Silver Diamine Fluoride: Back to the Future

Alyssa Aberle RDH BSDH MBA

March 2021
Course Objectives

- Explain the history of silver nitrate and silver diamine fluoride (SDF)
- Describe what SDF is and how it works
- Discuss the safety and indications for use of SDF
- Present protocols for SDF application, available products, and follow-up recommendations
- Review CDT codes and recent legislation
History of Silver Nitrate

- Silver Fluoride (AgF)
  - Used in Japan for approximately 900 years
  - Intended for cosmetic blackening
  - Unintended effect was caries prevention

- Silver Nitrate
  - Caries arrest protocols documented in the 1800s
  - 1891: 87 of 142 treated lesions were arrested
Early 1900’s in the U.S.

- **G.V. Black**
  - “Father of Modern Dentistry”
  - In 1908, Black documented protocols for silver nitrate
  - Used to treat troops deployed in World War I
  - Side effect was that the silver nitrate made teeth brittle (loss of Calcium)
  - In 1909, Black traveled to Colorado Springs to learn about “Colorado brown stain”, which later proved to be the result of fluoride and led to a reduction in caries

- **Percy Howe**
  - First research director at Forsythe Institute in Boston and ADA President 1928-1929
  - Became well known for his successful treatment of caries with silver nitrate, that other dental professionals began calling it “Howe’s Solution”
  - Advertised in JADA

- **Water Fluoridation**
  - In the 1950’s, water fluoridation became the focus of prevention and interest in silver faded
Silver Diamine Fluoride

- Silver Diamine Fluoride (SDF) Development in Japan
  - Built upon AgF success
    - Added remineralization properties of fluoride to antimicrobial properties of silver
  - NH₃⁺ added to silver fluoride for stabilization
  - Mizuho Nishino researched SDF for PhD from 1965-1969
  - Nishino’s research was published in the Journal of Osaka University Dental Society in 1969
  - SDF product by the name Saforide was released
  - Over 2 million bottles sold. Zero adverse outcomes documented.
Recent Developments in the U.S.

- **FDA Approval in U.S.**
  - 2014: FDA approval for dentinal sensitivity
  - 2015: Elevate Oral Care releases Advantage Arrest (SDF)
  - 2016: Breakthrough Therapy Designation by FDA
  - 2018: SDI North America releases Riva Star (SDF+KI)

- **Publicity and Popularity**
  - PBS - January 2018
    - https://www.pbs.org/newshour/show/this-new-treatment-could-make-your-next-trip-to-the-dentist-more-bearable
  - JADA - August 2018
    - https://jada.ada.org/article/S0002-8177(18)30232-0/abstract
  - Washington Post - September 2020
    - Written by Colorado dental hygienist, Jennifer Geiselhofer
    - https://wapo.st/2FJSckn
Science Behind SDF

Formulation
- 25% silver (antimicrobial)
- 8% ammonia (solvent)
- 5% fluoride (remineralization)
  - Twice the concentration of fluoride is used, but less than half the volume compared to fluoride varnish, so overall fluoride exposure is less
*The rest of the solution is made up of water. In the Elevate Advantage Arrest, there is also <1% blue dye which dissipates as the solution dries.

Silver nitrate alone can make teeth brittle
- Formulations with fluoride help strengthen enamel and are optimal for long term outcomes

Multiple Benefits
- Arrests caries
- Prevents caries
- Decreases dentinal sensitivity
Caries Arrest

- Silver Ions
  - Bactericidal
  - Prevents bacterial growth
  - Deactivates proteins

How Silver Ions Work
They inhibit the reproduction of the microbe by:

1. Silver ions breaking through the cell wall
2. Silver ions attaching to the DNA of the microbe to stop cell replication
3. Silver ions disrupting the expression of the microbe
Caries Prevention

- Direct
  - Remineralizes dentin lesions
  - Increases lesion hardness
  - Prevents demineralization
    - SDF penetrates dentin up to 150 microns

- Indirect
  - Can inhibit plaque bacteria
    - Treated dentin resists biofilm formation
  - “Zombie Effect”
    - Silver-killed bacteria kill active bacteria

https://www.sciencemag.org/news/2015/05/silver-turns-bacteria-deadly-zombies
Efficacy

- Caries arrest
  - ~90% arrest with 2/year application.
  - 40-80% arrest with 1/year application.

