# Kalona Silver Nitrate Study Two Year Findings

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## Purpose of the Study

• To compare the conventional approach of restoring caries in the primary dentition, to medically managing caries using silver nitrate and fluoride varnish.

# **Study Population**

- Amish children living in Kalona, IA.
- Settlement established 1845
- Ave. family has 8 children
- High caries rate
- Low exposure to fluoride
- Limited access and utilization of regular dental care



#### Letter of Support from Bishop

Kalona, Jan. June 20, 2014

Dear Siv:

In reply to your letter of several weeks ago, the bishops were all gathered together on The eve and we were agreed to announce the suggestion that you made, but how the people will respond, we do not know, as it seems if our children do not complain of a toothacke, we rarely see a dentist.

# Timing of Study

- Oct, 2014 IRB approval (201406792)
- Nov, 2014 Subject recruitment, enrollment, random assignment, treatment began (rolling admissions)
- Nov, 2015 12 month recalls began
- Nov, 2016 − 2 yr. recalls began

# Eligibility Criteria

- Ages 2-11
- Healthy
- Untreated caries into dentin in at least one primary tooth
- Teeth encroaching on the pulp not included in the study

### Materials & Methods

- Subjects randomized into two groups:
- Conventional group (CON)
  - Restorations (composites, glass ionomers, stainless steel crowns)
- Silver nitrate group (SN)
  - Medical management of carious lesions using silver nitrate and fluoride varnish
- Both groups received "best practice" prevention
  - Oral hygiene instruction
  - Fluoride varnish application
  - Diet counseling
- Subjects were randomized 2:1 (SN:CON)

### Materials & Methods

- Recall interval for both groups is 6 months
- New BW radiographs made each recall
- SN group receives application of silver nitrate to study teeth at each recall

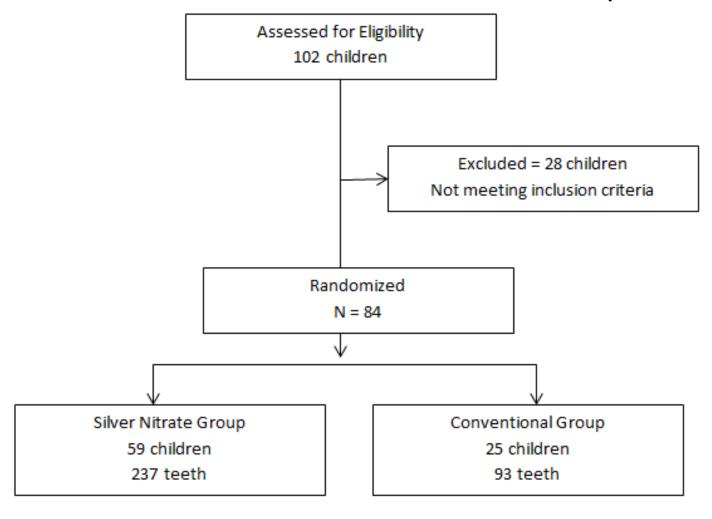
### Caries Outcome Measures

- Caries incidence (clinical and radiographic)
- Major and minor failures

# No significant difference between groups for: age, dmft, dmfs, gender

	Silver nitrate treatment group (n=50 children)		CONventional treatment group (n=24 children)		
	Mean (standard deviation)	Median (minimum, maximum)	Mean (standard deviation)	Median (minimum, maximum)	
					P-value*
Child's age in year	7.1 (2.2)	6.9 (3.1, 11.4)	7.7 (2.0)	8.0 (3.8, 11.0)	0.2752
dmft score	4.4 (2.8)	4.0 (0, 10.0)	5.1 (3.3)	5.0 (0, 11.0)	0.3713
dmfs score dmfs	9.2 (8.6)	7.0 (0, 41.0)	12.1 (11.3)	9.5 (0, 36.0)	0.5133
	Silver nitrate treatment group (n=50 children)		Conventional treatment group (n=24 children)		
	Frequency	Percent	Frequency	Percent	P-value**
Male	30	60.0%	17	70.8%	0.3648
Female	20	40.0%	7	29.2%	

### Flow Chart for the Silver Nitrate Study



# As of April 1, 2017

- 65 subjects have had their 24 month exam (77.4%)
- No subjects have been lost to follow-up

