

Evidence-based Clinical Practice Guideline for the Use of Pit-and-Fissure Sealants

Developed and Endorsed by

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Abstract

Background: This article presents evidence-based clinical recommendations for the use of pit-and-fissure sealants on the occlusal surfaces of primary and permanent molars in children and adolescents. A guideline panel convened by the American Dental Association (ADA) Council on Scientific Affairs and the American Academy of Pediatric Dentistry conducted a systematic review and formulated recommendations to address clinical questions in relation to the efficacy, retention, and potential side effects of sealants to prevent dental caries; their efficacy compared with fluoride varnishes; and a head-to-head comparison of the different types of sealant material used to prevent caries on pits-and-fissures of occlusal surfaces.

Types of studies reviewed: This is an update of the ADA 2008 recommendations on the use of pit-and-fissure sealants on the occlusal surfaces of primary and permanent molars. The authors conducted a systematic search in MEDLINE, Embase, Cochrane Central Register of Controlled Trials, and other sources to identify randomized controlled trials reporting on the effect of sealants (available on the U.S. market) when applied to the occlusal surfaces of primary and permanent molars. The authors used the Grading of Recommendations Assessment, Development, and Evaluation approach to assess the quality of the evidence and to move from the evidence to the decisions.

Results: The guideline panel formulated 3 main recommendations. They concluded that sealants are effective in preventing and arresting pit-and-fissure occlusal carious lesions of primary and permanent molars in children and adolescents compared with the nonuse of sealants or use of fluoride varnishes. They also concluded that sealants could minimize the progression of non-cavitated occlusal carious lesions (also referred to as initial lesions) that receive a sealant. Finally, based on the available limited evidence, the panel was unable to provide specific recommendations on the relative merits of 1 type of sealant material over the others.

Conclusions and practical implications: These recommendations are designed to inform practitioners during the clinical decision-making process in relation to the prevention of occlusal carious lesions in children and adolescents. Clinicians are encouraged to discuss the information in this guideline with patients or the parents of patients. The authors recommend that clinicians re-orient their efforts toward increasing the use of sealants on the occlusal surfaces of primary and permanent molars in children and adolescents.

KEYWORDS: PIT-AND-FISSURE SEALANTS, CLINICAL RECOMMENDATIONS, GUIDELINE, OCCLUSAL CARIES, CARIES PREVENTION, CARIES ARRESTING

Pit-and-fissure sealants have been used for nearly 5 decades to prevent and control carious lesions on primary and permanent teeth. Sealants are still underused despite their documented efficacy and the availability of clinical practice guidelines.^{1,2} New sealant materials and techniques continue to emerge for managing pit-and-fissure caries, further complicating the clinician's decision making. Accordingly, continuous critical review of the available evidence is necessary to update evidence-based recommendations and assist health care providers in clinical decision making.^{1,7}

The American Dental Association (ADA) Council on Scientific Affairs convened an expert panel to develop the previous

evidence-based clinical recommendations for the use of sealants, published in 2008.³ In an effort to update the 2008 recommendations, the ADA Council on Scientific Affairs and the ADA Center for Evidence-Based Dentistry, in collaboration with the American Academy of Pediatric Dentistry (AAPD), convened a new working group including clinical experts, stakeholders, and methodologists to develop a systematic review⁸ and accompanying evidence-based clinical practice recommendations for publication in 2016.

ABBREVIATIONS

AAPD: American Academy of Pediatric Dentistry. **ADA:** American Dental Association. **BPA:** Bisphenol A. **GI:** Glass ionomer. **GRADE:** Grading of Recommendations Assessment, Development and Evaluation. **NHANES:** National Health and Nutrition Examination Survey. **CI:** Confidence intervals.

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Our goal for this 2016 clinical practice guideline was to provide clinicians with updated evidence-based recommendations regarding when and how the placement of pit-and-fissure sealants is most likely to be effective in preventing carious lesions on the occlusal surfaces of primary and permanent teeth in children and adolescents. The target audience for this guideline includes general and pediatric dental practitioners and their support teams, public health dentists, dental hygienists, pediatricians, primary-care physicians, and community dental health coordinators; policy makers may also benefit from this guideline to inform clinical decision making, programmatic decisions, and public health policy.

Definition of Dental Caries

Dental caries is a disease caused by an ecological shift in the composition and activity of the bacterial biofilm when exposed over time to fermentable carbohydrates, leading to a break in the balance between demineralization and remineralization.⁴ Carious lesions are preventable by averting onset, and manageable by implementing interventions, which may halt progression from early stage of the disease to cavitation, characterized by enamel demineralization, to frank cavitation.³ In 2015, the ADA published the Caries Classification System, which defines a non-cavitated or initial lesion as “initial caries lesion development, before cavitation occurs. Noncavitated lesions are characterized by a change in color, glossiness, or surface structure as a result of demineralization before there is macroscopic breakdown in surface tooth structure.”⁴

Epidemiology

National Health and Nutrition Examination Survey (NHANES) 2011-2012⁵ data show that 21% of children aged 6 to 11 years and 58% of adolescents aged 12 to 19 years had experienced carious lesions (untreated and treated [restored]) in their permanent teeth.

The NHANES report also found the prevalence of carious lesions in permanent teeth increased with age and differed among sociodemographic groups. Children in the 9- to 11-year range had higher carious lesion prevalence (29%) compared with children in the 6- to 8-year range (14%). Similarly, children in the 16- to 19-year age range had higher carious lesion prevalence (67%) compared with children in the 12- to 15-year range (50%). In addition, dental caries incidence for both 6- to 11-year and 12- to 19-year age groups was highest among Hispanic children compared with non-Hispanic black children, non-Hispanic white children, and Asian children. The surgeon general’s report on oral health similarly indicated that Hispanic and non-Hispanic black children are at the highest risk of developing dental caries.⁶ Overall, NHANES 2011-2012 indicates a higher prevalence of untreated carious lesions in the 12- to 19-year age group (15%) compared with the 6- to 11-year age group (6%).⁵

Although there has been a decline in prevalence of caries in adolescents and children in particular, the decrease in occlusal surface caries has not kept pace with the decrease in the smooth

surface caries.⁷ Although this overall decline has been attributed to preventive interventions such as water fluoridation, fluoride tooth-paste, fluoride varnishes, and sealants, topical fluoride applications—such as fluoride varnishes—may have a greater effect reducing carious lesions on smooth surfaces compared with caries in pits and fissures.^{1-7,9,10}

NHANES 2011-2012 data show that 41% of children aged 9 to 11 years and 43% of adolescents aged 12 to 19 years had at least 1 dental sealant. Non-Hispanic black children had the lowest dental sealant prevalence in both age groups compared with Hispanic, non-Hispanic white, and Asian children.⁵ Therefore, underutilization of sealants is of key concern.

