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Silver Diamine Fluoride and Oral Health-Related Quality of Life

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Silver Diamine Fluoride Application and Oral Health-Related Quality of Life

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Dentistry at Virginia Commonwealth University.

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Abstract

SILVER DIAMINE FLUORIDE APPLICATION AND ORAL HEALTH-RELATED QUALITY OF LIFE

By Nazafarin Javdan DDS

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Dentistry at Virginia Commonwealth University.

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Purpose: The purpose of this study was to study the association between Silver Diamine Fluoride (SDF) and Oral Health-Related Quality of Life as assessed by "The Early Childhood Oral Health Impact Scale" questionnaire. **Methods**: Parents of healthy children (ASA I and II) ages 1-5 with early childhood caries with reversible pulpitis who had application of SDF filled out a questionnaire at baseline and again after one month. The questionnaire was designed to evaluate the child's behavior, physical abilities, pain, temperament, and how well the child gets along with others. **Results**: Wilcoxon Signed Rank Test was used to determine if responses to

various ECOHIS items and the total scores were different between the two time points.

Conclusion: Children with dental caries who had application of SDF reported less dental pain, less eating problems, higher quality of sleep and overall higher quality of life at one-month follow up compared with the baseline.

Introduction

Tooth decay or dental caries is the single most common chronic childhood disease.[1] It is five times more common than asthma, four times more common than early childhood obesity, and twenty times more common than diabetes.[1] Early Childhood Caries (ECC) has been defined as "the presence of one or more decayed (non-cavitated or cavitated lesions), missing (due to caries) or filled tooth surfaces in any primary tooth in a child 71 months of age or younger." [1] Other names for early childhood caries are baby bottle tooth decay, nursing caries, nursing bottle syndrome or night bottle mouth.[1]

ECC can have tremendous effects on different aspects of children's lives, such as physical development, emotional growth, qualify of life, and learning at school. Dental pain and discomfort have been described as the most common reasons for seeking dental care.[2] The preschool period is very crucial to a child's development.[3] If left untreated, ECC can destroy the child's teeth and have a strong, lasting effect on a child's overall health. Children with ECC often need extensive dental treatment that is completed under oral sedation (OS) or general anesthesia (GA), because they are unable to cooperate in order to complete treatment in a clinical setting.

For many years oral health was considered insignificant; however, over the past two decades, oral health related quality of life (OHRQoL) has gained interest on an international

level.[4] OHRQoL is a multidimensional construct that reflects people's comfort when eating, sleeping, and engaging in social interaction, their self-esteem, and their satisfaction with respect to their oral health.[1] The most common impacts of ECC on OHRQoL reported by parents were pain in the teeth, mouth or jaws, irritation or frustration, difficulty eating and trouble sleeping.[5]

The caries experience and its impact on preschool children's quality of life has been investigated in various studies. One study conducted an oral questionnaire on 5 to 6 year-old children in Bangkok about their oral health-related quality of life. Also, they sent out behavioral questionnaires to parents. They found that 28% of children experienced impacts on their quality of life. 58% reported dental pain and 45% reported eating difficulties as their main concern. In addition, children from low socioeconomic status had higher level of dental caries and thus a lower OHRQoL score.[5]

A similar study investigated the impact of ECC on OHRQoL of preschool children and their parents using The Early Childhood Caries Oral Health Impact Scale (ECOHIS). They concluded that ECC has a negative impact on OHRQoL of children ages 2-5 as well as their parents. Also, as ECC increased in severity, there was an increased negative impact on OHRQoL.[6] A study in Brazil also concluded that dental pain negatively affected OHRQoL in children.[7] In addition, the family's quality of life was also affected by the child's oral health. [7]

Dental caries remains a significant disease of childhood. Treatment of dental caries in young children is very challenging and might require advanced skills and at an increased cost. Children with ECC often need extensive dental treatment which is completed under GA or OS.

