

Silver Diamine Fluoride: Changing the Caries Management Paradigm and Potential Societal Impact

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Silver diamine fluoride is a topically-applied agent for managing dental caries. It stops caries lesion progression, turning them black and hard in a high percentage of cases. Populations including pediatric, geriatric, special health care needs, and those with limited access to oral health care can all benefit from silver diamine fluoride. This commentary addresses some of the many questions that have arisen with the availability of SDF and marked gaps in our knowledge.

Silver diamine fluoride (SDF) has been used for decades to help manage dental caries in several countries and became available in the United States in March 2015. The FDA approved SDF as a desensitizing agent. Its use as a caries management therapy is an off-label use similar to fluoride varnish [1]. SDF provides a new and effective chemotherapeutic agent that can stop the progression of caries lesions and aid in the management of dental caries. Over the past 100 years, cavitated lesions caused by dental caries have been primarily managed surgically to remove the diseased tissues and replace the lost tooth structure with a variety of dental materials [2]. There have been multiple clinical trials and several systematic reviews indicating application of SDF will arrest or stop progression of caries lesions in a high percentage of cases (30%–70%) [3–6]. Repeated applications increase the caries lesion arrest rate [6]. Treated caries lesions become hard and black when the treatment is successful. In some cases, arrested lesions will become caries active with renewed loss of mineral and tooth structure.

As marketed in the United States, SDF is a solution of 25% silver, 8% amine, 5% fluoride, and 62% water (AgNH₂F) and is the most concentrated fluoride product commercially available for caries management (see Table 1). It is a clear liquid (new product is tinted blue to aid in clinical visualiza-

tion) that is applied to caries lesions with a microbrush [7]. The relative newness of SDF in the United States has led to a variety of questions related to what populations might benefit most from SDF, patient/parent acceptance, practitioner acceptance, if SDF will result in a shift from a traditional surgical to a non-surgical caries management approach, who can and should be able to apply SDF, and cost implications.

Potential SDF Benefits to Specific Populations and Patient/Parental Acceptance

Dental caries remains the most common chronic disease in the United States, affecting almost 35% of children (aged 2–5 years) and most adults by the end of adolescence [8, 9]. Populations with lower socioeconomic status and those with special health care needs have disproportionately high disease rates compared with the rest of the general population [10]. Managing dental caries in the pediatric population, especially children under the age of 3 years, often requires pharmacological behavior management approaches, including sedation and/or general anesthesia. These approaches are expensive and carry the potential risk of death. For children under the age of 3, there are concerns about neurological development with prolonged or repeated general anesthesia [11]. The use of SDF to prevent or delay surgical intervention until after the age of 3 years makes it a potentially attractive adjunctive therapy for managing caries in the very young pediatric population.

The use of SDF in the geriatric population has been shown effective in arresting root caries [5, 6]. Surgical approaches for managing root caries remain a challenge in this population, and having a chemotherapeutic option that can be delivered in a non-clinical setting has additional advantages. Both geriatric and patients with special health care needs can benefit from non-surgical SDF treatment that has few contraindications (eg, silver allergy) and is clinically less complicated to deliver than restorative treatment [12].

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TABLE 1.
Fluoride Content of Caries Management Therapeutics

Product	Fluoride %	Fluoride PPM	F Ion mg/ml
SDF	5	44,800	44.8
Varnish 5%NaF	-2.2	22,600	22.6
Toothpaste	-0.11	1100	1.1

Source. Modified from Crystal YO, Niederman R [4].

Parental acceptance for the pediatric population varies based on the patient's age, patient's sex, and whether the lesion to be treated is in a front or back tooth. Parents are more accepting of SDF treatment and the resulting black lesions for posterior teeth than anterior teeth, and more accepting for boys vs girls. In a recent study, over 60% of parents were accepting of SDF treatment and tooth discoloration of posterior teeth, but only 29% were accepting for anterior teeth [13]. The esthetic consequences of SDF treatment make gaining informed consent critical. Showing parents clinical photographs of treated lesions is recommended (see Figure 1). There are no studies related to acceptance of SDF treatment in adolescents, adults, or patients with special health care needs.

