**Sequential Application of a Novel Silver Diamine Fluoride Gel and Sodium Fluoride Varnish Arrests Caries Lesions of Severe Early Childhood Caries: A Case Series**

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Clinical Trial Registration: NCT05395065

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**Abstract**

**Background.** Silver diamine fluoride gel was developed to overcome clinical limitations of liquids with children. The authors conducted a case series study to determine lesion arrest in primary teeth at 1-y of follow-up, where 38% SDF gel and 2.5% sodium fluoride varnish were applied sequentially at the same appointment. Parent satisfaction was assessed.

**Methods**. The design was an open-label prospective, single-center case series. Participants were 237 children, ages 3-4 y at enrollment, from five Centros Educativos Iniciales , Puno, Peru. Eligible children had ≥1 active lesion (d3). Teeth with active lesions (d1-3) were treated:1-2 drops 38% SDF gel (Advantage Silver Dental Arrest Gel®, Elevate Oral Care) was applied and excess dabbed with cotton. Treated teeth were covered with 2.5% NaF varnish (Fluorimax®, Elevate Oral Care) to mask the taste. Treatment was repeated at five months post-examination. The primary outcome is arrest at 1-y (d2-3 lesions).

**Results.** 219 children were available at follow-up. At baseline, median active surfaces were 21.0 (IQR= 13.0, 34.0). Median arrested surfaces were 92.6% (IQR=81.1,100.0), BCA bootstrap 95% CI 86.8, 95.2%. When parents were asked if they were bothered by the color change, the median response (IQR) was 1.0 (1.0,2.0) where the scale ranged from 1=Not Bothered at All to 10=Very Bothered.

**Conclusions.** Two applications of 38% SDF gel and 2.5% NaF varnish arrested > 90% of surfaces at 1-y with high parent satisfaction.

**Practical Implications.** Managing dental caries in young children is challenging. In a population with an extraordinary number of lesions, combined treatment was highly efficacious.

Key Words: Children, severe Early Childhood Caries, silver diamine fluoride, sodium fluoride varnish, dental caries arrest

**Background**

Severe Early Childhood Caries can be difficult to manage in young precooperative children, especially when there are many caries lesions to be treated. 38% silver diamine fluoride (SDF) has been demonstrated to arrest lesions, but multiple applications are more effective than a single treatment.1 Most studies have repeated treatment at about 6-m.

Although quite safe, the liquid form of SDF is difficult to control in young children increasing the possibility of inadvertent exposure of the soft tissues. Moreover, SDF alone is bitter and children with many teeth to be treated may respond negatively to the taste. A gel version of 38% SDF became available in the United States in early 2023. The gel is applied similarly to traditional SDF liquid and can be covered with sodium fluoride varnish (NaF varnish) to mask the taste of the gel alone. In contact with the surface of active lesions, the gel behaves similarly to the traditional liquid.2

Clinical case series have an integral role in describing clinicians’ experience with new treatments in settings where other study designs may be ethically or practically inappropriate. The purpose of this clinical case series was to determine the caries lesion arrest in primary teeth at 5-m and 1-y of follow-up, where SDF gel and 2.5% sodium fluoride varnish (NaF) were applied sequentially at the same visit.

**Methods**

This report follows an adaption of the PROCESS 2018 Statement guidelines for the reporting of case series in surgery.3 The clinical trials registration number is NCT05395065. The Universidad Nacional del Altiplano Puno and the WCG Institutional Review Boards approved this study (012-2022-CIEI-UNAPuno; WCG IRB 1333923). The local study name was *Kiru Poderoso*, a Quechua language expression that means “mighty teeth.”

**Study Design**

The study is a prospective, single center case series.

Study Setting and Participants

The study was conducted at five preschools (Centros Educativos Iniciales), Puno, Peru. The first child was enrolled on July 11, 2022 and the last patient was enrolled on July 21, 2022. The last child was evaluated at follow-up on July 17, 2023. The participants were 237 healthy children (ages 3-4 y) whose parents consented to treatment in Spanish. Copies of the consent form in English and Spanish are in the Supplemental Appendix. The study population was urban Hispanic American/South American Native. Peru is an upper-middle-income country undergoing nutrition transition towards a Westernized dietary pattern. The children were examined clinically by three trained and calibrated examiners (ICC=0.71-0.84). To be eligible a child needed to have ≥1 active lesion with dentin exposure (d3). Treatment was provided in the schools using portable equipment at no charge to the family.

**Examinations**

The exams were conducted following National Institute of Dental and Craniofacial Research Early Childhood Caries Collaborating Centers criteria and performed using a mouth mirror with artificial light.4 Round-ended probes were used in assessing caries activity. No radiographs were used. The teeth were dry brushed and dried with cotton gauze before examination. The caries activity was assessed at the surface level employing an adaptation of criteria developed by Nyvad and colleagues, which have previously been shown to be reliable.5 In larger lesions, the call was made based on whether most of the surface area was arrested.

**Intervention**

All teeth with enamel or dentin lesions (d1-3) were treated, immediately after the examination, by the same clinician who did the examination. 1-2 drops of the viscous 38% SDF gel (Advantage Silver Dental Arrest Gel®, Elevate Oral Care, LLC, W Palm Beach FL) from a multi-use bottle were expressed into a disposable dappen dish and applied with a microbrush, agitated to ensure coverage, and then the excess was dabbed away with cotton gauze. The treated teeth were then covered with 2.5% NaF varnish (Fluorimax®, Elevate Oral Care, LLC) applied by microbrush, to mask the taste of the SDF and provide additional prevention benefit. There were no post treatment restrictions. Treatments were repeated at about 5-m post initial treatment.

Fresh product was provided by the manufacturer at each treatment period. The manufacturer provided a Certificate of Analysis verifying that the products met United States Food and Drug Administration cleared specifications. The products were stored under the manufacturer’s recommended conditions. Children received toothbrushes and fluoridated toothpaste at each visit. There were no concurrent caries preventive or arresting treatments.

**Parent Questionnaire**

A 6-item previously validated English-language questionnaire was modified and translated into Spanish and then back into English by native speakers to assure readability and validity.6 Both the English and Spanish versions of the questionnaire are in Supplemental Appendix. The paper questionnaire was completed by a parent at the 1-y follow-up, either at the school or at home. The questionnaire asks the sex of the child, age at last birthday, how healthy are the child’s teeth and gums (response categories: not very healthy, generally okay, very healthy), about how many times per week does he/she clean their teeth with a toothbrush/toothpaste (response categories: not very often, about once a week, most days, all the time), have you noticed any changes in your child’s teeth (check all that apply: no changes, new darker color on the biting part of the tooth, new darker color on the front teeth, white spots on the gums), and how much were you bothered by the treatment your child received as part of *Kiru Poderoso* (10 point scale anchored by 1=not bothered at all and 10=very bothered).