Previous research has studied the quality of life of children before and after dental rehabilitation under GA.[8] For example, the association between early childhood caries and

behavior as measured by the Child Behavior Checklist has been studied.[8] They compared the behavior of caries free vs caries active children needing dental rehabilitation under GA. Sleep problems, aggressive behavior, attention deficit/hyperactivity problems, and total behavior problems were significantly more prevalent in caries-active children than in caries-free children.[8] OHQoL in young children after dental treatment under general anesthesia improved considerably.[9] As a result, parents reporting more smiling, improved school performance, and increased social interaction after dental rehabilitation under general anesthesia.[10]

Sometimes months will go by between the patient consultation and the actual treatment. This time lapse may be due to patient illness, family conflicts or provider conflicts. Untreated caries can lead to abscess formation, and the patient may therefore need to be seen in the Emergency Department (ED) for emergency care, which poses a societal financial burden. [11]

Until recently, caries in young children have been addressed through the use of sodium fluoride (NaF) varnish[12] and glass ionomer.[13] Silver Diamine Fluoride (SDF) is an FDA-approved for use as a desensitizing agent. It is a colorless solution which contains fluoride ions[14] and has proven to be effective in preventing and arresting dental caries[15] both for the primary teeth in preschool children [16] and the permanent teeth in older children.[17] It is also effective in the prevention of root caries in the elderly.[18]

Applications of SDF have been used to affect tooth enamel and prevent new caries formation. SDF has also been used to arrest caries on exposed dentin.[16,17] The recommended frequency of application to arrest caries is every six months to once a year.[16,17] SDF has been used to manage early childhood caries in children of low-income nations.[19] 38% SDF (44,800 ppm F) applied yearly to decayed surfaces of primary anterior teeth was found to be more effective in arresting caries than applications of NaF varnish every three months.[16] There are

several advantages in using SDF for caries treatment. It kills cariogenic bacteria and provides instant caries arrest. As result, it reduces pain and infection in children.[20] Furthermore, it is inexpensive and the treatment procedure is very simple and non-invasive. Thus, it is an effective material to use to arrest caries progression in very young children who are less cooperative until definitive restorative care can be completed. In addition, SDF can be used in community health clinics where there is limited access to dental care. Lastly, SDF has been used since the 1960s in Asian countries and no major complications have been reported. [20]

There are several disadvantages of using SDF, the first and foremost being that it stains the lesions black and has a metallic taste. [16] The black discoloration comes from a layer of silver phosphate (Ag_3PO_4), which is a hard and impermeable layer formed on the tooth upon application of SDF. [21] Ag_3PO_4 is yellow when it is first formed, but turns black under sunlight or reducing agents. The precipitation of silver sulphide also contributes to the dark color of caries lesions upon SDF application.[17] Another disadvantage of SDF application is that it can stain clothes and skin which cannot be easily washed away. Furthermore, gingival and mucosal irritation may occur and as a result, the affected tissue transiently turns white and may take one to two days to heal.[17] Lastly, SDF is sensitive to light and must be kept in dark containers.[20] In an effort to mask the dark discoloration, it has been suggested to use potassium iodide (KI), which reacts with the free silver ions to form a white substance of silver iodide. SDF/KI application has no significant difference in preventing biofilm formation[17] and bacterial inhibition compared with those of SDF alone.[22]

When SDF is applied, CaF_2, Ag_3PO_4 and Ag-protein are formed on the tooth surface. Ag-protein inhibits the growth of cariogenic bacteria and the formation of dental plaque.[23] CaF_2 provides a slow-release reservoir of fluoride ions for the formation of fluoroapatite ($Ca_{10}(PO_4)_6$

F_2), which is more resistant to acids than hydroxyapatite.[20] 38% SDF arrests dental caries by reducing the demineralization process. It minimizes the loss of mineral content and slows down collagen I destruction, which is the backbone of dentin matrix. Furthermore, it contains high concentrations of silver and fluoride ions, which can inhibit the growth of multi-species cariogenic biofilms.[24] 38% SDF results in a 96% reduction in caries for deciduous teeth, compared with a 55.6% reduction in caries for newly erupted permanent teeth. [25] Lastly, SDF has not been associated with an increased likelihood of teeth becoming non-vital after 30 months of its application.[16]

Zhang et al. concluded that the annual application of SDF along with oral hygiene instructions was effective in preventing new root caries formation and arresting existing root caries. [26] In addition, another study discovered that there were more surfaces with inactive caries and fewer new caries lesion surfaces in children who received SDF compared with children who did not. [27] 77% of the active caries that were treated became inactive during the study, and the efficacy of preventing new caries was 80% in the primary teeth and 65% in the first permanent molar.[27] Increasing the frequency of application of SDF from annually to every six months can increase caries arrest rate.[28]