Potential Role of Pit-and-Fissure Sealants in Primary and Secondary Prevention

From a primary prevention perspective, anatomic grooves or pits and fissures on occlusal surfaces of permanent molars trap food debris and promote the presence of bacterial biofilm, thereby increasing the risk of developing carious lesions. Effectively penetrating and sealing these surfaces with a dental material—for example, pit-and-fissure sealants—can prevent lesions and is part of a comprehensive caries management approach.¹¹

From a secondary prevention perspective, there is evidence that sealants also can inhibit the progression of noncavitated carious lesions.⁹ The use of sealants to arrest or inhibit the progression of carious lesions is important to the clinician when determining the appropriate intervention for noncavitated carious lesions.

Sealant Materials and Placement Techniques

For the purposes of this report, there are 4 sealant materials under a classification proposed by Anusavice and colleagues¹¹: resin-based sealants, glass ionomer (GI) cements, GI sealants, polyacid-modified resin sealants, and resin-modified GI sealants. They defined the materials as follows.¹¹

- Resin-based sealants are urethane dimethacrylate, “UDMA,” or bisphenol A-glycidyl methacrylate (also known as “bis-GMA”) monomers polymerized by either a chemical activator and initiator or light of a specific wavelength and intensity. Resin-based sealants come as unfilled, colorless, or tinted transparent materials or as filled, opaque, tooth-colored, or white materials.
- GI sealants are cements that were developed and are used for their fluoride-release properties, stemming from the acid-base reaction between a fluoroaluminosilicate glass powder and an aqueous-based polyacrylic acid solution.
- Polyacid-modified resin sealants, also referred to as compomers, combine resin-based material found in traditional resin-based sealants with the fluoride-releasing and adhesive properties of GI sealants.
- Resin-modified GI sealants are essentially GI sealants with resin components. This type of sealant has similar fluoride-release properties as GI, but it has a longer working time and less water sensitivity than do traditional GI sealants.

Placement techniques for pit-and-fissure sealants vary based on sealant type and the manufacturer or brand.³ Manufacturers' instructions usually detail cleaning and isolation of the occlusal surface and encourage a dry environment during sealant placement and curing. Acid etching of occlusal surfaces is required before resin-based sealant placement. Other techniques mentioned in the studies included in the 2008 report are the use of bonding agents or adhesives, as well as mechanical preparations such as air abrasion or enameloplasty.³

Clinical questions regarding pit-and-fissures sealants

To assist clinicians in the use of pit-and-fissure sealants in occlusal surfaces of primary and permanent molars, the guideline panel developed the following clinical questions:

- Should dental sealants, when compared with nonuse of sealants, be used in pits and fissures of occlusal surfaces of primary and permanent molars on teeth deemed to have clinically sound occlusal surfaces or noncavitated carious lesions?
- Should dental sealants, when compared with fluoride varnishes, be used in pits and fissures of occlusal surfaces of primary and permanent molars on teeth deemed to have clinically sound occlusal surfaces or noncavitated carious lesions?
- Which type of sealant material should be used in pits and fissures of occlusal surfaces of primary and permanent molars on teeth deemed to have clinically sound occlusal surfaces or noncavitated carious lesions?
- Are there any adverse events associated with the use of pit-and-fissure sealants?

Methods

This clinical practice guideline follows the recommendations of the Appraisal of Guidelines Research & Evaluation (known as "AGREE") reporting checklist.¹⁰

Guideline panel configuration. The ADA Council on Scientific Affairs and the AAPD convened a guideline panel in 2014. The members of this panel were recognized for their level of clinical and research expertise and represented the different perspectives required for clinical decision making (general dentists, pediatric dentists, dental hygienists, and health policy makers). Methodologists from the ADA Center for Evidence-Based Dentistry oversaw the guideline development process.

Scope and purpose. The purpose of these recommendations is to provide guidance on sealant use for the prevention of pit-and-fissure occlusal carious lesions in both primary and permanent molars. The target audience for this guideline are front-line clinicians in general practice, pediatric dentists, dental hygienists, dental therapists, community dental health coordinators, dental health policy makers and program planners, and other members of the dental team. Although the evidence came from various settings, we excluded those sealant materials not commercially available at the time of this review.

Retrieving the evidence. Our systematic review methodology for developing this guideline is presented elsewhere.⁸ Briefly, we conducted systematic searches in MEDLINE, Embase, Cochrane Central Register of Controlled Trials, and

other sources to identify randomized controlled trials reporting on the effect of sealants (available on the U.S. market) when applied to the occlusal surfaces of primary and permanent molars. After pairs of independent reviewers conducted title and abstract retrieval, full-text screening, and data extraction, we organized the data retrieved using Grading of Recommendations Assessment, Development, and Evaluation (GRADE) evidence profiles. In addition, we requested the guideline panel to rank the relative importance of outcomes for decision making in 3 categories (critical, important, and not important) following guidance from the GRADE working group.¹²

Assessing the certainty in the evidence. We assessed the certainty in the evidence (also known as the quality of the evidence) using the approach described by the GRADE working group.¹³ The certainty in the evidence in the context of clinical practice guidelines reflects the extent to which the guideline panel felt confident about the estimates of effect used for the decision-making process. The GRADE approach classifies the certainty in the evidence as high, moderate, low, or very low (Table 113-15), depending on whether the body of evidence at an outcome level includes serious or very serious issues as follows:

- Risk of bias: When the studies that are part of the body of evidence are affected by serious or very serious limitations in study design, the confidence in the estimates of effect is reduced owing to the increased risk of bias.¹⁶
- Imprecision: When the confidence intervals (CIs) of the data used for the treatment effects are too wide to make decisions, the confidence in the estimates of effect is reduced owing to issues of imprecision. Typically, imprecision occurs when the CIs suggest both a large benefit on one side and a large harm on the other side.¹⁷
- Inconsistency: When the studies comprising the body of evidence provide inconsistent results, the confidence in the estimates of effect is reduced owing to the unexplained heterogeneity among them.¹⁸
- Indirectness: When the population, interventions, comparator, or outcomes reported in the studies comprising the body of evidence do not directly match the ones the panel requires to make an informed decision, the confidence in the estimates of effect is reduced owing to this mismatching issue.¹⁹
- Publication bias: When there is suspicion that not all studies conducted to inform a particular treatment effect are available or they were selectively published or unpublished, the confidence in the estimates of effect is reduced owing to the suspicion of reporting bias.²⁰

Moving from the evidence to the decisions. To assist the guideline panel with formulating recommendations and grading the strength of the recommendations, we used the evidence-to-decision framework, including the following domains: balance between the desirable and undesirable consequences (net effect), certainty in the evidence (also called quality of the evidence), patients' values and preferences, and resource use.^{14,15} According to the GRADE approach, the strength of a recommendation is

either strong or conditional, in which each grade of the strength has different implications for patients, clinicians, and policy makers (Table 1).

