

Influence of caries risk on the retention of a resin-modified glass ionomer used as occlusal sealant: a clinical trial

Influência do risco de cárie na retenção de um ionômero de vidro modificado por resina usado como selante oclusal: ensaio clínico

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Resumo

Introdução: Pouco se sabe sobre a influência do risco de cárie na retenção de selantes oclusais. **Objetivo:** Avaliar as taxas de retenção de um cimento de ionômero de vidro modificado por resina utilizado como selante oclusal em primeiros molares permanentes de escolares de 6-8 anos, e analisar a influência do risco de cárie na taxa de retenção do selante, durante um período de 24 meses. **Material e método:** A aplicação do selante foi realizada em consultório odontológico no início do estudo, após as crianças serem alocadas no grupo de alto risco (AR) ou baixo risco (BR) de cárie. Os exames foram realizados pelo mesmo dentista calibrado em 0, 6, 12, 18 e 24 meses. As taxas de retenção foram estimadas e o método de Kaplan-Meier foi utilizado para estimar as probabilidades de sobrevivência. A comparação entre os grupos AR e BR foi avaliada pelos testes de Wilcoxon e log-rank. **Resultado:** Os resultados mostraram que 14% dos dentes selados apresentaram perda total (16% para AR e 12% para BR) e 46% apresentaram perda parcial durante o estudo (51% de AR e 41% para BR), em relação a amostra no início do estudo. Nenhuma diferença pode ser demonstrada pela análise de sobrevivência entre os grupos AR e BR ($p > 0,05$). **Conclusão:** O risco de cárie não influenciou as taxas de retenção de um cimento de ionômero de vidro modificado por resina usado como selante oclusal em escolares de 6-8 anos de idade.

Descritores: Escolares; cárie; risco; análise de sobrevivência.

Abstract

Introduction: Little is known whether caries risk influence occlusal sealants retention. **Objective:** To determine the retention rates (RR) of the resin-modified glass ionomer cement used as occlusal sealant in permanent first molars of 6-8-year old schoolchildren and to analyze the influence of caries risk at baseline on the RR of the sealant, over a 24-month period. **Material and method:** The sealant application was performed in a dental office at the beginning of the study, after children being allocated into high caries risk group (HR) and low caries risk group (LR). The examinations were performed by the same calibrated dentist at 0, 6, 12, 18 and 24 months. Retention rates were estimated, the Kaplan-Meier method was used to estimate the survival probabilities; and the comparison between HR and LR groups was evaluated by Wilcoxon and log-rank test. **Result:** The results showed that 14% of sealed teeth showed total loss (16% for HR and 12% for LR) and 46% showed partial loss during the study (51% for HR and 41% for LR), in relation to the baseline sample. No difference could be demonstrated by the survival analysis between HR and LR groups ($p > 0.05$). **Conclusion:** Caries risk did not influence the retention rates of a resin-modified glass ionomer cement used as occlusal sealant in 6-8-year old schoolchildren.

Descriptors: Schoolchildren; caries; risk; survival analysis.

INTRODUCTION

Several improvements have been made in the materials that are used to prevent dental caries. One such development was the introduction of the resin-modified glass-ionomer cement (RMGIC)

patented in the late 1980s¹. This innovation was an attempt to help overcome the problems traditionally associated with the conventional glass ionomer cements (GICs) due to its low physical

properties and high rate of loss along of longitudinal evaluations. The RMGICs present adhesion and fluoride release offering some protection against dental caries while still maintaining the properties of traditional GICs².

When used as pit and fissure sealants, GICs have poor retention rates³. Regarding the retention loss, Wright et al.⁴ did not find sufficient evidence in a systematic review to suggest the relative merits of each of the following materials used as dental sealants: glass ionomer, resin, resin-modified glass ionomer and polyacid-modified resin. Overall, all relevant studies agree on a gradual decline in sealant retention after a single application with the increase of the follow-up period⁵.

However, poor retention rates do not mean poor effectiveness on caries prevention. Several studies have showed that sealing pit and fissures with GICs can effectively prevent dental caries^{5,6}. Still, in a systematic review, Mickenautsch, Yengopal⁷ studied the evidence concerning the retention rate and caries occurrence on teeth sealed with resin and GICs and concluded that the sealant retention cannot be considered a valid surrogate for caries prevention.

Nevertheless, in a meta-analysis conducted by Kühnisch et al.³, the longevity of the sealant material was considered clinically important, especially regarding to the clinical indication of placing sealants to stop the progression of initial caries lesions. Moreover, little is known about variables that can influence sealants retention. A study has found that the higher the dft (decayed and filled primary teeth), the higher is the risk of sealant failure⁸.

