

Silver Diamine Fluoride: A Game Changer in Managing Caries in High-Risk Populations?

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- This webinar will be recorded and archived on the ASTDD website;
- Questions will be addressed after the speakers are finished so if you have questions, please make a note of them. When we are ready for questions, if you wish to ask one, please click on the Set Status icon which is the little man with his arm raised on either the upper left or the top of your screen. Click on “raise hand.” We will then call on you to ask your question.
- Please respond to the polling questions at the conclusion of the webinar.

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Disclosures

I have no financial interests in any silver diamine fluoride product and photographs of specific products does not imply endorsement of any kind by either myself or ASTDD.

Outline

- What is SDF?
- Evidence of efficacy
- How does SDF work?
- How to use SDF
- Safety considerations
- Consent issues
- Public health uses for SDF
- Regulatory issues
- Reimbursement issues

SDF – what is it?

- Colorless liquid
- pH around 10
- 25% **silver**: antimicrobial
- 8% **ammonia**: solvent
- 5% **fluoride**: remineralization

Fluoride

- Promotes remineralization
- Inhibits demineralization
- Can inhibit plaque bacteria



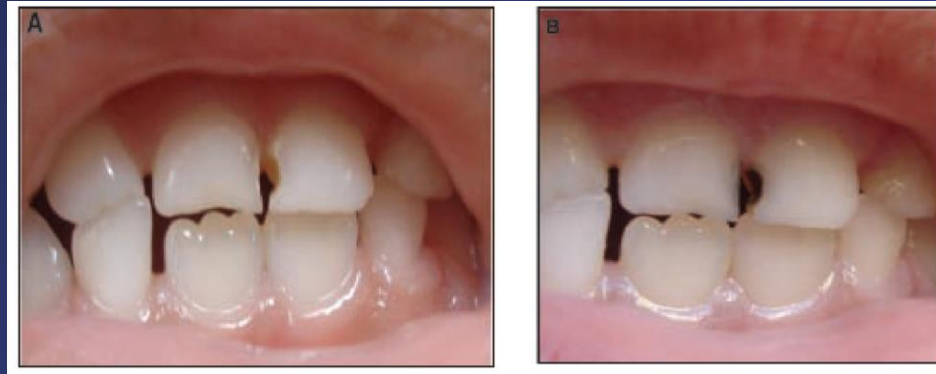
Antimicrobial Uses of Silver



Silver Nitrate



SDF - what does it do?



- Arrests dental caries
- Prevents dental caries
 - *directly & indirectly*
- Decreases dentin hypersensitivity