It has been shown that application of 38% SDF arrests dentin caries in a shorter period of time compared with sodium fluoride (NaF) varnish application. [3] A study conducted in China concluded that an annual application of 38% SDF was more effective in hardening or arresting dentin caries in upper anterior primary teeth than the application of a 5% NaF varnish at 3-month intervals.[29] There was no difference in the ability to arrest caries between children who had their soft dentin caries removed prior to application of fluoride agents as compared with children who did not have their soft dentin caries removed. Thus, the application of SDF without prior removal

of caries makes the process of SDF application very easy, and this makes SDF advantageous for children who are pre-cooperative for routine dental care. Also, in areas where access to care is difficult for young children, SDF will make it possible for providers who lack the experience in the treatment of small children to successfully arrest carious lesions and monitor or refer to appropriate provider for more definitive care.

When looking at the effectiveness of SDF as compared to the traditional methods of caries control, one study compared the effectiveness of SDF and interim restorative treatment (IRT) using glass ionomer in arresting caries. [22] The results showed that there was a higher rate of failure when glass ionomer cements were used compared with when SDF was used. [22]

The purpose of this study was two-fold: to investigate the Oral Health-Related Quality of Life (OHRQoL) in preschool children with dental caries who had an application of SDF. In addition, we investigated the associations between oral health outcomes and patients' sociodemographic characteristics and oral health-related behaviors. Thus far, there has not been a study investigating the OHRQoL of children who have had application of SDF. Moreover, we included participants from various ages and genders. A parent-filled questionnaire (ECOHIS) was used to analyze the association between application of SDF and improvement in child's OHRQoL.[30] This questionnaire was designed to address the characteristics that affect oral health-related outcomes.[30]

Materials and Methods

The participants for the study were recruited from VCU Pediatric Dental clinic between February 2016 and November 2016, when they came to the clinic for a new patient examination or a consultation. Inclusion criteria were as follows:

1) Healthy children (ASA I and II) ages one through five with ECC who were difficult to treat due to behavior or medical management

2) Healthy children (ASA I and II) ages one through five with ECC that may not be treated in one visit

3) Healthy children (ASA I and II) ages one through five with ECC who benefitted from having their caries arrested and monitored until the patient is able to cooperative and have treatment successfully completed

4) Healthy children (ASA I and II) ages one through five with ECC who were high risk for developing more caries and 5) health children whose parents spoke English or Spanish

Exclusion criteria were as follows:

1) Children with complex medical history (ASA III or IV)

2) Children with silver allergy

3) Children with ulcerative gingivitis or stomatitis

4) Children who are cooperative enough to have definitive restorations placed

5) Children whose parents did not speak English or Spanish

Silver Diamine Fluoride was placed on carious teeth to help arrest caries, reduce symptoms for the time being until they were old enough to have definitive treatment in the chair or until their appointment for treatment under GA or OS. The extent of caries was quantified based on visual clinical examinations at VCU's Dental Clinic. We used the number of carious surfaces of the teeth to calculate a caries score for each patient, which was then used to summarize a child's OHRQoL based on their caries risk.

ECOHIS is a standardized instrument that has been used in literature before to measure OHRQoL.[30] This questionnaire consists of 13 oral health-related behaviors and asks parents various questions related to the child's behavior, physical abilities, growth/development, bodily pain/discomfort, temperament and moods, and how well the child gets along with others.[30] ECOHIS consists of two subscales: CIS (Childhood Impact Scores) and FIS (Family Impact Scores). CIS show the impact of dental caries on the child and FIS demonstrate the impact of dental caries on the family.

Data was collected through administering the "The Early Childhood Oral Health Impact Scale (ECOHIS)" questionnaire to parents when they came in for their child's new patient examinations or during consultations appointments for OS or GA. The ECOHIS was re-administered to the legal guardian after one month either in person for those who returned for the one-month follow-up or over the phone for those who did not return for the one-month follow-up or those who had treatment completed with oral sedation or under general anesthesia.

