The Effectiveness of Silver Diamine Fluoride when used to Arrest Caries in Children and Associated Oral Health-Related Quality of Life

by

Rena Sihra

A Thesis submitted to the Faculty of Graduate Studies of

The University of Manitoba

in partial fulfilment of the requirements of the degree of

MASTER OF DENTISTRY

Department of Preventive Dental Science

Dr. Gerald Niznick College of Dentistry

Rady Faculty of Health Sciences

University of Manitoba

Winnipeg, Manitoba, Canada

Abstract:

Objective: To investigate the efficacy of silver diamine fluoride (SDF) with 5% fluoride varnish (FV) in treating cavitated caries in young children and to explore the association between SDF treatment and oral health-related quality of life (OHRQoL).

Methods: Children with active dentinal caries lesions (ICDAS 5 or 6) in primary teeth underwent treatment with 38% SDF and 5% FV at baseline and 4 months later. Treated lesions were assessed 4 and 8 months after baseline to determine arrest. Participants were deemed Completely Successful (CS) if all treated lesions were arrested and Incompletely Successful (IS) if at least one lesion was not arrested. The early childhood oral health impact scale (ECOHIS) questionnaire was completed at second and third visits. Statistical analyses included descriptive and bivariate methods. A P value ≤ 0.05 was significant.

Results: Forty children with 239 caries lesions were enrolled; mean age 40.2 ± 14.9 months and 45% male. Lesion arrest rates after one and two applications of SDF were 74.1% and 96.2%, respectively. Children who reportedly brushed twice daily were more likely to be in the CS group compared to those who brushed less (p=0.006). Participants in the CS group had a significantly lower mean baseline dmft score than those in the IS group (p= 0.048). No significant difference in OHRQoL was observed between CS and IS groups.

Conclusions: SDF with 5% FV is an effective approach to the management of ECC; more than one application is recommended along with regular follow-up of patients

and twice daily brushing. OHRQoL was not found to be affected by the level of success of SDF treatment.

Table of Contents

List of Tables and Figures

Introduction:

A common form of dental caries affecting the pediatric population is early childhood caries (ECC), which is defined as the presence of one or more decayed, missing, or filled primary tooth in those <6 years of age.[1] The extent and severity of ECC in very young children poses treatment challenges for those who are unable to cooperate for the delivery of conventional dental treatment in community-based clinical settings.[2] Consequently, many children with ECC must be treated under general anesthesia (GA). Manitoba has some of the highest rates of day surgery to treat ECC in Canada, an increasing trend especially in certain northern and inner-city communities.[3,4] Unfortunately, while the surgical approach to managing ECC is often needed, it does not address underlying risk factors for caries. In fact, studies have found relapse rates ranging from 22% to 58.5% after treatment for ECC under GA.[5,6] As a result, many children treated for ECC in this manner require repeat GA, an undesirable outcome given the risks and costs associated with this treatment modality.[7]

Silver diamine fluoride (SDF) represents a minimally-invasive approach to the management of ECC, which has traditionally employed surgical intervention.[8] Although SDF has been successfully utilized in other countries for decades, it was not approved for use in Canada until 2017.[9,10] To the best of our knowledge, there are no published studies investigating the use of SDF in the Canadian population, particularly in toddlers and preschool children. While several systematic reviews support the efficacy of SDF, they all indicate that further research and clinical trials

are needed to establish protocols for optimal case selection and utilization of SDF.[11–14]

To our knowledge, only one other study has investigated the relationship between oral health-related quality of life (OHRQoL) and SDF treatment of ECC.[15] This is an important concept to explore as it may provide valuable insight into how children and parents perceive the effects of this treatment modality and how it might affect children's OHRQoL. Additionally, it may aid in clinical decision making regarding which patients may benefit from SDF treatment and which patients may be more appropriately managed with conventional surgical treatment.

The aim of our study was twofold; to investigate the feasibility and efficacy of SDF in treating cavitated caries in young children and to explore the association between SDF treatment and OHRQoL.

Literature Review:

The burden of ECC is not distributed equally amongst the population and instead falls heavily upon certain socially disadvantaged subsets including racial and ethnic minorities, the poor, rural dwellers, and immigrants.[16] Early childhood prevalence rates within Canada have been reported to range from 53%[17] to over 90%[18] in disadvantaged urban populations and First Nations communities, compared to less than 5%[17,19] in the general population. The unequal distribution of this disease is also reflected in day surgery rates among different populations, with rates being 8.6 times as high for children from neighborhoods with high Aboriginal populations, 3.1 times as high for children from rural areas, and 3.9 times as high for children from the least affluent neighborhoods.[20]

The consequences of ECC are vast and can range from mild to severe to life-threatening.[21] Common sequelae of ECC include pain, infection, and dysfunctional eating and sleeping patterns.[21] ECC has been associated with altered nutritional status[22], behavioral problems[23], school absences and poorer school performance[24]. Overall, ECC has been found to negatively impact quality of life[25]. However, with the delivery of appropriate and timely treatment, oral health-related quality of life can be significantly improved.[26]

Silver diamine fluoride (SDF) provides an alternative for the management of ECC that is low cost, easy to use, minimally invasive, and requires no complex training or equipment, allowing it to be used in multiple settings beyond the community dental office.[27] SDF is a colorless liquid that is composed of silver, ammonia, and sodium fluoride and is used as a topical agent for the arrest of active

caries lesions.[9] While the silver exerts antimicrobial action upon cariogenic bacteria such as Streptococcus mutans, sodium fluoride promotes remineralization and inhibits cariogenic biofilm, and ammonia stabilizes the concentrations in solution.[28] SDF has been used in Japan since the 1960s[10] and in Australia, Brazil, Argentina, Mexico and China since the 1980s.[9] It was approved for use in the U.S.A. by the Food and Drug Administration in 2014 as Advantage Arrest (Elevate Oral Care) which is a 38% formulation. More recently, 38% SDF Advantage Arrest (Oral Science) received approval by Health Canada in February 2017.[9]

