth clinical assessments and record findings:
    - Plaque Index (PI)
    - Bleeding on Probing (BOP)

- Gingival Abrasion Score
- Periodontal Probing Depths (PPD)
- Clinical Attachment Loss (CAL)

10. Supervise a 2-minute brushing session using the assigned toothbrush and a half-inch length of toothpaste.
11. Apply plaque disclosing agent again to stain hard and soft tissues.
12. Take post-brushing intraoral photographs (frontal, left, right views).
13. Repeat clinical assessments (PI, BOP, Gingival Abrasion Score) following brushing to assess immediate effects.
14. Complete the study completion/exit form, including participant signature for compensation.
15. Distribute and document the issuance of the gift card/payment card as compensation.

XII. ADVERSE EXPERIENCES

Adverse Event Definition and Handling

An adverse event is any unexpected or serious medical occurrence in a clinical investigation subject during the study, whether or not related to the study product. All adverse events observed by the investigator and/or reported by the subject will be recorded throughout the entire study and documented. The Investigator will be asked to make a judgement on all adverse events as to their severity and possible relation to the study treatments.

More specifically, adverse events would include:

- Any unexpected event not seen before study initiation.
- Any pre-existing event that recurs with increased intensity or increased frequency subsequent to initial product treatment.

Adverse events will be reported to the investigator and the sponsor will be notified within 24 hours of any serious adverse events. All adverse events should be recorded on the appropriate case report form, including date of onset, severity, duration, treatment, and follow-up observation.

The following definitions will be used for grading severity of adverse events:

- Mild - Either asymptomatic, or subject is aware of the sign, symptom, or event, but it is easily tolerated.
- Moderate - Discomfort enough to cause interference with usual activity and may warrant intervention.
- Severe - Incapacitating with inability to do usual activities.

The investigator will make an assessment of the likelihood that there is a reasonable possibility of a causal relationship between a study product and the adverse event. This will be captured using the following criteria: product related, non-product related, non-product related but protocol related. The causal relationship to the product will be assessed as: definitely related, probably

related, possibly related, probably not related, or definitely not related.

Serious Adverse Event

A serious adverse event is any adverse event that:

- Results in death
- Is life threatening (i.e., immediate risk of death as the event occurred). A life-threatening event does not include an event that, had it occurred in a more severe form, might have caused death, but as it occurred did not create an immediate risk of death. For example, hepatitis that is resolved without evidence of hepatic failure would not be considered life threatening even though hepatitis of a more severe nature can be fatal. Similarly, an allergic reaction resulting in angioedema of the face would not be life threatening, even though angioedema of the larynx, allergic bronchospasm, or anaphylaxis can be fatal.
- Results in persistent or significant disability or incapacity (i.e., a substantial, persistent disruption in a subject's ability to conduct normal life functions).
- Requires inpatient hospitalization or prolongation of an existing hospitalization. Hospitalization or prolongation of a hospitalization constitutes criteria for an adverse event to be serious; however, it is not in itself considered a serious adverse event. In the absence of an adverse event, a hospitalization or prolongation of a hospitalization should not be reported as a serious adverse event by the participating Investigator. This is the case in the following situations:
- The hospitalization or prolongation of hospitalization is needed for a procedure required by the protocol.
- The hospitalization or prolongation of hospitalization is part of a routine procedure followed by the center. This should be recorded in the study file.

  In addition, a hospitalization for a pre-existing condition that has not worsened does not constitute a serious adverse event.

- Results in cancer: This criterion can be excluded as it's not technically part of the definition of serious adverse events.
- Results in a congenital anomaly or birth defect.

Additionally, important medical events 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, the event(s) may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in hospitalization, or the development of drug dependency or drug abuse. If there is any doubt whether the adverse event constitutes a serious adverse event, the information will be treated as a serious adverse event.

XIII. SUBJECT COMPLETION AND WITHDRAWAL

Subject Completion

Only subjects who complete all procedures and comply with all areas of the protocol will be deemed to have completed the study. If a subject voluntarily withdraws from the study, or if withdrawn by the Investigator for any reason, he/she will be compensated on a pro-rated basis. Subject compensation will be documented in the Informed Consent and will be approved by the IRB.

If subjects agree to take part in this research study, they will be paid up to $250, depending on their participation. Any payments made to the subjects will be in the form of a debit card and issued to them in person.

