

Full Board Continuing Review – APPROVAL NOTIFICATION

Date Issued: June 24, 2026
Principal Investigator: Marc Shlossman, DDS, MS
IRB ID: **13536-MShlossman**
Protocol: A Randomized Controlled Trial to Evaluate the Cariostatic Efficacy of Nano Silver Fluoride (NSF) vs. Silver Diamine Fluoride (SDF) in Children
Protocol No.: ATSU-YI-NSF 2025
Date of Review: June 23, 2026
Study Expiration Date: **June 22, 2027**
Study Status Report Due: **30 Days Prior to Expiration Date**
Sponsor: Young Innovations

This study was reviewed and approved for continuing review on June 23, 2026.

APPROVAL INCLUDES:

Protocol
Investigator's Qualifications
Participant Informed Consent Form(s) (if applicable)
Children's Assent (if applicable)
Amendment(s) & Advertisement(s) (if applicable)

The IRB reviewed the current documents for this study and determined that no changes are necessary. You may continue to use the current IRB approved documents for this study.

Sterling IRB has approved this Principal Investigator to conduct this study at the previously approved site(s). Approval will expire on the study expiration date listed herein, and if the study is to continue the Principal Investigator must receive Sterling IRB approval for study continuation prior to the expiration date. The Principal Investigator should submit a **Study Status Report** no less than one month prior to the last Sterling IRB meeting preceding the expiration date. If approval for study continuation is not obtained prior to the expiration date, the study will be considered to be in noncompliance with Federal Regulations and IRB requirements, may be suspended, and may be subject to termination. A final **Study Status Report** will be due at the conclusion of the study.

Any changes to the research must be submitted in writing to Sterling IRB for review and approval prior to implementation. Sterling IRB should be informed immediately of any serious adverse reaction or should any unanticipated problems involving risks to the subject or others occur or should the Sponsor provide safety information. Local prejudices or negative attitudes in the community toward the conduct of research projects must be reported immediately. State laws pertaining to Patient/Volunteer Bill of Rights and specific state laws concerning research which affect the conduct of clinical research must be enforced. Non-English speaking subjects enrolled in this study must be provided with an informed consent written in their fluent language, which must be approved by Sterling IRB before use.

The Principal Investigator is responsible for following all policies of Sterling IRB as described in the Investigator Compliance Agreement which was accepted with study submission. It is the Principal Investigator's responsibility to ensure this research is conducted in accordance with applicable regulations (local, state/provincial, and federal) as well as any requirements established by the IRB at the time of the approval. Refer to the Sterling IRB Handbook at www.sterlingirb.com for details of these responsibilities.

For item(s) reviewed by expedited review, the Board will be apprised of the approval.

Copy: Sponsor and/or CRO

PROTOCOL APPROVAL – INITIAL

Date Issued: July 09, 2025
Issued To: Sponsor and/or CRO
Protocol Title: A Randomized Controlled Trial to Evaluate the Cariostatic Efficacy of Nano Silver Fluoride (NSF)
vs. Silver Diamine Fluoride (SDF) in Children
Protocol Number: ATSU-YI-NSF 2025
IRB ID: 13536-*MASTER
Please include the IRB ID# on all correspondence pertaining to this study.
Sponsor: Young Innovations

Review Type:	Full Board
Review Determination:	Approved with Contingencies
Approval Date:	July 01, 2025
Contingency Verification Date (<i>if applicable</i>):	July 08, 2025
Study Expiration Date:	June 30, 2026
Study Status Report Due:	30 Days Prior to Expiration Date

Approved Principal Investigators: None

Please Note: This approval is for the protocol only. Each Principal Investigator that will be under Sterling IRB oversight must complete a separate Submission Application for the Investigator/Site and receive Sterling IRB review and approval prior to conducting this study.

Please see **Section A** for approved study items.

Please see **Section B** for additional study information.

Please see **Section C** for Sponsor Responsibilities.

The current Sterling IRB Membership List is available on our website, www.sterlingirb.com.

The above referenced protocol was reviewed and **approved** as indicated above. If applicable, satisfaction of the Board-determined contingencies was verified by the Chairperson or their designee on the date listed above.

Sterling IRB will conduct continuing review of this study. Approval will expire on the Study Expiration Date listed above, and if the study is to continue the Sponsor must receive Sterling IRB approval for study continuation prior to the expiration date. The Sponsor should submit the **Study Status Report** not less than one month prior to the last Sterling IRB meeting preceding the expiration date (form available in Sterling IRB's web portal, SilverLink). If approval for study continuation is not obtained prior to the expiration date, the study will be considered to be in noncompliance with Federal Regulations and/or IRB requirements, may be suspended, and may be subject to termination.

For item(s) reviewed by expedited review, the Board will be apprised of the approval.



SECTION A: APPROVED STUDY ITEMS

- Protocol
- * Parent/Legal Guardian Consent and Permission Form and Authorization to Use and Disclose Medical Information (Version Date: June 19, 2025)
- * Child Assent Form (Ages 7-10) (Version Date: June 19, 2025)
- Young ® ClearDefense™ SILVER FLUORIDE Instructions for Use (296905B 2025-02-28)
- Young ® ClearDefense™ SILVER FLUORIDE Information Sheet (Rev. 02/2025)

Recruitment Materials:

- * "Dear Parent," Recruitment Letter

For approved recruitment/study materials, you may insert or change site-specific information without resubmitting to the IRB. This is not applicable to the Informed Consent Form(s).

* For any approved items which are labeled with the **asterisk (*)** symbol, copies of these items can be found in SilverLink in the Attachments page for this submission's Event. Items not labeled with the asterisk (*) symbol will be provided by the Sponsor/CRO.

Please note, Sterling IRB issues a site-specific consent form containing approved site-specific information to each site. Sites must use the IRB approved/issued consent form for consenting participants. Instructions to locate IRB-approved site-specific consent form(s) are included within the Documents Available email sent to each site and can also be found in the Sterling IRB Handbook.

