EVIDENCE-BASED RECOMMENDATIONS FOR THE USE OF PIT AND FISSURE SEALANTS IN ONTARIO'S PUBLIC DENTAL HEALTH PROGRAMS

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1.0 The context for evidence-based recommendations

Public Health Departments in Ontario have a long history of providing dental treatment to children. Clinical and community-based preventive services, such as fluorides and education, have also been added.

Program guidelines have been developed to assist clinicians in making decisions on what services will be offered. The guidelines and the underlying evidence-based report, also assist managers to allocate resources to achieve maximum impact and to assure the quality of patient care. These guidelines assist staff in decision-making for quality care. They also assist the managers in their decisions on allocation of resources to best fit the needs and to maximize the impact of the services provided.

2.0 The need to examine the use of dental sealants

In 1993, the Community Dental Health Services Research Unit developed evidence-based recommendations for using pit and fissure sealants in the City of North York Public Health Department's Dental Program (1). In establishing these recommendations, three aspects of sealant use were addressed:

(1) Which teeth and tooth surfaces should be sealed?

(2) How soon after tooth eruption should sealants be placed?

(3) Which children should receive sealants?

The recommendations were based on: (a) the scientific findings on effectiveness of sealants in preventing and arresting occlusal decay, (b) the epidemiology of dental caries in school-aged children, and (c) the individual caries risk assessment science, all current to the year 1991.

In 1999, the 1993 document was updated based on relevant scientific evidence from the years 1991 to 1996. Studies which indicated changes in the epidemiology of dental caries and studies testing various caries risk prediction models were identified. During those five years new findings on the effectiveness of visible-light-curing sealants were reported, resin-based sealants containing fluoride were introduced to the market, and attempts were made to use glass ionomer cements as pit and fissure sealants.

Since 1996, new clinical studies concerning pit and fissure sealants have been published. This review provides an update to the 1999 document using scientific literature published between October 1996 and July 2000. The literature retrieved covered issues that had been reviewed in the reports published in 1993 and 1999. The updated sections are indicated in bold text.

3.0 Structure of this report

The structure of this report is based on the template proposed at the RCDSO/CDHSRU Workshop (Leake et al. 1996). The template covers the following areas:

1. Target population;
2. Clinical problem;
3. Clinical flexibility;
4. Search strategy;
5. Inclusion criteria;
6. Summary of evidence;
7. Comparison of costs;
8. Relative importance of the potential outcomes;
9. Evidence-based recommendations and
10. Comments or suggestions for further research

The update involved the following three steps:

(1) a review of relevant literature covering the period October 1996 to July 2000;

(2) an evaluation of the recommendations made in 1999 in light of new scientific evidence; and

(3) revision of the recommendations according to the evidence, where appropriate.

4.0 Target Population

These guidelines apply to children who receive dental care from Boards of Health in the province of Ontario.

5.0 Clinical Problem

These guidelines address the management of dental caries on pits and fissures (chewing surfaces) of children's primary and permanent posterior teeth. The guidelines focus on preventing and arresting the caries process in these susceptible teeth and surfaces through the use of dental sealants. These guidelines do not address the prevention and management of early enamel caries through other technologies, e.g., diet counselling, nor the management of the later stages of the disease when a restoration would, ordinarily, be required.

5.1 Prevalence of the problem: Tooth- and surface-specific caries attack rates

1999 Report

Between 1991 and 1996, two studies reported tooth-specific and surface-specific dental caries rates in school-aged populations. Li et al. (3) analysed data from the 1986-1987 National Survey of Oral Health in the United States. They found that, among 5 to 17 year-old children, occlusal caries accounted for more than a half (58%) of dental decay prevalence, and that pits and fissures of first and second molars, along with buccal and lingual pits of first molars were most susceptible to dental decay in the permanent dentition. The hierarchy of caries attack rates, from highest to lowest, was: occlusal surfaces of first molars (maxillary - 32.4%, mandibular - 31.3%), occlusal surfaces of second molars (mandibular - 21.0%, maxillary - 17.4%), buccal pits of mandibular first molars (19.1%), lingual grooves of maxillary first molars (15.6%), and occlusal surfaces of premolars (maxillary - 0.2%) and (mandibular - 0.5%). In the primary dentition, occlusal and proximal surfaces of molars were at highest risk to decay, with the rates not being as dissimilar between these surfaces as in the permanent dentition: 15.7%-27.1% and 10.5%-18.9%, respectively.

Chestnutt et al. (4) analysed data from a sample of 15-year-old children from Lanarkshire, Scotland. They found that 79.4% of occlusal surfaces of first molars were decayed or filled, accounting for 19.9% of caries prevalence. The second highest caries rate was for the occlusal surfaces of second molars: 38.5%.

However, as Rozier noted in his reaction paper to the recommendations for guidelines for sealant use from the workshop held in Albany, 1995 (5), few studies adjusted attack rates for the length of time that teeth had been at risk for caries. Since caries experience is cumulative, tooth-specific and surface-specific rates depend on the age composition of survey participants, and, therefore, are accurate only when derived taking the posteruptive age of teeth into account. For example, in the survey of 15 year-old Scottish children, first molars had been at risk for about twice as long as second molars, which might have inflated caries attack rates for occlusal surfaces of first molars compared to second molars. Rozier concluded that, in light of this approach to analysis of tooth-specific caries rates, occlusal surfaces of first and second permanent molars are at similar, if not equal risk for caries in the first posteruptive year. Therefore, second molars should also be considered for receiving sealants.

