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A field trial of resin-based and glass–ionomer fissure sealants: clinical and radiographic assessment of caries

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Abstract – *Objective:* The purpose of the present study was to provide further data for comparison of retention and caries-preventive effect of a resin-based sealant (Delton®), and a glass–ionomer sealant (Fuji III®). *Methods:* The study was conducted in the municipality of Værløse located 15 km north of Copenhagen, Denmark in the period 1996–2001. The study comprised 153 children aged 8–13 years with a total of 364 site-pairs. Caries was diagnosed both clinically and radiographically, and sealant retention was diagnosed clinically. Sealants were placed either by one of four dentists, who had the responsibility for the children's dental care, by a dental hygienist or a dental assistant. Mean follow-up time was 38–39 months for sites on first permanent molars and 28–29 months for sites on second permanent molars. *Results:* The retention rates were consistently, and considerably lower for Fuji III® than for Delton®. Relative risks of caries in Delton®-sealed teeth over Fuji III®-sealed teeth was 0.435 (95% CI 0.150–0.846) based on the clinical diagnosis, and 0.559 (95% CI 0.342–0.905) based on the radiographic diagnosis. The ratio of the relative risks (clinical over radiographic diagnosis) was close to 1 (0.778; 95% CI 0.272–1.481). *Conclusion:* In the present study, Delton®-sealed teeth had a lower risk than Fuji III®-sealed teeth of developing caries, independent of the caries diagnostic method used.

Key words: diagnosis; field trial; fissure sealants; glass–ionomer; radiography; resin; split mouth

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Fissure sealants are a well-established component in preventive dental care both for the individual patient and in dental public health programmes (1), and a recent *Cochrane Review* concluded, that 'sealing with resin based sealants is a recommended procedure to prevent caries of the occlusal surfaces of permanent molars' (2). Resin-based materials are usually considered the material of choice as they have high retention rates and a proven cariostatic effect (3). However, glass–ionomer cements (GIC) have also been suggested as sealant materials mainly for two reasons. First, GIC have the ability to take up, and release fluoride, which among other beneficial effects may result in an increased resistance of fissures to demineralization (4). Secondly, the retention of GIC is not as dependent on complete moisture control as the retention of resin-based materials, making the former more suitable for use in young children with incompletely erupted molars.

Recently published clinical trials have consistently found poorer retention of glass–ionomer sealants than resin-based sealants (5–8). The results on the effect of caries are however less conclusive, as the trials conducted by Forss et al. (6), and by Williams et al. (5) found no difference in the effect on caries 2 or 4 years, respectively, after the application, while an increased risk of caries in glass–ionomer-sealed teeth compared with resin-sealed teeth was found after 7 years of follow-up in

the trial conducted by Forss and Halme (7). This later finding is consistent with clinical results we have reported previously from an earlier study (8). The *Cochrane Review* was not able to reach any conclusion from comparing glass–ionomer fissure sealants and resin-based fissure sealants (2). The purpose of the present study was to provide further data for comparison of retention and caries-preventive effect of the two materials.

Material and methods

The study was conducted in the municipality of Værløse, 15 km north of Copenhagen, Denmark during 1996–2001. All children in the municipality were enrolled in the dental service and received free, systematic care from birth until 18 years of age. The fluoride content of the drinking water in the municipality is 0.25 ppm F^-. All Danish children commonly use fluoridated toothpaste. During the years 1995–1998, mean DMFS was between 0.5 and 0.7 for 12-year-old children and between 1.4 and 1.8 for 15-year-old children.

Study population and measurement of caries and sealant retention

Data for the present analysis were obtained from a larger community programme aimed at comparing retention and caries preventive effect of fissure sealing with Delton® (Ash Dentsply, York, PA, USA) and Fuji III® (GC Corporation, Tokyo, Japan), including 386 children 5–16 years of age. Clinical criteria for diagnosis of dental caries were those used in the reporting system for the Danish municipal dental service for children (9, 10). For each of the upper permanent molars, the mesial and the distal fissures were diagnosed as separate sites. Sound surfaces, and surfaces with initial or arrested caries (white or brown fissures) were sealed, if the dentist's clinical assessment indicated a caries risk. Prior to the study, several calibration sessions were held with all participating examiners, where the criteria for caries diagnosis, the indications for sealing, and the criteria for assessment of sealant retention were discussed. Furthermore, clinical photographs were available during the study period to support the examiners in their clinical assessment.