End of Section A



SECTION B: STUDY INFORMATION
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Sterling IRB has determined that the research involves greater than minimal risk.

Sterling IRB has determined that the research involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects. [45 CFR 46.405] [21 CFR 50.52]

Sterling IRB has determined that this study is a non-significant risk (NSR) device study.

End of Section B



SECTION C: SPONSOR RESPONSIBILITIES

The Sponsor is responsible for overseeing the initial and continuing review and approval of the proposed study. This includes an expectation that the Sponsor will monitor the conduct of research in accordance with applicable regulations as well as any other requirements established by the IRB at the time of approval. Please refer to Sterling IRB's website, located at www.sterlingirb.com, for a more detailed explanation of the Sponsor's responsibilities.

- Check all information in the Approval Document and Informed Consent Form(s) for accuracy. **Let our office know ASAP if there are any inaccuracies.**
- Please note the due date listed on the Approval Document for the Study Status Report. **This report is required by the Board and/or by Federal Regulations.**
- Please refer to Chapter 3 ('Principal Investigator and Sponsor Responsibilities') of the Sterling IRB Handbook (located on our website at www.sterlingirb.com) for additional information regarding the responsibilities of the Sponsor.
- Any changes to the research must be submitted in writing to Sterling IRB for review and approval prior to implementation.
- Sterling IRB should be informed immediately of any serious adverse reaction or should any unanticipated problems involving risks to the subject or others occur, or if any other safety information becomes available, irrespective of whether the event occurred at a Sterling IRB approved site.
- Local prejudices or negative attitudes in the community toward the conduct of research projects must be reported immediately.
- State laws pertaining to Patient/Volunteer Bill of Rights and specific state, provincial or local laws (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) concerning research which affect the conduct of clinical research must be enforced.
- Non-English speaking subjects enrolled in this study must be provided with an informed consent written in their fluent language, which must be approved by Sterling IRB before use.

If you have any questions please call our office at 888-636-1062. Thank you for choosing Sterling IRB to provide oversight for your research project.

End of Section C / End of Document

Full Board Continuing Review – APPROVAL NOTIFICATION

Date Issued: June 24, 2026
Principal Investigator: Marc Shlossman, DDS, MS
IRB ID: **13536-MShlossman**
Protocol: A Randomized Controlled Trial to Evaluate the Cariostatic Efficacy of Nano Silver Fluoride (NSF) vs. Silver Diamine Fluoride (SDF) in Children
Protocol No.: ATSU-YI-NSF 2025
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Amendment(s) & Advertisement(s) (if applicable)

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The Principal Investigator is responsible for following all policies of Sterling IRB as described in the Investigator Compliance Agreement which was accepted with study submission. It is the Principal Investigator's responsibility to ensure this research is conducted in accordance with applicable regulations (local, state/provincial, and federal) as well as any requirements established by the IRB at the time of the approval. Refer to the Sterling IRB Handbook at www.sterlingirb.com for details of these responsibilities.

For item(s) reviewed by expedited review, the Board will be apprised of the approval.

Copy: Sponsor and/or CRO

Study Protocol
Young Innovations and A.T. Still University
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**A Randomized Controlled Trial to Evaluate the Cariostatic Efficacy of Nano Silver
Fluoride (NSF) vs. Silver Diamine Fluoride (SDF) in Children**

Study Number:	ATSU-YI-NSF 2025
Study Site:	Arizona School of Dentistry & Oral Health A.T. Still University 5835 E. Still Circle Mesa, AZ 85206 Phone: 480-248-8153
Principal Investigator:	Marc Shlossman, DDS, MS Associate Director of Clinical Research
Co-Investigator and Institutional Oversight	Ann Eshenaur Spolarich, RDH, PhD Professor and Assistant Dean for Research
Co-Investigators:	Stefanie Sotello, DDS Director, Pediatric Dentistry TBD ASDOH Faculty, Pediatric Dentistry
Study Sponsor:	Young Innovations 2260 Wendt Street Algonquin, IL 60102
Sponsor's Project Manager:	Lauren Kanzigg, MS, RDH Director, Clinical Affairs Phone: 984-255-3592 E mail: LKanzigg@younginnovations.com
Study Monitor:	To be named

Study Title: A Randomized Controlled Trial to Evaluate the Cariostatic Efficacy of Nano Silver Fluoride (NSF) vs. Silver Diamine Fluoride (SDF) in Children

Objective

To validate the anticaries effect of Nano Silver Fluoride (Young Innovations ClearDefense®) as compared to Silver Diamine Fluoride (Elevate AdvantageArrest®) in pediatric dental patients with carious lesions on the occlusal surfaces of their primary molars and first permanent molars.

1. Study Design

This is a six-month, double blind, parallel group, single site, randomized controlled trial that will measure the cariostatic effects of two fluoride agents in children with active caries, as well as child, parent/guardian, and provider satisfaction with product use and acceptance. This clinical trial will compare a newly FDA-approved nano silver fluoride against the well-established standard silver diamine fluoride for anticaries efficacy, tolerability/adverse events, ease of use, and product acceptance. For this study, caries is defined as new “active” (untreated) carious lesions on the occlusal surfaces of deciduous molars and first permanent molars. The study will be powered as a non-inferiority trial.

The ***primary response variable*** will be the status of a carious lesion (active/arrested) after treatment with the assigned product.

There are several ***secondary response variables*** that will be assessed at designated timepoints in the study.

Tooth color: Pre-/post-treatment tooth color will be assessed using the Vita Easyshade V, a portable dental spectrophotometer at baseline and all study timepoints.