The guideline recommendations in this article were formulated collectively via 3 videoconferences with members of the guideline panel and methodologists from the ADA Center for Evidence-Based Dentistry and the AAPD held in January 2016. Deliberation and consensus were the main methods to develop these recommendations using the “evidence-to-decision” framework.^{14,15} When consensus was elusive, the panel was presented with the positions under assessment, and it voted accordingly.²¹ We identified potential conflicts of interest and managed them according to the recommendations from the World Health Organization and other guideline development agencies.²²

Guideline updating process. The ADA Center for Evidence-Based Dentistry and the AAPD monitor the literature to identify new studies that may be included in the recommendations. These recommendations will be updated 5 years from the date of submission for publication or when new evidence dictates that the panel change the course of action suggested in this guideline.

Recommendations

How to use these recommendations. The recommendations in this clinical practice guideline aim to assist patients, clinicians, and other stakeholders when making health care decisions. Although this clinical practice guideline covers the typical patient that the target audience treats on a daily basis, there may be specific situations in which clinicians may want to deviate from

the recommendations listed below. Clinical expertise plays a key role in determining which patients fit into the scope of this guideline and how these recommendations align with the values, preferences, and the context of an individual patient.²³

When the panel grades a recommendation as strong, this means that in most situations clinicians may want to follow the course of action suggested by the panel and only in a selected few circumstances may they need to deviate from it. Strong recommendations are usually associated with benefits or harms clearly outweighing one over the other, based on high- to moderate-quality evidence (certainty in the evidence), overall homogeneous values and preferences among patients, and inexpensive or easy-to-implement interventions.^{14,15} Conditional recommendations, on the other hand, indicate that clinicians may want to follow the course of action suggested by the panel; however, the panel also recognizes that different choices would be appropriate for individual patients. This type of recommendation is usually associated with a close balance between benefits and harms, low- to very low-quality evidence, important variability in patients’ values and preferences, and substantial costs or challenges when trying to implement the intervention (Table 1).^{4,14,15} When facing a conditional recommendation, clinicians should pay special attention to the reasons that justify such judgment from the guideline panel. This information can be found in the remarks section presented with each recommendation. Table 2 shows a summary of the key recommendations included in this guideline.

Table 1. DEFINITION OF QUALITY OF THE EVIDENCE AND STRENGTH OF RECOMMENDATIONS

EVIDENCE QUALITY AND CERTAINTY DEFINITIONS*		
Category	Definition	
High	We are very confident that the true effect lies close to that of the estimate of the effect	
Moderate	We are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different	
Low	Our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect	
Very Low	We have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect	
DEFINITION OF STRONG AND CONDITIONAL RECOMMENDATIONS AND IMPLICATIONS FOR STAKEHOLDERS†		
Implications	Strong recommendations	Conditional recommendations
For Patients	Most people in this situation would want the recommended course of action, and only a small proportion would not; formal decision aids are not likely to be needed to help people make decisions consistent with their values and preferences	Most people in this situation would want the suggested course of action, but many would not
For Clinicians	Most people should receive the intervention; adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator	Recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences; decision aids may be useful in helping people to make decisions consistent with their values and preferences
For Policy Makers	The recommendation can be adapted as policy in most situations	Policy making will require substantial debate and involvement of various stakeholders

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† Sources: Andrews and colleagues.^{14,15}

Table 2. SUMMARY OF CLINICAL RECOMMENDATIONS ON THE USE OF PIT-AND-FISSURE SEALANTS IN THE OCCLUSAL SURFACES OF PRIMARY AND PERMANENT MOLARS IN CHILDREN AND ADOLESCENTS

QUESTION	RECOMMENDATION	QUALITY OF THE EVIDENCE	STRENGTH OF RECOMMENDATION
Should dental sealants, when compared with nonuse of sealants, be used in pits and fissures of occlusal surfaces of primary and permanent molars on teeth deemed to have clinically sound occlusal surfaces or noncavitated carious lesions?	The sealant guideline panel recommends the use of sealants compared with nonuse in permanent molars with both sound occlusal surfaces and noncavitated occlusal carious lesions in children and adolescents*	Moderate	Strong
Should dental sealants, when compared with fluoride varnishes, be used in pits and fissures of occlusal surfaces of primary and permanent molars on teeth deemed to have clinically sound occlusal surfaces or noncavitated carious lesions?	The sealant guideline panel suggests the use of sealants compared with fluoride varnishes in permanent molars with both sound occlusal surfaces and noncavitated occlusal carious lesions in children and adolescents*	Low	Conditional
Which type of sealant material should be used in pits and fissures of occlusal surfaces of primary and permanent molars on teeth deemed to have clinically sound occlusal surfaces or noncavitated carious lesions?	The panel was unable to determine superiority of 1 type of sealant over another owing to the very low quality of evidence for comparative studies; the panel recommends that any of the materials evaluated (for example, resin-based sealants, resin-modified glass ionomer sealants, glass ionomer cements, and polyacid-modified resin sealants, in no particular order) can be used for application in permanent molars with both sound occlusal surfaces and noncavitated occlusal carious lesions in children and adolescents (conditional recommendation, very low-quality evidence)*†	Very low	Conditional

* These recommendations are applicable to both sound surfaces and noncavitated carious lesions: “Noncavitated lesions are characterized by a change in color, glossiness, or surface structure as a result of demineralization before there is macroscopic breakdown in surface tooth structure. These lesions represent areas with net mineral loss due to an imbalance between demineralization and remineralization. Reestablishing a balance between demineralization and remineralization may stop the caries disease process while leaving a visible clinical sign of past disease.”⁴

† The guideline panel suggests that clinicians should take into account the likelihood of experiencing lack of retention when choosing the type of sealant material most appropriate for a specific patient and clinical scenario. For example, in situations in which dry isolation is difficult, such as a tooth that is not fully erupted and has soft tissue impinging on the area to be sealed, then a material that is more hydrophilic (for example, glass ionomer) would be preferable to a hydrophobic resin-based sealant. On the other hand, if the tooth can be isolated to ensure a dry site and long-term retention is desired, then a resin-based sealant may be preferable.

Question 1. Should dental sealants, when compared with non-use of sealants, be used in pits and fissures of occlusal surfaces of primary and permanent molars on teeth deemed to have clinically sound occlusal surfaces or noncavitated carious lesions?

