Pit and fissure sealants versus fluoride varnishes for preventing dental decay in children and adolescents (Review)

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ABSTRACT

Background
The majority of the detected increment in dental caries is confined to pit and fissure surfaces of first molars. Application of pit and fissure sealants and topical fluorides are widely used procedures in the prevention of decay, and their effectiveness in caries prevention has been proved by systematic reviews.

Objectives
The objective of this study was to compare the effectiveness of pit and fissure sealants with fluoride varnishes in the prevention of dental decay on occlusal surfaces.

Search strategy
Electronic searching was performed on the following databases: the Cochrane Oral Health Group's Trials Register (last update November 2005), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2005, Issue 4), MEDLINE (from 1966 to December 2005), EMBASE (from 1974 to November 2004), SIGLE (from 1976 to December 2004), SCISEARCH, CAplus, INSPEC, JICST-EPLUS, NTIS, PASCAL (last update December 2004), DARE, NHS EED and HTA (last update November 2005). Reference lists from articles that fulfilled the inclusion criteria in this review and from review articles based on the search of MEDLINE were searched for additional relevant articles. Conference abstracts published as books or journals and handsearched by the Cochrane Oral Health Group were also included.

Selection criteria
The inclusion criteria for study selection were: random or quasi-random allocation study design; sealants versus fluoride varnish or sealants and fluoride varnish combination versus fluoride varnish alone; included studies included caries documentation on occlusal surfaces of permanent molars and the subjects were under 20 years of age. Both parallel and split-mouth study designs were accepted. The primary outcome of interest was the increment in the numbers of carious occlusal surfaces of premolars and molars. A study was excluded if sealants and fluoride varnish were not compared with each other.

Data collection and analysis
Two review authors carried out the baseline searches, selecting the papers on the basis of the title, keywords and abstract and making decisions about the eligibility and data extractions. The same review authors assessed the methodological quality of all included studies: for example, the allocation concealment, blinding, and completeness of follow up. Authors of the studies were contacted for additional information. Risk ratios (RR) as effect estimates were calculated for the differences in whether surfaces were carious or not in the treatment groups, along with the appropriate standard errors and 95% confidence intervals (CI). No data could be combined or meta-analyses undertaken due to the clinical and methodological diversity between study designs.

Main results
Four studies were eligible for inclusion in the review. Three of the four studies compared the effectiveness of sealants with fluoride varnish application, and one study compared the effectiveness of sealants and fluoride varnish combination with fluoride varnish alone.

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Results of two studies revealed the effectiveness of pit and fissure sealants to be statistically significantly higher than an application of fluoride varnish every 6 months in preventing occlusal decays of first molars at 23 months (RR 0.74, 95% CI 0.58 to 0.95) and at 9 years follow up (RR 0.48, 95% CI 0.29 to 0.79). One of these studies was classed as at low risk of bias, one of moderate to high risk. One small study at moderate to high risk of bias failed to find a statistically significant difference between sealants and fluoride varnishes. One study of low risk of bias found a statistically significant difference in favour of the sealants and fluoride varnish combination compared with merely fluoride varnish at 24 months follow up with RR 0.36 (95% CI 0.21 to 0.61). The age of children in the included studies was 5 to 9 years. Allocation concealment was classified adequate in two of these four studies.

Authors' conclusions

There was some evidence of the superiority of pit and fissure sealants over fluoride varnish application in the prevention of occlusal decays. However, it remained unclear to what extent there is difference between the effectiveness of pit and fissure sealants and fluoride varnishes. Therefore, more high quality research is needed. No recommendations for the clinical practice could be given and the benefit of pit and fissure sealants and fluoride varnishes should be considered locally and individually.

PLAIN LANGUAGE SUMMARY

Dental sealants reduce more tooth decay in the grooves of back teeth in children than fluoride varnish application but the number of studies supporting this evidence is very low

Sealants are coatings applied by the dentist or by another person in dental care on the grooves of back teeth. These coatings are intended to prevent decay in the grooves of back teeth.

Fluoride varnishes are sticky pastes that are professionally applied on teeth at a frequency of 2 to 4 times a year. The review found that dental sealants reduce more tooth decay in grooves of permanent teeth than fluoride varnishes. However, more high quality research is needed to clarify how big the difference is between the effectiveness of pit and fissure sealants and fluoride varnishes.

BACKGROUND

A reduction in caries prevalence has occurred in most industrialized countries. Many experts believe that the use of fluoride in various forms has contributed significantly to the decline in caries prevalence (Petersson 1996; Burt 1998). The decline in dental caries, its uneven distribution among the population, and its varying pattern of attack across surfaces calls for a targeting of the available resources in an effective manner. The majority of the detected increment in dental caries is confined to pit and fissure surfaces of first molars and this is a convincing argument for the utilization of dental sealants (Brown 1995).

Application of pit and fissure sealants and topical fluorides are widely used procedures in the prevention of decay. Pit and fissure sealants are used to prevent the impaction of food and growth of bacteria which promote decay (Ripa 1993). Two types of pit and fissure sealants are available: resin based and glass-ionomer cements. The resin based sealants are further divided into generations according to their mechanism for polymerization or content. Since the 1960s the development of pit and fissure sealants has progressed from the first generation (activated with ultraviolet light), through second (autopolymerized) and third (activated by visible light), to fourth generation (contains fluoride). The first generation pit and fissure sealants are no longer marketed.

Numerous studies have supported the effectiveness of dental sealants in preventing occlusal decay. According to a meta-analysis of 24 studies about autopolymerised second generation sealants, the overall effectiveness in preventing occlusal decay was 71% (95% confidence interval (CI) 70% to 73%) (Llodra 1993). Effectiveness decreased with time, and increased when drinking water was fluoridated. However, there was a significant diversity in the results of the individual studies.

The results of a recent meta-analysis of five split-mouth studies also clearly favoured the use of autopolymerised second generation resin sealants compared with no treatment (Ahovuo 2004). This review confirmed that the effectiveness of autopolymerised resin sealants decreased with time, as the risk ratios were 0.14 (95% CI 0.09 to 0.19), 0.24 (95% CI 0.20 to 0.30), 0.30 (95% CI 0.26 to 0.35), and 0.43 (95% CI 0.37 to 0.50) at 12, 24, 36 and 48 to 54 months follow up respectively. The reductions in caries ranged from 86% at 12 months to 57% at 48 to 54 months. One parallel design study confirmed the result. The effectiveness of resin sealants in reducing caries was clear but data on glass-ionomer sealants were less convincing.

