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Comparing the caries-preventive effect of two fissure sealing modalities in public health care: a single application of glass ionomer and a routine resin-based sealant programme. A randomized split-mouth clinical trial

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Aim. The aim of this study was to compare the caries-preventive effect of two types of sealant modalities and to evaluate whether the caries-preventive effect is related to sealant retention. A hypothesis was tested in which a glass ionomer sealant, once applied to the occlusal surface, was able to protect the fissure from caries even if the sealant appeared lost at visual inspection.

Design. A 3-year randomized split-mouth trial evaluating two sealant modalities was performed at a public health centre in Finland. A chemically curing glass ionomer cement (GIC) and light-curing resin-based (RB) sealant material were applied randomly to the permanent second molars. Sealant application as a routine treatment procedure was carried out to 599 children in the age group of 12–16 years. Caries rate of the sealed teeth and sealant retention with both materials were analysed by a modified McNemar's test. The effectiveness, rate difference, and relative risk with both sealant materials were measured.

Results. The difference in caries rate between the two modalities was highly significant. When compared to the GIC sealant method, the effectiveness of RB sealant method was 74.1% and the rate difference 3.2% (95% CI 1.44%, 4.98%). The relative risk for RB-sealed surfaces vs. GIC-sealed surfaces of having detectable dentin caries was 0.26 (95% CI 0.12, 0.57). The retention rate of sealants was higher with RB than GIC ($P < 0.001$). The effectiveness of the retention rate for RB sealants was 94.8% and the rate difference 87.2% (95% CI 83.86%, 90.50%). The relative risk during the 3-year study period of having a defective or lost RB sealant was 0.052 (95% CI 0.036, 0.075) when compared to having a defective or lost GIC sealant.

Conclusion. It is concluded that in preventing dentin caries a RB sealant programme including resealing when necessary was more effective than a single application of GIC. The original hypothesis was thus falsified.

Introduction

The prevalence of dental caries has been declining during the past decades in industrialized countries, but caries is still a widespread disease of multifactor nature, affecting the vast majority of people throughout the world[1,2]. Caries decline has taken place mostly within the smooth and proximal surfaces of the teeth whereas the proportional rate of occlusal caries (pits and fissures) shows a tendency to increase[3]. Pit and fissure sealants introduced by Cueto and Buonocore in 1967[4] have been accepted as an efficient caries-preventive method[5–7]. Most of the sealant materials used today are resin-based (RB) composite adhesives. Bis-GMA, the main constituent of RB sealants, has properties well suited for a sealant material. RB sealant forms a thin layer able to penetrate the narrow fissure walls, adheres to the enamel surface, and is resistant to occlusal stress. In a clinical trial in which decayed dentin lesions were sealed, the number of bacteria decreased in the lesions during 6 months[8]. It is assumed that the residual bacteria in the biofilm left in the fissure after

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thorough cleaning and sealing do not survive under properly applied sealant, or if they survive they cannot multiply[9,10]. Thus, the caries-preventive effect of RB sealant is considered to be strongly related to its retention rate and resealing is suggested in cases of lost or partially retained sealants[11,12].

Mejare and Mjör[13] found that glass ionomer cement (GIC) sealant applied to the pits and fissures gave long-lasting protection against caries. Pits and fissures, which on clinical observation showed a total loss of sealant, had small remnants of GIC when their replicas were observed under a microscope. Based on this finding, a hypothesis was formulated as follows: single application of GIC sealant can protect the fissure from dentin caries as effectively as the routinely used RB sealant programme, where the defective sealants are replaced. The aim of this study was to evaluate the feasibility of these two sealant programme modalities at the public health level as part of a routine treatment. Moreover, we wanted to assess the retention rate of sealants with both modalities, and the frequency of resealing with RB with respect to the development of caries over time.

Material and methods

The present study is a part of a larger study on sealants in Finland. Two sealant materials were applied to the second permanent molars in a split-mouth setting to children in the age group of 12–16 years. The Ethics Committee of the University of Helsinki has approved the study. All the children examined in the study and their parents were informed before and gave their consent.

