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

5/23/2017
Dear Sirs:

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 suggestions that you made, but how the people will respond, we do not know, as it seems if our children do not complain of a toothache, we rarely see a dentist.

Salona, Iowa
June 10, 2014
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

<table>
<thead>
<tr>
<th></th>
<th>Silver nitrate treatment group (n=50 children)</th>
<th>Conventional treatment group (n=24 children)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child's age in year</td>
<td>Mean (standard deviation)</td>
<td>Median (minimum, maximum)</td>
<td>Mean (standard deviation)</td>
</tr>
<tr>
<td></td>
<td>7.1 (2.2)</td>
<td>6.9 (3.1, 11.4)</td>
<td>7.7 (2.0)</td>
</tr>
<tr>
<td>dmft score</td>
<td>4.4 (2.8)</td>
<td>4.0 (0, 10.0)</td>
<td>5.1 (3.3)</td>
</tr>
<tr>
<td>dmfs score</td>
<td>9.2 (8.6)</td>
<td>7.0 (0, 41.0)</td>
<td>12.1 (11.3)</td>
</tr>
</tbody>
</table>

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<th>Conventional treatment group (n=24 children)</th>
<th>P-value**</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percent</td>
<td>Frequency</td>
</tr>
<tr>
<td>Male</td>
<td>30</td>
<td>60.0%</td>
<td>17</td>
</tr>
<tr>
<td>Female</td>
<td>20</td>
<td>40.0%</td>
<td>7</td>
</tr>
</tbody>
</table>
Flow Chart for the Silver Nitrate Study

- Assessed for Eligibility: 102 children
- Excluded = 28 children Not meeting inclusion criteria
- Randomized N = 84
- Silver Nitrate Group: 59 children, 237 teeth
- Conventional Group: 25 children, 93 teeth
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

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

- 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

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Interproximal (M,D)</th>
<th>NOT Interprox. (O,F,B,L)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silver Nitrate</td>
<td>43 (70.5%)</td>
<td>18 (29.5%)</td>
<td>61 (100%)</td>
</tr>
<tr>
<td>Conventional Treatment</td>
<td>20 (90.9%)</td>
<td>2 (9.1%)</td>
<td>22 (100%)</td>
</tr>
<tr>
<td>Total</td>
<td>63 (75.9%)</td>
<td>20 (24.1%)</td>
<td>83 (100%)</td>
</tr>
</tbody>
</table>

- 70.5% of SN patients new lesions were interproximal
- 90.9% of CON patients new lesions were interproximal
24 month Results - Major & Minor Failures

<table>
<thead>
<tr>
<th></th>
<th>Silver Nitrate Group</th>
<th>Conventional Treatment Group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Failure</td>
<td>17 / 237 (7.2%)</td>
<td>3 / 93 (3.2%)</td>
<td>20 / 330 (6.1%)</td>
</tr>
<tr>
<td>Minor Failure</td>
<td>5 / 237 (2.1%)</td>
<td>0 / 93 (0%)</td>
<td>5 / 330 (1.5%)</td>
</tr>
</tbody>
</table>

- 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

0 mos.

6 mos.

12 mos.

18 mos.
A Minor Failure Case

1/24/2015

12/12/2015
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 ?