The screening visit is required to determine eligibility for the study and there is no compensation to the subject for completing the screening visit.

Eligible subjects will receive the full amount of $250 at their last study visit (Visit 4).

If subjects withdraw from the study for any reason, they will be paid only for each visit they have completed, not including the screening visit: $75 for completing 1 study visit, $150 for completing 2 study visits. In these cases, the debit cards will be issued when the study team learns of subject's withdrawal and they will be asked to come to the DCRC clinic to sign their payment form and pick up their debit card.

Subject Withdrawal

Subjects are free to withdraw at any time during the clinical trial. Subjects may also be withdrawn from the study at any time at the discretion of the Investigator. All subject withdrawals will be documented in the study file. Where possible, the reason for the withdrawal will be documented. Any withdrawals as the result of an adverse event will be followed-up at the discretion of the Study Investigator. Withdrawn subjects will not be replaced.

Subject Discontinuation

A subject will be considered discontinued from the study at any time under the following circumstances:

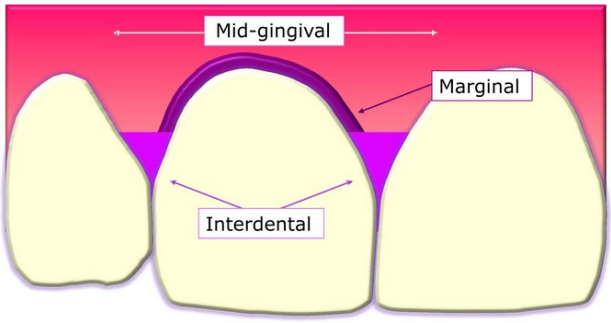
- Any subject who violates any condition of the entrance criteria after having been entered into the study.
- Any subject who develops a confounding concomitant illness (as determined by the subject, Research Coordinator, or Investigator) or a serious adverse event.
- Any subject who becomes uncooperative, does not adhere to the requirements of the study protocol, or refuses to complete the study.

XIV. EFFICACY

The primary outcome variables to be assessed are:

1) Gingival Abrasion Score (Van der Weijden et al. J Clin Periodontol. 2004)[6)]

After the gums are dried with compressed air, Mira-2-Ton® disclosing solution will be applied for better visualization of areas where the surface of the oral epithelium had been abraded. The gingival tissues will be divided into three areas: marginal (cervical free gingiva), interdental (papillary free gingiva) and mid-gingival (attached gingiva).



The gingival abrasion scores will be measured at every visit, both before and after on-site brushing to assess the one-time brushing effects. In addition, the gingival abrasion scores on week 0, week 2, and week 4 will provide insights into the cumulative effects of brushing over 2 and 4 weeks.

Gingival abrasion scores will be categorized based on abrasion size into the following groups: small (≤2 mm), medium (3–5 mm), and large (>5 mm). Measuring between 2 and 3 mm will be assigned a score of small or medium according to nearest mm mark on the probe.

To avoid double-counting gingival abrasion areas, scores will be recorded by interdental site rather than by tooth. Each interdental site will be assessed only once and treated as a unique unit. Interdental areas will be scored independently from marginal and mid-gingival regions, with each interproximal space counted as a distinct site.

Calculate and compare the mean and standard deviation (Mean +/- SD) of the gingival abrasion scores for each abrasion size category at each time point (before brushing, after brushing, week 0, week 2, and week 4). Express the frequency of different abrasion sizes at each time point to showcase changes over time. Interpret the findings in the context of this study, discussing both immediate and cumulative effects of brushing on gingival abrasion scores across different abrasion size categories.

2) Bleeding on Probing (BOP) Index (Lang et al. J Clin Dent. 1986)[7)]

Recorded from the gingival sulci of all teeth after periodontal probing at all six locations per tooth - mesial-buccal, buccal, distal-buccal, mesial-lingual, lingual, distal-lingual. The presence of any bleeding within 30 seconds of gentle probing will be considered a positive response and given a score of 1.