Descriptive statistics were used to summarize study participants. Wilcoxon Signed Rank Test was used to determine if responses to various ECOHIS items and the total scores were different between the two time points. All analyses were performed using system analytical

software (SAS). A significance level of 0.05 and SAS EG v. 6.1 was used for all analyses. The elements used were age, gender and extent of caries.

The participants were recruited by fully trained study staff (i.e., first and second year VCU pediatric dentistry residents and full-time faculty members) when patients presented to VCU Pediatric Dental Clinic for new patient exams or consultations. The study design, risks and benefits of SDF application, and the study forms were thoroughly explained to the parents by the study staff and informed consent was obtained from parents prior to application of SDF. Approval for this study was obtained from the Institutional Review Board, Committee on Human Research (VCU IRB# HM 20006295). Participation in the study was completely voluntary, and there was no charge to the patients for participation in the study. In addition, they were notified regarding the results of our study if they were interested.

Results

A total of 38 individuals were enrolled in the study between February 2016 and November 2016 and completed questionnaires at both time points. OHRQoL scores were calculated per the instructions. [30] Missing values were computed using the mean of the remaining items for the specific subscale CIS and FIS. Subjects who missed more than two items on the CIS and 1 on the FIS were excluded from analysis per the recommendations of the ECOHIS scoring. Thus, one subject was excluded due to skipping two of the FIS questions at baseline. A total of 37 subjects were included in the study. Demographics are given in Table 1.

As seen in Table 1, there were more female participants (68%) in the study than male participants (32%). In 78% of the participants, caries activity was monitored by scheduling patients for a one-month follow-up. 19% of participants had treatment under GA and 3% were treated under OS. The mean age was 2.9 years. In addition, there were more caries on the anterior teeth as opposed to caries on the posterior teeth. Consequently, more anterior teeth were treated with SDF than posterior teeth. The average time to follow-up was 32.7 days.

As demonstrated in Table 2, baseline CIS scores averaged 5.5 and follow-up CIS scores averaged 0.41. This average difference of 5.1 was statistically significant (p-value<0.0001). For

the FIS, the average baseline score was 2.5, which was reduced to 0.38 after SDF application (p-value=0.0004).

The baseline CIS standard deviation was 5.78 and the follow up CIS standard deviation was 1.14. Also, the baseline FIS standard deviation was 3.45, which was reduced to 1.20 after SDF application. Thus, there is a larger difference between the mean CIS and FIS baseline and follow up scores than there are in between the CIS and FIS standard deviation scores. This illustrates that there was a smaller range of scores at the follow up compared with the baseline. Thus, the improvement in the quality of life happened consistently.

Based on Table 3, each of the items on ECOHIS questionnaire demonstrated statistically significant reduction after SDF application. The items with the highest improvement rates were "having difficulty pronouncing any words" (46%) and "pain in the teeth, mouth or jaws" (41%) for the CIS and "feeling guilty" (35%) for the FIS.

As shown in r the FIS. , the majority of participants (27 out of 37) had a significantly lower CIS score at the follow up compared with the baseline. In 9 out of 37 participants, the CIS score stayed the same and in 1 participant, the CIS increased compared with the baseline. One participant (marked in red in Figure 1) reported having a worse sleep after SDF application. This could be due to not reading the questions correctly or personal bias.

As demonstrated in Figure 2, the majority of participants (18 out of 37) had a significantly lower FIS score at the follow up compared with the baseline. In 16 out of 37 participants, the FIS score stayed the same and in 2 participants, the CIS increased compared with the baseline. Two participants (marked in red in Figure 2) reported feeling guiltier and upset after SDF was applied.

This could be due to parents feeling guilty and upset over the fact that they failed to do a good job at keeping their child's teeth healthy and as evidenced by the discolored carious lesions.

Discussion

Tooth decay or dental caries is the single most common chronic childhood disease.[1] Early Childhood Caries is the presence of one or more decayed, missing or filled tooth surfaces in any primary tooth in a child 71 months of age or younger." ECC can have tremendous effects on different aspects of children's lives, such as physical development, emotional growth; qualify of life, and learning at school. Dental pain and discomfort have been described as the most common reasons for seeking dental care.[2] The preschool period is very crucial to a child's development.[3] If left untreated, ECC can result in significant destruction of the child's teeth, which in turn can result in lasting effects on a child's overall health. Children with ECC often need extensive dental treatment that is completed with oral sedation or under general anesthesia, because they are unable to cooperate in order to complete treatment in a clinical setting.