<u>2000 Update</u>

Only one study on the prevalence of dental caries was identified. Kaste et al. (45) analyzed coronal caries data from the 1988-1991 National Health and Nutrition Examination Survey (NHANES) in the United States for children aged 5 to 17 years. The estimates are nationally representative for the non-institutionalized population. The mean DMFS was found to be highest for occlusal surfaces (1.4), followed by buccolingual (0.8) and mesiodistal (0.3) surfaces. The corresponding values were 0.4, 0.3 and 0.1 in the age group 5-11 years and 2.4, 1.3 and 0.5 in the age group 12-17 years. Considering that the number of both mesiodistal and

buccolingual surfaces is twice the number of occlusal surfaces, these findings indicate that occlusal surfaces in the permanent dentition are far more susceptible to dental decay. However, this study did not provide either tooth-specific or surface-specific caries attack rates. Consequently, this study does not add to the body of knowledge concerning levels of caries risk for individual teeth and surfaces.

Conclusions:

- Pits and fissures of first and second permanent molars are at greatest risk for dental decay (3,4);
- First and second permanent molars are the priority teeth to be sealed (3-5).
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5.2 Caries susceptibility of pit and fissures over time

1999 Report

It has been held that the susceptibility of occlusal surfaces to caries is highest within two to four years following tooth eruption and decreases progressively thereafter. However, since the mid-1980s, evidence has started to emerge that pits and fissures of first permanent molars remain susceptible to primary dental decay longer than two to four years, into and well beyond adolescence. Studies published in the between 1991 and 1996 (4,6,7,8) replicated the findings of those published before 1991 (9-12). Hence, eight studies now indicate changes in the longitudinal pattern of pit and fissure caries occurrence.

In a three-year study of caries susceptibility of tooth surfaces in 12 year-old children from a fluoride-deficient area in Scotland, Chestnutt et al. (4) found high caries incidence in the pits and fissures of first molars. Even though these teeth had been erupted for at least six years at the beginning of the study, 40.6% of the occlusal surfaces, recorded as sound at baseline examination, became carious over the three years of follow-up.

Foreman (7) reported that 25% of US Navy personnel between ages 17 and 25 years (mean 20.9 years), presented with new pit and fissure caries while on active duty. He concluded that about one third of those in their late teens and early 20s have occlusal surfaces that become carious, unless they are sealed.

Stahl and Katz (6) conducted a retrospective analysis of dental records of the 1989 class at the US Coast Guard Academy. They found that 43% of the students, whose median age was 17 years on initial examination, developed decay on the occlusal surfaces over a period of 40 months, with first and second molars showing the highest incidence, 15%. The authors conclude that their results confirm that occlusal caries is increasingly becoming a disease of young adulthood. They also calculated that, assuming first molars erupted in the sixth year of life, the study participants exhibited 10% of their occlusal caries incidence rate 11-14 years after the teeth eruption. Likewise, assuming second molars erupted at the age of 12, the incidence 5-8 years after the eruption accounted for 14% of the incidence rate for these teeth. These figures are very conservative since they were only calculated for the occlusal caries in the presence of sound proximal surfaces.

In a similar study, Richardson and McIntyre (8) followed a cohort of Royal Air Force recruits between 1988 and 1992, and found that one in ten of the sound occlusal surfaces of first and second molars became carious over the four years. The tooth-specific incidence rates determined during the observation period were as follows: upper first molars - 5%, lower first molars - 8%, upper/lower second molars - 11%. The authors suggested that occlusal surfaces remain susceptible to dental decay in the late teens and early twenties.

These findings are biologically plausible. The first hints of occlusal caries attack on first permanent molars sustained beyond the first four posteruptive years coincided with the decrease in the rate of progression of dental lesions that became evident during the 1980s. The lengthening of the interval between caries initiation and its cavitation extends the period of primary dental caries activity on occlusal surfaces of first molars, which, in turn, might result in the extended period of caries susceptibility (13).

2000 Update

No new studies which addressed this question were published during the period October 1996-July 2000.

Conclusions:

Permanent molars appear to remain at high risk for dental decay beyond the four years of post-eruptive age (4,6-12). However, this is not yet conclusive due to the following:

- the relatively few number of studies conducted;
- differences in the age cohorts studied;
- variability in diagnostic techniques applied; and
- differences in the treatment thresholds of participating dentists.

5.3 Identifying children susceptible to pit and fissure caries

1999 Report

With an increasing proportion of caries-free children and a decreasing proportion of children with a high caries experience, coupled with diminishing resources for public dental programs, the correct prediction of the occurrence of dental decay on an individual basis is necessary for the cost-effective placement of pit and fissure sealants. Recently, much interest has been devoted to developing methods for the identification of individuals at risk for high levels of dental caries.

Research in the area of caries risk assessment has indicated numerous predictors of future high caries increments. The following indicators appear in the majority of the multivariable models developed to date:

- pit and fissure morphology;
- caries history in primary and permanent dentition; and
- current level of caries activity (14-20).

