FINAL REPORT

Study Title: **Plaque Removal Efficacy of AutoBrush®, a 360 Degree Sonic Power Toothbrush, in Children**

Study Number: Lander Enterprises, LLC study # AB-360-001-2022
IRB Study # U.S.IRB2022SRI/01
U.S. Investigational Review Board, Inc.
6400 SW 72 Court, Miami, Florida 33143

Study Dates:

Visit 1	**Visit 2**
14Feb2022	**17Feb2022**

Study Personnel: Jeffery L. Milleman, DDS, MPA: Principal Investigator
Kimberly R. Milleman, RDH, BSEd, PhD: Plaque Examiner
Julie E. Wygant: Front Desk, Recruitment
Abbie L. Yoder, BS: Study Coordinator, Randomization
Tori York, BSDH: Recorder
Melanie Sollberger, BS: Supervised Instruction
Ellen Lindsey, BS: Recruitment
Megan S. Gaff, BSDH: Informed Consent Process

IRB Approval: The U.S.IRB approved (February 8, 2022) the Final Clinical Protocol dated February 1, 2022: Research Subject Information and Consent Form dated February 8, 2022; Research Subject Information and Assent Form dated February 8, 2022; "Honey Comb" AutoBrush® Brushing Instructions; Safety Statement and the Investigators.

Conduct of Study: The study commenced on the 13th of February, 2022 with the SIV. The FSFV was performed on the 14th of February, 2022 and was conducted by Salus Research, Inc. in accordance with proposed guidelines for current good clinical practices (cGCP's). The study was conducted in compliance with the United States Federal Regulations governing informed consent (21 CFR 50), Institutional Review Boards (21 CFR 56), clinical investigations, and applicable regulations governing sponsor and investigator conduct (21 CFR 312/812). The study was completed on the 17th of February, 2022.

Informed Consent: Each subject and their parent or guardian read, understood, signed, and received an assent and informed consent form which had been approved by the Institutional Review Board prior to being entered into the study. The informed consent and assent form were in compliance with FDA regulations (21 CFR 50).

1 Objective

The objective of this single-use, examiner blinded, randomized, two-period, cross-over, IRB-approved clinical study was to evaluate the safety and plaque removal efficacy of AutoBrush®, a new children's 360° sonic toothbrush, compared to a marketed children's manual toothbrush.

1.1.1 Safety

Safety was assessed through oral clinical examinations and interviews to determine soft tissue or oral irritation symptoms.

1.1.2 Efficacy

Efficacy endpoints were:

- Mean change in Plaque Index (PI) scores post-brushing:
  - Whole mouth (all-surfaces)
  - Hard-to-reach areas
    - Proximal (mesial and distal) surfaces
    - Gingival/gumline (buccal and lingual)

2 Study Design

This single-center, single use, examiner-blind, randomized, two-period, cross-over study consisted of a Screening/Baseline visit during which potential subjects read and signed an assent to participate and a parent or legal guardian read and signed an informed consent form. Additionally, the subject's guardian completed health and dental questionnaires. The subjects received a clinical oral examination. The oral examination included assessments in the following order:

- Oral safety was assessed through soft and hard tissue examination for evidence of irritation or other abnormalities;
- Supragingival plaque levels, determined according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (PI).[9, 10]

Prior to each exam visit, subjects refrained from oral hygiene for 12 to 16 hours and had not eaten 30 minutes prior to the visit. Following informed consent/assent procedures and collection of Baseline demographics, qualified subjects received an oral examination and assessment for PI.

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

1) Control Group: Brushing with ADA reference manual soft toothbrush and ADA Accepted, 0.243% sodium fluoride Crest® Cavity Protection dentifrice (Procter & Gamble, Cincinnati, OH, USA), for 2 minutes;
2) AutoBrush® 360° Sonic Toothbrush Group: Brushing with AutoBrush® 360° sonic power toothbrush and ADA Accepted, 0.243% sodium fluoride Crest® Cavity Protection dentifrice (Procter & Gamble, Cincinnati, OH, USA), for one minute.

Subjects were provided verbal instructions on the use of their assigned toothbrush. After the PI exam, subjects were escorted to a separate room for product use. Subject's use of their assigned oral care

brushing at Visit 1 and Visit 2 were performed at the clinical site under the supervision of study personnel in front of a mirror, and out of the view of the study examiner. After brushing subjects had an OST examination and had their teeth disclosed again with the red dye and were evaluated for post-brushing plaque removal using PI.

Subjects were scheduled to return for the next visit (visit 2) following a 2-day washout period during which subjects resumed their normal brushing routine.

3 Study Population

Twenty-two (22) generally healthy male and female subjects 5-8 years of age were screened so that approximately 20 (20 per group) would complete this trial. To participate in this study, all subjects fulfilled the inclusion and exclusion criteria as outlined in sections 5.1 and 5.2.