Clinical studies have demonstrated the success of SDF in arresting dentinal caries in children. A 2016 meta-analysis of data from five studies using 38% SDF to arrest dentin caries in primary and permanent teeth of children found that the overall proportion of arrested dentin caries was 65.9% (95% CI: 41.2% - 90.7%; $p<0.001$).[12] Another 2016 meta-analysis of data from 8 studies using 38% SDF to arrest caries in primary teeth found that the overall percentage of active caries that became arrested was 81% (95% CI, 68% - 89%; $p<0.001$).[11] Studies have found biannual application of SDF to be more effective in arresting caries as compared to annual application.[29,30] Caries removal prior to the application of SDF has shown no benefit.[31] Studies comparing the caries arresting effect of SDF to sodium fluoride varnish have found SDF to be more effective.[31,32] SDF has also been shown to be more effective than interim restorative treatment and glass ionomer.[29,33]

A systematic review of several clinical studies found that the most common adverse effects resulting from the use of SDF, in order of frequency, were black staining of the carious tooth structure and oral soft tissue irritation.[13] The latter

adverse effect was reported in one study in which 3 out of 225 children who received treatment with 38% SDF experienced transient tissue irritation in the form of a small, slightly painful white lesion on the mucosa which resolved spontaneously within 48 hours.[34]

To date, only one other published study has examined the relationship between the treatment of ECC with SDF and the impact on OHRQoL.[15] This is an important relationship to explore as it can potentially provide support for the use of SDF in public health strategies targeting ECC. Furthermore, this information can assist in identifying those children who may benefit the most from this treatment. The Early Childhood Oral Health Impact Scale (ECOHIS) is a validated survey-based tool that can be used to measure the impact of dental disease and treatment experience on the OHRQoL of preschool-aged children and their caregivers.[35] Of significance is that this tool captures *parental* perceptions of how their children's oral health problems, disease, symptoms, and treatment influence their children's quality of life.[35] This information provides important insight as it is parents and caregivers who act as the decision makers with regards to their children's oral and overall health.

Methods:

This study was a prospective convenience sample cohort pilot feasibility trial. Ethics approval was obtained from the University of Manitoba's Health Research Ethics Board. Children were recruited from three community clinics in Winnipeg, Manitoba and the study was conducted between June 2017 and November 2018.

Cooperative children less than 72 months old with at least one carious primary tooth meeting ICDAS (International Caries Detection and Assessment System) 5 or 6 criteria (i.e., dentinal caries) and without symptoms of pulpal involvement were included. Children allergic to silver or having hereditary dental alterations of teeth were excluded as were children with severe medical problems or emergent dental needs.

After written informed consent was obtained, the child's caregiver completed a baseline questionnaire, via interview, pertaining to child and family demographics, oral hygiene routines, fluoride intake, dietary habits, dental history, and appearance of the teeth. Participants underwent a dental examination without radiographs. Eligible cavitated lesions were treated with 38% SDF (Advantage Arrest, Oral Science). No caries excavation was performed however gross debris was removed. Using cotton isolation, lesions were dried with air or gauze, and a microbrush was used to apply the SDF for up to one minute, depending on the child's cooperation. Treated lesions were then rinsed with water or wiped with wet gauze, followed by fluoride varnish application (NUPRO 5% NaF white varnish). Parents were

instructed to have their child avoid eating and drinking for thirty minutes and to refrain from brushing the teeth until the next morning.

Four months after the baseline visit, participants returned for a second visit during which treated lesions were assessed to determine caries arrest. Lesions hard to tactile probing and black in color were determined to be successfully arrested. A second application of 38% SDF with 5% FV was performed on all previously treated lesions. Parents were asked to complete an Early Childhood Oral Health Impact Scale (ECOHIS) questionnaire via interview. Approximately four months after this second visit, participants returned for a third and final visit to assess caries arrest and to complete a follow-up questionnaire and a second ECOHIS questionnaire.

The colour (yellow, brown, black) and hardness (very soft, medium, very hard) of treated lesions as well as the dmft score were recorded at baseline and at each follow-up visit. The hardness was assessed by applying light force to the caries lesion with a probe. A single experienced examiner was involved throughout the study and was responsible for the application of SDF as well as the assessment of caries arrest. Participants were deemed Completely Successful (CS) if all of their treated lesions were found to be arrested and Incompletely Successful (IS) if at least one lesion was found not to have arrested. Treated teeth were assessed for the presence of pain and/or infection at each follow-up visit. The behavior of the child and difficulty encountered in providing treatment was also documented.

The Early Childhood Oral Health Impact Scale (ECOHIS) is a validated questionnaire which uses caregiver responses to assess the OHRQoL in preschool

children and their families and was administered by interview.[35] ECOHIS consists of 13 questions and is divided into 2 sections; the child impacts section (CIS) which has 4 domains (symptoms, function, psychological, self-image/social interaction) and the family impacts section (FIS) which has 2 domains (parent distress, family function).[35] Responses were coded according to ECOHIS protocol: 0 = never, 1 = hardly ever, 2 = occasionally, 3 = often, 4 = very often, 5 = don't know.[35] Total scores were calculated as a simple sum of the responses.[35] The CIS score can range from 0 to 36 and the FIS from 0 to 16, with the total possible score ranging from 0 to 52.[35] A higher score indicates a greater impact and a lower OHRQoL.