Scores on the Early Childhood Oral Health Impact Scale (ECOHIS): The validated Early Childhood Oral Health Impact Scale (ECOHIS) will be used to assess the impact of oral health problems and related treatment experiences on the quality of life of study participants and their families. The scale consists of six subscales: Child Symptom Domain, Child Function Domain, Child Psychological Domain, Child Self-Image/social Interaction Domain, Parent Distress Domain, and Family Function Domain. Parents/guardians of child participants will complete the ECOHIS assessment.

Child behavior: The child participant’s behavior during study product application will be assessed as either cooperative or uncooperative. Lack of cooperation could affect optimal product placement.

Child oral hygiene behaviors: The child participant’s oral hygiene behaviors will be assessed for the potential to influence caries risk. Behaviors will be reported by the children’s parents/guardians and include the frequency of daily toothbrushing, use of fluoridated toothpaste, and drinking fluoridated water.

Daily sugar consumption score: The child participant's parent/guardian will report the child's intake of eight different sugary foods and beverages. Higher scores represent higher caries risk.

Number of dental visits in the past year: Parent/guardian reports of the number of dental visits that the child had in the past year will be documented, and whenever possible, will be confirmed via chart and/or provider audit. Receipt of regular professional care may influence caries risk.

Child satisfaction (Patient Reported Outcome Measure): Child participants' satisfaction will be captured regarding their experience with the treatment received, including tooth appearance, and product taste, measured using the validated TASTY scale.

Parent/Guardian satisfaction: Parent/guardian acceptability of the child's treatment will be assessed using a validated scale.

Provider satisfaction: Study investigators will provide their feedback about ease of product use and product performance at the end of the study.

Adverse events: The presence/absence of adverse events will be assessed and documented immediately after product application and at all timepoints. Adverse events include taste alteration, pulpal and soft tissue irritation, permanent staining of adjacent teeth and restorations, and temporary staining of soft tissues (intraoral: mucosa, tongue, gingiva; extraoral: lips, cheeks). Study participants will also be assessed for pain/discomfort in treated teeth at each timepoint.

2. Subjects and Sample Size

The study will be conducted with 60 medically healthy participants between ages 6 to 10 years who are receiving routine dental care at the Arizona School of Dentistry & Oral Health (ASDOH), A.T. Still University in Mesa, Arizona. Children must have a carious lesion (ICDAS II Stage 3, 4 5, 6) on the occlusal surface of at least one deciduous molar and/or one permanent first molar for eligibility to participate in the study.

Based on a generalized estimating equations (GEE) approach, and assuming an average of two carious teeth per patient with an intraclass correlation coefficient (ICC) of $\rho = 0.05$, a sample size of 30 patients per group will provide more than 80% power to demonstrate non-inferiority between the NSF group (with an event rate of $p_1 = 0.20$) and the SDF group (with an event rate of $p_2 = 0.10$). The non-inferiority margin is set at 0.10, with a significance level (alpha) of 0.05. This sample size calculation accounts for a projected 20% dropout rate ($n = 12$ patients) over the 6-month period. A total of 72 subjects will be recruited to ensure that the target number is reached.

3. Study Duration

Enrolled subjects will participate in the study for a minimum of six months, with an optional twelve-month follow-up visit. The duration of the study will be approximately two years.

4. Investigational Products

The two study products under investigation are ClearDefense®, a Nano Silver Fluoride product (manufacturer: Young Innovations) and AdvantageArrest®, a Silver Diamine Fluoride product (manufacturer: Elevate Oral Care). Both products are FDA-approved for the treatment of dentinal hypersensitivity and are used to arrest carious lesions on coronal and root surfaces.

5. Study Materials

Participants will be provided with a new age-appropriate toothbrush and one tube of pediatric fluoridated toothpaste at the baseline study visit, and at each of the remaining three study visits (3, 6 and 12 months).

1. Pediatric toothbrushes (72 x 4 = 288)
2. Pediatric fluoridated toothpaste (72 x 8 = 576)

Young Innovations will provide the following products

1. ClearDefense® Nano Silver Fluoride
2. Tapered brush prophylaxis angles (Denticator®) for use with occlusal surface debridement prior to examination and treatment (72 x 4 = 288)
3. One iPad for raffle for child participants as a study incentive

6. Inclusion Criteria

Children will be accepted for candidates for study participation if:

- They are between the ages of 6 to 10 years.
- They are medically healthy.
- They have a minimum of one permanent deciduous molar tooth and one permanent first molar with an occlusal and/or proximal carious lesion classified as ICDAS II (International Caries Detection and Assessment System) Stage 3-4 (moderate caries) or Stage 5-6 (advanced caries).
- They and their parents/guardians must be able to understand and be willing to provide written child assent and parent/guardian consent for study participation.
- They and their parents/guardians must be willing and able to attend all study visits.
- They and their parents/guardians must be able to read and understand English and/or Spanish.
- Their parents/guardians must be willing to provide feedback about study outcomes in their child (patient-reported/parent-reported outcome measures).

7. Exclusion Criteria

Children will be excluded as candidates for study participation if:

- They have a known sensitivity/allergy to fluoride, silver or other heavy-metal ions.

- They have a significant medical history, such as cardiac conditions that require antibiotic prophylaxis prior to dental treatment, or poorly controlled/uncontrolled diabetes.
- They present with ulcerative gingivitis or aphthous stomatitis.
- They have a history of full mouth gingivectomy.
- They chronically take medications that reduce salivary flow, including stimulants for ADHD and antihistamines for seasonal allergies.
- They have a history of systemic disease that reduces salivary flow, such as an autoimmune disease.
- Their deciduous molars are loose at the initial screening examination visit.
- Their deciduous molars or first permanent molars with occlusal and/or proximal caries have an existing restoration or recurrent caries at the site of potential study treatment.
- Their deciduous molars or first permanent molars have extensive occlusal and/or proximal caries with pulpal involvement and/or require surgical intervention for treatment.

