



Complete Summary

GUIDELINE TITLE

Evidence-based clinical recommendations for the use of pit-and-fissure sealants. A report of the American Dental Association Council on Scientific Affairs.

BIBLIOGRAPHIC SOURCE(S)

Beauchamp J, Caufield PW, Crall JJ, Donly K, Feigal R, Gooch B, Ismail A, Kohn W, Siegal M, Simonsen R, American Dental Association Council on Scientific Affairs. Evidence-based clinical recommendations for the use of pit-and-fissure sealants: a report of the American Dental Association Council on Scientific Affairs. J Am Dent Assoc 2008 Mar;139(3):257-68. [99 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Dental caries

Note: Caries is an infectious oral disease that can be arrested in its early stages.

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Evaluation
Prevention

Risk Assessment
Treatment

CLINICAL SPECIALTY

Dentistry

INTENDED USERS

Dentists

GUIDELINE OBJECTIVE(S)

To provide a critical evaluation and summary of the relevant scientific evidence and to provide recommendations that will assist clinicians with their decision-making process

TARGET POPULATION

General population of all ages with natural teeth

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Risk Assessment

1. Tooth cleaning and drying
2. Visual examination to detect early noncavitated lesions
3. Evaluation of patient's caries risk status
4. Recent radiographs (but only if available)
5. Periodic re-evaluation of patient's risk status

Prevention

1. Bonding agents (total and self-etch systems)
2. Pit-and-fissure sealants, utilizing a four-handed technique
 - Resin-based sealants (polymerized by autopolymerization, photopolymerization using visible light or a combination of the two processes)
 - Glass ionomer cements (conventional and resin-modified)

MAJOR OUTCOMES CONSIDERED

Incidence of dental caries

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Search Strategy

Systematic Reviews

Systematic reviews of randomized clinical trials are the highest level of scientific evidence to support clinical recommendations. Staff of the American Dental Association (ADA) Division of Science searched MEDLINE for all systematic reviews published in English on pit-and-fissure sealants through Oct. 4, 2006. They used the "Find Systematic Reviews" tool of the [PubMed Clinical Queries search engine](#). Search terms, identified elsewhere in this document as the "standard search terms," were as follows: "Sealants, Dental" OR "Dental Sealants" OR "Pit Fissure Sealants" OR "Fissure Sealants, Pit" OR "Sealants, Pit Fissure" OR "Fissure Sealants" OR "Sealants, Fissure" OR "Sealants, Tooth" OR "Tooth Sealants" OR "Resin Cements" OR "Glass Ionomer Cements".

The ADA staff members identified 77 articles. They screened titles and abstracts and consulted the full texts of selected publications. Inclusion criteria were as follows:

- Publications that address one or more of the identified clinical questions
- Publications that had a documented search strategy to systematically identify the evidence
- Publications written in English

The ADA staff members screened references cited in selected systematic reviews to identify additional systematic reviews not identified through the search strategy. Thus, they identified 10 systematic reviews. One member of the expert panel identified an additional systematic review that had been published since the literature search was conducted. Members of the expert panel had the opportunity to identify any additional systematic reviews that should be considered. Representatives of the panel from the U.S. Centers for Disease Control and Prevention (CDC) shared with the panel a prepublication copy of additional systematic reviews recently completed by CDC. (Those manuscripts since have been published.) The panelists considered a total of 12 systematic reviews.

Newly Published Studies

ADA Division of Science staff conducted a search for articles published between Dec. 1, 2002 and Sept. 15, 2006, by using MEDLINE to identify any newly published studies using the standard search terms described above. They selected search dates on the basis of the search strategies of the most current systematic reviews that address each of the clinical questions:

- **Under what conditions should sealants be placed to prevent caries?** (The literature searches for this systematic review included studies published through June 2005.)

- **Does placing sealants over early (noncavitated) lesions prevent progression of the lesions?** (The literature search for this systematic review included studies published through June 2005.)
- **Are there conditions that favor the placement of resin-based versus glass ionomer cement sealants in retention or caries prevention?** (The literature search for this systematic review included studies published through December 2002.)
- **Are there any techniques that could improve sealants' retention and effectiveness in caries prevention?** (The literature search for this systematic review included studies published through December 2004).

This literature search for clinical studies identified 2,130 articles. ADA Division of Science staff members screened titles and abstracts and consulted the full texts of selected publications.

