

Caries Preventive Effect of Occlusal Sealant Extension to ART Restorations Compared with Non-Extended Amalgam Restorations

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Purpose: To estimate the survival of retention of sealant extension to occlusal ART restorations over 6.3 years; and to test the null-hypothesis that there is no difference in dentine caries lesion development in sealant extension to ART restorations in comparison with sealant free extensions to amalgam restorations in occlusal surfaces over 6.3 years.

Materials and Methods: In a parallel group design, 318 and 254 grade 2 children were randomly assigned to the ART and amalgam group respectively. Eight dentists placed 925 evaluatable single- and multiple-surfaces restorations. A total of 424 sealed extensions to occlusal ART and 284 sealant free extensions to occlusal amalgam restorations were available for analyses. The modified actuarial method was used to estimate survival percentages. The jackknife method was applied to calculate the SE in the cumulative survival percentages.

Results: After 6.3 years, 11.2% (SE = 2.2%) of sealant extensions were fully retained and 16.7% (SE = 2.8%) were partially retained. After 6.3 years, 86.4% (SE = 2.2%) of the sealed pits and fissures adjacent to occlusal ART restorations and 89.9% (SE = 2.4%) of non-sealed pits and fissures adjacent to occlusal amalgam restorations were free of dentine caries lesions. Neither this difference nor those at earlier evaluation years were statistically significant ($p > 0.05$).

Conclusion: Sealing pits and fissures adjacent to occlusal ART restorations did not result in a caries preventive benefit over non-sealed pits and fissures adjacent to occlusal amalgam restorations in this group of children over 6.3 years.

Key words: amalgam, atraumatic restorative treatment, glass-ionomer, sealant extension, survival

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At the beginning of the investigations into the effectiveness of the atraumatic restorative treatment (ART) approach, only the cavitated dentine lesion was restored with a glass-ionomer. In the course of these investigations, it was suggested not only to restore the cavity but also to seal adjacent pits and fissures in

order to prevent caries lesion development on that part of the tooth surface (Frencken et al, 1996). The top layer of glass-ionomer is then placed over the cavity opening and the pits and fissures and pushed into place under pressure of a petroleum jelly coated finger. The fissure penetration depth of the so-called 'press-finger technique' has been reported to be very good in in-vitro studies (Smales et al, 1997; Beiruti et al, 2006). The press-finger technique is also used to place ART sealants. The retention of ART sealants using high-viscosity glass-ionomers over time appears to be higher than that of commonly used low-viscosity glass-ionomer sealants (Weerheijm et al, 1996; Frencken and Holmgren, 2004).

The retention and caries preventive effect of sealing pits and fissures adjacent to ART restorations have not been evaluated on a long-term basis (Ho et al, 1999; Mickenautsch et al, 1999; Ziraps and Honkala, 2002;

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Gao et al, 2003; Loh, 2003). In only one short-term study the caries preventive effect of fissure sealants adjacent to ART restorations were compared with non-sealed fissures alongside amalgam restorations (Rahimtoola and van Amerongen, 2002).

Recently, survival analyses of a 6.3-year-long comparative study between single-surface ART and amalgam restorations have been completed (Frencken et al, 2006). Secondary analyses included the investigation into the effectiveness of sealing pits and fissures adjacent to occlusal ART restorations. The purpose of the study was: 1) to estimate the survival of retention of sealant extension to occlusal ART restorations over 6.3 years; and 2) to test the null-hypothesis that there is no difference in dentine caries lesion development in sealant extension to ART restorations in comparison with sealant free extensions to amalgam restorations in occlusal surfaces over 6.3 years.

MATERIALS AND METHODS

Sampling procedure

Ethical clearance for conducting the study was obtained from both the Ministry of Health and Ministry of Education of Syria. Parental consent was obtained in writing and collected through the school authorities. A convenience sample of grade 2 pupils, with an age range of 6–9 years, was taken from 49 schools situated in the vicinity of the World Health Organization (WHO) Regional Centre in Damascus. Three calibrated examiners diagnosed dental caries. The prevalence of dental caries in permanent teeth of the children examined was 57.6%. The mean DMFS and DMFT scores were 1.6 (SD = 1.5) and 1.4 (SD = 1.3) respectively.

The inclusion criteria for a child to enter the randomised clinical restoration comparative trial were the presence of a dentinal lesion in one or more permanent teeth that had an opening wide enough for the smallest excavator to enter ($\varnothing = 0.9$ mm) without suspected pulp involvement. There was no inclusion criteria set for the actual size of the cavity.