Children with ECC are considered to be at high caries risk, which means that the potential for future caries in these children is very high.[31] In addition to improvement in the quality of life for young patients, SDF can be used to decrease the incidence of future caries by allowing the provider to establish a dental home for these young patients where carious lesions are continually monitored while oral hygiene and dietary instructions are reinforced. [32]

Several different medicaments have been traditionally used to address caries in young children, such as sodium fluoride (NaF) varnish[12] and glass ionomer.[13] The advantages in using

SDF are that it kills cariogenic bacteria and provides instant caries arrest. Thus, it reduces pain and infection in children.[20] Moreover, it is inexpensive and the treatment procedure is very simple and non-invasive. As a result, it is an effective material to use to arrest caries progression in very young children who are less cooperative until definitive restorative care can be completed. In addition, SDF can be used in community health clinics where there is limited access to dental care. Lastly, SDF has been used since the 1960s in Asian countries and no major complications have been reported.[20] The major disadvantages of using SDF are its black staining on carious areas of the teeth and the possible gingival and mucosal irritation which may occur.

The significance of the current study is that we expanded our participants to all healthy children (ASA I and II) with early childhood caries with reversible pulpitis who benefited from application of SDF. Moreover, we included participants from various ages and genders. Lastly, we quantified the extent of caries observed in patients from all these categories and related extent of caries to overall quality of life. A comprehensive study similar to this study had not been completed before. A parent-filled "The Early Childhood Oral Health Impact Scale (ECOHIS)" questionnaire was used to analyze the association between application of SDF and child's Oral Health-Related Quality of Life. This questionnaire was designed such that it addressed the characteristics which affect oral health-related outcomes. We used the number of carious surfaces of the teeth to calculate a caries score for each patient which was then used to summarize a child's OHRQoL based on their caries risk. This study showed that there were statistically significant improvements in the quality of life of children and their families after SDF was applied. Children reported significantly less pain in the teeth, mouth or jaws, improvements pronouncing words, fewer missed preschool, daycare or school days and being less irritable and frustrated. In addition, families reported less financial impact from the child's

dental problems or treatment and feeling less guilty. Therefore, the results of this study show an association between SDF application and quality of life.

Primary school children are usually the main objective for oral health services and the preschool children are often overlooked.[5] The implication of this study is that more government resources should be allocated to have SDF readily available at community health centers to arrest dental caries in preschool children. Thus, government leaders and oral health care services should focus on raising awareness about oral health issues in preschool children.

This study had several limitations. We were not able to recruit a large number of patients as some parents opted out of the application of SDF for their child due to the black discoloration that results from it. Furthermore, there could have been bias in the responses of parents regarding their child's symptoms. For example, some parents might have reported fewer symptoms to avoid being perceived at as careless parents. In addition, some parents might not have spent adequate time to answer the questions on ECOHIS questionnaire. Many (approximately 50%) of the one month follow-ups were completed over the phone which could have resulted in a less accurate response rate versus the in person follow-ups in the clinic.

Future research is needed to explore a good material to avoid or reduce the amount of black staining which results from application of SDF on caries lesions. In addition, future studies should try to recruit more participants by using a material which would cover up the black discoloration which results from application of SDF. Future studies can include a larger sample size with greater consistency in the response rate by requiring that the follow-ups take place face to face in the clinic.

Conclusion

The goal of this study was to investigate the association between Silver Diamine Fluoride and Oral Health-Related Quality of Life as assessed by "The Early Childhood Oral Health Impact Scale (ECOHIS)" questionnaire. The following conclusions can be made from this study: ECOHIS consists of 2 subscales: CIS (Childhood Impact Scores) and FIS (Family Impact Scores). Each of the items on ECOHIS questionnaire demonstrated statistically significant reduction after SDF application. The items with the highest improvement rates were "having difficulty pronouncing any words" (46%) and "pain in the teeth, mouth or jaws" (41%) for the CIS and "feeling guilty" (35%) for the FIS. Considering these results, SDF can be presented as a alternative treatment option in patients who are not candidates for treatment under GA or OS due to various reasons such as age, medical history or finances. Moreover, SDF can be utilized as a temporary medicament to arrest caries for patients who will be receiving definitive treatment under GA or OS.