Inclusion criteria were as follows:

- Clinical studies that addressed one of the identified clinical questions
- Studies published within the inclusion dates listed above
- Publications written in English

The staff members identified 16 clinical studies. Members of the expert panel had the opportunity to identify additional clinical studies that should be considered for inclusion. The panelists chose to analyze individually seven clinical studies from the 2001 systematic review conducted by Tinanoff and Douglass. They selected these publications because they addressed one of the clinical questions. The panelists also identified seven additional clinical studies for consideration. Four of those studies, published in 1997 or later, evaluated the use of adhesives or bonding agents in sealant placement. The panel excluded studies on adhesive or bonding agents that are no longer marketed in the United States. While developing these clinical recommendations, the panelists learned of an additional study that was accepted for publication (now published). The lead author of that study provided the accepted manuscript for the panel's consideration.

Two- or Four-handed Sealant Placement Technique

The panelists determined that the systematic reviews and newly identified studies were insufficient to determine whether use of a four-handed versus a two-handed technique improves sealant retention or caries prevention. Staff of the ADA Division of Science conducted a literature search using MEDLINE for clinical studies that directly compared sealant outcomes resulting from two- or four-handed sealant placement technique, examining literature from January 1975 through January 2007 using the following search terms: ("Dental Sealants" OR "Pit Fissure Sealants" OR "Fissure Sealants, Pit" OR "Sealants, Pit Fissure" OR "Fissure Sealants" OR "Sealants, Fissure" OR "Sealants, Tooth" OR "Tooth Sealants" OR "Resin Cements" OR "Glass Ionomer Cements") AND ("two-hand" OR "two hand" OR "2 hand" OR "2-hand" OR "four-hand" OR "four hand" OR "4 hand" OR "4-hand" OR "dentists" OR "hygienist" OR "assistant" OR "Dental team" OR "Auxiliary team" OR "Auxiliary"). The search identified 412 articles. ADA Division of Science staff screened titles and abstracts, and they reviewed the full texts of selected publications. Inclusion criteria were as follows:

- Clinical studies of two- and/or four-handed dentistry
- Publications written in English

The staff members identified no clinical studies on this topic.

Members of the expert panel presented an unpublished manuscript (now published) that examined individual studies included in three recent systematic reviews on sealant effectiveness. CDC completed a multivariate analyses of factors, including use of two-handed or four-handed method, associated with sealant retention. The included studies evaluated the retention of second- or third-generation resin-based sealant materials and provided data on whether sealant was applied with a two-handed or a four-handed method.

Enamel Preparation Techniques

The panelists determined that the systematic reviews and newly identified studies were insufficient to determine whether enamel preparation, including air abrasion or enameloplasty, would improve sealant retention or caries prevention. ADA Division of Science staff conducted an additional literature search to identify clinical studies published since 1975.

The ADA staff members searched the literature from January 1975 through January 2007 using MEDLINE for selected studies evaluating enamel preparation techniques using the following search terms: ("Dental Sealants" OR "Pit Fissure Sealants" OR "Fissure Sealants, Pit" OR "Sealants, Pit Fissure" OR "Fissure Sealants" OR "Sealants, Fissure" OR "Sealants, Tooth" OR "Tooth Sealants" OR "Resin Cements" OR "Glass Ionomer Cements") AND ("enamel preparation" OR "air abrasion" OR "fissurotomy" OR "enamelplasty" OR "enameloplasty" OR "fissurotomy"). The search identified 605 articles. ADA Division of Science staff screened titles and abstracts and consulted and the full texts of selected publications. Inclusion criteria were as follows:

- Clinical studies of enamel preparation techniques
- Publications written in English

The staff members identified four additional reports on this topic. Members of the expert panel were aware of three additional reports that were considered for these clinical recommendations.

NUMBER OF SOURCE DOCUMENTS

56

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

System Used For Grading the Evidence*	
Grade	Category of Evidence
Ia	Evidence from systematic reviews of randomized controlled trials
Ib	Evidence from at least one randomized controlled trial
IIa	Evidence from at least one controlled study without randomization
IIb	Evidence from at least one other type of quasiexperimental study, such as time series analysis or studies in which the unit of analysis is not the individual
III	Evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, cohort studies and case-control studies
IV	Evidence from expert committee reports or opinions or clinical experience of respected authorities
<p>* Amended with permission of the British Medical Journal (BMJ) Publishing Group from Shekelle and colleagues (Shekelle PG, Woolf SH, Eccles M, Grimshaw J. Clinical guidelines: developing guidelines. Brit Med J 1999;318 [7183]:593-6.)</p>	

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The American Dental Association Council on Scientific Affairs convened a panel of experts to evaluate the identified systematic reviews and clinical trials. The Council selected panelists on the basis of their expertise in the relevant subject matter. The expert panel convened at a workshop held at the American Dental Association (ADA) Headquarters in Chicago November 13-15, 2006, to evaluate the collective evidence. The expert panel subsequently convened through multiple conference calls.