3.1 Inclusion Criteria

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

1. Generally healthy males and females at least 5-8 years of age.
2. Volunteers must had provided assent to participate and consent from a parent or legal guardian prior to being enrolled into the study.
3. A minimum of 12 natural teeth with scorable facial and lingual surfaces. Partially erupted permanent teeth and primary teeth that were loose or in the process of exfoliation were not included in the tooth count. Teeth that were grossly carious, orthodontically banded, exhibiting general cervical abrasion and/or enamel abrasion were not included in the tooth count.
4. A plaque index score ≥ 1.80 according to the Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index, following 12 to 16 hours plaque accumulation period.

3.2 Exclusion Criteria

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

1) Having a history of adverse effects, oral soft or hard tissue sensitivity, to any ingredient in the test materials.
2) Having self-reported serious medical conditions.
3) Being under treatment for a heart condition requiring use of a pacemaker.
4) Having anything that, in the opinion of the investigator, would place the subject at increased risk or preclude the subject's full compliance with or completion of the study.
5) Having had antibiotic, anti-inflammatory, anti-coagulant medication or chemotherapeutic antiplaque/antigingivitis therapy within 30 days of screening exams.
6) Having participated in any study involving oral care products, concurrently or within the 30 days of screening exams.
7) Presence of severe periodontal disease or being actively treated for periodontal disease.
8) Having grossly carious, fully crowned, or extensively restored teeth.
9) Having orthodontic appliances, peri/oral piercings, or removable partial dentures.
10) Having significant oral soft tissue pathology based on a visual examination.

If the subject reported taking medication, a history of allergy, and/or a chronic disease which in the opinion of investigator would not affect the clinical parameter(s) being assessed or the safety of the subject, the subject was enrolled in the study and the conditions were noted on the Subject's source document.

3.3 Subject Identification, Screening and Enrollment

Subjects were recruited from the local population utilizing the Salus Research database. Subject screening, enrollment, product assignments, and dental assessments were conducted at the clinic site. The investigator maintained a screening and enrollment log of all subjects who signed an ICF for this study. The log included unique subject identification numbers/screening numbers (1001-1030) and the dates of subject screening, enrollment and completion (or early termination). Once a number had been assigned to a subject, it was not reassigned to another subject. The Investigator maintained a confidential identification list containing each enrolled subject's name and corresponding unique subject number, to enable records to be identified.

3.4 Treatment Assignment Procedures

22 qualified subjects were randomly assigned to one of two treatment groups. Upon qualification, each enrolled subject was sequentially issued a unique subject randomization number (001-030), which determined the treatment assignments according to a randomization scheme (AB; BA). Subjects were randomized to one of two treatment groups:

1) Control Group: Brushing with ADA reference manual soft toothbrush and Crest® Cavity Protection dentifrice for 2 minutes;
2) AutoBrush® 360° Sonic Toothbrush Group: Brushing with AutoBrush® 360° Sonic power toothbrush and Crest® Cavity Protection dentifrice for 1 minute.

The Investigator or designee maintained the randomization worksheets documenting the subject assignment to treatment groups.

3.4.1 Withdrawal

Every effort was made within the bounds of safety and subject choice to have each subject complete the study. A discontinuation occurred when an enrolled subject ceased participation in the study, regardless of the circumstances, prior to completion of the protocol. The reason for a subject discontinuation from the study would have been reported in the case report form. The investigators would have attempted to determine the primary reason for discontinuation. A study subject would have been discontinued from participation in the study if:

- Any clinical adverse event (AE), intercurrent illness, or other medical condition or situation occurred such that continued participation in the study would have not been in the best interest of the subject;
- The subject was determined to become ineligible due to an exclusion criterion (i.e., either newly developed or not previously recognized).

Subjects were free to withdraw from participation in the study at any time upon request. A discontinuation must be immediately reported to the sponsor or his/her designated representative if it is

due to a serious adverse event. The final evaluation required by the protocol would have been performed at the time of study discontinuation.

3.4.2 Termination of Study

This study may have been prematurely terminated if, in the opinion of the investigator or the sponsor, there was sufficient reasonable cause. Written notification, documenting the reason for study termination, would have been provided to the investigator or sponsor by the terminating party. Circumstances that may have warranted termination include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to subjects;
- Insufficient adherence to protocol requirements;
- Data that are not sufficiently complete and/or evaluable;
- Plans to modify, suspend or discontinue the development of the experimental test article.

If the study was prematurely terminated or suspended, the sponsor would have promptly informed the investigators/institutions, of the termination or suspension and the reason(s) for the termination or suspension. The IRB would also have been informed promptly and provided the reason(s) for the termination or suspension by the investigator/institution.

4 Investigational Product

4.1 Study Material Description

Manual Toothbrush Control:	**Manual toothbrush**
Trade name	Colgate, Full Head / Soft Bristles
Dosage form	Single use brushing at research site
Packaging	Single packaging

Power Toothbrush:	**AutoBrush® Sonic Rechargeable Power Toothbrush**
Trade name	AutoBrush®
Manufacturer	AutoBrush®
Dosage form	Single use brushing at research site
Packaging	Single packaging

Ancillary supplies included a single tube of Crest® Cavity Protection dentifrice (0.243% sodium fluoride, Procter & Gamble, Cincinnati, OH, USA), a travel size tube.

