

Caries-preventive Effect of Supervised Toothbrushing and Sealants

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Abstract

To investigate the effectiveness of 3 caries-preventive measures on high- and low-caries risk occlusal surfaces of first permanent molars over 3 y. This cluster-randomized controlled clinical trial covered 242 schoolchildren, 6 to 7 y old, from low socioeconomic areas. At baseline, caries risk was assessed at the tooth surface level, through a combination of ICDAS II (International Caries Detection and Assessment System) and fissure depth codes. High-caries risk occlusal surfaces were treated according to daily supervised toothbrushing (STB) at school and 2 sealants: composite resin (CR) and atraumatic restorative treatment–high-viscosity glass-ionomer cement (ART-GIC). Low-caries risk occlusal surfaces received STB or no intervention. Evaluations were performed after 0.5, 1, 2, and 3 y. A cavitated dentine carious lesion was considered a failure. Data were analyzed according to the proportional hazard rate regression model with frailty correction, Wald test, analysis of variance, and *t* test, according to the jackknife procedure for calculating standard errors. The cumulative survival rates of cavitated dentine carious lesion-free, high-caries risk occlusal surfaces were 95.6%, 91.4%, and 90.2% for STB, CR, and ART-GIC, respectively, over 3 y, which were not statistically significantly different. For low-caries risk occlusal surfaces, no statistically significant difference was observed between the cumulative survival rate of the STB group (94.8%) and the no-intervention group (92.1%) over 3 y. There was neither a difference among STB, CR, and ART-GIC on school premises in preventing cavitated dentine carious lesions in high-caries risk occlusal surfaces of first permanent molars nor a difference between STB and no intervention for low-caries risk occlusal surfaces of first permanent molars over 3 y.

Keywords: dental caries, caries prevention, glass-ionomer cements, resin composite, atraumatic restorative treatment, ART sealants

Introduction

The caries process is predominantly driven by the presence of a cariogenic biofilm. Its regular mechanical removal or disruption is an adequate measure for preventing carious lesion development and promoting its arrestment (Deery 2013). However, good standards of oral care are not always achieved, as exemplified by the fact that among 291 diseases and injuries, untreated caries in permanent teeth was ranked the most prevalent disease (Marcenes et al. 2013).

Dental caries is a site-specific disease predominantly occurring in pits and fissures of occlusal surfaces (Carvalho et al. 1989; Vehkalahti et al. 1991). Sealing permanent molars is an effective method for preventing and controlling carious lesion development in pits and fissures (Ahovuo-Saloranta et al. 2013). Resin and glass-ionomers are the materials predominantly used. Although resin-based sealants usually present higher retention rates (Kühnisch et al. 2012), systematic reviews have reported no evidence of the caries-preventive superiority of either material (Beirut, Frencken, van't Hof, and van Palenstein Helderma 2006; Yengopal et al. 2009; Ahovuo-Saloranta et al. 2013). Placement of sealants, whether for preventive or therapeutic reasons, should be based on caries risk assessment (Deery 2013) at patient and tooth surface levels (Splieth et al. 2010).

Preventing carious lesions in children relies in large part on educating them in removing the biofilm regularly with toothbrush and fluoridated toothpaste (Marinho et al. 2003; Walsh et al. 2010). School-based supervised toothbrushing (STB) appears to reduce carious lesion progression (Curnow et al. 2002; Jackson et al. 2005). However, the question that remains unanswered is whether STB at school is equally effective in preventing carious lesion development in occlusal surfaces of permanent teeth as is sealing these. This question is particularly relevant in disadvantaged populations that may have access to toothbrushes and toothpaste but lack access to oral health care services.

The possibility of answering this question arose from a primary oral health care study conducted in primary schools in

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Brazil. To manage the prevention and progression of carious lesions in primary teeth, 3 treatment protocols were compared (Mijan et al. 2014). As part of these protocols, the caries-preventive effect on permanent first molars was investigated with respect to an STB program, a composite resin (CR), and an atraumatic restorative treatment–high-viscosity glass-ionomer cement (ART-GIC) sealant.