8. Screening

Potential study candidates will be identified and recruited by the dental faculty in the ASDOH Pediatric Dental Clinic during their regularly scheduled dental appointments. At that time, parents/guardians of potential candidates will be informed about the study to gauge their interest in their children's participation. Potential candidates and their parents/guardians will be referred to one of the study investigators for additional screening.

During the screening visit, every potential candidate and their parent/guardian will be interviewed and examined by a study investigator to determine eligibility according to stated inclusion/exclusion criteria. The study investigator will explain the study procedures, with risks and benefits of participation, and the candidate and parent/guardian will be given the opportunity to ask questions.

- a. Screening Interview: The candidate and parent/guardian will be asked about inclusion and exclusion criteria, and demographic information. The following will also be reviewed:
 - i. Medical History and Medications: A brief medical history for each candidate will be recorded.
- b. Screening Oral Examination: The candidate will undergo a brief oral examination with a mouth mirror and dental explorer to determine the number of deciduous molars present. A tapered brush prophylaxis angle may be used to remove heavy plaque deposits on occlusal surfaces of deciduous molars to improve visibility. Candidates must have at least one deciduous molar and/or first permanent molar with a carious lesion on the occlusal surface to be eligible to participate. The occlusal carious lesion must be classified as ICDAS II 3, 4, 5, or 6. Radiographic confirmation may be required for lesion classification.
- c. Enrollment Determination:
 - a. Upon completion of the screening visit, the study investigator will review the screening documents and determine whether or not the potential candidate qualifies for study enrollment.

- b. If the candidate qualifies, an appointment date will be scheduled for the baseline examination with study treatment. Note: The baseline examination and treatment may be performed on the day of the screening examination pending receipt of informed consent and availability in the schedule.

9. Enrollment and Consent

All candidates who successfully complete the screening will be invited to participate. At this time, written informed consent will be obtained from the parent/guardian. Written child assent will be obtained from the subject. The written informed consent documents must be signed and personally dated by the subject and parent/guardian to be fully executed informed consent documents and will be processed per the institution's standard operating procedures. A copy of the signed informed consent documents will be provided upon request.

Before recruitment and enrollment may begin, a copy of the written institutional review board (IRB) approval of the protocol, Informed Consent form (ICF), Child Assent Form, and all other applicable subject information and/or recruitment materials must be on file at the institution.

Subjects who are consented and enrolled in the study will be assigned a unique identification number (UIN). This number will be used to identify the subject throughout the study and will be used on all applicable study documentation related to that subject. The subject's UIN will remain constant throughout the study. Subject identification numbers will begin with 100 and continue to be assigned sequentially.

10. Registration/Randomization

Upon receipt of ATSU Mesa IRB approval, the institution will register the clinical trial and its protocol at Clinicaltrials.gov. Reporting requirements for trial registration will be met by the institution throughout all phases of the study, including study close-out documentation and posting of the final dataset.

Subjects will be randomly assigned to one of two treatment arms. Randomization will be determined using an online random number generator. A third-party (study coordinator) will conceal the identity of the assigned product from the study investigator who will apply the product at the baseline visit, as well as from the study examiners who will check the treated tooth/teeth afterwards for caries arrest (allocation concealment). It may be impossible to completely mask the product identities from the study investigators/examiners due to differences in staining potential.

11. Study Procedures

Subjects who are enrolled in the study will be scheduled for their Baseline appointment (Visit 1).

At the Baseline appointment (Visit 1, Day 0), the subject will have an examination to identify eligible teeth for study treatment. Radiographs will be taken to confirm the caries diagnosis. Intraoral photographs will be taken of the eligible teeth before and after treatment.

Carious Lesion Staging

Eligibility of carious teeth will be determined using ICDAS II criteria, Stage 3-4 (moderate stage caries) or Stage 5-6 (advanced stage caries) on the occlusal and/or proximal surface(s).¹⁻⁵

Activity Criteria of Coronal Primary Caries According to ICDAS II ^{6,7}

ICDAS code	Characteristics of Lesion	
	Active Lesion	Inactive Lesion
1, 2, or 3	Surface of enamel is whitish/yellowish opaque with loss of luster, feels rough when the tip of the probe is moved. Lesion is in a plaque stagnation area, i.e. pits and fissures, near the gingival and approximal surface below the contact point.	Surface of enamel is whitish, brownish or black. Enamel may be shiny and feels hard and smooth when the tip of the probe is moved. For smooth surfaces, caries lesion is typically located at some distance from the gingival margin.
4	Probably active	
5 or 6	Cavity feels soft or leathery on gently probing the dentin.	Cavity may be shiny and feels hard on gently probing the dentin.

Table sourced from: Dikmen B. Icdas II criteria (international caries detection and assessment system). J Istanb Univ Fac Dent. 2015 Oct 21;49(3):63-72.⁶

The carious lesion is deemed “active” if there is a greater likelihood of progression into the deeper layers of tooth structure. Other clinical characteristics include:⁸

- Stage 3: Localized enamel breakdown with no visible dentin or underlying shadow, or discontinuity of surface enamel and widening of the fissure. Enamel breakdown is often viewed best when the tooth is air-dried. Lesion depth in pits and fissures with 77% in dentin
- Stage 4: Underlying dark shadow from dentin with or without localized enamel breakdown. Shadowing from dentinal caries is often best seen with a wet tooth surface. Lesion depth in pits and fissures with 88% into dentin.
- Stage 5: Distinct cavity with visible dentin; frank cavitation involving less than half of a tooth surface. Lesion depth in pits and fissures with 100% in dentin.
- Stage 6: Extensive distinct cavity with dentin; cavity is deep and wide involving more than half of the tooth. Lesion depth in P/F 100% reaching inner one third of dentin.

Carious teeth must not be causing the child any symptoms of pain or show clinical or radiographic signs of pulpal infection (confirmed via exam and x-rays).

The study investigator will document the tooth/teeth to be treated with the corresponding ICDAS II staging code (3, 4, 5 or 6).

