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Dental Sealant Systematic Review Work
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ABSTRACT

A barrier to providing sealants is concern about inadvertently sealing over caries. This meta-analysis examined the effectiveness of sealants in preventing caries progression. We searched electronic databases for comparative studies examining caries progression in sealed permanent teeth. We used a random-effects model to estimate percentage reduction in the probability of caries progression in sealed vs. unsealed carious teeth. Six studies, including 4 randomized-controlled trials (RCT) judged to be of fair quality, were included in the analysis (384 persons, 840 teeth, and 1090 surfaces). The median annual percentage of non-cavitated lesions progressing was 2.6% for sealed and 12.6% for unsealed carious teeth. The summary prevented fraction for RCT was 71.3% (95%CI: 52.8%-82.5, no heterogeneity) up to 5 years after placement. Despite variation among studies in design and conduct, sensitivity analysis found the effect to be consistent in size and direction. Sealing non-cavitated caries in permanent teeth is effective in reducing caries progression.

KEY WORDS: pit and fissure sealants, caries.

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The Effectiveness of Sealants in Managing Caries Lesions

INTRODUCTION

There is strong evidence that sealants are effective in both clinical and school settings for preventing caries in children at various levels of risk (Truman *et al.*, 2002; Ahovuo-Saloranta *et al.*, 2004). The evidence for sealant effectiveness in the management of dental caries is limited, however. One review that examined the effectiveness of interventions to manage caries for the National Institutes of Health (NIH) Caries Consensus Development Conference included only 1 study on sealants (Bader *et al.*, 2001). Despite the strong evidence of primary effectiveness, sealant prevalence among lower-income children (who are at higher risk for dental caries) is about 30% (Dye *et al.*, 2007), well below the Healthy People 2010 objective of 50%.

Analysis of survey data from dentists suggests that one barrier to providing sealants is concern about inadvertently sealing over caries (Chapko, 1987; Primosch and Barr, 2001). This concern has also been a barrier to implementing school-based sealant programs (Association of State and Territorial Dental Directors, unpublished data, 2005).

Documenting the effectiveness of sealants in the management of existing caries is therefore important, and such documentation could potentially remove barriers to the provision of a proven intervention. The purpose of this meta-analysis is to examine the effectiveness of dental sealants in preventing the progression of caries lesions in the pits and fissures of permanent teeth.

METHODS

Inclusion Criteria

This analysis was part of a broader systematic review of sealant effectiveness in the management of caries in the permanent dentition. Initially, we included all *in vivo* studies published in English that compared caries progression or bacteria levels in permanent teeth that did and did not receive sealants. Comparisons could be concurrent or measured over time (time-series or before-after) in the same groups. In the current meta-analysis, study designs were limited to randomized and non-randomized controlled trials and cohort studies that provided concurrent comparisons of % of lesions progressing. There were no restrictions on study populations.

Identification of Studies

In our search of MEDLINE (1966 to June, 2005), using a modified version of the strategy used by the NIH Caries Consensus Development Conference (University of Michigan, 2003), we identified 1872 records. The MEDLINE search strategy was adapted to search EMBASE (1980 to June, 2005), which identified 71 records, and the Cochrane Central Register of Controlled Trials (accessed the first week of September, 2005), which identified 79 records. In total, there were 1905 unique records. Two reviewers independently examined the titles and abstracts of these records for systematic or narrative reviews of the effectiveness of sealants in preventing or managing caries and primary studies on managing caries. We accessed 262 articles. From our examination of their

Table 1. Description of Studies Whose Data Were Used to Calculate Summary Measures

