Pit and Fissure Sealants in High-Caries-Risk Individuals

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Abstract: This paper examines the evidence demonstrating the effectiveness of sealants in high-caries-risk children and discusses the Research Triangle Institute/University of North Carolina’s (RTI/UNC) systematic review. The strict RTI/UNC protocol limited the number of sealant studies that could be included. This analysis expanded their criteria to permit additional methods of determining caries risk (for example, past caries experience, less than two pairs of sound first permanent molars available/child in half-mouth designs) and outcome measures in addition to DMFS (that is, percent sealant retention, survival rates, cost-effectiveness, changes in salivary S. mutans levels). Nine clinical studies with a randomized, half-mouth, clinical trial design and seven studies with observational study designs were included. There is good evidence that sealants can be used efficaciously and effectively in high-risk children as long as the sealant is retained. Sealants are more effective in preventing further caries and providing cost savings in a shorter time span if placed in children who have higher rather than lower caries risk.

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In 1983, the NIH hosted a consensus development conference on dental sealants in the prevention of tooth decay. The panel concluded, “The placement of sealants is a highly effective means of preventing pit and fissure caries.” The conclusions indicated that sealants were 100 percent effective in pits and fissures that remained completely sealed, though sealant retention declined over time. Since then, comprehensive reviews and a meta-analysis have confirmed the effectiveness of sealants, and a workshop developed guidelines for their use.

Results from the 1988-94 Third National Health and Nutrition Examination Survey (NHANES-III) found that 78 percent of seventeen-year-olds have experienced dental caries. Estimates indicate that 90 percent of dental caries in children occur in pits and fissures. The high prevalence of pit and fissure caries provides the rationale for sealant use. However, according to the NHANES-III baseline utilization data for the U.S. Healthy People 2010 national health objectives, only 23 percent of eight-year-olds and 15 percent of fourteen-year-olds had received sealants, even though the objective for both 2000 and 2010 is to increase the utilization percentage to 50 percent. There are also major disparities in sealant utilization by race/ethnicity and socioeconomic status. Children who are non-Hispanic white, have well-educated parents, and/or are well above the poverty level are much more likely to have sealants than Mexican-American or African-American children, children with caregivers with low levels of education, or children living below the poverty level.

The driving factor for developing methods for targeting children at high risk is the desire for cost-effective use of limited financial and human resources. Since sealants are professionally applied on an individual basis, they are a relatively expensive preventive measure, though very effective. Over the last three decades of research, sealant materials and methods have continued to advance. For example, Feigal and colleagues have reported improved sealant retention using a bonding agent between the sealant and saliva-contaminated enamel.

My charge, for this conference, was to examine the evidence demonstrating the effectiveness of sealants in high-caries-risk children and to discuss the findings of the systematic review conducted by the Research Triangle Institute/University of North Carolina (RTI/UNC).

RTI/UNC Criteria and Findings

The RTI/UNC group had several initial criteria for caries management studies:
1) professional provision of intervention,
2) in vivo studies,
3) concurrent comparison group, and
4) traditional outcome measures of caries experience.
In addition, the caries risk determination must have been made “on an individual subject level based on carious lesion experience and/or bacteriologic testing.” Because of these restrictive criteria, the RTI/UNC investigators’ literature search led to only three studies that met their criteria: one study by Heller and colleagues that examined sealant use on tooth surfaces that were sound or had incipient lesions; a second study by Sheykholeslam and Houpt that used sealants alone; and a third study by Zickert and colleagues that used sealants in combination with other preventive agents (chlorhexidine gel, and 0.2% NaF mouth rinse) for high-risk individuals. Consequently, due to the limited number of studies and the limitations in some of the study designs, the RTI/UNC group rated the caries management evidence involving sealants as incomplete.