The aim of topical fluoride application is to treat the hard tooth surfaces in such a way that caries is arrested or reversed. Professionally applied topical fluorides are usually in the form of varnishes or gels. Fluoride varnishes were developed as adjuncts to

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the conventional topical agents such as toothpastes, mainly to prolong contact time between fluoride and teeth (de Bruyn 1987). The first commercially produced fluoride varnish was introduced by Schmidt in 1964 under the trademark Duraphat. In 1975, a second fluoride varnish, Fluor Protector was marketed by Arends and Schuthof. Since then, some novel fluoride varnish products have been introduced, none of which are widely used today.

It has been recommended that fluoride varnishes should be applied at intervals of 3 to 6 months in high caries risk groups (Seppä 1990). Since fluorides are toxic materials when overdosed, some caution should be taken in their use. If the varnish is applied according to manufacturer's instructions, no adverse effects should occur (Primosch 1985). Although fluoride varnishes have a very high fluoride concentration, their use is safe due to a quick-setting base, slow release of fluoride over time and the comparatively small amounts of varnish required for the whole dentition (Petersson 1993).

Meta-analyses have shown a substantial caries-inhibiting effect of fluoride varnish in the permanent dentition (Helfenstein 1994; Marinho 2002). According to a meta-analysis of eight studies, the overall effect size of fluoride varnishes was 38% (95% CI 19% to 57%) on permanent teeth when fluoride varnish was applied twice during 1 to 5-year follow ups (Helfenstein 1994). The caries reduction was negatively correlated with the duration of the study. In the other meta-analyses of the seven studies, the decayed, missing and filled surfaces (DMFS) pooled prevented fraction estimate of fluoride varnish application was 46% (95% CI, 30% to 63%) in the permanent dentition (Marinho 2002).

Fluoride varnishes and sealants, though effective, are expensive procedures requiring careful application and selection of teeth to be efficient (Burt 1998). The application of sealants is especially time-consuming and relatively expensive compared to topical fluoride application (Raadal 1990) but it seems to be more effective in the prevention of pit and fissures caries (Bravo 1997). Sometimes the topical fluoride has been combined with an application of sealants in order to strengthen the overall effectiveness in the prevention of dental decays (Bagramian 1978; Raadal 1990; Selwitz 1995).

The aim of this systematic review was to compare the effectiveness of pit and fissure sealants and fluoride varnishes in the prevention of dental decay on occlusal surfaces in children and adolescents.

OBJECTIVES

The objective of this study is to compare the relative effectiveness of pit and fissure sealants with fluoride varnishes in the prevention of dental decay on occlusal surfaces.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

We aimed to identify all randomised and quasi-randomised controlled trials that compared pit and fissure sealants with fluoride varnish. Both parallel group and split-mouth study designs were included, but split-mouth designs were handled separately. The unit of randomisation could be the individual, the group (school, school class etc.), the tooth or tooth-pair as long as this was taken into account in the analysis.

Types of participants

Children and adolescents under 20 years of age.

Types of intervention

The following intervention groups were accepted.
(1) Pit and fissure sealants of all generations versus fluoride varnish.
(2) Pit and fissure sealants and fluoride varnish combination versus fluoride varnish.

The intervention groups were either the sealant group or the sealant and fluoride varnish combination group. The control group was the fluoride varnish group.

Studies that considered only one of the preventive procedures were excluded.

Types of outcome measures

The primary outcomes of interest during follow up were.
(1) Incidence of dentinal carious lesion on treated occlusal surfaces of molars or premolars (yes or no).
(2) The changes in decayed, missing and filled (DMF) figures at surface, tooth and whole mouth level.
(3) Progression of caries lesion into enamel or dentine.

The secondary outcomes documented and reported in the review were.
(1) Time taken to apply pit and fissure sealant or fluoride varnish.
(2) Number of visits to the dentist for repair of sealant or fluoride varnish application.
(3) Safety of sealants and fluoride varnishes.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Oral Health Group methods used in reviews.

Electronic searching

For the identification of studies included in, or considered for this review, detailed search strategies were developed for each electronic database searched. Electronic searching was performed on the following databases:

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- the Cochrane Oral Health Group's Trials Register (last update November 2005)
- the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2005, Issue 4)
- MEDLINE (from 1966 to December 2005)
- EMBASE (from 1974 to November 2004)
- SIGLE (from 1976 to December 2004)
- SCISEARCH, CAplus, INSPEC, JICST-EPLUS, NTIS, PASCAL (last update December 2004)
- DARE, NHS EED and HTA (last update November 2005).

The following comprehensive search strategy for CENTRAL was formulated around four concepts: fluorides topical, pit and fissure sealants, glass ionomer cements, and resin cements, and included 'controlled vocabulary' (MeSH terms) and 'free text' terms, without any limitation on publication type (controlled vocabulary is given in upper case type and free text terms in lower case):

#1 FLUORIDES TOPICAL (single MeSH term)
#2 (topical* NEXT fluoride*)
#3 ((fluoride* or fluorine*) AND (varnish* OR lacquer* OR laquer* OR lakk* OR verniz* OR silane* OR polyurethane*))
#4 (#1 OR #2 OR #3)
#5 PIT AND FISSURE SEALANTS (Single MeSH term)
#6 fissure* NEAR seal*
#7 GLASS IONOMER CEMENTS (Explode MeSH term)
#8 glass ionomer*
#9 cermet cement*
#10 RESIN CEMENTS (Single MeSH term)
#11 resin cement*
#12 (#5 OR #6 OR #7 OR #8 OR #9 OR #10)
#13 #4 AND #12

This search strategy was revised appropriately for the search of the Cochrane Oral Health Group's Trials Register and the search of MEDLINE via OVID.

The search of EMBASE was based on the search strategy developed for MEDLINE but with adaptations.

The System for Information on Grey Literature in Europe (SIGLE) database was searched to locate unpublished literature in STN Easy using the following search strategy:
fluor? AND silane? or polyurethane? or lack? or laquer? or lacquer? or varnish? or verniz? or vernis?

The following databases were searched in STN Easy: SCISEARCH, CAplus, INSPEC, JICST-EPLUS, NTIS, PASCAL. The search strategy was the following:
fluor? or fluor* AND silane* or polyurethane* or varnish* or laquer* or lacquer* or verniz* or vernis* or lack* or laka* AND "fissure sealant*" or "ionomer*" AND dental or tooth or teeth or enamel*.