Summary of findings. Data from 9 randomized controlled trials^{9, 24-31} showed that in children and adolescents with sound occlusal surfaces, the use of pit-and-fissure sealants compared with nonuse of sealants, reduces the incidence of occlusal carious lesions in permanent molars by 76% after 2 to 3 years of follow-up (odds ratio [OR], 0.24; 95% CI, 0.19-0.30) (sTable 1, available in the supplemental data following references). In absolute terms, for a population with a caries baseline risk (prevalence) of 30%, 207 carious lesions would be prevented out of 1,000 sealant applications (95% CI, 186-225 fewer lesions) after 2 to 3 years of follow-up. Available data assessing the effect of sealants compared with a control without sealants in a mixed population of patients with sound occlusal surfaces and noncavitated occlusal carious lesions showed that sealants reduced the incidence of carious lesions in this population by 75% (OR, 0.25; 95% CI, 0.19-0.34) after 2 to 3 years of follow-up. The guideline panel determined the overall quality of the evidence for this comparison as moderate owing to serious issues of

risk of bias (unclear method for randomization and allocation concealment) in the included studies. No data on the effect of sealants in adult patients were identified.

Recommendation. The sealant guideline panel recommends the use of sealants compared with nonuse in primary and permanent molars with both sound occlusal surfaces and noncavitated occlusal carious lesions in children and adolescents. (**Strong recommendation, moderate-quality evidence.**)

Remarks.

- No studies were identified regarding the effect of sealants on preventing and arresting occlusal carious lesions in adult patients. For clinicians and patients attempting to extend this recommendation to adults, the guideline panel suggests that similar treatment effects may be expected for other age groups, particularly in adults with a recent history of dental caries. The lack of direct evidence informing this recommendation restrained the guideline panel from formulating a more definitive recommendation in this regard.
- This recommendation is intended to inform clinicians about the benefit of sealing a tooth compared with not sealing it, irrespective of the type of sealant material applied.
- The panel highlighted that a number of studies have shown that sealing children’s and adolescents’ permanent molars

reduces costs to the health system by delaying and preventing the need for invasive restorative treatment, particularly when these patients are classified as having an “elevated caries risk” (that is, previous caries experience).³² Under these conditions, dental sealants seem to be a cost-effective intervention.³³⁻³⁶

- In addition to the evidence collected by the panel from randomized controlled trials suggesting a beneficial effect of sealants in noncavitated occlusal carious lesions, the body of evidence from observational studies shows similar results.^{37,38}

Research priorities.

- Although the analysis was stratified using 2 caries baseline risks (30% caries prevalence in the article and 70% caries prevalence in the tables), the guideline panel acknowledged that clinicians lack a valid and reliable tool to conduct a chair-side caries risk assessment, especially when it comes to assessing a specific tooth surface or site. There is a need for such a tool to enable clinicians to perform a more accurate assessment of the patient’s caries risk and to enable the panel to provide more specific recommendations using an accurate patient caries risk estimation.
- The panel highlighted the need for additional studies assessing the effect of sealants in the primary dentition.

Question 2. Should dental sealants, when compared with fluoride varnishes, be used in pits and fissures of occlusal surfaces of primary and permanent molars on teeth deemed to have clinically sound occlusal surfaces or noncavitated carious lesions?

Summary of findings. Data from 3 randomized controlled trials^{25,27,39} suggest that in children and adolescents with sound occlusal surfaces, the use of pit-and-fissure sealants compared with fluoride varnishes may reduce the incidence of occlusal carious lesions in permanent molars by 73% after 2 to 3 years of follow-up (OR, 0.27; 95% CI, 0.11-0.69) (sTable 2, available in the supplemental data following references). In absolute terms, for a population with a caries baseline risk (prevalence) of 30%, 196 carious lesions would be prevented out of 1,000 sealant applications (95% CI, 72-255 fewer lesions) when using sealants compared with using fluoride varnish after 2 to 3 years of follow-up. When assessing the effect of sealants compared with fluoride varnishes in a mixed population of patients with sound occlusal surfaces and noncavitated occlusal carious lesions, sealants may reduce the incidence of caries by 34%; however, this difference was not statistically significant (OR, 0.66; $P=.30$; 95% CI, 0.30-1.44). The guideline panel determined the overall quality of the evidence for this comparison as low owing to serious issues of risk of bias (unclear method for randomization and allocation concealment) and inconsistency. No data on the effect of sealants versus fluoride varnish in adult patients were identified.

Recommendation. The sealant guideline panel suggests the use of sealants compared with fluoride varnishes in primary and permanent molars, with both sound occlusal surfaces and noncavitated occlusal carious lesions, in children and adolescents. (Conditional recommendation, low-quality evidence.)

Research priorities.

- Although the analysis was stratified using 2 caries baseline risks (30% caries prevalence in the article and 70% caries prevalence in the tables), the guideline panel acknowledged that clinicians lack a valid and reliable tool to conduct a chairside caries risk assessment. There is a need for such a tool to enable clinicians to understand the evidence in the context of different caries risk estimations.
- The guideline panel suggests that more research should be conducted on other noninvasive approaches for caries arrest in occlusal surfaces of primary and permanent molars (for example, silver diamine fluoride).

Question 3. Which type of sealant material should be used in pits and fissures of occlusal surfaces of primary and permanent molars on teeth deemed to have clinically sound occlusal surfaces or noncavitated carious lesions in children and adolescents?

Comparison 3.1. GI sealants compared with resin-based sealants.

Summary of findings. Data from 10 randomized controlled trials⁴⁰⁻⁴⁹ included in the meta-analysis suggest that in children and adolescents with sound occlusal surfaces, the use of GI sealants compared with resin-based sealants may reduce the incidence of occlusal carious lesions in permanent molars by 37% after 2 to 3 years of follow-up (OR, 0.71; 95% CI, 0.32-1.57); however, this difference was not statistically significant ($P=.39$) (sTable 3, available in the supplemental data following references). In absolute terms, for a population with a caries baseline risk (prevalence) of 30%, this means that use of a GI sealant would prevent 67 carious lesions out of 1,000 sealant applications (95% CI, 102 more -179 fewer lesions) compared with using a resin-based sealant after 2 to 3 years of follow-up; however, this difference was not statistically significant. One additional study with 200 participants that we were unable to include in the meta-analysis owing to the data presentation failed to show a clinically or statistically significant difference in caries incidence when GI sealants and resin-based sealants were placed on the occlusal surfaces of primary and permanent molars.⁵⁰ When looking at available data assessing the effect of GI sealants compared with resin-based sealants in a population of patients with noncavitated occlusal carious lesions, the data suggest that GI sealants may increase the incidence of carious lesions by 53% (OR, 1.53; 95% CI, 0.58-4.07); however, this difference was not statistically significant ($P=.39$). When assessing retention, glass ionomer sealants may have 5 times greater risk of experiencing loss of retention from the tooth compared with resin-based sealants after 2 to 3 years of follow-up (OR, 5.06; 95% CI, 1.81-14.13). The guideline panel determined the overall quality of the evidence for this comparison as very low owing to serious issues of risk of bias (unclear method for randomization and allocation concealment), inconsistency, and imprecision. No data on the effect of GI versus resin-based sealants in adult patients were identified.