For each identified systematic review and clinical study, the panel determined final exclusion of publications. They excluded publications on the basis of the following criteria:

- They did not directly address one of the identified clinical questions
- The sealant materials they described were not available in the United States
- The panelists had concerns about the methodology described

(Appendix 2 [See "Availability of Companion Documents" field] is a list of excluded publications.)

For each included publication, the panel developed an evidence statement and graded the evidence statement based on a system modified from that of Shekelle and colleagues (see "Rating Scheme for the Strength of Evidence" field).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The expert panel also developed evidence-based clinical recommendations on pit-and-fissure sealants. For each included publication, the panel developed clinical recommendations that were based on the evidence statements. They classified clinical recommendations according to the strength of the evidence that forms the basis for the recommendation, again using a system modified from that of Shekelle and colleagues (see "Rating Scheme for the Strength of Recommendations" field). It is important to note that while the classification of the recommendation may not directly reflect the importance of the recommendation, it does reflect the quality of scientific evidence that supports the recommendation.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

System Used for Classifying the Strength of the Recommendations*	
Classification	Strength of Recommendations
A	Directly based on category I evidence
B	Directly based on category II evidence or extrapolated recommendation from category I evidence
C	Directly based on category III evidence or extrapolated recommendation from category I, II, or III evidence
D	Directly based on category IV evidence or extrapolated recommendation from category I, II, or III evidence

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COST ANALYSIS

These clinical recommendations do not address the cost-effectiveness of using pit-and-fissure sealants. However, multiple models have shown that basing selection criteria for sealant placement on caries risk is cost-effective. Readers are referred to resources cited in the reference list of the original guideline document for further discussion of cost-effectiveness.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The panel submitted the clinical recommendations they developed to numerous scientific experts and organizations for review. The expert panel scrutinized all comments received and made appropriate revisions in the recommendations. (Appendix 3 in the supplemental data online provides a list of external reviewers [see "Availability of Companion Documents" field of this summary]). The final clinical recommendations were approved by the American Dental Association Council on Scientific Affairs.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (Ia-IV) and the classification of recommendations (A-D) are defined at the end of the "Major Recommendations" field.

Summary of Evidence-based Clinical Recommendations Regarding Pit-and-Fissure Sealants

The clinical recommendations in this table are a resource for dentists to use in clinical decision making. These clinical recommendations must be balanced with the practitioner's professional judgment and the individual patient's needs and preferences.

Dentists are encouraged to employ caries risk assessment strategies to determine whether placement of pit-and-fissure sealants is indicated as a primary preventive measure. The risk of experiencing dental caries exists on a continuum and changes across time as risk factors change. Therefore, caries risk status should be re-evaluated periodically. Manufacturers' instructions for sealant placement should be consulted, and a dry field should be maintained during placement.

TOPIC	RECOMMENDATION	GRADE OF EVIDENCE	STRENGTH OF RECOMMENDATION
Caries Prevention	Sealants should be placed in pits and fissures of children's primary teeth when it is determined that the tooth, or the patient, is at risk of developing caries*†	III	D
	Sealants should be placed on pits and fissures of children's and adolescents' permanent teeth when it is determined that the tooth, or the patient, is at risk of	Ia	B

Summary of Evidence-based Clinical Recommendations Regarding Pit-and-Fissure Sealants			
	developing caries*†		
	Sealants should be placed on pits and fissures of adults' permanent teeth when it is determined that the tooth, or the patient, is at risk of developing caries*†	Ia	D
Noncavitated Carious Lesions‡	Pit-and-fissure sealants should be placed on early (noncavitated) carious lesions, as defined in this document, in children, adolescents and young adults to reduce the percentage of lesions that progress†	Ia	B
	Pit-and-fissure sealants should be placed on early (noncavitated) carious lesions, as defined in this document, in adults to reduce the percentage of lesions that progress†	Ia	D
Resin-Based Versus Glass Ionomer Cement	Resin-based sealants are the first choice of material for dental sealants	Ia	A
	Glass ionomer cement may be used as an interim preventive agent when there are indications for placement of a resin-based sealant but concerns about moisture control may compromise such placement§	IV	D
Placement Techniques	A compatible one-bottle bonding agent, which contains both an adhesive and a primer, may be used between the previously acid-etched enamel surface and the sealant material when, in the opinion of the dental professional, the bonding agent would enhance sealant retention in the clinical situation§	Ib	B
	Use of available self-etching bonding agents, which do not involve a separate etching step, may provide less retention than the standard acid-etching technique and is not	Ib	B

Summary of Evidence-based Clinical Recommendations Regarding Pit-and-Fissure Sealants

	recommended		
	Routine mechanical preparation of enamel before acid etching is not recommended	I Ib	B
	When possible, a four-handed technique should be used for placement of resin-based sealants	III	C
	When possible, a four-handed technique should be used for placement of glass ionomer cement sealants	IV	D
	The oral health care professional should monitor and reapply sealants as needed to maximize effectiveness	IV	D

* Change in caries susceptibility can occur. It is important to consider that the risk of developing dental caries exists on a continuum and changes across time as risk factors change. Therefore, clinicians should re-evaluate each patient's caries risk status periodically.