Data from the clinical assessments as well as from the ECOHIS questionnaires were entered into an Excel (Microsoft Office) database. Statistical analyses were performed using the Number Cruncher Statistical Software (NCSS-12, Kaysville, Utah). Both descriptive (frequencies and means) and bivariate (T-tests, and Fisher's exact tests) analyses were performed. A P value ≤ 0.05 was significant.

Results:

Participant Characteristics

A total of 40 children (45% male) with a mean age of 40.2 ± 14.9 months were recruited. Table 1 presents characteristics of children. Approximately one-third identified as refugees or newcomers (defined as <2 years in Canada). The mean number of ICDAS 5 and 6 lesions treated per child was 6.0 ± 3.8.

Lesion-level Analysis

A total of 239 caries lesions (111 anterior, 128 posterior) were treated with SDF at the baseline visit. The treated lesions were located on primary incisors (40.2%), canines (6.3%), first molars (30.5%), and second molars (23.0%). All participants returned for the second visit. It was determined that 74.1% lesions had arrested after one application of SDF (Figure 1). Two children presented with an abscessed SDF-treated tooth and one child had an abscessed tooth extracted prior to the second visit. The mean dmft score increased from 5.9 ± 3.2 at baseline to 6.0 ± 3.3. The mean time elapsed between the baseline and second visit was 16.7 ± 2.8 weeks.

All participants returned for the third and final visit. Two lesions were excluded from analysis as one tooth was extracted for an unknown reason prior to the third visit, and another had insufficient data recorded to determine arrest, reducing the total lesions to 237 (111 anterior, 126 posterior). It was determined that 96.2% lesions had arrested after two applications of SDF (Figure 1). The mean dmft score increased significantly from 6.0 ± 3.3 at second visit to 6.3 ± 3.3 (paired

t-test, p=0.036). The mean time elapsed between the second and third visit was 18.0 ± 3.6 weeks.

Figure 2 presents the success of SDF by specific primary teeth. Other than the mandibular incisors and canines, which had only five lesions, the mandibular first molar had the lowest arrest rate (66.7%) of all teeth after one application of SDF. Arrest rates for all teeth were higher after two applications of SDF. While the success of SDF in arresting interproximal lesions versus those on other surfaces was comparable after a single application, interproximal lesions on posterior teeth were found to have a notably lower arrest rate after two applications (Figure 3).

Child-level analysis

At the second visit, 17 (42.5%) participants were determined to be in the CS (completely successful) group and 23 (57.5%) in the IS (incompletely successful) group. Participants noted above who presented with abscessed teeth following SDF application or for whom arrest data was unknown or missing were classified as IS. Chi-square analyses revealed no significant relationships between arrest and sex, frequency of toothbrushing, difficulty providing treatment, or use of fluoridated toothpaste (Table 2).

At the third visit, 34 (85.0%) participants were found to be CS and 6 (15.0%) were found to be IS. Chi-square analysis revealed a significant relationship between the frequency of toothbrushing and successful arrest, with brushing twice daily associated with a greater likelihood of being in the CS group (p=0.006). A significant association was observed between baseline dmft score and arrest at third visit, with

participants in the CS group having a lower mean score of 5.4 compared to 8.8 in the IS group (two-sample t-test, p= 0.048).

ECOHIS

ECOHIS results are shown in Table 3. At the second visit, mean total ECOHIS score was 3.8 ± 4.4 (out of a possible score of 52), with the mean CIS score of 1.9 ± 3.1 (out of a possible 36) and mean FIS score of 1.9 ± 2.1 (out of a possible 16). Third visit mean scores were 2.7 ± 3.8, 1.3 ± 2.8 and 1.4 ± 2.0 respectively and were not significantly different than second visit scores. Only two parameters had an increased score; "difficulty drinking" in the CIS and "felt guilty" in the FIS. There was no significant difference in mean total, CIS, or FIS scores between CS and IS groups.

Discussion:

This study was a pilot feasibility trial which sought to investigate the efficacy of SDF with 5% FV in treating cavitated caries lesions in young children and the association with OHRQoL. There are few definitive guidelines for its use in this population as a nonsurgical alternative to caries management. Our study may contribute to the formation of a protocol which can be utilized by clinicians to appropriately select and treat patients with SDF, particularly those patients for whom conventional surgical management is difficult (due to special needs, behavior, young age, or lack of access to care), not indicated, or delayed (due to long GA waitlist times or administrative barriers).

Our study demonstrated that two applications of SDF are more effective than a single application. Although variability in arrest rates was observed amongst tooth types and location, arrest rates in all situations were higher after two applications. Increased success with more frequent applications of SDF has been reported in other studies.[29,30] Zhi et al. conducted a 24 month study and reported an arrest rate of 79% when SDF was applied every 12 months and 91% when applied every 6 months.[29] A 30 month study by Fung et al. reported a 66.9% arrest rate for annual application and 75.7% for biannual application.[30] As a result of these findings, it is recommended that patients receive more than one application of SDF for optimal results.

In our study, higher arrest rates were observed for anterior (ie., incisors and canines) as compared to posterior lesions. This finding is consistent with several other studies and may be attributed to the increased accessibility of anterior lesions

for cleansing.[29,30] While the arrest rates of lesions located on both interproximal and other (i.e., occlusal, buccal, lingual) surfaces were comparable after a single application of SDF, posterior interproximal lesions were found to have a notably lower arrest rate as compared to those on other surfaces after two applications. Other studies have also found interproximal lesions to be less successfully treated as compared to other surfaces.[29,30] This also may be due to the increased difficulty in cleansing these surfaces as well as the increased likelihood for food impaction to occur.