In a previous study, it was found that sealing occlusal surfaces of children at high and low caries risk with a resin-modified glass ionomer cement (RMGIC) was effective in preventing new caries lesions⁹. Now, we aimed to determine the retention rates (RR) of the RMGIC used as occlusal sealant in permanent first molars of 6-8-year old schoolchildren and to analyze the influence of caries risk at baseline on the RR of the sealant, in a period of 24 months.

MATERIAL AND METHOD

Study Design

In this 24-month longitudinal study, data on the retention rates of a resin-modified glass ionomer cement used as occlusal sealant in high/low caries risk schoolchildren are presented.

It is important to mention that data for the present study are derived from a major study designed to measure the effectiveness of preventive methods for occlusal surfaces⁹. In the major study schoolchildren from Piracicaba [low caries prevalence: DMFT=0.85 for 12-year-olds¹⁰], SP, Brazil, were submitted to: a) oral health education every three months - OHE (Control groups); b) OHE plus varnish application biannually on the occlusal surfaces of permanent first molars (Varnish groups); c) OHE plus a single sealant application (Sealant groups)⁹.

Ethical Aspects

The experiments were undertaken with the understanding and written consent of parents and according to the principles stated in the Declaration of Helsinki. The major study has been independently

reviewed and approved by the Research Ethics Committee of the Piracicaba Dental School, University of Campinas (UNICAMP); (protocol number #025/2004).

Participants

Participants were selected among schoolchildren from two public schools that participated in a longitudinal collaborative project, supported by the Piracicaba government, Arcellor Mittal Foundation and the Piracicaba Dental School. In this collaborative project, children received restorative and/or preventive care in a clinical setting, in addition to oral health education activities performed at school. In order to avoid bias during the study, the dental chart of each volunteer was identified with a yellow label requesting that he/she should not be submitted to any preventive procedure other than those performed by the main researcher (E.P.S.T.).

Inclusion criteria to participate in the major study⁹ were: aged 6-8 years; living in Piracicaba, São Paulo, Brazil; with at least two sound permanent first molars; presenting dmft ≥ 3 or at least one active cavitated lesion or dmfs+DMFS = 0; and a parent or legal guardian providing signed informed consent. Children were excluded if they had systemic diseases, communication and/or neuromuscular problems, fixed orthodontic appliances, severe hypoplasia/fluorosis, and/or allergy to the colophony component of the varnish.

The baseline and follow-up examinations were performed by the same calibrated examiner (V.P.; Kappa > 0.90), who was blinded to the group allocation, following the same protocol, within a period of 24 months. Details on the calibration process are reported elsewhere⁹. The dental examinations were carried out at school in well-lit areas, using natural light, on sunny days only, using dental mirror and explorer after tooth brushing and air-drying. The teeth were dried with clean, dry, compressed air (Transport II, Portable Electric Dental Unit, SEA-425, Asepta, Inc., Woodinville, WA, USA). All volunteers received a kit containing a toothbrush, fluoridated toothpaste and dental floss. They performed tooth brushing supervised by a dental hygienist before the examination.

After the baseline examination, performed in accordance with the World Health Organization recommendations¹¹ and others¹²⁻¹⁵, each volunteer was classified, by the main researcher (E.P.S.T.), as follows:

- High caries risk (HR) children: those with dmft ≥ 3 , because the mean dmft of the target population obtained in an initial screening was 2.2, and/or with at least one active cavitated lesion. Children with caries experience were classified as high risk because studies have shown that previous caries history has been the best predictor of the disease¹⁶;
- Low caries risk (LR) children = those with dmft+DMFT=0.

Systematic allocation was used for the major study⁹, because preventive interventions would need to be initiated before other schoolchildren being examined at baseline. Thus, each schoolchildren, after being examined at baseline and classified in high or low caries risk, was allocated in the control, varnish and sealants groups, in this sequence. It is worth to emphasize that this sequence was defined at random, prior to the examination, and that schoolchildren were called for examination, at random, without knowledge on their caries risk.

For the present study, 55 children with 196 permanent first molars (PFM) participated in the high risk group and 53 children with 194 PFM participated in the low risk group (total= 390 PFM). Sample size for each study group was calculated for the major study⁹, considering a minimum significant difference of 0.5 in DMFS increment, considering a standard deviation of 0.72 DMFS with 80% power and 5% statistical significance level.

