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## 3-year survival rates of retained composite resin and ART sealants using two assessment criteria

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**Abstract:** The aim was to test the null-hypothesis that there is no difference in the cumulative survival rate of retained composite resin (CR) sealants and a high-viscosity glass-ionomer Atraumatic Restorative Treatment (ART) sealant in first permanent molars calculated according to the traditional and the modified retention assessment criteria over a period of 3 years. This cluster-randomized controlled clinical trial consisted of 123 schoolchildren, 6–7-years-old. At baseline, high-caries risk pits and fissures of fully erupted first permanent molars were treated with CR and ART sealants. Evaluations were performed after 0.5, 1, 2 and 3 years. Retention was scored for free-smooth surface and for each of three sections into which the occlusal surface had been divided. The modified criterion differed from the traditional in that it determined an occlusal sealant to be a failure when at least one section contained no visible sealant material. Data were analysed according to the PHREG model with frailty correction, Wald-test, ANOVA and t-test, using the Jackknife procedure. The cumulative survival rates for retained CR and ART sealants in free-smooth and occlusal surfaces for both criteria were not statistically significantly different over the 3 years. A higher percentage of retained CR sealants on occlusal surfaces was observed at longer evaluations. Cumulative survival rates were statistically significantly lower for the modified criterion in comparison to the traditional. The modified retention assessment criterion should be used in future sealant-retention studies.

**Keywords:** Pit and Fissure Sealants; Dental Caries; Dental Atraumatic Restorative Treatment; Pediatric Dentistry.

### Introduction

Dental carious lesions predominantly occur in pits and fissures of occlusal surfaces in recently erupted molars.<sup>1,2</sup> Placing sealants on occlusal surfaces of permanent molars is an effective method for preventing and controlling carious lesion development in pits and fissures.<sup>3</sup> Currently, the main materials used for sealing pits and fissures are resin- and glass-ionomer-based.<sup>4,5</sup> Retention of sealants is considered a surrogate endpoint for determining the caries-preventive effectiveness of sealants since it is believed that loss of retention would determine sealant failure. However, obtaining a real clinical endpoint by comparing sealed and



non-sealed surfaces is difficult for ethical reasons, since the effectiveness of sealants for high-caries risk populations has already been established.<sup>5,6</sup>

Resin-based sealants usually present higher retention rates than glass-ionomer (GIC) based sealants.<sup>6</sup> Despite differences in their retention, systematic reviews have reported no evidence of caries-preventive superiority of either material.<sup>3,4,7,8</sup> In the past, low- and medium-viscosity glass-ionomers were used as sealant material but these have been replaced by high-viscosity glass-ionomers, as the latter have increased mechanical properties, which have enhanced sealant retention.<sup>9</sup> Retention of high-viscosity glass-ionomers may further be increased through the development of new formulas in the glass-ionomer technology, such as has been reported regarding its powder composition.<sup>10</sup>

In calculating survival of sealants' retention, the traditional criterion considers a sealant a failure if all material has disappeared from the total sealed tooth surface. However, this criterion is questioned since absence of material in just a section of the occlusal surface re-exposes that section to the oral environment, which increases the chance that a new carious lesion is initiated or that an existing one progresses. This has led Chen et al.<sup>11</sup> to suggest a new way of determining sealant retention. The so called: 'modified' retention criterion fails a sealant for its retention on the occlusal surface when only one section is re-exposed. Only a few studies have investigated the effect of the modified retention criterion on carious lesion development and, consequently, the need for resealing re-exposed pits and fissures.<sup>11,12</sup>

In 2009, a cluster-randomized clinical trial was undertaken to compare the effectiveness of three treatment protocols among primary school going children.<sup>13</sup> Investigating the caries-preventive effect on permanent first molars of a supervised tooth brushing (STB) programme, a composite resin (CR) sealant and a newly formulated high-viscosity glass-ionomer sealant applied with finger pressure (Atraumatic Restorative Treatment or ART sealant) were part of the trial.<sup>14</sup> The study provided the opportunity to test the following null-hypothesis: there is no difference in the cumulative survival rate of retained CR and newly formulated high-viscosity

glass-ionomer cement ART sealants in permanent molars calculated according to the traditional and the modified retention assessment criteria over a period of 3 years. Furthermore, secondary analyses tested whether or not the level of sealant retention is related to the prevalence of cavitated dentine carious lesions over a period of 3 years.