Treatment procedure

Eight dentists, assisted by a chairside assistant, conducted this randomised clinical trial in the well-equipped clinical department of the WHO Regional Centre during October–December 1997. Prior to being treated, all children attended group oral health education sessions and were taught individually how best

to clean their teeth with fluoridated toothpaste by experienced oral health educators.

The conventional treatment procedure consisted of removing caries using the drill followed by restoring the cavity with Avalloy® (Cavex, Haarlem, The Netherlands), a powder/liquid non-gamma 2-trituated amalgam. Cavities were prepared without using the 'extension for prevention' concept but retention niches were created. Metal bands and wedges were placed for restoring class II cavities. Isolation and washing/drying of teeth was achieved using cotton wool rolls and through the use of suction and three-way syringe systems. This procedure was termed 'minimal traditional approach' (TA). The ART approach consisted of opening the cavity with a dental hatchet, removing soft carious tooth tissues with an excavator and filling the cavity and the adjacent pits and fissures with a glass-ionomer. Two brands of glass-ionomers were used: Fuji IX® (GC Europe, Leuven, Belgium) and KetacMolar® (3M/ESPE, Seefeld, Germany), both in a hand-mix formula. The chairside assistant mixed the glass-ionomers according to the manufacturers' instructions. A wet cotton wool pellet, dipped in a drop of polyacrylic acid, was used for conditioning the cavity and adjacent pits and fissures for 10–15 seconds. Before glass-ionomer was inserted, the conditioner was washed away with wet cotton wool pellets and the tooth surfaces were dried with dry cotton wool pellets. Moisture isolation was achieved using cotton wool rolls and cavities were washed and dried through the use of cotton wool pellets. Excess material was removed using an applier/carver instrument and the restoration was coated with a layer of petroleum jelly (Frencken et al, 1996). Multiple-surface cavities were filled after placement of plastic bands and wedges. Local anaesthesia was rarely administered.

All 8 dentists had participated previously in a related clinical trial studying the survival of ART and amalgam restorations in deciduous dentitions (Taifour et al, 2002). They had ample experience in applying the ART approach. The TA procedure was known and practised by all dentists routinely.

All eligible pupils were randomly assigned to one of the treatments (ART or TA) using a gender-stratified class list by the principal investigator (DT).

Evaluation

The actual coverage of the pits and fissures with sealant material adjacent to ART restorations was not recorded at baseline. The evaluation was based on the 'intention to treat' concept, which means that it was as-

Table 1 Caries diagnostic classifications used in the present study

Score	Lesion description
0	Sound surface
1	Early enamel lesion. Whiten /opaque or brownish/dark lesion in enamel only, including loss of tooth surface; considered being active or inactive
2	Carious lesion involving the dentine slightly; lesion cannot be penetrated with smallest excavator
3	Dentinal lesion; lesion can be penetrated with smallest excavator
4	Dentinal lesion; pulp possibly or definitely exposed
5	Restoration
9	Unable to make diagnosis

Table 2 Inter-examiner consistency assessments in recording sealant retention (full/partial/absent) alongside occlusal ART restorations and in diagnosing dentine caries lesion (present/absent) in pits and fissures alongside occlusal ART and amalgam restorations over the 6.3 years

Year of evaluation	Sealant retention		Dentine caries lesion	
	Kappa	SE	Kappa	SE
1.3	1.00	0.00	1.00	0.00
3.3, 4.3 and 6.3	0.62	0.10	0.57	0.19

sumed that all relevant pits and fissures were covered with sealant material at baseline. The following sealant retention criteria were used: 0 = no pits and fissures visible; 1 = part of pits and fissures visible; 2 = all pits and fissures visible. Caries was recorded according to the criteria described in Table 1. Caries scores 2, 3 and 4 were considered failures. Visible debris and plaque were removed with the aid of an explorer. Teeth were dried using an air syringe. The examination site was well illuminated. Both caries and sealant criteria were applied to each of the three sections (mesial-central-distal) into which the occlusal surface was arbitrarily divided. Pits and fissure sites that were included in a replacement restoration (caries score = 5) were excluded from the database because of the common practice of 'extension for prevention' principle in cavity preparation amongst Syrian dentists who placed these replacement restorations.