Children who reportedly brushed twice daily were more likely to be CS at the third visit as compared to those who brushed less. Also, children who were CS at third visit were found to have a lower baseline dmft compared to those who were IS. One study found that poor oral hygiene as indicated by higher VPI (visible plaque index) was associated with a lower arrest rate with annual application of SDF; however, the arrest rate increased with biannual application.[30] In contrast, another study found no association between baseline dmft or frequency of toothbrushing with caries arrest.[29] This discrepancy is possibly due to toothbrushing being a less accurate measure of oral hygiene than VPI, with the former being dependent upon technique and parental report. The results of the present study suggest that children with poor adherence to recommended oral hygiene practices and those who have a higher baseline dmft may require more frequent recall and application of SDF. However, VPI may be a more accurate parameter of oral hygiene to include in a future study design.

The increase in dmft observed between visits suggests that new caries lesions can still develop despite treatment with SDF on other teeth and surfaces. While one study had a similar finding, others found a significant reduction in the development of new caries in children treated with SDF as compared with children receiving no treatment.[30,34,36] Although the development of new caries lesions may be reduced with SDF treatment, no studies have demonstrated an absolute reduction. Therefore, it is prudent to emphasize the importance of maintaining good oral hygiene practices in conjunction with SDF treatment. After all, SDF also does not address underlying risk factors for ECC.

No difference in OHRQoL was observed between CS and IS groups, a finding consistent with another study.[15] This is likely because children who had emergent treatment needs were excluded and therefore participants of the study had less extensive dental needs and presumably higher OHRQoL initially, making treatment effects less pronounced. This may also explain why ECOHIS scores were low overall. The increase in the parental distress parameter "felt guilty" was also observed in the other study and may be explained by the black staining which serves as a daily visual reminder to the parents of their child's past caries experience.[15] Of note, among all of the parents who were approached to have their child(ren) participate in the study, only one parent declined, suggesting high parental acceptance of SDF treatment. Fortunately, there was also a qualitative component of this study, which should elicit further information on parental views and attitudes towards SDF as a caries management agent and will be reported subsequently.

A study limitation was the lack of a baseline ECOHIS assessment. Without this information, a potential decrease in OHRQoL between the baseline and second visit would not be identified. Other limitations include a small sample size and no control group as our study was a pilot feasibility trial. Due to the obvious black staining resulting from SDF treatment, it was not possible to include a blind observer in the study design. No radiographs were obtained due to the young age and resultant guarded cooperation of the participants. As a result, eligible teeth were selected based on clinical examination which may have failed to accurately assess the proximity of caries to the pulp in some cases. Study strengths are a longitudinal design with no participant drop-out and a sample representative of the patients who may benefit the most from SDF, with a high proportion of refugees and newcomers.

This study can inform both general and pediatric dentists of optimal patient selection and treatment protocol for the management of ECC with SDF. It can also support the validation and refinement of protocol and research methodology for future investigations and clinical use. SDF has the capacity to be utilized in a vast array of situations due to its low cost, simple application, and minimal requirement for special equipment. Patients who may not otherwise receive dental care due to financial or geographic barriers could benefit greatly from SDF treatment. SDF may be used as definitive treatment in situations where the tooth is expected to exfoliate shortly, and the loss of tooth structure does not severely compromise function. Consideration should be given to routinely employing SDF as an adjunct to surgical treatment in order to slow or halt disease progression while children await GA. If

such use becomes the standard of care, the morbidity associated with ECC could be greatly reduced in that fewer extractions and pulp treatments may be required by the time the child is seen for definitive treatment. SDF can also be used to manage ECC until the child's age and cooperation allow for conventional treatment in a clinical setting, thereby reducing the dependence on GA and alleviating scarce hospital and health care system resources. This would allow for the reallocation of funds to more effective primary and secondary methods of prevention.

Conclusions:

In the short term – at least up to 8 months – SDF with 5% FV is an effective secondary prevention approach to the management of ECC and more than one application is recommended along with regular follow-up of patients. The importance of optimal homecare including twice daily brushing must be emphasized in patients undergoing treatment with SDF in order to maximize efficacy and prevent the development of new caries. Children with relatively lower baseline dmft scores may experience greater success with SDF treatment as compared to those with higher scores. OHRQoL assessment may guide patient selection and help to differentiate children with lower disease severity who may be treated with SDF from those with more severe disease, especially in the molars, who may require more conventional surgical treatment. From the clinical practice perspective, it will be essential to perform follow-up studies to determine how SDF-treated children compare to those treated by conventional methods over the long-term.

Acknowledgements:

Dr. Schroth holds a Canadian Institutes of Health Research Embedded Clinician Researcher salary award in "Improving access to oral health care and oral health care delivery for at-risk young children in Manitoba." Operating funds for this research were provided through Dr. Schroth's CIHR Embedded Clinician Researcher program funds as well as the Dr. Gerald Niznick College of Dentistry, University of Manitoba. Thank you to Jeanette Edwards BOT, MHA, Pamela Dahl DMD, Geert W 'tJong, Lisette Dufour RDH, and Khalida Hai-Santiago DMD for their contributions.