## Methodology

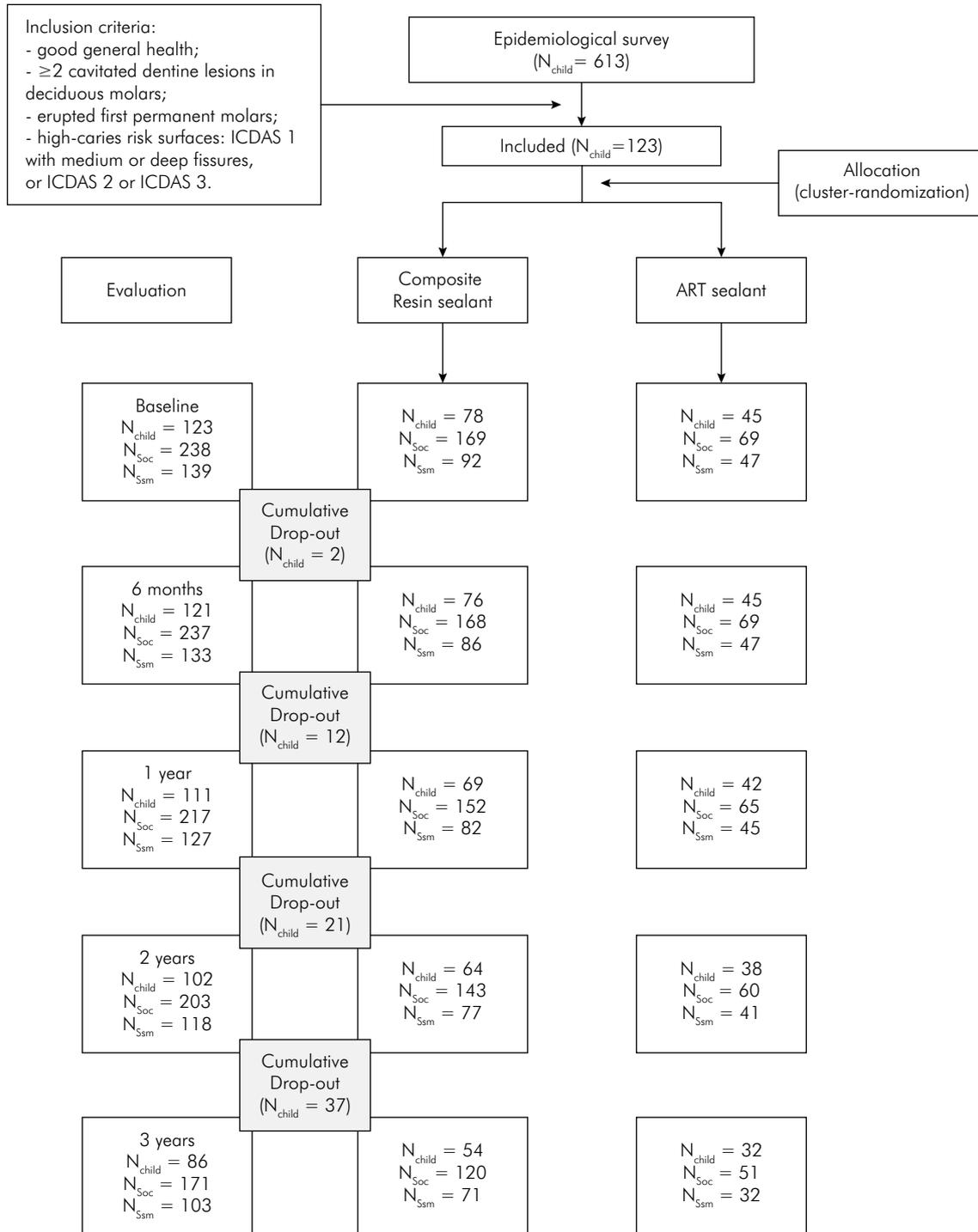
### Sampling procedure

The reporting of the study is based on the CONSORT Statement.<sup>15</sup>

This equivalence cluster-randomized controlled clinical trial used a parallel group design. It was carried out in four public primary schools of Paranoá, a deprived suburban area of Brasilia, Brazil. The sample of this study was obtained from an oral health epidemiological survey among 6- and 7-year-old children attending all the schools in this area.<sup>16</sup> The inclusion criteria were: a. good general health; b. at least two cavitated dentine carious lesions in vital pain-free primary molars assessed according to the ICDAS II index;<sup>17</sup> c. erupted first permanent molars with pits and fissures fully visible and accessible; d. high-caries risk surfaces, determined by ICDAS II codes 2 and 3 or a combination of ICDAS II code 1 and medium or deep fissures assessed according to the Symons criteria;<sup>18</sup> and e. having a signed consent form.

The study covered two groups to treat high-caries risk surfaces of first permanent molars. These were: CR sealants and ART sealants. The sampling unit was the school (two schools per cluster). Two of the schools were equipped with a dental unit and were allocated to the CR sealants group. The other two schools (ART group) were allocated by coin toss. A CONSORT flowchart that depicts the study design is presented in Figure 1.

The trial was approved by the Research Ethics Committee of the University of Brasilia Medical School (reference number 081/2008) and was registered at The Netherlands Trial Register (reference number 1699). Parents and/or carers were informed in writing about the investigation and were asked to sign a consent form that authorized their children to participate.