Investigators at the University of North Carolina conducted a study of caries risk in 5,233 first and fifth grade children residing in communities with low water fluoride levels between 1986 and 1989 (14,15). Four categories of information were collected at baseline examination: clinical indicators, microbiologic assays of stimulated saliva, sociodemographic data and health-related behaviours. High caries risk was defined as a DMFS increment of ≥ 4 for a grade 1 cohort, and ≥ 5 for a grade 5 cohort. Clinical indicators were the major contributors to the models, resulting in an average sensitivity of 0.61 and an average specificity of 0.83. For grade 1 these were: the initial dmfs and DMFS, and pit and fissure morphology score; for grade 5: the initial DMFS, pit and fissure morphology, and mean plaque score.

Demeres et al. (16) identified past caries experience as the best predictor for caries increments of one or more carious lesions in the primary dentition over one year in five-year old Montreal children. This predictor alone achieved 0.78 for sensitivity and 0.77 for specificity.

In a series of studies, Steiner, Helfenstein and Marthaler (17,18,19) found that the number of decayed and treated primary molars, and the number of decayed and treated permanent first molars were the best and the most consistent predictors of high caries increments among 5, 7 and 10 year-old children. For increments of at least two, four or six new carious lesions over four years in 7 year-old children, the two-predictor models had sensitivities of 0.65, 0.78 and 0.81, and specificities of 0.65, 0.78 and 0.77, for the cut-off points from the lowest to the highest. The authors achieved almost the same result in predicting 5-year increments in 7-year-old children using only one predictor: the number of decayed and treated primary molars.

By plotting the receiver operator characteristic (ROC) curve, ter Pelkwijk et al. (20) determined that at the age of 7 the best screening criterion for a DMFS>0 at age 9 is a dmft of =5 and for a caries increment (ΔDMFS>0) between ages 7 and 9 is a dmft of=4, while for a DMFS>0 at age 11 and for a ΔDMFS>0 between ages 7 and 11, the critical screening criteria at age 7 appear to be a dmft =4 and a dmft =3, respectively.

Given the characteristics of risk assessment, a model that can be applied with 100% accuracy at the level of the individual will never be available. Considering variations in caries levels and disease-promoting factors between age cohorts, socioeconomic and cultural groups, as well as differences in dental public programs' resources, a single highly accurate model applicable across all age and all population groups is probably unrealistic (14,15,21). Instead, different criteria have to be applied in different communities to categorize a given child as a high caries risk individual. When deciding on the cut-off point, clinical and economic trade-offs (proportion of misclassified children) have to be considered (14,15).

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In a retrospective cohort study, Al-Shalan et al. (46) investigated the relationship between early childhood caries (ECC) and occlusal caries in the first permanent molars. It involved a review of dental charts of patients who had been examined at the Pediatric Dental Clinic, School of Dentistry, University of Minnesota when they were younger than 4 years and at least once when they were older than 6 years. The number of ECC and non-ECC children was 58 and 57, respectively. The participants were medically healthy and had no developmental dental defects. ECC was a risk factor for occlusal caries in first permanent molars. It had an independent effect, with an odds ratio of 3.4, after adjusting for age at last examination, the number of recall visits per year over the observational period, and the number of pit and fissure sealants.

Conclusion

Factors associated with the incidence of dental caries independent of the above mentioned variations are:

- *Past caries activity*: susceptibility to further dental decay onset is positively associated with a child's previous dmfs/DMFS scores (14-20)
- *Pit and fissure morphology*: children with deep pits and fissures are at higher risk for dental decay on pits and fissures (14,15)

6.0 Clinical flexibility

The following guidelines do not apply if dental caries is rampant, although sealants may be part of an overall management approach. The guidelines need not be followed where a parent with full information as to the harms and benefits of sealants declines to accept these recommendations, or where a child is unable to co-operate sufficiently to allow the procedure to be undertaken.

7.0 Evidence for the effectiveness of sealants

7.1 Search Strategy for the 2000 Update

The literature was searched to compile:

(1) Papers pertaining to:

(a) tooth-specific and surface-specific caries attack rates;

(b) susceptibility of occlusal surfaces to dental caries in relation to posteruptive tooth age

(c) individual-based clinical indicators for the use of sealants;

(d) cariostatic effectiveness of all currently used and tested sealants.

(2) Documents reporting recommendations and expert opinions regarding the use of sealants.

The dental literature was searched from October 1996 to July 2000. The search strategies were: (i) a search of the Medline database, (ii) a specific search of the Index Medicus and the Index to the Dental Literature, (iii) a hand search of journals known to publish information of interest for the year 1996 (Community Dentistry and Oral Epidemiology, Journal of Public Health Dentistry, Journal of the American Dental Association, Journal of the Canadian Dental Association, Journal of Dentistry for Children, British Dental Journal, Acta Odontologica Scandinavica, Scandinavian Journal for Dental Research, Quintessence International, Journal of Preventive Dentistry, Community Dental Health), and (iv) a review of the references of documents identified through 1, 2, and 3. The search was limited to the English-language literature involving human subjects. No attempt was made to identify unpublished studies.

The Medical Subject Headings (MeSH) used were: pit and fissure sealants, effectiveness, dental caries, and dental fissures. The Medline was also searched under the following key-words: pit and fissure sealant, prevention, dental caries, retention rate, caries

susceptibility, tooth surface, pit and fissure, caries incidence, caries prediction, past caries, caries risk assessment.

