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Caries-preventive effect of sealants produced with altered glass-ionomer materials, after 2 years

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ABSTRACT

Objectives. The aim of the present study was to investigate the caries-preventive effect of sealants produced with a high-viscosity glass-ionomer with an elevated powder-liquid ratio (ART), of having energy added to this glass-ionomer, and that of glass-carbomer, in comparison to that of resin composite sealants.

Methods. The randomized controlled trial covered 407 children, with a mean age of 8 years. At a school compound three dentists placed sealants in pits and fissures of high caries-risk children. Evaluation by two independent evaluators was conducted after 0.5, 1 and 2 years. The Kaplan–Meier survival method, ANOVA and t-test were used in analyzing the data.

Results. 1352 first permanent molars were sealed. 6.6% of children and 6.8% of sealants dropped out within 2 years. 27 re-exposed pits and fissures, 20 in occlusal and 7 in smooth surfaces, in 25 children, developed a dentin carious lesion. The cumulative survival of dentin carious lesion-free pits and fissures in the glass-carbomer sealant group was statistically significantly lower (97.4%) than those in the high-viscosity glass-ionomer with energy supplied (99%) and the resin-composite (98.9%) sealant groups. There was no statistically significant difference in the cumulative survival of dentin carious lesion-free pits and fissures, between the high-viscosity glass-ionomer with (99%) and without (98.3%) energy supplied sealant groups, after 2 years.

Significance. The survival of dentin carious lesion-free pits and fissures was high in all sealant types. More dentin carious lesions were observed in the glass-carbomer sealant group.

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1. Introduction

In the permanent dentition of young children, carious lesions most frequently develop in pits and fissures of 1st molars. Sealing those pits and fissures is considered the most effective way of interfering with the development of carious lesions over a long period [1]. In a well-structured oral health service system, failed sealants can be resealed and thus continue to exercise their caries-preventive action for an indefinite period [2,3]. In contrast, in low and developing market economies, where a recall system is usually unavailable, sealants, once placed, continue to function without the possibility of repair if this is needed. To ensure a high level of sealant effectiveness over long periods in such countries, a sealant material should be used that bonds to the enamel surface longer than those currently used.

Resin- and glass-ionomer-based materials are used for sealing pits and fissures. Glass-ionomer-based sealant materials have evolved from a low-viscosity type used in the seventies and eighties, to a high-viscosity type used since the mid-nineties [4,5]. Not too long ago, a high-viscosity glass-ionomer with an elevated powder-liquid ratio was marketed. This was assigned higher physical–mechanical properties, including a higher level of adhesion to enamel, than the previous ones [6]. Changing the application procedure by adding heat to the setting high-viscosity glass-ionomer through the use of a high energy curing light, was also found to increase the retention, and consequently the longevity, of sealants [7]. An additional option for a sealant material with increased retention was introduced through the marketing of a novel glass-ionomer-based material, fluorapatite-containing glass-carbomer, with powder particles reduced to nano size [8].

China is a country in transition. Its economy has increased tremendously over the last decades. Although the caries prevalence and severity in permanent dentition of young children has been relatively low and stable for decades [9,10], there are signs that caries severity is increasing in 1st molars of young children [11]. The National Association of Preventive Oral Health, recently recommended, as part of a wider program, that caries prevention in children in China should focus on the application of sealants and on self-care through plaque control with a toothbrush and fluoride-containing toothpaste.

The aim of the present study was to investigate the caries-preventive effects of high-viscosity glass-ionomer sealants with an elevated powder-liquid ratio, of having energy added to this glass-ionomer, and that of glass-carbomer, in comparison with those of resin-composite sealants. The hypotheses tested were: (1) the cumulative survival rate of caries-free pits and fissures of glass-carbomer sealants is higher than those of high-viscosity glass-ionomer sealants, with and without energy supplied, and of resin-composite, after 2 years; (2) the cumulative survival rate of caries-free pits and fissures, of high-viscosity glass-ionomer sealants with energy supplied is higher than that of high-viscosity glass-ionomer sealants without energy supplied, after 2 years.