The null hypotheses tested were as follows: 1) there is no difference in the caries-preventive effects of STB, CR, and ART-GIC sealant on high–caries risk occlusal surfaces of first permanent molars over 3 y; 2) there is no difference between STB and no intervention in their caries-preventive effects on low–caries risk occlusal surfaces of first permanent molars over 3 y.

Materials and Methods

Sampling Procedure

This cluster-randomized controlled clinical trial used a parallel-group design and was carried out in all 6 public primary schools of Paranoá, a deprived suburban area of Brasilia whose water system was artificially fluoridated. The sample was nested in an epidemiologic survey of 6- and 7-y-olds attending these schools (de Amorim et al. 2012). The inclusion criteria for the main oral health care study were as follows: 1) good general health; 2) at least 2 cavitated dentine carious lesions in vital pain-free primary molars, assessed according to the second digit of the ICDAS II (International Caries Detection and Assessment System); 3) erupted first permanent molars, with the occlusal surface fully visible and accessible; 4) high–caries risk occlusal surfaces in first permanent molars, determined by ICDAS II codes 2 and 3 or by a combination of ICDAS II code 1 and medium or deep fissures (assessed according to Symons et al. 1996); and 5) a signed consent form. Low–caries risk occlusal surfaces were determined by ICDAS II code 0 or 1 and shallow fissures.

The study covered 3 groups for treatment of high–caries risk occlusal surfaces: STB on school premises, CR sealant, and ART-GIC sealant. The sampling unit was the school (2 schools per cluster). As 2 of the 6 schools were equipped with a dental unit, these schools were allocated to the CR group. The remaining 4 schools were randomly allocated to the ART-GIC and STB groups. At the start of the study and during the evaluation periods, all children were individually instructed by the dentist on how to brush their teeth.

Low–caries risk occlusal surfaces of the first permanent molars of children in the CR and ART-GIC groups did not receive any special intervention. But the low–caries risk occlusal surfaces of the permanent teeth of children in the STB group were brushed under supervision, as brushing only the high–caries risk occlusal surfaces was not possible. Therefore, for the low–caries risk occlusal surfaces, there were 2 groups: STB and no intervention (Fig.). This implies that teeth from the STB group could belong to the high– or the low–caries risk group.

The trial was approved by the Research Ethics Committee of the University of Brasilia Medical School (reference no. 081/2008) and registered at the Netherlands Trial Register (reference no. 1699). Parents and/or carers were informed in writing about the investigation and treatments.

Implementation

Sealants were placed by 3 trained and calibrated pedodontists who were aided by trained dental assistants, between May and July 2009 on the school premises. Two experienced dentists conducted training and calibration exercises. Toothbrushing was supervised from May 2009 to December 2012. All children received an oral hygiene kit containing a toothbrush, a 1,000-ppm fluoridated dentifrice, plaque-disclosing dentifrice, and dental floss. They were instructed on how to use these devices and were encouraged to brush their teeth twice daily.

CR sealant group. Children were positioned in a dental chair. Isolation was performed with cotton wool rolls and a suction device. With use of the operation lamp, the occlusal surface was cleaned with a rotating brush, acid etched for 30 s with 37% phosphoric acid (Acigel, SSWhite, Rio de Janeiro, Brazil), rinsed, and dried with 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 when necessary with rotary instruments.

ART-GIC group. Pits and fissures were cleaned with toothbrush and toothpaste before the children lay on the portable bed. Isolation was performed with cotton wool rolls. Plaque was further removed with a dental probe and cotton wool pellets under light provided by a portable headlamp. The occlusal surface was conditioned with polyacrylic acid for 10 to 15 s and washed and dried with wet and dry cotton wool pellets, respectively. Ketac Molar Easymix (3MESPE, Seefeld, Germany) was hand mixed according to the manufacturer's instructions, applied on the occlusal surface with an atraumatic restorative treatment applicator instrument (Henry Schein, Chicago, USA), and pressed into pits and fissures by a petroleum jelly–coated finger for 15 s (Frencken et al. 1996). Excess material was removed with the atraumatic restorative treatment–carving instrument after bite registration with carbon paper. The sealant was coated with petroleum jelly, and children were told not to eat for 1 h.