The volunteers with treatment needs were referred to Piracicaba Dental School, where graduate students under supervision of dentists from the public service, performed restorations, extractions, pulpotomies and supragingival scaling.

Resin-Modified Glass Ionomer Cement Application on the Occlusal Surfaces

The main researcher (E.P.S.T.), assisted by a dental hygienist, performed the sealant application (Vitremer™, 3M ESPE, St Louis, MI, USA) in a dental office. The first permanent molars were cleaned with a pumice slurry in Robinson brushes, washed, etched with 37% phosphoric acid (15 seconds), washed (15 seconds) and air-dried. Under isolation with cotton rolls, the material was applied as follows¹⁷: a) primer application (30 seconds), air drying and light-polymerization (20 seconds); b) mixing the powder into the liquid (power/liquid ratio of 1:2 by weight); c) placing the material into fissures with an explorer and light-polymerization (40 seconds); d) application of 'finishing gloss' and light-polymerization (20 seconds); e) checking the occlusal contacts. No reapplication of sealant was performed during the study⁹.

Follow-Up and Retention Rate Examinations

The follow-up examinations were performed every six months by the same examiner (V.P.), following the same protocol, within a period of 24 months.

The retention rate was evaluated by a calibrated and experienced examiner¹⁷. Each occlusal sealed surface was examined using criterion¹⁸ which classifies dental sealants in:

- Total retention (TR): total retention of the sealant on the occlusal surface;
- Partial retention type 1 (PR1): presence of sealant in two-thirds of pit extension, with small loss and fractures of material;
- Partial retention type 2 (PR2): presence of sealant in one-third of pit extension with fractures and losses of material;
- Total loss (TL): absence of sealant on the occlusal surface of the teeth.

Data Analysis

The Kaplan-Meier method¹⁹ was used to estimate the survival probabilities (time to completely lose the sealant). The survival analysis was chosen because the study presented censored data, i.e. the time of the total sealant lost was unknown; or the sealant was not completely lost at the end of the study or because the child abandoned the study.

The comparison between the groups of high and low risk was performed by Wilcoxon and log-rank test. The survival analysis is useful for analyzing time-related events, where the focus of interest is the time from an initial event to an endpoint²⁰. The advantage of this type of statistical method over conventional statistical methods is the inclusion of censored observations in data analysis. Information obtained from children who had at least two examinations were used in the statistical analysis²¹.

RESULT

Tables 1 and 2 show the results of survival analysis, considering the total loss of the sealant as the time to failure. The comparison between the survival curves of high and low risk groups (log-rank and Wilcoxon test) indicated no difference between the groups ($p>0.05$). The results showed that 14% of sealed teeth showed total loss during the study (16% for high risk and 12% for low risk children), in relation to the baseline sample. In addition, total losses began to be detected after 12 months of follow-up, for both high and low-risk children.

Tables 3 and 4 show the results of the survival analysis considering the partial loss of the ionomer sealant as the time to failure. None statistically significant differences were found in the comparison between the survival curves of the high and low caries risk groups ($p>0.05$). The results also showed that 46% of sealed teeth showed partial loss during the study (51% for high risk and 41% for low risk), in relation to the baseline sample. Partial losses began to be detected as early as the second examination at 6 months follow-up, for both high and low-risk children.

DISCUSSION

Most of the caries lesions have been concentrated in occlusal surfaces⁹ and the occlusal sealing has been an effective preventive measure. In this investigation, we assessed the retention rates of RMGIC cement used as occlusal sealant in schoolchildren aged 6-8-years, according to caries risk.

Table 1. Frequency distribution of failures and censored observations, considering as time of failure the "total lost of the sealant", according to caries risk

Risk	Frequency (n)	Frequency of failures (n)	Frequency of censored data (n)	% of Censored data
High	196	31	165	84.18
Low	194	23	171	88.14
Total	390	54	336	86.15

Table 2. Kaplan–Meier survival analysis related to caries risk (censored data = time of unknown total lost; Failure time= time of total lost of sealant), during the course of 24 months

Risk	Sealant follow-up (months)	Frequency (n)	Censored data (n)	Failures (n)	% of survival (SE)
High	0	196			100.00 (0.00)
	6	185	11	0	100.00 (0.00)
	12	179	2	4	97.84 (1.07)
	18	164	7	8	93.47 (1.82)
	24	0	145	19	82.64 (2.84)
Low	0	194			100.00 (0.00)
	6	194	0	0	100.00 (0.00)
	12	176	15	3	98.45 (0.89)
	18	166	4	6	95.10 (1.60)
	24	0	152	14	87.08 (2.52)

Wilcoxon test: $p=0.2459$ (comparing low and high caries risk); Log-rank test: $p=0.2442$ (comparing low and high caries risk).