2. Materials and methods

2.1. Study population and treatment allocation

The present study was conducted in 5 public schools in the urban area of Wuhan, the capital of Hubei province, China. Wuhan has a population of about 8 million people. The average income of its citizens increased from US$ 89.- in 1978, to US$ 2777.- in 2009.

The sample of subjects for the present investigation resulted from data derived from an oral health epidemiological survey of grade 2 children attending the primary schools. The sampling procedure was based on the caries experience of the children, assessed according to the ART caries criteria (Table 1), and on the morphology of pits and fissures in 1st permanent molars, assessed according to the criteria described by Symons et al. [12]. The inclusion criteria for enrolment in the treatment study were: a fully erupted first permanent molar, no dentin caries lesion in pits and fissures of these molars, deep and/or intermediate pits or fissures, and a dmft $\geq$ 2. For a child to be eligible for inclusion in the study, all these criteria needed to be present.

The study was a randomized controlled trial with sealants clustered in each child. Per school, the first author randomly allocated each included child to one of the 4 sealant groups, using a list obtained after block randomization (12 children per block for 3 operators) that was prepared by a statistician, from the Dental School in Nijmegen, The Netherlands, who did not do the analyses. This list was prepared about 7 weeks before the start of the study, placed in a closed envelope and kept concealed until the day before the treatment started. Assignment of treatment to the treatment group number and that of operator to the operator number was done during the week before the study started by the senior investigator (JF). Per child, all 1st permanent molars with eligible pits and fissures were

Table 1 – Dental caries diagnostic index used in the present study (ART caries assessment criteria).

Code		Description
Permanent	Deciduous	
0	A	Sound surface
1	B	Early enamel lesion. White/opaque or brownish/dark lesion in enamel only, including loss of tooth surface; considered as being active or inactive
2	C	Carious lesion involving the dentin slightly; lesion cannot be penetrated with CPI probe
3	D	Dentinal lesion: lesion can be penetrated with CPI probe
4	E	Dentinal lesion: pulp possibly or definitely exposed
5	F	Restoration
6	G	Sealant
7	H	Missing due to caries
8	8	Unerupted permanent tooth
9	9	Unable to make diagnosis

Table 2 – The number of sealants placed, by operator, school and type of jaw at baseline.

	Operator			School					Jaw	
	1	2	3	1	2	3	4	5	Upper	Lower
Noc	437	455	452	335	285	238	188	298	674	670
Nsm	228	115	172	146	120	93	52	104	159	356
Total	665	570	624	481	405	331	240	402	833	1026

Noc, number of sealants in occlusal surface; Nsm, number of sealants in smooth surfaces.

sealed according to one procedure only. Children's parents or guardians received and signed individual informed consent forms containing information about the aim of the study and the treatment procedures. Children whose parents declined to sign the consent form were excluded from the study. The trial was approved by the Research Ethics Committee of Wuhan University, Reference No. 200704, and was registered at the Dutch Trial Registration Center, with Reference Number 1411.

As the application procedure of placing glass-ionomer and glass-carbomer sealants was new to the three operating dentists and the two dental ancillaries, and as resin-composite sealants had been very rarely used by 2 of the 3 operators, a four-week laboratory and field training program, which further included the process of recording data, was carried out in a primary school before the start of the clinical trial.

On the school premises portable equipment was used for placing the sealants in 1st permanent molars over a period of 2 months. The number of sealants placed is presented in Table 2, according to operator, school and type of jaw. Children received instructions about good oral health behavior and final year dental students showed them, on an individual basis, how to clean their teeth. For the included children, the operators provided emergency treatment for teeth excluded from the study at baseline and, after each evaluation, teeth with failed sealants (dentin caries lesion development in re-exposed pits and fissures) were restored. Lost sealant material was not replaced.