The evaluations took place after 1.3, 2.3, 3.3, 4.3 and 6.3 years. The 5.3-year evaluation was not performed because of the war in neighbouring Iraq. The same two Syrian dentists carried out the evaluation at years 1.3 and 2.3. They were unable to participate at

the third year of evaluation. Instead, two experienced evaluators from the Netherlands replaced them. These evaluators had been calibrated with the Syrian colleagues and had participated in a related evaluation (Taifour et al, 2002). One of the two Syrian and one of the two Dutch evaluators carried out the evaluation at years 4.3 and 6.3. Evaluators were calibrated at the start of each evaluation. The evaluators were not involved in the planning and treatment provision of the trial. The inter-evaluator consistency test was based on duplicate examinations on an average of 10% of subjects per year but was not carried out at evaluation year 2.3. The results of the inter-evaluator consistency test for assessing sealant retention and diagnosing dental caries, expressed in kappa coefficients (Landis and Koch, 1977), is presented in Table 2.

Statistical methods

The data were recorded on a case report form by the principal investigator, who was not an operator, and later entered into a database at the College of Dental

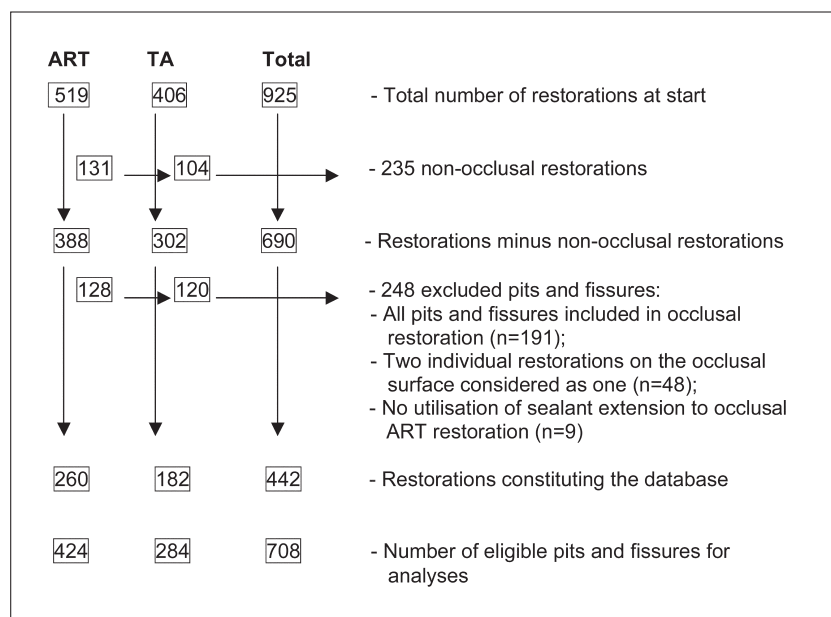


Fig 1 Flow chart of pits and fissures alongside occlusal ART and amalgam restorations eligible for analyses.

Sciences in Nijmegen. There the data were checked for mistakes, and analysed using SPSS 12.0 by an oral statistician (Mvth). Statistical analysis in this parallel group design aims to describe the survival curves of caries free pits and fissures adjacent to both occlusal ART and amalgam restorations and of fully and partially retained glass-ionomer sealants adjacent to occlusal ART restorations. The actuarial method was applied, with the modification that restorations lost to follow-up after a certain evaluation session do not count for half of the time, but for none of the time. The usual method to calculate the standard error (SE) in the cumulative survival percentages (Greenwood, 1926) is not appropriate in this situation with several sealant extensions per child. Instead, the jackknife method (leaving one patient out) (Efron, 1982) was applied to deal with the dependency of the data and to calculate the SEs for the survival percentages, so that the patient is the statistical unit while the sealant is the computational unit. The difference between the survival percentages of dentine caries lesion-free pits and fissures adjacent to ART and amalgam restorations was tested using the jackknife SEs of the differences. Statistical significance was set at $\alpha = 0.05$. As there was no statistically significant difference in survival percentages of all ART restorations between the two types of glass-ionomers (Frencken et al, 2006) observed, types of glass-ionomer was not considered a variable in the analyses.

RESULTS

Disposition of subjects and restorations

The study group consisted of 572 children, of which 275 were boys and 297 were girls, with a mean age of 7.5 years. The ART group consisted of 318 and the TA group of 254 children. The total number of restorations available for longitudinal analyses was 925 and these were divided over 519 ART and 406 amalgam restorations. The percentage of children with 1, 2 and 3 or more restorations was 59%, 27% and 14% respectively. The mean number of restorations placed per child was 1.6 (SD = 0.9).