**Statistical Analysis**

The sample size was determined to ensure high precision of estimates for the rate of caries lesion arrest at 5-m and 1-y follow-up, based on a ½ width of a 95% Confidence Interval (CI). The caries arrest rate was expected to be as high as 50% by 5-m and as high as 70% by the 1-y of follow-up. In a prior study on caries arrest in preschool children the average caries arrest rate was 72% and the within-child correlation between caries lesion arrest was 0.44.7 In a prior caries prevention trial for young Peruvian children the mean number of carious surfaces (standard deviation) in 4-year-olds was 14 (9).8 In a randomized clinical trial of fluoride varnish in the Federated States of Micronesia the mean number of carious surfaces (standard deviation) was 19 (17) in 4-year-olds and the within child correlation between new caries lesions was 0.29.9

For the sample size determination10, we assumed an average of at least 10 treated caries surfaces on average per child with a coefficient of variation of 0.64 (9/14), a within-child correlation of 0.45 and a caries lesion arrest rate of 50% to 70%. Based on a sample size of 200 children, the precision to estimate the rate of caries arrest is at least ±6.3%. To accommodate up to 15% attrition, 237 children were enrolled.

**Data Analysis**

Data were recorded on paper forms by a trained assistant and entered by one of authors (CMVR) into a Microsoft Excel spreadsheet. Similarly, data from the parent questionnaire were transcribed from the paper forms and entered in an Excel spreadsheet and both were checked for accuracy.

The primary outcome is caries lesion arrest and measured by the median proportion (interquartile Range, IQR) of treated d2 and d3 lesion-surfaces with arrested lesions at 5-m and 1-y follow-up. Bias-corrected bootstrap 95% Confidence Intervals using 10,000 replications were computed for the median proportion of caries lesion arrest at 5-m and 1-y follow-up.10-11

Log-linear regression, implemented using generalized estimating equation (GEE) methods and robust standard errors, was used as a confirmatory analysis, estimating the rate of caries lesion arrest at 5-m and 1-y follow-up.13 The outcome variable is the number of arrested lesions (tooth-level outcome), and the number of treated surfaces is accounted for by including the logarithm of the number of treated surfaces as an offset term in the log-linear regression model.

Secondary outcomes are the number of new caries surfaces (d2-3s) and the rate of new caries lesions per 1 surface-year at risk (number of new caries surfaces divided by the number of surface years at risk for caries) at 5-m and 1-y of follow-up. Because the distribution of the number of new caries lesions is skewed, the median and bias-corrected bootstrap 95% CI for the median are reported. Log-linear regression using GEE methods were used to estimate the rate of new caries lesions at 5-m and 1-year follow-up.

Additional analyses estimated caries lesion arrest and the rate of new caries lesions by participant characteristics (e.g., sex and grade, as a proxy for age). All analyses are based on the intention-to-treat principle. Given that attrition over 1 y was <10% and unlikely to affect the results, no methods were used to account for the missing data due to attrition. Analyses were performed with R.

Descriptive statistics (median, IQR, frequency and percent) were calculated for the parent questionnaire and associations between these responses and lesion arrest were assessed using chi-square test and non-parametric methods.

**Results**

Figure 1 is a flow chart of participants and procedures. Loss to follow-up was low: 212 (89.4%) and 219/237 (92.4%) of enrolled children were available at 5-m and 1-y follow-up, respectively. The primary reason for missing the follow-up examination was that the child had moved.

At baseline, median active surfaces were 21.0 (IQR= 13.0, 34.0). There were no differences in baseline active surfaces between children with and without follow-up (Table 1).

Median arrested surfaces at 1-y were 92.6% (IQR=81.1,100%), bias-corrected accelerated (BCA) 95% CI 86.8, 95.2%. Median arrested surfaces at 5-m were 82.1 (IQR=66.4, 94.6%), bias-corrected accelerated (BCA) bootstrap 95% CI 78.1, 85.7% (Figure 2).

At 1-y (Table 2), more advanced lesions (d3) with dentin exposed had a high but significantly lower median arrest rate (92.5%, 95% CI, 88.7,100%) than lesions (d2) only in the enamel (100%, 95% CI 100, 100%) (d3 vs d2, RR = 0.92, 95% CI 0.89, 0.95, P <.001). Median caries arrest was higher in anterior teeth (100%, 95% CI 100, 100%) than in posterior teeth (92.3%, 95% CI 86.2, 96.3%), RR=1.10, 95% CI 1.06, 1.14, P < 0.001). Similar differences were seen at 5-m but the rate of arrest was higher at 1-y.

Using GEE log-linear regression, the rate of caries lesion arrest at 1-y did not significantly increase with baseline d2-4mfs (RR = 1.0003, 95% CI 0.998, 1.002, P = .64), whereas at 5-m the rate of caries lesion arrest significantly decreased with higher baseline d2-4mfs (RR = 0.997, 95% CI 0.994, 0.999, P = .017).

The caries arrest rate for d1 lesions was similar to, or higher than the caries arrest rate for d2 lesions both at 5-m (median (IQR) = 100% (100, 100%), 95% CI 100, 100%) and at 1-y (median (IQR) = 100% (100, 100%), 95% CI 100, 100%).

**Secondary Caries Outcomes**

Median number of new caries by 1-y was 4 (IQR = 2, 8), 95% CI 4, 5 and median new rate of new caries (per 1 surface-year at risk) was 0.08 (IQR = 0.04, 0.14), 95% CI 0.07, 0.10. Median number of new caries by 5-m was 2 (IQR = 1, 5), 95% CI 2, 3 and median new rate of new caries (per 1 surface-year at risk) was 0.10 (IQR = 0.03, 0.22), 95% CI 0.07, 0.15. At 1-y the rate of new caries lesions was higher in posterior teeth (median = 0.16) than anterior teeth (median 0.03, RR = 3.8, 95% CI 3.1, 4.7, P < .001). There were no differences by sex or grade. (Table 3). Similar differences were seen at 5-m (not shown).

