



Sealing of cavitated occlusal carious lesions in the dentine of deciduous molars: a two-year randomised controlled clinical trial

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Abstract

Objectives This two-arm, parallel-group, tooth-randomised, controlled noninferiority clinical trial aimed to compare survival rates between the sealing and restoring of cavitated occlusal carious lesions in dentine [International Caries Detection and Assessment System (ICDAS) 5] of deciduous molars using resin-modified glass-ionomer cement (RMGIC) and to assess caries progression radiographically.

Materials and methods A total of 68 molars with ICDAS 5 occlusal lesions were randomly allocated into two groups, a sealing group (n = 31), in which RMGIC was placed directly over the carious lesion, and a restoration group (n = 37), in which a restoration with the same material was placed after selective caries removal. During the baseline and follow-up visits, dental caries was registered and caries activity was assessed according to a visuotactile criterion. At baseline, patient caries status (dmf-t) and cavity depth and extent (mesiodistal and buccolingual) were measured before RMGIC placement. An independent and blinded examiner evaluated the treated teeth using the USPHS criteria after one and two years. Standardised interproximal radiographs were taken for caries progression assessments.

Results During the follow-up period, no lesion progression was observed radiographically. After one year (n = 60; 27 sealed and 33 restored) and two years (n = 48; 23 sealed and 25 restored) of follow-up, the treatment success rates were 78.8% and 76.0% in the restoration group and 59.3% and 47.8% in the sealing group, respectively. Multivariate Cox regression showed that lesions smaller than 2 mm in the mesiodistal extent were less prone to fail after one year (p = 0.03). However, survival curves (log-rank test) were statistically significantly different only after two years (p < 0.001).

Conclusions Sealing ICDAS 5 occlusal lesions of deciduous molars using RMGIC achieved lower survival rates than restorations. Both sealing and restoration effectively arrested caries progression for two years.

Clinical relevance

Sealing dentine carious lesions can be effective for treating lesions involving the inner and outer half of the dentine. Ultraconservative treatments can arrest carious lesions presenting obvious cavitation in primary molars. Trial Registration: ReBEC Register no. RBR-225n35.

Keywords Sealing · Dental caries · Dentine · Glass-ionomer cement · Deciduous tooth

Introduction

For many years, cavitated dentine caries lesions have been treated invasively by removing the carious tissue in full. However, minimal intervention approaches have been studied and are strongly recommended to preserve dental tissue, arrest early carious lesions and avoid caries progression. Regarding minimally invasive interventions, restorative procedures after selective caries removal have been consistently indicated for deep cavitated carious lesions, achieving good results in terms of preserving

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remineralisable tissue and maintaining pulpal health over time [1, 2]. Some studies showed that placing a restorative material after selective caries removal can seal the cavity and reduce the microbiota qualitatively and quantitatively in both permanent and primary teeth. In this case, the carious process is arrested and pulp vitality is maintained due to the absence of substrate [3].

According to a cariology consensus meeting [2], a more conservative approach consists of sealing (mechanically blocking) microcavitated carious lesions [International Caries Detection and Assessment System (ICDAS) grades 3 and 4] without performing any previous carious tissue removal, preserving the tooth for as long as possible. This approach is very convenient for primary teeth, which are temporary and have a shorter lifespan than permanent teeth. Although scarce, the literature has reported that sealing dentine carious lesions can also be effective for managing lesions involving the outer half of the dentine. Good results regarding caries arrest have been observed using flowable resin composites with no removal of caries tissue in primary teeth [4, 5]. However, the literature is still unconvincing with respect to clinical studies involving ultraconservative treatments aiming to arrest caries lesions presenting obvious cavitation in primary molars. Additionally, there is no evidence available concerning carious lesion size or depth threshold to recommend these ultraconservative approaches.