Table 3. Frequency distribution of failures and censored observations, considering as time of failure the “partial lost of the sealant”, according to caries risk

Risk	Frequency (n)	Frequency of failures (n)	Frequency of censored data (n)	% of censored data
High	196	99	97	49.49
Low	194	80	114	58.76
Total	390	179	211	54.10

Table 4. Kaplan–Meier survival analysis related to caries risk (censored data = time of unknown partial lost; Failure time= time of partial lost of sealant), during the course of 24 months

Risk	Sealant follow-up (months)	Frequency (n)	Censored data (n)	Failures (n)	% of survival (SE)
High	0	196			100.00 (0.00)
	6	174	7	15	92.35 (1.90)
	12	142	2	30	76.43 (0.31)
	18	112	7	23	64.05 (3.50)
	24	0	81	31	46.32 (3.71)
Low	0	194			100.00 (0.00)
	6	182	0	12	93.81 (1.7)
	12	138	11	33	76.80 (3.0)
	18	117	3	18	66.79 (3.43)
	24	0	100	17	57.08 (3.65)

Wilcoxon test: $p=0.1790$ (comparing low and high caries risk); Log-rank test: $p=0.0908$ (comparing low and high caries risk).

Ionomeric material can be an alternative for fissure sealing. Although it has been known to have poorer retention than resin based sealants, Yengopal et al.²² have found no evidence that either material was superior to the other in the prevention of dental caries, in a systematic review with meta-analysis. It has been suggested that small portions of ionomeric materials can be retained at the bottom of the fissure and release fluoride²³, thus protecting

the region against future attacks demineralization. Vitremer is a resin-modified glass ionomer cement and can be used for sealing occlusal surfaces when it is prepared in power/liquid ratio of 1:2 by weight so that the mixture flows into fissures¹⁷.

This study showed that 14% of sealed teeth showed total loss of sealant (Table 1). The literature about retention rates of Vitremer is diverse. In a previous study, Vitremer was totally

lost in 74% of teeth, in a period of 5 years¹⁷. In a study²⁴ that evaluated Vitremer with a 0.25:1 powder/liquid proportion; Primer + Vitremer with a 0.25:1 powder/liquid proportion; and Vitremer with a 1:1 powder/liquid proportion, the total retention rate after 12 months were respectively: 52%, 41% and 12% and, according to the authors, the RMGIC may be a promising alternative as an occlusal sealant. On the other hand, other authors have suggested that RMGIC should be used only as a transitional sealant, applied to newly erupting teeth throughout the eruptive process, since 5.1% of RMGIC applied on permanent second molars of young patients aged between 12 and 16 years were intact after 3 years²⁵. Morales-Chávez, Nualart-Grollmus²⁶ found, after six months of follow-up, that Vitremer was lost in 37.5% of sealed permanent molars of special patients, aged 7-18 years. It has been suggested that the retention of dental sealants can be related to wear resistance of the material, position of the teeth in the mouth, clinical skills of the operator, and the age of the patient²⁷. Moreover, the length of the studies could also explain the distinct results found in the literature.

The results also indicated that caries risk did not influence significantly the retention rate of sealants; since the survival curves of the groups of high and low risk did not differ statistically. As previous mentioned, little is known about variables that can influence retention rates of occlusal sealants. Other variables that

were not assessed in this study (e.g. tooth position, occlusion and level of eruption) could be influencing the retention rate of the RMGIC sealant and should be studied in the future. The sample of this present study received oral health education at each 3 months until the final of the evaluation period, and it is valid to speculate that they were constantly motivated and an improvement of self-oral care was achieved.

Despite the partial or total loss of sealants, the effectiveness of sealing could be proven, as evidenced by the results previously published. Occlusal sealing with RMGIC in high and low caries risk children was effective in preventing the development of new lesions since those with sealed molars presented similar caries experience on occlusal treated surfaces at both cavitated and non-cavitated levels, at baseline and final examinations⁹.

This study has some limitations, previously discussed⁹, such as its conduction in a low caries prevalence area and the use of a convenience sample. However, the latter allowed us to monitor the schoolchildren enrolled in the project, avoiding them to be submitted to any other preventive measure than those tested by this study.

In conclusion, the results of this study showed that caries risk did not influence the retention rates of a resin-modified glass ionomer cement used as occlusal sealant in 6-8-year old schoolchildren.

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CONFLICTS OF INTERESTS

The authors declare no conflicts of interest.

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