**Figure 1.** Consort flowchart. ( $N_{child}$ =Number of children;  $N_{Soc}$ : number of occlusal surfaces;  $N_{Ssm}$ : number of smooth surfaces; ART: atraumatic restorative treatment). Reasons for dropouts were: moving to another city and irregular school attendance.

### Implementation

Sealants were placed by three trained and calibrated paedodontists, aided by trained dental assistants, between May and July 2009 at the school premises.

Children received an oral hygiene kit (toothbrush, fluoridated dentifrice, plaque-disclosing dentifrice and dental floss) and instructions on how to use its content at the start of the study. These instructions

were repeated during the evaluation sessions. Children were encouraged to brush twice daily.

### Composite resin sealant group (CR)

Children were positioned in a dental chair. Isolation was obtained with cotton wool rolls and a suction device. Under good visibility from the operation lamp, the surface to be treated was cleaned with a rotating brush, acid-etched for 30 s with a 37% phosphoric acid gel (Acigel, SSWhite, Rio de Janeiro, Brazil), rinsed and dried, using a 3-way syringe. The sealant material, Fluoroshield (Dentsply, Petrópolis, Brazil), was placed in a dappen glass, transported to pits and fissures with a ball-ended probe (Duflex, Rio de Janeiro, Brazil) and light-cured for 40 s (Ultralux, Dabi Atlante, Ribeirão Preto, Brazil). Occlusion was checked with carbon paper and adjusted where necessary with rotary instruments.

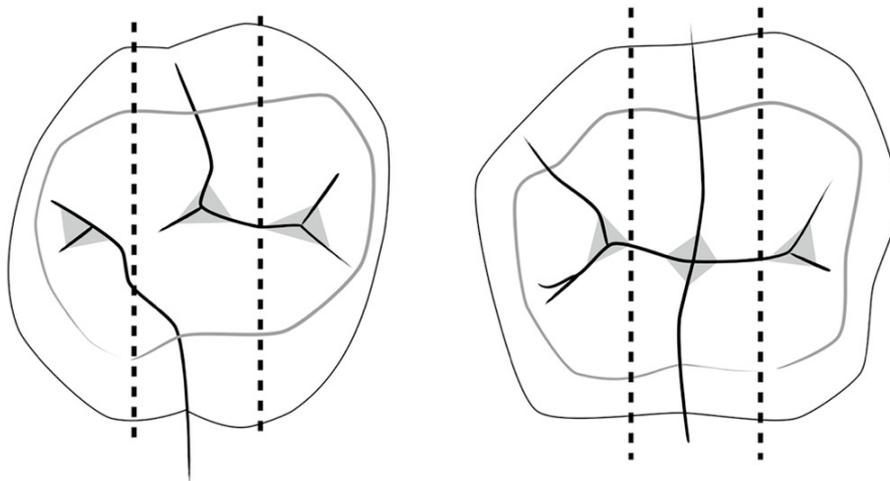
### High-viscosity glass-ionomer ART sealant group (ART)

Pits and fissures were cleaned with a toothbrush and toothpaste before the children lay on a portable bed. Isolation was obtained using cotton wool rolls. The occlusal surface was further cleaned with a dental probe and cotton wool pellets under artificial light provided by a portable headlamp. The surface was

conditioned with polyacrylic acid for 10–15 s, washed with wet cotton wool pellets and dried with dry cotton wool pellets. Ketac Molar EasyMix (3M ESPE, Seefeld, Germany) was hand-mixed according to the manufacturer's instructions, applied on the surface with an ART applicator instrument (Henry Schein, Chicago, USA) and pressed into the pits and fissures with a petroleum jelly-coated finger for 15 s.<sup>19</sup> Excess material was removed with the ART carving instrument after the occlusion was checked with carbon paper. The sealant was coated with petroleum jelly and the children were told not to eat for 1 hour.

### Evaluation

For evaluating sealant retention and carious lesion development, the occlusal surfaces of the first permanent molars were divided into three sections (mesial-central-distal) (Figure 2) but the free-smooth surfaces were not. Each of these sections and free-smooth surfaces were assessed for the presence of carious lesions using ICDAS II. Retention was scored according to the codes: 0 (a sealant is present, good seal in the main pits and fissures initially sealed); 1 (partial loss of sealant that exposes the main pits and fissures); or 6 (no sealant is visible, main pits and fissures are completely exposed). The same



**Figure 2.** Schematic illustration of the division of the occlusal surfaces of first permanent molars into three sections. Each section was separately assessed for retention of sealants.

two independent evaluators (dentists) performed the evaluations at the school premises after 6 months, 1, 2 and 3 years.

The evaluators were trained and calibrated before each evaluation session by an experienced dental epidemiologist (JF). Battery-illuminated dental mirrors (Kudos®, Hong Kong, China), CPITN probe (Golgran®, São Caetano do Sul, Brazil) and compressed air aided the evaluation. A total of 67 surfaces were re-examined for reproducibility testing. The kappa coefficient value for the inter-evaluator consistency test in assessing retention over the four evaluation times was 0.77 while the percentage of agreement was 86.6%.