Parent/Guardian Reported Outcomes on Behalf of the Child

While the child is undergoing an examination and radiographs, the parent/guardian will be asked to complete the following assessment tools:

Early Childhood Oral Health Impact Scale (ECOHIS)

The validated ECOHIS will be used to assess the impact of oral health problems and related treatment experiences on the quality of life of study participants and their families. The scale consists of six subscales: Child Symptom Domain, Child Function Domain, Child Psychological Domain, Child Self-Image/social Interaction Domain, Parent Distress Domain, and Family Function Domain.⁹ The ECOHIS consists of 13 items that are scored using a Likert scale:

Response options: 1. Never, 2. Hardly ever, 3. Occasionally, 4. Often, 5. Very often, and 6. Don't know.

<i>(Child symptom domain)</i>						
How often has your child had pain in the teeth, mouth or jaw?	Never	Hardly ever	Occasionally	Often	Very often	Don't know
How often has your child.....because of dental problem or dental treatments?						
<i>(Child function domain)</i>						
Had difficulty drinking hot or cold beverages	Never	Hardly ever	Occasionally	Often	Very often	Don't know
Had difficulty eating some foods	Never	Hardly ever	Occasionally	Often	Very often	Don't know
Had difficulty pronouncing any words	Never	Hardly ever	Occasionally	Often	Very often	Don't know
Missed preschool, daycare or school	Never	Hardly ever	Occasionally	Often	Very often	Don't know
How often has your child.....because of dental problems or dental treatments?						
<i>(Child psychological domain)</i>						
Had trouble sleeping	Never	Hardly ever	Occasionally	Often	Very often	Don't know
Been irritable or frustrated	Never	Hardly ever	Occasionally	Often	Very often	Don't know
How often has your child....because of dental problems or dental treatments?						

<i>(Child self-image/social interaction domain)</i>						
Avoided smiling or laughing when around other children	Never	Hardly ever	Occasionally	Often	Very often	Don't know
Avoided talking with other children	Never	Hardly ever	Occasionally	Often	Very often	Don't know
How often have you or another family member....because of your child's dental problems or dental treatments?						
<i>(Parent distress domain)</i>						
Been upset	Never	Hardly ever	Occasionally	Often	Very often	Don't know
Felt guilty	Never	Hardly ever	Occasionally	Often	Very often	Don't know
How often....						
<i>(Family function domain)</i>						
Have you or another family member taken time off from work because of your child's dental problems or dental treatments	Never	Hardly ever	Occasionally	Often	Very often	Don't know
Has your child had dental problems or dental treatments that had a financial impact on your family?	Never	Hardly ever	Occasionally	Often	Very often	Don't know

Parents/guardians will be guided to complete the ECOHIS using the following instructions:⁹

- *Problems with the teeth, mouth or jaws and their treatment can affect the well-being and everyday lives of children and their families. For each of the following questions, please circle the number next to the response that best describes your child's experiences or your own. Consider the child's entire life from birth until now when answering each question. If a question does not apply, check "Never".*

Child Oral Hygiene Behaviors

The subject's oral hygiene behaviors will be assessed for the potential to influence caries risk. Behaviors will be reported by the children's parents/guardians and include the frequency of daily toothbrushing, use of fluoridated toothpaste, and drinking fluoridated water.^{10,11}

Oral Hygiene Behavior	Score
How many times does your child typically brush their teeth on any given day?	None One Two More than two times
How does your child brush their teeth?	Child brushes their own teeth (unsupervised brushing)

	Both the child and parent brush the child's teeth Parent brushes the child's teeth Child brushes their own teeth but the parent watches (supervised brushing)
Does your child use a toothpaste that contains fluoride?	Yes No I don't know
What brand of toothpaste does your child use?	Enter brand name: I don't know
Does your child drink fluoridated water (tap water)?	Yes No
What is your zipcode where you live?	Enter XXXXX

Daily Sugar Consumption Score

The child participant's parent/guardian will report the child's intake of eight different sugary foods and beverages. Higher scores represent higher caries risk.^{10,11}

Which if the following foods or drinks does your child use at least one time each day?

Candies, fruit roll-ups	
Cookies and cakes	
Fruit: fresh fruit, fruit cocktail	
Sugar-added chewing gums	
Jam, Jelly or Honey	
Carbonated beverages (sodas)	
Sugar-sweetened milk	
Sweetened hot drinks	

Total: ____/8

Number of Dental Visits in the Past Year

The number of dental visits that the child had in the past year will be documented, and whenever possible, will be confirmed via chart and/or provider audit. Receipt of regular professional care may influence caries risk.^{10,11}

Study Treatment Procedures

After the eligible tooth/teeth have been verified, the study investigator will treat the tooth/teeth. The study investigator will be blinded to the product identity. A third party (study coordinator) will preset a tray with the necessary supplies for the treatment session, selecting the appropriate treatment agent from the randomization list so that the study investigator remains blinded. Two drops of the study product will be placed in a disposable dappen dish and placed on the tray so that the study investigator does not see the bottle of the agent being applied.