I broadened the criteria to better reflect the nature of dental sealant studies, especially with regard to study designs, type of comparison groups, and outcome measures. Prospective and retrospective studies were included that have unsealed teeth or children without sealants as the comparison group. Outcome measures are usually reported in terms of percent effectiveness, using either a paired or unpaired analysis, or percent sealant retention. Retention and effectiveness are highly correlated. The protocols are often limited to posterior teeth and, most frequently, to only first permanent molars. Traditional DMFS or DMFT measures are usually not reported.

There is a continuum in the spectrum of caries risk, disease status, and treatment options, from low risk to high risk, sound to carious, and none to invasive restorative treatment. Improved caries detection and diagnostic methods would help determine the appropriate cutpoint or threshold separating the clinical decisions to either do nothing or preventively seal, or to therapeutically seal or surgically treat and restore. A caries detection device such as the Diagnodent, which uses a laser fluorescence system to detect bacterial by-products on the occlusal surface, has been used in Europe for caries management and was recently introduced in the United States. Theoretically, laser fluorescence could be useful for determining whether a tooth is sound and does not require intervention, has evidence of a low level of caries activity and is an appropriate candidate for sealant application, or has a higher level of disease severity that requires surgical intervention. Ideally, it could subsequently be used to monitor sealant effectiveness to determine if any caries activity beneath the surface has regressed. In 1991, Handelman reviewed radiographic and bacteriologic studies investigating the therapeutic use of sealants and concluded “caries is inhibited and may in fact regress under intact sealants.” Some have raised concern about occlusal radiolucencies beneath sealed surfaces, referred to as hidden caries. The use of a device such as the Diagnodent that potentially could detect caries beneath an unfilled sealed surface could help alleviate this concern.

Since Rozier conducted a formal systematic review for this conference, I conducted an English-language Medline search and reviewed abstracts to identify additional studies from 1988 to 2000 not included in the RTI/UNC evidence report. My prior published dental sealant literature review was used to select earlier studies. Table 1 summarizes the studies utilizing a half-mouth design, and Table 2 those with other types of designs.

**Additional Studies: Half-Mouth and Other Study Designs**

Many of the first sealant trials used a randomized, half-mouth design where children with pairs of eligible, sound, first permanent molars were selected so that one member of the pair could be sealed and the other molar left unsealed. One or two pairs of sound first, permanent molars were included. If two available sound molar pairs were required, selected children may have been at lower risk than the children who were excluded because some of their first molars had already become carious. Conversely, if no sound molar pairs were available, those children may have been at even higher caries risk and excluded. Studies where children were included if they had one or two pairs of sound molars may include a mix of low- and high-risk children. The proportion of sound molar pairs available may be a surrogate for caries risk. For example, a study by McCune and colleagues examined paired and unpaired molars and found that caries incidence was higher among the unpaired teeth.

In the nine studies identified with randomized, half-mouth designs with unsealed control teeth, the sealant type and application technique, age of children, selection criteria, sample size, and study duration varied. Four studies required prior caries experience or excluded children who were caries-free. Thus, the children in these studies all had some caries risk. Five studies included a mixture of children with one or two sound molar pairs or paired and unpaired molars. Thus, these five studies included a mixture of potentially low- and high-caries-risk children.

Buonocore, the inventor of dental sealants, in one of these first sealant studies, reported two-year results in 1971. An excerpt of his description of tooth
Table 1. Pit and fissure sealants in high-risk children: half-mouth study design