### Statistical analyses

The sample for this investigation was obtained from a main study that investigated the effectiveness of protocols for treating dentine carious lesions in primary teeth.<sup>13</sup> Focusing on the carious-lesion preventive effect of CR (79%) and ART (94%) sealants after 5 years,<sup>20</sup> a power of 80%, a dropout rate of 30% and a correction for dependency of measurements of 20% gave a sample size of 117 sealants per group.

The statistical analyses were performed by a biostatistician using SAS version 9.2 software (Cary, NC, USA). The dependent variables were survival rate of retained sealants calculated according to the traditional and the modified retention criteria:

- Traditional criterion:* a failure is determined by the total loss of sealant material on the entire surface (code 6). For the occlusal surface, all three sections should present a code 6 for the surface to be considered a failure.
- Modified criterion:* a failure is determined when at least one section of an occlusal surface presents no visible sealant material (code 6).

Treatment group (CR, ART), age, gender, type of jaw, operator and baseline caries experience ( $D_2$ MFT,  $D_3$ MFT and  $d_3$ mft) were the independent variables.  $D_2$  represents ICDAS II codes 1-6 and  $D_3/d_3$  represents ICDAS II codes 4-6. ANOVA and chi-square tests were used in testing for differences between the independent variables at baseline and the treatment groups, and for the non-response analysis. The Proportional Hazard Rate Regression

model (PHREG)<sup>21</sup> with frailty correction<sup>22</sup> was used to estimate cumulative survival retention rates. The Wald test (chi-square) was used to test for differences in survival rates and for estimating effects of the independent variables. The Jackknife method<sup>23</sup> was applied in calculating standard errors for comparison of survival rates between treatment groups per interval using a t-test. Statistical significance was set at  $\alpha = 0.05$ .

## Results

### Disposition of subjects

A total of 123 children (62 boys, 61 girls) with a mean age of 6.8 years were enrolled in the study. At baseline, 238 occlusal surfaces and 139 free-smooth surfaces in first permanent molars of these children met the inclusion criteria. Mean age, mean  $d_3$ mft,  $D_2$ MFT and  $D_3$ MFT counts of the participating children according to treatment group are presented in Table 1. A statistically significant difference at baseline between the treatment groups was found for age. Children in the ART sealant group were approximately two months older than children of the CR sealant group. From the 377 sealed surfaces at baseline, 274 surfaces (72.7%) were examined after 3 years and almost 30% of the sample was lost to follow-up during that period (Figure 1). Non-response analyses revealed no effect for treatment group ( $p = 1.00$ ), age ( $p = 0.88$ ), gender ( $p = 0.85$ ), baseline  $d_3$ mft ( $p = 0.78$ ), baseline  $D_2$ MFT ( $p = 0.16$ ) and baseline  $D_3$ MFT ( $p = 0.38$ ) counts.

**Table 1.** Mean and standard deviations (SD) of age,  $D_2$ MFT,  $D_3$ MFT and  $d_3$ mft counts of participating children at baseline according to treatment group.

Variable	CR sealant		ART sealant	
	(N <sub>child</sub> = 78)		(N <sub>child</sub> = 45)	
	Mean	SD	Mean	SD
Age	6.72	0.33	6.88	0.33
$D_2$ MFT	3.33	1.04	3.00	1.19
$D_3$ MFT	0.26	0.55	0.33	0.56
$d_3$ mft	5.86	3.08	5.80	2.33

Nchild: number of children; CR: composite resin; ART: atraumatic restorative treatment. Age,  $p < 0.01$ ;  $D_2$ MFT,  $p = 0.11$ ;  $D_3$ MFT,  $p = 0.46$ ;  $d_3$ mft,  $p = 0.90$ .

### Cumulative retention of sealants

Frequency distributions of fully and partially retained and fully lost sealants for occlusal and free-smooth surfaces over the 3-year follow-up period by treatment group are presented in Table 2. The prevalence of fully retained sealants in occlusal surfaces after 3 years was low: 15.8% for CR and 7.8% for ART sealants. The percentages of fully retained sealants in free-smooth surfaces after 3 years were 49.3 for CR and 43.8 for ART sealants.

The cumulative survival rates of the two types of sealants retained in occlusal and free-smooth surfaces over 3 years using the traditional retention criterion are presented in Table 3. For occlusal surfaces, there

was no statistically significant difference between survival rates of retained CR and ART sealants over the total 3-year follow-up period ( $p = 0.05$ ). However, a statistically significant difference was observed at the 1y, 2y and 3y evaluation intervals, which showed a higher retention survival rate for CR sealants. For the cumulative survival rates of retained sealants on free-smooth surfaces, no statistically significant difference was observed between the treatment groups over the 3-year period ( $p = 0.34$ ) nor at any evaluation interval.