STB group. Children were told to clean their teeth at least twice a day, and on every school day a dental assistant, trained in identifying plaque, supervised the toothbrushing sessions. Brushing instructions were repeated if needed. A conventional toothbrush and fluoridated toothpaste were used. Children were encouraged to maintain the same hygiene pattern at home and during school vacations.

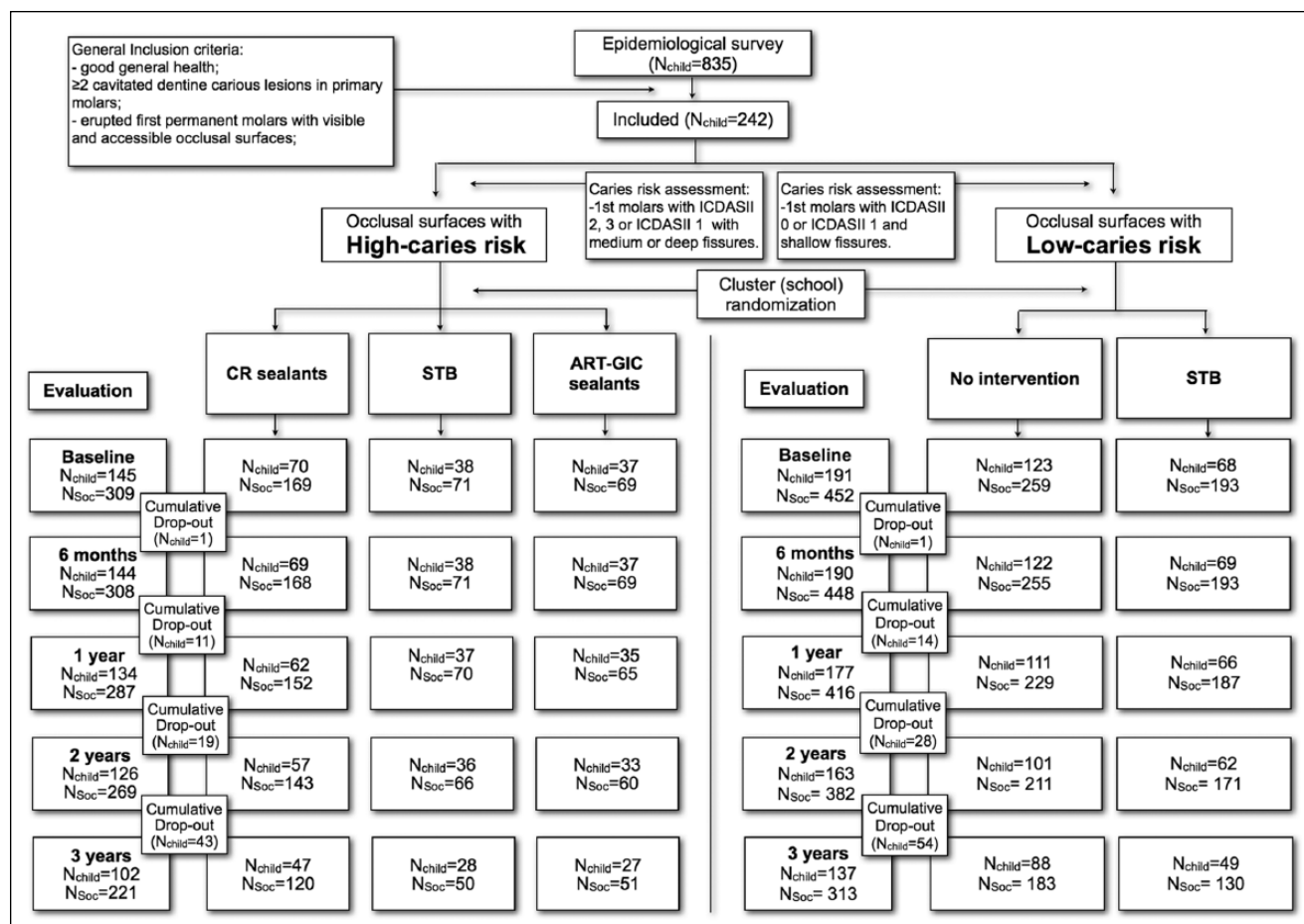


Figure. CONSORT flowchart. Reasons for dropouts: moving to another city and irregular school attendance. ART-GIC, atraumatic restorative treatment–high-viscosity glass-ionomer cement; CR, composite resin; ICDAS II, International Caries Detection and Assessment System; N_{child}, number of children; N_{Soc}, number of occlusal surfaces; STB, supervised toothbrushing.