**Adverse Effects**

There were no adverse or unanticipated effects of the treatments either observed at follow-up examinations or reported by participants. No patient withdrew or was lost to follow-up because of adverse effects from the treatment.

**Parent Satisfaction**

The questionnaire return rate was 90.7%: 215 questionnaires were available for analysis. None were excluded because of missing information. On a scale of 1= Not Bothered at All to 10=Very Bothered, 74.5% of parents were not bothered at all, 9.0% responded between 2 and 4, and 16.5% responded between 5 and 10. (Table 4) At 1-y less than one-third of parents noticed new darker color of front teeth (31.2%) or noticed new darker color on biting part of the teeth (30.7%). There were no differences in the “bothered” score by child sex or grade, or by whether the parent was aware of the changes in the color of treated teeth. Children of parents who responded between 5 and 10 on the bother scale had a higher number of arrested lesions (median (IQR) = 27 (18, 34)) compared to children whose parents were not at all bothered (median (IQR) = 18 (11, 31)) or responded between 2 and 4 (median (IQR) = 14 (9, 24), Kruskal-Wallis P = .038). However, there was no difference for the caries arrest rates (median caries rate 92.0% to 95.2%, Kruskal-Wallis P = .63).

**Discussion**

**Caries Arrest**

Over 90% of treated caries surfaces arrested after application of the SDF gel followed immediately by the NaF varnish treatment. This result is consistent with the findings in studies of the SDF liquid alone1 although a recent study reported a higher rate at six months with sequential treatment after a single treatment with the same SDF liquid product but another brand of fluoride varnish.14 An artificial caries study that evaluated a combined treatment like that used in the present study suggested the addition of the 5% NaF varnish did not contribute significantly to caries arrest.15

Similarly, the results for the combined treatment regarding lower arrest rates in the posterior teeth are also consistent with previous results. The differences may be a consequence of the higher degree of caries destruction in the anterior teeth, exposing greater amounts of dentin to the remineralization process. Additionally, studies have shown that teeth/surfaces with better plaque control demonstrate more effective SDF treatment.1  It is reassuring that the combined treatment arrest rates in both the anterior and posterior increased with a second application. The clinical take home message, nonetheless, is that lesions with dentin exposure and those in posterior teeth require more than two applications within a year to reach the same level of arrest as in the anterior. We do not know the number of applications required to achieve full arrest.

The treatment in this case series involved sequential application of the SDF gel followed by the NaF varnish. The approach was chosen mainly because the children had very large numbers of decayed teeth and the flavored varnish reduces child upset. The chemical characteristics of SDF make altering its taste not feasible. Practically speaking, using the SDF gel alone to ascertain the precise contribution of the NaF varnish was not possible. A clinical trial reported in 2001 directly compared caries lesion arrest by a yearly application 38% SDF, 5% NaF varnish alone, and water control. This trial found a large effect of SDF on the whole mouth when only the anterior teeth were treated but no difference between the NaF varnish and the water control.16

**Limitations**

We carried out a rigorous clinical case series study to ascertain the rate of caries lesion arrest with sequential treatment using the new SDF gel and NaF varnish. A factorial design comparing the gel and traditional SDF liquid, with or without NaF varnish was not possible in this setting. A randomized controlled trial comparing this SDF gel and the traditional liquid is planned elsewhere (personal communication, CH Chu).

The design also did not allow for testing whether the sequential treatment prevented new lesions. Nevertheless, a recent trial certainly suggests that 38% SDF alone is more effective in prevention than NaF varnish. Thus, the preventive effect of the sequential treatment is likely greater than either alone.18

The original design for the present study planned for the interim examination and second application at about 6-m. This was changed to 5-m to accommodate the school schedule. We do not know if the rate of arrest at 6-m would have been the same nor do we know whether the one year rate might have been even higher had the interval between treatments been four months or less. Nevertheless, in practice patients often do not return for recall at precise intervals so our results provide practical insights.

This study used a unique 2.5% NaF varnish produced by the same manufacturer of the SDF gel. Fluoride release from this varnish is similar or exceeds that of the typical 5% NaF products. Nevertheless, because of the study design, we could not ascertain whether the results with a standard varnish would have been similar.

**Practical Implications**

Most dentists are already using sodium fluoride varnish. This study suggests that the addition of a 38% SDF gel would increase the effectiveness of care to arrest active lesions. These products are inexpensive and simple to apply. The results suggest strongly that insurance programs that limit combinations of treatments, the number of applications, or the interval between treatments may be working against the best interests of patients.

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**Table 1: Baseline active surfaces of the children in the clinical case series**

|  | | All | 1-y follow-up | No 1-y follow-up |  |
| --- | --- | --- | --- | --- | --- |
| **Characteristic** | N = 237 | | N = 219 | N = 18 | P VALUE1 |
| No. of active surfaces, baseline |  | |  |  | 0.34 |
| Mean (SD) | 26.3 (15.6) | | 26.6 (15.9) | 22.3 (11.8) |  |
| Median (IQR) | 22 (14, 37) | | 22.0 (14, 38) | 19.5 (15, 29) |  |
| Range | 2, 80 | | 2, 80 | 7, 47 |  |
| No. of d2 and d3 surfaces, baseline |  | |  |  | 0.38 |
| Mean (SD) | 24.5 (14.6) | | 24.8 (14.9) | 20.9 (10.5) |  |
| Median (IQR) | 21 (13, 33) | | 21 (13, 34) | 19 (14, 25) |  |
| Range | 2, 73 | | 2, 73 | 7, 44 |  |
| No. of d1 surfaces, baseline |  | |  |  | 0.70 |
| Mean (SD) | 1.1 (1.9) | | 1.1 (1.8) | 1.2 (2.8) |  |
| Median (IQR) | 0 (0, 1) | | 0 (0, 2) | 0.5 (0, 1) |  |
| Range | 0, 12 | | 0, 10 | 0, 12 |  |
| No. of d2 surfaces, baseline |  | |  |  | 0.99 |
| Mean (SD) | 7.3 (6.3) | | 7.4 (6.4) | 6.9 (5.5) |  |
| Median (IQR) | 5 (3, 10) | | 5 (3, 10) | 6 (3, 10) |  |
| Range | 0, 41 | | 0, 41 | 0, 18 |  |
| No. of d3 surfaces, baseline |  | |  |  | 0.62 |
| Mean (SD) | 17.2 (13.1) | | 17.4 (13.4) | 13.9 (7.5) |  |
| Median (IQR) | 13 (7, 25) | | 13 (6, 26) | 14 (8, 17) |  |
| Range | 1, 64 | | 1, 64 | 2, 29 |  |
| No. of d4 surfaces, baseline |  | |  |  | 0.44 |
| Mean (SD) | 0.7 (2.5) | | 0.7 (2.6) | 0.2 (0.9) |  |
| Median (IQR) | 0 (0, 0) | | 0 (0, 0) | 0 (0, 0) |  |
| Range | 0, 21 | | 0, 21 | 0, 4 |  |