Handling of longitudinal series of fully and partially retained sealant and dentine caries lesion development

Fig 1 shows a flow chart of the number of excluded ART and amalgam restorations from the database by reason for exclusion. Each of the 442 restorations was associated with the longitudinal evaluation series of its corresponding 3 (sub-) surfaces for the variables full and partial retention, and presence of a dentine caries lesion. These longitudinal series were mostly uniquely interpretable (no error, censored or a distinct moment of failure). In some cases an error was encountered (i.e. detection of regression of a dentine caries lesion or re-appearance of a sealant or part of it). This could

Table 3 Results (%) of handling of longitudinal evaluation series over the 6.3 years by ability to interpret recordings correctly

	Full sealant retention	Partial sealant retention	Dentine caries lesion development
Uniquely interpretable	85.9	78.7	97.6
Almost uniquely interpretable	3.0	7.4	1.0
Multi-interpretable	11.1	13.9	1.4

Table 4 Modified actuarial cumulative survival (%) and jackknife standard error (SE) of full and partially retained sealant extensions to occlusal ART restorations over the 6.3 year study period

Interval (year)	Full retention				Partial retention			
	N _{child}	N _{ext}	N _{fail}	Survival ± SE (%)	N _{child}	N _{ext}	N _{fail}	Survival ± SE (%)
0.0–1.3	208	424	207	51.2 ± 3.1	208	424	13	96.9 ± 1.1
1.3–2.3	114	186	85	27.8 ± 2.7	173	352	177	48.2 ± 3.1
2.3–3.3	68	93	23	20.9 ± 2.4	100	160	39	36.4 ± 3.0
3.3–4.3	44	54	14	15.5 ± 2.3	64	93	25	26.7 ± 2.9
5.3–6.3	24	29	8	11.2 ± 2.2	36	51	19	16.7 ± 2.8

N_{ext}, number of extensions at entry of interval

N_{fail}, number of failures at end of interval

N_{child}, number of children at entry of interval

be repaired if a failed recording was followed up at least twice by a sound recording (almost uniquely interpretable). In some of the series no distinct moment of failure could be specified (multi-interpretable) and the moment of failure was chosen in the middle of the range of possible moments by consensus of 2 investigators (JF and MvTH). The results of the handling of the longitudinal data are presented in Table 3. The large majority of longitudinal evaluation series for the three variables studied were (almost) uniquely interpretable. A total of 424 sealed occlusal extensions to ART and 284 sealant free extensions to occlusal amalgam restorations were available for analyses (Fig 1). There were 96 occlusal ART restorations with one extension and 164 occlusal ART restorations with two extensions, whereas one extension was observed alongside 80 occlusal amalgam restorations and two extensions alongside 102 occlusal amalgam restorations.

Survival of fully and partially retained sealants

The modified actuarial cumulative survival results and jackknife standard error (SE) of fully and partially re-

tained sealant extensions to occlusal ART restorations over the 6.3 year study period is presented in Table 4. After 6.3 years, 11.2% (SE = 2.2%) of sealant extensions were fully retained and 16.7% (SE = 2.8%) were partially retained.

Comparison of dentine caries lesion development

The modified actuarial cumulative survival results and jackknifes SE of dentine caries lesion-free extensions adjacent to occlusal restorations produced through the ART and traditional amalgam approach over the 6.3-year study period are presented in Table 5. After 6.3 years, 86.4% (SE = 2.2%) of the sealed pits and fissures adjacent to occlusal ART restorations and 89.9% (SE = 2.4%) of non-sealed pits and fissures adjacent to occlusal amalgam restorations were free of dentine caries lesions. Neither this difference nor those at earlier evaluation years were statistically significant ($p > 0.05$). The null-hypothesis is accepted.

Table 5 Modified actuarial cumulative survival (%) and jackknife standard error (SE) of dentine caries lesion-free extensions adjacent to occlusal restorations produced through the ART and traditional amalgam approach over the 6.3 year study period

Interval (year)	ART approach				Traditional amalgam approach				p-value ^a
	N _{child}	N _{ext}	N _{caries}	Survival ± SE (%)	N _{child}	N _{ext}	N _{caries}	Survival ± SE (%)	
0.0–1.3	208	424	9	97.9 ± 0.9	143	284	6	97.9 ± 0.9	0.99
1.3–2.3	173	356	13	94.3 ± 1.4	125	239	6	95.4 ± 1.4	0.57
2.3–3.3	155	309	7	92.1 ± 1.7	109	205	5	93.1 ± 1.8	0.70
3.3–4.3	126	245	7	89.5 ± 2.0	84	150	3	91.2 ± 2.0	0.54
5.3–6.3	73	143	5	86.4 ± 2.2	41	70	1	89.9 ± 2.4	0.28

N_{ext}, number of extensions at entry of interval
N_{caries}, number of dentine caries lesion extensions at end of interval
N_{child}, number of children at entry of interval
^a p-value for the difference between dentine caries lesion free pits and fissures adjacent to occlusal ART and amalgam restorations

DISCUSSION

All possible efforts were exercised to trace the participating children at the evaluation periods. However, a large number of children had left the primary school for an intermediate school during evaluation interval 4.3–6.3 years, and some had left the city. This resulted in a substantial reduction of eligible pits and fissures during the last two evaluation intervals.