2.2. *Sealant procedures*

2.2.1. *Group 1 – glass-ionomer*

Ketac Molar Easymix® (3MESPE, Seefeld, Germany). Sealant application followed the ART sealant procedure [13]. The occlusal surface and pits and fissures were cleaned with wet cotton wool pellets and a No. 6 explorer, dried with dry cotton wool pellets, conditioned with a moist pellet dipped in the glass-ionomer liquid for 10 s, then washed twice with wet cotton wool pellets and dried with dry ones. Isolation was achieved using cotton wool rolls. Glass-ionomer powder and liquid were mixed within 30 s, applied to the surface with an applier/carver ART instrument (Henry Schein, Chicago, USA) and firmly pressed into place for 5–10 s by a petroleum jelly coated index finger (press-finger technique). After bite check, excess material and the petroleum jelly coated top layer were removed, using the applier/carver ART instrument. The smooth curved angle of the ART applier instrument was used for burnishing the surface which was finally, covered with a new layer of petroleum jelly. Children were advised not to eat or bite for at least 1 h.

2.2.2. *Group 2 – glass-ionomer plus added energy*

Ketac Molar Easymix® plus LED high energy curing light, Elipar™ Freelight 2 (3MESPE, Seefeld, Germany), producing 850 mV/cm^2. The sealant application described for Group 1 was followed, except that the surface was cured for 60 s after burnishing and before placement of the layer of petroleum jelly. The output light intensity of the LED curing light was checked every week to ensure that the wave strength was above 750 mW/cm^2.

2.2.3. *Group 3 – glass-carbomer*

Glass Carbomer® (First Scientific Dental, Elmshorn, Germany). Cleaning of the occlusal surface and pits and fissures was done under cotton wool isolation as described for Group 1. Thereafter, a cotton pellet dipped in Glass Carbomer Tooth Cleaner (First Scientific Dental, Elmshorn, Germany) was wiped over the tooth surface for 20 s for further cleaning. Washing and drying of the surface with two wet and dry cotton pellets respectively, followed. The Glass Carbomer® capsule was activated, mixed for 15 s in a RotomixTM (3MESPE, Seefeld, Germany), extruded onto the tooth surface within 1 min from the start of mixing, spread into a thin film, covered with Glass carbomer Surface Gloss (First Scientific Dental, Elmshorn, Germany) and held under finger pressure for 5–10 s. After bite check, the applier/carver ART instrument was used for removing excess material and its smooth curved angle, for burnishing the surface. Thereafter, the material was light-cured for 75 s with the same LED light as used in Group 2 and the same advice as Group 1 received was given.

2.2.4. *Group 4 – composite resin*

Clinpro® (3MESPE, Minneapolis, USA). The occlusal surface and pits and fissures were cleaned with a rotating brush: Prophy Angle (3MESPE, Wuhan, China), and a No. 6 explorer. After thorough rinsing and drying, the occlusal surface was acid etched, with Scotchbond™ etchant (3MESPE, St. Pauls, Minneapolis, USA) for 20 s, rinsed and dried using a portable suction machine. The sealant material was placed in the pits and fissures, manipulated with an explorer to free potential air-bubbles and cured for 20 s with the LED curing light 1 mm above the surface. Carbon paper and rotary instruments were used in bite adjustment.

2.3. *Evaluation*

The coverage of the pits and fissures with sealant material was recorded at baseline. A dentin carious lesion was recorded if the enamel surface was cavitated and the carious lesion was judged to have involved the dentin (Table 1, codes 2–4). Caries assessment was applied to each of the three

sections (mesial–central–distal) into which the occlusal surface was arbitrarily divided. Teeth were cleaned with a toothbrush and toothpaste before the start of the evaluation. Remaining visible debris and plaque were removed with the aid of an explorer. Before examination, the sealed tooth surface was dried with a piece of cotton tightly attached to the end of a stick. If sealant material was judged to have disappeared completely from the tooth surface or from a section of it, the re-exposed pits and fissure(s) were dried with an air syringe and judged again. The examination site was well-illuminated by an intra-oral light with attached disposable mirrors (Kudos, Hong Kong).