1Wilcoxon rank sum test

**Table 2.** Caries arrest at 5-m and 1-y after sequential treatment with 38% SDF gel and 2.5%NaF varnish.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Characteristic** | **N** | **Median (IQR)** | **95% CI** | **RR (95% CI)** | **P VALUE2** |
|  |  | 5-m follow-up | | | |
| Baseline surface score |  |  |  |  |  |
| d2 | 196 | 94.9 (80.0, 100) | 88.9, 100 | 1 |  |
| d3 | 212 | 78.4 (57.9, 100) | 74.1, 82.7 | 0.81 (0.77, 0.84) | <.001 |
|  |  |  |  |  |  |
| Tooth position |  |  |  |  |  |
| Posterior | 209 | 77.8 (54.5, 95.2) | 69.2, 81.8 | 1 |  |
| Anterior | 186 | 100 (83.6, 100) | 100, 100 | 1.21 (1.15, 1.29) | <.001 |
|  |  |  |  |  |  |
| Sex1 |  |  |  |  |  |
| Female | 111 | 80.0 (68.9, 93.3) | 75.4, 84.5 | 1 |  |
| Male | 104 | 84.8 (62.8, 95.2) | 77.3, 88.9 | 0.96 (0.89, 1.14) | .37 |
|  |  |  |  |  |  |
|  |  | 1-y follow-up | | | |
| Baseline surface score |  |  |  |  |  |
| d2 | 204 | 100 (92.3, 100) | 100, 100 | 1 |  |
| d3 | 219 | 92.9 (75.7, 100) | 88.7, 97.4 | 0.92 (0.89, 0.55) | <.001 |
|  |  |  |  |  |  |
| Tooth position |  |  |  |  |  |
| Posterior | 216 | 92.3 (72.0, 100) | 86.2, 96.3 | 1 |  |
| Anterior | 191 | 100 (100, 100) | 100, 100 | 1.10 (1.06, 1.14) | <.001 |
|  |  |  |  |  |  |
| Sex1 |  |  |  |  |  |
| Female | 111 | 90.9 (77.1, 100) | 85.7, 94.4 | 1 |  |
| Male | 104 | 94.5 (83.2, 100) | 90.9, 100 | 1.06 (1.01, 1.10) | .013 |
|  |  |  |  |  |  |
| School grade at baseline\* |  |  |  |  |  |
| 3 | 92 | 94.3 (81.9, 100) | 87.1, 100 | 1 |  |
| 4 | 127 | 92.3 (80.9, 100) | 88.9, 95.2 | 1.01 (0.97, 1.05) | .70 |

**\***School grade is equivalent to age at enrollment for most children.

1Child’s sex only available for 193 of the 212 children with 5-m follow-up, and for 215 of the 219 children with 1-y follow-up.

2GEE log-linear regression.

**Table 3.** New caries rate (per 1 surface-year at risk) by 1-y after sequential treatment with 38% SDF gel and 2.5%NaF varnish.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Characteristic** | **N** | **Median (IQR)** | **95% CI** | **RR (95% CI)** | **P VALUE2** |
| Tooth position |  |  |  |  |  |
| Posterior | 219 | 0.16 (0.09, 0.31) | 0.13, 0.18 | 1 |  |
| Anterior | 219 | 0.03 (0.00, 0.07) | 0.02, 0.03 | 3.83 (3.14, 4.67) | <.001 |
|  |  |  |  |  |  |
| Sex1 |  |  |  |  |  |
| Female | 111 | 0.08 (0.04, 0.14) | 0.07, 0.10 | 1 |  |
| Male | 104 | 0.08 (0.04, 0.14) | 0.07, 0.12 | 0.99 (0.76, 1.28) | .91 |
|  |  |  |  |  |  |
| School grade at baseline\* |  |  |  |  |  |
| 3 | 92 | 0.08 (0.04, 0.14) | 0.06, 0.11 | 1 |  |
| 4 | 127 | 0.08 (0.04, 0.14) | 0.07, 0.10 | 1.13 (0.87, 1.47) | .36 |

**\***School grade is equivalent to age at enrollment for most children.

1Child’s sex only available for 215 of the 219 children with 1-y follow-up.

2GEE log-linear regression.

**Table 4** Parent Satisfaction: Bothered by treatment at 1-y.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Bothered by treatment** | | | | |  |
|  |  |  |  | 1 | 2 to 4 | 5 to 10 |  |
| **Characteristic** | **N (%)** | **Median (IQR)** | **P VALUE1** | **n (%)** | **n (%)** | **n (%)** | **P VALUE2** |
| All children | 215 (100%) | 1.0 (1.0, 2.0) |  | 158 (74.5) | 19 (9.0) | 35 (16.5) |  |
|  |  |  |  |  |  |  |  |
| Sex |  |  | 0.16 |  |  |  | 0.32 |
| Female | 111 (51.6%) | 1.0 (1.0, 2.0) |  | 77 (70.6) | 10 (9.2) | 22 (20.2) |  |
| Male | 104 (48.4%) | 1.0 (1.0, 1.0) |  | 81 (78.6) | 9 (8.7) | 13 (12.6) |  |
|  |  |  |  |  |  |  |  |
| School grade at baseline\* |  |  | 0.40 |  |  |  | 0.41 |
| 3 | 89 (41.4%) | 1.0 (1.0, 1.0) |  | 67 (77.0) | 9 (10.3) | 11 (12.6) |  |
| 4 | 126 (58.6%) | 1.0 (1.0, 2.0) |  | 91 (72.8) | 10 (8.0) | 24 (19.2) |  |
|  |  |  |  |  |  |  |  |
| Noticed new darker color on front teeth at 1-y |  |  | 0.025 |  |  |  | 0.087 |
| No | 148 (68.8%) | 1.0 (1.0, 1.0) |  | 115 (78.8) | 12 (8.2) | 19 (13.0) |  |
| Yes | 67 (31.2%) | 1.0 (1.0, 3.0) |  | 43 (65.2) | 7 (10.6) | 16 (24.2) |  |
|  |  |  |  |  |  |  |  |
| Noticed new darker color on biting part of teeth at 1-y |  |  |  |  |  |  | 0.31 |
| No | 149 (69.3%) | 1.0 (1.0, 2.0) | 0.36 | 106 (72.6) | 16 (11.0) | 24 (16.4) |  |
| Yes | 66 (30.7%) | 1.0 (1.0, 1.0) |  | 52 (78.8) | 3 (4.5) | 11 (16.7) |  |