Evidence: Caries Arrest

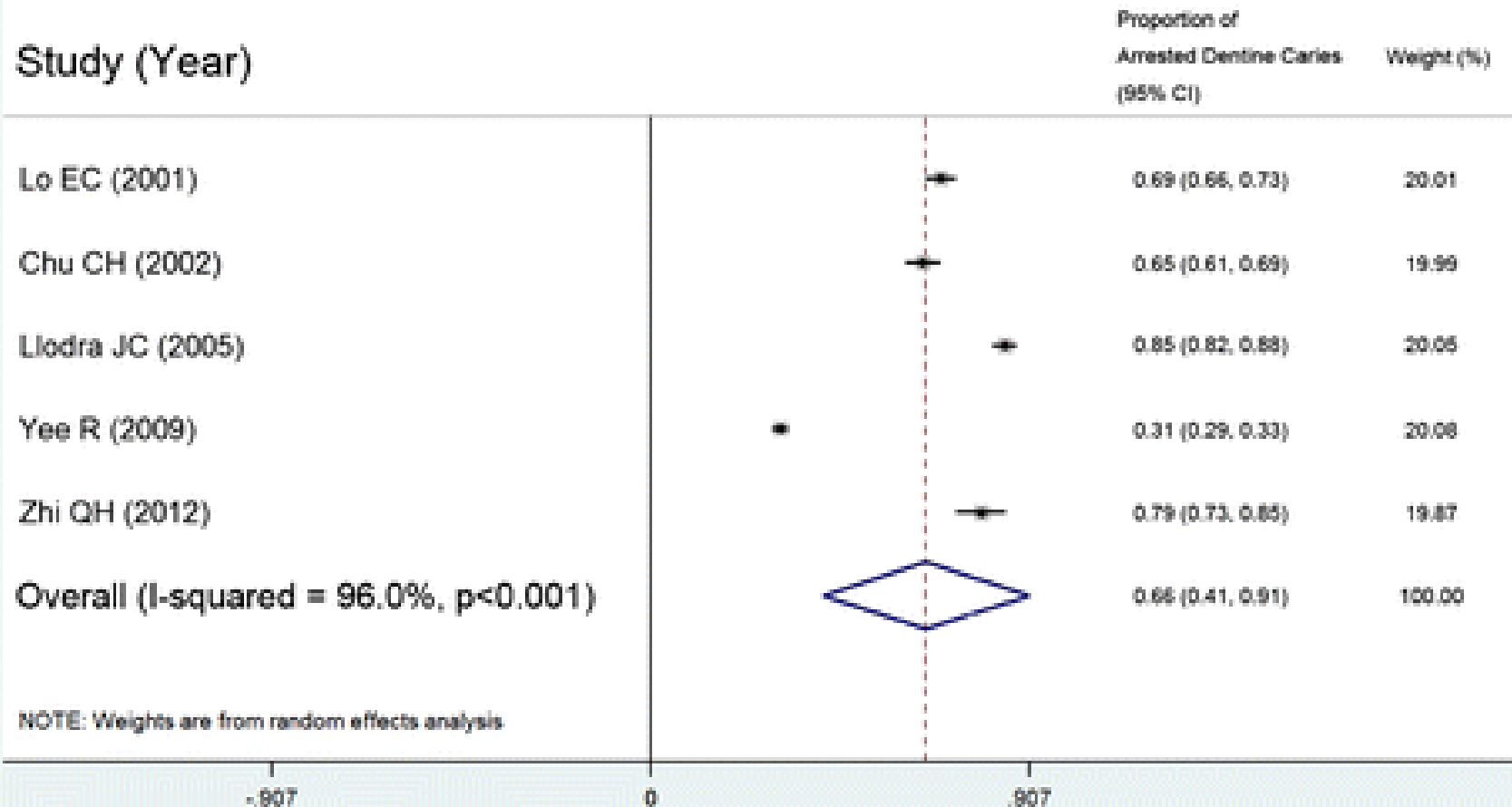
- 5 clinical trials of 38% SDF for dentin caries arrest in children
 - 3 used annual application¹: arrested caries range: 65.2% – 79.2%
 - 1 applied q 6 mo²: 84.8% arrested
 - 1 used single application³: 31.2% arrested

¹ Lo et al. J Dent Res 2001;80:2071–4; Chu et al. J Dent Res 2002;767–70; Zhi et al. J Dent 2012;962–7.

² Llodra et al. J Dent Res 2005;84:721–4

³ Yee et al. J Dent Res 2009;88:644–7.

SDF Caries Arrest in Children: Meta-Analysis



Caries prevented fraction in children, SDF clinical trials (only applied to lesions)

- Llodra et al. 2005: 79.7%
 - New surfaces w/ active lesions at 36 months: 0.3 SDF vs. 1.4 Control
- Chu et al. 2002: 70.3%
 - New surfaces w/ active lesions at 30 months: 0.47 SDF vs. 1.58 Control

Llodra et al. *J Dent Res* 2005;84:721–4

Chu et al. *J Dent Res* 2002;767–70

SDF 38% to Arrest and Prevent Root Surface Caries

- Zhang et al. *Caries Res* 2013;47:284-90
 - 227 adults age 60-89 followed for 24 mos.
 - Randomized to 3 arms, applied baseline & 12 mos:
 - OHI + SDF 38%
 - OHI + SDF 38% + Oral Health Education
 - OHI + placebo (control)
 - At 24 mos., mean number of new arrested surfaces 7–8 times greater in SDF groups (.28, .33) than in control (.04) ($p=.003$)
 - Significantly lower incidence of new root surface lesions in SDF groups (33-47% reduction, $p=.033$)

SDF 38% to Arrest Root Surface Caries

- Li et al. *J Dent* 2016;51:15-20
 - 67 adults age (mean age 72.2 y) with 100 root caries lesions followed for 30 mos.
 - Randomized to 3 arms, applied baseline, 12, & 24 mo.:
 - SDF 38%
 - SDF 38% + KI
 - Placebo (control)
 - Arrest rates at 30 mos.
 - SDF: 90%
 - SDF + KI: 93%
 - Placebo control: 45% ($P < .001$)
 - No significant difference in arrest or staining between SDF groups