Regarding dental materials used in paediatric patients, glass-ionomer (GI) cements have frequently been applied, although evidence supporting their longevity is still limited [6]. GI is a more hydrophilic material compared to composite resin, which facilitates its use in patients presenting difficulties in managing their behaviour and when moisture control is a challenge. Two systematic reviews [7, 8] reported no difference in the survival rates of restorations performed using composite resin and RMGIC. These results can be attributed to the technical sensitivity of composite resin, which is affected by the presence of water or saliva, and to the fact that sometimes moisture control is difficult in paediatric patients, so a lower degree of performance can be expected. Finally, no study yet has tested the effectiveness of a resin-modified GI cement (RMGIC) to seal cavitated occlusal dentine carious lesions scored as ICDAS grade 5 (clear cavity with visible dentine).

Therefore, this two-year randomised controlled clinical trial aimed to compare the survival rates of sealing and restoring cavitated occlusal dentine carious lesions (ICDAS grade 5) in primary molars using RMGIC. Secondly, this study aimed to assess radiographic carious lesions progression. The null hypothesis was that there would be no difference in the survival rates or the radiographic carious progression between the two treatments.

Materials and methods

Trial design

This was a two-arm, parallel-group, tooth-randomised, controlled noninferiority trial with a 1:1 allocation ratio. Children aged three to nine years old were eligible to be included in this study, which reports the two-year follow-up results of the sealing of occlusal dentine caries in primary molars performed in 2017 and 2018 at the Pediatric Dental Clinic of the Federal University of Rio Grande do Sul, School of Dentistry, Porto Alegre, Brazil.

Ethical aspects.

This study was approved by the Research Ethics Committee of the Federal University of Rio Grande do Sul, Brazil (CAAE no. 63778617.6.0000.5347) and registered in the Brazilian Registry of Clinical Trials database (registration no. RBR-225n35, registered on 13/09/2019). Eligible children had the trial purpose and protocols and all the treatment details explained to them and were invited to accept or decline to participate using an assent form. Written informed consent was obtained from all participants and their parents or legal guardians. All study methods were carried out as per relevant guidelines and the study is reported according to the CONSORT statement criteria.

Sample size

The study's sample size was calculated based on a previous study performed in primary teeth that evaluated the success of sealing external half-dentine lesions [4], with a power of 80%, a noninferiority margin of -0.10 and a level of significance of 5%, accepting a success rate of 64.7% in the test group and 100% in the control group, with a 30% sample loss rate and 20% cluster effect. A total of 23 teeth were included per group ($n=46$ teeth total).

Participants

Ninety-three children aged between three and nine years old seeking dental treatment were evaluated ($n=698$ teeth) and 32 (mean \pm standard deviation age: 6 ± 1.5 years) were included after anamnesis, clinical and radiographic examinations ($n=60$). Visible Plaque Index (VPI), Gingival Bleeding Index (GBI) and clinical examinations were performed by two operators (N. M. S. and D. B. G.), who were trained and calibrated for caries assessment (presence and depth) using a digital learning tool [9, 10] according to the ICDAS, and by a senior researcher (J. A. R.) for caries activity according to visuotactile criteria [11]. The Kappa inter-examiner value was 0.83, while the intra-examiner

values were 0.83 (N. M. S.) and 0.97 (D. B. G.). To evaluate carious lesion depth and pulp and periapical condition, standardised modified interproximal radiographs were taken using an Emmenix Film Holder (Hager & Werken, Duisburg, North Rhine-Westphalia, Germany), which allows for film displacement and, therefore, the assessment of the periapical area.

The inclusion criteria were children aged three to nine years old, in good general health and presenting at least one cavitated dentine occlusal caries lesion (ICDAS grade 5) in a primary molar with a radiographically measurable depth either in the outer or inner half of the dentine [12], for which restorative treatment was indicated. Moreover, teeth had to have at least two-thirds of the root visible in the radiographic exam. The exclusion criteria comprised teeth with signs of spontaneous pain, fistula or mobility not compatible with the root resorption period and advanced rhizolysis; children who were unable to cooperate during clinical appointments; patients/guardians who decided no longer to participate in the study, who did not show up to the two-year appointment or who moved out of the city.

Randomisation

Once the child was in the chair, a third researcher who was neither involved in the clinical procedures (i.e., assessment and sealant or restoration placement) nor in the data analysis randomly allocated the selected tooth into one of the two intervention groups, using a previously prepared computer-generated list of random numbers (Microsoft Excel; Microsoft Corporation, Redmond, WA, USA). Opaque, sealed and sequentially numbered envelopes were used to randomise participants into the treatment (sealing and restoring) groups.