<table>
<thead>
<tr>
<th>First Author(s)</th>
<th>Pub. Year</th>
<th>Type of sealant</th>
<th>N at start</th>
<th>Age at start</th>
<th>Caries Risk Determination</th>
<th>Follow-up Years</th>
<th>% Full Retention (at final exam)</th>
<th>% Effectiveness (at final exam)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buonocore</td>
<td>1970-1971</td>
<td>UV-light</td>
<td>60</td>
<td>4-15 (mean 9)</td>
<td>Caries-free individuals with well-coalesced occlusal surfaces excluded</td>
<td>2</td>
<td>87%</td>
<td>99% - permanent teeth 87% - primary teeth</td>
</tr>
<tr>
<td>McCune Horowitz</td>
<td>1973-1976</td>
<td>UV-light Nuva-Seal</td>
<td>128-301</td>
<td>6th, 7th grades, Total</td>
<td>Sealant placed on paired and unpaired teeth (usually homologue had already decayed)</td>
<td>5</td>
<td>42% (50% and 26% in paired and unpaired teeth after 4 years)</td>
<td>30% - younger group 38% - older group</td>
</tr>
<tr>
<td></td>
<td>1976-1977</td>
<td></td>
<td>429</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>98% - where sealant completely present</td>
</tr>
<tr>
<td>Brooks Mertz-Fairhurst</td>
<td>1976-1984</td>
<td>Nuva-Seal, Delton</td>
<td>385</td>
<td>6-8</td>
<td>Caries-free children excluded (about 48% of those screened). 79% of possible first permanent molar pairs treated</td>
<td>7</td>
<td>31% Nuva-Seal, 66% Delton</td>
<td>12% Nuva-Seal, 55% Delton (10% of completely sealed teeth became cariuous-combined data from both sealant types)</td>
</tr>
<tr>
<td>Sheykholeslam Houpit</td>
<td>1978-1979</td>
<td>Delton</td>
<td>205</td>
<td>6-10 (mean 7.5)</td>
<td>Evidence of caries and a pair of caries-free homologous first permanent molars (21% screened were eligible).</td>
<td>6</td>
<td>58%</td>
<td>56%</td>
</tr>
<tr>
<td></td>
<td>1983</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Charbeneau</td>
<td>1977-1979</td>
<td>Kerr, Chemcured</td>
<td>143</td>
<td>5-8</td>
<td>81% of possible first permanent molar pairs included</td>
<td>4</td>
<td>52.4%</td>
<td>53.4%</td>
</tr>
<tr>
<td>McCune</td>
<td>1979</td>
<td>Delton</td>
<td>200</td>
<td>6-8</td>
<td>Child had at least one carious tooth</td>
<td>3</td>
<td>87%</td>
<td>85%</td>
</tr>
<tr>
<td>Thylstrup</td>
<td>1976-1978</td>
<td>Concise Chem-polymer</td>
<td>217</td>
<td>7</td>
<td>40% one first permanent molar pair; 60%; two pairs</td>
<td>2</td>
<td>60%</td>
<td>98% - full 50% - partial 10% - lost</td>
</tr>
<tr>
<td>Richardson Gibson</td>
<td>1980-1982</td>
<td>Chem-cure, pink colored</td>
<td>266</td>
<td>2nd grade</td>
<td>80% of eligible molars, teeth sealed if sound or “sticky”</td>
<td>5</td>
<td>67.4%</td>
<td>51.2%</td>
</tr>
<tr>
<td>Vrbic</td>
<td>1983-1986</td>
<td>Contact Seal</td>
<td>244</td>
<td>6.8</td>
<td>76% of possible first permanent molar pairs</td>
<td>5</td>
<td>52%</td>
<td>55%</td>
</tr>
</tbody>
</table>
Table 2: Pit and fissure sealants in high-risk children: other study designs