- Caries prevention
  - “SDF prevents 61% of caries lesions. [all studies, weighted average]”¹
  - SDF inhibited the metabolic activity (acid production) of S.mutans more than NaF.²
  - Meta Analysis shows new caries decreased by 77% in children ³

¹ Prevention of Dental Caries by Silver Diamine Fluoride, Compendium 2019, Horst & Herma
² Journal of Dentistry, Ishiguro et.al.
³ The Effect of Silver Diamine Fluoride in Preventing Caries in Primary Dentition; A Systematic Review and Meta-Analysis, Oliveira et.al.
Indications for Use (and limitations)

- **Indications**
  - Extreme caries risk (xerostomia, severe ECC)
  - Behavior or medical management challenges
  - More lesions than treatable at 1 visit
  - Difficult to treat lesions
  - Patients without access to care
  - Patients looking for minimally invasive treatment options
  - Reduce gingival inflammation/gingivitis
  - Caries Prevention
  - Possible use as indirect pulp cap*
  - Reduce aerosol generating procedures

- **Contraindications and limitations**
  - Possible concerns with silver allergy
    - Though some research says that this is not a concern because it contains silver ions
  - Do not use if there is exposed pulp in lesion
    - Can cause sensitivity and “zinging” feeling

**No adverse reports in over 80 years in Japan**
SDF For Gingival Inflammation

Texas A&M College of Dentistry, Dallas, TX, USA
Differences in gingival index (GI) and plaque index (PI) between SDF and control (S) groups at each time point

<table>
<thead>
<tr>
<th>Time</th>
<th>SDF group GI (M±SD)</th>
<th>Control group GI (M±SD)</th>
<th>P-value</th>
<th>SDF group PI (M±SD)</th>
<th>Control group PI (M±SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL</td>
<td>1.89±0.39</td>
<td>1.35±0.15</td>
<td>0.000</td>
<td>1.89±0.44</td>
<td>1.14±0.25</td>
<td>0.000</td>
</tr>
<tr>
<td>W3</td>
<td>0.97±0.53</td>
<td>1.22±0.18</td>
<td>0.156</td>
<td>0.66±0.53</td>
<td>1.11±0.37</td>
<td>0.031</td>
</tr>
<tr>
<td>W5</td>
<td>0.70±0.46</td>
<td>1.28±0.20</td>
<td>0.001</td>
<td>0.65±0.40</td>
<td>1.24±0.44</td>
<td>0.002</td>
</tr>
<tr>
<td>W7</td>
<td>0.61±0.34</td>
<td>1.33±0.19</td>
<td>0.000</td>
<td>0.78±0.37</td>
<td>1.17±0.35</td>
<td>0.014</td>
</tr>
</tbody>
</table>

BL: Baseline, W: Week, SDF: Silver diamine fluoride, S: Saline, M: Mean, SD: Standard deviation

Texas A&M College of Dentistry, Dallas, TX, USA
COVID-19 and Minimally Invasive Options

- CDC recommends that minimally invasive and non-aerosol procedures be prioritized during this time (and that is also stated in the PHO)

- During this time:
  - SDF can be applied without aerosols
  - ITR can be placed without a handpiece, or other aerosols

- Optimize schedules (for dentist OR hygienist) by:
  - Scheduling more patients for less time
  - Addressing treatment that was left undone for the past 3 months and buy time for treatment plans to be completed
  - Minimize aerosols in the office
  - Consider remote/community based options for SDF/ITR to keep patients from needing to come in the office as many times, or for as long of appointments

*Video of non-aerosol application of SDF - https://www.youtube.com/watch?v=TaLiyRnXhQE
Safety

- Silver
  - 25% silver
  - No known medical risks of ingesting silver
  - Argyria: bluing of the skin
    - EPA lifetime exposure = 1 gram
    - Highest applied dose for 3 permanent teeth = 2.37 mg
    - ~1,266 treatments to reach lifetime maximum exposure

- Toxicity
  - Max dose of 1 drop per 10kg (22lbs) body weight with weekly intervals
  - This takes into consideration that the lethal subcutaneous dose (LD50) is 380mg/kg and gives a five-hundredfold safety margin (UCSF Protocol)

- SDF Side Effects
  - Possible small white mucosal lesion - will disappear in 48 hours
  - It **WILL** stain lesion black (caused by the silver precipitating out of the solution)

- Other
  - No research to show safety of SDF in pregnancy or breastfeeding. However, research is available to show that Ag, F, and KI are all safe during pregnancy and breastfeeding in low doses.
Getting Started