Children with at least one pair of sealed permanent molars, and a set of bitewing radiographs were subsequently identified, and included in the present analysis. The bitewing radiographs were taken as part of the routine dental examination. As the children were recruited into the study over time, the number of teeth sealed per child, as well as the age at which the teeth were sealed varied. The study comprised 153 children with a total of 364 site-pairs. Table 1 shows, that the average age of the children when the first permanent molars were sealed was $7\frac{1}{2}$ to 8 years, while the average age at which the second permanent molars were sealed was 13 years.

The same dentists who recorded caries recorded retention of sealant clinically at the follow-up examinations as 'complete retention', 'partial retention' or 'complete loss'. Radiographs were only taken at the end of the study. All radiographs were read by the same examiner (U.J.) who was not aware of the clinical status of the tooth or of the type of sealant used. The occlusal surfaces were classified according to the scale shown below:

- No radiolucency in dentine;
- Radiolucency less than one-third into dentine;
- Radiolucency more than one-third, but less that two-third into dentine;
- Radiolucency more that two-third into dentine;
- Filled.

Hypoplastic areas, and buccal pits were excluded. For the analysis of the cariostatic effect of the two materials, all lesions into dentine and fillings were combined. The reproducibility of the caries diagnoses was assessed by double reading 30 sets of bitewing radiographs, which resulted in a kappa-value of 0.855 (95% CI 0.775–0.965).

Table 1. Number of sealed sites, age in years at which they were sealed and length of follow-up period (in months)

		Age in years at sealing (years)				Follow-up period (months)			
Site-pair	*n*	Minimum	Maximum	Mean	SD	Minimum	Maximum	Mean	SD
17d & 27d	74	9.94	15.48	12.95	1.28	16.82	45.64	27.80	6.78
17m & 27m	84	9.94	15.48	12.96	1.25	11.64	45.64	27.62	7.03
16d & 26d	43	5.53	14.31	7.97	1.85	11.90	56.30	38.69	8.42
16m & 26m	44	5.53	14.31	7.96	1.84	11.90	56.30	38.85	8.39
47 & 37	81	9.94	15.71	12.94	1.30	16.82	46.98	28.87	7.02
46 & 36	38	5.16	11.14	7.50	1.30	11.90	50.95	38.00	7.73

Intervention

The two materials tested were UV-light-cured opaque Delton®, and Fuji III®. Both materials were used according to the instructions of the manufacturers. The sealing procedure was reviewed, and the UV-lamps checked. The sealants were applied either by one of the 4 dentists, a dental hygienist or a chairside dental assistant. The present analysis is based on the 364 site-pairs, resulting in a total of 728 sealed sites. Of these, 74.9% of the sites were sealed by the dental hygienist or a dental assistant.

The allocation of the two sealant materials was done using the child's birthday: children born on even dates having Fuji III® placed on the teeth in the right side of the mouth and Delton® placed on the teeth in the left side of the mouth. Children born on odd dates had the opposite allocation of the materials. The same material was used in the upper and the lower jaw. The project was approved by the Danish Data Protection Agency.

Statistical analysis

Comparison of the cariostatic effect was performed using only those children, who had clinical recordings as well as radiographs, the later being taken within 30 days from the date of the clinical examination, a total of 153 children. Mean follow-up time was 38 to 39 months for sites on first permanent molars and 28 to 29 months for sites on second permanent molars (Table 1). Table 2 shows, that almost all children contributed with one, two or three site-pairs, while a single child contributed with six site-pairs.

Relative risk of caries in Delton®-sealed teeth versus Fuji III®-sealed teeth was computed for both method of diagnosis and the ratio of the relative risk (clinical versus radiological) was used to assess if the result depended on the method of diagnosis. Standard methods for calculation of confidence intervals do not account for the varying number of sites per individual. Therefore, re-sampling methodology with the individual as the sampling unit was used to derive confidence intervals for the relative risks and their ratio. The confidence intervals are based on 10 000 bootstrap simulations (11). Stata 8 (12) was used for these calculations.

Table 2. Distribution of individuals in the study group according to number of site-pairs

Number of site-pairs	Number of individuals (%)
1	30 (19.6)
2	38 (24.8)
3	84 (54.9)
4	0 (0.0)
5	0 (0.0)
6	1 (0.7)
Total	153 (100.0)

Results

Table 3 shows that retention varied considerably for both materials from site to site. Complete retention was found in approximately 60–80% of the sites sealed with Delton®, but in <10% of the sites sealed with Fuji III®.