4.2 Packaging, Labeling and Storage

All products were stored by the clinical site at room temperature. Manual toothbrushes, AutoBrush® 360° Sonic Toothbrush and Crest® Cavity Protection toothpaste were supplied in the original marketed packages with no overwrap.

The research site stored used products in a bag that contained the label noting the relevant subject number.
No study products were issued to the subjects for home-use.

4.3 Dosage, Preparation and Administration of Investigational Product

No study products were administered for subject use at home. A single supervised use took place at each visit according to the randomization.

4.4 Accountability Procedures for the Investigational Product(s)

Lander Enterprises, LLC provided the investigator with sufficient amounts of the investigational AutoBrushes. All other test materials were provided by the research site. The investigator ensured that deliveries of investigational product from the sponsor were received by a responsible person, that all receipts were recorded in writing and that the product was stored in a secure area under recommended storage conditions. It was also the responsibility of the investigator to ensure that the integrity of packaged study product was not jeopardized prior to dispensing. The investigator dispensed the test material only to subjects included in this study following the procedures specified in the study protocol. Each subject was only administered the test material carrying his/her randomization number. All dispensing was documented. The investigator maintained 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.

4.5 Assessment of Subject Compliance with Investigational Product

Due to the cross-over design of this study, no investigational product left the research site. All use of investigational product was supervised. Therefore, subject compliance was not included in this study.

4.6 Concomitant Medications/Treatments

Any medication the subject took during the study was considered concomitant medication. All concomitant medications and non-drug therapy (e.g., tooth extraction, endodontic treatment, etc.) would have been recorded in the subject's medical source document.

5 Study Procedures, Evaluation and Schedule

The schedule of observations and assessments was provided in Sec. 15, Table 1, Study Flow Chart.

5.1 Screening/Baseline Exam (Visit 1)

Prior to randomization to treatment groups, the following procedures were performed:

- Informed consent/assent form, medical and dental history.
- Inclusion/Exclusion Criteria checklist.
- Clinical exams:
  - Oral soft and hard tissue evaluation for safety assessment;
  - Lobene-Soparkar Modification of the Turesky Modification of the Quigley-Hein Plaque Index (PI);
  - Identify subjects with qualifying levels of plaque PI ≥ 1.80.

If subject met entry criteria, the following procedures were performed:

- Pre-Treatment oral soft and hard tissue evaluation

- Pre-Treatment PI
- Randomization to test groups.
- Supervised use of assigned test products.
- Post-Treatment oral soft and hard tissue evaluation
- Post-Treatment (PI.)
- Appoint subjects for next visit.

5.2 Visit 2 (≥ 2 days) from visit 1

- Queried to update medical and oral health and record adverse events and concomitant medications.
- Pre-Treatment oral soft and hard tissue evaluation
- Pre-Treatment PI
- Supervised use of assigned test products.
- Post-Treatment oral soft and hard tissue evaluation
- Post-Treatment (PI)
- Discharge subject and provide final instructions for follow-up of ongoing adverse events, as applicable.

5.3 Early Termination Visit

If a subject discontinued from the study for any reason prior to the final visit, the following procedures would have been conducted:

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

6 Study Procedures/Evaluations

6.1 Demographics

Demographic information was collected at the Screening/Baseline Visit and included the subject's race, gender and age.

6.2 *Safety Assessments*

6.2.1 Oral Examinations

An oral examination was conducted at all visits to monitor the effect of the test articles on the soft and hard tissues. Lips, buccal, labial and sublingual mucosae, tongue, hard and soft palate, uvula and oropharynx, and teeth were examined for signs of reddening/inflammation, ulceration, white patches and desquamation/ sloughing of mucosal tissues and findings were recorded on the Oral Exam CRF. Changes from Baseline were recorded and deviations from normal were recorded.

Clinically significant findings were recorded as adverse events and an assessment was made regarding relationship to test materials.

6.3 Efficacy Assessments

Clinical efficacy assessments were performed by a single examiner pre- and post-brushing at both visit 1 and 2 for plaque.

6.3.1 Plaque Index

Supragingival dental plaque was assessed according to the Turesky Modification of the Quigley-Hein Plaque Index as further modified by Lobene and Soparkar (PI).[9,10] Plaque was disclosed using a red disclosing solution and each tooth was 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.

A whole mouth plaque index was 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 were calculated for gingival margin (gumline) and the interproximal surfaces. Gumline PI scores were calculated by summing the number of gingival margin (buccal and lingual) scores and dividing by the number of measurements. Interproximal PI scores (mesial and distal) were calculated by summing the number of interproximal site scores (distobuccal, mesiobuccal, distolingual and mesiolingual) and dividing by the number of measurements.

6.4 Examiner Repeatability Exercises

A single trained dental examiner performed the oral examinations and PI assessments. If the research site examiner had not scored plaque for another clinical trial in the last 30 days, prior to Baseline exams, at least 10 subjects would have been assessed for plaque levels, according to the PI with at least 10 minutes between repeat examinations. Repeatability was 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) would have been performed if the evaluated level of reliability was judged to be low.