The following databases: Database of Abstracts of Reviews of Effectiveness (DARE), NHS Economic Evaluation Database (NHS EED) and Health Technology Assessment Database (HTA) were searched by the CAIRS web interface using the following search strategy:
fluor/all fields AND (varnish OR lackuer OR laquer OR lack OR vernis OR verniz OR silane OR polyurethane/all fields) AND (dental or tooth or teeth or enamel/all fields).

Searching other sources
Reference lists from articles that fulfilled the inclusion criteria in this review and from review articles based on the search of MEDLINE were searched for additional relevant articles. Conference abstracts published as books or journals and handsearched by the Cochrane Oral Health Group were also included.
All potentially relevant studies in all languages were translated and assessed.

METHODS OF THE REVIEW

Study selection
The baseline searches were carried out by two review authors (Anne Hiiri (AH) and Anneli Ahovuo Saloranta (AAS)). The selection of papers on the basis of the title, keywords and abstract and decisions about eligibility were carried out independently, in duplicate, by the same review authors. Reports that were obviously irrelevant (according to study design/duration, participants, or interventions/comparisons) were discarded. The full text of every article considered for inclusion was obtained. If the information relevant to the inclusion criteria was not available in the abstract or if the title was relevant but the abstract was not available, the full text of the report was obtained. All information and data recording was done independently and any disagreements were resolved by discussion with a third review author (Anne Nordblad (AN) or Marjukka Mäkelä (MM)). One review author (AAS) contacted the authors for additional information about randomisation methods, blinding, calibration and other issues that were not obtained from the articles.

The inclusion criteria for study selection were: random or quasi-random allocation study design, pit and fissure sealant versus fluoride varnish or pit and fissure sealants and fluoride varnish combination versus fluoride varnish alone; caries documentation on occlusal surfaces of permanent molars or premolars was included; and the subjects were under 20 years of age. Both parallel and split-mouth study designs were accepted. The primary outcomes of interest were the incidence of dentinal caries on any treated surfaces of molars or premolars, the changes in decayed, missing and filled (DMF) figures at surface, tooth and whole mouth level and progression of caries lesion into enamel or dentine. The study was excluded if pit and fissure sealants or fluoride varnish were compared with no treatment alone.

All potentially relevant studies in all languages were translated and assessed. Efforts were also made to obtain translations of non-

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English studies by means of The Cochrane Collaboration. Authors of all potential studies published in non-English languages were contacted for further information.

Quality assessment

Two review authors (AH and AAS) assessed the quality of all included studies. Any disagreements between the review authors were resolved by consensus in the review group. The methodological quality of the included studies was assessed using allocation concealment, blinding and completeness of follow up. The authors were contacted to clarify issues such as what was the method used to conceal allocation, or whether assessment of the main outcome had been carried out blind, or what were the drop-out proportions and the explanations for such.

The classification of allocation concealment was based on criteria described in the *Cochrane Handbook for Systematic Reviews of Interventions* 4.2.5 (Higgins 2005) concerning allocation concealment as follows:
(A) adequate concealment, (B) 'random' allocation reported but the actual method used to conceal it is not known, (C) inadequate concealment, and (D) allocation concealment not used. Codes of allocation concealment assessments are described in the table of included studies. If there was no random/quasi-random allocation, the study was excluded.

Information on the blinding of the outcome assessment was documented if the study stated blind outcome assessment or blinding was indicated. However, blinding of the examiner is not particularly possible in these kinds of studies, as the examiner may have noticed whether the tooth was sealed or not. The completeness of follow up and the proportion of drop outs were documented from the studies or from the information supplied by the authors. Risk of bias was assessed for each study. To be classed as low risk of bias the allocation concealment had adequate, and there had to be complete information on drop outs by study group.

Data extraction

Data from all included studies were extracted by two review authors (AH, AAS). The review authors were in full agreement about the excluded data and there was no need for discussion or consultation with a third review author. Data presented only in graphs and figures were extracted whenever possible. Attempts were made to contact authors in order to obtain missing information or for clarification whenever necessary.

Characteristics relating to participants that were extracted included: number of children and their teeth in treatment, and control groups at start and after follow up, age (range) and mean age at start, caries severity at start (average number of decayed, missing and filled deciduous teeth (dmft); decayed, missing and filled deciduous surfaces (dmfs); decayed, missing and filled permanent surfaces (DMFS); decayed, filled permanent surfaces (DFS); or other measure), background exposure to other fluoride sources (toothpaste, water etc.), the year when study began, location where study was conducted (country and setting where participants were recruited). Characteristics of the intervention that were extracted included: parallel or split-mouth design, criteria for accepting subjects into study (intact surfaces or incipient caries lesions allowed), different intervention comparisons (sealant versus fluoride varnish or sealant and varnish combination versus fluoride varnish), materials used in the study, reapplication of sealants and frequency of fluoride varnish application. Information about co-intervention reported in the studies was also gathered during data extraction.

Additional information relating to study methodology or quality that was extracted included: randomisation methods as described in the study, blinding, study duration (years of follow up) and percentage of drop outs during follow up. Information relating to calibration of examiners and kappa statistics were also extracted.

Outcome information was mainly extracted as the number of dentinal carious lesions or non-carious lesions on occlusal surfaces of treatment and control teeth at different follow ups.The data of the studies of Raadal 1984, Florio 2001, and Splieth 2001 are collected in the Additional Table 03, Table 02 and Table 04, respectively. The data in the Bravo 2005 study was extracted after a request to the authors, and the subsequent data sent (risk ratio (RR) with adjusted standard error (SE) (ln(RR)) were used in the analyses. If a filling had been put on the occlusal surface or the tooth had been extracted due to caries during the study, it was coded as caries. In addition, caries increments as changes in DMFS/DMFT scores and progression of caries lesion in enamel or dentine have been recorded whenever the authors reported them. Also the following secondary outcomes were recorded when reported: time taken to apply pit and fissure sealant or fluoride varnish, number of visits to the dentist for repair or reapplication of sealant or fluoride varnish application and safety of sealants and fluoride varnishes.

Data synthesis

No data could be combined or meta-analyses undertaken, due to the diversity between study designs. In all four included studies the outcome results were presented in dichotomous form. In order to make the included studies comparable, the risk ratios as effect estimates along with 95% confidence intervals were calculated for each study.