Table 1: Baseline characteristics of participants

	N (%)
Sex	
Male	18 (45.0)
Female	22 (55.0)
Age (months) ± SD, range	40.2 ± 14.9, 17-71
Dental Insurance	
Yes	12 (30.0)
No	25 (62.5)
Unsure	3 (7.5)
Refugee/Newcomer	
Yes	14 (35.0)
No	26 (65.0)
Ethnicity	
African	16 (40.0)
Asian	17 (42.5)
Caucasian	3 (7.5)
Other	4 (10.0)
Use of fluoridated toothpaste	
Yes	25 (62.5)
No	1 (2.5)
Unsure	14 (35.0)
Frequency of toothbrushing	
Once daily	9 (22.5)
Twice daily	28 (70.0)
Every other day	2 (5.0)
Never	1 (2.5)
	Mean (±SD)
Baseline dmft	5.9 ± 3.2
Number of lesions treated per child (ICDAS 5 and 6)	6.0 ± 3.8

Figure 1: Arrest rates for all lesions, anterior lesions, and posterior lesions after SDF treatment

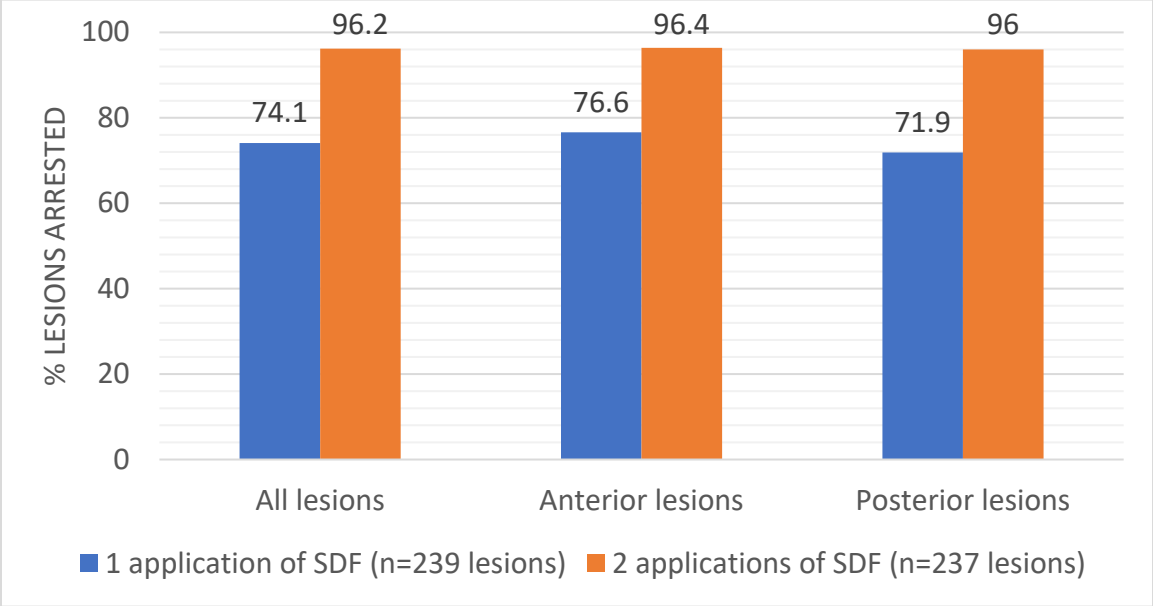

Figure 2: Arrest rates by tooth type after SDF treatment

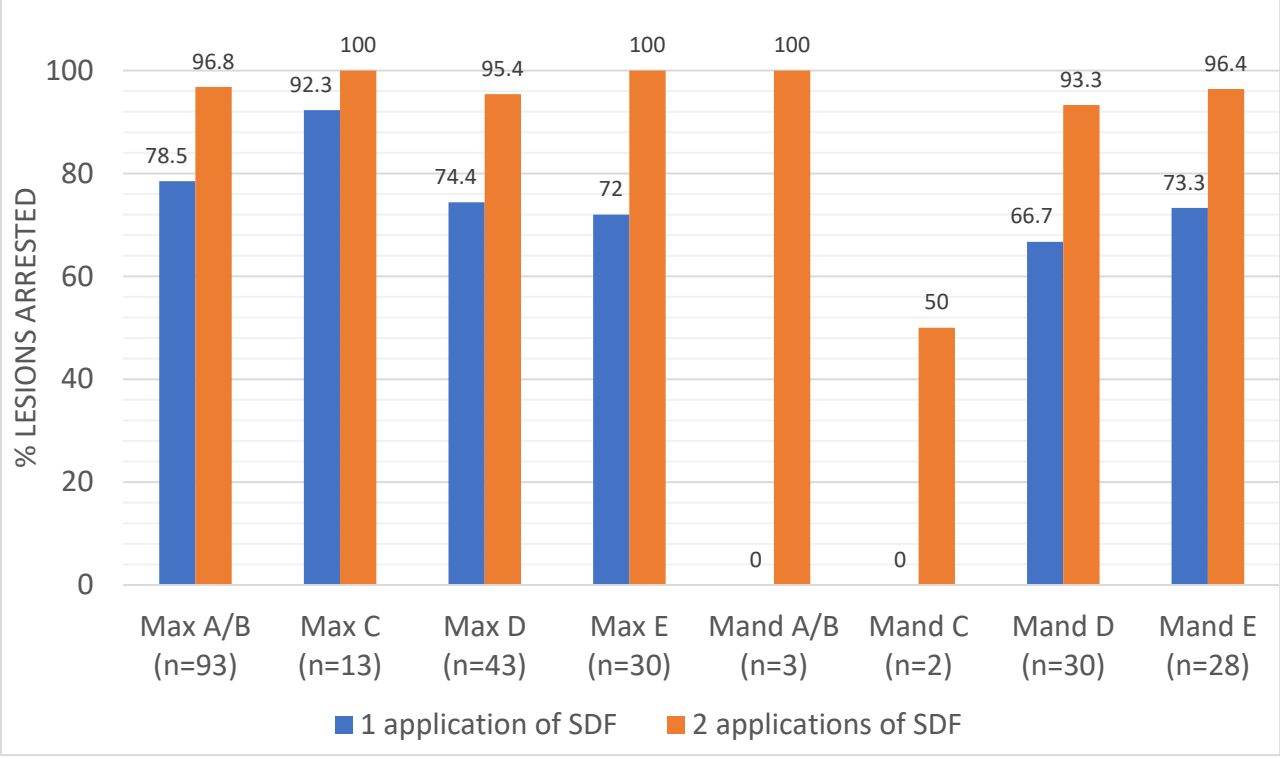

Figure 3: Arrest rates by location and surface after SDF treatment