The influence of independent variables on the survival model for retained occlusal sealants using the traditional retention criterion showed the

**Table 2.** Frequency distributions of fully and partially retained and fully lost sealants for occlusal and free-smooth surfaces according to treatment group and interval.

Interval	CR sealant						ART sealant					
	Fully retained		Partially retained		Fully lost		Fully retained		Partially retained		Fully lost	
yrs	N <sub>Soc</sub>	%	N <sub>Soc</sub>	%	N <sub>Soc</sub>	%	N <sub>Soc</sub>	%	N <sub>Soc</sub>	%	N <sub>Soc</sub>	%
Occlusal surfaces												
0.5	140	83.3	25	14.9	3	1.8	53	76.8	13	18.8	3	4.4
1	89	58.6	51	33.6	12	7.9	32	49.2	21	32.3	12	18.5
2	50	35.0	67	46.9	26	25.2	12	20.0	32	53.3	16	26.7
3	19	15.8	62	51.7	39	32.5	4	7.8	24	47.1	23	45.1
Free-smooth surfaces												
0.5	77	89.5	6	7.0	3	3.5	40	85.1	5	10.6	2	4.2
1	67	81.7	5	6.1	10	12.2	33	73.3	4	8.9	8	17.8
2	55	71.4	4	5.2	18	23.4	22	53.6	4	9.8	15	36.6
3	35	49.3	6	8.5	30	42.3	14	43.8	2	6.3	16	50.0

NSoc: number of occlusal surfaces; NSsm: number of free-smooth surfaces; CR: composite resin; ART: atraumatic restorative treatment.

**Table 3.** Cumulative survival rates (%) and standard errors (SE) of fully and partially retained sealants calculated according to the traditional criterion in occlusal and free-smooth surfaces over a period of 3 years.

Variable	Occlusal surfaces				Free-smooth surfaces			
	CR sealant		ART sealant		CR sealant		ART sealant	
Interval	%	SE	%	SE	%	SE	%	SE
0.5y	98.2	1.0	95.7	2.4	96.5	1.9	95.7	3.1
1y	91.6 <sup>a</sup>	2.4	82.2 <sup>b</sup>	5.5	88.0	3.6	82.4	5.7
2y	80.6 <sup>c</sup>	4.0	67.7 <sup>d</sup>	6.5	77.5	4.9	64.9	7.8
3y	66.3 <sup>e</sup>	4.9	50.8 <sup>f</sup>	8.0	56.3	6.7	49.5	9.2

CR: composite resin; ART: atraumatic restorative treatment. Occlusal surfaces: Over 3y survival model,  $p = 0.05$ ; <sup>a-b</sup>,  $p = 0.03$ ; <sup>c-d</sup>,  $p = 0.02$ ; <sup>e-f</sup>,  $p = 0.02$ ; Free-smooth surfaces: Over 3y survival model,  $p = 0.34$ .

following findings: no effects of gender ( $p = 0.61$ ), baseline  $d_3\text{mft}$  ( $p = 0.47$ ), baseline  $D_2\text{MFT}$  ( $p = 0.07$ ), baseline  $D_3\text{MFT}$  ( $p = 0.41$ ) counts, type of jaw ( $p = 0.97$ ), operator ( $p = 0.14$ ) or age ( $p = 0.76$ ) were found. For free-smooth surfaces, no effects of baseline  $d_3\text{mft}$  ( $p = 0.60$ ), baseline  $D_2\text{MFT}$  ( $p = 0.83$ ), baseline  $D_3\text{MFT}$  ( $p = 0.28$ ) counts, type of jaw ( $p = 0.09$ ) or operator ( $p = 0.48$ ) were found. A statistically significant effect of gender ( $p = 0.02$ ) and age ( $p = 0.04$ ) was observed for these surfaces. Boys presented higher retention rates than girls and they were slightly younger than the girls. In an adjusted retention survival model, including the variables gender, age and treatment group, no effects of treatment group ( $p = 0.77$ ), age ( $p = 0.07$ ) and gender ( $p = 0.05$ ) were found.

The cumulative survival rates of both types of sealants retained in occlusal surfaces over the 3-year period according to the modified retention criterion are presented in Table 4. For occlusal surfaces, no statistically significant difference between cumulative survival rates of retained CR and ART sealants over the total 3-year follow-up period ( $p = 0.05$ ) was observed. A statistically significant difference was observed at the 2y and 3y evaluation intervals, showing a higher survival rate for CR than for ART sealants. Analyses of the influence of independent variables on the survival model for occlusal sealant retention using the modified retention criterion showed no effects of gender ( $p = 0.70$ ), baseline  $d_3\text{mft}$  ( $p = 0.07$ ) and baseline  $D_2\text{MFT}$  counts ( $p = 0.09$ ) or age ( $p = 0.87$ ). Statistically significant effects were found for