For the parallel group studies, risk ratios were calculated for differences in the pit and fissure sealant (S) and fluoride varnish (F) groups as to whether occlusal surfaces were carious or not, along with appropriate standard errors and 95% confidence intervals, using RevMan 4.2. In parallel group studies, one or more tooth surfaces per child might be included in the intervention. In the case more than one tooth surface per child has been included in the intervention, the clustering of teeth within a child should be taken into account in the analyses, otherwise the confidence intervals of the treatment effect will be biased. If the clustering of teeth within children was not taken into account in the analysis, it was

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decided the data would be analysed at the child level (i.e. the data were dichotomised - did a child have caries or not) (Florio 2001). In the cluster randomised study of Bravo 2005 standard errors were adjusted for multiple molars in the child and for randomly allocated school classes by using SAS SUDAAN software.

For split-mouth studies, risk ratios were calculated for the paired differences on whether surfaces were carious or not, along with the appropriate standard errors and 95% confidence intervals, using Stata version 9.1.
In split-mouth studies, one or more pairs of tooth surfaces per child might be included in the intervention. The tooth surfaces were randomly allocated within each pair into treatment groups. These pairs are not independent and should be analysed as 'paired data' on a child basis. However, the data presented in the studies did not enable taking into account the dependence of the tooth-pairs on a child basis. Therefore, the confidence intervals of the risk ratios at study level might be slightly narrower than it actually should be.

Originally the plan was to assess heterogeneity by inspecting the graphical display of the estimated risk ratios from the trials along with the 95% confidence intervals and by Cochran's heterogeneity test, and to conduct meta-analyses to estimate the summary risk ratios at different follow ups. In addition, we planned to undertake a sensitivity analysis to examine the effect of concealed allocation on the overall effect estimates. However, there were insufficient trials to undertake each of these steps.

Further aims to investigate the clinical heterogeneity by examining the different levels of baseline caries prevalence between the trials were not realised, again due to the insufficient number of trials. Finally, the lack of trials also prevented an investigation into the publication bias using both the Begg and Mazumdar rank correlation test and the Eggar regression asymmetry test.

The results of the included studies as risk ratios are presented in RevMan graphs; one graph for each study.

DESCRIPTION OF STUDIES

Search results and selection of studies

The electronic searches based on 14 databases yielded 515 records, many of which were duplicates. The numbers of studies according to sources were as follows: the Cochrane Oral Health Group's Trials Register and the Cochrane Central Register of Controlled Trials (CENTRAL) (altogether 56 records), the comprehensive search without methodological limits from MEDLINE (339 records) and EMBASE (six records). The search of the STN Easy database yielded 92 records (SIGLE 18 records, SCISEARCH 41 records, CAplus 26 records, INSPEC no hits, JICST-EPLUS six records, NTIS one record and PASCAL no hits). Searching the databases DARE, NHS EED, HTA yielded 15 records. In addition to electronic searches, eight potentially relevant reports were found from the reference lists of review articles and articles which fulfilled the inclusion criteria of this review.

Records were checked on the basis of the title, keywords and abstract. All potentially relevant records were noted and duplicates were omitted. Four hundred and seventy five records were clearly irrelevant for this review and 40 reports remained for further assessment. All these reports were found from the Cochrane Oral Health Group's Trials Register, CENTRAL and MEDLINE databases.

Some 33 of the 40 full-text reports were in English or had an abstract in English and seven were non-English (one Polish, two Russian, two German, one Swedish, one Portuguese). Twelve of these 33 reports in English were clearly irrelevant to this review, with 21 remaining for further assessment. Seven non-English articles were translated so as to identify if they were eligible studies. The members of the review group translated reports in German and in Swedish. Other reports were translated via contacts through The Cochrane Collaboration. Two non-English reports were excluded and five reports remained. The main reasons for all exclusions were: studies dealt with interventions without controls, studies included only one or the other of fluoride varnish or pit and fissure sealants applications or other caries prevention programs were involved in the intervention.

This left 16 studies with 26 reports remaining for further detailed consideration (11 English studies with 21 follow-up reports and five non-English studies). A further five of the 16 studies were excluded because the topical fluoride used in the studies was other than fluoride varnish and seven studies because fluoride varnish was not compared with sealants or there was no mention of random or quasi-random allocation. Finally, four studies were eligible for inclusion in the review (Raadal 1984; Florio 2001; Splieth 2001; Bravo 2005).

Characteristics of included studies

See 'Characteristics of included studies' table.

The four eligible studies for the review were conducted in Norway (Raadal 1984), Spain (Bravo 2005), Germany (Splieth 2001) and Brazil (Florio 2001).

Study design and methods

A parallel group design was used in two of the four studies (Florio 2001; Bravo 2005) and two were split-mouth designs (Raadal 1984; Splieth 2001). All these studies were randomised, none being quasi-randomised. The randomisation unit in the study of Bravo 2005 was a school-class (cluster randomised design).

The follow-up times were 1 year in the study of Florio 2001 and 2 years in the studies of Raadal 1984 and Splieth 2001. Bravo 2005 reported results over a 9-year period consisting of 4 years active caries preventive program plus 5 years after that.
In most studies children were recruited from public dental clinics or schools. In one study children were from private dental practice (Splieth 2001).

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The studies supplied data for two kinds of comparisons:
(a) Pit and fissure sealants versus fluoride varnish application (Raadal 1984; Florio 2001; Bravo 2005)
(b) Pit and fissure sealants with fluoride varnish application combination versus fluoride varnish application (Splieth 2001).

Participants
The age of children in the included studies was between 5 to 9 years at start. In the studies comparing parallel groups the sample size was 75 children with 242 occlusal surfaces (Bravo 2005) and 23 children with 71 occlusal surfaces (Florio 2001). The average number of treated teeth was 3 per child.

Correspondingly, in the split-mouth studies the sample size was 121 children with 210 tooth sites (Raadal 1984) and 98 children with 181 tooth-pairs (Splieth 2001). The average number of treated tooth-pairs per child was 1.8.

Almost all studies stated the caries prevalence of the study population at baseline. In the study of Bravo 2005, the baseline mean decayed, filled deciduous teeth (dft) in the sealant group was 2.2 (standard deviation (SD) 2.6) and in the varnish group 2.4 (SD 3.3). The difference between groups was not statistically significant. The study of Florio 2001 stated the mean initial decayed, missing, filled deciduous surfaces (dmfs) in the sealant group was 3.8 (SD 2.5) and in the fluoride varnish group 4.5 (SD 2.7). Raadal 1984 stated the initial mean decayed, missing, filled deciduous teeth (dmft) as 4.7 (SD 3.3) and Splieth 2001 reported the initial mean decayed, missing, filled permanent surfaces (DMFS) as 0.2.

Intervention
All studies reported caries increment on occlusal surfaces of first permanent molars. There was no study reporting outcomes on second permanent molars or on premolars.