The bibliographies of the retrieved papers and articles were reviewed to:

- screen for further references; and
- retrieve references that were the basis for sealant use recommendations identified through the literature search. The latter were used to evaluate the validity of these recommendations.

7.2 Criteria used to include/exclude evidence

The retrieved documents were subjected to a preliminary evaluation. According to the objectives of the project, the following were excluded: (i) studies on the short-term (<2 years) effectiveness of autopolymerizing and visible-light-curing sealants, (ii) studies where sealants were associated with other preventive measures so that the effects of the individual interventions could not be differentiated, (iii) studies assessing only caries predictors other than clinical, (iv) studies on the effectiveness of sealants in arresting dental decay advanced beyond incipient enamel caries, (v) documents with recommendations for sealant use not supported with scientific evidence, and (vi) studies where adults were the study population.

Initially, 51 papers were identified. Using the above criteria, 19 were retained. One reported on the epidemiology of dental decay, and one examined caries risk indicators. These two papers are summarized in the appropriate sections above. Of the remaining 17 papers, 12 were concerned with the cariostatic effectiveness of sealants, four examined the effects of different tooth cleaning and enamel preparation methods or times on sealant retention, and one studied the adverse systemic health effects of sealants.

7.3 Description of possible options

Caries in the pits and fissures of teeth are reduced by fluorides (22) and by dental sealants. Tooth-brushing by itself is thought to have almost no effect since the diameter of an individual bristle is larger than the diameter of the fissure, meaning that even an individual bristle can not enter to the bottom of the fissure. Therefore toothbrushing cannot debride the fissure of plaque or nutrients for bacteria. Fluorides, while efficacious, are evidently insufficient to completely prevent the decay of pits and fissures since pit and fissure decay persists and constitutes the major component of the burden of illness. Accordingly, the current best option to manage pit and fissure caries, at a stage prior to restoration, in susceptible individuals is dental sealants. Thus options occur with respect to the questions posed in the earlier review:

1. Which teeth and tooth surfaces should be sealed?
2. How soon after tooth eruption should sealant be placed?
3. Which children should receive sealants?
4. Which material to use?

Sections 5.1, 5.2 and 5.3 described the prevalence of occlusal caries, pit and fissure caries susceptibility over time and the prediction of pit and fissure caries. The conclusions from that section addressed the first three of these questions.

7.3.1 Devices and clinical procedure

In the clinical procedure for sealant placement, the surface of the tooth to be treated is cleaned with pumice in water using a rotating bristle brush; the surface of the tooth is etched with a mild (orthophosphoric) acid; the acid is rinsed off; the tooth is isolated from the saliva, air-dried and the liquid sealant is applied and cured (23).

The literature search identified studies evaluating the effects of: (a) techniques of cleaning fissures other than pumice prophylaxis, (b) air abrasion as a method of enamel

preparation and (c) different etching times on the longevity of sealants. These issues were not addressed in the previous reports but were included in this update.

A split-mouth design study (59) found similar complete retention rates at a 12-month follow-up for sealants placed on occlusal surfaces of first permanent molars that had been chosen randomly to be cleaned using a brush attached to a rotary instrument with fluoridated prophy paste (pumice prophylaxis) or a toothbrush without paste (dry cleaning). These rates were 97.6% and 99.2% respectively. Kanellis (60) found that total retention rates on occlusal surfaces when enamel had been prepared by acid etching or air abrasion were 97% vs 96% at 6-months follow-up and 95% vs 87% (p=.14) at 1-year follow-up, respectively. There was no significant difference in the retention rates of a visible-light-curing sealant applied on first permanent molars when the etching times were different: 15, 30, 45 and 60 seconds (61). The maxillary and mandibular quadrants were randomly assigned for etching time. At a 6-month follow-up they were 60.7%, 62.5% , 65.2% and 57.1%, respectively. The corresponding retention rates at a 12-month follow-up were 40.0%, 50.9%, 41.8%, 43.6%.

7.3.2 Ease of use in clinical settings

Sealant placement is relatively straightforward and in most dental offices is carried out by dental hygienists. Attention must be paid to keeping the freshly etched surface dry and, in particular, away from any contamination by saliva. As with other agents, the etch and the sealant should be kept away from the eyes and skin of patients.

7.3.3 Cost of providing sealants: training and equipment

Sealants are an established technology, provided in most dental offices, and there is little concern over the costs of training or new equipment.

7.3.4 Likely cost per patient treated

The major cost incurred in providing sealants is staff time. A 1994 study of the times required to provide different services in the North York Health Department (NYPHD) showed that an auto-polymerizing sealant required 11.5 minutes (95% CL = 9.5-13.5 min) (24). At the time of the 1994 study NYPHD did not provide light-cured sealants or glass ionomer cements (GIC's).

Sealants can be applied by dental hygienists, whereas amalgams have to be provided by dentists. Within the context of a public health dental program, sealants have the advantage of lower dollar costs of application, in comparison to amalgams, because of the costs of the labour inputs.

7.3.5 Evidence for the effectiveness of sealants

Sealants in wide use today are resin-based, classified by the polymerization method as auto-curing or visible-light-curing. **The latter are either unfilled or filled with fluoride particles.** Glass ionomer cements, both **conventional (chemically cured) and resin-reinforced (light cured), are also used** as pit and fissure sealants. Studies of the effectiveness of these different types of sealants are reviewed below.