7 Adverse Event Reporting and Documentation

Adverse events were determined by visual examination of the oral cavity by the dental examiner. In addition, clinical research center personnel asked 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, were recorded on the adverse event page(s) of the case report form.

7.1 Adverse Events

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

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

Pre-existing conditions were not regarded as AEs if the condition followed a normal course
Of recovery, unless it worsened after exposure to the investigational product.

7.2 Definition of a Serious Adverse Event (SAE)

The Investigator or other study personnel would have immediately (within 24 hours) informed the Sponsor of all Serious Adverse Events (SAEs) that occurred 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.

7.3 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 investigational plan, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

7.4 Recording an Adverse Event

All serious adverse events would have been 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 would have reviewed all AEs/SAEs and determined the

severity, relationship (of the AE/SAE to the test article/investigational product), and outcome. The PI also would have determined whether the subject remained in the study.
Severity, relationship and outcome was 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	

7.5 Follow-up

Study-related adverse events were monitored to resolution by the Investigator for at least 30 days following study completion or discontinuing use of the investigational product.
Serious Adverse Events/Experiences would have been followed to resolution to the extent possible (e.g., medical attention by subject's primary care physician).

7.6 Reporting Adverse Events

The Investigator would have reported all serious adverse events immediately to the Sponsor and would have completed a Serious Adverse Event Form within the following timelines:

- All deaths and immediately life-threatening events, whether related or unrelated, were to be recorded on the Serious Adverse Event Form and sent by email within 24 hours of site awareness to the attention of Christopher Lander at chrislander@thebasis.io.
- Serious adverse events other than death and immediately life-threatening events, regardless of relationship, were to be reported by email within 72 hours of site awareness to the attention of Christopher Lander at chrislander@thebasis.io.

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

7.7 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.

8 Statistical Considerations

Data were manually recorded on Case Report Forms (CRFs). Salus Research was responsible for data entry and statistical analysis of the data was performed by Reinhard Schuller Consulting.

8.1 Sample Size Considerations

It was expected that the active treatments improvement would exceed that of the negative control by at least 25%. This translates into active treatments being superior by 0.4 with respect to PI when compared to the negative control at each post brushing assessment. A sample size of 20 completed evaluable subjects achieves a 90% power to detect treatment differences. This assumed improvements by 0.4 with respect to PI, when compared to the negative control, with an effect size (mean/standard deviation) of 0.7. These calculations are based on two-sided tests at the 0.05 significance level.

8.2 Safety Review

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

8.3 Demographic and Baseline Characteristics

Demographic and Baseline characteristics were summarized for age, gender, and mean PI. Data were summarized using appropriate descriptive statistics (mean, median, minimum, maximum) by treatment group and overall. Categorical demographic and baseline data were evaluated using Fisher's Exactness Test and continuous demographic and baseline data was evaluated using ANOVA. All tests were two-sided and conducted at the 0.05 significance level. No adjustments for multiple comparisons or multiple testing were made.

8.4 Efficacy Review

Post-treatment efficacy endpoints were:

- Mean change in PI scores at Pre - Post-brushing:
  - Whole mouth (all-surfaces)
  - Hard-to-reach areas
    - Proximal (mesial and distal) surfaces
    - Gingival/gumline (buccal and lingual)

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

Analyses were performed using the ANCOVA model with treatment as a factor and the corresponding pre-brushing value as a covariate. The comparisons were made at the 0.05 level, 2-sided. Tables comparing treatment groups provided differences in the least squares mean, the standard error of the differences, the confidence interval for the difference, and the p-value. Post ANCOVA pairwise comparisons between the treatment and the negative control were made using a two-sided Dunnett's test, which controls the error rate for the simultaneous comparisons.[13] Differences between the means, simultaneous 95% confidence intervals and test results were presented.

8.5 *Data Sets to be Analyzed*

Data analysis sets included evaluable subjects, defined as subjects who did not have major protocol violations. Data for safety analysis included all subjects who received treatment.

9 Data Handling and Record Keeping

The investigator was responsible to ensure the accuracy, completeness, legibility, and timeliness of the data reported. All source documents were completed in a neat, legible manner to ensure accurate interpretation of data. Dark ink was required to ensure clarity of reproduced copies. When making changes or corrections, cross out the original entry with a single line, and initial and date the change. DO NOT ERASE, OVERWRITE, OR USE CORRECTION FLUID OR TAPE ON THE ORIGINAL.

The investigator prepared and maintained 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 included 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) was completed for each subject enrolled in the study and included documenting subject demographics and subject's study completion status. All information recorded on the CRFs for this study was consistent with the subject's source documentation records. The Investigator or designee reviewed all entries for completeness and correctness.

The Investigator or designee agreed 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

was placed in the investigator's study file and the original was taken by the site monitor and provided to the Sponsor.

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

9.1 Study Records Retention

Study documents will 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 will 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.

9.2 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 was 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 would have been promptly reported to the Sponsor and would have been 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 were responsible for knowing and adhering to their IRB requirements.

10 Ethics

10.1 Institutional Review Board

This study was reviewed by U.S. Investigational Review Board which is an appropriately constituted Institutional Review Board (IRB) as outlined in 21 CFR Part 56. The IRB reviewed the protocol, any amendments, the informed consent form (ICF), subject instructions, safety information, Investigator's curriculum vitae (CV) and advertisements.
Approval by the Board was obtained prior to the initiation of the study.