Children born from 1980 to 1983 and attending routinely the free community-organized dental health care were examined at the health centre of Varkaus, Finland, during the period 1993–1996. All second molars of the 599 participants were examined. At baseline a majority of the 2356 second permanent molars were considered to be at risk for caries and were thus included in the study (Table 1). The second molars that had not erupted or were still erupting at the baseline were evaluated after every 6 months and included in the study after total eruption in cases the teeth were considered to be at risk for caries. Second molars, which were not considered to be at risk, were sealed earlier, or had detectable dentin caries or fillings were excluded from the study. No other exclusion criteria were used.

Table 1. Initial status of the second molars.

Baseline diagnosis of Each second molar	*N*	%	Male	Female
Intact, not in risk	36	1.5	19	17
At risk for caries	1345	57.1	686	659
Detected dentin caries	26	1.1	15	11
Large dentin caries lesion	19	0.8	10	9
Erupting/not erupted	709	30.1	424	285
Sealed	210	8.9	108	102
Filled	4	0.2	3	1
Extracted	0			
Other diagnosis	0			
Preventive resin restoration	0			
Missing values	7	0.3		
Total	2356	100.0	1265	1084

Second molars at risk for caries were sealed. Small lesions where caries had proceeded to dentin were preferably treated by a preventive resin restoration. Large dentin caries cavitations were filled. Teeth that had not erupted were re-examined after every 6-month period and included in the study after eruption.

The diagnosis and risk assessment of each second molar was based on the case history and on the clinical status of each child. If the child had earlier dentin caries in either the deciduous teeth or in the first permanent molars, he or she was included in the caries risk group. Increased caries activity of a sibling also indicated caries risk in this study. The total DMFT of each child was registered.

The initial examination and the caries risk assessment of each second molar was performed by 1 of the 10 local dentists working at the health centre at the time of the examination. No clinical calibration between the dentists was carried out at this point. All the participating dentists, however, had been calibrated and the inter- and intraexaminer variables calculated in occlusal caries diagnostics before the trial. The mean interexaminer reproducibility for 10 dentists using fibre-optic transillumination (FOTI) as a diagnostic aid in the examination showed fair agreement (kappa value 0.42, SD = 0.19)[14].

The teeth considered to be at risk for caries were sealed randomly with either the RB or

GIC sealant method. The criteria for sealing a tooth were as follows: no risk for dentin caries – no clinical procedures; risk for dentin caries – sealant application. In questionable cases, the rule was: 'when in doubt – seal'[14]. Visual inspection and FOTI were used routinely at examinations while radiological examination was not routinely used. Detected dentin caries of a second molar or a present restoration in the tooth indicated exclusion from the sealant study.

Sealants were applied by a dentist working with a chair-side assistant, or by a dental hygienist operating alone. All operators, 10 dentists and 4 dental hygienists, were experienced with both the sealant materials and methods and were further instructed before the study. The sealed teeth were followed for a 3-year period until the end of 1999.

The sealant materials were the chemically curing glass ionomer Fuji III® (GC Corporation, Tokyo, Japan), and the light-curing resin-based Delton® (Johnson & Johnson, East Windsor, NJ, USA; later Dentsply). Both materials were applied according to the manufacturers' instructions with one modification: a standard probe was used instead of the applicator provided by the manufacturer. A split-mouth randomization was applied as follows: the sealant material for the first tooth to be sealed per mouth was chosen according to the child's birth date; odd numbers indicating RB, and even numbers indicating GIC. For the following tooth in order of the same child (starting from the upper right quadrant, followed by the upper left, lower left, and finally lower right quadrant), the opposite material was chosen. In case the second upper molar at the right side had not erupted at the time of examination and the others had, the molar from the left side determined the sealant material used. The evaluation was made by combining tooth pairs on contralateral sides in both the upper and lower jaws.

Each tooth was examined at baseline and re-examined at 6, 12, 24, and 36 months after sealant application. The condition of each tooth was registered as sound if no dentin caries was detected or carious if dentin caries could be detected. Sealant was classified as intact or partially or totally lost. Teeth with a defective RB sealant or with a re-exposed fissure were resealed with RB. Defective or lost GIC sealants were not replaced. Once carious, the tooth was excluded from the study. No other exclusion criteria were applied.