Comparison 3.2. Glass ionomer sealants compared with resin-modified GI sealants

Summary of findings. Data from 1 randomized controlled trial²⁹ suggest that in children and adolescents with sound occlusal surfaces the use of GI sealants compared with resin-modified GI sealants may increase the incidence of occlusal carious lesions in permanent molars by 41% after 2 to 3 years of follow-up (OR, 1.41; 95% CI, 0.65-3.07); however, this difference was not statistically significant ($P=.38$) (**sTable 4**, available in the supplemental data following references). In absolute terms, for a population with a caries baseline risk (prevalence) of 30%, we are expecting to have 77 more carious lesions over 1,000 sealant applications (95% CI, 82 fewer-268 more lesions) when using GI sealants compared with using a resin-modified glass ionomer sealant after 2 to 3 years of follow-up; however, this difference was not statistically significant. When assessing retention, GI sealants would have 3 times greater risk of experiencing retention loss from the tooth compared with resin-modified glass ionomer sealants after 2 to 3 years of follow-up (OR, 3.21; 95% CI, 1.87-5.51). The guideline panel determined the overall quality of the evidence for this comparison as very low owing to serious issues of risk of bias (unclear method for randomization and allocation concealment), and very serious issues of imprecision. No data on the effect of GI versus resin-modified GI sealants in adult patients were identified.

Comparison 3.3. Resin-modified glass ionomer sealants compared with polyacid-modified resin sealants.

Summary of findings. Data from 1 randomized controlled trial⁴⁸ suggest that in children and adolescents with sound occlusal surfaces, the use of resin-modified GI sealants compared with polyacid-modified GI sealants may reduce the incidence of occlusal carious lesions in permanent molars by 56% after 2 to 3 years of follow-up (OR, 0.44; 95% CI, 0.11-1.82); however, this difference was not statistically significant ($P=.26$) (**sTable 5**, available in the supplemental data following references). In absolute terms, for a population with a caries baseline risk (prevalence) of 30% this means that use of resin-modified GI sealants would prevent 141 carious lesions out of 1,000 sealant applications (95% CI, 138 more-255 fewer lesions) compared with the use of polyacid-modified resin sealants after 2 to 3 years of follow-up; but this difference was not statistically significant. When assessing retention, resin-modified GI sealants may increase the risk of loss of retention by 17% compared with polyacid-modified resin sealants after 2 to 3 years of follow-up (OR, 1.17; 95% CI, 0.52-2.66); however, this difference was not statistically significant ($P=.70$). The guideline panel determined the overall quality of the evidence for this comparison as very low owing to serious issues of risk of bias (unclear method for randomization and allocation concealment) and very serious issues of imprecision. No data on the effect of resin-modified versus polyacid-modified resin sealants in adult patients were identified.

Comparison 3.4. Polyacid-modified resin sealants compared with resin-based sealants.

Summary of findings. Data from 2 randomized controlled trials^{48,51} suggest that in children and adolescents with sound occlusal surfaces, the use of polyacid-modified resin sealants compared with resin-based sealants may increase the incidence of occlusal carious lesions in permanent molars by 1% after 2 to 3 years of follow-up (OR, 1.01; 95% CI, 0.48-2.14); however, this difference was not statistically significant ($P=.97$) (**sTable 6**, available in the supplemental data following references). In absolute terms, for a population with a caries baseline risk (prevalence) of 30%, the use of polyacid-modified resin sealant would increase carious lesions by 2 out of 1,000 sealant applications (95% CI, 129 fewer-178 more lesions) compared with using a resin-based sealant after 2 to 3 years of follow-up; however, this difference was not statistically significant. When assessing the outcome retention, polyacid-modified resin sealants seem to reduce the risk of loss of retention by 13% compared with resin-based sealants after 2 to 3 years of follow-up (OR, 0.87; 95% CI, 0.12-6.21); however, this difference was not statistically significant ($P=.89$). The guideline panel determined the overall quality of the evidence for this comparison as very low owing to serious issues of risk of bias (unclear method for randomization and allocation concealment) and very serious issues of imprecision. No data on the effect of polyacid-modified resin versus resin-based sealants in adult patients were identified.

Recommendation. The panel was unable to determine superiority of 1 type of sealant over another owing to the very low quality of evidence for comparative studies. The panel recommends that any of the materials evaluated (for example, resin-based sealants, resin-modified GI sealants, GI cements, and polyacid-modified resin sealants in no particular order) can be used for application in permanent molars with both sound occlusal surfaces and noncavitated occlusal carious lesions in children and adolescents. (**Conditional recommendation, very low-quality evidence.**)

Remarks.

- The head-to-head analyses of all comparisons did not allow the guideline panel to provide specific recommendations using a hierarchy of effectiveness for the sealant materials. In addition, the quality of the evidence across head-to-head comparisons was assessed to be low to very low at best. The guideline panel suggests that clinicians take into account the likelihood of experiencing lack of retention when choosing the type of sealant material most appropriate for a specific patient and clinical scenario. For example, in situations in which dry isolation is difficult, such as a tooth that is not fully erupted and has soft tissue impinging on the area to be sealed, then a material that is more hydrophilic (for example, GI) would be preferable to a hydrophobic resin-based sealant. On the other hand, if the tooth can be isolated to ensure a dry site and long-term retention is desired, then a resin-based sealant may be preferable.

- The lack of reporting in relation to resealing did not allow the panel to include this as 1 more element for decision making. However, it can be inferred from the data on retention loss that clinicians may need to monitor sealants showing a higher risk of experiencing retention loss more often.
- To obtain optimal levels of retention, the guideline panel suggests clinicians carefully follow the manufacturers' instructions for each type of sealant material.

Research priorities.

- The panel urges the research community to conduct high-quality randomized controlled trials to understand further the relative merits of the different types of sealant materials. Such studies should meet the optimal information size¹⁷ to reduce the very serious issues of imprecision affecting this body of evidence.
- New trials should improve reporting quality to allow the panel to conduct a more accurate assessment of the risk of bias.
- Further research is needed to understand the role of different types of sealant materials in the primary dentition and adult population.
- Although the analysis conducted was stratified using 2 caries baseline risks (30% caries prevalence in the article and 70% caries prevalence in the tables), the guideline panel acknowledged that clinicians lack a reliable and valid chairside tool to conduct a caries risk assessment. There is a need for such a tool to enable clinicians to extrapolate the results from this analysis to their patients in a more accurate manner.
- The poor quality or complete lack of reporting in relation to resealing prevented the panel from using this information during the decision-making process. The panel highlighted the need for improving the report of reapplication of sealants as 1 more relevant outcome in primary studies assessing the effect of this intervention.

