Clinical Interventions: Pit and fissure sealants

Systematic Reviews - effectiveness

Author Ahovuo-Saloranta A, Hiiri A, Norblad A, et al.

Title Pit and fissure sealants for preventing dental decay in the permanent teeth of children and adolescents. *Cochrane Database of Systematic Reviews* 2008; Issue 4: Art No. CD001830.DOI:10.1002/14651858.CD0001830.pub3.

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results				
Systematic	1++	16 	Children and	Not reported	1-9 years	Resin sealant	No sealant	Caries Yes/No	Resin FS	6 vs No	sealant (7 s	tudies)	
review of RCTs or quasi-		studies 13 split-	adolescents under the age of 20 years					on occlusal surfaces of permanent	Time mths	RR	(95% CI)	% caries reduction	No. studies
randomised		mouth	Participants Exposed to fluoridated water					molar teeth	12	0.13	0.09-0.20	87%	3
trials		3 parallel	in 5 studies					Caries defined	24	0.22	0.15-0.34	78%	3
								as caries into	36 48-54	0.30	0.22-0.40	70% 60%	3
								dentine	108	0.40	0.22-0.55	65%	1
									100	0.00	0.22 0.00	0070	
						Glass ionomer	No sealant		1 study –	non sig	nificant resu	It	
						Resin sealant	Glass ionomer		3 studies: 2 studies:	: resin b : GI bett : no diffe	etter caries r er caries red	ner sealant reductions tha luctions than ries reduction	an GI resin
						Resin sealant	Compomer		studies)	ence in d	-	at 24 months	
								Secondary outcome: sealant retention	79% to 92 71% to 85 61% to 80 52% at 48	e Retent 2% at 12 5% at 24 0% at 36 8 month	ion ranged fr 2 months 4 months 6 months s72% at 54 r		months)

Author Ahovuo-Saloranta A, Hiiri A, Norblad A, et al.

Title Pit and fissure sealants for preventing dental decay in the permanent teeth of children and adolescents. *Cochrane Database of Systematic Reviews* 2008; Issue 4: Art No. CD001830.DOI:10.1002/14651858.CDO001830.pub3.

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
									Resin sealant v Glass ionomer sealant
									4 studies: retention with resin better than GI
									3 studies: low retention reported for both types of sealant
									Resin sealant v Compomer
									1 study: Complete retention of over 70% for both materials
									1 study: Complete retention 16% for compomer and 66% for resin

Author conclusions: Sealing is a recommended procedure to prevent caries of the occlusal surfaces of permanent molars. The effectiveness of sealants is obvious at high caries risk but information on the benefit of sealing related to different caries risks is lacking. More research is needed on the effectiveness of sealants at different caries risk levels and to clarify the relative effectiveness of different sealant materials.

Reviewer comments: The review update added 8 new studies to the review. Overall, the clinical conclusions were unchanged from the previous version of the review.

Author Ahovuo-Saloranta A, Hiiri A, Norblad A et al.

Title Pit and Fissure sealants for preventing dental decay in the permanent teeth of children and adolescents, 2004. *The Cochrane Database of Systematic Reviews* Issue 4, Art. No.: CD001830. DOI: 001810.001002/14651858.CD14001830.pub14651853.

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results				
Systematic review of RCTs or quasi- randomised trials	1++	8 studies 7 split- mouth 1 parallel	The age range of children in the included studies was from 5-13 years, recruited from selected schools or dental clinics.	Not reported		Resin sealant	No treatment	Caries Yes/No at various time points			(95% CI) 0.09- 0.19 0.23-0.30 0.26-0.35 0.37-0.50 ventive effect o ed over time.	% caries reduction 86% 76% 70% 57% f the resin-bas	No. studies 3 3 3 2 2
						Glass ionomer	No treatment	mean difference	1 study	– non s	significant resul	t	
						Glass ionomer	Resin sealant	Caries Yes/No at various time points	findings ionome sealant	s were c r sealar . As the	involved in this conflicting. One and the two of results of the s ta analysis wa	study favoure others favoure studies were s	ed glass d resin
						Any sealant		Sealant retention	from 79 months Retenti	– 92% and 61° on of gla	tion of resin-ba at 12 months to % -80% at 36 n ass ionomer se onths and 3% a	o 71% -85% a nonths. alant ranged f	t 24

Author conclusions: Sealing is a recommended procedure to prevent caries of the occlusal surfaces of permanent molars. However, we recommend that the caries prevalence level of both individuals and the population should be taken into account. Only 2 studies in the review reported baseline levels of caries, so it was not possible to analyse if this has an effect on sealant retention. *Future*: The methodological quality of published studies concerning pit and fissure sealants was poorer than expected. Further research in the area of fissure sealants should comply with current criteria for RCTs (CONSORT statement) and include baseline level of caries, exposure to fluoride and other preventive measures. More research is needed to clarify the effectiveness of glass ionomer sealants.

Author Hiiri A, Ahovuo-Saloranta A, Norblad A, et al.

 Title
 Pit and fissure sealants versus fluoride varnishes for preventing dental decay in children and adolescents. Cochrane Database of Systematic Reviews 2009. Issue

 2. Art No. CD003067.DOI:10.1002/14651858.CD003067.pub2

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results		
Systematic review of RCTs or quasi- randomised trials	1+	4 1 cluster randomised parallel trial (Bravo 2005) 1 parallel (Florio 2001) 2 split mouth (Raadal 1984, Spleith 2001)	Age 5–9 years Exposure to F water in 1 study. School F mouthrinsing and F tablets recommended in 1 study. Motivation and DHE in 3 studies	No meta analysis conducted	1-9 years	FS and fluoride Varnish	Floride Varnish (Duraphat) Fluoride Varnish (Duraphat)	Risk ratio for difference in caries on occlusal surfaces	FS v Varnish (Bravo, 2005 N=75 children Florio, 2001* N=23 children Raadal, 1984 N=121 *FS was RMGIC FS + Varnish v Spleith, 2001 N=98 children	Duration 4 years 9 years 12 mths 23 mths	RR (95% CI) 0.42 (0.21, 0.84) 0.48 (0.29, 0.79) In favour of sealant 0.22 (0.01, 4.06) Difference NS 0.74 (0.58, 0.95) In favour of sealant RR (95% CI) 0.36 (0.21, 0.61) In favour of FS+varnish
								Secondary outcome: Number of visits to repair sealants or to apply varnish	No. visits/applic Bravo, 2005^ Raadal, 1984, Florio, 2001 Spleith, 2001 ^no. visits during	FS group 2.2 visits (SD1.1) 1 application 1 application 29 min tx tim	n 2 application ne 9 min tx time

Author Hiiri A, Ahovuo-Saloranta A, Norblad A, et al.

Title Pit and fissure sealants versus fluoride varnishes for preventing dental decay in children and adolescents. Cochrane Database of Systematic Reviews 2009. Issue 2. Art No. CD003067.DOI:10.1002/14651858.CD003067.pub2

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results		
								Sealant Retention	Sealant retentio	n Duration	Complete retention
									Bravo, 2005	4 years 9 years	63% 39%
									Raadal, 1984,	23 mths	63%
									Florio, 2001	12 mths	66%
									Spleith 2001*	24mths	81%
									*sealants repa	ired during stuc	ly

Authors' conclusion: There is some evidence about the superiority of pit and fissure sealants over fluoride varnish application, but the extent was not determined. No recommendations for the clinical practice could be given and the benefit of pit and fissure sealants and varnish should be considered locally and individually. More high quality studies are required to confirm to what extent there is a difference in the effectiveness of the pit and fissure sealants and fluoride varnishes. The carry over effect of the fluoride varnish in the split mouth study cannot be totally ruled out. Therefore parallel studies are recommended.

Reviewer comment: Insufficient trials to conduct heterogeneity and sensitivity analyses could not be conducted.

Author Llodra J C, Bravo M, Delgado-Rodriguez, M et al.

Title Factors influencing the effectiveness of sealants: a meta-analysis. *Community Dent Oral Epidemiol* 1993; 21: 261–8.

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1+	24 studies reported in 36 articles	Age range of children at start of trials 5-15 yrs	Not reported	3-120 mths	UV light-cured sealant or autopolymerised sealant applied to permanent teeth (mostly first permanent molar)	No treatment.		Autopolymerised sealant significantly more effective than UV light-cured sealant PF 71.4% (95% Cl 73.3 – 81.4) v 45.9% (95% Cl 43.5 – 48.2 Effectiveness decreases over time for both types of sealant Effectiveness increased when water was fluoridated (PF 82.7% v 71.3%) There was significant heterogeneity between studies and evidence of publication bias.