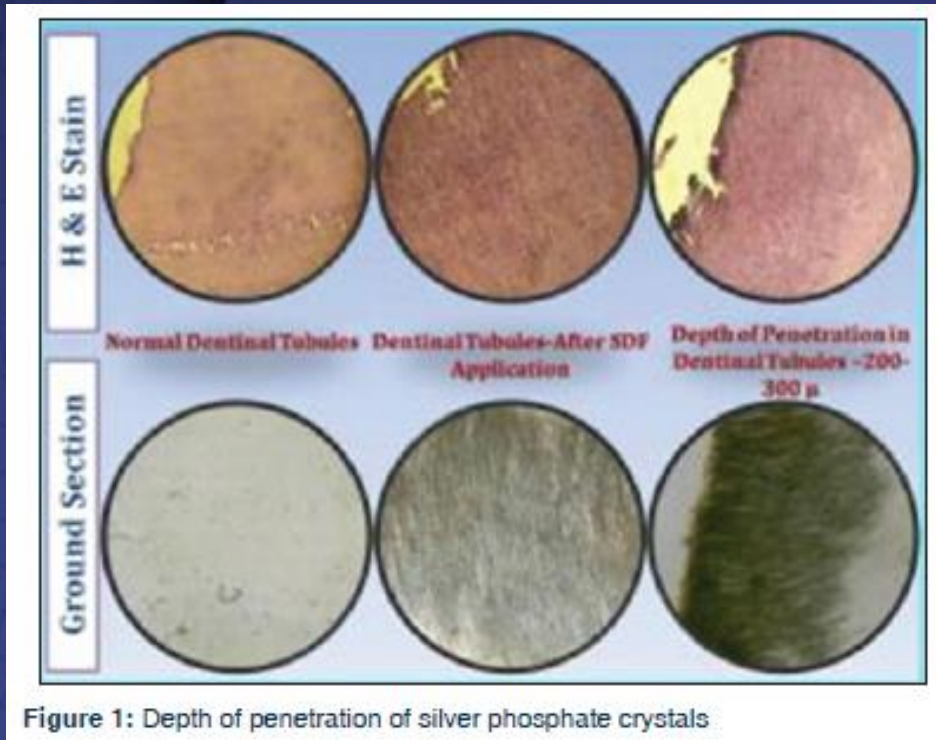
SDF – how does it work?

- 38% SDF contains 44,800 ppm F & 253,870 ppm Ag
- Sodium fluoride (NaF) & Silver nitrate (AgNO₃)
- Reacts with hydroxyapatite producing calcium fluoride (CaF₂) and silver phosphate (Ag₃PO₄)
 - CaF₂
 - Reservoir of fluoride
 - Neutralizes imbalance in demineralization/mineralization
 - Ag₃PO₄
 - Crystal of low solubility in the oral environment
 - Yellowish color – darkened by sunlight or reducing agents

SDF – how does it work?

- SDF inhibits dentin demineralization, preserves collagen and inhibits collagen breakdown, increases dentin hardness
 - Forms silver-protein conjugate on decayed dentin, increasing resistance to acid dissolution and enzymatic digestion
 - Hydroxyapatite and fluorapatite form on exposed organic matrix
 - Inhibits proteins that break down exposed dentin organic matrix

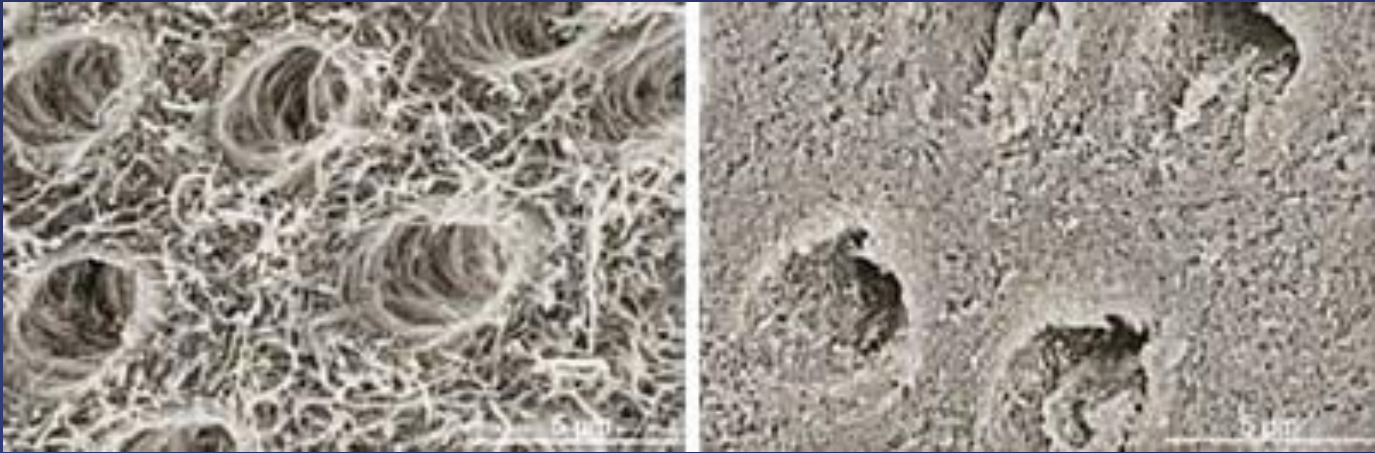
SDF – how does it work?