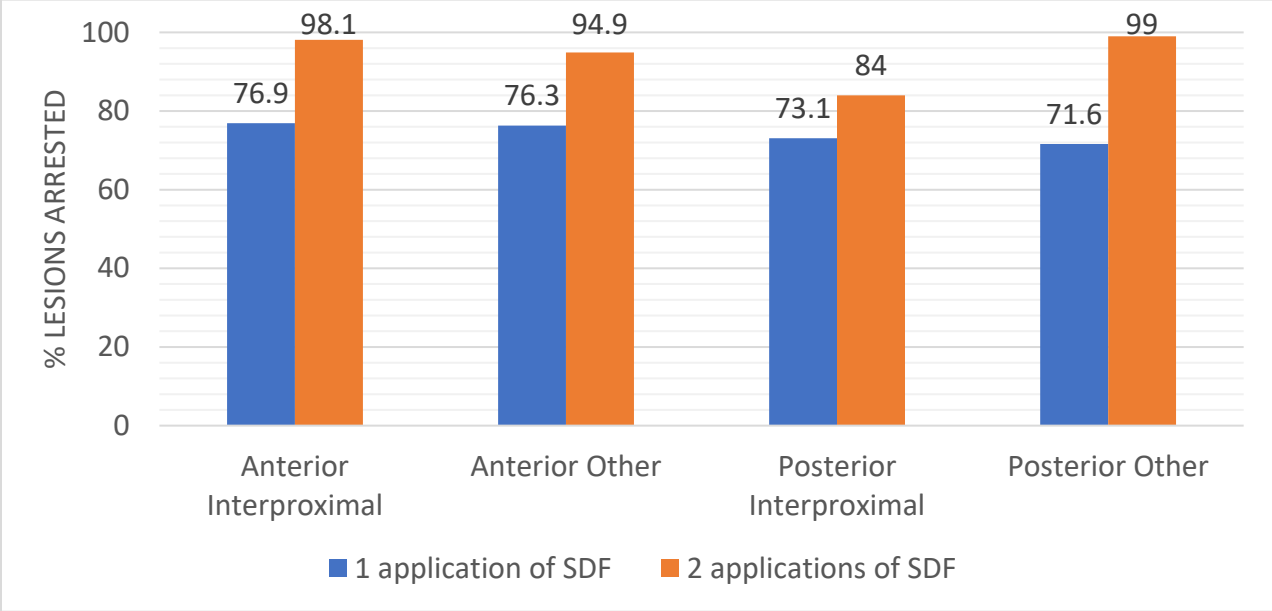

Table 2: Results of Fisher's exact tests to determine association between child-level factors and success of SDF treatment

	Second Visit			**Third Visit**		
	Complete Success N (%)	Incomplete Success N (%)	P-value	Complete Success N (%)	Incomplete Success N (%)	P-value
Sex						
Male	6 (33.3)	12 (66.7)		14 (77.8)	4 (22.2)	
Female	11 (50.0)	11 (50.0)	0.289	20 (90.9)	2 (9.1)	0.381
Frequency of toothbrushing						
2x Daily	12 (42.9)	16 (57.1)		27 (96.4)	1 (3.6)	
<2x Daily	5 (41.7)	7 (58.3)	0.944	7 (58.3)	5 (41.7)	0.006
Difficulty providing treatment						
Yes	3 (33.3)	6 (66.7)		7 (70.0)	3 (30.0)	
No	14 (45.2)	17 (54.8)	0.527	27 (90.0)	3 (10.0)	0.153
Use of fluoridated toothpaste						
Yes	13 (52.0)	12 (48.0)		21 (84.0)	4 (16.0)	
No/Unsure	4 (26.7)	11 (73.3)	0.117	13 (86.7)	2 (13.3)	1.000

Table 3: Baseline and follow-up ECOHIS scores (n=40)