7.3.5.1 Effectiveness of sealants in preventing dental decay

1999 Report

The effectiveness of sealants in preventing pit and fissure caries was originally evaluated in clinical trials with a half-mouth design. They were conducted to determine relative caries reduction rates. A meta-analysis (25) of 44 such studies found that the proportion of occlusal decay prevented in the experimental group (PF) by a one-time application of autopolymerizing sealants was 69.3%, 68.9% and 58.6% at 25-36, 37-48 and 48 month follow-ups, respectively. PF was calculated as $(I_0-I_1)/I_0$, where I_1 is the incidence of occlusal caries in the group of teeth treated with sealants, and I_0 the incidence in the control group. Since the rate of clinical wear of sealants is highest during the first two years following application (38), these studies established the cariostatic effectiveness of clinically worn sealants.

After sealants had been officially recognized as an effective caries preventive measure, studies with non-treated control teeth were no longer ethically acceptable. Since occlusal caries does not develop as long as the sealant remains adhered to the tooth, the longevity of retention has been adopted as a surrogate measure of their efectiveness in preventing occlusal caries (26).

Between 1991 and 1996, several studies on sealant effectiveness were published. Clinical evaluation of *autopolymerizing sealants* was extended beyond 10 years. In a study with a two-cohort design, Simonsen (27) found that the complete retention rate on permanent first molars 15 years after a single application was 27.6%, with a caries reduction rate of 52%. Findings of shorter-term studies were similar to those published before 1991: 81% (28) and 61% (29) of sealed first permanent molars remained fully covered after four years.

Visible-light-curing sealants were evaluated in three clinical studies between 1991 and 1996. Raadal et al (30) found a complete retention rate of 97% and Gandini et al a retention rate of 66% (31), after two years. In the Manitoba Fissure Sealant Pilot Project, 85% of permanent first and second molars were completely sealed at two-year follow-up (32).

A review of studies on glass ionomer cements used as pit and fissure sealants, published in 1996 (33), indicated comparatively low short-term complete retention rates. In three clinical trials, these rates were: 23% at one-year (33), 26% at two years (34), and 4% at four years (29). In a field trial (36) only 2% to 6% of treated surfaces remained completely covered with glass ionomer after six months.

A review of studies on the effectiveness of autopolymerizing sealants by Ripa (26) suggested that the highest rate of sealant loss occured during the first year after application, and declined significantly thereafter. Futatsuki (37) confirmed these findings, reporting high early loss of sealants: 14.4% at 3-months recall, with a further loss of 7.0% at 6-months recall.

2000 Update

- **No new studies evaluating the effectiveness of autopolymerizing sealants were identified for the period October 1996-July 2000**

- **Twelve studies which evaluated the effectivenes of conventional visible light curing sealants, fluoride-containing visible light curing sealants, conventional (autopolymerizing) glass ionomer cements, resin-modified (light-cured) glass ionomer cements and resin-bonded amalgam were identified for the period October 1996-July 2000 (Table 1). The studies were either one-cohort or half-mouth randomized clinical trials. The latter compared the effectiveness of two types of sealants.**

One-cohort studies

Holst et al. (47) reported a complete retention rate of 69% after five years in a study of a visible-light-curing sealant (Delton) applied to the first and second permanent molars of children by unaided dental assistants trained in a two-day course. The failure rate was highest during the first year, accounting for 35% of lost sealants. Differences in complete retention rates between first and second molars as well as between the upper and lower arches were small.

In a Slovenian study of permanent molars and premolars treated with a fluoride-containing visible-light-curing sealant (Helioseal-F), 95.8% of the former and 91.5% of the latter teeth were completely sealed after three years (48). The study participants were children attending a primary school with a public health dental clinic on its premises.

Carlsson et al (49) found a total retention rate of 76.6% at a two-year follow-up in a study where permanent molars of six and seven year-old children were sealed with Helioseal-F. The treatment was carried out by dental hygienists in public dental health clinics.

Comparison studies

Conventional vs. Fluoride-containing visible-light-curing sealants

Boksman et al. (50) found that 93.7% of permanent molars and premolars were fully sealed at a two-year follow up. Two fluoride-containing visible-light-curing sealants were used: UltraSeal XT and FluoroShield in a split-mouth design. Their complete retention rates were 96.3% and 91.4%, respectively. There were no new pit and fissure carious lesions over the two years of the study. The participants were patients in the private practices of the investigators.

One year after the placement of a fluoride-containing visible-light-curing sealant (Helioseal-F), 90.3% of mandibular first permanent molars were fully covered (51). In the same study, the complete retention rate of a conventional visible-light-curing sealant (Delton) was 96.8%. This was a split-mouth study with 31 pairs of teeth.

In a split-mouth design study with 144 pairs of upper and lower first permanent molars in children aged seven and eight years, Lygidakis et al (52) reported complete retention rates of 77% for a fluoride-containing sealant (Fluorshield) and 89% for a conventional (Delton) visible-light-curing sealant after four years. Fourteen percent and 6% respectively were partly sealed (p=0.001). However, the total loss and the caries increment were similar in both groups (9% vs 5% and 9% vs 10% respectively).