Initial treatment procedures are as follows:¹¹⁻¹⁴

- Protective eyewear will be placed on the subject.
- A tapered brush prophylaxis angle will be used to gently remove visible plaque from the occlusal surfaces to be treated.
- Pretreatment tooth shade will be captured using a Vita Easyshade V and documented.
- The tooth/teeth to be treated will be isolated using cotton rolls and cotton gauze squares as needed. A saliva ejector and high-speed evacuation will be used as needed during the appointment.
- The occlusal surface will then be dried using the air water syringe.
- Using a microbrush, two (2) drops of either SDF 38% or NSF 3% sodium fluoride + 0.2% silver ion will be applied directly to the carious lesion, ensuring that the product is applied to the entire lesion.
- The product will be allowed to sit on the tooth for at least one minute. The surrounding soft tissues (cheeks and tongue) should be retracted away from the treatment surface to avoid staining.
- Remaining product will be removed using either a cotton roll or gauze.
- The study investigator will immediately check the treated surface(s) and document whether the carious lesion is active or arrested.
- The subject will be asked whether they are experiencing any pain or discomfort immediately after treatment. The subject's response will be documented by the study investigator.
- A post-treatment tooth shade will be captured using the Vita EasyShade V and documented.
- Intraoral photographs will be taken of the treated teeth.
- Adverse events will be assessed and documented.
- A second study examiner, who is also blinded to the treatment intervention, will then immediately check the treated surface(s) and will separately document whether the carious lesion is active or arrested.
- The child subject and parent/guardian will be instructed not to drink water or eat food for at least 30 minutes after product application.
- Child and parent/guardian reported satisfaction (outcome measures) will be collected.
- The child subject will be given a new toothbrush and tube of fluoridated pediatric toothbrush with instructions for twice daily oral hygiene.
- The next study visits will be scheduled for follow-up. Follow-up visits will occur at three- and six-months post-treatment. An optional twelve-month follow-up visit will also be requested.

Pretreatment/Post-Treatment Tooth Color

Pre-/post-treatment tooth color will be assessed using the Vita Easyshade V, a portable dental spectrophotometer at baseline and all study timepoints. A digital shade will be captured three times for each site, then the average shade will be recorded.

Child Behavior

The subject's behavior during study product application will be documented as either cooperative or uncooperative. Lack of cooperation could affect optimal product placement.

Adverse Events

The presence/absence of adverse events will be assessed and documented immediately after product application and at all timepoints. Adverse events include taste alteration, pulpal and soft tissue irritation, permanent staining of adjacent teeth and restorations, and temporary staining of soft tissues (intraoral: mucosa, tongue, gingiva; extraoral: lips, cheeks).

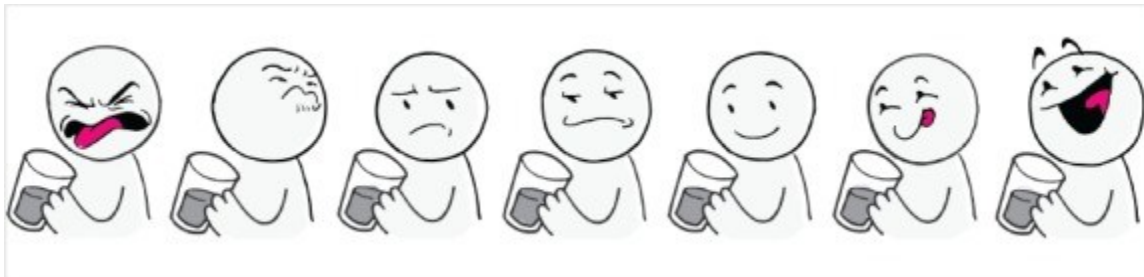
Child, Parent/Guardian and Provider Reported Outcomes

At the baseline treatment visit and various follow-up visits, the following outcomes will be assessed:

Child satisfaction (Patient Reported Outcome Measure): Child subjects' satisfaction will be captured regarding their experience with the treatment received, including tooth appearance, and product taste, measured using the validated TASTY scale.

Immediately after treatment, the subject will be asked: *How happy are you with how your teeth look?* Children will be asked to rate their satisfaction with the appearance of their treated teeth, using a three-item Likert scale: happy, unsure, or sad.¹⁵ Child satisfaction with the appearance of their teeth will be assessed at the baseline immediately post-treatment and at all study visits.

They will then be asked to use the validated TASTY scale to assess their satisfaction with product taste. The TASTY scale is a seven-item Likert scale, with visual graphics that are then coded numerically for a taste score.¹⁶ Child satisfaction with product taste will be assessed at the baseline visit only.



Parent/Guardian Satisfaction (Reported Outcome Measure):

Parent/guardian acceptability of treatment will be measured using a published, 4-item, 5-level Likert-scale assess feelings about the application procedure.¹⁷⁻¹⁹ The scale is scored from Strongly Agree to Strongly Disagree for the following items:

- The study product application is an easy process.
- I am comfortable with discoloration of cavities after study product placement.
- The study product application as pain free for my child.
- The taste of the study product was acceptable to my child.

Parent/guardian satisfaction will be assessed at the baseline visit immediately post-treatment and at all study visits.

Provider Satisfaction (Reported Outcome Measure):

Study investigators will provide their feedback about ease of product use and product performance at the end of the study using a Likert scale. The scale is scored from Strongly Agree to Strongly Disagree for the following items:

- It was easy for me to identify which product was applied due to the degree of post-treatment staining of the carious lesion.
- It was easy for me to identify which product was applied due to the degree of post-treatment staining of the surrounding soft tissues.
- There was a noticeable difference between the two products based on their efficacy with arresting the carious lesion(s).

Then, the following questions will be asked about each product (SDF and NSF) separately using the same Likert scale:

- The study product application was easy.
- The study product application was time-efficient.
- The study product performance with arresting caries was satisfactory with one treatment.
- The children seemed to tolerate this product well.
- The children appeared dissatisfied with the appearance of their tooth/teeth after treatment.
- The children appeared dissatisfied with the taste of the product after treatment.
- I intend to continue the use of this product in my pediatric dental patients.