The evaluation was done after 0.5, 1 and 2 years by calibrated and experienced independent evaluators, one from Hong Kong and one from Beijing Dental School, who were kept uninformed about the sealant materials used. They were assisted during the first evaluation by trained recorders who had also assisted the operators. Different final year dental students assisted the evaluators in recording the data at the 1 and 2 year evaluation point. Before and during the morning of the first day of evaluation years 1 and 2, evaluators were re-calibrated by examining the first arriving children twice. In the presence of the senior investigator, differences in scores were discussed and consensus was reached. This exercise continued until a series of satisfying agreements (4–5 children) was obtained. No radiographs were taken.

The caries status of the children was re-assessed 1.5 years after the sealants had been placed. For this, the same caries assessment criteria as used at baseline were applied (Table 1) by two calibrated examiners, one of whom participated in the oral health epidemiological survey at baseline.

For evaluators 1 and 2 respectively, the intra-evaluator consistency in diagnosing dentin carious lesions was assessed by re-examining 199 and 192 pairs of sealed tooth sections, while the inter-evaluator consistency was assessed by re-examining 1226 pairs of sealed tooth sections. The kappa-coefficient for intra-evaluator consistency was 0.90 for both evaluators, and 0.63 for the inter-evaluator consistency. Fig. 1 shows a flowchart of the number of participants and tooth surfaces sealed for the four treatment groups, and the number of drop-outs at each evaluation stage of the study.

2.4. Statistical analysis

A power calculation preceded the sampling procedure. On the basis of an accepted difference of 15% between the survival of caries-free pits and fissures sealed with high-viscosity glass-ionomer (94%) and composite resin (79%) after 5 years [13], a total of 77 sealants was needed. As glass-carbomer and high-viscosity glass-ionomer with light-curing were new and as sealants placed with these procedures were expected to result in a higher survival of caries-free pits and fissures (99%) than produced by high-viscosity glass-ionomer (94%) after 5 years, a total of 208 sealants was required. Using the survival percentages and a power of 80%, tested two ways, a drop-out of 30% after 5 years and a correction for the use of the dependency of measurements of 20%, the maximum number of sealants per group would be 312. Depending on the number of eligible sealants per child, the number of children per group was required to be 156 (2 sealants) or 104 (3 sealants).

The data were entered into a database, checked for errors and analyzed, using SAS software (version 9.2). Statistical analyses aimed to describe the survival curves of dentin carious lesion-free surfaces in 1st molars. The data were censored, owing to drop-out and the restricted general follow-up period of two years. The Kaplan–Meier survival method was applied to estimate survival percentages. Owing to the dependence of data on different sealants in one child, the Greenwood approximation for the standard error (SE) of the survival percentages was not valid [14]. Therefore, the Jackknife method [15] (leaving one patient out) was applied in calculating the SE's.

The $d_2$mft and D_2MFT counts were composed of caries codes B–F and H, and 1–5 and 7, respectively, whereas caries codes C–F and H, and 2–5 and 7 were used to construct the $d_3$mft and D_3MFT counts, respectively. ANOVA was used to test for a caries experience effect between the four sealant groups at baseline. The *t*-test was used to test for the difference between the sealant survival percentages of the four sealant procedures, and between the mean dmft and DMFT scores at baseline and follow-up examinations. The significant difference was set at $p < 0.05$.

3. Results

3.1. Disposition of subjects

A total of 407 children with an average age of 8.0 years (range 7.0–9.1 years) participated in the trial. In total, 1352 first permanent molars were sealed (mean = 3.3 first permanent molars per child). The percentages of children with 1, 2, 3 and 4 first permanent molars sealed at baseline were 5.2, 16.0, 20.4 and 58.5, respectively. The number of children and sealants that dropped-out over the 2 study years is presented in Fig. 1 and were regarded as being low (6.6% of children and 7.1% of sealants at evaluation year 2).