Evaluation

Two independent evaluators (dentists) assessed teeth for the presence of carious lesions according to ICDAS II on the school premises after 6 mo and 1, 2, and 3 y. Evaluators were trained and calibrated before each evaluation session by an experienced dental epidemiologist (J.E.F.). 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 210 sections were reexamined for reproducibility testing. The kappa coefficient value was 0.76 for the interevaluator consistency test in assessing carious lesions over the 4 evaluation times. The percentage of agreement of scores was 86.7%.

Statistical Analysis

The sample size of the present study relied on the power calculation of the main primary oral health care study. Regarding the carious lesion–preventive effect of CR (79%) and ART-GIC (94%) sealants after 5 y (Beirut, Frencken, van't Hof, Taifour, et al. 2006), 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 9.2 software (Cary, NC, USA). The dependent variable was survival rate of cavitated dentine carious lesion–free occlusal surfaces. ICDAS II codes 0 to 4 indicated survival; codes 5 and 6, failures; and codes 96 and 99, censored observations. Treatment group (CR, STB, ART-GIC), age, sex, and baseline caries experience (D_{2MFT} , D_{3MFT} , and d_{3mft}) were the independent variables (D_{2} represents ICDAS II codes 1 to 6; D_{3}/d_{3} represents ICDAS II codes 4 to 6). Analysis of variance and chi-square tests were used in testing for differences between the independent variables at baseline and for the nonresponse analysis. The proportional hazard rate regression model (Cox 1972) with frailty correction (Hougaard 1995) was used to estimate cumulative survival 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 (Efron 1982) was applied in calculating standard errors for comparing survival rates between groups at 1 interval according to *t* test. Statistical significance was set at $\alpha = 0.05$.

Table 1. Participating Children with High-carries Risk Occlusal Surfaces at Baseline According to Treatment Groups: Age and D₂MFT, D₃MFT, and d₃mft Counts.

	CR Sealants (n = 70)		STB (n = 38)		ART-GIC Sealants (n = 37)	
	Mean	SD	Mean	SD	Mean	SD
Age ^a	6.72	0.34	6.98	0.34	6.87	0.32
D ₂ MFT ^a	3.37	1.02	2.53	1.22	3.00	1.13
D ₃ MFT ^b	0.27	0.56	0.23	0.42	0.27	0.51
d ₃ mft ^c	6.11	3.12	5.18	2.51	5.78	3.94

ART-GIC, atraumatic restorative treatment–high-viscosity glass-ionomer cement; CR, composite resin; STB, supervised toothbrushing.

^aP < 0.01.

^bP = 0.36.

^cP = 0.26.

Table 2. Cavitated Dentine Carious Lesion-free High-carries Risk Occlusal Surfaces in First Permanent Molars over 3 y: Cumulative Percentage Survival Rates and Standard Error.

Interval, y	CR Sealants (n _{soc} = 169)			STB (n _{soc} = 71)			ART-GIC Sealants (n _{soc} = 69)		
	n	%	SE	n	%	SE	n	%	SE
0.5	1	99.4	0.1	0	100.0	0.0	2	97.1	2.0
1	3	98.1	0.6	1	98.6	0.2	2	97.1	2.0
2	7	95.4	2.0	3	95.6	2.5	4	93.9	3.7
3	12	91.4	2.9	3	95.6	2.5	6	90.2	5.0

ART-GIC, atraumatic restorative treatment–high-viscosity glass-ionomer cement; CR, composite resin; n, number of cavitated dentine carious lesions; n_{soc}, number of occlusal surfaces at baseline; STB, supervised toothbrushing.