penetrates deep
~25 microns in enamel
50–200 microns in dentin

reacts with everything

SDF resists demineralization

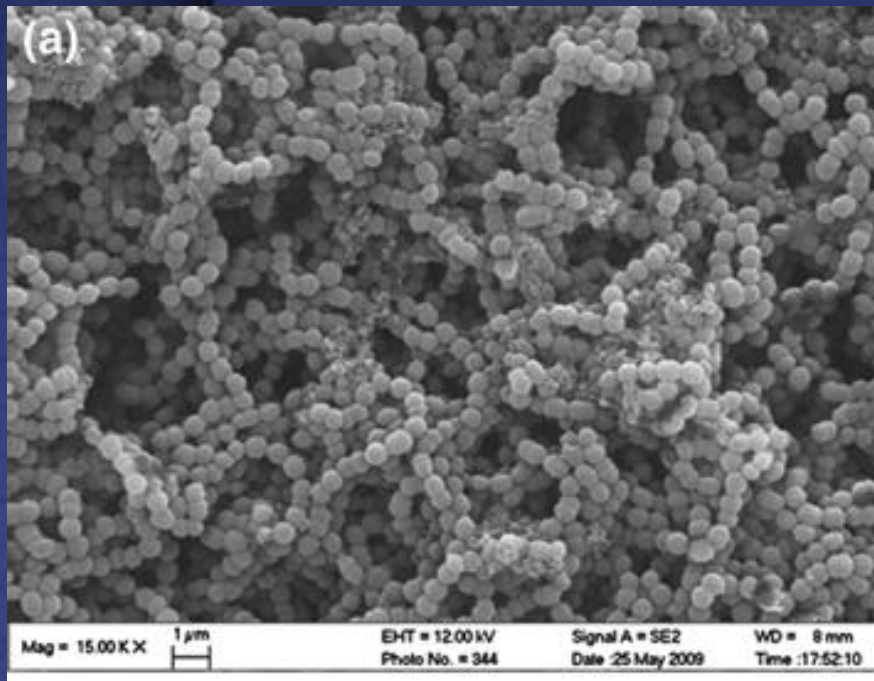


Control

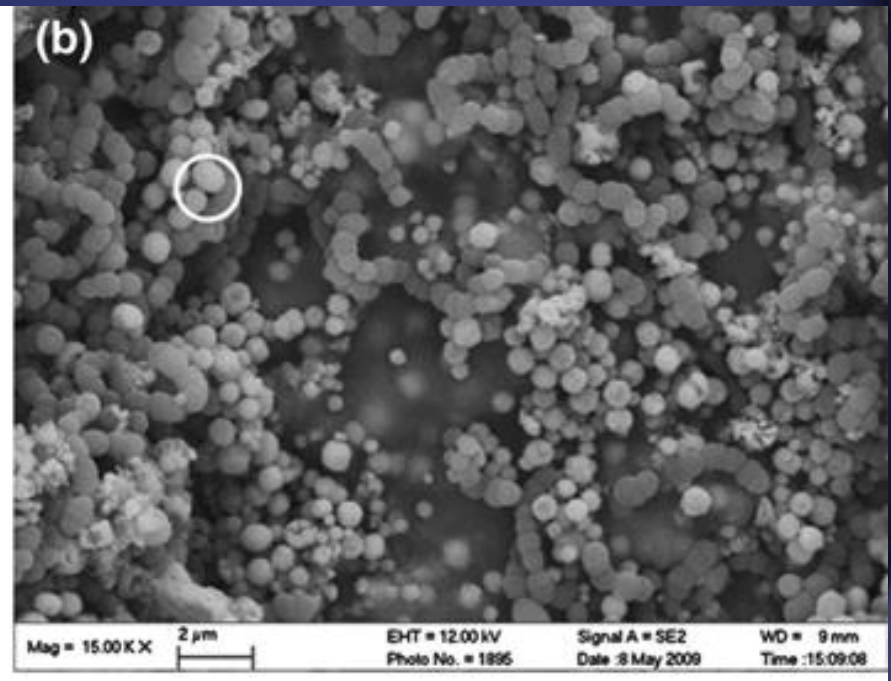
Silver diamine fluoride

Effects of silver diamine fluoride on *Streptococcus mutans* biofilm

Control

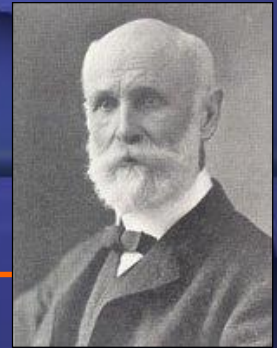


SDF





Where did this come from?



GV Black

- Silver Nitrate used globally for >1000 years.
 - Caries arrest case series & protocols in 1800s
 - 1891: 87 of 142 treated lesions were arrested
 - Founding fathers of dentistry had protocols
- AgF used in Japan for ~900 years
 - Cosmetic blackening of teeth
 - Known to prevent caries
- NH_3^+ added >80 years ago = SDF