State Dental Boards have different regulations regarding who can apply SDF to patients. In Oregon and Washington, SDF can be applied by hygienists, while in North Carolina the Dental Board has taken the position that SDF should be applied by dentists. The North Carolina State Dental Board feels that arresting a carious lesion and turning it black is an irreversible procedure and should therefore be done by a dentist; the Board will have a hearing in November to discuss whether or not dental providers other than dentists (eg, dental hygienists) can place SDF. Restriction of SDF placement to only dentists has implications related to the availability of SDF to specific segments of the population (eg, nursing home occupants). Physicians and nurses can apply SDF in accordance with their state's practice acts.

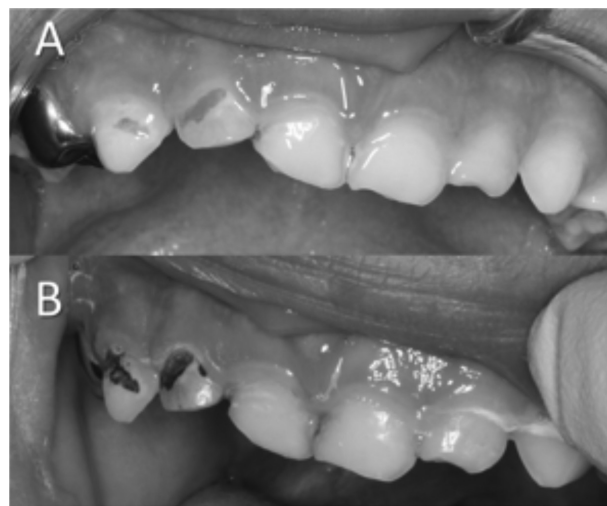
Practitioner Acceptance and Adoption (Surgical vs Non-Surgical Management)

Traditionally, dental practitioners have been educated and trained to manage cavitated caries lesions through a surgical approach. Studies show that removing bacteria-laden, demineralized dental tissues does not, in and of itself, change the individual's disease trajectory for developing new dental caries [14]. Adoption of new approaches for managing caries lesions by different providers of the oral health care delivery system varies, but adoption of non-surgical approaches, such as pit and fissure sealants, has been slow [15]. There are barriers to adoption of a new therapeutic approach such as SDF. For example, the use of SDF has not been taught in most dental schools and has only recently become a topic in pediatric dentistry residencies [16]. Common barriers to adopting new therapies and treatments include concerns regarding safety, efficacy, the variation in clinical trial methodologies, lack of clear treatment guidelines, regulation, patient attitudes, and reimbursement, to name a few.

Access to Care and Cost

The American Dental Association (ADA) adopted a billing code (D1354) that can be used for chemotherapeutic caries management that encompasses the use of SDF. There have been different interpretations of this code and whether

FIGURE 1. Carious lesions in these primary teeth prior to SDF show a yellow brownish discoloration (A). These same lesions seen one month after SDF treatment show the typically black discoloration (B) and had hardened or re-mineralized based on probing with a dental explorer.



Source. Modified from Crystal YO, Niederman R [4].

it should be reimbursed on a per visit bases or per tooth basis. North Carolina Medicaid set a reimbursement rate of \$24.18 per visit for application of SDF regardless of the number of teeth or dental surfaces treated. Reimbursement for SDF treatment has only been adopted by a few state Medicaid Programs and insurance carriers at this time, but others are examining inclusion of SDF as a reimbursable caries management therapy. As of August 2017, there were 14 state Medicaid programs that either had adopted (North Carolina has adopted coverage) or were considering reimbursement for SDF treatment. Without coverage by insurance programs, SDF has largely been paid for out-of-pocket, creating a significant barrier to its use. Millions of older and disabled individuals in the United States have to pay for their dental care as these services are not covered by Medicare [17].