† Clinicians should use recent radiographs, if available, in the decision-making process, but should not obtain radiographs for the sole purpose of placing sealants. Clinicians should consult the [American Dental Association/U.S. Food and Drug Administration](#) guidelines regarding selection criteria for dental radiographs.

‡ "Noncavitated carious lesion" refers to pits and fissures in fully erupted teeth that may display discoloration not due to extrinsic staining, developmental opacities or fluorosis. The discoloration may be confined to the size of a pit or fissure or may extend to the cusp inclines surrounding a pit or fissure. The tooth surface should have no evidence of a shadow indicating dentinal caries, and, if radiographs are available, they should be evaluated to determine that neither the occlusal nor the proximal surfaces have signs of dentinal caries.

§ These clinical recommendations offer two options for situations in which moisture control, such as with a newly erupted tooth at risk of developing caries, patient compliance or both are a concern. These options include use of a glass ionomer cement material or use of a compatible one-bottle bonding agent, which contains both an adhesive and a primer. Clinicians should use their expertise to determine which technique is most appropriate for an individual patient.

¶ Clinicians should consult with the manufacturer of the adhesive and/or sealant to determine material compatibility.

Definitions:

System Used For Grading the Evidence*	
Grade	Category of Evidence
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IIa	Evidence from at least one controlled study without randomization
IIb	Evidence from at least one other type of quasiexperimental study, such as time series analysis or studies in which the unit of analysis is not the individual
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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of pit-and-fissure sealants for prevention of dental caries

POTENTIAL HARMS

A transient amount of bisphenol-A (BPA) may be detected in the saliva of some patients immediately after initial application of certain sealants as a result of the action of salivary enzymes on bisphenol-dimethacrylate, a component of some sealant materials. According to research, systemic BPA has not been detected as a result of the use of such sealants, and potential estrogenicity at such low levels of exposure has not been documented.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical recommendations are not a standard of care, but rather a useful tool for dentists to use in making clinically sound decisions about sealant use. These clinical recommendations should be integrated with the practitioner's professional judgment and the individual patient's needs and preferences. While these recommendations are applicable to multiple settings, the Centers for Disease Control and Prevention (CDC) is developing recommendations for use of pit-and-fissure sealants specific for school-based programs.
- See also Box 1, "Qualifying notes on clinical recommendations" in the original guideline document.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources
Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Beauchamp J, Caufield PW, Crall JJ, Donly K, Feigal R, Gooch B, Ismail A, Kohn W, Siegal M, Simonsen R, American Dental Association Council on Scientific Affairs. Evidence-based clinical recommendations for the use of pit-and-fissure sealants: a report of the American Dental Association Council on Scientific Affairs. *J Am Dent Assoc* 2008 Mar;139(3):257-68. [99 references] [PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Mar

GUIDELINE DEVELOPER(S)

American Dental Association - Professional Association

SOURCE(S) OF FUNDING

American Dental Association

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Panelists were required to sign a disclosure stating that they have no significant financial interest (nor did their spouses and any dependent children) that reasonably would appear to be affected by the development of these recommendations.

None of the authors reported any disclosures.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [American Dental Association Web site](#).

Print copies: Available from the American Dental Association, 211 E. Chicago Avenue, Chicago, IL 60611

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Executive summary of evidence-based clinical recommendations for the use of pit-and-fissure sealants. A report of the American Dental Association Council on Scientific Affairs. 4 p. Available in Portable Document Format (PDF) from the [American Dental Association Web site](#).
- Appendixes to evidence-based clinical recommendations for the use of pit-and-fissure sealants. A report of the American Dental Association Council on Scientific Affairs, 24 p. Available in Portable Document Format (PDF) from the [American Dental Association Web site](#).

Print copies: Available from the American Dental Association, 211 E. Chicago Avenue, Chicago, IL 60611

PATIENT RESOURCES

The following is available:

- Dental sealants. Preventing and halting decay. 1 p. 2008 Mar. Available in Portable Document Format (PDF) from the [American Dental Association Web site](#).

Print copies: Available from the American Dental Association, 211 E. Chicago Avenue, Chicago, IL 60611

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical

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NGC STATUS

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