Results

Disposition of Subjects

A total of 242 children (126 boys, 116 girls) with a mean age of 6.8 y (SD = 0.4) were enrolled in the study. At baseline, 761 first permanent molars were examined. Table 1 presents the children's mean age and their D₂MFT, D₃MFT, and d₃mft counts, according to individuals having high-carries risk occlusal surfaces in first permanent molars. A statistically significant difference at baseline between treatment groups was found for age and D₂MFT counts. Children of the STB group were approximately 3 mo older than children who received CR sealants and had lower mean D₂MFT counts. A CONSORT flow diagram is presented in the Figure. After 3 y, overall drop-out was 227 occlusal surfaces (29.8%).

Survival of Cavitated Dentine Carious Lesion-free Occlusal Surfaces in First Permanent Molars

The numbers of cavitated dentine carious lesions in occlusal surfaces, cumulative survival rates, and standard error according to the jackknife procedure for high- and low-carries risk occlusal surfaces in first permanent molars are presented in Tables 2 and 3, respectively. In high- and low-carries risk occlusal surfaces, 21 (6.8%) and 26 (5.8%), respectively, developed a cavitated dentine carious lesion over the 3 y of follow-up.

The cumulative survival rates of cavitated dentine carious lesion-free occlusal surfaces of high-carries risk among the 3 treatment groups did not differ statistically significantly (*P* =

0.59; Table 2). There was no statistically significant difference (*P* = 0.43) in cumulative survival rates of cavitated dentine carious lesion-free occlusal surfaces of low risk between those that were brushed under supervision and those that received no intervention (Table 3).

Analyses of Independent Variables and Nonresponse

The proportional hazard rate regression model showed no effects of age (*P* = 0.27); sex (*P* = 0.85); and baseline d₃mft (*P* = 0.15), D₂MFT (*P* = 0.80), D₃MFT (*P* = 0.09) counts on the survival rates of cavitated dentine carious lesion-free high-carries risk occlusal surfaces by treatment group. Nonresponse analysis revealed no effect for treatment group (*P* = 0.72); age (*P* = 0.90); sex (*P* = 0.72); and baseline d₃mft (*P* = 0.38), D₂MFT (*P* = 0.82), and D₃MFT (*P* = 0.52) counts.

For the low-carries risk occlusal surfaces, age (*P* = 0.98); sex (*P* = 0.32); and baseline d₃mft (*P* = 0.17), D₂MFT (*P* = 0.86), and D₃MFT (*P* = 0.86) counts had no effect on the cumulative survival rates. Nonresponse analysis showed that there was no effect for supervised brushing (*P* = 1.00); age (*P* = 0.69); sex (*P* = 0.75); and baseline d₃mft (*P* = 0.63), D₂MFT (*P* = 0.42), and D₃MFT (*P* = 0.62) counts.

Development of Cavitated Dentine Carious Lesions over 3 y

The frequency distribution of components of the inclusion criteria and cavitated dentine carious lesion development during

Table 3. Cavitated Dentine Carious Lesion-free Low-carries Risk Occlusal Surfaces in First Permanent Molars over 3 y: Cumulative Percentage Survival Rates and Standard Error.

Interval, y	No Intervention ($n_{\text{Soc}} = 259$)			STB ($n_{\text{Soc}} = 193$)		
	<i>n</i>	%	SE	<i>n</i>	%	SE
0.5	3	98.8	0.7	4	97.9	1.0
1	9	96.2	1.4	4	97.9	1.0
2	10	95.8	1.4	7	96.2	1.6
3	17	92.1	2.1	9	94.8	1.6

n, number of cavitated dentine carious lesions; n_{Soc} , number of occlusal surfaces at baseline; STB, supervised toothbrushing.

Table 4. Baseline Frequency Distribution of Components of the Inclusion Criteria and Cavitated Dentine Carious Lesion Development in Occlusal Surfaces in First Permanent Molars over 3 y.