**\***School grade is equivalent to age at enrollment for most children.

1Wilcoxon rank sum test

2Pearson's chi-square test

**Figure 1: FLOW CHART**

Children whose parents provided informed consent (n=289)

## Enrollment

Allocated to intervention (n=237)

* Received allocated intervention: (n=237)

Treatment with SDF and NaF varnish

Children meeting eligibility criteria (n=237)

Excluded (n = 52)

* Child absent for exam / treatment (n=15)
* No active d3 (dentin exposure) lesion (n=23)
* Unable to cooperate for exam / treatment

(n=14)

## Allocation

## Follow-Up

5 month follow-up exam & treatment (n=212)

* + Child absent (n=20)
  + Lost to follow-up (n=2)
  + Parent withdrew consent (n=2)
  + Uncooperative behavior (n=1)

1 year follow-up exam (n=219)

* + Child absent (n=1)
  + Lost to follow-up (n=14)
  + Parent withdrew consent (n=3)

Included in analysis (n=219)

## Analysis

**Figure 2.** Caries arrest rate (%) at 5-m and 1-y for d2 and d3 lesions after sequential treatment with 38% SDF gel and 2.5%NaF varnish. Median bias-corrected accelerated bootstrap 95% Confidence Interval.

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**SUPPLEMENTAL APPENDIX**

**University of Washington**

**ANNEX 5**

**INFORMED CONSENT**

**Title:** Evaluation of the Response of Caries Lesions in Dentin after Application of Silver Diamine Fluoride Gel: A Case Series

**Protocol No.:** Gel 2022-1

IRB Protocol #20222675

STUDY00015421

**Sponsor:** Advantage Silver Dental Arrest, LLC

**Co-Investigators:** Tania Carola Padilla-Caceres, BDS, MS, PhD

Av. Floral No. 1153

District and Department of Puno

Puno 21001

Peru

Peter Milgrom, DDS

1959 NE Pacific Street

Seattle, Washington 98195

United States

**STUDY-RELATED**

**PHONE NUMBER(S):** 51 958 199 952 (24 hours)

1. **INFORMATION FOR THE PARTICIPANT**

The research entitled "Evaluation of the response of caries lesions in dentin after the APPLICATION of fluoride dianimo de plata IN PUNO: A SERIES OF CASES", will be carried out by Dr. Tania Padilla Cáceres professor of the National University of the Altiplano Puno, Dr. Jorge Luis Castillo Cevallos Professor at the Peruvian University Cayetano Heredia of Lima, Ms. Marilynn L. Rothen and Dr. Peter Milgrom Professors at the University of Washington, Seattle, WA, United States, with the purpose of evaluating the response of caries lesions in dentin after the application of 38% silver diamine fluoride gel and 2.5% sodium fluoride varnish at one year of follow-up. You are invited to let your child participate in this research. You can consult with another person before making the decision. Your decision to enter your child into this study is entirely voluntary.

The procedure is explained below:

* You child will have a dental examination at their initial educational center to evaluate whether they have at least one active tooth decay lesion with dentin exposure. If they do, with your consent, any lesions will be treated with silver diamine fluoride and sodium fluoride. Another treatment will be given at 5-6 months. They will have oral examinations at 6 months and one year after the first application to evaluate the response. Parents are also asked to fill out a short questionnaire about how they rate the health of their child’s teeth and their satisfaction with the treatment.
* The 38% silver diamine fluoride gel to be applied is a dental material that is already used and is from the brand *Advantage Silver Dental Arrest Gel, Elevate Oral Care, LLC, W Palm Beach FL*
* The application of the 38% silver diamine fluoride gel will be done manually with a dental microbrush, on the chosen tooth for 1 min and then rinsed with water. This procedure is non-invasive and carries no serious risk to the child's health. The tooth is then coated with 2.5% NaF varnish (Fluorimax, Elevate Oral care, LLC)
* This application will be performed by trained pediatric dentists
* There are no restrictions on eating or drinking after treatment with silver diamino fluoride.
* All data collected will be handled anonymously even in the publication of your results
* You may refuse to have your child participate. Participants once included in the study may withdraw if they choose. There will be no penalty or loss of benefits to which they are otherwise entitled whatever you decide.
* If you do not want to participate, the alternative is for your child to have their regular dental care.
* Potential benefits are that your child’s dental caries may stop progressing, but this cannot be guaranteed. The information learned may also help others in the future.
* Dental evaluation and application of 38% silver diamine fluoride gel and 2.5% sodium fluoride varnish does not cause harm or risk to children's health, although it may cause irritation of the gums or discoloration of the teeth. This dental material (38% Silver Fluoride Advantage Silver Dental Arrest Gel, Elevate Oral Care, LLC, W Palm Beach FL) is already used commercially.
* All children in the initial schools participating in the study, including 5-year-olds, will receive oral hygiene implements (toothbrush and toothpaste)
* The documents that are generated as a result of this research, informed consents, data collection sheets will remain in the custody of the main researcher until the publication of their results and available to the CIEI of the UNA Puno when required. This information may also be seen by the Sponsor, the ethics review board, and regulatory authorities.
* This research will be evaluated by the CIEI of the National University of the Altiplano whose responsibilities are to help ensure the protection of the rights, security and well-being of human beings who, in use of their faculties and free will, accept to be subjects of health research. You can contact its president Dr. Lidia Caballero Gutiérrez telf.: 951 052 792, email: [dginvestigacion@unap.edu.pe](mailto:dginvestigacion@unap.edu.pe)
* The researcher for this study, Dr. Peter Milgrom, is receiving payment from the study sponsor, Advantage Silver Dental Arrest, LLC, and Elevate Oral Care, LLC for the time spent completing study-related duties.
* Dr. Milgrom has a financial or other relationship with Advantage Silver Dental Arrest, LLC. The University of Washington (UW) developed a Conflict Management Plan to reduce the possible effects of this relationship on your safety or welfare.