Author conclusions: Fissure sealants are effective in preventing caries. Their effectiveness decreases with time and periodic reapplication is advisable. There appears to be a positive interaction between fluoride in the drinking water and fissure sealants in preventing caries.

Reviewer comment: All but one of the included studies was carried out in the 1970s

Author Mejare I, Lingstrom P, Petersson L *et al.*

Title Caries preventive effect of fissure sealant: a systematic review. *Acta Odontol Scand* 2003; 61: 321–330.

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1+	13	Age range 5-14. Studies where children were selected on the basis of special general health conditions were excluded Children had to have at least one pair of caries free molars in order to qualify for a split-mouth study	No. children not reported No. teeth = 4,024	2-5 years	UV-cured, autopolymerised sealant, glass ionomer sealant or resin-modified glass ionomer sealant	Studies involving other preventive measures were not specifically excluded from the review.		The pooled estimate of relative risk reduction of resin- based sealants on first permanent molars compared to unsealed was 33% (RR 0.67 95% Cl 0.55 -0.83). The level of evidence was graded as "limited" 4 studies showed a close relationship between sealant retention and caries risk reduction. (Relative risk reduction >80% where sealants retained and < 20% where sealants lost) 2 studies that replaced defective sealants had risk reductions of 69% and 93% The evidence of effectiveness of sealants was incomplete for permanent 2 nd molars, premolars and primary molars, and for glass ionomer cements.

Author conclusions: There remains a need for well designed randomised, controlled trials, particularly in child populations with low and high caries risk, which take into account the benefit, cost effectiveness and long term effects of sealants.

Author Muller-Bolla M, Courson F, Droz D *et al.*

Title Retention of resin-based pit and fissure sealants: a systematic review. Community Dent Oral Epidemiol 2006; 34: 321-36

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results			
Systematic review	1+	 31 studies 16 studies compared one resin- based sealant with another. 15 studies focused on sealant application 	Minimum age 5 yrs	Not reported	At least 6 months	Visible Light cured resin sealant (LRBS)	Autopolymerised resin sealant (ARBS)	Complete retention of sealant according to duration of follow up.	Time mths 6 12 24 36 60 (no signi types of s		(95% CI) 0.87-1.11 0.91-1.00 0.93-1.06 0.93-1.07 0.92-1.07 erence in retenti	No. studies (total =7) 2 6 4 2 1 ion between the 2
		technique				Visible Light cured resin sealant (LRBS)	Fluoride- containing resin- based sealant	Complete retention of sealant	Time mths	RR	(95% CI)	No. studies (total=9)
							(FRBS)	according to duration of	12	1.01	0.96-1.06	5
								follow up.	24	0.95	0.79-1.15	1
									48	0.80	0.72-0.89*	2
									54	0.80	0.68-0.93*	2
											nce in complete ant without F	retention, in favo
						Rubber dam (RD)	Cotton wool roll (CW) isolation Using autopolymerised and fluoride containing resin- based sealants	Complete retention of sealant	using rub studies) Sealant r containin used RR There we	etention s g light cu t = 2.03 9 ere too fev	or cotton wool re	er for fluoride en rubber dam w 1 study

Author conclusions: The authors noted the small number of studies meeting the inclusion criteria, and their low to moderate quality. They also noted that further RCTs of FRBS retention should consider RBS filler It was not possible to determine the best clinical procedure for sealant application because of the insufficient number of studies. They concluded that "It is still necessary to carry out well-designed, randomised clinical trials focused on sealant retention considering different procedures, particularly new enamel preparation techniques such as air-abrasion or sono-abrasion."

Author Truman B, Gooch B, Sulemana I et al.

 Title
 Reviews of Evidence on Interventions to Prevent Dental Caries, Oral and Pharyngeal Cancers and Sports-related Craniofacial Injuries. Am J Prev Med 2002;23(1S) 21-54

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review of studies of different design	2+	10 in total 1 before/after 4 non- randomised trials 1 retrospective cohort 3 RCTs 1 time series 4 USA studies 6 non-USA studies	Children aged 6-17	Meta-analysis not conducted. However, a median percent change in occlusal caries is reported	2-5 years	Exposure to RBS FS applied as part of school-based* or school-linked ^sealant programme *FS programme conducted in the school ^ FS programme conducted in schools, private dental practices and clinic settings outside of schools.	No exposure to FS as part of a school-based or school-linked programme	Median percent change in occlusal caries	All studies: Median (range) 60% (5% - 93%) USA studies vs non-USA studies 60% (23% -78%) vs 60% (5% -93%) School-based vs School-linked 65% (23% - 93%) vs 37% (5% - 93%) Reapplication vs no reapplication 65% (23% - 93%) vs 30% (5% - 93%)

Author conclusions: According to the Community Guide rules of evidence, strong evidence shows that school-based and school-linked sealant delivery programs are effective in reducing decay in pits and fissures of children's teeth.

Reviewer conclusions: The range of effect of the included studies indicates heterogeneity between the included studies. However, the lowest median caries median reduction was 30%, which is a substantial effect.

Systematic reviews

Sealants and caries progression

Author Griffin SO, Oong E, Kohn W, et al.

Title The effectiveness of sealants in managing caries lesions. *J Dent Res* 2008;87(2):169-174

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1++	6 Rated as 'fair' quality.	There were no restrictions on study populations to be included in the meta- analysis. Study populations included children, adolescents and young adults ranging in age from 6 to 19 years.	384 patients, 840 teeth and 1090 surfaces	Varied from 12 - 60 months	Sealants applied to cavitated or non cavitated lesions	No sealants applied	% of lesions progressing Progression defined as demineralisatio n or loss of tooth structure or placement of a restoration.	Median annualized progression rates:Sealed lesions:5%Unsealed lesions:16.1%Prevented fractions for individual studies ranged from 61.6% to 100% (median 74.2%)Summary prevented fraction:Assuming perfect correlation among teeth:75% (95%Cl 59.8-82.2%)Assuming no correlation among teeth:75% (95%Cl 67.1-81.1%)Assuming 30% correlation among teeth:74.1 (95%Cl 63.8-81.4%)Relative risk ratio for the individual studies: ranged from 20.8%-53.2%

Author conclusions: 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

Reviewer comments: The USPSTF grades the quality of the evidence on a 3 point scale (Good, Fair, Poor) The 6 studies (4 RCTs and 2 cohort studies) included in this review were rated Fair quality: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes. Although the quality of the trials included in this review was not high, the results were consistent across the 6 studies.

Author Oong EM, Griffin SO, Kohn WG, Gooch BF, Caulfield PW.

Title The effect of dental sealants on bacteria levels in caries lesions. A review of the evidence. J Am Dent Assoc 2008;139(3): 271-278

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1+	6 studies 3RCTs 2CCTs 1 before- and – after study	There were no restrictions regarding study populations. Age ranged from 6 to 25 years. Fluoridation status not reported for 3 studies, exposure to F water in 2 trials & no fluoridation in 1 trial. Criteria for including teeth in the trials: 1 RCT- Enamel (explorer catch) or dentinal (explorer stick/penetration) 1 RCT- dentinal lesion aperture 1- 3mm 1 RCT- dentinal, from DEJ to pulp 2CCTs-Dentinal, no more than half the distance between DEJ and pulp Before-after- Dentinal, visible lesion	Not reported	Ranged from 1 to 60 months	Resin-based sealant/GIC applied to teeth with enamel or dentinal caries lesions. 3 studies used UV polymerised RBS, 2 used autopolymerise d RBS and 1 used GIC+Visible light polymerised RBS	Unsealed carious teeth 5 studies; bacterial samples from unsealed teeth obtained at baseline while samples from sealed teeth obtained at follow-up (unsealed teeth diagnosed as carious at follow-up, sealed teeth diagnosed at baseline)	Mean viable bacteria count (VBC) measured using CFU/mg % of samples with VBC greater than zero to measure activity for total bacteria, SM and LB	 Total bacteria: There were no findings of significant increases in total bacteria under sealants. Reduction in log 10 mean VBC at the last period in each study was approx threefold in 3 studies and twofold in 2 studies. Overall median and mean reductions 3.01 and 2.56 and increased with time since sealant placement. Reduction in proportion of samples with viable bacteria attributable to sealants ranged from 0-100% (median 50%, mean 51.6%) Excluding results for deep dentinal lesions : median 87.5% mean 71.8% Effect of sealants in reducing levels of S M utans and Lactobacilli was strong in two of the three studies that reported this outcome.

Author conclusions: Sealants reduced bacteria in carious lesions, but in some studies low levels of bacteria persisted. These findings do not support reported concerns about poorer outcomes associated with inadvertently sealing caries.