Question 4. Are there any adverse events when using pit-and-fissure sealants?

Summary of findings. There has been concern that dental sealants might exhibit adverse effects. This is primarily associated with bisphenol A (BPA). It has been suggested that the BPA present in some sealants may have estrogenlike effects^{52,53}; however, the evidence does not support the transient effect of a small amount of BPA in placing patients at risk.⁵⁴ Studies also have evaluated the correlation of developing carious lesions in teeth with fully or partially lost sealants and found no greater risk than in teeth that had never been sealed.⁵⁵ Two randomized controlled trials measuring the occurrence of adverse effects associated with sealants found no events related to this outcome.^{27,56,57}

Conclusions

The evidence shows that sealants available in the U.S. market at the time of this systematic review are an effective intervention for reducing the incidence of carious lesions in the occlusal surfaces of primary and permanent molars in children and adolescents

compared with the nonuse of sealants or fluoride varnishes. This benefit is inclusive to both sound occlusal surfaces and non-cavitated occlusal carious lesions. Clinicians should use these recommendations but consider carefully individual patient factors, especially where the guideline panel offered conditional recommendations. In addition, sealant use should be increased along with other preventive interventions to manage the caries disease process, especially in patients with an elevated risk of developing caries. Further research is needed to provide more risk-oriented recommendations, particularly regarding the development of a valid and reliable chairside tool for clinicians to assess a patient's caries risk.

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Supplemental data

Table 1. EVIDENCE PROFILE: SEALANTS COMPARED WITH NONUSE OF SEALANTS IN PIT-AND-FISSURE OCCLUSAL SURFACES IN CHILDREN AND ADOLESCENTS.*

QUALITY ASSESSMENT						
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Caries incidence (follow-up: range 2-3 y)[‡]						
9	Randomized trials	Serious [§]	Not serious	Not serious	Not serious	None
Caries incidence (follow-up: range 4-7 y)[#]						
3	Randomized trials	Serious [§]	Serious**	Not serious	Not serious	None
Caries incidence (follow-up: range 7 y or more)[#]						
2	Randomized trials	Serious [§]	Not serious	Not serious	Not serious	None
Lack of retention (follow-up: range 2-3 y)						
9	Randomized trials	Serious [§]	Not serious	Not serious	Not serious	None

Table continues on next page

sTable 1. CONTINUED					
PATIENTS (N)		Relative odds ratio (95% confidence interval)	EFFECT	QUALITY	IMPORTANCE
Sealants	Nonuse of sealants†				
194/1,799 (12.0%)	584/1,743 (37.3%)¶ 30.0% 70.0%	0.24 (0.19-0.30)	248 fewer per 1,000 (221-271 fewer) 207 fewer per 1,000 (186-225 fewer) 341 fewer per 1,000 (288-393 fewer)	Moderate	Critical
74/368 (20.1%)	206/384 (53.6%)†† 30.0% 70.0%	0.21 (0.10-0.44)	341 fewer per 1,000 (199-433 fewer) 217 fewer per 1,000 (141-259 fewer) 371 fewer per 1,000 (193-511 fewer)	Low	Critical
62/215 (28.8%)	170/231 (73.6%)‡‡ 30.0% 70.0%	0.15 (0.08-0.27)	441 fewer per 1,000 (307-554 fewer) 240 fewer per 1,000 (196-267 fewer) 441 fewer per 1,000 (313-543 fewer)	Moderate	Critical
Including all sealant material types and tooth preparation techniques, 55.6% of sealants were fully retained at 2 y, and 59.3% were fully or partially retained at 2 y; at 3 y, 56.4% of all sealants were fully retained, and 58.8% were fully or partially retained after 3.6 y				Moderate	Important

* Sources: Bravo and colleagues,⁵¹ Liu and colleagues,⁵² Mertz-Fairhurst and colleagues,⁵³ Splieth and colleagues,⁵⁴ Bojanini and colleagues,⁵⁵ Richardson and colleagues,⁵⁶ Erdogan and colleagues,⁵⁷ Tagliaferro and colleagues,⁵⁸ and Pereira and colleagues.⁵⁹

** Unexplained heterogeneity ($P < .0001$, $I^2 = 77\%$).

† The percentages (30% and 70%) indicate the control group baseline risk (caries prevalence).

†† 2 of 3 studies reported being conducted in water-fluoridated communities.

‡ A subgroup analysis conducted to determine whether there was a difference in the caries incidence depending on whether the sealant was placed in patients with noncavitated carious lesions or deep fissures and pits, no caries in the occlusal surface, and a mix of caries free and noncavitated carious lesions, showed no statistically significant differences ($P = .58$). Studies including a mixed population (recruiting both patients with noncavitated initial occlusal caries and caries-free occlusal surfaces) showed a 76% reduction in caries incidence after 2- to 3-y follow-up (odds ratio, 0.24; 95% confidence interval, 0.19-0.30).

‡‡ 2 of 2 studies reported being conducted in water-fluoridated communities.

§ Most studies were classified as unclear for the "allocation concealment" and "masking" domains.

¶ 4 of 9 studies reported being conducted in water-fluoridated communities.

Studies only reported data for this outcome in patients who were caries-free. Patients with noncavitated carious lesions or deep pits and fissures were not included in the studies.

Table 2. EVIDENCE PROFILE: SEALANTS COMPARED WITH FLUORIDE VARNISHES IN PIT-AND-FISSURE OCCLUSAL SURFACES IN CHILDREN AND ADOLESCENTS.*

QUALITY ASSESSMENT						
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Caries incidence (follow-up: range 2-3 y) ‡						
3	Randomized trials	Serious§	Serious¶	Not serious	Not serious	None
Caries incidence (follow-up: range 4-7 y)**						
2	Randomized trials	Serious§	Serious††	Not serious	Not serious	None
Caries incidence (follow-up: range 7 y or more)						
1	Randomized trials	Very serious§	Not serious	Not serious	Not serious	None
Lack of retention (follow-up: range 2-3 y)						
2	Randomized trials	Serious§	Not serious	Not serious	Not serious	None

PATIENTS (N)		EFFECT		QUALITY	IMPORTANCE
Sealants	Fluoride varnishes†	Relative odds ratio (95% confidence interval)	Absolute (95% confidence interval)		
66/855 (7.7%)	364/860 (42.3%)# 30.0% 70.0%	0.27 (0.11-0.69)	258 fewer per 1,000 (87-349 fewer) 196 fewer per 1,000 (72-255 fewer) 313 fewer per 1,000 (83-496 fewer)	Low	Critical
46/228 (20.2%)	131/244 (53.7%)‡‡ 30.0% 70.0%	0.19 (0.07-0.51)	356 fewer per 1,000 (165-462 fewer) 225 fewer per 1,000 (121-271 fewer) 393 fewer per 1,000 (157-560 fewer)	Low	Critical
30/113 (26.5%)	72/129 (55.8%)§§ 30.0% 70.0%	0.29 (0.17-0.49)	290 fewer per 1,000 (176-381 fewer) 189 fewer per 1,000 (126-232 fewer) 296 fewer per 1,000 (167-416 fewer)	Low	Critical
Including all sealant material types and tooth preparation techniques, 55.6% of sealants were fully retained at 2 y, and 59.3% were fully or partially retained at 2 y; at 3 y, 56.4% of all sealants were fully retained, and 58.8% were fully or partially retained at 3 y				Moderate	Important

* Sources: Houpt and colleagues,^{s10} Bravo and colleagues,^{s1} and Liu and colleagues.^{s2} ** The studies only reported the outcome in patients who were caries-free.