	SECOND VISIT (N = 40) ***THIRD VISIT (N=40)***					
CHILD IMPACT SECTION	**Mean (±SD)**	Never N (%)	Hardly ever N (%)	Occasionally N (%)	Often N (%)	Very Often N (%)
Child Symptoms: Question one	**0.60 (0.87)** ***0.30 (0.72)***					
1) Oral/dental pain		25 (62.5) *33 (82.5)*	7 (17.5) *3 (7.5)*	7 (17.5) *3 (7.5)*	1 (2.5) *1 (2.5)*	0 (0) *0 (0)*
Child Functions: Questions two through five	**0.78 (1.73)** ***0.73 (1.48)***					
2) Difficulty drinking		37 (92.5) *34 (85.0)*	1 (2.5) *3 (7.5)*	1 (2.5) *3 (7.5)*	1 (2.5) *0 (0)*	0 (0) *0 (0)*
3) Difficulty eating		35 (87.5) *35 (85.7)*	2 (5.0) *2 (5.0)*	1 (2.5) *1 (2.5)*	1 (2.5) *1 (2.5)*	1 (2.5) *1 (2.5)*
4) Difficulty pronouncing words		35 (87.5) *37 (92.5)*	2 (5.0) *0 (0)*	0 (0) *2 (5.0)*	3 (7.5) *1 (2.5)*	0 (0) *0 (0)*
5) Missed preschool or school		37 (92.5) *38 (95.0)*	3 (7.5) *2 (5.0)*	0 (0) *0 (0)*	0 (0) *0 (0)*	0 (0) *0 (0)*
Child Psychological: Questions six and seven	**0.33 (0.76)** ***0.2 (0.85)***					
6) Trouble sleeping		37 (92.5) *37 (92.5)*	2 (5.0) *3 (7.5)*	1 (2.5) *0 (0)*	0 (0) *0 (0)*	0 (0) *0 (0)*
7) Irritable or frustrated		35 (87.5) *38 (95.0)*	2 (5.0) *1 (2.5)*	2 (5.0) *0 (0)*	1 (2.5) *0 (0)*	0 (0) *1 (2.5)*
Child Self Image/Social Interaction: Questions eight and nine	**0.23 (0.70)** ***0.08 (0.47)***					
8) Avoid smiling or laughing		36 (90.0) *39 (97.5)*	2 (5.0) *0 (0)*	2 (5.0) *0 (0)*	0 (0) *1 (2.5)*	0 (0) *0 (0)*
9) Avoid talking		38 (95.0) *40 (100.0)*	1 (2.5) *0 (0)*	1 (2.5) *0 (0)*	0 (0) *0 (0)*	0 (0) *0 (0)*
Child Section Total Questions one through nine	**1.93 (3.13)** ***1.30 (2.84)***					
FAMILY IMPACT SECTION						
Parental Distress: Questions ten and eleven	**1.03 (1.69)** ***0.93 (1.58)***					
10) Been upset		29 (72.5) *35 (87.5)*	3 (7.5) *0 (0)*	6 (15.0) *5 (12.5)*	1 (2.5) *0 (0)*	1 (2.5) *0 (0)*
11) Felt guilty		31 (77.5) *29 (72.5)*	1 (2.5) *1 (2.5)*	6 (15.0) *6 (15.0)*	2 (5.0) *2 (5.0)*	0 (0) *2 (5.0)*
Family Function: Questions twelve and thirteen	**0.83 (1.30)** ***0.5 (1.06)***					
12) Time off work		31 (77.5) *32 (80.0)*	2 (5.0) *3 (7.5)*	5 (12.5) *4 (10.0)*	2 (5.0) *1 (2.5)*	0 (0) *0 (0)*
13) Financial impact		32 (80.0) *36 (90.0)*	2 (5.0) *2 (5.0)*	5 (12.5) *2 (5.0)*	1 (2.5) *0 (0)*	0 (0) *0 (0)*
Family Section Total Questions ten through thirteen	**1.85 (2.07)** ***1.43 (1.95)***					
Total ECOHIS Score Questions one through thirteen	**3.78 (4.44)** ***2.73 (3.75)***					

References:

1. American Academy of Pediatric Dentistry. Policy on Early Childhood Caries (ECC): Classifications, Consequences, and Preventive Strategies. *Pediatr Dent Ref Man*. 2016;38(6):52-54.
2. American Academy of Pediatric Dentistry. Behavior Guidance for the Pediatric Dental Patient. *Pediatr Dent Ref Man*. 2018;40(6):254-267.
3. Schroth RJ, Quiñonez C, Shwart L, Wagar B. Treating early childhood caries under general anesthesia: a national review of Canadian data. *J Can Dent Assoc (Tor)*. 2016;82(g20).
4. Schroth RJ, Pang JL, Levi JA, Martens PJ, Brownell MD. Trends in pediatric dental surgery for severe early childhood caries in Manitoba, Canada. *J Can Dent Assoc*. 2014;80(e65).
5. Amin M, Nouri R, ElSalhy M, Shah P, Azarpazhooh A. Caries recurrence after treatment under general anaesthesia for early childhood caries: a retrospective cohort study. *Eur Arch Paediatr Dent*. 2015;16:325-331. doi:10.1007/s40368-014-0166-4.
6. Batawi HY El. Factors affecting clinical outcome following treatment of early childhood caries under general anaesthesia: a two-year follow-up. *Eur Arch Paediatr Dent*. 2014;15:183-189. doi:10.1007/s40368-013-0081-0.
7. Schroth RJ, Smith W. A review of repeat general anesthesia for pediatric dental surgery in Alberta, Canada. *Pediatr Dent*. 2007;29(6):480-487.
8. Clarkson BH, Exterkate RAM. Noninvasive dentistry: A dream or reality? *Caries Res*. 2015;49 suppl 1(1):11-17. doi:10.1159/000380887.
9. Martel S. Silver Diamine Fluoride: New in North America! *Oral Health*. July 2017:36-38.
10. Yee R, Holmgren C, Mulder J, Lama D, Walker D, van Palenstein Helderman W. Efficacy of silver diamine fluoride for arresting caries treatment. *J Dent Res*. 2009;88(7):644-647. doi:10.1177/0022034509338671.
11. Gao S, Zhao I, Hiraishi N, et al. Clinical trials of silver diamine fluoride in arresting caries among children: a systematic review. *JDR Clin Transl Res*. 2016;1(3):201-210.
12. Gao SS, Zhang S, Mei ML, Lo EC-M, Chu C-H. Caries remineralisation and arresting effect in children by professionally applied fluoride treatment – a systematic review. *BMC Oral Health*. 2016;16(12). doi:10.1186/s12903-016-0171-6.
13. Contreras V, Toro MJ, Eliás-Boneta AR, Encarnación-Burgos A. Effectiveness of silver diamine fluoride in caries prevention and arrest: A systematic literature review. *Gen Dent*. 2017;65(3):22-29.
14. Duangthip D, Jiang M, Chu CH, Lo EC. Non-surgical treatment of dentin caries in preschool children – systematic review. *BMC Oral Health*. 2015;15(44). doi:10.1186/s12903-015-0033-7.
15. Duangthip D, Gao SS, Chen KJ, Lo ECM, Chu CH. Oral health-related quality of life of preschool children receiving silver diamine fluoride therapy: A prospective 6-month study. *J Dent*. 2019. doi:10.1016/j.jdent.2018.12.004.
16. Vargas CM, Ronzio CR. Disparities in Early Childhood Caries. *BMC Oral Health*.