Reviewer comments: Although data were abstracted from the original studies to assess study quality and are presented in table 1, no overall scores for study quality are presented, and the effect of study quality on the results are not considered. As many of the studies included in the review appear to have been of questionable quality (no examiner blinding, no reporting of drop outs) this may have been an important omission.

Author Bader J and Shugars D

Title The evidence supporting alternative management strategies for Early Occlusal Caries and Suspected Occlusal Dentinal Caries. *J Evid Base Dent Pract* 2006;6:91-100

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Review	2+	N=7 studies for sealing Early occlusal caries: N=7 studies for sealing suspicious areas: Design of included studies not specified.	Not reported for enamel caries. Age 6-15 for suspicious areas or dentine caries	No meta analysis	1-5 years for sealant studiess	Sealant applied over early enamel caries or suspicious areas Other interventions considered were: No treatment Fluorides Antimicrobials Operative treatment (suspicious areas only)	Unclear if there were untreated comparison groups/teeth or if the included studies were prospective cohort studies measuring lesion progression over time	Lesion progression/regression	 Enamel caries and sealant: (7 studies) Lesion progression of sealed enamel lesions or "failure" (i.e. lost sealant & caries requiring restoration) ranged from 0% after 2 years to 11% after 5 years. Suspicious lesions and sealant: 5 of the 7 studies reported rate of lesion progression, which ranged from 0% to 19%, with 2 studies only reporting a "decease". The rate of caries regression, when reported, ranged from 25%-89% for sealed teeth. The rate of caries progression tended to be higher, and regression lower when sealant was defective. Enamel caries and no treatment:(6 studies) Progression, at least in permanent teeth Suspicious lesions and no treatment : No conclusions could be drawn about caries progression for untreated suspicious lesions due to the small number of studies and the wide variation in reported rates of lesion progression between older and more recent studies (16% - 77%). Enamel caries and fluoride: (4 studies) 3 out of the 4 studies found in favour of fluoride, but in only 1 study was the difference statistically significant. There was no evidence for fluorides and suspicious lesions, or for anti-microbials for either enamel or suspicious lesions. Ozone was not effective for suspicious lesions.

Author conclusions: The available evidence suggests that sealing both enamel caries and suspected occlusal dentinal caries is the most effective management approach if subsequent maintenance of the sealed surfaces can be assured.

Reviewer comments: The review lacks information on the methods used to identify and appraise the included studies. The authors stress the weakness of the available evidence and highlight the need for further research and for clinicians to apply the evidence in light of the specific information that a patient presents.

Risk of caries following sealant loss

Author Griffin SO, Kolavic Gray S, Malvitz DM, Gooch BF.

Title Caries risk in formerly sealed teeth. J Am Dent Assoc 2009;140;415-423

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1+	7 No quality score but selected aspects of study quality are describe d	Aged 5-14 years 3 studies reported children exposed to community-based water fluoridation/fluoride mouthrinse programmes Caries incidence among never sealed teeth after 1 year ranged from 24-47%	1973 children 4847 teeth	1.5-4 years	Formerly sealed teeth (with partially or fully lost sealant)	Never sealed teeth	The risk of a formerly sealed tooth developing caries was compared to the risk of a never sealed tooth developing caries at each annual follow- up using relative risk % FS developing caries/%NS developing caries	One year after placement: RR range: 0.828-1.118 Weighted mean RR 0.998 (95%CI 0.817-1.220) Two years after placement: RR range: 0.467-1.186 Weighted mean RR 0.912 (95%CI 0.793-1.048) Three years after placement: RR range: 0.761-1.111 Weighted mean RR 0.901 (95%CI 0.789-1.029) Four years after placement: RR range: 0.693-1.083 Weighted mean RR 0.936 (95%CI 0.896-0.978) The findings indicate that teeth with partial or complete loss of sealant are not at higher risk of developing caries than they would be if they had never been sealed.

Author conclusions: "The values for both the weighted mean and the median RR suggest that FS teeth with fully or partially lost sealant were not at a higher risk of developing caries than were NS teeth. Thus, the inability to provide a retention examination to all children participating in school-based sealant programs because of potential loss to follow-up should not exclude any child from having access to the well-documented caries-preventive benefit of a retained sealant."

Four-handed versus two-handed application technique

Griffin SO, Jones K, Kolavic Gray S et al. Author

Title

Exploring four-handed delivery and retention of resin-based sealants. J Am Dent Assoc 2008; 139:281-289

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Indirect comparison of effect of two-handed v four- handed dentistry using studies included in systematic reviews.	3	11 8 four- handed 3 two- handed Most studies began between 1973 and 1995	Between 5 and 10 years old. 7 studies conducted in high income countries (4 conducted in 'not high income' countries) No studies directly compared sealant outcomes with two- handed v four- handed sealant application	8 four-handed studies represented 1189 children and 1944 teeth. 3 two-handed studies represented 885 children and 1000 teeth. Multivariate analysis of the association between sealant retention and four-handed delivery was conducted	1-3 years	Sealant application using four- handed dentistry Auto polymerised sealant	Sealant application using two- handed dentistry Auto polymerised sealant	Sealants retention	Four-handed dentistry increased sealant retention by a statistically significant 9 percentage points. Sealant retention decreased with: o years since placement o study conducted in a high income country o prophylaxis performed with a handpiece before sealant placement o dentist as primary operator

Author conclusions: For this group of studies, four-handed delivery of autopolymerised sealants was associated with increased sealant retention. Using four-handed delivery to place resin-based sealants may increase retention.

Systematic reviews

Resin-based sealant v Glass ionomer sealant

Author Beiruti, N., Frencken J E, van 't Hof M A & van Palenstein Helderman W H.

Title

Caries preventive effect of resin-based and glass ionomer sealants over time: a systematic review. Community Dent Oral Epidemiol 2006; 34: 403–9.

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review of RCTs	1-	12 All split mouth trials (2 includec in Cochrane review)	Not reported	No meta analysis performed	from 1-7 years	Glass ionomer sealant (categorised separately as low and medium viscosity) Or Low viscosity resin-modified Gl sealant	Resin-based sealant (RBS) (auto-cured (AC) or light cured (LC)	Attributable risk (percent difference in caries incidence between RBS and GI sealants)	Meta analysis not possible due to heterogeneity between studies. AC RBS v low viscosity GI: (4 studies) Significantly more caries for teeth sealed with GI in 2 trials (at 2 and 3 years) Difference NS in remaining 2 trials LC RBS v low viscosity GI (4 studies) Significantly more caries in RBS teeth in 2 trials (at 2 and 3.8 years). Difference NS in other 2 trials. AC RBS v medium viscosity GI (2 studies) Significantly more caries in RBS teeth in 1 trial at 3.6 years. Difference NS in other trial LC RBS v low viscosity RMGIC (2 studies) Significantly more caries in GI teeth in both trials at 2 and 3 years.

Author conclusions: There is no evidence that either resin-based or glass ionomer sealant material is superior in preventing caries development in pits and fissures over time.

Reviewer comments: The authors of this review make the point that the effectiveness of sealant should be based on caries prevention rather than retention. This review included 2 of the 3 studies that met the inclusion criteria for the original Cochrane FS review (2004). Of the remaining 10 trials, 9 had been excluded from the Cochrane review because pair-wise data was not presented. Statistical methods were used to calculate pair-wise comparisons for the included studies in this review. The conclusion of the authors, based on this analysis, is consistent with the results of the review. The lower level of evidence given to this review is based on the fact that the authors did not conduct a quality assessment of the included studies.

Author Yengopal V, Mickenautsch S, Bezerra A, Leal S

Title Caries preventive effect of glass ionomer and resin-based fissure sealants on permanent teeth: a meta analysis. Journal of Oral Science 2009; 51: 373–82.

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1-	8 trials 7 split mouth 1 parallel group 4 included in Cochran e review	Age 6-16 1 st permanent molar sealed except for 1 trial where 2 nd permanent molar sealed. F water exposure in 2 trials ranging from 0.1-0.7ppm	6 trials included in the meta analysis	1-3.6 yrs	GIC sealant	Resin-based sealant	Odds ratio for Caries	 4 trials found in favour of RBS* 3 trials found both GI and RBS were effective 1 trial found in favour of GIC * 1 study repaired RBS but not GIC sealants Meta analysis of 6 split mouth trials Pooled OR: 0.96 (95% CI 0.62 – 1.49) suggests neither material is more effective at preventing caries. Heterogeneity (l²) 87.6%

Author conclusions: This systematic review with meta analysis found no evidence that either material was superior to the other in the prevention of dental caries. Thus, both materials appear equally suitable for clinical application as a fissure sealant material.