Re-restorations were not included in the database for the following reasons. A number of teeth were evaluated with a re-restoration for the first time after a number of years. It was not known if the replacement restoration was placed because of caries development in the pits and fissures or because of a faulty restoration. Non-study operators who may have extended the original restoration replaced faulty restorations and we were unable to determine if the included pits and fissures were decayed or if the operator applied the 'extension for prevention' concept that is very common in Syria.

In long-term clinical trials such as the present study, incomplete series of longitudinal data occur. The analyst has to handle this situation in a logical manner but cannot always determine the exact moment of failure, thus introducing a possible error. Handling of longitudinal data, including possible errors, are rarely presented and discussed in the dental literature. In the present study it happened that imputation was quite possible, resulting in a high level of accuracy of the longitudinal series, particularly for dentine lesions.

The survival percentages in this parallel group study design were analysed at surface level. This assumes

independence of the survival percentages of children. The jackknife method was applied to deal with the dependency of sealant and dentine lesion outcomes and resulted in higher SE values than those calculated through the commonly used Greenwood (1926) method.

The cumulative survival results of fully and partially retained sealant extensions to occlusal ART restorations were not very high after 6.3 years. In a comparable age group, a success rate for fully and partially retained sealants adjacent to occlusal ART restorations of 73.5% was reported after 4 years (Loh, 2003). Similar high survival rates (71.2%) for these conditions were reported in a slightly higher age group (7–14 years) after 2 years (Ziraps and Honkala, 2002). The success rate for fully and partially retained sealants adjacent to ART restorations in adults was 65.5% after 2 years (Ho et al, 1999). In contrast, Rahimtoola and van Amerongen (2002) reported a full retention of sealants adjacent to Class I ART restorations of only 5.4% after 2 years. There appear to be large variations in survival results of fully and partially retained sealants adjacent to occlusal ART restorations. All referred studies used the same high-viscous glass-ionomer (Fuji IX[®]); one study (Ziraps and Honkala, 2002) used a second high-viscous glass-ionomer (ChemFlex[®]) and one study (Ho et al, 1999), a medium-viscous glass-ionomer (ChemFil Superior[®]). The survival results of ART restorations in the cited and present studies hardly differed after 2 and 4 years; the survival results of ART restorations in the present study being lowest. A reason for the variation in survival results is currently not apparent. A study into de-

terminants of sealant retention adjacent to ART restorations, such as pits and fissure depth and quality of the glass-ionomer mixture, would assist in providing useful information on this issue.

Retention of sealants is considered a surrogate endpoint (Frencken and Holmgren, 2004); the outcome variable should be its caries preventive effect. There was no statistically significant difference observed in dentine caries lesion development between sealed extensions to occlusal ART and non-sealed extensions to occlusal amalgam restorations in the present study. This finding was also reported in the only other comparable study after 2 years (Rahimtoola and van Amerongen, 2002). There was a higher percentage of dentine caries lesions (13.6%) diagnosed in sealed pits and fissures adjacent to occlusal ART restorations in the present study after 6.3 years than in previous studies; 0.3% after 2 years (Rahimtoola and van Amerongen, 2002), 5.3% after 2 years (Ho et al, 1999), 4% after 4 years (Loh, 2003), and no dentine caries lesion development reported after 2 years (Ziraps and Honkala, 2002) and 2.5 years (Gao et al, 2003). The level of caries risk in the study subjects will undoubtedly have played a significant role in the different findings reported. The children in the present study were considered to belong to a caries high-risk group (mean DMFT score = 5.5 at 13.8 years) compared with the children in the Pakistan study (mean DMFT score = 3.2 at 11.4 years) (Rahimtoola and van Amerongen, 2002) and those of the Malaysian study (mean DMFT score = 0.24 at 8.2 years) (Loh, 2003). There were no DMFT scores presented in the two other studies that investigated the caries preventive effect of sealed versus non-sealed extensions to ART restorations (Ziraps and Honkala, 2002; Gao et al, 2003). We have no explanation why there was no difference observed in dentine caries lesion development between the sealed and non-sealed extension to ART and amalgam restorations respectively in the present study.

We conclude that sealing pits and fissures adjacent to occlusal ART restorations did not result in a caries preventive benefit over comparable non-sealed pits and fissures adjacent to occlusal amalgam restorations in this group of children over 6.3 years.

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