ICDAS II	n_{Soc} (%)	n_{DCav} (%)	n_{Soc} (%)	n_{DCav} (%)	n_{Soc} (%)	n_{DCav} (%)
High-carries Risk Occlusal Surfaces						
	CR Sealants		STB		ART-GIC Sealants	
1 (F2)	67 (39.9)	3 (4.5)	38 (53.5)	1 (2.6)	42 (60.9)	2 (4.8)
1 (F3)	10 (6.0)	0 (0.0)	2 (2.8)	0 (0.0)	3 (4.3)	0 (0.0)
2	65 (38.7)	4 (6.2)	25 (35.2)	2 (8.0)	15 (21.7)	2 (13.3)
3	26 (15.5)	5 (19.2)	6 (8.5)	0 (0.0)	9 (13.0)	2 (22.2)
Low-carries Risk Occlusal Surfaces						
	No Intervention		STB			
0	183 (71.8)	13 (7.1)	143 (74.1)	3 (2.1)		
1 (F1)	72 (28.2)	4 (5.5)	50 (25.9)	6 (12)		

ART-GIC, atraumatic restorative treatment-high-viscosity glass-ionomer cement; CR, composite resin; F1, shallow fissures; F2, medium fissures; F3, deep fissures; ICDAS II, International Caries Detection and Assessment System; *n*, number of cavitated dentine carious lesions; n_{DCav} , number of cavitated dentine carious lesions; n_{Soc} , number of occlusal surfaces; STB, supervised toothbrushing.

3 y is presented in Table 4 by occlusal surface level of caries risk assessment and treatment group. At baseline, no statistically significant difference was observed in the distribution of components of the inclusion criteria by treatment group (high caries risk, $P = 0.06$; low caries risk, $P = 0.58$). For the high-carries risk occlusal surfaces, there was a higher percentage of ICDAS II codes 2 and 3 than code 1 that progressed into a cavitated dentin carious lesion (10.3% vs. 3.1%, $P = 0.02$). Notably, in the STB group, all 6 lesions that were scored code 3 at baseline did not progress into a cavitated dentine carious lesion.

Discussion

Methodology

Allocation of children to the treatment groups was performed by cluster sampling because 2 of the 6 public primary schools in this low socioeconomic area had a fully equipped dental unit. However, children from these schools had no obvious advantage in terms of better oral health knowledge than children of the other 4 schools, as no dentist had been employed for many years. Despite a significant difference observed in age and mean D_2 MFT counts between the treatment groups at baseline, these variables had no effect on the survival rate of

cavitated dentine carious lesion-free surfaces for high- and low-carries risk occlusal surfaces of first permanent molars over the 3 y. Moreover, nonresponse analysis did not show a significant difference for any of the variables under study. All these findings support the assumption that bias was controlled in the composition of the treatment groups and in that of caries load in occlusal surfaces within the study groups.

A surface-level risk assessment was used for determining the risk category of erupted first permanent molars. Use of initial signs of carious lesions and fissure classification allowed for a more realistic comparison between treatments for occlusal surfaces than what is usually possible if caries risk is determined at the child level only (Heller et al. 1995; Splieth et al. 2010). Also the surface-level risk assessment grouped the same stages of carious lesion development at baseline, avoiding comparison of surfaces that, at the beginning, had no signs of a carious lesion with those that already contained an enamel carious lesion—a situation often seen in sealant studies.

Children were blinded to the treatment that they received, as only 1 type of treatment was provided per school. Operators could not be blinded, since the sealant application protocols were considerably different. Evaluators also could not be blinded, as they could distinguish the sealant materials. During the later evaluations, when the sealant materials had disappeared from a

sizable number of occlusal surfaces, it was possible that evaluators examined the occlusal surfaces in a reasonably blind way. The statistician was blinded to the meaning of the group codes in the database. The dropout rates were considerable, despite the many efforts made to recall the children. Considering the above, the internal validity of the present study can be considered substantial for a trial of this nature (Schulz and Grimes 2002). External validity is dependent on the experiences of the operators, the dedication of supervising persons, and the participation of children and parents in brushing teeth during non-school days and is therefore considered not very high.