Reviewer comments: The high value for l² (87.6%) indicates a high level of heterogeneity between the trials, which calls into question the validity of pooling the results in a meta analysis. The conclusion that both materials are equally suitable for clinical application is therefore misleading.

Author Yengopal V & Mickenautsch S

	Title	Resin-modified glass ionomer cements versus resin-based materials as fissure sealants: a meta analysis of clinical trials. Euro Arch Paediatr Dent 2010; 11:18–25.	
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Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1+	6	Age 5-27 FPMs (3 trials), FPMs & SPMs (1 trial) Premolars (one trial). No further data provided	4 trials 719 teeth	12-36 mths	Resin-modified glass ionomer sealant	Resin-based sealant or flowable resin	Caries	12 months (4 trials) Pooled RR= 1.00 95% Cl 0.96-1.04, p=0.99 NS 24 months (2 trials) Pooled RR = 1.01 95% Cl 0.84-1.21, p=0.91

Author conclusions: This meta analysis found no conclusive evidence that either material was superior to the other in preventing dental caries. Therefore both materials appear to be equally suitable for clinical application as FS for a period of up to 2 years. However, the poor quality of the included trials warrants that further high quality RCTs are needed to obtain conclusive evidence of equivalence or difference in caries prevention.

Reviewer comment: Of the 6 included trials, all scored "Unclear" for randomisation and the authors state that the "quality assessment of these trials warrants that the data be treated with caution, owing to the increased risk of bias" which is at odds with the decisive conclusion that "both materials appear to be equally suitable for clinical application as FS for a period of up to 2 years".

Primary studies

Resin-based sealant v Glass ionomer sealant; Trials since the reviews

Author Oba AA, Dulgergil T, Sonmez IS, Dogan S.

Title Comparison of caries prevention with glass ionomer and composite resin fissure sealants. J Formos Med Assoc 2009; 108:11: 844-848

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Field trial Split mouth Random allocation of sealant to teeth indicated but not described.	1-	N=70 children 207 teeth Drop outs Children(n=29) 41% Teeth (n=70) 34% (teeth)	Age 7-11 Attending boarding school in Turkey Caries free or enamel caries lesions on pits and fissures of FPMs	3 years	High viscosity GIC sealant (Ketac Molar) applied using ART technique (in school, no suction, no water, hand pump for drying teeth, no chairside assistance) 4 dentists	LC Resin-based sealant (Fissurit F) applied under same conditions	Retention Caries	Total retention Total loss Caries Difference in reter (one way analysis Difference in carie significant, p>0.05	s of variance)	0

Author conclusions: Under field conditions where moisture control might not be effective, a high-viscosity and less technique sensitive GIC can be used as a feasible and effective sealant, which is equivalent to its resin counterparts.

Reviewer comments: The conditions for sealant placement were so poor in this study that they did not favour either sealant, but particularly not RBS, almost all of which was lost. To state that GIC was equivalent to RBS in this situation, is misleading since almost all the RBS sealants were lost. There was no difference in caries levels between the 2 groups. The lack of information on randomisation, index used for recording caries, number of dentists involved in outcome measurement calibration ,inter/intra examiner reliability and the high dropout mean that this study has a high risk of bias.

Author Amin, HE.

Title Clinical and antibacterial effectiveness of 3 different sealant materials. *J Dent Hygiene* 2008. 82; 5: 1-10

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results			
CCT Parallel group Random allocation of subjects to test groups indicated but not described	1+	N=45 children N=90 teeth Drop outs N=6 children (13%) N=12 teeth (13.5%)	Age 7-11 Attending Paedodontic clinic in University in Egypt Must have 2 caries free lower FPMs at least 2/3rds erupted, with deep narrow fissures and grooves	2 years	Group 2: Resin modified GIC (Fuji II LC) Group 3: flowable composite (Tetric Flow) All materials applied after prophy with dry bristle brush, under RD in clinic Groups I and 3 applied using 37% phosphoric acid gel. Etch time: 30 sec Group 2 applied using conditioner	Group 1: RBS (Helioseal F)	Retention Caries	Complete retention Caries *Complete re p<0.05	RBS n=26 21 (81%) 1 (4%) tention significa	RMGIC n=24 6 (25%)* 1 (4%) ntly poorer in R	Flowable composite n=28 24 (86%) 1 (4%) MGIC group

Reviewer comments:

Author Barja-Fidalgo F, Maroun S, de Oliveira BH.

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Effectiveness of a glass ionomer cement used as a pit and fissure sealant in recently erupted permanent first molars. J Dent Child 2009; 76;1: 34-40

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
RCT Parallel group Random allocation using list of random numbers Examiner blind to group assignment of child	1+	N=36 children N=92 teeth Age 6-8 years (mean 6.8) Drop outs N=16 children (45%) N=49 teeth (47%)	Low SES Brazilian children Age 6-8 years (mean 6.8) At least 1 FPM , sound or with non-cavitated enamel lesions, and ≥2dmft Baseline dmfs 16.5 in GIC group and 13.3 in RBS group (clinical and radiographic) F Toothpaste use widespread	5 years	High viscosity GIC (Fuji IX) Applied by graduate students without chairside assistance Surface conditioned with diluted GIC liquid for 15 sec, washed 15 sec, dried with cotton pellets GIC applied with an instrument and pressed into the pits and fissures using finger pressure	Auto polymerised RBS (Delton) CWR isolation 37% phosphoric acid, 30 sec	Complete retention At 5 years	Overall, the DMI	significant: p=0.27 FS of the GIC grou 2.2 v1.6), reflectin	ıp was higher thar

Author conclusions: High viscosity glass ionomer cement can provide some level of protection against dental caries when used as a dental sealant in situations where it is not possible to adequately isolate the tooth from saliva contamination during sealant application i.e. incompletely erupted or uncooperative children, and where complete GIC sealant retention may not be necessary for its caries preventive effect.

Reviewer comments: Small sample size and high drop out rate limit the conclusions that can be drawn from this otherwise well-conducted trial. Baseline characteristics of the drop outs indicate that they had higher baseline dmfs, were from families with lower mean monthly incomes and were less likely to perform supervised toothbrushing.

Resin-based sealant v F-containing RBS

Author Lygidakis N and Oulis K.

Title A comparison of Fluorshield with Delton Fissure sealant: four year results. *Pediatr Dent* 1998. 21;429-431

Split mouth Split mouth allocation of tect on one side of mouth to test & other to control material 1+ N=112 children Age 7-8 years Age 7-8 years 4 years Fluoroshield - a light- cured filled, F- releasing sealant Delton (LC, unfilled) Sealant retention Fluoroshield Delton N=161 Delton N=162 Random allocation of tect on one side of mouth to test & other to control material 1+ N=112 children (28%) Age 7-8 years 4 years Fluoroshield - a light- cured filled, F- releasing sealant Delton (LC, unfilled) Sealant retention N=161 N=162 Caries Complete retention* 124 (77%) 144 (89% V No difference in caries a preventive programme CWR Acid Etch: 60 sec CWR No difference in caries 9% v 10% in Fluoroshield & Delton groups	Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
	Random allocation of eeth on one side of mouth to rest & other o control	1+	448 FPMs 4 FPMs sealed/child Drop outs: N=31 children	Baseline dft= 1.94 Topical F gel provided to all children as part of a preventive	4 years	cured filled, F- releasing sealant Mechanical preparation CWR	Delton (LC,unfilled)		retention* P=0.01 No difference in 9% v 10% in Flu	N=161 124 (77%) caries	N=162 144 (89%)

Author Kargul B, Tanboga I, Gulman N.

Title	A compa	arative study of f	issure sealants He	elioseal Cle	ear Chroma and Delto	on FS+: 3 year results	. Eur Arch Paediatr	Dent 2009;	10: 218-222	
Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Split mouth Random allocation side of mouth to each sealant	1+	N=31 children N=121 teeth N=8 children (26%) N=29 teeth (24%)	Age 6-9 years 4 erupted, caries free, FPMs without hypoplasia All had good OH. Regular Topical F applied throughout study	3 years	Helioseal Chroma (transparent sealant that temporarily changes colour when exposed to curing light, to make it easier to monitor retention) CWR Applied using standard acid etch technique	Delton FS+, an opaque sealant with fluoride	Retention Caries Yes/No	% Caries 12 24 36	Delton FS+ 50% 46% 30% for each time com free teeth 98% 98% 91% at 36mths not statis	89% 87% 80%

Author conclusions: Delton FS+ showed a better complete retention rate for occlusal FS at one year. Both FS were aesthetically acceptable and easy to see during application and follow up periods and gave significant protection from occlusal decay.