operator ( $p = 0.01$ ), type of jaw ( $p = 0.04$ ) and baseline  $D_3\text{MFT}$  counts ( $p = 0.04$ ). One of the operators performed a higher number of CR sealants than the other two. For CR sealants, the retention rate in first molars of the lower jaw was higher than in those of the upper jaw ( $p < 0.01$ ). Type of jaw had no effect on the retention rate of ART sealants ( $p = 0.28$ ). The adjusted retention survival model, including operator, type of jaw, baseline  $D_3\text{MFT}$  count and treatment group, showed no effect of treatment group ( $p = 0.22$ ) and baseline  $D_3\text{MFT}$  count ( $p = 0.15$ ). Operator ( $p = 0.03$ ) and type of jaw ( $p = 0.03$ ) still presented a significant effect.

For both the CR and ART sealants, the survival model presented lower retention rates with the use of the modified retention criterion than with the traditional retention criterion over the 3-year period ( $p < 0.01$ ).

### Loss of sealant retention and cavitated dentine carious lesion development in occlusal surfaces

Table 5 presents the cumulative survival rate of cavitated dentine carious lesion-free occlusal surfaces by evaluation interval,<sup>14</sup> the frequency distribution of the location of the cavitated dentine carious lesions and the number of surfaces having a retention failure according to the traditional and the modified retention criterion at the time that those carious lesions were detected.

Of the 18 cavitated dentine carious lesions that were detected (12 in the CR sealant group and 6 in the ART sealant group), 15 (83.3%) were located on the distal section of the occlusal surface. Eight cavitated dentine carious lesions occurred in lower first permanent molars and 10 such lesions in comparable teeth in the upper jaw. According to the traditional retention criterion, 8 of the 18 cavitated dentine carious lesions in occlusal surfaces (44.4%) were found on surfaces that had been determined as 'failed' for retention at the time that the carious lesion had been detected, while 14 of the 18 cavitated dentine carious lesions in occlusal surfaces (77.8%) occurred on 'failed' retention surfaces when the modified retention criterion was applied.

**Table 4.** Cumulative survival rates (%) and standard errors (SE) of fully and partially retained sealants calculated according to the modified criterion in occlusal surfaces over a period of 3 years.

Interval	Occlusal surface				
	CR sealant		ART sealant		
yrs	%	SE	%	SE	
0.5	91.1	2.3	85.5	5.8	
1	70.1	4.5	60.0	7.5	
2	47.6 <sup>a</sup>	5.3	29.2 <sup>b</sup>	6.1	
3	29.8 <sup>c</sup>	5.4	15.5 <sup>d</sup>	5.0	

CR: composite resin; ART: atraumatic restorative treatment. Over 3y survival model,  $p = 0.05$  <sup>a-b</sup>,  $p < 0.01$ ; <sup>c-d</sup>,  $p = 0.01$ .

**Table 5.** Cumulative survival of cavitated dentine carious lesion-free occlusal surfaces [% (SE)], frequency distribution of cavitated dentine carious lesion location, percentage of occlusal sections with partial or fully lost sealants and retention failures at lesion detection according to the traditional and modified retention criteria.

Variables	Interval yrs	Cumulative survival of DCav-free occlusal surfaces			NDCav <sub>new</sub>	New lesion location		% of occlusal sections with partial and fully lost sealants	Number of occlusal surfaces considered a 'retention failure' when a cavitated dentine carious lesion was assessed, according to the retention assessment criteria	
		%	SE	Tooth		Occlusal section	Traditional		Modified	
CR sealant	0.5	99.4	0.1	1	46	od	10.3	0	1	
	1	98.1	0.6	2	16	od	26.1	0	2	
					36	od				
					16	od, od				
	2	95.4	2.0	4	26	od	43.8	1	3	
					46	od				
					16	oc, od				
	3	91.4	2.9	5	26	od	63.6	3	3	
					36	oc				
					46	od				
ART sealant	0.5	97.1	2.0	2	26	od	15.5	1	1	
	1	97.1	2.0	0	-	-	32.8	-	-	
					36	od				
	2	93.9	2.0	2	36	oc, od	56.1	2	2	
	3	90.2	5.0	2	16	od	73.8	1	2	
26					od					

DCav-free: cavitated dentine carious lesion-free surface; NDCavnew: number of new cavitated dentine carious lesions; oc: occlusal central; od: occlusal distal.

## Discussion

### Methodology

Sampling of the population of this study was based on the selection and randomization process of the main study, which compared treatment protocols in primary molars. From the included high-caries risk children, only first permanent molars that had erupted and also presented a high-caries risk profile at surface-level were sealed. Cluster-randomization by school was defined by the fact that two of the four public primary schools had a dental room with a fully equipped dental unit and these schools were allocated to the CR sealant group. However, as no dentist had been employed at these schools for many years, children from these schools had no expected advantage in terms of oral health care or knowledge over the children of the other two schools. Although socio-economic status was not assessed, there is no

reason to believe that any difference among schools and treatment groups occurred in this aspect, since all children came from the same area of social and economical deprivation.