Primary school children are usually the main objective for oral health services, and the preschool children are often overlooked.[5] The implication of this study is that more government resources should be allocated to have SDF readily available at community health centers to arrest

dental caries in preschool children to improve their quality of life. Thus, government leaders and oral health services should focus on raising awareness about oral health in preschool children.

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Table 1: Sample Demographics

	n, %	
Gender		
Male	12, 32%	
Female	25, 68%	
Treatment Plan		
Monitoring	29, 78%	
OS	1, 3%	
GA	7, 19%	
	Mean, SD	Range
Age (mean, SD)	2.9, 1.3	1-6
Caries Score	4.2, 2.76	1-12
Anterior Cavities	2.4, 2.18	0-10
Anterior Treated with SDF	2.1, 2.18	0-10
Posterior Cavities	1.8, 1.97	0-7
Posterior Treated with SDF	1.5, 1.79	0-7
Time Between QOL Questionnaires (days)	32.7, 8.4	7-63

Table 2: Average ECOHIS Score at Baseline and Follow-up

	Baseline Mean, SD	Follow-up Mean, SD	Average Paired Difference, SD	P-value*
Child Impact Score	5.5, 5.78	0.41, 1.14	5.1, 5.66	<0.0001
Family Impact Score	2.5, 3.45	0.38, 1.20	2.1, 3.74	0.0004

*Wilcoxon Signed Rank Test

Table 3: Changes in ECOHIS Items and Subscales between Baseline and After SDF Application

CIS	Improved	Same	Worse	P-value*
Missed preschool, daycare or school.	14, 38%	23, 62%	0, 0%	0.0001
Had difficulty eating some food.	12, 32%	25, 68%	0, 0%	0.0005
Been irritable or frustrated.	14, 38%	23, 62%	0, 0%	0.0001
Pain in the teeth, mouth or jaws?	15, 41%	22, 59%	0, 0%	<0.0001
Had trouble sleeping.	13, 35%	23, 62%	1, 3%	0.001
Avoided smiling or laughing.	9, 24%	27, 73%	1, 3%	0.0391
Avoided talking.	10, 27%	27, 73%	0, 0%	0.002
Had difficulty drinking hot or cold beverages.	13, 35%	23, 62%	1, 3%	0.0045
Had difficulty pronouncing any words.	17, 46%	20, 54%	0, 0%	<0.0001
Total CIS Score	27, 73%	9, 24%	1, 3%	<0.0001
FIS				
Financial Impact on family from child's dental problems or treatments	10, 27%	26, 70%	1, 3%	0.0244
Felt guilty	13, 35%	22, 59%	2, 5%	0.0085
Been upset	11, 30%	24, 65%	2, 5%	0.0256
Taken time off from work	0, 0%	37, 100%	0, 0%	0.0001
Total FIS Score	18, 49%	17, 46%	2, 5%	0.0004

***from Wilcoxon Signed Rank Test**

Figure 1: Paired Child Impact Scores (CIS)