Reviewer comments: Retention rates for both materials were low, even at 1 year. Criteria for recording caries are not provided (merely present or not present).

Methods of cleaning the tooth

Toothbrush v handpiece

Author Kolavic Gray S, Griffin SO, Malvitz DM, Gooch BF.

Title A comparision of the effects of toothbrushing and handpiece prophylaxis on retention of sealants. J Am Dent Assoc 2009. 140: 38-46

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review and Indirect comparison of data from studies included in systematic reviews of effect of FS Also, summary of manufacturers' instructions for use of 10 different unfilled sealants	3	2 studies included for direct evidence 11 studies from 4 systematic reviews met inclusion criteria for indirect comparison	Age 5-10	Not reported	12-60 mths	Tooth surface preparation using a toothbrush, with or without toothpaste (2 studies)	Tooth surface preparation using Handpiece prophylaxis with pumice or paste (10 studies)	Complete retention at each year of follow-up	Complete retention in year 1 was significantly better for TB compared to handpiece. (94% v 87%, based on 2 TB studies and 5 HP studies) No significant difference in retention between the 2 methods was found for years 2-5.

Author conclusions: Levels of sealant retention after surface cleaning with toothbrush prophylaxis were at least as high as those associated with handpiece prophylaxis.

Reviewer comments: The one study that directly compared dry toothbrushing with handpiece prophylaxis (Gillcrist 1998) found no difference at 1 year between the 2 methods. The indirect comparison involved grouping selected studies by method of surface cleaning and comparing retention rates in bivariate analysis, without controlling for other factors that might have influenced sealant retention, such as age of participants, (which ranged from 5-8 in one study to 8-10 in another) state of eruption of teeth or method of isolation. The authors refer to another review (Griffin et al, 2009) which analysed the same group of studies using multivariate analysis (to investigate the effect of 4-handed v 2-handed sealant application) and found that toothbrush prophylaxis was associated with higher sealant retention than handpiece prophy.

Toothbrush v handpiece

Author Gillcrist JA, Vaughan MP, Plumlee GN, Wade G.

Title Clinical Sealant retention following two different tooth-cleaning techniques. J Public Health Dent 1998. 58 (3) 254-6

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results					
Split mouth Quasi	Asi domised ernation ween R & (44 teeth) de for aning		USA Age 6-8 years	r your	Handpiece prophy for 15 second on upper and lower molars on	L molars without toothpaste on	Sealant retention	Complete retention					
randomised		a la il aluana	mouth. Fluoridated prophy paste used.		opposite side of mouth Same procedure for			Handpiece	ТВ	Both			
Alternation between R &		children Co-operative						N=126	N=126	N=252			
L side for cleaning method				FS application		12 mth	98%	99%	98.4%				
memou					CWR isolation				<u> </u>	<u> </u>			
Blind outcome assesment					A/E: 37% OPA, 20 sec								
					LCRBS (Helioseal)								
Author concl	usions:. Dry	/ brushing by the op	berator may be an acc	eptable alteri	native to using a rotary in	strument with brush and p	baste						

Reviewer comments: Limitations of the study are the short follow up and the relatively small sample size. The authors make the point that almost one third of school-based sealant programmes use a toothbrush to clean the teeth before sealant application, sometimes by the children themselves. therefore the acceptability of this technique is important.

Air and water

Author Donnan FM, Ball IA.

Title A double-blind clinical trial to determine the importance of pumice prophylaxis on fissure sealant retention. Br Dent J 1988. 165; 8: 283-6

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Split mouth Random ised	1+	N=59 children 350 sites Drop out: 8 children (13.5%)	UK Age 7-16 Attending community dental clinic	12 mths	Fissures cleaned of debris with a sharp probe, used without force, and then washed with forceful atomised water spray from 3 in 1 syringe Isolation: CWR or dry guards A/E: 37% PA, 60 sec LCRBS - Helioseal	Handpiece Prophylaxis with pumice Same technique for sealant application	Sealant retention	Complete retention	Handpiece 149 sites 144 (96.6%)	Probe & water 149 sites 145 (97.3%)

Author conclusions: The results of this clinical study show no statistically significant differences between the 2 treatment groups. Therefore, from a clinical standpoint, it can be concluded that prophylaxis of teeth with pumice prior to etching contributes little towards sealant retention, and this step can be legitimately omitted. The elimination of this preparatory pre-etch stage makes the procedure less involved and less time consuming for the operator and more acceptable for the young patient.

Reviewer comments: The authors make the point that "in situations where teeth are so heavily coated with plaque that examination of the tooth surface is impossible, cleaning would be required in the first instance to enable valid clinical inspection." This implies that the non-pumiced teeth sealed in this study must have been quite clean at the outset. The study did not evaluate patient acceptance of the procedure with and without pumicing, therefore the conclusion that not pumicing is more acceptable for the young patient is not based on the results.

Air abrasion

Author Yazici AR, Kiremitci A, Celik C et al.

Title A two-year clinical evaluation of pit and fissure sealants placed with and without air abrasion pretreatment in teenagers. J Am Dent Assoc 2006. 137;1401-1405

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Split mouth Random assignment of teeth to etch. Blind outcome assessment	1+	N=16 N=162 teeth (116 premolars (72%) 46 molars) Drop outs: 0	Age 16-17 Patients at Dental School in Ankara, Turkey No restoration or sealant on fissures	2 years	Pumice prophy Air abrasion followed by A/E 35% PA, 30 sec LCRBS (Concise) Rubber dam isolation	No air abrasion Otherwise, same procedure as test group	Sealant retention	12* 24^ * p=0.025 ^ p= 0.002	Air abrasion + etch N=81 95% 91%	Etch only N=81 84% 76.5%

Author conclusions: As air abrasion followed by acid etching resulted in significantly higher sealant retention rates, this method could be a good choice for fissure preparation before sealant placement for longterm success.

Reviewer comments: Most of the teeth sealed were premolars, which show higher retention rates than molars. The distribution of premolars/molars between the 2 groups is not described. The small sample size limits the generalisability of the results of this study. Data not analysed as paired data. The ADA evidence statement that "there is limited and inconclusive evidence in favour of using air abrasion as a cleaning method before acid etching to improve sealant retention" is justified. It might be more accurate to say there is limited evidence that air abrasion prior to acid etching increases sealant retention after 2 years, when used mostly on premolar teeth.

Author Kanellis MJ, Warren JJ, Levy SM.

Title

A comparison of sealant placement techniques and 12-month retention rates. J Public Health Dent 2000. 60(1): 53-56

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Parallel group Randomised Blind outcome assessment	1+	N=74 children N=539 surfaces Drop outs: N=58 (31%)	Grade 1-4 (? Age 7-10?) ≥1 FPM sufficiently erupted & sound	1 year	Children dry-brushed their teeth 15 sec air abrasion CWR & DryAid isolation LCRBS Helioseal	Children dry brushed teeth 37% PA, 30 sec Cotton wool roll & DryAid isolation Helioseal	Retention by tooth surface (occlusal, buccal, palatal) and for all surfaces	All surfaces 12 month Complete reter *surfaces Complete retention 12mth p<0.01 Complete retention was and palatal surfaces with buccals and 58% v 28% No significant difference occlusal surfaces (97.5° abrasion respectively parallel Air abrasion was approximately parallel Complete retention was approximately parallel Air abrasion was approximately pa	Air abrasion N=169 57% s significantly h air abrasior of or palatals(e in retention % v 89% for e =0.17 ximately 30%	n (65% v 6.5% fo p<0.01) was found for etch and air quicker than acio

Author conclusions:. Although more research is needed to improve air-abrasion application s, it does not appear that air abrasion without acid etching offers a significant advantage over traditional se placement methods, and in fact appears to be inferior to the acid-etching technique for use in public health settings.

Reviewer comment: Drop outs were high in this study – approximately 1/3rd of children after only 1 year. The authors also make the point that in a public health setting , the air abrasion equipment adds to costs, even though the treatment time is lower.

Mechanical preparation

Author Shapira J and Eidelman E

Title The influence of mechanical preparation of enamel prior to etching on the retention of sealants: three year follow up. *J Pedodontics* 1984;8: 272-77

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Split mouth Randomised		N=47 children 61 pairs of molars Drop outs: 13 children (21%)	Age 6-9 Attending clinic in Jerusalem dental school At least 1 pair of homologous caries free, fully erupted FPMs, Non-fluoridated	3 years	Mechanical preparation of fissure using a no. 1 round steel bur Pumice, A/E 60 sec ACRBS (Delton) Isolation not described	No mechanical preparation Same sealant application procedure	Sealant retention	Complete retention All teeth N=96 Maxillary teeth (n=22) Of the 48 tooth pairs a showed complete reter teeth, 7 pairs had parti control teeth and 1 pai tooth. All but 1 of the failures The difference in seala was borderline non-sig	ntion in both tes al or complete l r had partial los occurred in ma unt retention in i	et and control loss in the es in the test uxillary teeth. maxillary molars

Author conclusions: It can be concluded that mechanical preparation results in higher retention rates of sealants for maxillary first molars.