12. Summary of Study Visits

Screening, Enrollment and Consent

Visit 1 (Day 0) = Baseline

- Update medical history
- Examination to verify eligible tooth/teeth
- Clean occlusal surfaces with prophylaxis brush
- Radiographs to confirm caries diagnosis
- Pre-treatment intraoral photographs
- Pre-treatment tooth shade using Vita EasyShade V
- Stage and record carious lesion (ICDAS II code)
- Parent/guardian completes ECOHIS, Child Oral Hygiene Behaviors, Daily Sugar Consumption and Number of Dental Visits in Past Year
- Treat eligible tooth/teeth with assigned study product
- Assess child for pain/discomfort in treated tooth/teeth (if yes, continue assessment and proceed with appropriate course of continued care if necessary)
- Examine and document caries status as active/arrested
- Document child behavior as cooperative/uncooperative
- Post-treatment tooth shade using Vita EasyShade V
- Post-treatment intraoral photographs

- Assess and document adverse events
- Second examiner examines tooth/teeth and documents caries status as active/arrested
- Child (appearance and taste) and parent/guardian satisfaction scales
- Instructions given not to eat or drink for 30 minutes
- Child given new toothbrush and fluoridated toothpaste and oral hygiene instructions
- Enroll child in raffle to win an iPad (eligible only if all study visits are completed at 6 months)
- Schedule next study visit for 3 months (Day 90)

Visit 2 (Day 90) = 3-month follow-up visit

- Update medical history
- Clean occlusal surfaces of treated teeth with prophylaxis brush
- Examine and document caries status in treated teeth as active/arrested
 - Treated teeth that have new or recurrent decay will be recorded as “active” and appropriate treatment should be provided^{20,21}
 - Teeth that require restorative treatment or extractions at 90 days are recorded as “active”^{20,21}
- Assess child for pain/discomfort in treated tooth/teeth (if yes, continue assessment and proceed with appropriate course of continued care as necessary)
- Document any treated teeth that have exfoliated
- Post-treatment tooth shade using Vita EasyShade V
- Post-treatment intraoral photographs
- Assess and document adverse events
- Second examiner examines tooth/teeth and documents caries status as active/arrested
- Child (appearance only) and parent/guardian satisfaction scales
- Child given new toothbrush and fluoridated toothpaste and oral hygiene instructions
- Schedule next study visit for 6 months (Day 180)

Visit 3 (Day 180) = 6-month follow-up visit

- Update medical history
- Clean occlusal surfaces of treated teeth with prophylaxis brush
- Radiographs taken of treated teeth
- Examine and document caries status in treated teeth as active/arrested
 - Treated teeth that have new or recurrent decay will be recorded as “active” and appropriate treatment should be provided^{20,21}
- Assess child for pain/discomfort in treated tooth/teeth (if yes, continue assessment and proceed with appropriate course of continued care as necessary)
- Document any treated teeth that have exfoliated
- Post-treatment tooth shade using Vita EasyShade V
- Post-treatment intraoral photographs
- Assess and document adverse events
- Second examiner examines tooth/teeth and documents caries status as active/arrested
- Child (appearance only) and parent/guardian satisfaction scales
- Parent/guardian completes ECOHIS scale

- Incentive for participation distributed if all study visits/procedures have been completed
- Schedule next study visit for 12 months (Day 360) *optional, otherwise, subject is closed out of the study (participation completed)
- Child given new toothbrush and fluoridated toothpaste and oral hygiene instructions if enrollment will continue to 12 months

Visit 4 (Day 360) = 12-month follow-up visit (*optional)

- Update medical history
- Clean occlusal surfaces of treated teeth with prophylaxis brush
- Radiographs taken of treated teeth
- Examine and document caries status in treated teeth as active/arrested
 - Treated teeth that have new or recurrent decay will be recorded as “active” and appropriate treatment should be provided
- Assess child for pain/discomfort in treated tooth/teeth (if yes, continue assessment and proceed with appropriate course of continued care as necessary)
- Document any treated teeth that have exfoliated
- Post-treatment tooth shade using Vita EasyShade V
- Post-treatment intraoral photographs
- Assess and document adverse events
- Second examiner examines tooth/teeth and documents caries status as active/arrested
- Child (appearance only) and parent/guardian satisfaction scales
- Parent/guardian completes ECOHIS scale
- Second incentive for participation distributed if all study visits/procedures have been completed
- Subject is closed out of the study (participation completed)

End of Study (all subjects completed)

- Provider satisfaction scale
- Select and contact child subject winner of the iPad raffle

13. Study Incentives

Child subjects will receive a \$100 gift card if they successfully complete all study procedures and attend all study visits up to and including the 6-month study visit. [The gift card is given as compensation for completed study visits with study treatment received during those visits.](#) [Partial compensation is given in the form of treatment of eligible carious teeth with either SDF or NSF, provided free of charge.](#) [Child subjects also receive a free dental examination at the 3-month and 6-month study visits.](#) Child subjects will be enrolled in a raffle to win a new iPad for their participation; however, eligibility to win will be dependent upon successful completion of all study procedures and attendance at all scheduled study visits up to and including the 6-month study visit. A second [bonus](#) \$100 gift card will be awarded to child subjects who complete the optional 12-month study visit. Payment for any additional dental treatment deemed necessary to restore carious teeth that were initially treated as part of the study will be the responsibility of the child subject’s parent/guardian.

14. Subject Withdrawal from Study

All subjects withdrawn from the study by request or by the Principal Investigator must be seen, if they consent, for a closeout evaluation. The Principal Investigator will record the reason for withdrawal. Subjects who experience complications and discontinue the study on their own will be scheduled, if they consent, for an immediate follow-up/closeout examination to determine if an adverse event is present, and if so, the causation of the adverse event will be recorded. Every effort will be made to follow-up with subjects who withdraw from the study.

15. Off Study

Subjects will be considered off study when all planned study visits, early termination, and follow-up visits have been completed, unless death or withdrawal of consent to continue participation occurs.

16. Removal of Subjects

Subjects and/or their parents/guardians have the right to withdraw from the study at any time and for any reason without prejudice to their future dental care at the institution. If this occurs, the Principal Investigator, or designee, is to discuss with the subject's parent/guardian the safe and appropriate processes for discontinuation from the study.

The Principal Investigator must document the change in status of the subject's participation in the study. Subject withdrawal of consent for a study indicates that the subject does not wish to receive further protocol required procedures, and the subject or their parent/guardian does not wish to, or is unable to continue further study participation. Subject data only up to the time when consent is withdrawn will be included in the analysis of the study.