10.2 Ethical Conduct of the Study

This study was conducted in accordance with 21 Code of Federal Regulations (CFR) Parts 50 and 56. The study was 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 would have promptly notified participating Investigators and regulatory authorities of findings that could have adversely affected the safety of subjects, impacted the conduct of the study, or altered the IRB's approval to continue the study. Lander Enterprises, LLC would have promptly reported 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.

10.3 Subject Information and Consent

Subject consent/assent was obtained prior to participation in the study as required by the regulatory guidelines (21 CFR Part 50). Subjects were given ample opportunity to read the consent/assent form and had all questions regarding study participation answered prior to signing the consent/assent form. Each subject was provided with a signed copy of the ICF to retain for his or her records. The original signed ICF was retained on file at the study center.

10.4 Authorization to Disclose Protected Health Information

Subjects were 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 was incorporated into the informed consent process and was obtained prior to the subject entering the study. Each subject was provided with a signed copy of the authorization and the original was retained on file at the study center.

Subject confidentiality was strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. This confidentiality was 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 was held in strict confidence. No information concerning the study or the data were 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.

11 MONITORING

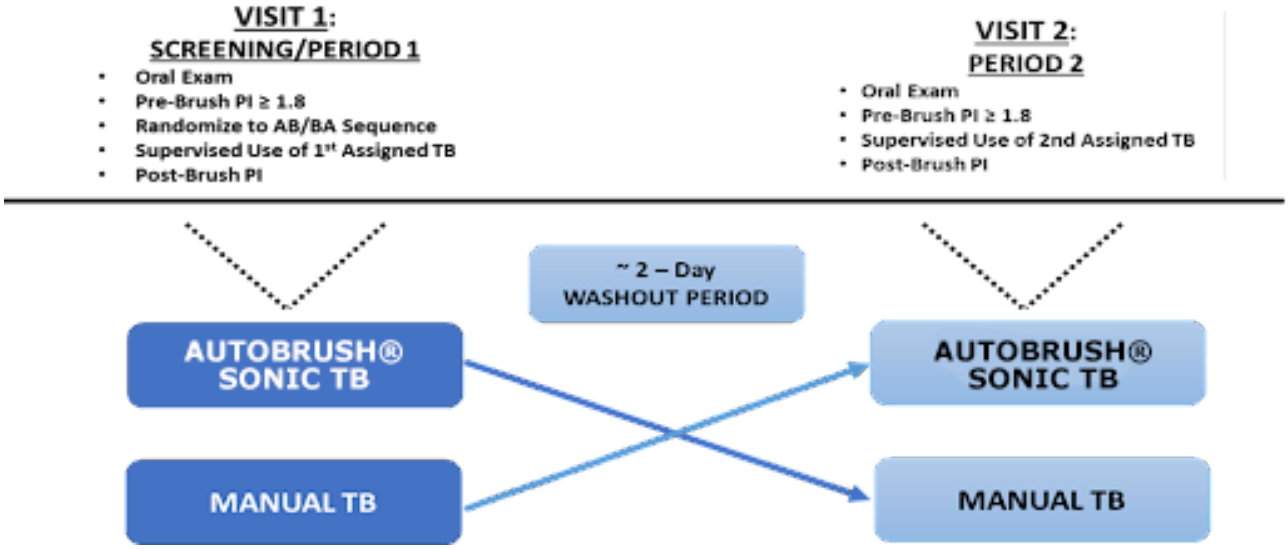
A Sponsor representative may meet with the Investigator and his/her staff prior to the entrance of the first subject to review the procedures to be followed in conducting the study. After the enrollment of the first subject, the Investigator would have permitted the Sponsor to monitor the progress of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

12 AMENDMENTS/MODIFICATION OF THIS PROTOCOL

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

13 Table 1. Study Flow Chart

Procedures:	Visit 1 Screening/ Period 1 Single-Use Exams	Visit 2 Period 2 Single-Use Exams
Informed Consent, Assent	X	
Confirm continuing informed consent/assent		X
Demographics, Med/Dent History, Concomitant Medications	X	
Inclusion/Exclusion Criteria	X	X
Randomization	X	
Update Medical/Dental History		X
Oral Soft & Hard Tissue Exam	X	X
Plaque Exam Pre-Brushing Qualification	X	X
Supervised Brushing	X	X
Plaque Exam Post-Brushing	X	X
Query Parent/Legal Guardian & Subject for Adverse Events	X	X
Schedule appointment for next visit	X	
Study Conclusion and Exit		X



Statistical Report

Protocol Title:

Plaque Removal Efficacy of AutoBrush®, a 360 Degree Sonic Toothbrush, in Children

Protocol:

AutoBrush® Study Number: AB-360-001-2022

By Reinhard Schuller

Final

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Executive Summary

Primary Objectives

The objective of this single-use, examiner blinded, randomized, two-period, cross-over, IRB-approved clinical study is to evaluate the safety and plaque removal efficacy of AutoBrush®, a new children's 360-degree sonic toothbrush, compared to a marketed children's manual toothbrush.