Reviewer comments: The authors used auto-cured sealant, and state that on maxillary molars, the sealant tends to flow off the tooth surface distally, leaving a thin layer of sealant, which may not polymerise correctly. They suggest mechanical preparation on maxillary teeth allows a thicker layer of sealant. The applicability of mechanical preparation to modern light-cured sealants is unclear.

Author Shapira J and Eidelman E

Title Six year clinical evaluation of fissure sealants placed after mechanical preparation: a matched pair study. *Pediatr Dent* 1986;8: 204-5

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Split mouth Randomised	1+	N=47 children 61 pairs of molars Drop outs: 27 tooth pairs (44%)	Age 6-9 Attending clinic in Jerusalem dental school At least 1 pair of homologous caries free, fully erupted FPMs, Non-fluoridated	6 years	Mechanical preparation of fissure using a no. 1 round steel bur Pumice, A/E 60 sec ACRBS (Delton) Isolation not described	No mechanical preparation Same sealant application procedure	Sealant retention	Complete retention All teeth N=68 Maxillary teeth (n=30) Mandibular teeth N=38 * p<0.02, ^ p<0.016	Mechanical preparation 30 (88%) 13 (87%) 17 (89.5%)	Acid Etch 32 (65%)* 7 (47%)^ 15 (79%)

Author conclusions: It was concluded that mechanical preparation resulted in a significantly higher retention rate of sealant placed on maxillary molar teeth.

Reviewer comments: The high losses to follow up limit the conclusions that can be drawn from the results. The authors used auto-cured sealant, and state that on maxillary molars, the sealant tends to flow off the tooth surface distally, leaving a thin layer of sealant, which may not polymerise correctly. They suggest mechanical preparation on maxillary teeth allows a thicker layer of sealant. The applicability of mechanical preparation to modern light-cured sealants is unclear.

Self-etch v acid etch

Author Feigal RJ & Qualhas I

Title Clinical trial of self-etching adhesive for sealant application: Success at 24 months with Prompt L-Pop. Am J Dent 2003; 16: 249-51

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
SM randomised	1+	36 teeth (18 tooth pairs) No. children or tooth pairs at baseline not reported Drop outs: 0?	Age 7-13 Mean age = 10.5 Attending Paediatric dental clinic Low to moderate caries risk Mixed fluoride region 28/36 sealed teeth were FPMs	24 mths	Prompt L-Pop self- etch 1-bottle adhesive 15 sec application LCRBS: Delton CWR isolation	A-E 30sec PA Delton CWR	Retention	Self-etchAcid EtchComplete11/18 (61%)retention11/18 (61%)Mc Nemar's Chi Square Paired analysis: p>0.8Clinical time for application significantly different:3.1 min for Acid Etch and 1.8 min for self-etch

Author conclusions: We conclude that Prompt L-Pop self-etching primer/adhesive will effectively bond sealant to enamel and will simplify the procedure in patients for whom the standard etching methods pose a compliance problem.

Reviewer comments: The conclusions are based on the results. The authors do not report the number of children or tooth pairs at baseline, but simply present the 24 month results. The reader must assume that there had been no drop outs.

Author Venker DJ, Kuthy RA, Qian F et al.

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Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Retrospective Chart analysis of cohort	3	272 children Drop out: 64 children (23.5%)	Age 9 (range 7.4 – 10.3) 45 (22%) sealed with self-etch technique 163 (78%) sealed using acid etch technique Participating in school-based sealant programme in Des Moines, Iowa	12 mths	Prompt L-Pop self- etch 1-bottle adhesive 15 sec application LCRBS: Delton Opaque DryAngle & CWR isolation	Acid etch (PA) 15-20 sec LCRBS: Delton Opaque DryAngle & CWR isolation	Retention (measured at surface, tooth and subject levell)	Acid etch te complete re	chnique were 6 ti	Acid Etch 75% (584/774) 72% (391/545) who were sealed with mes more likely to have to Prompt L-pop teeth p <0.0001

Title Twelve-month sealant retention in a school-based program using a self-etching primer/adhesive. J Public Health Dent 2004 64;4:191-197

Author conclusions:. Though sealants were retained in larger numbers with phosphoric acid, overall sealant retention at the tooth level was lower than previously published for clinical studies and school-based programmes. Examining retention data at the person level however, allows programme administrators to plan resources more effectively and re-evaluate sealant protocol to ensure as few children return for sealant reapplication.

Reviewer comments: SBS programme. 1 school used Prompt L-Pop, 4 used acid etch. 2 hygienists. Complete or partial loss was considered a failure. Retention at the person level was considered a failure if any surface had failed. Outcome assessment was not blind, since the examiner was aware of the school in which the self-etch technique. This, coupled with the stringent criteria for failure at the subject level, could lead to an overestimate of the difference in effect between the 2 methods

Author Lampa E, Brechter A, van Dijken JWV.

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Effect of a non-rinse conditioner on the durability of a polyacid-modified resin composite fissure sealant. J Dent Child 2004; 71:152-7

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
SM Randomised	1+	N=31 children 98 teeth Drop out: 2 children (9%)	8 (6-13) Attending public dental clinic in Kiruna, Sweden	24 mths	No rinse conditioner+ Prime & Bond No-rinse conditioner: 20 sec application Self-etch primer:20 sec Dyract Seal (compomer) CWR & dry tip isolation	1. A-E: 36% PA 60 sec LCRBS: Delton DDS opaque 2. A-E + Prime & Bond + Dyract Seal CWR & dry tip isolation	Sealant retention Marginal adaptation Caries	Dyract seal No Caries 12 mth 24 mth P not repo Due to poor 1 conditioner a was created, Bond + Dyra Complete Re was better th months (89%	100% 98% rted retention in of the t 6 months, a sep (n=25 children, a ct Seal was applie etention of Dyract an Dyract seal with	94% 91% Dyract seal with parate comparison group ge 6-16) where Prime& ed using A-E technique. seal placed with A-E ith conditioner at 12 Retention was also

Author conclusions: Conditioning with No rinse conditioner prior to sealant application cannot be recommended.

Reviewer comments: The conclusion is consistent with the results. However, it would have been more informative if the study had included a no-rinse conditioner Delton control group.

Self-etch v acid etch with bonding

Author Burbridge L, Nugent Z, Deery C.

Title A randomised controlled trial of the effectiveness of a one-step conditioning agent in fissure sealant placement: 12 month results. Eur Ach Paediatr Dent 2007;8:49-54

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results	
SM Randomised	1+	60 children 81 pairs of molars (mostly mandibular) Dropouts: 24 children (37%)	Mean age 9.15 Range:5-13 Regularly attending Dental hospital & community clinics in Lothian area of Scotland Molars sufficiently erupted for isolation and children co operative	12 months	XenoIII self-etch 2- bottle Adhesive 20 sec application Delton opaque CWR isolation	A-E: 37% PA 20 sec Prime and Bond 20 sec Delton opaque CWR isolation	Sealant replacement Sealant coverage Caries		A-E, Prime&Bond + Delton N=50 teeth 12 (24%) en in caries levels ths. (actual values not
						estudy does not control fo			

Author Yazici AR, Karaman E, Baseren M *et al.*

Clinical evaluation of a nanofilled fissure sealant placed with different adhesive systems: 24-month results

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
SM Randomised	1+	N=16 adults 244 sealants Drop out: 1 adult 16 teeth (6.5%)	Mean age=20 (range 18-21) Attending University dental Faculty, Ankara, Turkey	24 mths	One step Self-etch adhesive (FuturaBond NR) Nano-filled Fissure sealant (Grandio Seal) CWR isolation	Etch and rinse adhesive (Solo Bond M) 34.5% PA 30 sec Nano-filled Fissure sealant (Grandio Seal) CWR isolation	Sealant retention	Complete retention 12 mths n=122 24 mths n=114 Difference bett points, P<0.00 No caries was)1	Acid etch adhesive system Solo Bond M 109 (89.3%) 93 (81.6%) ficant at both time

Author conclusions: Fissure sealants placed with etch and rinse adhesive showed better retention rates than those placed with self-etch adhesive.

Reviewer comments: Subjects in this study had an average of 15 sealants placed and the analysis does not take account of clustering. There were 4 operators, and there is no measure off operator variability.