3.2. Dental caries situation

The mean dmft and DMFT scores and standard deviation by sealant group at baseline and follow-up examinations are presented in Table 3. No difference in caries experience was observed between the 4 groups at baseline ($d_2$mft: $p = 0.95$; D_2MFT: $p = 0.68$; $d_3$mft: $p = 0.86$; D_3MFT: $p = 0.47$).

3.3. Survival of dentin carious lesion-free pits and fissures in 1st permanent molars

The cumulative survival percentages and SEs, calculated according to the Jackknife procedure, of dentin carious lesion free pits and fissures in occlusal and smooth surfaces of 1st permanent molars combined over a period of 2 years are presented in Table 4. A total of 27 re-exposed pits and fissures, 20 in occlusal and 7 in smooth surfaces, in 25 children, developed a dentin carious lesion over the 2-year period. The mean D_2MFS ($p = 0.25$) and D_3MFS scores ($p = 0.68$) of these 25 children were not statistically significantly higher than the caries experience scores of the children without a newly developed dentin carious lesion in pits and fissures previously sealed, after 2 years.

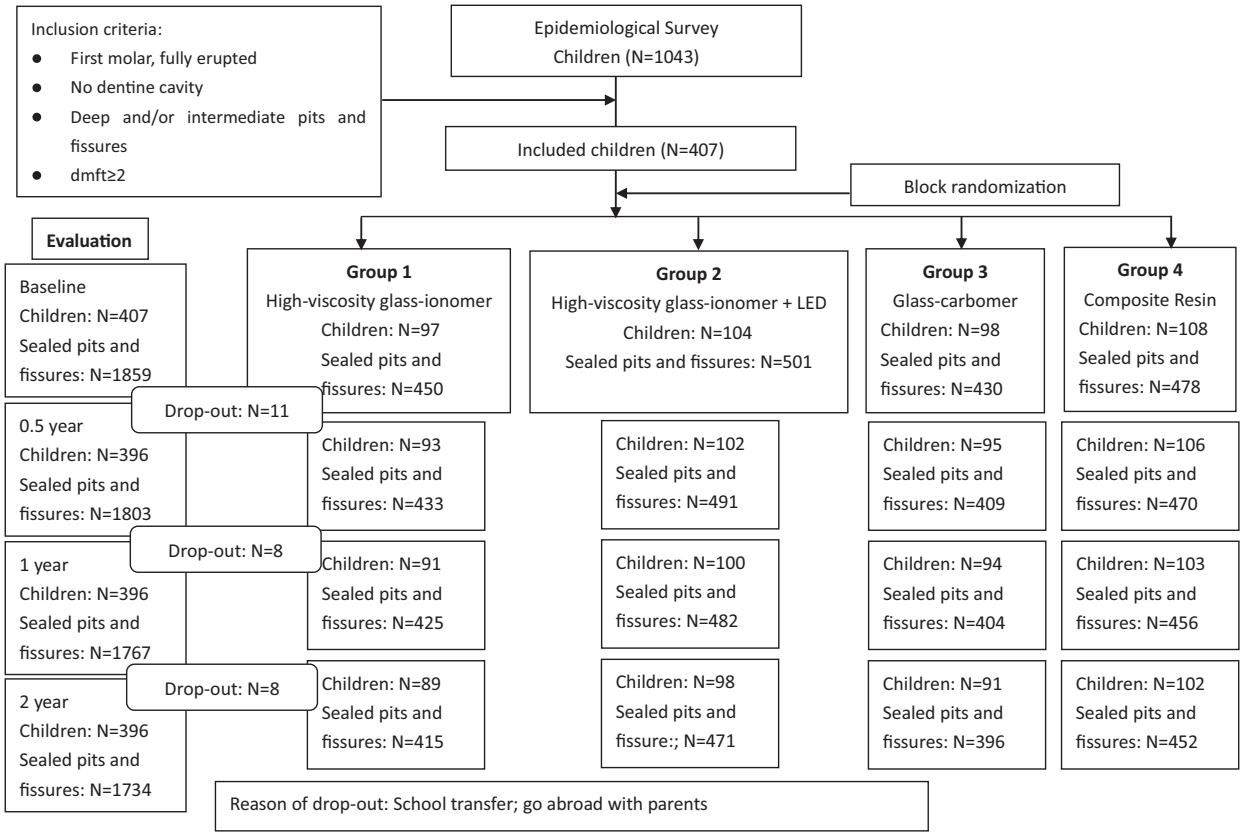

Fig. 1 – Consort flow diagram of the current investigation. N = number.

Table 3 – Mean dmft and DMFT scores and standard deviation, by sealant group at baseline and follow-up examination.

Group	High viscosity glass-ionomer			High viscosity glass-ionomer + LED			Glass-carbomer			Composite resin		
	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD
Baseline												
$d_2$mft	97	6.2	2.8	104	6.3	2.9	98	6.3	2.8	108	6.4	2.7
$d_3$mft		4.8	2.6		4.9	2.6		4.7	2.6		5.0	2.4
D_2MFT		0.9	1.3		0.9	1.4		0.8	1.2		0.7	1.2
D_3MFT		0.1	0.4		0.2	0.4		0.1	0.3		0.1	0.4
Follow-up												
$d_2$mft	88	4.7	2.6	99	4.9	2.5	91	4.9	2.6	103	4.8	2.7
$d_3$mft		4.1	2.5		4.2	2.4		4.3	2.7		4.0	2.5
D_2MFT		0.8	1.2		0.6	0.9		0.9	1.3		0.5	1.0
D_3MFT		0.3	0.7		0.3	0.6		0.3	0.7		0.2	0.6

N, number of children.