### 24-month Results - New Caries Lesions

Silver Nitrate Group N = 59		Conventional Treatment Group N = 25		Total N = 84	
Pts w/ new Lesions N (%)	No New lesions N (%)	Pts w/ new Lesions N (%)	No New lesions N (%)	Pts w/ new Lesions N (%)	No New lesions N (%)
28 (47.5)	31 (52.5)	13 (52.0)	12 (48.0)	41 (48.8)	43 (51.2)

- 47.5% of SN patients had recurrent caries within 24 months
- 52% of CON patients had recurrent caries within 24 months

### 24-month Results - Location of New Lesions

	Interproximal (M,D)	NOT Interprox. (O,F,B,L)	Total
Silver Nitrate	43 (70.5%)	18 (29.5%)	61 (100%)
Conventional Treatment	20 (90.9%)	2 (9.1%)	22 (100%)
Total	63 (75.9%)	20 (24.1%)	83 (100%)

- 70.5% of SN patients new lesions were interproximal
- 90.9% of CON patients new lesions were interproximal

### 24 month Results - Major & Minor Failures

Silver Nitrate Group		Conventional Treatment Group		Total	
Major Failure	Minor Failure	Major Failure	Minor Failure	Major Failure	Minor Failure
17 / 237 (7.2%)	5 / 237 (2.1%)	3 / 93 (3.2%)	0 / 93 (0%)	20 / 330 (6.1%)	5 / 330 (1.5%)

- 7.2 % of SN lesions experiences major failure
- 3.2 % of CON lesions experiences major failure
- Numbers presented are teeth, not subjects
- Major failure includes all failures that necessitate extraction of the tooth
- Minor failures includes lost fillings that required replacement, pulp therapy, but not extraction

# A Major Failure Case

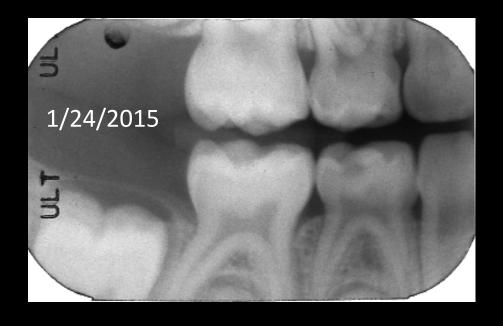


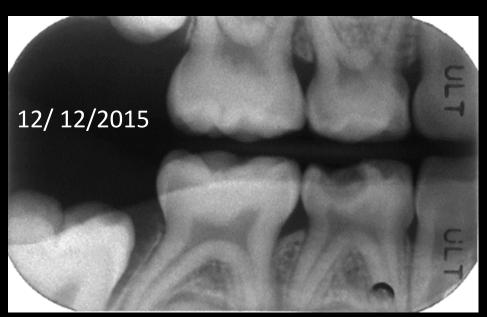






# A Minor Failure Case









**Lessons Learned** 

(with this population)

### Silver nitrate is not a "silver bullet"

- Decay continues to progress following silver nitrate application
  - Food impaction
  - Cariogenic diet
  - Poor oral hygiene
  - Lower fluoride exposure
- New caries diagnosed in children treated with silver nitrate
  - 47.5% of children treated with SN had new caries develop
  - 70.5% of new lesions were interproximal and diagnosed with radiographs

# Radiographs are helpful

• In Silver Nitrate group, 70.5% of new lesions were interproximal and diagnosed with radiographs

# Despite failures, most teeth are doing well

- 90.7 % Silver Nitrate group carious teeth are doing fine
- 96.8% Conventional group carious teeth are doing fine

### Location and size of lesions matter

- Anterior teeth do better than posterior teeth
- All major failures have occurred on posterior teeth
- Lesions that pack food do not do as well as other lesions



## Case selection is important

- For larger lesions, or lesions that could lead to food impaction
- Consider A.R.T. (glass ionomer)
- Consider SSC (Hall technique)

# "Collateral benefit" from silver nitrate



# Silver nitrate stains decalcified enamel

• 1 month following SN treatment



Following rubber cup prophy



Following polish with finishing bur



# Interproximal application is a challenge





# Cleaning SN off of hard surfaces









# Cleaning SN off lips and faces

• Wipe face with gauze dipped in Sodium Chloride (salt) solution

# Questions?