Acid etch + adhesive system v acid etch without adhesive

Author Feigal RJ, Musherure B, Gillespie M et al

Title Improved sealant retention with bonding agents: A clinical study of two-bottle and single-bottle systems. J Dent Res 2000. 79;11: 1850-56

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
SM Randomised	1+	N=165 children 617 teeth FPMs & SPMs Loss = 17% at 24 mths & 38% at 48 & 60mth		60 mths	A-E: PA 30 sec + 2 bottle bond system (Tenure) + Fluoroshield A-E + 2 bottle bond system (Scotchbond) + Fluoroshield A-E + one bottle system: (3 diff brands): Prime& Bond Single Bond Tenure Quik + Fluoroshield CWR	A-E: PA 30 sec Fluoroshield CWR isolation	Sealant survival (measured according to score obtained for marginal integrity, marginal discolouration, anatomic form as well as presence of dental caries.)	Sealant survival over time was significantly better on occlusal (p=0.014) and buccal/palatal surfaces (p=0.006) using the one bottle system compared to the control. The risk of sealant failure on occlusal surfaces in the one-bottle group was approximately half that of the control group. (Hazard ratio (HR) 0.53, p=0.014) There was no difference in sealant survival with Tenure compared to control, and Scotchbond was detrimental to sealant survival on occlusal surfaces Other factors significantly associated with sealant failure on occlusal surfaces were: Non ideal Patient behaviour: HR=1.96, p=0.0007 Non ideal Saliva control: HR=1.73, p=0.002 Arch (lower v upper): HR=0.77, p=0.038 Incomplete state of eruption*: HR=2.9,p<0.0001 Alteration in enamel: HR=1.51, p=0.018 Provider HR=0.31,p=0.037 (provider 1 reduced risk of failure) *operculum or gingival level with distal marginal ridge v completely erupted)

Author conclusions:. Findings indicate a beneficial effect of single-bottle adhesive systems. When used between enamel and sealant, these agents yield half the usual risk of failure for occlusal sealants and one third the risk for buccal/lingual sealants. In addition, significant negative effects on sealant survival were observed with early eruption, enamel alterations, less than ideal patient behaviour and less than ideal saliva control.

Reviewer comments:

Author Boksman L, Mc Connell RJ, Carson B, Mc Cutcheon-Jones EF.

Title A 2-year clinical evaluation of two pit and fissure sealants placed with and without the use of a bonding agent. *Quintessence Int* 1993. 24;131-133

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
SM Not randomised Teeth on L side received bond	1-	No. participants not reported No. teeth=402 Drop out: 103 (26%) at 12 mths 181 (45%) at 24 mths	Healthy Adolescents (no. not reported) Fluoridated Attending private practice At least 2 pit and fissure sites on opposite sides of the mouth Teeth sufficiently erupted to allow RD isolation		A-E 37% PA 60 sec Scotchbond 2 LCRBS: Concise RD isolation A-E 37% PA 60 sec Universal Bond LCRBS: Prisma Shield RD isolation	A-E 37% PA 60 sec LCRBS: Concise RD isolation A-E 37% PA 60 sec LCRBS: Prisma Shield RD isolation	Complete retention		With bonding agent 122 (41%) 82 (37%) without bonding a but the difference	Without bonding agent 127 (43%) 92 (42%) gent had higher was not significant

Author conclusions:. The results of this study indicated that the use of a bonding agent prior to the application of a pit and fissure sealant does not increase the retention rate.

Reviewer comments: Although this is a split mouth trial, allocation of the teeth to receive bonding agent was not randomised, just the choice of bonding agent and sealant. Blind outcome assessment is not indicated and is unlikely

Author Mascarenhas AK, Nazar H, Al-Mutawaa S, Soparkar .

Title Effectiveness of primer and bond in sealant retention and caries prevention. *Pediatr Dent* 2008; 30;25-8

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Split mouth Randomised	1+	N=78 children 86% female 312 FPMs (4 per child) No losses reported " all children with sealed teeth were recalled)	78 children Mean age:7.7 (6- 9) 4 sound FPMs Participating in School Oral Health programme in Kuwait	24 mths	A-E: 15 sec Scotchbond Multipurpose Plus system primer and bond LCRBS: Delton Plus RD isolation	A-E: 15 sec LCRBS: Delton Plus RD isolation	Sealant retention Caries	^ p=0.56 Paired analysis: OR for complete Multivariate ana No difference in	e retention: 1.29 lysis sealant retention	Without primer and bond 68%* 26%^ ot significant (p=0.22) 95% CI 0.8-2.1 NS n with or without bond, tooth surface and

Author conclusions: When a proper technique is used in sealant placement, use of a primer and bond did not enhance sealant retention

Reviewer comments: The authors suggest that the Scotchbond Multipurpose Plus system might not have been compatible with the Delton sealant, and this may have led to no difference being seen. Single examiner, no intra-examiner reliability, no criteria reported for recording of caries.

Author Pinar A, Sepet E, Gamze Aren *et al*

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
SM Randomised	1+	N=30 children 120 FPM surfaces	Age 8-10 Attending Paediatric dentistry clinic, in Instanbul, Turkey All 4 FPMs sound and unsealed at baseline	24 mths	A-E: PA 30 sec One Coat Bond LCRBS: Fissurit F CWR isolation	A-E: PA 30 sec LCRBS: Fissurit F	Anatomic form (corresponds to extent of tooth surface covered with sealant) Marginal integrity Marginal discolouration	Complete retention at 12 mths (As defined by authors: Score 0,1 & 2a) Complete retention (Score 0,1 & 2a) at 24 mths Difference at eac	With bonding agent 40/48 (83%) 35/44 (79.5%)	Without bonding agent 39/48 (81%) 33/44 (75%)

Title Clinical performance of sealants with and without a bonding agent. Quintessence Int 2005. 36: 355-360

Author conclusions: The success of a sealant is related to whether the sealant is applied under optimal conditions. The results of this study show that at the 2-year mark, the placement of a bonding agent under sealants did not significantly affect the clinical success of sealants.

Reviewer comments: 2 examiners in this study. No indication of examiner calibration or of inter and intra-examiner reliability

Author Lykidakis N, Dimou G, Stamakaki E.

 Title
 Retention of fissure sealants using two different methods of application in teeth with hypomineralised molars (MIH): a 4 year clinical study Eur Arch Paediatr Dent 2009. 10:4; 223-226

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Split mouth Random assignment of FPMs to test and control	1+	N=54 children Drop outs: n=7 (18.5%)	Age 6-7 yrs Regular attenders at the Community Dental Centre, Athens At least 2 contralateral, fully erupted, caries- free FPMs with mild defects without breakdown Baseline mean dft = 1.04	48 months	Enamel prep with round bur ¼ slow handpiece Bristle brush with non-F paste Acid etch: 37% PA etch 30sec Adhesive (One-step) applied twice and polymerised FS (brand name not given) Cotton wool isolation 1 operator	FS only Same procedure without adhesive	Retention Caries	(p<0.001)	difference for c	Without bonding agent 79% 47% 28% 26% in bond group at 4 y earies (3 teeth in test

Author conclusions:. In hypomineralised molars with occlusal opacities, sealants appear to have greater retention when applied using 5th generation adhesive systems prior to sealant.

Reviewer comments: Criteria for MIH were non-disintegrated occlusal demarcated opacities (mild defect), and therefore results can only be generalised to similarly affected teeth. The adhesive used is similar to the single bottle bonding agent recommended in the ADA guideline

Isolation

Author Straffon LH, Dennison JB, More FG.

Title Three-year evaluation of sealant: effect of isolation on efficacy. J Am Dent Assoc 1985. 110; 714-717

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Split mouth Quasi- randomised (alternation)	2+	N=29 children 50 pairs of teeth Drop outs: 24 surfaces lost to follow-up	Selected from a paedodontic clinic Age range: 5-14 (5-9 for FPMs, 11-14 for SPMs) 2 contra-lateral partially erupted or newly erupted FPMs or SPMs with deep grooves with no significant explorer catch indicating caries	36 mths	Fissure sealant (not described) applied under rubber dam using topical anaesthetic Pumice prophylaxis Etch 60 sec Dried 30 sec Applied by trained practitioner with the aid of trained auxiliary personnel Defective sealants were retreated at each 6mthly recall visit in both the intervention and comparison groups	Cotton wool roll isolation using various CWR holders, "Theta dri- angles" and evacuation Same sealant application procedure and retreatment	Sealant retention Sealant retreatment Caries	Complete retention at 36 mths (without retreatment) Complete retention at 36 mths (with retreatment) Average Retreatment rate over 36 mths Difference in reten average retreatme Of the 76 surfaces 31.6%) had been r required only one in The highest retrea after application) a	nt rate was not si evaluated at 36 etreated, and 80 retreatment. tment rate was at nd at 6mths	ignificant months, 24 (% of these teeth t baseline (2 weeks

Author conclusions:. The average retention rate over the 36 months was 94.7%, with cotton roll isolation at 95% and rubber dam at 94.3%. No caries occurred in any sealed surface when sealants were periodically evaluated using specific criteria and new sealant was applied to defective area of the existing sealant. The retreatment rate was highest at baseline (8%) and at 6 months (11.3%). Of the total number o sealants retreated, (n=31), 61% (n=19) were from the mandibular arch. At 36 months, 31% (n=24) of the treated teeth required treatment. Of the 24 teeth retreated, 19 (80%) required only one retreatment.