There has been no actual cost analysis published regarding the use of SDF and its impact on oral health care expense. Evaluation of caries management approaches and costs for silver nitrate and fluoride varnish (SN/FV) in an Oregon-based study showed the SN/FV group received more preventive services, fewer restorative services, had fewer extractions, and had reduced billing for sedation [18]. However, the overall costs for care were 55% higher in the SN/FV group compared with those patients receiving conventional treatment. It is not known if there would be cost savings realized beyond the 2 years evaluated in the Oregon cohort study.

A fiscal impact study by North Carolina State Dental Medicaid found that \$35 million was spent for dental services provided with the aid of general anesthesia to chil-

dren 0–8 years of age. If only 10% of dental treatment with general anesthesia were prevented by SDF applications for 4–5-year-olds, the savings would be about \$746,000 (North Carolina Division of Medical Assistance, unpublished data, 2016). Other models included allowing SDF-treated teeth to exfoliate without needing restorative care. Treatment protocols for SDF do not require as many applications as are recommended for caries management with SN/FV. This difference could make SDF caries management more cost-effective than SN/FV, but studies need to be completed to better understand the real costs of SDF use in different populations.

States differ significantly in their regulations as to who and what is covered. For example, in Michigan this benefit is covered for all ages, while in North Carolina only children 5 years of age and younger are included. Programs also are limiting the service to 2 treatments per year and a lifetime cap of 6 total treatments. Some Medicaid programs state this is a temporary measure for caries management and is only to be applied when traditional restorative measures are not available (eg, Michigan). This approach has significant cost implications regarding the use of SDF, making it potentially an added cost as opposed to a cost-saving therapy.

Discussion

Dental caries continues to be highly prevalent in the United States and around the world, causing significant morbidity, including pain, suffering, loss of work and school time, loss of income, and the spending of billions of health care dollars [19]. The availability of SDF as a caries management therapeutic provides a potentially valuable new approach that could help stem the tide of the dental caries epidemic. There are diverse implications to broad use of SDF for managing dental caries that range from fiscal issues to oral health-related quality of life. There are numerous perceived and real barriers to the acceptance and application of new treatment approaches in health care, and there is little doubt that adoption of SDF by the dental community will face challenges [20]. Clinical trial methodologies have been variable, although the American Academy of Pediatric Dentistry has developed a recently published clinical care guideline for SDF [21].

The surgical paradigm for caries management is pervasive in dental education and practice, and significant shifts in philosophies for treatment and reimbursement are needed to manage dental caries as a chronic disease. Dental fear is a strong predictor of oral health-related quality of life. Similarly, pain as the reason for seeking recent dental care also is associated with a decreased oral health-related quality of life in children [22]. Caries management with SDF is a relatively simple and painless procedure (moisten caries lesion with the solution). It is not known whether broader use of this chemotherapeutic, non-surgical approach will over time decrease the pervasive fear of dentistry that is often associated with fear of injections and fear of pain.

Broader use of SDF could affect the use of protective stabilization or restraint to deliver conventional restorative treatment in young, pre-cooperative children.

It remains to be seen whether SDF will provide an alternative to conventional restorative treatment in significant numbers of children under the age of 3 years that might otherwise require treatment with the aid of sedation or general anesthesia. If SDF treatment is used to successfully manage early childhood caries and reduces the need for sedation and general anesthesia, the cost implications for delivery of care could be significantly reduced. Alternatively, if SDF is primarily used only as a temporary measure to stabilize the disease until conventional restorative treatment can be implemented, then the oral health care costs may actually increase. There is evidence that even if health care costs increase, as was observed with SN/FV treatment, the need for extractions, endodontics, and restorative treatment decreased [18]. Thus, while the cost implications of broadened use of SDF are not clear, there is evidence that a chemotherapeutic approach can decrease the need for surgical care.

In summary, it is likely that SDF will usher in a new caries management approach, moving dentistry toward more frequent non-surgical management of dental caries. There are many potential benefits of broader adoption of SDF that could include lower rates of surgical care, tooth loss, reduction in the prevalence of dental-related infections, and improved oral health-related quality of life. It is not clear what the cost implications will be, and reimbursement remains a barrier to broader adoption of this new therapy by the dental community. **NCMJ**

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