Blinding

Blinding operators, children and parents was not possible as the two treatments used different techniques. Only the outcome evaluator was blinded.

Interventions

Two interventions were tested: sealing and restoring ICDAS 5 caries lesions. The main difference between the two consisted in the fact that in the sealing group, the RMGIC was placed without any caries removal, while in the restoration group, selective caries removal was performed before restoration placement. Before the treatment, patients received dental prophylaxis and oral hygiene instructions using a toothbrush with fluoride dentifrice and floss, and dietary counselling. The treatments were performed by two experienced paediatric dental specialists (D. B. G. and N. M. S.).

Initially, the occlusal surface was cleaned with a Robinson bristle brush, pumice and water, then treated according to the protocol of the group into which the tooth was allocated, as follows:

- 1) Sealing group (n = 27, test): the teeth allocated to this group had their occlusal lesions sealed with RMGIC (GC Fuji II LC® capsule; GC Corporation, Tokyo, Japan) under cotton roll isolation and suction. As recommended by the manufacturer, Vitro conditioner (polyacrylic acid 11.5%; New DFL, Rio de Janeiro, RJ, Brazil) was applied for 15 s, then rinsed. Afterwards, the RMGIC was inserted into the cavity with the aid of a hand instrument and light-cured for 20 s (1250 mW/cm²) (Emitter C®; Schuster, Santa Maria, Brazil). For cavities that measured deeper than 1.8 mm, the material was applied in two layers. Finishing and polishing were performed using diamond drills and silicone tips. No patient in this group required local anaesthesia.
- 2) Restoration group (n = 33, control): the teeth allocated in this group were restored with the same RMGIC material as that used in the test group (GC Fuji II LC® capsule; GC Corporation, Tokyo, Japan), following the manufacturer's instructions and under the clinical conditions mentioned above. However, before placing the material, selective caries removal was performed using a sterile slow-spinning round steel burr, according to the clinical hardness criteria. No patient in this group required local anaesthesia.

In both groups, the mesiodistal (MD) and buccal-lingual (BL) extent and depth of the cavity were assessed with a millimetre probe before placing the RMGIC. The probe was positioned horizontally over the cavity in both the MD and BL directions and vertically inside the cavity. The resulting values were registered in millimetres.

Follow-up assessments and radiographic analysis

Patients returned at six, 12, 18 and 24 months after treatment. During these follow-up visits, after prophylaxis with Robinson bristle brushes, pumice and water, clinical examinations (ICDAS, caries activity status) were performed as mentioned above. Based on the United States Public Health Service (USPHS) criteria [13], a blinded trained and calibrated paediatric dentist (C. S. S.) evaluated the teeth included in the trial, considering the following criteria: I (retention), III (marginal integrity), VII (postoperative sensitivity according to patient report) and IX (secondary caries) (see Table 1).

A standardised and modified interproximal radiograph was taken at each follow-up assessment, as mentioned above. Lesions were classified as either 'progressed' or 'arrested'

Table 1 Summary of USPHS [13] criteria. Asterisks show the score considered to be a failure

Criteria	Test procedure	USPHS score	
I. Retention	Visual inspection with mirror at 18 inches	Complete retention of the restoration	Alpha
		Mobilisation of the restoration, still present	Bravo
		Loss of the restoration	Charlie*
III. Marginal integrity	Visual inspection with mirror at 18 inches	Absence of discrepancy at probing	Alpha
		Presence of discrepancy at probing, without dentine exposure	Bravo
		Probe penetrates in the discrepancy at probing, with dentine exposure	Charlie*
VII. Postoperative sensitivity	Ask patients	Absence of dentinal hypersensitivity	Alpha
		Presence of mild and transient hypersensitivity	Bravo
		Presence of strong and intolerable hypersensitivity	Charlie*
IX. Secondary caries	Visual inspection with explorer and mirror, if needed	No evidence of caries	Alpha
		Evidence of caries along the margin of the restoration	Bravo*

by a trained and calibrated senior researcher (J. A. R.), who assessed the radiographs through paired evaluations, comparing two by two, without the aid of any magnification loops and while blinded regarding the chronological order of the radiographs.