Table 4 – The cumulative survival percentages and SEs, calculated using the Jackknife procedure, of dentin carious lesion free pits and fissures in occlusal and smooth surfaces of 1st permanent molars combined over a period of 2 years.

Group	1 High viscosity glass-ionomer		2 High viscosity glass-ionomer + LED		3 Glass-carbomer		4 Composite resin	
Year	%	SE	%	SE	%	SE	%	SE
0–0.5	99.5	0.003	100.0	0.0	100.0	0.0	100.0	0.0
0.5–1	99.1	0.005	99.6	0.003	99.5	0.004	99.8	0.000
1–2	98.3	0.006	99.0	0.005[b]	97.4	0.009[a]	98.9	0.005[b]

SE, standard error.
$P^{a-b} = 0.02$.

The prevalence of dentin carious lesion-free pits and fissures was high for all sealant groups. The cumulative survival of dentin carious lesion-free pits and fissures in the glass-carbomer sealant group was statistically significantly lower (97.4%) than those in the high-viscosity glass-ionomer with energy supplied (99%) and the resin-composite (98.9%) sealant groups ($p = 0.02$). After 2 years there was no statistically significant difference in the cumulative survival of dentin carious lesion-free pits and fissures between the high-viscosity glass-ionomer with (99%), and without (98.3%) energy supplied sealant groups ($p = 0.13$).

4. Discussion

4.1. *Methodology*

The study design was a clustered randomized controlled trial, with the sealants in the oral cavity as the cluster. Sealants were not independent units and compensatory measures were taken in the statistical analysis. The Jackknife procedure was used in dealing with the dependency of the clustered data.

There was no difference in the caries experience in primary and permanent dentitions in children of the four sealant groups at baseline. The drop-out rate after 2 years was very low compared to those of other clinical sealant studies [16,17]. Another factor promoting the reliability of the outcomes is the high kappa coefficient value for intra- and inter-evaluator consistency.