Conventional visible-light-curing sealants vs. Resin-modified glass ionomer cements

Raadal et al (53) undertook a split-mouth single application study and found a complete retention rate of 9% for a resin-modified glass ionomer cement (Vitrebond) and 97% for a light-cured resin-based sealant (Concise) at a three-year follow-up. The resin-modified glass ionomer sealants were progressively lost over the study period: 6% at 1 month, 51% at 6 months, 74% at 12 months and 87% at 2 years. In contrast, the visible-light-curing sealant was fully retained in all teeth at the end of the 2-year period. The study participants were

patients in a public dental clinic. The teeth treated were newly erupted permanent first and second molars.

Forss et al (54) compared the retention rates of a resin modified glass ionomer cement (Fuji III) and a conventional visible-light-curing sealant (Delton) on matched contralateral newly erupted first and second molars. After seven years, 10.3% of the former and 45.4% of the latter sealants were totally present. Retention was somewhat better on lower than on upper molars regardless of the sealant type.

<u>Fluoride-containing visible-light-curing sealants vs. Resin-modified glass ionomer cements</u>

A three-year study comparing a fluoride-containing visible-light-curing sealant (FluoroShield) and a resin-modified glass ionomer cement (Baseline) showed a complete retention rate of 70% for the former and 0% for the latter (55). Baseline was lost from all except two teeth within six months. The proportion of teeth fully covered by FluoroShield at the end of the observational period was significantly higher in the lower (78.5%) than the upper (61.5%) arch. The sealants were applied to matched contralateral first permanent molars in children aged seven to eight years.

<u>Conventional glass ionomer vs. Resin-modified glass ionomer cements</u>

In a half-mouth design study (56), the complete retention rates of a conventional glass ionomer cement (Ketac-Bond) and a resin-modified glass ionomer cemement (Vitremer) were 24% and 59% at the six-month follow-up, and 15% and 36% at the one-year follow-up. They were placed in the first permanent molars of children aged six to eight years.

<u>Conventional visible-light-curing selants vs. Conventional glass-ionomer cements</u>

In a four-year study of first molars, Williams et al (58) found that a glass ionomer cement (Fuji III) was nearly all lost after four years, whereas 61% of a resin-based sealant (Delton)

were still fully retained. At the two-year follow up the retention rates were 4% and 80% respectively.

Conventional visible-light-curing sealants and Resin-bonded amalgam

In a comparative study, Staninec et al (57) evaluated a resin-bonded amalgam sealant and a visible-light-curing sealant placed on the occlusal surfaces of matched contralateral permanent molars in patients aged six to 25 years. The complete retention rates after two years were 46% and 59% respectively.

7.3.5.2 Effectiveness of sealants in arresting dental decay

1999 Report

In 1991, Handelman (38) published a review of clinical trials of the progression of incipient occlusal caries sealed with autopolymerizing sealants. These studies were originally designed to allay the profession's concern about inadvertent sealing of dental decay. The results not only dispelled this concern, but suggested that resin-based sealants should be considered as a new approach to the treatment of caries confined to the enamel. The overall finding was that the carious process is inhibited and may even regress under clinically intact sealants. The effect of sealants was assessed using radiographs and/or bacterial counts. Radiographic evidence presented in this review showed that dental decay was arrested and might have regressed, if pits and fissures remained sealed. In the study from 1981, where carious first permanent molars of six to nine year-old children were sealed, there was no progression at the annual examination and up to four years later and a significant decrease in the penetration rating was registered. In a very similar study from 1985, the penetration ratings fluctuated by only 0.1-0.3 points at three annual recalls. A study conducted in 1986 did not find any change in the depth of sealed occlusal lesions of first and second permanent molars over two years in a group of 12 to 15 year-old children. In these studies caries penetration was measured using a scale of 0-4, with '0' indicating no penetration and '4' being one-quarter to one-half penetration into dentin. Bacteriological evaluation demonstrated a major reduction (1,000-

fold at one year; 2,000-fold at two year) in the count of cultivable microorganisms over time, in a medium taken from the infected dentin, when the retention of sealants was complete.

These findings were confirmed by Weerheijm et al (39). They found a decrease of on average 100-fold in the number of microorganisms in samples taken before and after caries had been sealed with resin-based sealants.

Mertz-Fairhurst et al (40,41) examined the effect of composite resin restorations on the carious process penetrating as far as halfway through dentin. Serial standardized radiographs taken over six years did not show any obvious progression of the sealed lesions, confirming the previous finding. In this study, the tooth preparation involved enamel bevelling only, regardless of the depth of dental decay.

Based on this evidence on the cariostatic effectiveness of sealants, the newest edition of "The Art and Science of Operative Dentistry" (42), a standard textbook of operative dentistry used in Canadian dental schools, recommends that non-cavitated carious lesions are to '...receive either 'no treatment' or are to be treated with sealants, antimicrobials, or both...'.

2000 Update

No new evidence concerning the effectiveness of sealants in arresting incipient pit and fissure caries was identified for the period October 1996-July 2000

7.3.5.3 Adverse systemic health effects

1999 Report

No papers on the potential adverse systemic health effects of dental sealants were published prior to 1999. This issue was not addressed in the 1999 report.