Treatment groups are as follows:

Groups

- Experimental Group – AutoBrush® 360 Degree Sonic Toothbrush (AB)
- Control Group - ADA Manual Toothbrush (MB)

Demographic and Baseline Data

Twenty-two (22) children were randomized to receive each treatment and completed the study. The gender breakdown was 9 females and 13 males. The mean age was 6.5 with the minimum age being 5 years and the maximum being 8 years. Plaque baseline scores were comparable for both treatments. Full demographic summary data are given in Appendix Table 1.

Plaque Results

The AutoBrush® 360-degree sonic toothbrush did an excellent job of reducing plaque, for example a minimum reduction of 1 unit on the plaque index (see Appendix Table 2) for whole mouth. Executive Summary Table 1 below indicates that the plaque reduction for whole mouth was 50.6%. This reduction was statistically significant ($p<0.001$; see variable Whole from Appendix Table 2). The reduction for whole mouth for the manual toothbrush was only 1.9%. The other endpoints in the table below also showed clinically meaningful reductions for the AutoBrush® 360-degree sonic toothbrush, and these reductions were also statistically significant ($p<0.001$; see Appendix Table 2). The

AutoBrush® sonic toothbrush was statistically superior to the manual brush ($p<0.001$; see Executive Summary Table 1).

Executive Summary Table 1: Plaque Reduction

	Reduction (%)				
	Whole Mouth	Gumline	Proximal	Facial	Lingual
AB	50.6	71.2	40.7	52.3	48.6
MB	1.9	3.5	1.1	5.1	-2.2
	Statistical Comparison of AB with MB				
	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001

AB = AutoBrush® 360 Degree Sonic Toothbrush
MB = ADA Manual Toothbrush

Executive Summary Table 2 below provides summary results for harder to reach areas: facial and lingual gumline, and facial and lingual proximal sites. Facial gumline and lingual gumline reductions both exceeded 70%. These reductions were statistically significant ($p<0.001$; Appendix Table 2). The other endpoints in the table also showed meaningful reductions for the AutoBrush® 360-degree sonic toothbrush, and these reductions were also statistically significant ($p<0.001$; for all endpoints from Appendix Table 2). The AutoBrush® 360-degree sonic toothbrush was statistically superior to the manual brush in reducing hard to reach plaque ($p<0.001$) as seen in Executive Summary Table 2 below.

Executive Summary Table 2: Plaque Reduction

	Reduction (%)			
	Facial Gumline	Lingual Gumline	Facial Proximal	Lingual Proximal
AB	72.0	70.0	42.6	38.4
MB	7.1	-1.3	4.1	-2.6
	Statistical Comparison of AB with MB			

	p<0.001	p<0.001	p<0.001	p<0.001

AB = AutoBrush® 360 Degree Sonic Toothbrush
MB = ADA Manual Toothbrush

Appendix Table 4 provides more summary data for the superiority of the AutoBrush® sonic toothbrush compared to manual toothbrush.

No plaque improvement was seen for any lingual surfaces: lingual, lingual facial and lingual proximal for the manual toothbrush. In contrast, the AutoBrush® sonic toothbrush produced 48.6% reduction for lingual surfaces (Executive Summary Table 1), 70% reduction for lingual gumline surfaces, and 38.4% reduction for lingual proximal surfaces (Executive Summary Table 2). All three of these reductions were statistically significant (p<0.001; Appendix Table 2).

Summary and Conclusions:

- No safety issues arose from the use of the AutoBrush® 360 Degree Sonic Toothbrush
- The AutoBrush® 360 Degree Sonic Toothbrush showed significant plaque reduction for all endpoints evaluated.
- The manual toothbrush did not remove plaque from any lingual surfaces whereas the AutoBrush® 360 Degree Sonic Toothbrush did remove lingual surface plaque.

Study Report

Objectives

See the Executive Summary.

Study Design

See the Protocol.

Statistical Analysis

Plaque Index (PI) was measured as the Turesky Modification of the Quigley-Hein Plaque Index as further modified by Lobene and Spakar . Analyses were performed using an analysis of covariance (ANCOVA) model for single-use brushing PI scores with nine (9) separate endpoints: whole mouth, gumline, proximal, facial, lingual, facial gumline, lingual gumline, facial proximal, and lingual proximal. See the Protocol for further details.

Data Displays

Computer-generated tables adhere to the following specifications. Unless otherwise specified, the estimated mean for a set of values should be printed to one more decimal place than the raw (observed) data and rounded appropriately. Standard errors should be printed to two more additional decimal places than the raw (observed) data and rounded appropriately. For example, for plaque (i.e., data in integer values) data presentations will follow the following example given below.