- Informed Consent
  - Separate consent is not REQUIRED, but since the products and procedure are "new" to most people, a consent is helpful for patients/parents to fully understand
  - An extra measure to ensure treatment option discussion has covered all the important points
  - Should include color photos so that patients/parents can not claim later that they were not aware of the staining/color change that would happen
  - Sample consent form - www.codha.org/legal

- Basic Setup
Protocols

1. Prepare setup with proper isolation and PPE
   - Plastic-lined tray cover, cotton roll(s), gauze, dry angle(s), microbrush, plastic dappen dish, 1-2 drops of SDF, fluoride varnish, Superfloss (if needed), air/water syringe, basic kit with mirror and explorer, gloves, mask, patient bib.
2. Isolate lesion(s) using cotton roll, dry angle, and/or bite block.
3. Dry with air/water syringe
4. Dip microbrush in SDF (from dappen dish) and apply a small amount for 60 seconds.
   - Do not need to excavate caries prior to application
   - Let solution air dry for 60 seconds. Do not dry with air/water syringe or solution will spread to other areas.
   - Do not light cure!
5. Apply fluoride varnish
   - Helps mask taste of SDF and “seals” over application site so that it does not wash away with saliva or contact mucosa
   - You can wipe with gauze if fluoride varnish is not desired

*Note: SDF will stain everything it touches (countertops, clothes, etc.). Be careful to isolate well and only apply to lesions. Intraorally, only demineralized areas and soft tissue will become stained. Healthy tooth structure will not stain, and mucosal stains will resolve in approximately 48 hours.
# Product Comparison

<table>
<thead>
<tr>
<th></th>
<th><strong>Advantage Arrest</strong> (Elevate Oral Care)</th>
<th><strong>Riva Star</strong> (SDI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cost</strong></td>
<td>Unit Dose = $4 = $2 per drop (unit dose contains 2 drops, can treat 10+ lesions)</td>
<td>$8 per dose</td>
</tr>
<tr>
<td></td>
<td>Bottle = $162/250 drops = $0.64 per drop</td>
<td></td>
</tr>
<tr>
<td><strong>Storage &amp; Shelf Life</strong></td>
<td>Room Temperature 3 years</td>
<td>Refrigerated 2 years</td>
</tr>
<tr>
<td><strong>Distribution</strong></td>
<td>Direct Only (elevateoralcare.com)</td>
<td>Dental Distributors Only (Schein, Patterson, Benco, etc.)</td>
</tr>
<tr>
<td><strong>Stains Teeth</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Application Technique</strong></td>
<td>One-Step</td>
<td>Two-Step (SDF + KI)</td>
</tr>
<tr>
<td><strong>Special Features</strong></td>
<td>Tinted blue so that clinician can see area where solution was applied</td>
<td>Additional step of applying potassium iodide can decrease staining</td>
</tr>
<tr>
<td><strong>Other Considerations</strong></td>
<td></td>
<td>- KI can lower zone of inhibition.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Not intended for preventive use, and instructions say to place GI restoration immediately after use</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Indicated for use on adults over age 21</td>
</tr>
</tbody>
</table>

[New study regarding KI after SDF application](https://bit.ly/3bbbkpc)
RIVA STAR SDF + K1

Cathy Boyce, Oral Health Therapist, AU
Follow-Up

- Schedule patient for follow up visit 2-4 weeks after initial application
  - Ensure that lesion is hard and dark black. If not, reapply.
  - Place restoration at this visit, if applicable.
- Best results if SDF is reapplied at least twice per year for at least 2 years
  - Unless restoration is placed over application site
- SDF treatment can be the definitive treatment, or part of a larger treatment plan, depending on patient’s needs and desires

- Additional treatment options:
  - Can be used to treat interproximal lesions using Superfloss
  - Can be used in combination with other restorations, ideally glass ionomer
    - SMART technique
    - Can be placed same day or at future appointment
  - Can be used for primary crowns (Hall Crowns)
Dr. Jeanette MacLean kidsteethand braces.com

SMART w/nitrous oxide, no local anesthesia

Shofu Beautifil Opaque + Fuji EQUIA Forte.
SDF + Fuji EQUIA Forte to treat a 7 year old

With severely hypoplastic and hypersensitive

Permanent first molars w/out sedation or GA

Dr. Jeanette MacLean kidsteethandbraces.com
7/20/17

3/5/18

10/17/18

4/18/16 3 years old. SDF to avoid sedation

6/26/17 lesions stable after SDF applied x3

Dr. Jeanette MacLean kidsteethandbraces.com

Dr. Jeanette MacLean kidsteethandbraces.com
CDT Procedure Codes and Billing

- **D1354** - Interim Caries Arresting Medicament Application - per tooth
  - When SDF is used primarily to arrest caries, either prior to a restoration placement, or as a way to “buy time” due to cooperation limitations of patients, or because of medical, behavioral, and physical, or financial limitations.