Study ^a	Subjects ^b	Sealants ^c	Study Quality ^d
Flório <i>et al.</i> , 2001; Brazil; 12	6-year-olds; prophylaxis every 3 mos; NC ^e	Resin-modified GIC; No; 65.5%	23; 72; NA ^f ; RCT ^g (parallel groups); 1 yr DO = 9%; Direct digital radiography; NR ^h ; NR
Frencken <i>et al.</i> , 1998; Zimbabwe; 36	Secondary school students (mean age = 13.9 yrs); NR; NC	GIC; No; 20.4%	NR; at follow-up 368; NA; Prospective cohort (parallel groups); 3-year DO for sealed group = 39%; VT ⁱ ; Yes; NR
Gibson ; and Richardson, 1980 Canada; 30	2nd graders; NR; NC	RB2i; NR; NR (1-yr retention = 89.6% for entire study)	NR; at follow-up -79; 111; Subgroup of RCT (originally designed as split-mouth design, but in this analysis, control and treatment teeth not necessarily in same child); For entire RCT, and 2-year DO = 8 and 17%, respectively; VT examination and radiograph; NA; NR
Going <i>et al.</i> , 1976 ^k ; 1976; United States; 12	10- to 14-year-olds; no fluoridation; NC/C	RB1; Yes ^l ; NR (1-yr retention = 81% for entire study)	NR; 85 (first follow-up); NA; Subgroup of RCT (originally designed as split-mouth design, but in this analysis, control and treatment teeth not necessarily in same child); 1-year DO for entire RCT = 6%; VT; NR; Yes
Heller <i>et al.</i> , 1995; United States; 60	1st graders; fluoridation; NC	RB3; Yes; NR	71; NR; 436 surfaces (approximately 2 surfaces per tooth); NA; Retrospective cohort (parallel groups); NR; VT; NA; No
Mertz-Fairhurst <i>et al.</i> , 1986; United States; 12	9 to 19 yrs; NR; C	RB2; NR; NR	20; 40; NA; RCT (split-mouth design); 1-yr DO = 30%; Bodecker device; NR; Yes

^a First author; year published; country where conducted; duration (mos).

^b Age range; background prevention exposure; baseline caries severity.

^c Material; sealants maintained/repared; retention rate.

^d Number of subjects at baseline; number of teeth; number of sites; design; drop-out rate for teeth (DO); how caries progression measured; examiner calibration; examiner blinding.

^e NC = non-cavitated and C = cavitated.

^f NA = not applicable.

^g RCT = randomized controlled trial.

^h NR = not reported.

ⁱ VT = visual-tactile examination.

^j RB1, Resin-based-UV light polymerized; RB2, Resin-based-autopolymerized; RB3, Resin-based-light polymerized.

^k This was the only study that reported effectiveness for multiple follow-ups. We used the first-year results because Going *et al.* used NuvaSeal, which may have lower retention rates than currently used sealant materials.

^l For sealed teeth, year 1 findings reported for teeth retaining their sealant.

references, we accessed an additional 49 articles, for a total of 311.

Study Selection

One investigator (SG) screened all articles and identified 31 potential qualifying studies. After review by three investigators (BG, SG, and WK), consensus was reached that 26 studies should be evaluated further. Of the 19 studies included in the larger systematic review, 10 had information on % of lesions progressing. Of these 10 studies, 6 had a concurrent control group (see QUOROM flow diagram in APPENDIX).

Data Abstraction and Quality Assessment

Two reviewers (SG and EO) abstracted studies using a slightly modified version of a form developed for the NIH Caries Consensus Conference. The abstraction forms were jointly reviewed by three investigators (BG, SG, and EO) to assess study quality using criteria established by the third US Preventive Services Task Force (USPSTF; Harris *et al.*, 2001). These criteria are further described in the APPENDIX.

Outcome and Effect Measures

Our outcome measure was the percentage of caries lesions progressing, where progression was defined as demineralization or loss of tooth structure. In 4 studies, restorations were placed after study examiners determined that caries progression had exceeded given thresholds. For 2 studies, where children had access to outside care, placement of a restoration indicated caries progression. To measure effectiveness, we calculated the relative risk ratio (RR)

$$R = \frac{\% \text{ lesions progressing}_{\text{SEALED}}}{\% \text{ lesions progressing}_{\text{NOT SEALED}}}$$

and its 95% confidence interval (CI). One can obtain the prevented fraction by subtracting the RR from 1, and the upper/lower 95%CI by subtracting the lower/higher 95%CI of the RR ratio from 1.

Synthesis of Findings

We calculated the median percentage of lesions progressing in

sealed and unsealed surfaces, as well as the median prevented fraction, for all studies and for subgroups of studies with selected characteristics. We classified baseline caries as non-cavitated if the study described caries as incipient or restricted to the enamel, or if there were no apparent defects in the enamel, or the lesion did not permit explorer penetration. We classified caries as cavitated if the study stated that cavitation was visually detectable, or the lesion allowed for explorer penetration.