Parameter	Data Presentation in Output
Raw data (e.g., age)	X
Mean	X.X
Standard Deviation (Standard Error)	X.XX
Min - Max	X.X – X.X

The p value will be printed in tables rounded to three (3) decimal places and formatted as ‘0.xxx’. P values less than 0.001 will be formatted in the tables as ‘p<0.001’. All fractional numeric values are printed with a zero to the left of the decimal point (e.g., 0.8). A percentage of less than one hundred is printed to a least one decimal place. Summaries are provided in Executive Summary Tables, and Appendix Tables in this report. For plaque data, improvement summaries and comparisons will be provided in tables. Tables providing summary statistics (e.g., mean, standard deviation, and one-way analysis for individual treatment change from baseline p-values) will appear in the Appendix.

Results

Safety

No safety issues arose during the conduct of the study.

Demographic and Baseline Characteristics

Full results are given in Appendix Table 1. (See Executive Summary for some highlights.)

Baseline Comparability of Endpoints

Baseline values were comparable for both treatments for all endpoints (data on file).

Plaque

See the Executive Summary and Appendix Tables 2-4 for the highlights and data. Appendix Table 4 provides the results for the analysis of covariance model along with the least square means (LSMeans) and summary statistics for the LSMeans. All endpoints showed statistically significant differences between the two products ($p<0.001$) and the confidence intervals indicated that the AutoBrush® 360 Degree Sonic Toothbrush was significantly superior in plaque reduction to the ADA manual toothbrush.

Conclusion

See the Summary in the Executive Summary

Appendix

Appendix Table 1

Demographics

Age (years)	
Mean	6.5
Standard Deviation	1.10
Standard Error	0.23
Minimum	5.0
Maximum	8.0
Gender	
Male	13 (59.1%)
Female	9 (40.9.%)
Race	
White	19 (86.4%)
African American / White	2 (9.1%)
Native Hawaiian / Other Pacific Islander	1 (4.5%)
Ethnicity	
Non-Hispanic / Non-Latino	22 (100%)

Appendix Table 2

Plaque Index

AutoBrush® 360 Degree Sonic Toothbrush

Variable	n	mean	std	stderr	median	min	max	range	t	p-value
pre whole	22	3.4	0.36	0.08	3.5	2.6	4.0	1.4		
post_whole	22	1.7	0.52	0.11	1.6	0.5	2.9	2.4		
whole	22	1.7	0.33	0.07	1.8	1.0	2.3	1.3	24.5	<0.001
pre gumline	22	3.4	0.35	0.08	3.5	2.6	3.9	1.3		
post gumline	22	1.0	0.49	0.10	0.9	0.2	2.1	1.9		
gumline	22	2.4	0.39	0.08	2.4	1.7	3.0	1.3	28.6	<0.001
pre proximal	22	3.5	0.36	0.08	3.5	2.7	4.1	1.4		
post proximal	22	2.1	0.59	0.13	2.0	0.7	3.3	2.6		
proximal	22	1.4	0.37	0.08	1.5	0.6	2.2	1.6	18.1	<0.001
pre facial	22	3.8	0.52	0.11	3.9	2.6	4.5	1.9		
post facial	22	1.8	0.68	0.15	1.9	0.3	3.4	3.0		
facial	22	2.0	0.49	0.11	2.1	1.1	2.9	1.8	19.1	<0.001
pre lingual	22	3.0	0.34	0.07	3.0	2.4	3.8	1.4		
post lingual	22	1.6	0.46	0.10	1.6	0.7	2.5	1.8		
lingual	22	1.5	0.31	0.07	1.4	0.9	2.0	1.1	22.5	<0.001
pre_facial_gumline	22	3.8	0.53	0.11	3.8	2.6	4.5	1.9		

post_facial_gumline	22	1.1	0.66	0.14	1.0	0.0	2.6	2.6		
facial_gumline	22	2.7	0.56	0.12	2.9	1.9	3.8	1.9	22.8	<0.001
pre_lingual_gumline	22	2.9	0.33	0.07	2.9	2.4	3.8	1.4		
post_lingual_gumline	22	0.9	0.45	0.10	0.8	0.2	1.9	1.8		
lingual gumline	22	2.0	0.41	0.09	2.1	1.2	2.8	1.6	23.2	<0.001
pre_facial_proximal	22	3.9	0.51	0.11	3.9	2.7	4.5	1.9		
post_facial_proximal	22	2.2	0.75	0.16	2.3	0.5	3.8	3.3		
facial proximal	22	1.6	0.53	0.11	1.7	0.6	2.8	2.1	14.6	<0.001
pre_lingual_proximal	22	3.1	0.35	0.08	3.1	2.5	3.9	1.4		
post_lingual_proximal	22	1.9	0.52	0.11	1.9	0.8	2.9	2.0		
lingual proximal	22	1.2	0.33	0.07	1.1	0.5	1.7	1.2	16.9	<0.001