The sealant material in the study of Florio 2001 was a resin-modified glass ionomer and in the other three studies resin based sealants: visible-light-polymerized resin sealant (Splieth 2001; Bravo 2005), and autopolymerized resin sealant (Raadal 1984). Reapplication of sealants was reported in two studies (Splieth 2001; Bravo 2005). Sealant was applied either on sound surfaces (Bravo 2005), surfaces with incipient lesion (Florio 2001) or in the same study either on the sound surface or on the incipient lesion (Raadal 1984; Splieth 2001). In the study of Raadal 1984, the surfaces with incipient caries in enamel to be sealed were prepared mechanically and caries removed before sealant application.

The fluoride varnish used was Duraphat in all four studies. In the study of Splieth 2001 fluoride varnish was applied biannually on all teeth and in the studies of Florio 2001 and Raadal 1984 only on the control teeth. In the study of Bravo 2005, Duraphat was applied to all healthy permanent first molars with partially or fully erupted occlusal surfaces. After 6, 12, 18, 24, 30, 36, and 42 months, varnish was applied to newly erupted molars and was reapplied to all molars that had remained healthy.

Besides pit and fissure sealing and fluoride varnish application, the studies included other co-interventions. In one study the subjects followed a fluoride rinsing program at schools during the follow up (Raadal 1984). In other study tap water was fluoridated and had a professional profylaxis during dental examination visits (Florio 2001). Two of the studies reported motivation and instruction of the subjects towards good oral hygiene (Florio 2001; Splieth 2001).

Outcomes
All of the included studies reported the incidence of dentinal carious lesions in terms of numbers of carious or non-carious occlusal surfaces of the treatment and control first permanent molars. One of the studies also reported the changes in decayed, missing and filled (DMF) scores at the whole mouth level (Splieth 2001). Intra- and inter-examiner agreement for caries diagnosis was stated in one study (Bravo 2005). The intra- and inter-examiner kappa coefficients were greater than 0.68 in all measurements.

Splieth 2001 reported an average treatment time for sealing and fluoride varnish application. The number of visits for repair of sealants or fluoride varnish applications were not directly reported but could be counted from the articles. In three studies the examinations were done every 6 months (Raadal 1984; Splieth 2001; Bravo 2005) and in one study quarterly every year (Florio 2001). None of the included studies reported possible adverse effects of sealants or fluoride varnishes.

Characteristics of the excluded studies
See ' Characteristics of excluded studies' table.

The table of excluded studies includes those studies in which both sealants and fluoride varnishes were used for caries prevention but the study design was not comparing these materials, or if the design was comparing these materials there was no mention of random or quasi-random allocation. There were two studies comparing sealants with fluoride varnish without information on random or quasi-random allocation. Four studies were not eligible for this review because they did not compare sealants with fluoride varnish or the study design was not clear. One parallel group randomised study did not state the number of the children and there were no contact details for further information.

METHODOLOGICAL QUALITY

The authors of all included studies delivered additional information that helped us to assess the methodological quality of the included studies. Allocation concealment was classified as adequate concealment (A) in two studies (Raadal 1984; Splieth 2001). In both studies the randomisation method was tossing a coin. 'Random' allocation and the randomisation method were reported in two studies but the actual concealment remained unclear (B) (Florio 2001; Bravo 2005). The two review authors achieved full agreement on the independent allocation concealment classifications.

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According to articles and information given by the authors, blinding was not used or it was found impossible in the included studies. In one study they tried to get observer blinded examinations as the dentist did not have access to previous records (Bravo 2005). All studies reported drop-out rates adequately by study group. Two studies were assessed as at low risk of bias (Raadal 1984; Splieth 2001). The reported drop-out rates were between 1% at 2-year and 47% at 9-year follow up.

RESULTS

Meta-analyses were not undertaken, due to the clinical and methodological diversity between these trials. The study results were therefore handled separately.

Pit and fissure sealant (S) versus fluoride varnish (F)
Three studies are included in this comparison; two studies comparing parallel groups (Florio 2001; Bravo 2005) and one split-mouth study (Raadal 1984).

Two studies, one study with parallel groups and one split-mouth study (Raadal 1984; Bravo 2005), found a significant difference in favour of the sealants compared to fluoride varnish. The study of Bravo 2005 found a clear benefit for visible-light-polymerized resin sealant compared to fluoride varnish at 9 years with risk ratio (RR) 0.48 (95% confidence interval (CI) 0.29 to 0.79). Bravo 2005 considered only sound occlusal surfaces. Raadal 1984 found a benefit for autopolymerized resin sealant compared to fluoride varnish at 23 months with RR 0.74 (95% CI 0.58 to 0.95). In the study of Raadal 1984 the surfaces with incipient caries in enamel to be sealed were prepared mechanically and caries removed before sealant application.

The study of Florio 2001 failed to find a statistically significant difference with sealant material resin-modified glass ionomer at 12 months. Both the sample sizes and the number of events were small at 1-year follow up in the Florio 2001 study. All occlusal surfaces under examination were with incipient lesion in the Florio 2001 study.

Pit and fissure sealant and fluoride varnish combination (S+F) versus fluoride varnish (F)
One split-mouth study was included in this comparison (Splieth 2001). This study found a significant difference in favour of the sealants concurrently with fluoride varnish compared to merely fluoride varnish at 24 months with RR 0.36 (95% CI 0.21 to 0.61). The study considered both sound occlusal surfaces and surfaces with incipient lesion.

Changes in decayed, missing and filled (DMF) figures at surface, tooth and whole mouth level
Only Splieth 2001 reported the changes in DMF figures on whole mouth during the study. The mean decayed, missing, and filled permanent surfaces (DMFS) score of the whole mouth in study population increased from 0.2 to 0.6 after 1 year and to 1.1 after 2 years. The authors reported that most of the caries still occurred on the occlusal surfaces of first permanent molars (50.9%).

Progression of caries lesion into enamel or dentine
None of the studies compared the progression of caries lesion into enamel or dentine between pit and fissure sealant group and fluoride varnish group.

Secondary outcomes
The number of visits for repair or reapplication of sealants or fluoride varnish applications was reported directly only by Bravo 2005. In that study the average number of treatment visits per child during the active phase of the program was 2.2 (standard deviation (SD) = 1.1) (maximum 6) for children in the sealant group and 7.3 (SD = 1.0) (maximum 8) for children in the varnish group. This difference is great, because the sealant was reapplied only when a partial or total loss occurred, whereas the varnish was systematically reapplied. In the study of Raadal 1984, the sealants were applied only once and fluoride varnish four times before the 23-month examination. Sealant application was done also in one visit at the beginning of the Brazilian study and fluoride varnish was applied twice in a 1-year follow up (Florio 2001).