In adjusting the data for differences in study design, multiple observations *per* subject, and 100% or 0% progression rates (LaPlace adjustment), we made conservative assumptions that would bias the results toward finding no statistical significance (APPENDIX). We used the Der Simonian and Laird (DSL) random-effects model (Stijnen, 1999) to obtain the summary RR and its 95% confidence interval. We tested for homogeneity of effect size using the quantity I^2 (Higgins *et al.*, 2003). Finally, we conducted sensitivity analysis to determine how robust our findings were to excluding cohort studies and assuming higher values of intra-oral correlation (APPENDIX).

RESULTS

Characteristics of Studies

The 6 studies included in this analysis (representing an estimated 384 persons, 840 teeth, and 1090 surfaces) varied in design (4 RCTs), baseline caries classifications, and types of sealant material (Table 1). Four studies primarily sealed non-cavitated lesions, 1 exclusively sealed cavitated lesions, and 1 sealed both cavitated and non-cavitated lesions. Three studies used 2nd- or 3rd-generation resin-based sealants, 2 used glass-ionomer cement (GIC), and 1 used 1st-generation resin-based sealants. Study populations included children, adolescents, and young adults ranging in age from 6 to 19 yrs.

Quality of Studies

All the studies were rated as "fair" quality (Table 2). It is likely that comparable groups were assembled in 5 studies—4 RCTs and 1 cohort study where baseline sealant prevalence and DFS did not differ between the sealed and not-sealed groups. All studies clearly defined the intervention. The 2 cohort studies did not report drop-out rates, and 1 RCT of split-mouth design reported a one-year drop-out rate of 30%. In the 3 remaining RCTs, however, the one-year drop-out rate was less than 10% (this included the 2 larger studies that supported subgroup analyses of sealed caries lesions).

In the absence of sealant removal prior to follow-up examination, we assumed that outcome assessment was not

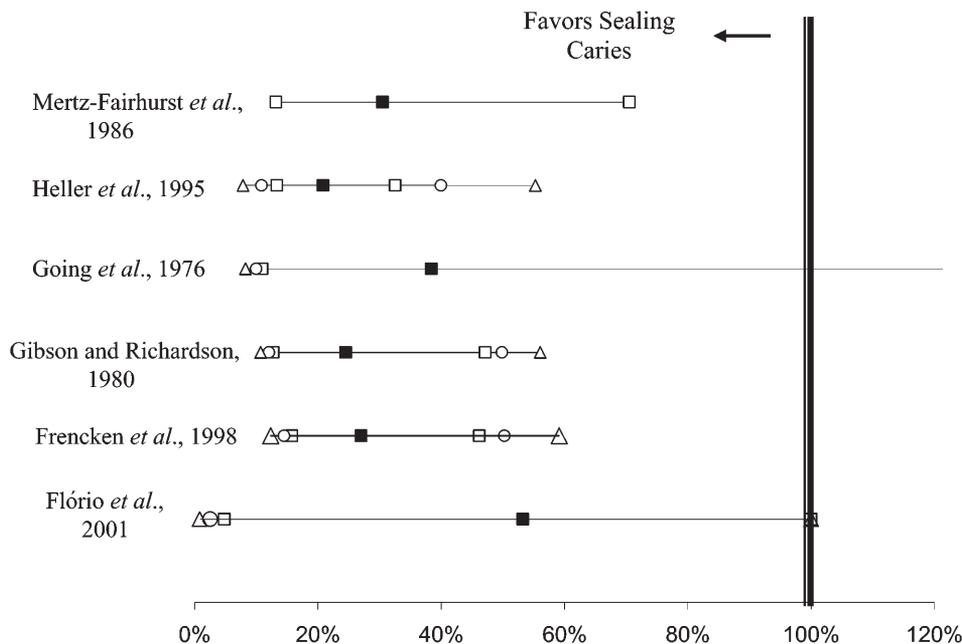


Figure. Adjusted relative risk ratios and 95% confidence interval, assuming 0, 30%, and 100% correlation among teeth. Progression rates of 0% or 100% adjusted according to the LaPlace procedure, described in the text.