2000 Update

Olea et al (62) analyzed samples of whole saliva from patients treated with 50 mg of resin-based visible-light-curing pit and fissure sealants, of which the main component is bisphenol-A diglycidylether methacrylate (bis-GMA). The bisphenol-A and bisphenol-A dimethacrylate in the range of 90-931 μg were identified one hour after sealants were applied, while the pre-treatment samples were monomer free. These compounds were found to demonstrate an estrogen-like activity when added to tissue cultures of breast tumor cells.

Conclusions

- One-time applied *autopolymerizing sealants* have high long-term retention rates (25,27). At least 60% of surfaces remain completely covered after five to seven years (25), if the recommended application technique (particularly moisture control) is followed;

- Since the *visible-light-curing sealants* are newer, only their short-term effectiveness has been evaluated, with the longest follow-up being five years in **two one-cohort studies, and seven years in one split-mouth design study**. Their retention rates have been within the range of those for autopolymerizing sealants for the equivalent follow-up periods (30-32);

- **The *fluoride-containing visible-light-curing sealants* have been evaluated in short-term studies. The follow-up periods have been two and three years in one-cohort studies, and one, three and four years in split-mouth design studies. The rationale for incorporating fluoride into sealants was to enhance inhibition of incipient and inadvertently sealed hidden caries. The retention rates are within the range reported for autopolymerizing and conventional visible-light-curing sealants. Whether these sealants achieve higher caries reduction rates than visible-light-curing sealants has not yet been determined. Studies comparing the caries experience of matched teeth treated with these two types of sealants need to be conducted.**

- The longevity of *glass ionomer cements* as sealants, **both conventional and resin-reinforced,** is significantly lower than of resin-based sealants, rendering them unsuccessful in pit and fissure applications (29,33,34);

- **There is considerable variation in retention rates between studies (see Table 2 which compares annualized loss rates across studies and sealant types) that may be due to factors such as patient age, tooth type, pit and fissure type, application technique (method of tooth isolation: cotton roll/rubber dam; enamel preparation: acid etch, bur, air abrasion; tooth cleaning method: pumice prophylaxis, toothbrushing), tooth eruption stage, and operator technique. These factors need to be investigated to determine their effect on retention rates and may need to be considered when sealants are placed.**

- Research findings are conclusive that resin-based sealants arrest pit and fissure caries confined to the enamel, provided a sealant remains intact (38,39). There is also an indication that dental decay may even regress when sealed (38-41);

- Since the risk of sealant failure is highest soon after application (26,37), sealants should be evaluated clinically within one year of their placement, especially when used as restorative materials (11).

- **Concerns about the estrogenicity of resin-based sealants have been raised. However, before definitive conclusions can be reached, it is necessary to determine blood levels of monomers following sealant placement, the long-term leachability of sealant monomers and the effects of monomers in normal human cells rather than in cancerous cells.**

8.0 Comparison of relative outcomes and costs

In comparison to the evidence of the effectiveness of autopolymerizing BIS-GMA sealants:

- glass ionomer cements are less effective and cost about the same
- light-cured sealants are similarly effective but have additional capital and maintenance costs of the light curing 'gun'.

9.0 Relative importance of potential outcomes

Pit and fissure decay, if not prevented, is treated with a relatively simple restoration. This requires a local anaesthetic and staff time of about 23 minutes for composites and 17 minutes for amalgam, but leaves the child with a restored tooth. Restorations have to be replaced. There is great variability in their survival but posterior composites last about four years and amalgams more than twice as long, according to Mjor et al (43). Periodically there are concerns over potential hazards associated with dental amalgam, but the hazards of the other restorative or sealant materials have not been subjected to the same degree of concern or examination. Generally the public accepts that there is little hazard associated with the provision of dental restorations.

Teeth, with well-restored pits and fissures, function as well as the natural tooth. However, if restored with amalgam, they have a compromised appearance. For most children this is not an aesthetic issue when the restoration is placed on the chewing surfaces of molar teeth. Thus, restorations on pits and fissures provide a treatment acceptable to the patient.

Pit and fissure caries is not easy to diagnose in the early stages. There is evidence that dentists in Canada are currently restoring non-cavitated lesions in children (44).

From the perspective of the patient, the additional benefit of preventing decay through sealants (rather than early restoration of that same tooth after it is decayed) may be marginal. The prime benefit is in the retention of the natural tooth material and the avoidance of the treatment and retreatment cycle. The second benefit to patients is that sealants could prevent unnecessary dental restorations perhaps arising from dentists' false-positive findings on examination. However, that implies that sealants have been placed on teeth that were not going to decay – a false-positive prediction.

From the perspective of public health, sealants are to be preferred over waiting for the tooth to decay and providing an amalgam since the same or better outcomes can be provided with lower labour costs. This only holds true as long as the accuracy of the predictive methods are high and few efforts are wasted on false-positive predictions, and few teeth decay because of false-negative predictions.

10.0 Evidence-based recommendations

The system developed by the Canadian Task Force on the Periodic Health Examination (CTFPHE) (63) for classifying levels of evidence and the strength of the recommendations based on that evidence was used in developing the following recommendations (See Table 3).