<table>
<thead>
<tr>
<th>First Author</th>
<th>Pub. Date</th>
<th>Study design</th>
<th>Control/comparison</th>
<th>Type of sealant</th>
<th>N at start</th>
<th>Age at start</th>
<th>Follow-up years</th>
<th>Caries Risk Determination</th>
<th>Outcome</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leverett</td>
<td>1983</td>
<td>Half-mouth, benefit/cost analysis</td>
<td>Sealants on one side, restorative care on other</td>
<td>Nuva-Seal</td>
<td>292</td>
<td>6-9</td>
<td>4</td>
<td>Caries-active (sealants placed on a carious surface) Caries-inactive (sealant placed on sound surface)</td>
<td>1 year retention – 52%, re-sealed; After 4 years, sealed surfaces 74% less caries increment than unsealed</td>
<td>Benefit cost ratios based on time or costs were more favorable for caries-active. Sealants should not be used unless evidence of past or current caries experience.</td>
</tr>
<tr>
<td>Weintraub</td>
<td>1993</td>
<td>Retrospective cohort study, patient records, Life table analysis, cost-effectiveness</td>
<td>Children with none, any or 4 molars sealants; children with and without prior restorations</td>
<td>Varied</td>
<td>275</td>
<td>7.4</td>
<td>5.8 – mean (up to 11 years)</td>
<td>Restorations on first molars prior to sealant placement on remaining molars</td>
<td>8-year survival: sealed teeth with and without prior restoration – 85% and 94%; unsealed teeth – 23% and 46%</td>
<td>Cost savings from sealants was obtained within 4-6 years for children with prior restorations, after 8 years without prior restorations</td>
</tr>
<tr>
<td>Heller</td>
<td>1995</td>
<td>Retrospective cohort study, patient health center records</td>
<td>96 children with and 17 without sealants, sealed and unsealed teeth</td>
<td>Delton</td>
<td>113</td>
<td>1st grade</td>
<td>5</td>
<td>Tooth surfaces rated sound, &quot;incipient,&quot; or frank caries</td>
<td>Decay rates for initially sound sealed and non-sealed surfaces were 0.81 and 0.125 (OR=1.63); for initially incipient surfaces, 108 and 518 (OR=88)</td>
<td>Initially sound teeth were unlikely to become carious in 5 years; sealants more effective in preventing further caries on surfaces initially with incipient lesions</td>
</tr>
<tr>
<td>Kumar</td>
<td>1997</td>
<td>Survival analysis</td>
<td>Sealed high risk first molars (65% sites) compared to unsealed low risk first molars (35% sites)</td>
<td>Helioseal, Delton</td>
<td>1,122</td>
<td>7-9</td>
<td>4</td>
<td>Eligibility required child’s prior caries experience. Teeth with shallow anatomy, occlusal or proximal D or F excluded</td>
<td>Retention (with some rescaling) – 65-82%; Time to restoration or caries similar for both groups. Cum. Survival rate for 4 years: 89-94</td>
<td>Targeting approach was effective.</td>
</tr>
<tr>
<td>Carlsson</td>
<td>1997</td>
<td>Prospective study, txs based on caries risk assessment, radiographs used</td>
<td>High risk children (21) received sealant, low risk did not (83)</td>
<td>Helioseal-F (fluoride)</td>
<td>204</td>
<td>6-7</td>
<td>2</td>
<td>Risk based on salivary mutans streptococci, lactobacilli, buffer capacity, past caries experience, cariogenic diet</td>
<td>76.6% complete sealant retention, first molar DFS and DS incidence lower for sealed group, but NS, enamel caries incidence sig diff in both dentitions</td>
<td>Two-year caries incidence was 11-70% lower in high risk sealed group (range based on dentition and outcome measure)</td>
</tr>
<tr>
<td>Mass</td>
<td>1999</td>
<td>Prospective study of two groups receiving sealants; sealant delayed 3 months on one side</td>
<td>Group 1 – mean deft = 2.40 (low risk), Group 2 – mean deft = 6.60 (high risk);</td>
<td>Helioseal</td>
<td>52</td>
<td>6-8</td>
<td>0.5</td>
<td>Initially, deft “Microbial replica” measured occlusal S. mutans</td>
<td>For both groups, S. mutans was sig. reduced immediately after sealing and lasted up to six months.</td>
<td>Sealants reduced bacterial levels for both low and high risk groups.</td>
</tr>
<tr>
<td>Weintraub</td>
<td>In Press</td>
<td>Retrospective cohort, Medicaid claims, discrete time hazard model</td>
<td>Sealed and unsealed teeth</td>
<td>Dentists’ choice</td>
<td>15,438</td>
<td>4-7</td>
<td>8</td>
<td>Low risk: no prior Caries-Related Service involving Occlusal surface (CRSO) Middle risk: 1 prior CRSO, High risk ≥ 2 prior CRSO</td>
<td>Unsealed molars 3x more likely to get CRSO than sealed molars. Low risk: sealants effective up to 4 years, Middle risk: lower odds for 6 years. High risk: reductions up to 7 years.</td>
<td>Medicaid expenditure savings for high risk children within two years, not for low risk.</td>
</tr>
</tbody>
</table>
selection is informative: “The permanent teeth selected for this study generally had well-defined pits and fissures or deep fossae, or both, and as a rule were found in mouths in which decay already was present in other teeth. Caries-free individuals with relatively well coalesced occlusal surfaces were not included in the study.” This study may have been the first sealant trial in high-risk children and teeth.