† The percentages (30% and 70%) indicate the control group baseline risk (caries prevalence).

†† Unexplained heterogeneity ($P=.03$, $I^2=80%$).

‡ A subgroup effect was identified for this outcome ($P=.04$). Patients who were caries-free (odds ratio, 0.19; 95% confidence interval, 0.07-0.47) and mixed population (odds ratio, 0.66; 95% confidence interval, 0.30-1.44).

‡‡ 2 of 2 studies reported being conducted in water-fluoridated communities.

§ Most studies were classified as unclear for the "allocation concealment" and "masking" domains.

§§ The study reported being conducted in water-fluoridated communities.

¶ Unexplained heterogeneity ($P=.0002$, $I^2=88%$).

2 of 3 studies reported being conducted in water-fluoridated communities.

Table 3. EVIDENCE PROFILE: GLASS IONOMER SEALANTS COMPARED WITH RESIN-BASED SEALANTS IN PIT-AND-FISSURE OCCLUSAL SURFACES IN CHILDREN AND ADOLESCENTS.*

QUALITY ASSESSMENT						
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Caries incidence (follow-up: range 2-3 y)^{‡,§}						
10	Randomized trials	Serious [¶]	Serious [#]	Not serious	Serious ^{**}	None
Caries incidence (follow-up: range 4-7 y)^{‡‡}						
2	Randomized trials	Serious ^{§§}	Not serious	Not serious	Very serious ^{¶¶}	None
Caries incidence (follow-up: range 7 yr or more)—not reported						
— ^{##}	—	—	—	—	—	—
Lack of retention (follow-up: range 2-3 yr)						
10	Randomized trials	Serious [¶]	Serious ^{***}	Not serious	Not serious	None
Lack of retention (follow-up: range 4-7 yr)—not reported						
2	Randomized trials	Serious ^{§§}	Not serious	Not serious	Serious ^{†††}	—
Lack of retention—not reported						
—	—	—	—	—	—	—
PATIENTS (N)		EFFECT		QUALITY	IMPORTANCE	
Glass ionomer sealants	Resin-based sealants [†]	Relative odds ratio (95% confidence interval)	Absolute (95% confidence interval)			
179/2,727 (6.6%)	141/2,014 (7.0%) ^{††} 30.0% 70.0%	0.71 (0.32-1.57)	19 fewer per 1,000 (36 more-46 fewer) 67 fewer per 1,000 (102 more-179 fewer) 76 fewer per 1,000 (86 more-273 fewer)	Very low	Critical	
6/61 (9.8%)	19/84 (22.6%) 30.0% 70.0%	0.37 (0.14-1.00)	154 fewer per 1,000 (0-228 fewer) 163 fewer per 1,000 (0-243 fewer) 237 fewer per 1,000 (0-454 fewer)	Very low	Critical	
—	—	—	—	—	Critical	
1875/2,727 (68.8%)	596/2,014 (29.6%)	5.06 (1.81-14.13)	384 more per 1,000 (136-560 more)	Low	Important	
46/61 (75.4%)	50/84 (59.5%)	2.08 (0.15-27.95)	158 more per 1,000 (381 more-415 fewer)	Low	Important	
—	—	—	—	—	Important	

* Sources: Chen and colleagues,^{s11,s12} Chen and Liu,^{s13} Amin,^{s14} Antonson and colleagues,^{s15} Arrow and Riordan,^{s16} Baseggio and colleagues,^{s17} Pardi and colleagues,^{s18} Guler and Yilmaz,^{s19} Dhar and Chen,^{s20} and Haznedaroglu and Guner.^{s21} ** 95% confidence interval suggests large benefit and a large harm (95% confidence interval, 68% reduction-57% increase). *** Unexplained heterogeneity ($P \leq .00001$, $I^2=97\%$).

† The percentages (30% and 70%) indicate the control group baseline risk (caries prevalence). †† 1 of 10 studies reported being conducted in water-fluoridated communities. ††† 95% confidence interval suggests a large benefit and a large harm (95% confidence interval, 85% reduction-2,695% increase).

‡ A subgroup analysis conducted to determine whether there was a difference in the caries incidence depending on whether the sealant was placed in non-cavitated carious lesions or deep fissures and pits, no caries in the occlusal surface, and a mix of caries free and noncavitated carious lesions, showed no statistically significant differences (odds ratio, 1.53; 95% confidence interval, 0.58-4.07; $P=.19$). ‡‡ Only 2 studies reported this outcome. No subgroup analysis was conducted.

§ One additional study including 200 participants that was not included in the meta-analysis due to the data presentation failure to show a clinically or statistically significant difference in caries incidence when glass ionomer sealants and resin-based sealants were placed in the occlusal surfaces of primary and permanent teeth. §§ The "randomization" and "allocation concealment" domains were classified as "unclear" risk of bias for most studies.

¶ Most studies were classified as unclear for the "allocation concealment" and "masking" domains. ¶¶ 95% confidence interval suggests a large benefit and a large harm (95% confidence interval, 96% reduction-0% increase).

Unexplained heterogeneity ($P < .00001$, $I^2=81\%$). ## Dashes indicate data not available.