17. Study Outcomes

This study will assess the cariostatic effects of two fluoride agents in children with active caries, as well as child, parent/guardian, and provider experiences with product use and acceptance. Differences in clinical outcome (status of arrested carious lesions) will be assessed at three and six months, with an optional 12-month follow-up visit.

Secondary outcomes will be assessed at different timepoints, depending upon the measure. Child-related variables, including oral hygiene behaviors, daily sugar consumption score, and the number of dental visits in the past year will be parent/guardian reported and assessed only at baseline. Child satisfaction with tooth appearance will be assessed immediately post-treatment and at all subsequent study visits. Child satisfaction with product taste will be assessed only at the baseline visit immediately post-treatment. The parent/guardian related variable of satisfaction with treatment will be assessed immediately post-treatment and at all subsequent study visits. Parent/guardian ECOHIS scores will be assessed at baseline and at six and 12 months.

Provider satisfaction scores with product experience will be assessed at study close-out when all study subjects have completed the protocol.

18. Hypotheses

The hypotheses for the study are as follows:

1. There is no difference in anticaries efficacy, as defined by the presence of arrested decay in active carious lesions immediately post-treatment and at 3, 6 and 12 months, between Silver Diamine Fluoride (SDF) and Nano Silver Fluoride (NSF) in deciduous molars with ICDAS II moderate caries (stage 3-4).
2. There is no difference in tooth color, as measured by tooth shade determined by the Vita EasyShade V spectrophotometer, in deciduous molars treated with SDF or NSF immediately post-treatment and at 3, 6 and 12 months.
3. There is no difference in parent/guardian reported ECOHIS scores at baseline, 6 and 12 months between children treated with SDF or NSF.
4. There is no difference in child reported satisfaction scores for tooth appearance immediately post-treatment and at 3, 6 and 12 months between children treated with SDF or NSF.
5. There is no difference in child reported satisfaction scores for product taste immediately post-treatment between children treated with SDF or NSF.
6. There is no difference in the occurrence of adverse events, immediately post-treatment and at 3, 6 and 12 months, in children treated with SDF or NSF.

19. Statistical Considerations

Non-inferiority analyses of the primary outcome, incidence of caries, will be conducted, independently, for the 3-month and 6-month measurements. Correlated measurement error (multiple teeth within patient) will be addressed using a GEE approach. It is hypothesized that the NSF treatment will yield no more than a 10% increase in caries relative to the SDF treatment, thus supporting non-inferiority. A logit link will be employed, and the working correlation matrix will be identified empirically.

The following patient variables will be evaluated for balance between the NSF and SDF groups: age, sex assigned at birth, race/ethnicity, cooperation during treatment, and oral hygiene behaviors. Oral hygiene behaviors include the frequency of tooth brushing, use of fluoridated toothpaste, consumption of fluoridated water, daily sugar consumption scores, and the number of dental visits in the past year.

If any of these variables show significant differences between groups, they will be tested as potential covariates in the non-inferiority analysis. Variables that contribute to the outcome by narrowing the confidence interval of the estimate may be retained in the final analysis.

The report will include summary data for all these variables, presented as means with standard deviations, medians with interquartile ranges, and/or counts with percentages.

Child and parental satisfaction across treatment groups will be compared using either an independent samples t-test or a Mann-Whitney test, depending on whether the data meet the assumptions of normality. Additionally, the correlation between parental ECOHIS scores and the caries arrest rate will be assessed using Spearman's rho.

A significance level of $\alpha = 0.05$ will be applied to determine statistical significance. Data will be coded and entered into an Excel spreadsheet, which will be imported into SPSS (version 29; IBM

Corp., Armonk, NY) for analysis. Data will be de-identified to protect participant confidentiality and reported in aggregate form only.

20. Data Management Plans: All appropriate records will be retained and maintained as stated in the Agreement.

- **Data Collection and Electronic Capture:** Digital consent forms will be used to collect written informed consent. All data will be captured electronically via a tablet using Qualtrics. Clinical data (e.g. treated teeth) will be entered into a spreadsheet by study investigators at each study visit. Each child subject will be assigned a UIN, ensuring that no personally identifiable information is linked directly to the research data. The Principal Investigator (PI) and members of the research team will oversee data collection, ensuring adherence to confidentiality protocols.
- **Data Coding and Entry:** Data will be deidentified and entered into a secure, password-protected electronic database (Excel) housed on encrypted, password-protected university computers. Any paper-based data (e.g., UIN master list) will be stored separately in a locked file cabinet within the ASDOH Oral Health Research Center with restricted-access limited to members of the study team. Study co-investigators are responsible for maintaining data security and subject confidentiality throughout the study.
- **Data Transfer and Storage:** Electronic data will be stored on ATSU secure servers and encrypted cloud storage with multi-factor authentication. Data transfers between ASDOH and the Sponsor will be conducted using encrypted file-sharing methods. No research data will be stored on personal devices or unsecured external drives.
- **Data Analysis:** All data analysis will be conducted using secure ATSU computers with restricted access to approved research personnel only. All data on the Excel spreadsheet will be deidentified and coded. Results will be reported in aggregate form only.
- **Data Access and Security Measures:** Access to data will be restricted based on role-specific authorization. The PI will oversee the chain of custody and ensure compliance with data security protocols.
- **Data Retention and Destruction:** Data will be securely retained for three years after study completion, in accordance with ATSU's institutional policies and federal regulations. After the retention period, all electronic data will be permanently deleted using secure data-wiping software. Physical records (e.g., consent forms) will be shredded using ATSU's secure document disposal system.

21. Monitoring Visits: An independent third-party monitor (to be named) and other required members designated by the Sponsor will make initiation, periodic monitoring, and closeout visits to the study sites.

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