Appendix Table 3

Plaque Index

ADA Manual Toothbrush

Variable	n	mean	std	stderr	median	min	max	range	t	p-value
pre whole	22	3.5	0.35	0.07	3.6	2.7	4.0	1.2		
post_whole	22	3.4	0.34	0.07	3.4	2.6	4.0	1.3		
whole	22	0.1	0.13	0.03	0.1	-0.1	0.3	0.5	2.4	0.025
pre gumline	22	3.4	0.36	0.08	3.5	2.6	3.9	1.3		
post gumline	22	3.3	0.36	0.08	3.3	2.5	3.9	1.4		
gumline	22	0.1	0.17	0.04	0.1	-0.1	0.5	0.6	3.2	0.005
pre proximal	22	3.5	0.34	0.07	3.6	2.8	4.0	1.2		
post proximal	22	3.5	0.34	0.07	3.5	2.7	4.0	1.3		
proximal	22	0.0	0.11	0.02	0.0	-0.2	0.3	0.4	1.6	0.115
pre facial	22	3.9	0.46	0.10	4.1	2.9	4.6	1.7		
post facial	22	3.7	0.46	0.10	3.7	2.7	4.4	1.7		
facial	22	0.2	0.19	0.04	0.2	0.0	0.6	0.6	4.9	<0.001
pre lingual	22	3.1	0.35	0.08	3.1	2.5	3.8	1.4		
post lingual	22	3.1	0.34	0.07	3.1	2.6	3.8	1.2		
lingual	22	-0.1	0.12	0.03	0.0	-0.4	0.1	0.5	2.6	0.017
pre_facial_gumline	22	3.8	0.49	0.10	4.0	2.7	4.6	1.9		

post_facial_gumline	22	3.6	0.52	0.11	3.5	2.5	4.4	1.9		
facial_gumline	22	0.3	0.24	0.05	0.2	-0.1	0.9	0.9	5.2	<0.001
pre_lingual_gumline	22	3.0	0.36	0.08	3.0	2.5	3.8	1.4		
post_lingual_gumline	22	3.0	0.32	0.07	3.0	2.5	3.8	1.2		
lingual gumline	22	0.0	0.16	0.03	0.0	-0.4	0.3	0.7	1.1	0.295
pre_facial_proximal	22	3.9	0.44	0.09	4.1	2.9	4.5	1.6		
post_facial_proximal	22	3.8	0.44	0.09	3.8	2.9	4.5	1.6		
facial proximal	22	0.2	0.17	0.04	0.1	-0.1	0.6	0.7	4.3	<0.001
pre_lingual_proximal	22	3.1	0.36	0.08	3.1	2.5	3.9	1.4		
post_lingual_proximal	22	3.2	0.35	0.08	3.2	2.6	3.8	1.2		
lingual proximal	22	-0.1	0.11	0.02	-0.1	-0.4	0.1	0.5	3.5	0.002

Appendix Table 4

Statistical Results for Plaque Analyses

Variable	LSMean Difference	LSMean Difference Stderr	p-value	LSMean Difference Lower CI	LSMean Difference Upper CI
Whole Mouth	1.7	0.08	<0.001	1.5	1.8
Gumline	2.3	0.09	<0.001	2.1	2.5
Proximal	1.4	0.08	<0.001	1.2	1.5

Facial	1.8	0.11	<0.001	1.6	2.1
Lingual	1.5	0.07	<0.001	1.3	1.7
Facial Gumline	2.5	0.13	<0.001	2.2	2.7
Lingual Gumline	2.1	0.09	<0.001	1.9	2.3
Facial Proximal	1.5	0.12	<0.001	1.2	1.7
Lingual Proximal	1.3	0.07	<0.001	1.1	1.4

LSMean Difference = Mean difference of the covariate adjusted treatment means

p-value = p-value of the test of the LSMean difference

LSMean Difference Lower / Upper CI = 95% Confidence Limit Upper / Lower Bound

Study Population/Enrollment:

Recruited / Scheduled	22 (twenty-two)
Cancelled / No show	0 (zero)
Subjects Consented	22 (twenty-two)
Screening/Baseline Failures	0 (zero)
Randomized to Product	22 (twenty-two)
Received Product	22 (twenty-two)
Disqualified / Dropped	0 (zero)
Completed	22 (twenty-two)

Subject Withdrawal/Disqualification: Zero (0)

Subject Compliance: All subjects who completed the study showed satisfactory compliance.

Protocol Revisions: None

Oral Tissue Exam: The examination of the oral cavity included the gingival (free and attached), hard and soft palate, oropharynx, buccal mucosa, tongue, floor of the mouth, labial mucosa, mucobuccal/mucolabial folds, lips and perioral area.
There were no observed and/or reported evidence of any hard or soft tissue damage associated with the use of test product.

Adverse Events Summary: None (0) Adverse Events:

Disposition of Study Supplies:

Supplies Received
20 – AutoBrush® for Kids (Daniel Tiger's Neighborhood)
20 – Colgate Full Head / Soft Bristled Toothbrush
1 – 8.2oz Crest Cool Mint Gel, 0.243% NaF, Procter & Gamble

All study materials were inventoried and logged upon receipt by the Investigator's representative. All study materials were stored under secure, dry, room temperature conditions until assignment to subjects.

Data Management: All raw data (Case Report Forms) were screened for quality assurance by the Investigators' Quality Assurance officer (QA) and found to be in compliance with protocol requirements before being sent to the Sponsor.

Principal Investigator Signature and Date:

Principal Investigator

07 MAR 2022
Date

Christopher Lander
Sponsor of Clinical Trial

3/4/2022
Date