Results among the nine studies, based on percent complete sealant retention, indicate that sealant retention began high and generally declined over time, regardless of the mix of caries risk participants. This trend is more apparent if longitudinal results of the individual studies are examined. The current effectiveness of sealants is underestimated if based on early sealant trials because the first generation of material used, polymerized by ultraviolet light, was less effective than newer materials and is no longer in use. Retention rate in any sealant trial is also dependent on the accuracy with which examiners can identify the presence of sealant. Misclassification occurs more often when a clear rather than opaque resin is used.

By 1980, Simonsen had reported that it was considered unethical to have a randomized clinical trial with half of the children or half of the teeth left unsealed. Most studies after this time utilized other designs.

Seven studies that involved high-risk children or teeth are shown in Table 2; four are prospective and three are retrospective. Prospective studies compared sealants on carious versus noncarious teeth, sealed incipient versus sound surfaces, or sealed high-risk children or teeth versus low-risk children or teeth. In retrospective sealant studies, dentists may or may not have selected high-risk children for sealant placement, and children were not randomly assigned to a sealed or unsealed group, but sealed and unsealed teeth can be compared in children based on their prior caries experience as a measure of their caries risk status.

Outcome measures included percent sealant retention, survival rates, caries rates, changes in salivary mutans streptococci levels, cost-effectiveness, or cost-benefit analyses. The results of these studies show that sealants are more effective from a cost and time perspective if placed on high-risk rather than low-risk children, though it may take several years for savings to accrue. Approaches to target high-risk children for sealants were successful in balancing their caries incidence or survival rate compared to unsealed low-risk children. Most studies have used evidence of prior or current caries as a critical component of their caries risk assessment method. From my perspective, ideal caries risk assessment methods should predict risk prior to any clinical caries experience.

Conclusions

From this literature review, we can conclude that:

1. Sealants are very effective in preventing pit and fissure caries if completely retained on the tooth surface.
2. Most sealant studies have included low-risk, high-risk, or a mixture of both low- and high-risk children. However, analyses may not have been conducted stratified by caries risk status. Sealants have been effective to varying degrees in all of these studies.
3. There is evidence that sealants are more effective in preventing further caries and providing cost savings in a shorter time span if placed in children (or in teeth) with high caries risk compared to children with low caries risk.
4. Most caries risk assessment methods used in these studies have relied on past or current caries experience. Caries risk assessment methods are needed to predict high risk, prior to clinical caries development, so that sealants can be used to prevent caries on all susceptible teeth throughout life.
5. The strict RTI/UNC protocol limited the number of sealant studies that could be included in their review. When studies with other outcome measures are included, there is good evidence that sealants can be used efficaciously and effectively in high-risk children as long as the sealant is retained. Although study designs and outcome measures vary, the results across studies are consistent.

REFERENCES