The sample size of the two sealant groups differed. This is not unusual in clinical trials. The main reason for the difference is most likely that the school, rather than the number of children or the number of tooth surfaces that required a sealant, was chosen as the unit of randomization. The schools that had a dental unit and that, consequently, were used for placing CR sealants contained many more children than the schools in which the ART sealant was placed. But it is very unlikely that the unequal sample size caused a bias in the comparison of results of the two sealant groups. It is argued that, whilst an equal sample size provides the highest level of power, a deviation from it only reduces the power slightly, provided the sample size is not very low. For comparing survival results

between groups, the standard error, a correction for the dependency of data within a child and the number of sealants in the group with the lowest size, are important factors. In the present study, the Jackknife standard error was calculated for compensation of the dependency of data and the lowest group size was 69 and 47 sealants in occlusal and free-smooth surfaces, respectively, falling short of the requested sample size but being large enough for a comparison between groups. Although lower than anticipated, these numbers are sufficiently high to allow for a controlled comparison between the two sealant groups.

At baseline, all caries experience counts ( $d_3mft$ ,  $D_2MFT$  and  $D_3MFT$ ) were similar between treatment groups. A slight, but significant difference of age was found. Children that received ART sealants were, on average, almost two months older than children of the CR sealant group. In the retention survival models, age was a significant factor for free-smooth surfaces only. These results support the assumption that there is no reason to presume bias in the composition of the treatment groups at start. The quality of the results is further increased by the observation that there was no difference in independent variables observed between the study and the non-response groups.

Using initial signs of carious lesions and a fissure depth classification (caries risk assessment at surface-level) as criteria for sealing pits and fissures allowed for a more realistic assessment of the effectiveness of a sealant compared to a situation in which the caries risk is determined at child-level only.<sup>24,25</sup> The latter approach often includes pits and fissures that are shallow and/or deep but free of a carious lesion. Without the inclusion of an assessment of the caries situation at surface level, a true comparison between sealants of different materials is not possible. However, sealing occlusal surfaces of molar teeth without a carious lesion assessment at surface level is not uncommon in sealant studies.<sup>26,27,28</sup>

Resin-based sealants are preferably performed under rubber dam isolation. In the present study, rubber dam isolation was not used, as had been reported for many other sealant studies.<sup>20,27,29,30,31,32</sup> This deviation from the going protocol for resin-based procedures is justified since it was

shown that rubber dam does not improve the retention of resin-based sealants.<sup>33</sup>

It was possible to blind treatment for the children, as only one kind of treatment was performed at each of the schools. Operators were not blinded since the sealing protocols were different. Owing to the different clinical aspects of the CR and ART sealants, it was not possible to blind the evaluators. The statistician was blinded by not knowing the meaning of the treatment group codes. The loss-to-follow-up rates were high despite the many efforts made to trace children for examination. Considering the nature of this clinical trial, we consider its internal validity to be substantial but its external validity to be low.<sup>34</sup>

## Outcomes

### Cumulative survival of retained sealants

The null-hypothesis failed to be rejected. No differences were found in the survival rates of retained CR and the newly formulated high-viscosity glass-ionomer ART sealants in both occlusal and free-smooth surfaces in permanent molars over the total period of 3 years according to both the traditional and the modified retention criteria. This outcome is different from that usually reported in retention studies between resin-based and glass-ionomer-based sealant materials in occlusal surfaces according to the traditional retention criterion. A reason for this situation might be the use of a potentially mechanically stronger high-viscosity glass-ionomer, the different application procedure that pushes the glass-ionomer into the pits and fissures with a finger (ART) and the fact that the generally accepted difference in retention rates between the two sealant materials has been derived from comparing results from studies that were not comparable and that had applied different retention assessment criteria.<sup>6</sup> However, if a high-viscosity glass-ionomer ART sealant is compared to a CR sealant in one and the same study over time, using the same retention assessment criteria and performed in children of similar age, then a true comparison between the two types of sealant is possible. Comparing the results of such studies gives the following outcome: no significant difference at all 1- to 5-year interval periods (mean

age: 7.8 years);<sup>20</sup> higher retention survival rate for CR sealants (81%) than for ART sealants (56%) after 4 years (mean age: 8 years);<sup>12</sup> and higher retention survival rate for CR sealants (73%) than for ART sealants (50%) after 2 years (mean age: 7.8 years).<sup>29</sup> The children in the present study were one year younger than the children in the studies referred to. At that age, a difference of one year can make a difference, perhaps not so much in the retention survival rate of the high-viscosity glass-ionomer, but more likely in that of the resin-composite sealant, as the latter requires a moist-free environment, which, in general, is more difficult to obtain in on average 6.8 year olds (present study) than in on average 7.8–8 year olds.<sup>12,29</sup> Whether age, therefore, is a reason for the difference in outcomes in the comparison between the CR and ART sealants of the present study and the Liu et al.<sup>29</sup> and Zhang et al.<sup>12</sup> studies, both of which used Clinpro and Ketac Molar Easymix as sealant materials, is difficult to say. The pattern of retention survival rates between the two types of sealants in the Beiruti et al.<sup>20</sup> study is strange, with a sudden steep drop in retention survival rates between years 2 and 3, and, therefore, is left out of the comparison.