Selection bias was controlled by having the block randomization done by an outside expert and by keeping the list concealed to the operators until the time the treatment started. Operators only knew which procedure they should provide when the child was in the chair and the assistant instructed them. Because of the nature of the study, the operators were not blinded which may have influenced the study outcomes. To what extent the latter may have happened is difficult to say. Almost all procedures were new to the three operators, so prior preference for a certain procedure was very unlikely. Children were considered blinded to the procedure as for many, this was the first ever treatment they had received. As sealant application is not so frequently performed in dental practice in China as, for example, in practices in The Netherlands, we do not think that the treated children had a prior preference to a particular treatment procedure. Blinding of the evaluators was accomplished by not informing them about the sealant materials used. We have no evidence that the junior recorders have had an influence on the performance of the senior, both in age and status, evaluators. As the clinical appearance from the resin-composite sealant material only is to a certain extent distinguishable in color and texture from the materials used in the other three treatment groups, the level of blinding of evaluators is very substantial. Blinding of the statistician was achieved, as coded numericals were provided and were decoded only at the end of the analyses.

Considering the manner in which the randomization process was carried out, and the achieved levels of blinding of children, operators, evaluators and statistician, it is fair to conclude that the internal and external validity of the outcomes appear to be substantial to high.

4.2. *Outcomes*

The first hypothesis was rejected. A higher number of dentin carious lesions were present in pits and fissures previously sealed with glass-carbomer than in those sealed with materials of the other groups. As glass-carbomer is a rather new material, no other study has published results about it as a sealant material. Thus study comparisons were not possible. However, the survival percentage of partial and fully retained glass-carbomer sealants of the present study, after 2 years, has been published [18]. This survival rate was significantly lower than those of high-viscosity materials with and without energy supplied, and that of resin composite. One reason may be the related to the samples received from the manufacturer who, according to the originator of the glass-carbomer, were produced at a below-standard level.

The study group comprised children with an elevated risk of developing carious lesions. Comparison with the mean percentage of dentin carious lesion-free pits and fissures previously sealed, after 2 years, and those reported in a systematic review [19], shows that the percentage of dentin carious lesions in re-exposed pits and fissures in all four groups in the present study was lower. This may have been, in part, due to the strict and consistent training of the team of operators and assistants. Only when the operators felt confident that they managed the four different sealant applications well, and when the supervisor was satisfied with their performance, did the trial commence. This may have contributed to an optimum sealant retention, which in turn is a prerequisite for the development of fewer dentin carious lesions in the first two years of a sealant. Another possible reason for the difference observed may be the use of many different sealant materials; some old, some newer, used in the studies covered by the systematic review.

The result of the present study, that after 2 years no significant difference was observed between the survival of dentin carious lesion-free pits and fissures previously sealed with a high-viscosity glass-ionomer and those sealed with a resin-based material, is in agreement with the conclusion of the three published systematic reviews dealing with this comparison [19–21]. Specifically, the significant difference between the caries-preventive effect of the ART sealants and resin-composite sealants, as observed in Syria [13], was not observed in this group of age mates in China. Evaluation of these sealants in future years will assist in deciding which sealant material is most appropriate for use in countries without a proper functioning recall system.

The second hypothesis was also rejected. Prevention of dentin carious lesion development by added energy to the setting of the high-viscosity glass-ionomer sealant was not superior to that of the high-viscosity glass-ionomer which was allowed to set in the normal way. No difference in retention of fully and partially retained sealants after 2 years was found between the two procedures [18].

5. Conclusion

It is concluded that the survival of dentin carious lesions-free pits and fissures was high in all type of sealants. More

dentin carious lesions were observed in the glass-carbomer group than in the others. The application of high energy to the setting high-viscosity glass-ionomer did not produce superior effectiveness in the prevention of dentin carious lesion development in pits and fissures previously sealed, after 2 years.

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