 - Approved & monitored by Japan
- Available in Australia, Brazil, Argentina, Cuba, China since 1980s or before...



SDF in the U.S.



- Currently only one manufacturer



FDA clearance = hypersensitivity

Off label use = caries treatment

This is the same as fluoride varnish

Advantage Arrest 38% SDF

- 8 ml bottle
- Provides ~250 drops
- \$149 / bottle (\$0.60/drop)
(lower with larger orders)
- Discount pricing for educational institutions
- Elevate Oral Care, West Palm Beach, FL
www.elevateoralcare.com

Advantage Arrest SDF 38% Unit Dose

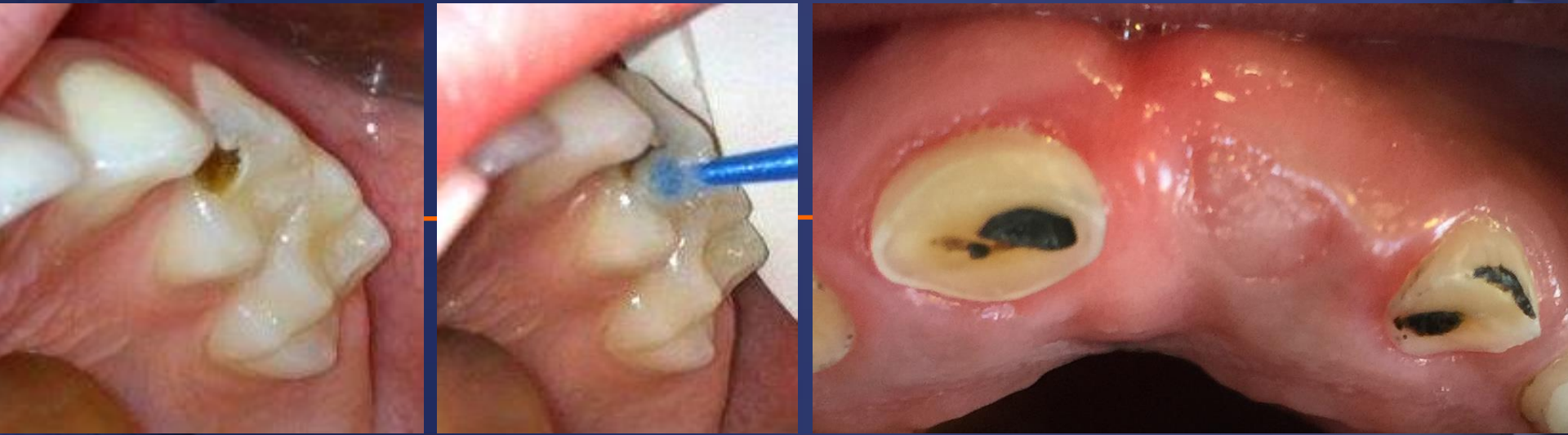
- 30 doses
- 30 small applicators
- 30 regular applicators
- Instruction card
- Price:
 - 1 @ \$119.95 \$3.99/each
 - 3+ @ \$99.95 \$3.33/each