The fact that the difference between the two types of sealants over the total 3-year period in the present study was of borderline significance and that a significant difference in the cumulative retention survival rate between the two types of sealants was found at the evaluation intervals of 1, 2 and 3 years, being higher for CR sealants, should not go undiscussed. That information and the 1-year younger age of the children in the present study makes it fair to conclude that, even in true comparison studies, the cumulative retention survival rate of CR sealants is probably higher than that of high-viscosity glass-ionomer ART sealants. It appears that the newly formulated high-viscosity glass-ionomer, used in the present study, did not increase the retention survival rate sufficiently, at least, to equal that of composite resin.

The present study did not show a significant difference between the cumulative retention survival rate of CR and ART sealants in free-smooth surfaces over the total 3-year period and at any of the three time intervals. This finding is different from those reported by Zhang et al.<sup>12</sup> In that study, the cumulative retention

survival rate in free-smooth surfaces after 4 years was significantly higher in CR (81%) than in high-viscosity glass-ionomer ART sealants (57%). As very few true comparison studies have been carried out using CR and ART sealants in free-smooth surfaces, it is not possible to speculate about the difference in the study outcomes.

### Sealant retention assessment criteria

In the present study, the pattern of results obtained after using the modified retention criterion for calculating cumulative survival rates of the two types of sealants was similar to that of the traditional criterion. The main difference between the two retention assessment criteria concerned the significantly lower cumulative survival rates of retained sealants obtained when the modified retention criterion was applied. This finding was expected considering the change in the definition of 'failed' retained sealant, and it is in line with results reported after 2 years.<sup>11</sup> As the pattern of results between the two retention assessment criteria is similar and as the modified retention criterion fails a sealant earlier, would it not be better to assess sealant retention through applying the modified retention criterion instead of the traditional one, which has been used for decades? Using the former would allow the dental professional to intervene earlier by either resealing or applying other caries-preventive measures, but only if needed, if the child and/or tooth surfaces are still at a high-caries risk.

### Relationship between loss of sealant retention and cavitated dentine carious lesion

Sealant retention has been used for decades as a surrogate endpoint for determining its caries-preventive effectiveness. To what extent the retention of a sealant is a prerequisite for its preventive effect has not been reported frequently.<sup>5,35,36</sup> In the present study, 84% of the occlusal surfaces sealed with CR and 92% of those sealed according to ART were either partially or completely re-exposed after 3 years while in only approximately 9% of the sealed occlusal surfaces did a cavitated dentine carious lesion develop during the 3-year study period.<sup>14</sup> This indicates that loss of sealant material does not appear to be an indicator for the development of cavitated dentine carious lesions

in re-exposed occlusal surfaces. Furthermore, the manner in which retention survival of sealants was calculated appears to be related to the prevalence of cavitated dentine carious lesions. Using the modified retention criterion, a higher percentage of cavitated dentine carious lesions (78%) occurred in an occlusal surface that was assessed a failure compared to the traditional criterion (44%). Despite the fact that the percentage of cavitated dentine carious lesions was low, the finding suggests that the modified retention criterion is more suitable for indicating re-exposed occlusal surfaces at risk for cavitated dentine carious lesion development.

What appears to be clear from the present study is that solely using loss of sealant retention as a reason to re-seal is an over-treatment with a questionable cost-effectiveness ratio. Therefore, sealant retention can only be considered a surrogate endpoint and, perhaps, should not be considered an endpoint at all, as was advocated recently.<sup>5</sup> Another remarkable observation was that, although only occlusal surfaces in first permanent molars at high-carries risk were sealed, the level of caries risk in these molars, and perhaps in the mouth, probably became substantially lower over the study years. Whether this is due to the placement of the sealants (despite the low retention over the final evaluated intervals) or to the improved oral health habits of the children over the years is difficult to say. Notwithstanding, this observation

fosters the understanding that sealants are truly important but should be considered an interim treatment only for children with molar teeth that have a high risk for carious lesion development.

## Conclusions

Cumulative survival rates of retained CR and ART sealants for both occlusal and free-smooth surfaces were not significantly different from each other over the total follow-up period of 3 years. The modified retention criterion presented significantly lower retention rates than the traditional criterion. Despite low retention rates, survival rates of cavitated dentine carious lesion-free occlusal surfaces were high after 3 years. Using retention survival rates as a surrogate endpoint to determine sealant effectiveness is questioned.

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