Reviewer comments: Although this was conducted as a split mouth trial, the data were not paired for analysis. In fact, it is unclear what statistical method, if any, was used to analyse the data. Although the authors state "There was no significant difference in retention for the two isolation methods used" there is no reference to statistical analysis, so it is possible that the authors may mean clinical significance

Author Ganss C, Klimek J, Gleim A

Title

One-year clinical evaluation of the retention and quality of 2 fluoride releasing sealants. Clin Oral Invest 1999. 3:188-193

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results			
Split mouth Randomised	1+	N=58 203 teeth Drop outs: 4 subjects (7%) and 10 teeth (5%) lost to follow-up	Mean age: 13.7 ± 3.6 126 (65%) of the teeth sealed were premolars Patients of private practice 39% female	12 mths	Helioseal F (LC) applied under RD or with CWR Pumice prophylaxis Stained fissures enlarged with carbide bur 37% PA 40 sec Dried 20 sec Applied by same clinician in private practice	Fissurit F (LC) applied under RD or with CWR Same application procedure	Sealant retention assessed clinically and photographically Sealant surface quality Sealant margin (visual/tactile and staining with dye application) Caries	Complete retention at 12 Helioseal F Fissurit F ^Retention of He overall (p<0.05). between the 2 m isolation was use was used Complete sealan higher for both m compared to cott 4 patients (10 tee sealant all had be	A significant aterials was d (p<0.05) b t retention ra laterials with on wool isola eth) develope	difference ir seen when c ut not when tes were sig rubber dam ation p<0.00 ed caries – ir	n retention cotton wool rubber dan nificantly isolation 1 n all cases,

Reviewer comments: The conclusions are consistent with the results.

Author Eidelman E, Fuks A, Chosack A.

Title

The retention of fissure sealants: rubber dam or cotton rolls in private practice ASDC J Dent Child 1983. 50 (4); 259-61

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results			
Prospective Observational	3	N=95 233 teeth	Age range:6-14 65% were aged		92 teeth were sealed using RD isolation	141 teeth sealed with CW isolation		Complete retention	CWR	RD	Total
cohort			6-8		RD was used in quadrants where restorative work was			12 months	121/131 (92.4%)	47/80 (92.5%)	
					required			24 months	53/60 (88.3%)	26/27 (96.3%)	
								Statistical analys observed freque showed no signi rate in the two tr	ncies with a ficant differer	normal appro	oximation
Author conclus			that retention rates of	f Delton fissu	ire sealant were not signi	ficantly affected by the m	ethod of isolation				

only be interpreted as an observational study.

Effectiveness in primary teeth

Author Chadwick B, Treasure E, Playle, R.

Title A randomised controlled trial to determine the effectiveness of glass ionomer sealants in pre-school children. *Caries Research* 2005;39:34-40.

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Parallel group RCT	1+	N=508 children Test= 241 Control = 267	South Wales Mean age: 2 yrs Age range: 1.0 –	3.4 yr (average) Variable follow-up	Single application of GIC to first primary molars No suction, CWR isolation	No GIC sealant DHE, Toothbrush &Toothpaste	Sealant retention % of children with caries in occlusal surface of primary molar	No. (%) of children with sealants present	Test (n=221) 69 (31.2%)	Control (n=228) 3 (1.3%)
		Loss to follow- up: Test = 8%	2.7 yrs High caries area	(mean 1.38 yrs in test & 1.30 yrs in	Child on parent's lap DHE, Toothbrush &Toothpaste provided		Oral Hygiene	No. (%) with caries on occlusal surface of 1 st primary molar	17 (7.7%)	24 (10.5)*
	Test = 8% Control= 15%	n control. Range: 0.95-3.54 yrs	65% of all appointments were made to child's home			No. (%) with dmft>0 Difference: 2.8 (95%)	52 (23.5%) CI -2.6 to 8.3%) N	55 (24.1%) S		

Reviewer comments: The authors note that recruitment to the study was difficult, and as a result, much of the treatment seems to have been conducted in the home, in less than optimal conditions, which would

not favour sealant retention. The conclusions drawn by the authors are valid.

Author Poulsen, P

Title Retention of glass ionomer sealant in primary teeth in young children. *Eur J Paediatr Dent* 2003;4:96-8.

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Split mouth Random allocation of side of mouth to sealant	1+	N=65	Denmark Mean age=53.2 mths (4 yr 5 mth) Range: 3.25 – 8.5 yrs	Variable Mean=23.5 mths Range: 7 - 35 mths	GIC sealant (Fuji II) LC used without conditioner	No sealant on contra lateral teeth	(Scores for Fully and partly retained sealant were combined) Sealant survival time by tooth type	Sealant retention* rate in 2 nd primary molars Sealant	12 mths ~75% < 50%	24 mths ~40% ~30%
using table of random numbers Blinding not possible			Low caries population Background use of fluoride TP						or sealants place ess than 2 years,	ed on second primary , and approximately 1
possible Author concl		-	of fluoride TP		isfactory. However, higi ulating sealant retentior	h quality randomised cl		molars was slightly l year for 1 st primary r caries preventive effe	ess than 2 years, nolars ct are still needed	, and approxima

Author Corona SAM , Borsatto MC, Garcia L et al.

Title Randomized, controlled trial comparing the retention of a flowable restorative system with a conventional resin sealant: one-year follow up. *Int J Paed Dent* 2005; 15:44-50

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Split mouth Random assignment of molars	1+	N=40 children 80 primary molars(40 pairs) 80 permanent molars Drop out = 0	Brazilian Age range: 4-7	1 year	Flowable resin composite (Flow-it) Total etch Single bottle adhesive system (Bond 1)	RBS (Fluorshield)	Complete retention	Complete retention Primary n= 80 teeth Permanent n=80 teeth	Flowable resin 95% 100%	RBS 77% p<0.01 95% NS
uthor conclu	usions: The	flowable restorativ	e system yielded opt	imal retentio	n on both primary and p	permanent molars. Over	all retention rate was h	igher than that of the conven	tional pit and fi	ssure sealant on

Reviewer comments: No indication given of the characteristics of the participants or of distribution of age (mostly younger or older?) Analysis not done as paired data. Trial stopped after 1 year because of high dropout, so 1-year result may be an overestimate of the effect, since retention declines with time.

Author Hardison J, Collier D, Sprouse L et al.

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Prospective cohort observational study	3	Not reported 1,871 children originally received sealant A random sample of these was followed up 781 surfaces were examined	Tennessee Age= 3-4 years at placement Low income, high caries risk (Medicaid)	1 year follow up	Sealant placed 1 year previously as part of a sealant programme "Visibly detectable" sealant was used	No sealant	Sealant retention (Sealed, partly sealed & missing)	Sealed: 88.2% Differences in sealant retention rates were recorded betwee different regions (range 74% - 96.3%)

Author Hotuman E, Rolling I, Poulsen P.

Title Fissure sealants in a group of 3-4 year old children. Int J Paediatr Dent 1998;8(2):159-60. Study Type Evidence No. of Patient Study Intervention Comparison Outcome measure Res

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results		
Split mouth Teeth in each tooth pair randomly assigned to test or control sealant	1+	N=52 children Drop out not reported. 52 pairs of primary molars evaluated at follow up.but no. of pairs of primary molars originally sealed is not reported	Denmark Median age: 3.7 yrs Age range: 2 yrs 11 mths to 4 yrs 11 mths Attending municipal dental clinics	Mean 2.2 years Range: 2.0– 3.3yrs	Delton (AC)	Prisma Shield LC	Complete retention Caries	Complete retention Difference NS: Caries Difference NS	Delton AC 3(5.9%) p=0.49 70.6%	Prisma Shield 5(9.8%) 76.5%

Reviewer comments: Same dentist who applied the sealants measured the outcome, which may have introduced examiner bias.