Applicator for SDF



How do you use it?



dry & apply, 2+ times per year

Protocol

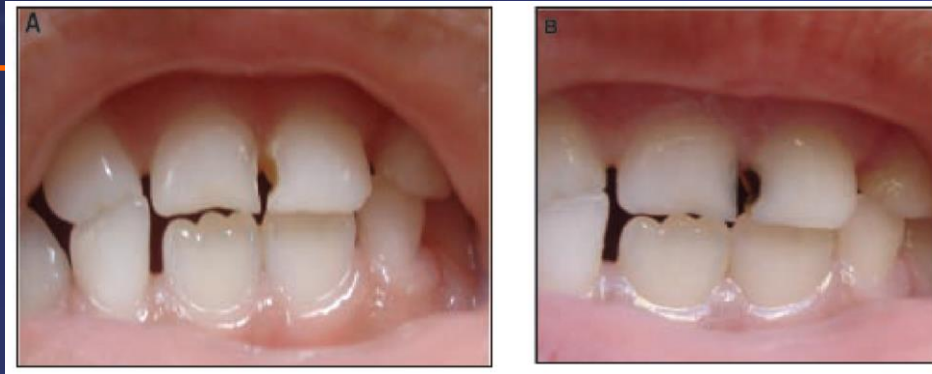
- ❖ Prophylaxis
- ❖ Vaseline – adjacent soft tissue
- ❖ Relative isolation: cotton rolls /gauze
- ❖ Suction / Drying
- ❖ Application using a microbrush or applicator for ~2–3 min
- ❖ Wash with water
- ❖ No specification for number of applications

Protocol

- ❖ SDF is an approach to caries management
- ❖ Choice when IRT (Interim Restorative Treatment) not possible, e.g. infants, young kids
- ❖ Use in public health: provides treatment and prevention at the same time, easy to apply, noninvasive, requires minimal training, inexpensive

Rosenblatt et al. *J Dent Res* 2009;88:116-25

SDF staining



time 0

1 day

1 week

CONSENT FOR SILVER DIAMINE FLUORIDE TREATMENT

Child's Name: _____ Date: _____

Parent's or Caregiver's Name: _____

I understand that my child is having the following treatment performed:

Silver Diamine Fluoride treatment to stop cavities from progressing or treat hypersensitivity

I may refuse this treatment. Other treatment options may include: fluoride varnish, fillings, tooth removal, or advanced procedures.

My dentist will: Dry the tooth. Put a small amount of Silver Diamine Fluoride on the cavity. This will help to stop the cavity.

This may need to be done again at future appointments. I understand that treated teeth may still need other treatments, such as fillings, crowns, or tooth removal.

I will tell my dentist if I might have a silver allergy.

I will tell my dentist if I have had ulcerative gingivitis or stomatitis in the past.

Side effects:

1. The cavity will change color to brown or black. This means the treatment is stopping the cavity. The dark stain is like a scar. Healthy tooth enamel will not stain.
2. Fillings and crowns may also change color if Silver Diamine Fluoride gets on them.
3. If Silver Diamine Fluoride touches the skin or gums, they may turn brown. The stain will not harm my child. The stain will not wash off. It will go away in 1-3 weeks.
4. These side effects may not include all of the possible situations reported by the manufacturer. I will let my dentist know if I notice any other side effects.

After the Silver Diamine Fluoride treatment, I will avoid food and drink for one hour. This will help the treatment to work better.

I AGREE THAT: I HAVE READ AND UNDERSTOOD THIS FORM. MY DENTIST EXPLAINED AND ANSWERED MY QUESTIONS ABOUT THE TREATMENT: BENEFITS, SIDE EFFECTS, AND RISKS. MY DENTIST TOLD ME ABOUT OTHER OPTIONS AND THEIR RISKS AND BENEFITS. I HAVE HAD THE CHANCE TO ASK QUESTIONS. I CONSENT TO THIS TREATMENT.

Date _____

Signature _____

Relationship to patient _____

Witness: _____

When would you use SDF?