You will not be paid for being in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The questions, concerns, or complaints that arise about the dental material to be used will be answered by the main researcher, as well as any complications that arise from the application of silver diamine fluoride will be solved by Dr. Tania Padilla Cáceres telf.: 51958199952 email: [tpadilla@unap.edu.pe](mailto:tpadilla@unap.edu.pe)

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or [researchquestions@wcgirb.com](mailto:researchquestions@wcgirb.com) if:

* You have questions, concerns, or complaints that are not being answered by the research team.
* You are not getting answers from the research team.
* You cannot reach the research team.
* You want to talk to someone else about the research.
* You have questions about your rights as a research subject.

If you are injured or get sick because of being in this research, call the study dentist, Dr. Tania Padilla Cáceres immediately. She will provide emergency treatment at no cost.

Scientific evidence on the use of silver diamine fluoride is widely reported in effectiveness and safety. Attached are some titles of articles that can be reviewed

1. Castillo JL, Rivera S, Aparicio T, Lazo R, Aw T.C, Manc L.L, Milgrom P, The Short-term Effects of Diammine Silver Fluoride on Tooth Sensitivity: a Randomized Controlled Trial. J Dent Res 90(2):203-208, 2011.
2. Chopra I. 2007. The increasing use of silver-based products as antimicrobial agents: a useful development or a cause for concern? J Antimicrob Chemoth. 59:587-590.
3. [Chu CH](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Chu%20CH%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Lo EC](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Lo%20EC%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Lin HC](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Lin%20HC%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus). Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin caries in Chinese pre-school children. [J Dent Res.](javascript:AL_get(this,%20'jour',%20'J%20Dent%20Res.');) 2002 Nov ;81(11):767-70.
4. [Llodra JC](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Llodra%20JC%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Rodriguez A](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Rodriguez%20A%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Ferrer B](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Ferrer%20B%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Menardia V](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Menardia%20V%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Ramos T](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Ramos%20T%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Morato M](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Morato%20M%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus). Efficacy of silver diamine fluoride for caries reduction in primary teeth and first permanent molars of schoolchildren: 36-month clinical trial. [J Dent Res.](javascript:AL_get(this,%20'jour',%20'J%20Dent%20Res.');) 2005 Aug;84(8):721-4
5. **INFORMED CONSENT FORM FOR SIGNATURE**

Assent of children is not required.

Documentation of assent is not required.

I, ................................................... guardian of the minor ............................................................................................................................... of ..........years of age. I agree that it has been clearly explained to us what this research consists of and that my child's participation is voluntary, and if I decide that I no longer want my child to participate I can stop at any time. It has also been explained to us that the application of the dental material will not cause serious damage or risk to the health of my child, and that the data will be handled anonymously.

In case you require information about this research you can contact the main researcher Dr. Tania Padilla Cáceres telf.: 51958199952 (24 hours) email: [tpadilla@unap.edu](mailto:tpadilla@unap.edu)

In this sense I sign this document, after having read and discussed the information contained in this consent sheet.

Consent of the parent or proxy.

Names and Surnames:

......................................................................................................................................

Signature:...........................

Date:.............................

Full name of the minor: ....................................................................................................

I have explained the content of this consent sheet with the above signatory.

Name of the researcher: Tania Padilla Cáceres Signature:...................................

**University of Washington**

**ANEXO 5**

**CONSENTIMIENTO INFORMADO**

**TÍTULO:** Evaluación de la respuesta de las lesiones de caries en la dentina después de la aplicación de fluoruro diamino de plata en gel: Serie de casos.

**N.° de protocolo:** Gel 2022-1

N.° de protocolo del IRB 20222675

STUDY00015421

**Patrocinador:** Advantage Silver Dental Arrest, LLC

**Investigadores**

**adjuntos:** Tania Carola Padilla-Caceres, BDS, MS, PhD

Av. Floral No. 1153

Distrito y Departamento de Puno

Puno 21001

Perú

Peter Milgrom, DDS

1959 NE Pacific Street

Seattle, Washington 98195

Estados Unidos

**NÚMERO DE TELÉFONO**

**DEL ESTUDIO:** 51 958 199 952 (las 24 horas)

1. **INFORMACIÓN PARA EL PARTICIPANTE**

La investigación titulada “Evaluación de la respuesta de las lesiones de caries en la dentina después de la APLICACIÓN de fluoruro diamino de plata EN PUNO: SERIE DE CASOS”, estará a cargo de la Dra. Tania Padilla Cáceres, profesora de la Universidad Nacional del Altiplano - Puno, del Dr. Jorge Luis Castillo Cevallos, profesor de la Universidad Peruana Cayetano Heredia de Lima, de Marilynn L. Rothen y del Dr. Peter Milgrom, profesores de University of Washington, Seattle, WA, Estados Unidos, con el fin de evaluar la respuesta de las lesiones de caries en la dentina tras la aplicación de fluoruro diamino de plata en gel al 38 % y barniz de fluoruro de sodio al 2.5 % en el primer año de seguimiento. Se lo invita a que permita que su hijo participe en esta investigación. Puede consultar este tema con otra persona antes de tomar una decisión. Su decisión de inscribir a su hijo en este estudio es totalmente voluntaria.

El procedimiento se explica a continuación:

* Se le realizará un examen odontológico a su hijo en su centro de educación básica para evaluar si tiene por lo menos una lesión de caries dental activa con exposición de dentina. Si es así, con su consentimiento, se tratará cualquier lesión con fluoruro diamino de plata y fluoruro de sodio. Se administrará otro tratamiento a los 5 o 6 meses. Se harán exámenes odontológicos a los 6 meses y un año después de la primera aplicación para evaluar la respuesta. También se les pide a los padres que completen un cuestionario breve sobre cómo califican la salud odontológica de sus hijos y qué tan satisfechos están con el tratamiento.
* El gel de fluoruro diamino de plata al 38 % que se va a aplicar es un material dental que ya se usa y pertenece a la marca *Advantage Silver Dental Arrest Gel, Elevate Oral Care, LLC, W Palm Beach FL.*
* La aplicación del gel de fluoruro diamino de plata al 38 % se realizará de forma manual con un microcepillo dental, sobre el diente elegido durante 1 minuto y luego se enjuagará con agua. Este procedimiento no es invasivo y no implica ningún riesgo grave para la salud del niño. Luego, el diente se recubre con un barniz de NaF al 2.5 % (Fluorimax, Elevate Oral care, LLC).
* Esta aplicación la realizarán dentistas pediátricos capacitados.
* No hay restricciones para comer o beber después del tratamiento con fluoruro diamino de plata.
* Todos los datos reunidos se manejarán de forma anónima incluso si se publican sus resultados.
* Puede negarse a que su hijo participe. Una vez que se los incluya en el estudio, los participantes pueden retirarse si así lo deciden y no sufrirán ningún castigo ni la pérdida de los beneficios que de otro modo les corresponden, independientemente de la decisión que tomen.
* Si no desea participar, la alternativa es que su hijo reciba la atención odontológica habitual.
* Un posible beneficio es que se pueda impedir el avance de la caries dental que tiene su hijo, pero esto no se puede garantizar. La información que se obtenga también puede ayudar a otras personas en el futuro.
* La evaluación dental y la aplicación de gel de fluoruro diamino de plata al 38 % y del barniz de fluoruro de sodio al 2.5 % no causa daño ni riesgo para la salud de los niños, aunque puede causar irritación de las encías o decoloración de los dientes. Este material dental (fluoruro diamino de plata al 38 %, Advantage Silver Dental Arrest Gel, Elevate Oral Care, LLC, W Palm Beach FL) ya se usa comercialmente.
* Todos los niños en las escuelas de formación básica que participan en el estudio, incluidos los de 5 años, recibirán artículos de higiene bucal (cepillo y pasta de dientes).
* Los documentos que se generen como resultado de esta investigación, los consentimientos informados y hojas de obtención de datos, permanecerán en custodia del investigador principal hasta la publicación de sus resultados y a disposición del CIEI de la UNA de Puno cuando sea necesario. Es posible que el patrocinador, el comité de revisión de ética y las autoridades reguladoras también revisen esta información.
* Esta investigación será evaluada por el CIEI de la Universidad Nacional del Altiplano cuyas responsabilidades son ayudar a garantizar la protección de los derechos, la seguridad y el bienestar de los seres humanos que, en uso de sus facultades y libremente, aceptan ser sujetos que participan en una investigación relacionada con la salud. Puede comunicarse con su presidenta, la Dra. Lidia Caballero Gutiérrez al teléfono: 951 052 792 o enviar un correo electrónico a: [dginvestigacion@unap.edu.pe](file:///C:\Users\dfrc\Documents\OneDrive%20-%20UW%20Office%20365\silver%20fluoride\Gel\CLINICAL%20CASE%20SERIES\IRB\WICG\FINAL%20DOCS\Intermediate%20files\3%20Rev\dginvestigacion@unap.edu.pe)
* El investigador de este estudio, el Dr. Peter Milgrom, recibe un pago del patrocinador del estudio, Advantage Silver Dental Arrest, LLC, y Elevate Oral Care, LLC por el tiempo dedicado a completar las obligaciones relacionadas con el estudio.
* El Dr. Milgrom tiene una relación económica o de otro tipo con Advantage Silver Dental Arrest, LLC. University of Washington (UW) desarrolló un plan de manejo de conflictos para disminuir los efectos posibles de esta relación en su seguridad y bienestar.

No se le pagará por participar en este estudio.

En http://www.ClinicalTrials.gov estará disponible una descripción de este ensayo clínico, según lo exigen las leyes de los Estados Unidos. Este sitio web no incluirá información que permita identificarlo. A lo sumo, incluirá un resumen de los resultados. Puede explorar este sitio web en cualquier momento.

El investigador principal responderá las preguntas, preocupaciones o quejas que surjan sobre el material dental que se utilizará. De igual manera, comuníquese con la Dra. Tania Padilla Cáceres en relación con cualquier complicación que surja por la aplicación del fluoruro diamino de plata al teléfono: 51958199952 o envíe un correo electrónico a: [tpadilla@unap.edu.pe](file:///C:\Users\dfrc\Documents\OneDrive%20-%20UW%20Office%20365\silver%20fluoride\Gel\CLINICAL%20CASE%20SERIES\IRB\WICG\FINAL%20DOCS\Intermediate%20files\3%20Rev\tpadilla@unap.edu.pe)

El WCG IRB supervisa esta investigación. Un IRB es un grupo de personas que realizan revisiones de los estudios de investigación de manera independiente. Puede hablar con ellos al 855-818-2289 o en [researchquestions@wcgirb.com](file:///C:\Users\dfrc\Documents\OneDrive%20-%20UW%20Office%20365\silver%20fluoride\Gel\CLINICAL%20CASE%20SERIES\IRB\WICG\FINAL%20DOCS\Intermediate%20files\3%20Rev\researchquestions@wcgirb.com) si:

* Tiene preguntas, preocupaciones o quejas y el equipo de la investigación no le brinda una respuesta.
* No recibe respuestas del equipo de la investigación.
* No puede comunicarse con el equipo de la investigación.
* Desea hablar con otra persona sobre la investigación.
* Tiene preguntas sobre sus derechos como participante de una investigación.

Si sufre una lesión o se enferma debido a la participación en esta investigación, llame de inmediato a la odontóloga del estudio, la Dra. Tania Padilla Cáceres, quien le brindará tratamiento de emergencia sin costo alguno.

Existe una gran variedad de informes sobre la evidencia científica sobre el uso de fluoruro diamino de plata en cuanto a la eficacia y la seguridad. Se adjuntan algunos títulos de artículos que se pueden revisar:

1. Castillo JL, Rivera S, Aparicio T, Lazo R, Aw T.C, Manc L.L, Milgrom P, The Short-term Effects of Diammine Silver Fluoride on Tooth Sensitivity: a Randomized Controlled Trial. J Dent Res 90(2):203-208, 2011.
2. Chopra I. 2007. The increasing use of silver-based products as antimicrobial agents: a useful development or a cause for concern? J Antimicrob Chemoth. 59:587-590.
3. [Chu CH](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=), [Lo EC](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=), [Lin HC](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=). Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin caries in Chinese pre-school children.  
   [J Dent Res.](javascript:AL_get(this,%20'jour',%20'J%20Dent%20Res.');) 2002 Nov;81(11):767-70.
4. [Llodra JC](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=), [Rodriguez A](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=), [Ferrer B](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=), [Menardia V](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=), [Ramos T](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=), [Morato M](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=). Efficacy of silver diamine fluoride for caries reduction in primary teeth and first permanent molars of schoolchildren: 36-month clinical trial.[J Dent Res.](javascript:AL_get(this,%20'jour',%20'J%20Dent%20Res.');) 2005 Aug;84(8):721-4
5. **FORMULARIO DE CONSENTIMIENTO INFORMADO PARA LA FIRMA**

No se requiere la aceptación de los menores de edad.