2006;6(Suppl I:S3). doi:10.1186/1472-6831-6-S1-S3.
17. Schroth RJ, Moore P, Brothwell DJ. Prevalence of Early Childhood Caries in 4 Manitoba Communities. *J Can Dent Assoc*. 2005;71(8):567.
18. Schroth RJ, Smith PJ, Whalen JC, Lekic C, Moffatt MEK. Prevalence of caries among preschool-aged children in a Northern Manitoba Community. *J Can Dent Assoc (Tor)*. 2005;71(1):27.
19. Al-Jewair TS, Leake JL. The Prevalence and Risks of Early Childhood Caries (ECC) in Toronto, Canada. *J Contemp Dent Pract*. 2010;11(5):1-9.
20. Canadian Institute for Health Information. *Treatment of Preventable Dental Cavities in Preschoolers: A Focus on Day Surgery Under General Anesthesia*. Ottawa, ON; 2013.
21. Casamassimo PS, Thikkurissy S, Edelstein BL, Maiorini E. Beyond the dmft. *J Am Dent Assoc*. 2009;140(6):650-657. doi:10.14219/jada.archive.2009.0250.
22. Khanh LN, Ivey SL, Sokal-Gutierrez K, et al. Early childhood caries, mouth pain, and nutritional threats in Vietnam. *Am J Public Health*. 2015;105(12):2510-2517.
23. Williamson R, Oueis H, Casamassimo PS, Thikkurissy S. Association between early childhood caries and behaviour as measured by the child behaviour checklist. *Pediatr Dent*. 2008;30(6):505-509.
24. Jackson SL, Vann Jr. WF, Kotch JB, Pahel BT, Lee JY. Impact of poor oral health on children's school attendance and performance. *Am J Public Health*. 2011;101(10):1900-1906.
25. Cunnion D, Casamassimo MP, Spiro III MA, et al. Pediatric oral health-related quality of life improvement after treatment of early childhood caries: a prospective multisite study. *J Dent Child*. 2010;77(1):4-11.
26. Jankauskiene B, Virtanen JI, Kubilius R, Narbutaite J. Oral health-related quality of life after dental general anesthesia treatment among children: a follow-up study. *BMC Oral Health*. 2014;14(81).
27. Chu C LE. Promoting caries arrest in children with silver diamine fluoride: a review. *Oral Heal Prev Dent*. 2008;6:315-321.
28. Rosenblatt A, Stamford TCM, Niederman R. Silver diamine fluoride: a caries "silver-fluoride bullet." *J Dent Res*. 2009;88(2):116-125. doi:10.1177/0022034508329406.
29. Zhi QH, Lo ECM, Lin HC. Randomized clinical trial on effectiveness of silver diamine fluoride and glass ionomer in arresting dentine caries in preschool children. *J Dent*. 2012;40:962-967. doi:10.1016/j.jdent.2012.08.002.
30. Fung M, Duangthip D, Wong M, Lo E, Chu C. Randomized clinical trial of 12% and 38% silver diamine fluoride treatment. *J Dent Res*. 2017.
31. Chu C, Lo E, Lin H. Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin caries in Chinese pre-school children. *J Dent Res*. 2002;81(11):767-770.
32. Duangthip D, Chu CH, Lo ECM. A randomized clinical trial on arresting dentine caries in preschool children by topical fluorides - 18 month results. *J Dent*. 2016;44:57-63. doi:10.1016/j.jdent.2015.05.006.
33. Dos Santos VE, De Vasconcelos FMN, Ribeiro AG, Rosenblatt A. Paradigm shift in the effective treatment of caries in schoolchildren at risk. *Int Dent J*.

2012;62:47-51. doi:10.1111/j.1875-595X.2011.00088.x.
34. Llodra J, Rodriguez A, Ferrer B, Menardia V, Ramos T, Morato M. Efficacy of Silver Diamine Fluoride for Caries Reduction in Primary Teeth and First Permanent Molars of Schoolchildren: 36-month Clinical Trial. *J Dent Res*. 2005;84(8):721-724.
35. Pahel BT, Rozier G, Slade GD. Parental perceptions of children's oral health: The Early Childhood Oral Health Impact Scale (ECOHIS). *Health Qual Life Outcomes*. 2007;5(6). doi:10.1186/1477-7525-5-6.
36. Lo ECM, Chu CH, Lin HC. A Community-based Caries Control Program for Pre-school Children Using Topical Fluorides: 18-month Results. *J Dent Res*. 2001. doi:10.1177/00220345010800120901.