In the German study, the fluoride varnish application was done four times before the final examination at 24 months (Splieth 2001). The number of treatment visits for sealant application or repair was not reported in this study, but the authors reported the time taken to apply two pit and fissure sealants or fluoride varnish on control teeth. The total time needed for sealing and resealing of two teeth was on average 29 minutes during 2 years, of which most of the time was spent for the initial sealants (about 17 minutes). The mean treatment time for each fluoride varnish application was under 3 minutes (total time during intervention 9 minutes).

None of the studies reported possible harmful effects of sealants or fluoride varnishes.

Additional outcomes
The complete retention of the pit and fissure sealants was 66% at 12 months (Florio 2001), 81% at 24 months (Splieth 2001) and 63% at 23 months follow up (Raadal 1984). The highest retention rate 81% was received in the study where totally or partially retained sealants were reapplied in a biannual examination (Splieth 2001). After the 9-year follow up, the complete retention rate of resin based sealants was still 39% (Bravo 2005).

DISCUSSION

The objective of this review was to compare the effectiveness of pit and fissure sealants with fluoride varnishes in the prevention of occlusal dental decaying in children. The objective was to compare also the effectiveness of pit and fissure sealants and fluoride varnish

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combination with fluoride varnish alone and factors potentially modifying their effect.

There was some evidence about the superiority of pit and fissure sealants over fluoride varnish application in the prevention of occlusal decays. The results of this review were based only on four trials which all had different study or intervention designs. Because of this diversity, no meta-analysis was carried out in this systematic review and no overall effectiveness could be established. In order to make the included studies comparable, the risk ratios (RR) with 95% confidence intervals (CI) were calculated or obtained from authors for each study.

Two studies found a significant difference in favour of the sealants compared to fluoride varnish (Raadal 1984; Bravo 2005). Better results about the effectiveness of sealants compared with fluoride varnish application were received in the Spanish study (RR 0.48, 95% CI 0.29 to 0.79) of Bravo 2005. In that study the sealants were placed on sound surfaces and reapplied when the sealant was partially or totally lost in the 4-year preventive program. This study with a 9-year follow up (the active intervention lasted for the first 4 years, the 9-year results were gathered 5 years after that) brings important information about the long term effectiveness of sealing and fluoride varnish application 5 years after discontinuation of the active program. Even though Bravo 2005 had reported also results after 2 and 4 years follow ups, only the latest results with 9-year follow up were used in this review. The reason for that is that the possible influence of cluster randomisation on the results were not taken into account in the earlier reports.

Results of the Norwegian study (Raadal 1984) revealed that pit and fissure sealants were more effective in preventing occlusal caries of first molars fluoride varnish applications every 6 months at the 23-month follow up (RR 0.74, 95% CI 0.58 to 0.95). In this study the occlusal surfaces with incipient caries lesions were opened mechanically before sealant application and sound occlusal surfaces were sealed without opening. The sealants were not reapplied during the study and the complete retention rate was moderate after follow up. This has probably influenced the success of the sealants because numerous studies have confirmed the association between the effectiveness and retention of resin based sealants.

The German study comparing sealant and fluoride varnish combination to fluoride varnish alone confirmed the effectiveness of sealants at 24 months follow up with RR 0.36 (95% CI 0.21 to 0.61) (Splieth 2001). The good result even in the low-caries-risk population might be the consequence of high retention rate of the sealants or the combination of pit and fissure sealant and fluoride varnish. However, the definitive reasons for the result remained unclear.

In a split-mouth design the fluoride varnish applied on the control teeth might also impact the teeth in the intervention side through saliva. However, the results of a split-mouth study showed that fluoride varnish application elevated fluoride concentrations of dental plaque locally in the treated teeth quadrant but fluoride concentrations were not elevated in the opposite untreated quadrant (Sköld-Larsson 2000). The carry-over effect of the fluoride varnishes is most probably dose-dependent and we assessed that the carry-over effect on sealed occlusal surfaces to be insignificant due to a fast-setting base and the small amount of fluoride varnish applied on one or two control teeth. Therefore we decided to accept split-mouth studies into review.

AUTHORS' CONCLUSIONS

Implications for practice

There was some evidence about the superiority of pit and fissure sealants over fluoride varnish application in the prevention of occlusal decays. However, it remained unclear to what extent there is difference between the effectiveness of pit and fissure sealants and fluoride varnishes. No recommendations for the clinical practice could be given and the benefit of pit and fissure sealants over fluoride varnishes should be considered locally and individually.

Implications for research

The number of the included clinical trials was small and more high quality research is needed to confirm to what extent there is difference in the effectiveness of the pit and fissure sealants and fluoride varnishes. In a split-mouth study design the carry-over effect of the fluoride varnish applications on the sealed teeth cannot be totally ruled out. Therefore a parallel group design would give more reliable information about the difference in the effectiveness of pit and fissure sealants and fluoride varnishes. Proper documentation and description of study population, intervention study designs, follow-up periods, drop outs and outcomes as described in the CONSORT statement are recommended.

POTENTIAL CONFLICT OF INTEREST

None known.

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* *Indicates the major publication for the study*

TABLES

Characteristics of included studies

Study	Bravo 2005
Methods	Cluster randomised survival study design, randomisation unit a school-class (n = 15). Follow up 9 years in total: 4 years during caries preventive program plus 5 years after active program. 3 groups: sealant group, fluoride varnish group and control group. Blind outcome assessment (new records). Drop-out rate 47%.
Participants	Spain, study started 1990; 226 children having at least 1 completely erupted and sound permanent molar at the beginning and examined at 4-year follow up. These 226 children (84 control, 69 sealant, 73 varnish) had 701 occlusal surfaces of first permanent molars to be treated. Age range 6 to 8 years at the beginning. Children were selected from schools representing middle socio-economic level.