Statistical analysis

The split-mouth study design led to a situation where either one or two tooth pairs were observed per mouth. The problem of dependent pairs was treated by using a modified McNemar's test according to Durkalski *et al.*[15]. In this procedure, each mouth is considered as a cluster and the observation (RB-GIC sealant pair) is treated as a matched pair. According to the modified method, the estimate of the variance of the difference of dentin caries or retention probabilities is derived using the method of moments that takes into account the varying number of RB-GIC pairs observed per mouth. The rate difference or net gain, the relative risk and the effectiveness of the detected dentin caries, and the sealant retention rate with both materials are reported, as well as the 95% confidence interval[16]. In analysing the caries rate of the sealed teeth and the operator effect between dental hygienists and dentists, the Huber–White method was used to obtain estimates and *P*-values from maximum-likelihood method that were corrected for the correlated responses of clustered (mouth/teeth) observations.

Results

Caries lesions in the pits and fissures of the sealed second molars in both material groups during the 3-year follow-up were few. Teeth sealed with GIC, however, had more carious lesions than teeth sealed with RB. The difference in the caries rate was statistically significant ($P < 0.001$). The effectiveness of RB sealant method in caries prevention was 74.1% (95% CI 43.40%, 88.13%) and the net gain or rate difference 3.2% (95% CI 1.44%, 4.98%) when compared to the GIC sealant method. The relative risk for RB-sealed surfaces vs. GIC-sealed surfaces of having detectable dentin caries was 0.26 (95% CI 0.12, 0.57). The relative risk for GIC-sealed surfaces of having dentin caries

Table 2. The cumulative caries rate of sealed tooth pairs after 3 years in the upper (dd 17/27) and lower (dd 37/47) jaw (*n* = 657 tooth pairs) from 436 children.

Detected dentin caries		Tooth pairs	
RB	GIC	*n*	%
No	No	625	95.1
No	Yes	25	3.8
Yes	No	5	0.8
Yes	Yes	2	0.3
Total		657	100.0

A total of 221 children contributed two pairs and 215 one pair per mouth. RB, resin-based sealant; GIC, glass ionomer sealant.

Table 3. Status of sealants in tooth pairs after 3 years in the upper (dd 17/27) and lower (dd 37/47) jaw (*n* = 559 tooth pairs) of 388 children.

		Tooth pairs	
RB	GIC	*N*	%
Intact	Intact	34	6.1
Intact	Partial/total loss	498	89.1
Partial/total loss	Intact	6	1.1
Partial/total loss	Partial/total loss	21	3.7
Total		559	100.0

A total of 171 children contributed two pairs and 217 one pair per mouth. RB, resin-based sealant; GIC, glass ionomer sealant.

was 3.9 (95% CI 1.77, 8.42) when compared to RB-sealed surfaces (Table 2). The DMFT in the 13-year age group was 0.57 in 1993; this group was the largest of all the age cohorts participating in the study.

The retention rate of RB sealants was high, whereas GIC sealants showed lower retention ($P < 0.001$). The effectiveness of the retention rate for RB sealants was 94.8% (95% CI 92.46%, 96.41%) and the rate difference 87.2% (95% CI 83.86%, 90.50%). The relative risk during the 3-year study period of having a defective or lost RB sealant was 0.052 (95% CI 0.036, 0.075) when compared to having a defective or lost GIC sealant. The relative risk of having a defective or lost GIC sealant was 19.2 (95% CI 13.25, 27.88) when compared to a defective or lost RB sealant (Table 3).

From the GIC-sealed teeth 94.3% were found defective or totally lost at any of the previous examinations. The GIC-sealed teeth where the sealant was totally lost were more

Table 4. Caries status of the GIC-sealed teeth at the end of the study compared to the sealant status (defective or totally lost) at the previous check-up.

Dentin caries detected at the end-point	Status of the GIC sealant at the previous examination	
	Defective	Totally lost
No	250	350
Yes	6	14
Total	256	364

Examinations were due at 6, 12, 24 and 36 months after sealant application. The end-point was at 36 months unless dentin caries was detected at the occlusal surface earlier. The defective glass ionomer cement (GIC) sealants were not resealed.

prone to have detectable dentin caries than those teeth where the sealant was only partially lost or defected ($P < 0.039$, adjusted). The rate difference was –1.5% (95% CI 4.54%, –1.53%) and the relative risk to develop dentin caries 0.60 (95% CI 0.21, 1.52) for teeth with defective GIC sealants in comparison to teeth where the sealants were totally lost (Table 4). No statistically significant difference was found in the caries rate of the sealed teeth between the two methods regardless on whether the sealants were applied by a hygienist or a dentist–nurse pair. The caries rate of the RB method was 0.42% for the hygienists and 1.48% for the dentists ($P = 0.21$), and 3.38% and 4.89% ($P = 0.40$) for the GIC method, respectively. A total of 15.2% of the initially RB-sealed teeth were resealed after the sealant was found to be defective. The dropout rate in this study was 20% at the end of the 3-year period.