Main Finding

The first null hypothesis was accepted. There is no difference in the caries-preventive effect of STB, CR, and ART-GIC on high-caries risk occlusal surfaces of first permanent molars over a period of 3 y. Evidence of the efficacy of sealants in preventing cavitated dentine carious lesions in high-caries risk children and adolescents, when compared with no sealants, is well established (Ahovuo-Saloranta et al. 2013). The absence of a difference in survival rates of cavitated dentine carious lesion-free occlusal surfaces between the 2 sealant groups in the present study is in agreement with Zhang et al. (2014) but not with Beirut, Frencken, van't Hof, Taifour, et al. (2006), who showed higher survival rates for ART-GIC than for CR.

The efficacy of STB in reducing development and promoting arrestment of enamel carious lesions has been described (Curnow et al. 2002; Jackson et al. 2005). Individualized non-operative intensive treatment based on patient education and professional tooth cleaning (Nexø model) has shown promising results in reducing operative treatment for occlusal surfaces of erupting first permanent molars (Carvalho et al. 1992). However, a direct comparison between different sealant materials and STB in a high-caries risk population after a tooth-level assessment of high-caries risk occlusal surfaces in first permanent molars, as investigated in the present study, is new to our current knowledge.

The CR and ART-GIC sealants used in the present study are both preventive measures that act as a diffusion barrier in areas that favor biofilm retention. By impeding biofilm accumulation in these areas, sealants are effective. Both sealants appear to release fluoride, although this might occur for a short period only, as the migration of ions are stopped after the material has set fully. However, STB acts by actively and repeatedly removing biofilm from the tooth surfaces supported by the fluoridated toothpaste. When the 3 protocols used for high-caries risk occlusal surfaces are compared, it is possible to say that all protocols act by interfering in the accumulation of the biofilm and by the action of fluorides.

The finding that daily STB is as good as sealants in preventing cavitated dentine carious lesions stimulates the discussion about the conditions under which sealants are really indicated and when STB is a real option indeed. This discussion is of great importance in establishing guidelines for school-based preventive strategies for children at high risk of developing

occlusal carious lesions (Carvalho et al. 1989; Vehkalahti et al. 1991; Carvalho 2014). While sealants are surface-located treatments, educating children in applying oral hygiene daily through STB might have a further-reaching impact through preventing carious lesions at any tooth in the mouth. Future studies should focus on the effects of STB on the overall caries experience in children, plaque deposition, gingival bleeding, and cost-effectiveness of this protocol in comparison with those of sealants.

An interesting finding was that all 6 ICDAS II code 3 lesions of the STB group in high-caries risk occlusal surfaces of first permanent molars did not progress to cavitation in dentine after 3 y. Although the number of such lesions was rather low, this finding may suggest that localized enamel lesions do not necessarily have to be treated with a sealant or even through an ultraconservative restoration, as was suggested recently (Ismail et al. 2013). The potential for arresting carious lesion progression solely with STB, even in high-caries risk surfaces, is very important, and the results of the present study should be confirmed by other research groups.

The second null hypothesis was accepted. There was no difference in caries-preventive effect between STB and no intervention for low-caries risk occlusal surfaces in first permanent molars over 3 y. The first permanent molars with initially sound occlusal surfaces and surfaces with initial stages of carious lesion development in combination with shallow fissures did not benefit more from the STB than from no intervention.

The combined outcome of the 2 hypotheses is that toothbrushing under daily supervision at schools, covering some 200 d per year, resulted in a very low percentage of cavitated dentine carious lesions over 3 y. It is concluded that there was no difference in preventing cavitated dentine carious lesions in occlusal surfaces of high-caries risk permanent first molars between daily STB and placing sealants on school premises over 3 y. For low-caries risk first permanent molars, supervised daily toothbrushing showed no difference with no intervention in preventing cavitated dentine carious lesions in occlusal surfaces over 3 y.

Author Contributions

L.A. Hilgert, contributed to data analysis and interpretation, drafted the manuscript; S.C. Leal, contributed to conception and design, critically revised the manuscript; J. Mulder, N.H.J. Creugers, contributed to data analysis and interpretation, critically revised the manuscript; J.E. Frencken, contributed to conception, design, data analysis, and interpretation, drafted the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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