(1) Sealants should be placed on pits and fissures of teeth to prevent and arrest caries (I-A);

(2) Children with current or previous caries experience should be considered for sealants (II-B); others should not (II-D);

(3) Occlusal surfaces of permanent molars should receive sealants if they exhibit:
   * deep and narrow pits and fissures (II-B);
   * questionable caries or caries confined to the enamel (1-A);
   * no concurrent interproximal lesion which would need restoration (III-B);

(4) Sealants should be placed as early as possible after the occlusal surface is completely free of gingival tissue, and up to four years after tooth eruption (II-B);

(5) Resin-based sealants should be used: autopolimerizing sealants (I-A); visible-light-cured sealants (II-B). Glass-ionomer cements should not be used to seal pits and fissures (I-A)

(6) Sealants should be evaluated clinically within one year of their placement, especially when used over incipient lesions (I-A).

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Table 1. Main characteristics of new studies evaluating the effectivenes of sealants in preventing dental decay

Study	Sealant	Subjects (Age: yrs)	Tooth type	Complete retention rate	Tooth surface	Study design	Follow-up	Setting	Operator
Holst, 1998	Conventional VLC	8 (mean) 13 (mean)	1st molars 2nd molars	69%		One cohort	5 yrs		Dental assistants (unassisted)
Vrbic, 1999	F-containing VLC	3rd & 4th grade	Molars Premolars	95.8% 91.5%		One cohort	3 yrs	School-based PDH clinic	Dentist (assisted)
Carlsson, 1997	F-containing VLC	6-7 yrs	1st molars	76.6%	Occlusal	One cohort	2 yrs	PDH clinic	Dental hygienists (unassisted)
Boksman, 1998	F-containing VLC(2)	Adolescents	Molars Premolars	96.3% 91.4%	Occlusal	Split-mouth RCT	2 yrs	Private practice	Investigators (assisted)
Koch, 1997	Conventional VLC F-containing VLC	5-16 yrs	1st lower molars	96.8% 90.3%	Occlusal; Buccal	Split-mouth RCT	1 yr		
Lygidakis, 1999	Conventional VLC F-containing VLC	7-8 yrs	1st molars	89.0% 77.0%		Split-mouth RCT	4 yrs		Investigators
Rock, 1996	F-containing VLC Conventional GIC	7-8 yrs	1st molars	0% 70.0%	Occlusal	Split-mouth RCT	3 yrs	Mobile unit	Investigators
Raadal, 1996	Conventional VLC Resin-modified GIC	5-7 &11-13 yrs	1st & 2nd molars	97.0% 9.0%	Occlusal;Buccal;Palatal	Split-mouth RCT	3 yrs	PDH clinic	Dentist (2)
Forss, 1998	Conventional VLC Resin-modified GIC	5-14 yrs	1st & 2nd molars	45.0% 10.3%		Split-mouth RCT	7 yrs		Investigators
Pereira, 1999	Conventional GIC Resin-modified GIC	6-8 yrs	1st molars	36.0% 15.0%	Occlusal	Split-mouth RCT	1 yr		Dentist (2) (assisted)
Staninec, 1998	Conventional VLC Resin-bonded amalgam	6-25 yrs	Molars	59.0% 45.0%		Split-mouth RCT	2 yrs	University dental clinic	Investigators
Williams, 1996	Conventional VLC Conventional GIC	6-8yrs	1st molars	61% 4%		Split-mouth RCT	4 yrs	Community dental clinic	Dentists

VLC – Visible ligh curing
GIC – Glass ionomer cement
F-releasing – Fluoride releasing

Table 2: Annualized loss rates for various types of sealants (%)

Study:	YRS	APS	VLC	VLC-f	GIC	GIC-rm	RBA
Simonsen, 1991	15	4.83					
Lygidakis et al, 1994	4	2.25					
Williams et al, 1996	4	9.75			24		
Raadal et al, 1991	2		1.5				
Gandini et al, 1991	2		17				
Cooney & Harvick, 1994	2		7.5				
Simonsen, 1996	1				77		
Sipahier & Ulusu, 1995	2				37		
Songpaisan et al, 1995	0.5				96*		
Holst et al, 1998	5		6.2				
Vrbic , 1999	3			1.4/2.8			
Carlsson et al, 1997	2			11.7			
Boksman & Carlsson, 1998	2			1.8/4.3			
Koch et al, 1997	1		3.2	9.7			
Lygidakis & Oulis, 1999	4		2.8	5.8			
Raadal et al, 1996	3		1.0			30.1	
Forss & Halme, 1998	7		7.8			12.8	
Rock et al, 1996	3			10.0		33.3	
Pereira et al, 1999	1				85.0	64.0	
Williams et al, 1996	2		10.0		48.0		
Staninec et al, 1998	2		15.5				27.0

YRS: Years of follow-up
APS: Autopolymerizing sealants
VLC: Visible light curing sealants
VLC-f: Fluoride containing visible light curing sealants
GIC: Conventional glass ionomer cements
GIC-rm: Resin modified glass ionomer cements
RBA: Resin bonded amalgam sealants

Table 3: Quality of evidence and classification of recommendations

Quality of evidence

I	Evidence obtained from at least one properly randomized controlled trial
II-1	Evidence obtained from well-designed controlled trials without randomization
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group
II-3	Evidence obtained from comparisons between times or places with or without the intervention.
III	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees

Classification of recommendations

A	There is good evidence to support the recommendation that the procedure be implemented
B	There is fair evidence to support the recommendation
C	There is poor evidence to support the recommendation
D	There is fair evidence to support the recommendation that the procedure not be implemented
E	There is good evidence to support the recommendation that the procedure not be implemented.