- Relative risk ratio.
- 95% confidence interval assuming no correlation ($\rho = 0.0$).
- 95% confidence interval assuming $\rho = 0.3$.
- △ 95% confidence interval assuming $\rho = 1.0$.

blinded. In only 1 RCT, however, were sealants removed prior to the follow-up examination, with teeth assessed by an examiner who did not know the initial group assignment. In 2 of the remaining 5 studies (1 RCT and 1 cohort study), however, either the examiner used new record forms at each follow-up examination (and thus was unaware of the child's previous findings), or there was an independent outside examiner. In the remaining 3 studies (2 RCTs and 1 cohort study), either the same examiner conducted both the baseline and follow-up examinations, or blinding was not described.

Effects of Sealants

The median annualized progression rates for sealed and unsealed lesions were, respectively, 5.0% and 16.1% (Table 3). If we classified all teeth in the study by Going *et al.* (1976) as cavitated, then, the annualized progression rates for cavitated lesions would be 19.4% (sealed) and 59.3% (not-sealed). The percentage of non-cavitated lesions progressing would be 2.6% (sealed) and 12.6% (not-sealed). Alternatively, if we classified all teeth in the Going study as non-cavitated, then the median annualized progression rates for non-cavitated lesions would be 2.9% (sealed) and 13.6% (not-sealed), respectively.

For the individual studies, the prevented fraction ranged from 61.6% to 100.0%, with a median of 74.2% (Table 3). The median prevented fraction did not vary greatly by grouping—the median value always exceeded 50% (Table 3).

The RR for the studies ranged from 0 to 38.4%, but after the LaPlace adjustment, it ranged from 20.8% to 53.2% (Fig.). The CI for each study widened as we made more conservative assumptions about correlation among teeth (Fig.), but changing the assumptions about correlation did not result in rejecting findings of

Table 2. Quality Assessment of 6 Studies with Concurrent Controls

Criteria	Study					
	Flório <i>et al.</i> , 2001	Frencken <i>et al.</i> , 1998	Gibson and Richardson, 1980	Going <i>et al.</i> , 1976	Heller <i>et al.</i> , 1995	Mertz-Fairhurst <i>et al.</i> , 1986
Initial assembly of comparable groups	Good—RCT ^a employing parallel group design, where children were randomly assigned to treatment group.	Fair—assignment based on returned permission slip.	Good—RCT with split-mouth design, where treatment teeth determined by dice.	Good—RCT with split-mouth design, where side of mouth receiving treatment was randomly selected.	Good—although assignment based on returned permission slip, study showed that baseline DFS did not differ between control and treatment groups.	Good—RCT with split-mouth design, where treatment tooth decided via randomized treatment assignment sheet.
Clear definition of intervention	Good—GIC sealants on NC lesions.	Good—GIC sealants on NC lesions.	Good—RB sealants on NC lesions.	Good—RB sealants on NC lesions.	Good—RB sealants on NC lesions.	Good—RB sealants on NC lesions.
Reliability and validity of measure of outcome	Fair—blinding not specified and whether same examiner interpreted digital radiographs at BL and FU indeterminant.	Fair—VT ^b and sealants not removed at FU ^c ; outside examiner.	Fair—no blinding and same examiner conducted VT BL ^d examination and read radiographs at FU; 71% of lesion progression due to restorations.	Fair—although examiners blinded as to previous caries score, caries score determined by VT and sealants not removed at FU, although new record forms were used at each examination.	Fair—no blinding, same examiner (not a primary investigator) at BL and FU, and VT where sealants not removed at FU, although subjects received regular clinical care (59% of sites progressing due to restorations).	Good—removed sealant, and blinded examiners assessed lesion progression.
No differential loss to FU or overall high loss to FU	Good—drop-out rate was 9%.	Fair—number of controls not reported.	Fair—drop-out rates not reported for subgroup; For entire study, 1- and 2-year drop-out rates for tooth pairs were 8 and 17%, respectively.	Fair—drop-out rates not reported for subgroup; For entire study, 1-year drop-out rate for subjects was 6%.	Fair—retrospective cohort study, so drop-out rate not reported.	Fair—1-year drop-out rate was 30%.
Other threats to validity:	Fair—small sample size.	None apparent	None apparent.	None apparent.	None apparent.	Fair—small sample size.
Quality score	Fair	Fair	Fair	Fair	Fair	Fair

a RCT = randomized controlled trial.

b VT = visual tactile examination.

c FU = follow-up examination.

d BL = baseline examination.

statistical significance for any of the 4 studies whose initial 95%CI did not achieve 100%.