- Extreme caries risk (xerostomia, S-ECC)
- Behavior or medical management challenges
- More lesions than treatable at 1 visit
- Difficult to treat lesions (including root surface caries)
- Patients without access to care
- Young patients wait-listed for OR-based dental treatment

Where We Now Use SDF

- Young patients wait-listed for OR- or sedation-based dental treatment
- Head Start
- WIC Centers

WCEP Pediatric
Dental Center
UNIVERSITY OF
UF FLORIDA
College of Dentistry
A Regis
Children's Education
Foundation Initiative

L



OR - 1 year



updated%

Lee = 2 years

Oral Sedation - 1 year



IV - Sedation - 2 years



Ongoing study at UF

- Research question: Can SDF reduce the risk for dental emergencies among children wait-listed for treatment under general anesthesia or sedation?
- Currently recruiting
- Comparing to historic control (chart review)

SDF CDT Codes

D1208 -Topical application of fluoride

D9910 - Application of a desensitizing medicament, per visit

D1999 - Unspecified preventive procedure by report

New 2016 CDT code for the use of caries arresting medicaments, the off-label use of Advantage Arrest:

D1354 - Interim caries arresting medicament application

"Conservative treatment of an active, non-symptomatic carious lesion by topical application of a caries arresting or inhibiting medicament and without mechanical removal of sound tooth structure."

Reimbursement Issues

- Wide range of coverage and fees, rapidly changing
- Avg. fee per application (not per tooth): \$75
- Average fee per tooth: \$20–\$25
- Medicaid Coverage Adopted
 - CA, IA, ME, MI, MN, NJ, OR, TN, VA
- Medicaid coverage proposed or under consideration
 - ID, IN, MA, NC

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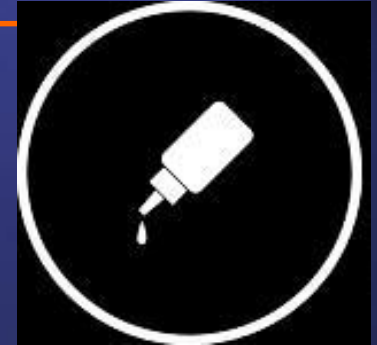
How safe is SDF?

- No adverse reports in >80 years of use in Japan
- **Contraindication**
 - Silver allergy
- **Relative contraindication**
 - Significant desquamative processes
e.g. ulcerative gingivitis, stomatitis
→ Protect by petroleum jelly
- **Side effects:**
 - Small, white mucosal lesions
 - disappear in 48 hours
 - Will stain the lesion black



How much *can* you use?

- FDA rat & mouse LD50 studies:
 - Oral LD50 = 520 mg/kg
 - Subcutaneous LD50 = 380 mg/kg
- 100% absorption of 20 μ L drop (9.5 mg SDF) in 10 kg child
= 0.95 mg/kg
 - 400-fold LD50 safety margin.
- No Observed Adverse Effect Level for 14 days of daily exposure = 1.3 mg/kg
 - Higher levels resulted in mild gastric inflammation