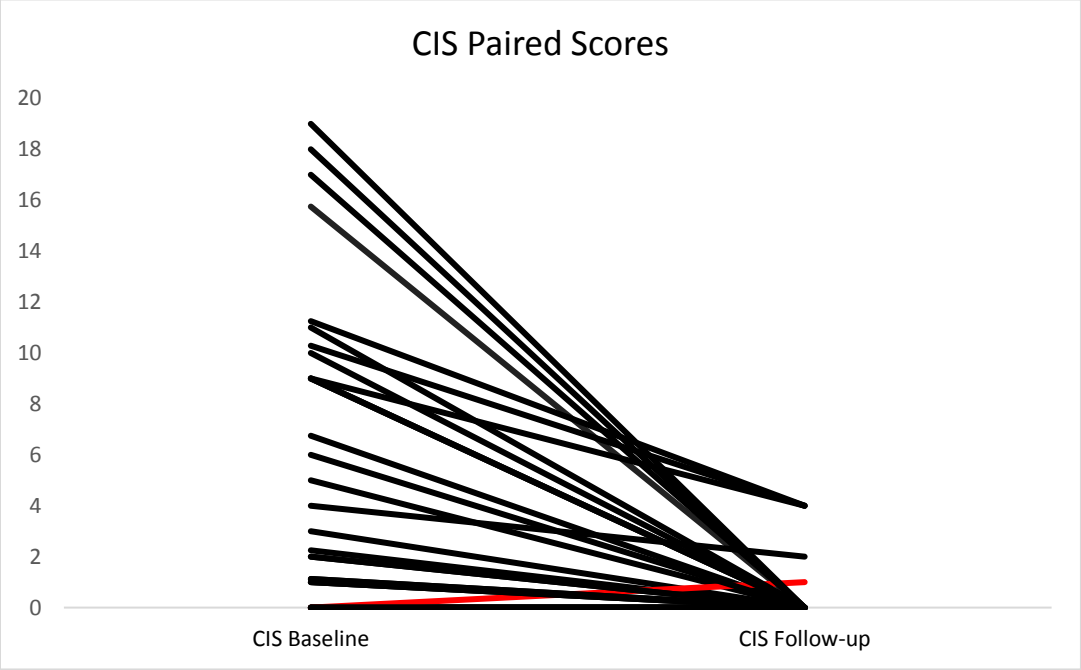
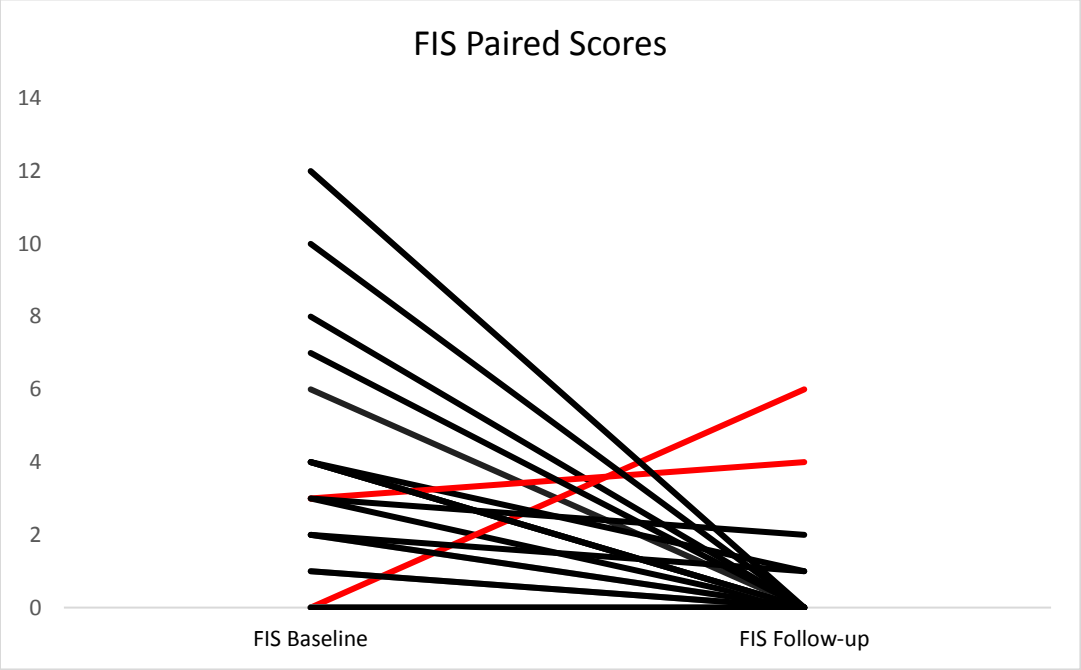


Figure 2: Paired Family Impact Scores (FIS)



Vita

Nazafarin Javdan was born on April 4, 1983 in Shiraz, Iran. She received her Bachelor of Science in Biologic Sciences from University of California, Los Angeles in 2008. She completed her Doctor of Dental Surgery degree from the University of California, Los Angeles in 2012. Nazafarin will complete her Pediatric Dentistry Residency at Virginia Commonwealth University in June 2017.