The summary prevented fraction ranged from 73.2% (95%CI: 59.8%-82.2%), assuming perfect correlation among teeth (adjusted n = 398), to 75.0% (95%CI: 67.1%-81.1%), assuming no correlation (adjusted n = 946), and equaled 74.1% (95%CI: 63.8%-81.4%), assuming 30% correlation (adjusted n = 638). When we

restricted the analysis to the 4 randomized trials, the summary prevented fraction ranged from 71.2% (95%CI: 50.3%-83.3%), assuming perfect correlation (adjusted n = 154), to 71.3% (95%CI: 54.1%-82.0%), assuming no correlation (adjusted n = 254), and equaled 71.3% (95%CI: 52.8%-82.5%), assuming 30% correlation (adjusted n = 207). The quantity I^2 was 0 regardless of our assumptions about correlation among teeth or whether to include

only randomized trials, which indicated no observed heterogeneity.

DISCUSSION

We found that sealing caries lesions reduced the probability of lesion progression. The summary prevented fraction was more than 70%, and in the sensitivity analyses, the lower bound of the 95%CI always exceeded 50%. The consistency in size and direction across included studies and under a range of conservative assumptions indicates that the findings are robust.

Because non-cavitated lesions accounted for almost 90% of teeth in this study, the evidence supporting the sealing of non-cavitated lesions (NC) was stronger than that for the sealing of cavitated (C) lesions. The median annualized probability of progression for NC lesions was very low (2.6%).

This finding does not support reported concerns about poorer outcomes associated with the inadvertent sealing of caries and should lessen the reluctance of practitioners to provide sealants—an intervention proven to be highly effective in preventing caries. The annualized probability reflects progression in lesions recognized as "early or incipient" and suggests that the probability of progression for pit-and-fissure surfaces with caries considered "questionable" could be even lower. These findings not only support the placement of sealants to manage and arrest lesions determined to be in the early carious stages, but also, just as importantly, support their placement for surfaces where caries status is uncertain.

Another notable finding of this review was the low annualized probability of progression (12.6%) for not-sealed, non-cavitated lesions. This finding suggests that immediate surgical treatment of such lesions may not be necessary. Thus, practitioners can consider sealing these surfaces or can simply wait and monitor them for signs of active progression. Approaches focusing on prevention and management (e.g., sealants) are particularly attractive, since they could potentially preserve tooth structure and lower the likelihood of future complex restorations.

There were variations among the studies included in this analysis. Sealant material included both resin-based and GIC sealants. Among the 4 studies that used resin-based sealants, 3 used 2nd- or 3rd-generation sealants, which have similar retention rates (Muller-Bolla *et al.*, 2006). The one-year retention rate of 81% for the 1 study using 1st-generation sealant material included in this meta-analysis was within the range of retention for auto-polymerized sealants reported in a meta-analysis on the primary effectiveness of sealants (Ahovuo-Saloranta *et al.*, 2004). Although

Table 3. Percentages of Sealed and Unsealed Caries Lesions Progressing and Prevented Fraction for Different Subgroups

	No. Teeth	No. Persons	No. Studies	Sealed Caries Lesions (%)		Unsealed Caries Lesions (%)		Prevented Fraction (%)	
				Median ^a	Range	Median	Range	Median	Range
All	840	384	6	9.6	0-28.6	41.4	6.1-100	74.2	61.6-100
RCT ^b	254	140	4	13.1	0-28.6	48.0	6.1-100	73.5	61.6-100
<= 12 mos	175	91	3	7.1	0-28.6	18.6	6.1-100	71.4	61.6-100
30-36 mos	447	222	2	13.7	8.4-19.0	54.2	31.1-77.4	74.2	73.0-75.5
60 mos	218	71	1	10.8	—	51.8	—	79.2	—
GIC ^c	430	193	2	4.2	0-8.4	18.6	6.1-31.1	86.5	73.0-100
RB1 ^d	85	57	1	7.1	—	18.6	—	61.6	—
RB2 ^e & RB3 ^f	225	134	3	19.0	10.8-28.6	77.4	51.8-100	75.5	71.4-79.2
Non-cavitated	727	313	4	9.6	0-19.0	41.4	6.1-51.8	77.3	73.0-100
Cavitated ^g	113	71	2	17.9	7.1-28.6	59.3	18.6-100	66.5	61.6-71.4
Annualized ^h									
All	840	384	6	5.0	0-31.7	16.1	6.1-100	78.7	68.3-100
RCT	254	140	4	7.6	0-31.7	31.7	6.1-100	75.2	68.3-100
GIC	430	193	2	1.4	0-2.9	8.9	6.1-11.7	87.7	75.3-100
RBI	85	57	1	7.1	—	18.6	—	61.6	—
RB2 & RB3	225	134	3	8.1	2.3-31.7	44.8	13.6-100	82.0	68.3-83.4
Non-cavitated	727	313	4	2.6	0-8.1	12.6	6.1-44.8	82.7	75.3-100
Cavitated ^g	113	71	2	19.4	7.1-31.7	59.3	18.6-100	65.0	61.6-68.3