Table 4. EVIDENCE PROFILE: GLASS IONOMER SEALANTS COMPARED WITH RESIN-MODIFIED GLASS IONOMER SEALANTS IN PIT-AND-FISSURE OCCLUSAL SURFACES IN CHILDREN AND ADOLESCENTS.*

QUALITY ASSESSMENT						
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Caries incidence (follow-up: range 2-3 y)‡						
1	Randomized trials	Serious§	Not serious	Not serious	Very serious¶	None
Caries incidence (follow-up: range 4-7 y)—not reported						
—**	—	—	—	—	—	—
Caries incidence (follow-up: range 7 y or more)—not reported						
—	—	—	—	—	—	—
Lack of retention (follow-up: range 2-3 y)						
1	Randomized trials	Serious§	Not serious	Not serious	Not serious	None
Lack of retention (follow-up: range 4-7 y)—not reported						
—	—	—	—	—	—	—
Lack of retention (follow-up: range 7 y or more)—not reported						
—	—	—	—	—	—	—
PATIENTS (N)		EFFECT		QUALITY	IMPORTANCE	
Glass ionomer sealants	Resin-modified glass ionomer sealants*	Relative odds ratio (95% confidence interval)	Absolute (95% confidence interval)			
27/172 (15.7%)	20/172 (11.6%)# 30.0% 70.0%	1.41 (0.65-3.07)	40 more per 1,000 (37 fewer-171 more) 77 more per 1,000 (82 fewer-268 more) 67 more per 1,000 (97 fewer-178 more)	Very low	Critical	
—	—	—	—	—	Critical	
—	—	—	—	—	Critical	
149/172 (86.6%)	115/172 (66.9%)	3.21 (1.87-5.51)	198 more per 1,000 (122-249 more)	Moderate	Important	
—	—	—	—	—	Important	
—	—	—	—	—	Important	

* Source: Pereira and colleagues.⁹⁹

** Dashes indicate data not available.

† The percentages (30% and 70%) indicate the control group baseline risk (caries prevalence).

‡ Only 1 study reported this outcome. No subgroup analysis was included.

§ All domains were classified as unclear, including the "allocation concealment" and "masking" domains.

¶ The 95% confidence interval suggests an appreciable benefit and an appreciable harm (95% confidence interval, 45% reduction-207% increase in caries incidence).

The study was conducted in water-fluoridated communities.

Table 5. EVIDENCE PROFILE: RESIN-MODIFIED GLASS IONOMER SEALANTS COMPARED WITH POLYACID-MODIFIED RESIN SEALANTS IN PIT-AND-FISSURE OCCLUSAL SURFACES IN CHILDREN AND ADOLESCENTS.*

QUALITY ASSESSMENT						
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations
Caries incidence (follow-up: range 2-3 y)†						
1	Randomized trials	Serious§	Not serious	Not serious	Very serious¶	None
Caries incidence (follow-up: range 4-7 y)-not reported						
—**	—	—	—	—	—	—
Caries incidence (follow-up: range 7 y or more)-not reported						
—	—	—	—	—	—	—
Lack of retention (follow-up: range 2-3 y)						
1	Randomized trials	Serious§	Not serious	Not serious	Very serious††	None
Lack of retention (follow-up: range 4-7 y)-not reported						
—	—	—	—	—	—	—
Lack of retention (follow-up: range 7 y or more)-not reported						
—	—	—	—	—	—	—

PATIENTS (N)		EFFECT		QUALITY	IMPORTANCE
Resin-modified glass ionomer sealants	Polyacid-modified resin sealants†	Relative odds ratio (95% confidence interval)	Absolute (95% confidence interval)		
3/97 (3.1%)	6/89 (6.7%)# 30.0% 70.0%	0.44 (0.11-1.82)	37 fewer per 1,000 (49 more-60 fewer) 141 fewer per 1,000 (138 more-255 fewer) 193 fewer per 1,000 (109 more-496 fewer)	Very low	Critical
—	—	—		—	
—	—	—		—	
15/97 (15.5%)	12/89 (13.5%)	1.17 (0.52-2.66)	19 more per 1,000 (60 fewer-158 more)	Very low	Important
—	—	—		—	
—	—	—		—	

* Source: Pardi and colleagues.¹⁸

** Dashes indicate data not available.

† The percentages (30% and 70%) indicate the control group baseline risk (caries prevalence).

†† 95% confidence interval suggests a large benefit and a large harm (95% confidence interval, 48% reduction-166% increase). Only 27 events are informing this outcome.

‡ Only 1 study reported this outcome. No subgroup analysis was conducted.

§ All risk of bias domains were classified as unclear.

¶ 95% confidence interval suggests a large benefit and a large harm (95% confidence interval, 89% reduction-82% increase). Only 9 events are informing this outcome.

The study was conducted in water-fluoridated communities.

Table 6. EVIDENCE PROFILE: POLYACID-MODIFIED RESIN SEALANTS COMPARED WITH RESIN-BASED SEALANTS IN PIT-AND-FISSURE OCCLUSAL SURFACES IN CHILDREN AND ADOLESCENTS.*

QUALITY ASSESSMENT						
No. of Studies	Study Design	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Considerations
Caries incidence (follow-up: range 2-3 y) [†]						
2	Randomized trials	Serious [§]	Not serious	Not serious	Very serious [¶]	None
Caries incidence (follow-up: range 4-7 y)-not reported						
—**	—	—	—	—	—	—
Caries incidence (follow-up: range 7 y or more)-not reported						
—	—	—	—	—	—	—
Lack of retention (follow-up: range 2-3 y)						
2	Randomized trials	Serious [§]	Serious ^{††}	Not serious	Serious ^{‡‡}	None
Lack of retention (follow-up: range 4-7 y)-not reported						
—	—	—	—	—	—	—
Lack of retention (follow-up: range 7 y or more)-not reported						
—	—	—	—	—	—	—
PATIENTS (N)		EFFECT		QUALITY	IMPORTANCE	
Polyacid-modified resin sealants	Resin-based sealants [†]	Relative odds ratio (95% confidence interval)	Absolute (95% confidence interval)			
16/159 (10.1%)	16/163 (9.8%) [#] 30.0% 70.0%	1.01 (0.48 to 2.14)	1 more per 1,000 (49 fewer-91 more) 2 more per 1,000 (129 fewer-178 more) 2 more per 1,000 (133 more-172 fewer)	Very low	Critical	
—	—	—	—	—	—	
—	—	—	—	—	—	
15/159 (9.4%)	15/163 (9.2%)	0.87 (0.12-6.21)	11 fewer per 1,000 (80 fewer-294 more)	Very low	Important	
—	—	—	—	—	—	
—	—	—	—	—	—	

* Sources: Gungor and colleagues^{s22} and Pardi and colleagues.^{s18}

† The percentages (30% and 70%) indicate the control group baseline risk (caries prevalence).

‡ The studies only reported the outcome in patients who were caries-free. No subgroup analysis was conducted.

§ The 2 studies were classified as "unclear" risk of bias for the domain "allocation concealment".

¶ 95% confidence interval suggests a large benefit and a large harm (95% confidence interval, 52% reduction-114% increase).

1 of 2 studies reported being conducted in water-fluoridated communities.

** Dashes indicate data not available.

†† Unexplained heterogeneity ($P < .00001$, $I^2 = 97%$).

‡‡ 95% confidence interval suggests a large benefit and a large harm (95% confidence interval, 88% reduction-521% increase).

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