Recommended limit: 1 drop per 10 kg per visit



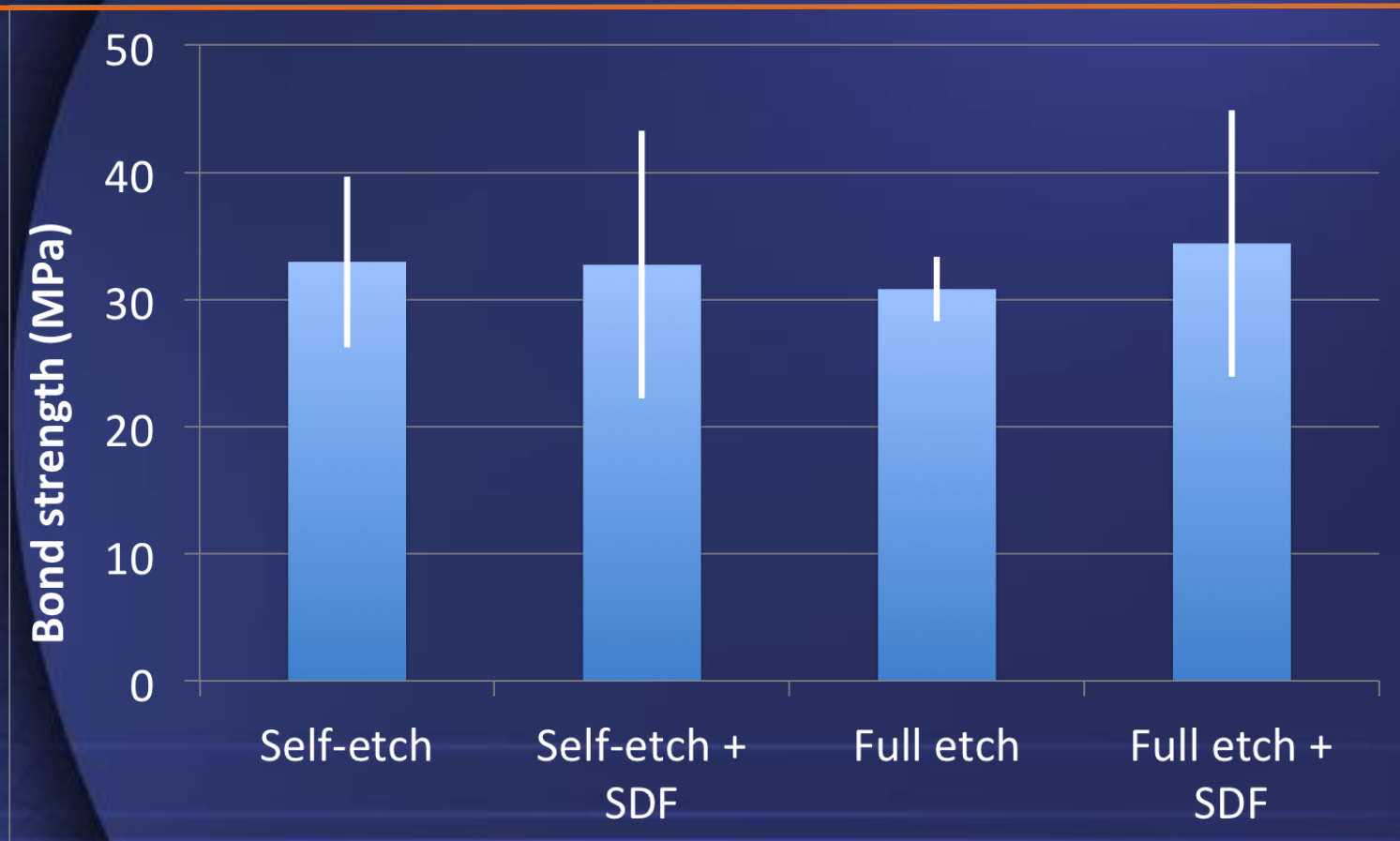
Person and Clinic Protection



- Permanent dark staining of clinic surfaces and clothes
 - Does not come out after setting (exceptions)
 - Clean immediately with copious water, ethanol, or high pH solvents such as ammonia
- Temporary staining of skin
 - Rinse
 - Will go away in days
 - No harm



Resin bond unaffected in *in vitro* study



n=7 for each

Quock et al. *Oper Dent* 2012;37:610-6

Combination with GIC sealants: Modified-ITRs (ITR=ART)

- Glass Ionomer Cements (GICs) add the benefit of sustained fluoride release and a seal
- Protocol: SDF, then standard GIC protocol.



(they darken over time)

Photos courtesy of Dr. John Frachella

NDC 0245-0003-31

SSKI®

Potassium Iodide
Oral Solution, USP
(saturated)

1 g/mL

Calibrated
Dropper
Enclosed

Color stain? Potassium iodide

- reduces Ag to *white* oxidation state
- *in vitro* studies show no impact on antimicrobial
- it does decrease stain
- avoid in pregnant/lactating women



Regulatory Issues

- SDF cleared by FDA as Class II medical device to treat tooth sensitivity.
- Treatment and prevention of dental caries is off-label use (same as F varnish)

Regulatory Issues

- Elevate Oral Care successfully petitioned FDA for “Breakthrough Therapy Status” of Advantage Arrest for caries arrest
- “. . . if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.”
- First dental drug/device to gain such status

Regulatory Issues

- Can Dental Hygienists use SDF under Public Health Supervision?
 - Explicitly approved by boards of dentistry in some states, being considered by others, most state boards currently treating it like other topical fluorides

Why I think SDF can be a game-changer in Dental Public Health

- SDF arrests >80% caries when used 2/year
- Powerful indirect prevention
- Inexpensive
- Benefits far outweigh risks
- Easily used in field settings
- May be applied by dental hygienist in most states

Q and A

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THANK YOU!

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