^a In most cases, mean was fairly close to median value.
^b Randomized controlled trial.
^c Glass-ionomer cement sealants.
^d 1st-generation resin-based sealants (UV light-polymerizing).
^e 2nd-generation resin-based sealants (auto-polymerizing).
^f 3rd-generation resin-based sealants (light-polymerizing).
^g Assumes that study by Going *et al.* exclusively sealed cavitated lesions.
^h Reported values annualized assuming a constant progression rate (PR). Annualized % progressing = 1 - [1 - (PR)^{1/n}], where n represents years since placement.

this same review found limited evidence to support the effectiveness of GIC sealant material as a primary preventive measure, 1 longitudinal study that sampled 24 teeth found no difference in bacteria levels between dentinal lesions sealed with resin-based and GIC sealants 7 mos after placement (Weerheijm *et al.*, 1993).

The studies also varied by how they assessed caries progression. Three studies assessed progression solely with a visual-tactile examination. In the absence of sealant loss or a restoration on a previously sealed caries lesion, visual-tactile assessment of caries under sealants is limited. In 1 of the 3 studies included in our meta-analysis, however, children received regular restorative care, and thus it is likely that sealed teeth were periodically assessed radiographically and restored if necessary.

All RCTs (4 studies) included in this review received a "fair" quality rating, primarily due to failure to blind outcome assessment (3 studies) and high loss to follow-up (1 study). It should be noted, however, that comparative studies examining the effectiveness of sealants for primary prevention typically do not remove sealants at follow-up. For example, none of the studies included in a recent systematic review of sealants removed sealant at the final follow-up examination (Ahovuo-Saloranta *et al.*, 2004).

While limitations of this analysis have been carefully described, the strengths of these studies, and of the meta-analysis as well, should be clearly noted. First, we conducted a sensitivity analysis that adjusted for correlation among multiple observations

per person to determine the most conservative (widest) confidence interval for the summary prevented fraction. Other systematic reviews of sealant effectiveness have included studies with multiple observations *per person*, and this systematic review is likely the first study that adjusted data for this limitation. In addition, the consistency of the effect measure across studies also lends support for the quality of the 6 studies; it is very unlikely that such consistency among estimates based on studies with noted variations occurred by chance alone.

There is additional evidence for sealant effectiveness in the management of caries. Two other studies identified in the larger systematic review also examined the impact of sealants on caries progression, but did not report % of lesions progressing. One study found that caries lesions measured by radiographic assessment were more likely to regress under intact sealants than under defective sealants (Handelman *et al.*, 1986). Another RCT found that the mean depth change in caries lesions was significantly lower in the sealed group than in the not-sealed group (49 μm vs. 614 μm depth change; Mertz-Fairhurst *et al.*, 1979). In addition, several studies have found that sealing caries reduces bacteria levels (Jeronimus *et al.*, 1975; Jensen and Handelman, 1980).

This review also supports the need for further studies that meet current standards of quality in design, conduct, and reporting, to continue to build the evidence related to sealant effectiveness in preventing caries progression, especially in cavitated lesions, which represented, at most, 14% of carious teeth in this analysis. Uniform criteria to assess progression from early demineralization to frank cavitation, as well as standardized methodologies to measure progression, are needed. This review would have been strengthened if all studies had used examiners calibrated to the same criteria and the same method to assess caries progression (*i.e.*, visual-tactile examination with removal of sealants).

In conclusion, the evidence supports the placement of sealants over non-cavitated caries lesions in the pits and fissures of permanent teeth in children, adolescents, and young adults. Despite variations in study design and conduct, subgroup and sensitivity analyses found the effect to be consistent in size and direction.

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