- **D1355** - caries preventive medicament application - per tooth
  - When SDF is used site specifically to offer prevention to high risk caries sites

- **D9910**
  - When SDF is used to treat dentinal hypersensitivity
Colorado Laws and Rules Regarding SDF

- HB 18-1045
  - Signed into law March 2018
  - Full text: [https://leg.colorado.gov/bills/hb18-1045](https://leg.colorado.gov/bills/hb18-1045)

- Rule XXVI
  - Approved by Colorado Dental Board in June 2018
  - Effective August 14, 2018 (Revised July 2019)
Colorado Laws and Rules Regarding SDF (cont.)

- Requirements for dental hygienists to use SDF in Colorado
  - Successfully complete course
    - Minimum of 1 hour, “live and interactive”
    - Approved by AGD/PACE, ADA/CERP, CODA accredited institution, and/or AMA
    - Carry professional liability insurance, as specified in 12-35-141
    - If using under indirect or telehealth supervision, have a written collaborative agreement with supervising dentist
      - Visit [www.codha.org/legal](http://www.codha.org/legal) for examples of collaborative agreement
  - Supervision required
    - Direct
    - Indirect
    - Telehealth

- SDF section of Practice Act is going through Sunset Review process and will be revised in 2021 legislative session.
Resources

- Dr. Jeanette Maclean DDS
  - www.kidsandbraces.com
  - Anterior application of SDF - [https://www.youtube.com/watch?v=zyvbnx3QElc&t=47s](https://www.youtube.com/watch?v=zyvbnx3QElc&t=47s)
  - SDF application without aerosols - [https://www.youtube.com/watch?v=7aiyRnXhQcE](https://www.youtube.com/watch?v=7aiyRnXhQcE)
  - Interproximal application of SDF - [https://www.youtube.com/watch?v=nPygzyfRfHQ](https://www.youtube.com/watch?v=nPygzyfRfHQ)
  - More videos - [https://www.youtube.com/channel/UCuJ6qgHP4Jxalq56JHSLmQ](https://www.youtube.com/channel/UCuJ6qgHP4Jxalq56JHSLmQ)

- Additional CE
  - Compendium SDF for Caries Prevention Free CE with code: CCEDORAL1
  - UCSF Protocol for Caries Arrest Using Silver Diamine Fluoride: Rationale, Indications, and Consent
    - [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4778976/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4778976/)
Resources (cont.)

- Research on Caries Arrest
  - “Silver Diamine Fluoride: a caries ‘silver-fluoride bullet’”
  - “Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin caries in Chinese pre-school children.”
    http://hub.hku.hk/bitstream/10722/53198/2/80787.pdf?accept=1
  - “Caries arrest and lesion appearance using two different silver fluoride therapies on primary teeth with and without potassium iodide: 12-month results” - https://bit.ly/3bBkpc

- Research on Caries Prevention
  - Folder with many studies - https://drive.google.com/drive/folders/1ejLyhLAQXQxDnY7sQQAIIJU6R1Y1NI?usp=sharing
Resources (cont.)

- ADA Articles
  - “Systematic Review of SDF Effectiveness and Application in Older Adults” https://www.ada.org/~/media/ADA/Public%20Programs/Files/MPRG_Systematic_Review_of_SDF_Effectiveness_and_Application_in_Older_Adults.pdf?la=en

- Colorado Laws and Regulations
  - Sample Consents and Collaborative Agreements - www.codha.org/legal
  - Current Practice Act and Rules and Regulations - www.codha.org/legislative-info
  - Updates on 2021 legislation regarding SDF - www.codha.org/legislative-info

- Tray Set Up and Procedure (video)
  - https://www.youtube.com/watch?v=SLJ7mFHe4e6&feature=youtu.be
Contacts

- **Colorado Dental Hygienists’ Association**
  Alyssa Aberle RDH, Executive Administrator
  alyssa@codha.org
  720.316.6282

- **Elevate Oral Care (Advantage Arrest)**
  Carly Ryan - Colorado Rep
  cryan@elevateoralcare.com
  303.828.7450

- **SDI (Riva Star)**
  Karen - Colorado Rep
  720.635.3400