No se requiere la documentación de la aceptación.

Yo, ..................................................., tutor del menor ............................................................................................. de ..........años de edad, acepto que se nos ha explicado claramente en qué consiste esta investigación y que la participación de mi hijo es voluntaria y que, si decido que ya no quiero que mi hijo participe, puedo retirarlo en cualquier momento. También se nos ha explicado que la aplicación del material dental no causará ningún daño o riesgo grave para la salud de mi hijo y que los datos se manejarán de forma anónima.

En caso de requerir información sobre esta investigación, puede comunicarse con la investigadora principal, la Dra. Tania Padilla Cáceres al teléfono: 51958199952   
(las 24 horas) o enviar un correo electrónico a: [tpadilla@unap.edu](file:///C:\Users\dfrc\Documents\OneDrive%20-%20UW%20Office%20365\silver%20fluoride\Gel\CLINICAL%20CASE%20SERIES\IRB\WICG\FINAL%20DOCS\Intermediate%20files\3%20Rev\tpadilla@unap.edu)

En este sentido firmo este documento, después de haber leído y analizado la información contenida en esta hoja de consentimiento.

Consentimiento del padre/de la madre o el apoderado.

Nombre y apellidos:

......................................................................................................................................

Firma: ...........................

Fecha: .............................

Nombre completo del menor: ...........................................................................................

He explicado el contenido de esta hoja de consentimiento al firmante que se menciona arriba.

Nombre de la investigadora: Tania Padilla Cáceres

Firma: ...................................

**ESCUELA PROFESIONAL DE ODONTOLOGÍA, UNIVERSIDAD NACIONAL DEL ALTIPLANO, PROFESORA PRINCIPAL TANIA PADILLA CÁCERES**

N.° 34273771.0

***KIRU PODEROSO***

*Estimado padre o madre: Le pedimos que responda este cuestionario breve porque su hijo recibió tratamiento para detener las caries con fluoruro diamino de plata y barniz de fluoruro como parte de un estudio que se lleva a cabo en la escuela de su hijo. Haga su mejor esfuerzo para responder todas las preguntas.*

1 ¿Su hijo es niño o niña? Encierre en un círculo una opción: NIÑO NIÑA

2 ¿Cuántos años tenía su hijo en su último cumpleaños? \_\_\_\_\_\_\_\_\_\_\_ años

3 ¿Qué tan saludables son los dientes y las encías de su hijo? Marque la mejor respuesta.

A. NO MUY SALUDABLES \_\_\_\_\_\_\_\_

B. BIEN EN GENERAL \_\_\_\_\_\_\_\_

C. MUY SALUDABLES \_\_\_\_\_\_\_\_

4 Aproximadamente, ¿cuántas veces por semana se limpia los dientes con un cepillo de dientes/pasta de dientes? Marque la mejor respuesta.

A. NO MUY A MENUDO \_\_\_\_\_

B. APROXIMADAMENTE UNA VEZ POR SEMANA \_\_\_\_\_

C. CASI TODOS LOS DÍAS \_\_\_\_\_

D. TODOS LOS DÍAS \_\_\_\_\_

5 ¿Ha notado algún cambio en los dientes de su hijo? Marque todas las opciones que correspondan.

A. SIN CAMBIOS \_\_\_\_\_\_\_

B. COLOR NUEVO Y MÁS OSCURO EN LA PARTE DEL DIENTE   
CON LA QUE SE MUERDE \_\_\_\_\_\_\_

C. COLOR NUEVO Y MÁS OSCURO EN LOS DIENTES DELANTEROS \_\_\_\_\_\_\_

D. MANCHAS BLANCAS EN LAS ENCÍAS \_\_\_\_\_\_\_

6 ¿Qué tanto le molestó a usted el trato que recibió su hijo como parte de ***KIRU PODEROSO***?Indique un número de 1 a 10, en donde 1 = NO HA MOLESTADO PARA NADA y   
10 = HA MOLESTADO MUCHO.

\_\_\_\_\_\_\_\_\_\_\_\_\_ (Escriba el número aquí)

***GRACIAS***

**SCHOOL OF PROFESSIONAL DENTISTRY, NATIONAL UNIVERSITY OF THE ALTIPLANO, PRINCIPAL PROFESSOR TANIA PADILLA CACERES**

#34273771.0

***KIRU PODEROSO***

*Dear Parent: We are asking you to complete this short questionnaire because your child received treatment to stop cavities with silver diamine fluoride and fluoride varnish as part of a study being conducted in your child’s school. Please do your best to answer all the questions.*

1. Is your child a boy or girl? Please circle one, BOY GIRL

2. How old was your child at his/her last birthday \_\_\_\_\_\_\_\_\_\_\_ years

3. How healthy are your child’s teeth and gums. Please check the best answer.

A. NOT VERY HEALTHY \_\_\_\_\_\_\_\_

B. GENERALLY OKAY \_\_\_\_\_\_\_\_

C. VERY HEALTHY \_\_\_\_\_\_\_\_

4. About how many times per week does he/she clean their teeth with a toothbrush/toothpaste Please check the best answer.

A. NOT VERY OFTEN \_\_\_\_\_

B. ABOUT ONCE PER WEEK \_\_\_\_\_

C. MOST DAYS \_\_\_\_\_

D. ALL THE TIME \_\_\_\_\_

5. Have you noticed any changes in your child’s teeth. Please check all that apply.

A. NO CHANGES \_\_\_\_\_\_\_

B. NEW DARKER COLOR ON THE BITING PART OF THE TOOTH \_\_\_\_\_\_\_

C. NEW DARKER COLOR ON THE FRONT TEETH \_\_\_\_\_\_\_

D. WHITE SPOTS ON THE GUMS \_\_\_\_\_\_\_

6. How much were you bothered by the treatment your child received as part of ***KIRU PODEROSO?*** Please give a number from 1 to 10 where 1=NOT BOTHERED AT ALL and 10=VERY BOTHERED.

\_\_\_\_\_\_\_\_\_\_\_\_\_ (Please put the number here)

***THANK YOU***