0 = No bleeding
1 = Bleeding

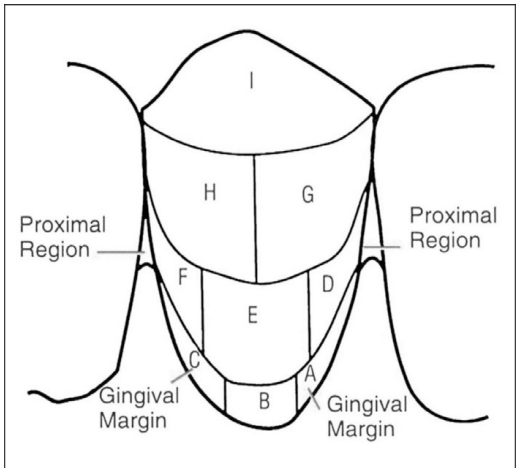
The BOP index will be measured at every visit both before and after on-site brushing to assess the

one-time brushing effects. In addition, the BOP index on week 0, week 2, and week 4 will provide insights into the cumulative effects of brushing over 2 and 4 weeks.

BOP index results will be expressed as the frequency of bleeding (1) at each time point to showcase changes over time. Compare the frequency of bleeding before and after brushing, as well as across different time points (week 0, week 2, week 4). Interpret the findings in the context of this study, discussing both immediate and cumulative effects of brushing on BOP index.

3) Rustogi Modified Navy Plaque Index (PI) (Rustogi et al. J Clin Dent. 1992)[5)]

After disclosing dental plaque on teeth with plaque disclosing solution (i.e., Mira-2-Ton), the Rustogi Modified Navy Plaque Index (PI) is evaluated as either present or absent (1 or 0) on each of the nine areas of the buccal and lingual tooth surfaces except for third molars. Whole tooth, marginal, and approximal areas are defined as shown below. Score of each area (from A to I) will be recorded for further assessments. In this study, the PI should be evaluated by only trained and calibrated examiners.



The PI values will be measured at every visit both before and after on-site brushing to assess the one-time brushing effects. In addition, the PI values on week 0, week 2, and week 4 will provide insights into the cumulative effects of brushing over 2 and 4 weeks.

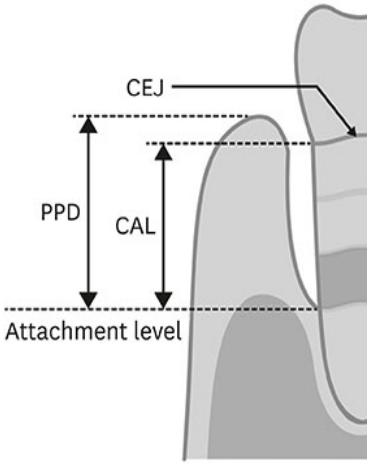
PI values will be expressed as the frequency of plaque presence (1) at each time point to showcase changes over time. Compare the frequency of plaque presence before and after brushing, as well as across different time points (week 0, week 2, week 4). Interpret the findings in the context of this study, discussing both immediate and cumulative effects of brushing on PI values.

4) Periodontal Probing Depth (PPD) and Clinical Attachment Loss (CAL)

PPD is the distance from the free gingival margin to the base of the sulcus as measured by the periodontal probe.

CAL, the position of the attached periodontal tissues ata the base of the pocket, will be determined by comparing the distance from the cement-enamel Junction (CEJ) to the base of the sulcus.

PPD and CAL will be determined at six sites per tooth (mesio-facial, mid facial, disto-facial, disto-lingual, mid lingual, and mesio-lingual). PPD and CAL values will be rounded up to the next whole millimeter value. Full-mouth periodontal probing will be performed by one study examiner, whose measurements will be previously calibrated to a trained and experienced periodontist.



XV. STATISTICAL ANALYSIS AND DATA MANAGEMENT

Descriptive statistics for all subjects will be performed for background and demographic variables. Continuous variables are expressed as mean +/- SD and categorical variables are expressed as frequencies (n) and percentages (%).

Student *t* test or Wilcoxon *rank sum* test where appropriate, will be used to compare among different bristles. For intragroup changes of endpoints before/after one-time brushing or use for 2 and 4-weeks, paired t test or Wilcoxon signed rank test will be used where appropriate. Spearman Rank Order Correlation was used to analyze correlations between the variables.

Safety parameters will include oral soft and hard tissues and subjective reports as well as any AEs. The analysis will include all observed effects which initially occurred or worsened following treatment. Any adverse effects will be summarized classified according to their intensity (mild, moderate, or severe) and relationship (definitely related, probably related, possibly related, probably not related, or definitely not related) to study product.

All statistical tests will be conducted using Minitab 18.

XVI. REFERENCES

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