Discussion

Our study clearly showed that the RB sealing modality was more effective in preventing caries than the GIC modality. The relative risk for GIC-sealed teeth to become carious indicates a strong risk factor (3.9). However, as the total caries rate with both the material groups was very low in this data, the risk considering GIC sealant method was high only when compared to teeth sealed with RB method. In a population where the caries rate is moderate or high, the choice of sealant material could play a more important role in this regard. The

study design was a split-mouth clinical trial where two kinds of sealant materials were used per mouth. The fact that GIC contains fluoride and RB does not could possibly interfere with the results as is always the situation in split-mouth studies. If the results had been equal with both treatment modalities, the fluoride component of the GIC sealants could have favoured the results of the RB-sealed teeth. However, as the caries-preventive effect with GIC sealant method was less effective than with RB sealant method, we do not believe that the fluoride in the GIC sealant could have caused a positive effect to the teeth sealed with another material since it did not prove to be as effective as RB in the fissures where it was applied.

Since the conditions of this split-mouth study reflect the conditions in real life with a large patient series, we assume that the results can be adapted to caries prevention and to a public health setting elsewhere. When compared to the average DMFT value in Finland, 1.1 (year 1997; age 12 years)[17], the total caries rate in the city of Varkaus in the beginning of the follow-up period was low, 0.57 (year 1993; age 13 years).

The original hypothesis stating that the residual GIC in the fissure after visible total loss of sealant could protect the tooth was falsified in this study since the teeth sealed with the GIC method developed caries. In our study, the number of occlusal dentin caries lesions of GIC-sealed teeth were over fourfold that of caries lesions found in the RB-sealed teeth. This is contradictory to the finding of Mejare and Mjör with no caries lesions in the GIC-sealed teeth[13]. In a later study, Beiruti *et al.* also found the GIC sealants more effective than RB sealants in preventing caries, but direct comparison to our study cannot be made, as in their study RB sealants were not resealed. Moreover, the GIC sealants were applied with another technique[18]. Contradictory to previous results[13], the caries rate was shown to be related to the retention rate also with the GIC material (Table 4). As no caries risk group was intentionally left without sealing we cannot estimate the actual caries-preventive effect of either of the materials or treatment modalities used, which is a weakness in this study. During the planning phase and in the beginning of 1990s when our trial started, it was considered unethical in Finland not to seal the permanent molars of a child in the caries risk group. In our study, most of the children were classified to the caries risk group, but the specific inclusion criteria applied were not recorded. Limiting the choice of sealant application to those children and teeth at high risk for caries increases the cost-effectiveness of sealants[7,19].

It cannot be estimated from this study whether the resealing of GI-sealed teeth would had rendered them as effective as the RB sealants, since the GIC sealants were intentionally not resealed after the failure of the sealant. However, based on the low retention rate of the GIC sealants, this approach obviously would have meant expensive resealing treatments and, thus, endangered the cost-effectiveness of this sealant method. We have previously shown that when the costs of the two sealant methods are compared, the light-curing RB is more cost-effective than the chemically curing GIC[20]. The resealing rate (15%) with RB sealant method in the present study is in line with that of earlier studies[11,21], even though all the lost RB sealants were routinely resealed. The present results are also in line with those of Songpaisan *et al.*[22], Forss and Halme[23], and Poulsen *et al.*[24], who found less caries in the RB-sealed teeth than in the GIC-sealed teeth.

Based on the present results, we conclude that in preventing dentin caries a RB sealant programme including resealing when necessary was more effective than the single application of GIC.

What this paper adds?

- Single application of GIC sealant does not prevent caries as effectively as the use of RB sealant method.
- Caries rate seems to be related to the retention rate of sealants with both sealant methods.

Why this paper is important to paediatric dentists?

- Although the role of sealants has been challenged, placing a fissure sealant is still the most efficient single method to arrest enamel caries lesions in the permanent molars.
- The choice of the most appropriate sealant material and method is of importance to every clinician treating children or young adolescents.

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