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Characteristics of included studies (*Continued*)

Interventions	Fissure sealant (visible-light-polymerized opaque Delton) compared with fluoride varnish (Duraphat). Sealant was applied on healthy permanent first molars with complete eruption of the occlusal surface. After 6, 12, 18, 24 and 36 months, sealant was applied to molars that had not previously erupted and was replaced if there had been partial or total loss since the previous examination. Varnish was applied to all healthy permanent first molars with partially or fully erupted occlusal surface. After 6, 12, 18, 24, 30, 36 and 42 months varnish was also applied on newly erupted molars and reapplied to all those that were still sound.
Outcomes	Sound or carious occlusal surface of molar.
Notes	The baseline mean dft in the sealant group 2.24 (SD 2.59) and in the fluoride varnish group 2.42 (SD 3.26). The kappa coefficients for intra- and inter-examiner reliability > 0.68 in all measurements. Complete sealant retention 39% at 9 years. Only the 9-year follow-up data were extracted.
Allocation concealment	B – Unclear

Study	**Florio 2001**
Methods	Parallel group study design, individual randomisation. 3 groups: sealant group, fluoride varnish group and control group. Follow up 12 months. Drop-out rate 9% at 12 months follow up. Water supply fluoridation. Professional prophylaxis during the follow-up consultations. The children were individually informed about the concepts of oral health.
Participants	Brazil, study started 1998; 34 6-year-old children (sealant 12, varnish 11, control 11) with 108 teeth. Children were from 4 public day nursery schools (families of low economic level). To be included, the children had to have at least 2 first permanent molars with restricted enamel decay.
Interventions	Fissure sealant (resin-modified glass ionomer Vitremer) compared with fluoride varnish (Duraphat) on the occlusal surfaces of first permanent molars with restricted enamel decay. No resealing. Fluoride varnish was applied every 6 months.
Outcomes	Occlusal surface of molar with incipient lesion or with caries.
Notes	The baseline mean dmfs in the sealant group 3.8 (SD 2.5) and in the fluoride varnish group 4.5 (SD 2.7). Complete sealant retention 66% at 12 months.
Allocation concealment	B – Unclear

Study	**Raadal 1984**
Methods	Split-mouth study design, sealant tooth randomised. Follow-up average 23 months. 0.5% NaF rinses during the trial.
Participants	Norway, 121 children (62 girls and 59 boys), aged of 6 to 9 years, with 210 tooth sites (110 in the maxilla and 100 in the mandible). Children were from a public dental clinic. To be included, the children had to have 1, recently erupted, caries-free homomaxillary pair of permanent first molars.
Interventions	Fissure sealant (autopolymerized resin-based Concise) compared with fluoride varnish (Duraphat) on the occlusal surfaces of sound first permanent molars or of surfaces with incipient lesion. The surfaces with incipient caries in enamel to be sealed were prepared mechanically and caries removed before sealant application. No resealing. Surfaces to be painted with fluoride varnish were treated every 6 months.
Outcomes	Sound or carious occlusal surface of molar.
Notes	The initial mean dmft 4.7 (SD 3.3). Complete sealant retention 63% at 23 months.
Allocation concealment	A – Adequate

Study	**Splieth 2001**
Methods	Split-mouth study design, sealant tooth randomised. Drop-out rate 6% at 24 months follow up. The fluoride concentration of the public water supply was 0.1 ppm. 5% of the children used fluoride tablets during the study. The mean frequency of cariogenic food intake per day was 15, including a high number of sweetened drinks. Oral hygiene was moderate.

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Participants	Germany, year study started 1995; 98 children aged of 5 to 8 years with 181 tooth-pairs. The children were from a private dental practice. The authors stated that to be included, the children had to have at least 1 pair of equivalent first permanent molars without carious defects.
Interventions	Fissure sealant (visible-light activated Fissurit Transparent) compared with fluoride varnish (Duraphat) on the occlusal surfaces of sound first permanent molars or of surfaces with incipient lesion. Fluoride varnish was applied to all teeth including the sealed tooth. Children were examined semiannually for 2 years, sealants were resealed if necessary, and fluoride varnish was applied to all teeth at examinations.
Outcomes	Status of sound/incipient/carious occlusal surfaces. Changes in DMF scores on whole mouth level. Average treatment time for sealing and varnish application.
Notes	The initial mean DMFS 0.2. Complete sealant retention 81% at 24 months.
Allocation concealment	A – Adequate

dft = decayed, filled deciduous teeth
dmfs = decayed, missing and filled deciduous surfaces
dmft = decayed, missing and filled deciduous teeth
DMF = decayed, missing and filled
DMFS = decayed, missing and filled permanent surfaces
SD = standard deviation

Characteristics of excluded studies

Study	Reason for exclusion
Fischman 1977	Not RCT. Random or quasi-random allocation not stated. Study design not comparing sealant with fluoride varnish.
Jaworska 1984	Not RCT. Random or quasi-random allocation not stated. Study design not clear. No contact details of author for further information.
Källestål 2005	Study design not eligible for this review. Study design not comparing sealant with fluoride varnish.
Petterson 1983	Parallel group randomised study. The number of the children not stated. No contact details of authors for further information.
Raadal 1990	Not RCT. Random or quasi-random allocation not stated. Study design not comparing sealant with fluoride varnish.
Riethe 1977	Not RCT. Random or quasi-random allocation not stated. No contact details of authors for further information.
Saifullina 1990	Not RCT. Random or quasi-random allocation not stated. No reply to letter requesting randomisation.

RCT = randomised controlled trial

ADDITIONAL TABLES

Table 01. Information collected of all studies

Study	Comparison	Study design	Follow up	RR (95% CI)
Bravo 2005	Sealant versus fluoride varnish	Cluster randomised survival study	9 years	0.48 (0.29, 0.79)
Florio 2001	Sealant versus fluoride varnish	Parallel group study	12 months	0.25 (0.01, 4.94)
Raadal 1984	Sealant versus fluoride varnish	Split-mouth study	23 months	0.74 (0.58, 0.95)
Splieth 2001	Sealant + fluoride varnish versus fluoride	Split-mouth study	24 months	0.36 (0.21, 0.61)

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Table 01. Information collected of all studies (*Continued*)

Study	Comparison	Study design	Follow up	RR (95% CI)
	varnish			

Table 02. The data of the study of Florio 2001

Analysis unit	Sealed (S) carious	Sealed (S) total	Varnished (F) cariou	Varnished (F) total
child	0	29	2	36

Table 03. The data of the study of Raadal 1984

Analysis unit	Both sound (+)	S(+) F(-)	S(-) F(+)	Both carious (-)
tooth-pair	131	31	15	31

Table 04. The data of the study of Splieth 2001

Analysis unit	Both sound (+)	S+F(+) F(-)	S+F(-) F(+)	Both carious (-)
tooth-pair	129	32	7	7

ANALYSES

Comparison 01. Sealant versus fluoride varnish (Bravo 2005)

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 caries yes/no at 9 years	1		RR (Fixed) 95% CI	0.48 [0.29, 0.79]