Table 4 shows the distribution of pairs of sites according to caries status, material, and method of caries diagnosis. Both for the clinical diagnosis and the radiographic diagnosis, the relative risk of caries for a Delton®-sealed tooth was lower than for a Fuji III®-sealed tooth (Table 5). The similarity of the relative risk using the clinical diagnosis, and the relative risk using the radiographic diagnosis was confirmed by the ratio of the relative risks

Table 3. Percentage distribution of sealed sites in the study group according to retention and material

Site	Material	Complete retention	Partial retention	Complete loss	Total
17d & 27d	Delton®	57.14	19.48	23.38	100.00
	Fuji III®	5.19	6.49	88.31	100.00
17m & 27m	Delton®	77.38	16.67	5.95	100.00
	Fuji III®	7.14	4.76	88.10	100.00
16d & 26d	Delton®	55.81	16.28	27.91	100.00
	Fuji III®	0.00	13.95	86.05	100.00
16m & 26m	Delton®	59.09	27.27	13.64	100.00
	Fuji III ®	11.36	11.36	77.27	100.00
47 & 37	Delton®	56.70	23.71	19.59	100.00
	Fuji III ®	6.19	23.71	70.10	100.00
46 & 36	Delton®	69.44	27.78	2.78	100.00
	Fuji III ®	8.33	11.11	80.56	100.00

Table 4. Distribution of pairs of sites in the study group according to material, clinical and radiographic caries diagnosis

	Fuji III®				
	Clinical sound		Clinical carious		
Delton®	Radiographically sound	Radiographically carious	Radiographically sound	Radiographically carious	Total
Clinical sound					
Radiographically sound	312	13	8	9	342
Radiographically carious	7	4	0	1	12
Clinical carious					
Radiographically sound	0	0	0	3	3
Radiographically carious	3	2	0	2	7
Total	322	19	8	15	364

Table 5. Relative risk (RR) of caries in a Delton®-sealed tooth versus a Fuji III®-sealed tooth, ratio of relative risk of clinical vs. radiographic diagnosis and 95% confidence limits

		95% Confidence limit	
	RR	Lower	Upper
Clinical	0.435	0.150	0.846
Radiological	0.559	0.342	0.905
Ratio of RR	0.778	0.272	1.481

being close to 1 (0.778; 95% CI 0.272–1.481). Thus, in the present study, Delton®-sealed teeth had a lower risk than Fuji III®-sealed teeth of developing caries, independent of the caries diagnostic method used.

Discussion

The finding of a lower retention rate of Fuji III® than of Delton® is consistent with several previous studies (5–8). The lower caries preventive effect found of sealing with Fuji III® compared with that of sealing with Delton® is also consistent with previous studies (7, 8). It has been speculated, that the caries preventive effect of Fuji III® sealants would be mediated through the ability of the glass–ionomer to act as a fluoride depot, thus retarding the progression of early caries lesions (13, 14). In the present study, both sound surfaces and surfaces with initial or arrested caries lesions were sealed. However, the size of our study was too small to allow for an analysis to address this question.

The data for the present study were generated from an established fissure-sealing programme in a municipal dental service. More than 350 children were originally included in the fissure sealing programme. In these children, sealing of all permanent molars and premolars that were eligible for sealing according to the criteria used in the municipal dental service was performed. Several of the children did however not have pairs of teeth available for sealing, and were thus not included in the present analyses. Furthermore, according to Danish regulations, radiographs can only be taken if a clinical indication is present (15), and only children with both clinical and radiographic data were included in the present study. Of the total of 386 children involved in the sealant programme, only half (153) fulfilled these criteria. It could be argued, that these two sources of selection could have biased the study. However, as the analyses presented in this paper were conducted according to a split-mouth design, and the effect assessed using estimates of relative risk, this would not jeopardize the conclusions of the study.

Another difference between the present study and most of the earlier fissure sealants studies is the use of four dentists as examiners, and the use of dentists, dental hygienists and chairside dental assistants as sealant operators. The majority of the sealants were, however placed by dental auxiliary personnel (dental hygienists or chairside dental assistants), thus reflecting a future distribution of work considered by many to be the most cost-efficient. The use of multiple examiners and sealant operator may have increased the variability in the data, but does on the contrary reflect the real-life situation, where diagnosis is subject to variation between examiners, and sealant retention subject to operator variation.

Finally, the method of allocation of sealant material was not a truly random procedure, as requested by the Consort Statement (16). This again is due to the pragmatic nature of the study. As the children were enrolled into the fissure-sealing programme over a time period of several years,

by several different operators, located in different clinics, a truly random allocation procedure (e.g. by the use of random numbers) was neither feasible nor practically possible to implement. Blinding of fissure sealant studies is generally not possible. To which extend these two factors have affected the results of the study cannot be assessed.

Conclusion

The present study found a lower retention rate of Fuji III® sealants than of Delton® sealants. Delton®-sealed teeth had a lower risk than Fuji III®-sealed teeth of developing caries, independent of the caries diagnostic method used.

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