Comparison 02. Sealant versus fluoride varnish (Florio 2001)

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 caries yes/no at 12 months	1	65	Relative Risk (Fixed) 95% CI	0.25 [0.01, 4.94]

Comparison 03. Sealant versus fluoride varnish (Raadal 1984)

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 caries yes/no at 23 months	1		RR (Fixed) 95% CI	0.74 [0.58, 0.95]

Comparison 04. Sealant plus fluoride varnish versus fluoride varnish (Splieth 2001)

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 caries yes/no at 24 months	1		RR (Fixed) 95% CI	0.36 [0.21, 0.61]

INDEX TERMS

Medical Subject Headings (MeSH)

Adolescent; Cariostatic Agents [*therapeutic use]; Dental Caries [*prevention & control]; Fluorides, Topical [*therapeutic use]; Pit and Fissure Sealants [*therapeutic use]; Randomized Controlled Trials

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MeSH check words

Child; Humans

COVER SHEET

Title	Pit and fissure sealants versus fluoride varnishes for preventing dental decay in children and adolescents
Authors	Hiiri A, Ahovuo-Saloranta A, Nordblad A, Mäkelä M
Contribution of author(s)	Writing of the protocol - Anne Hiiri (AH), Anneli Ahovuo-Saloranta (AAS), Anne Nordblad (AN) and Marjukka Makela (MM) Study selection - AH, AAS Data extraction - AH, AAS Data analysis - AAS Writing of the review - AH, AAS, AN and MM
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What's New	Information not supplied by author
Date new studies sought but none found	Information not supplied by author
Date new studies found but not yet included/excluded	Information not supplied by author
Date new studies found and included/excluded	Information not supplied by author
Date authors' conclusions section amended	Information not supplied by author
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Analysis 01.01. Comparison 01 Sealant versus fluoride varnish (Bravo 2005), Outcome 01 caries yes/no at 9 years

Review: Pit and fissure sealants versus fluoride varnishes for preventing dental decay in children and adolescents

Comparison: 01 Sealant versus fluoride varnish (Bravo 2005)

Outcome: 01 caries yes/no at 9 years

Study	log [RR] (SE)	RR (Fixed) 95% CI	Weight (%)	RR (Fixed) 95% CI
Bravo 2005	-0.74 (0.26)		100.0	0.48 [0.29, 0.79]
Total (95% CI)			100.0	0.48 [0.29, 0.79]
Test for heterogeneity: not applicable				
Test for overall effect z=2.85 p=0.004				

Analysis 02.01. Comparison 02 Sealant versus fluoride varnish (Florio 2001), Outcome 01 caries yes/no at 12 months

Review: Pit and fissure sealants versus fluoride varnishes for preventing dental decay in children and adolescents

Comparison: 02 Sealant versus fluoride varnish (Florio 2001)

Outcome: 01 caries yes/no at 12 months

Study	Sealant n/N	Varnish n/N	Relative Risk (Fixed) 95% CI	Weight (%)	Relative Risk (Fixed) 95% CI
Florio 2001	0/29	2/36		100.0	0.25 [0.01, 4.94]
Total (95% CI)	29	36		100.0	0.25 [0.01, 4.94]
Total events: 0 (Sealant), 2 (Varnish)					
Test for heterogeneity: not applicable					
Test for overall effect z=0.92 p=0.4					

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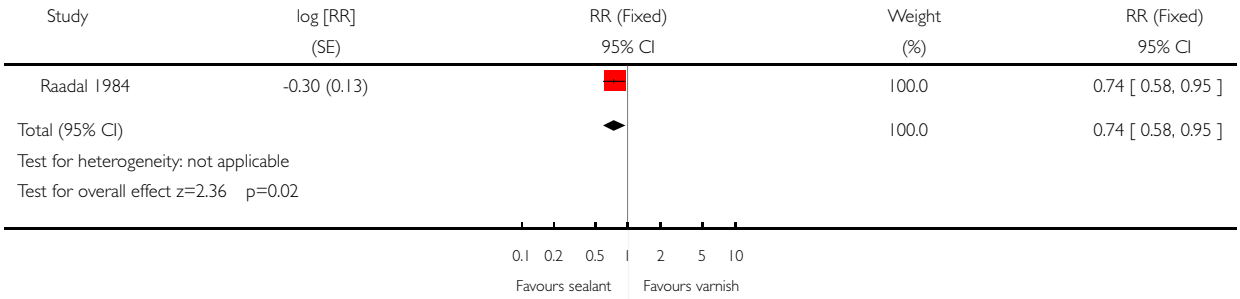
Analysis 03.01. Comparison 03 Sealant versus fluoride varnish (Raadal 1984), Outcome 01 caries yes/no at 23 months

Review: Pit and fissure sealants versus fluoride varnishes for preventing dental decay in children and adolescents

Comparison: 03 Sealant versus fluoride varnish (Raadal 1984)

Outcome: 01 caries yes/no at 23 months

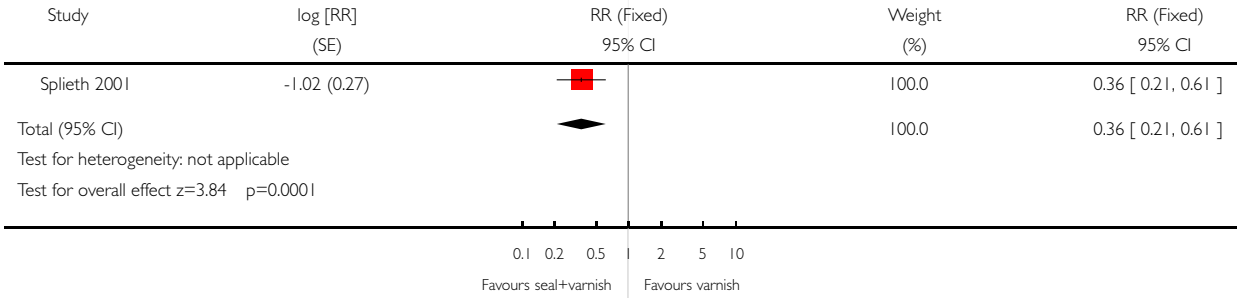


Analysis 04.01. Comparison 04 Sealant plus fluoride varnish versus fluoride varnish (Splieth 2001), Outcome 01 caries yes/no at 24 months

Review: Pit and fissure sealants versus fluoride varnishes for preventing dental decay in children and adolescents

Comparison: 04 Sealant plus fluoride varnish versus fluoride varnish (Splieth 2001)

Outcome: 01 caries yes/no at 24 months



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