Trial outcomes

The main study outcome variable was clinical failure, which was considered when the treated teeth were classified as I (C), VII (C) and IX (B) by USPHS. When these failures were observed, the teeth were assigned the appropriate treatment (restoration replacement, endodontic treatment or extraction) and the failure was registered. If a case of III (C) was observed and a failure was noted in the margins of the restoration, a re-intervention was indicated (repair) according to which group the tooth was initially allocated to. These teeth were maintained in the sample, albeit labelled as having undergone re-intervention. Second, radiographic caries progression status (absence or presence) was recorded. When radiographic progression was observed, the affected teeth were treated accordingly (endodontic treatment, restoration or extraction, depending on the progression level).

Statistical analysis

All analyses were performed considering a significance level of 5% and using adequate statistical software (IBM SPSS Statistics for Windows, version 20.0; IBM Corporation, Armonk, NY, USA). The results for the VPI, GBI and visual examination of caries lesions (dmf-t) were obtained using percentage means. Cox regression was used to assess the risk factors related to failure (i.e., treatment; age; sex; dmf-t; teeth; and lesion location, depth, volume and MD/BL extent). The Kaplan–Meier method was used to analyse

differences in the survival rates of treatments between the sealing and restoration groups. For both multivariate Cox regression and survival rates analyses, the cluster effect was considered. The log-rank test was used to compare the success rates of the sealing and restoration groups. The power of the sample test was calculated by a blinded researcher (M. N.) using the ‘powerMediation’ package from software R, version 3.5.1 (R Foundation for Statistical Computing, Vienna, Austria). An interim analysis at a follow-up of one year was also performed. Because this study was conducted on primary dentition, the results of an interim analysis can add important data to the literature, especially for teeth that will remain in the oral cavity for a short time until natural exfoliation.

Results

Thirty-two children (mean age: 5.79 ± 1.39 years), including 20 (62.5%) boys and 12 (37.5%) girls, were included and a total of 68 cavitated occlusal carious lesions in dentine were treated ($n = 31$ in the sealing group and $n = 37$ in the restoration group). No difference was observed between the sample characteristics at baseline (except for cavity volume, $p = 0.01$) as shown in Table 2. The number of children, teeth allocated in each group and dropouts can be observed in the flow diagram in Fig. 1.

For the interim analysis at the one-year point of follow-up, 60 teeth ($n = 27$ sealed and $n = 33$ restored) were clinically and radiographically evaluated. The dropout rate was 11.8% and the overall treatment success rate was 70.0% (59.3% for the sealing group and 78.8% for the restoration group). The log-rank test result was not significant ($p = 0.07$) (Fig. 2). Cox regression showed that lesions with

Table 2 Sample characteristics (chi-squared test)

	Groups	Sealing (n = 31)	Restoration (n = 37)	Total (n = 68)	p-value
Gender	Male	19	27	46	0.22
	Female	12	10	22	
VPI	≤ 10%	2	2	4	0.62
	> 10%	29	35	64	
GBI	≤ 10%	17	16	33	0.23
	> 10%	14	21	37	
dmf-t	≤ 3	1	4	5	0.23
	> 4	30	33	63	
Jaw	Upper	14	17	31	0.57
	Lower	17	20	37	
Jaw Side	Right	16	24	40	0.19
	Left	15	13	28	
Molar	First	14	11	25	0.14
	Second	17	26	43	
MD extent	Up to 2 mm	20	18	38	0.14
	> 3 mm	11	19	30	
BL extent	Up to 2 mm	19	16	52	0.10
	> 3 mm	12	21	33	
Lesion depth	Up to 2 mm	25	27	52	0.32
	> 3 mm	6	10	16	
Volume	> 70 mm ³	9	22	37	0.01
	≤ 69 mm ³	22	15	31	

a mesiodistal extent of less than 2 mm had a 77% reduced chance of failure (p = 0.03) (Table 3).

At the two-year point of follow-up, 48 teeth (n = 23 sealed and n = 25 restored) were clinically and radiographically evaluated (70.6% of baseline cohort). The treatment success

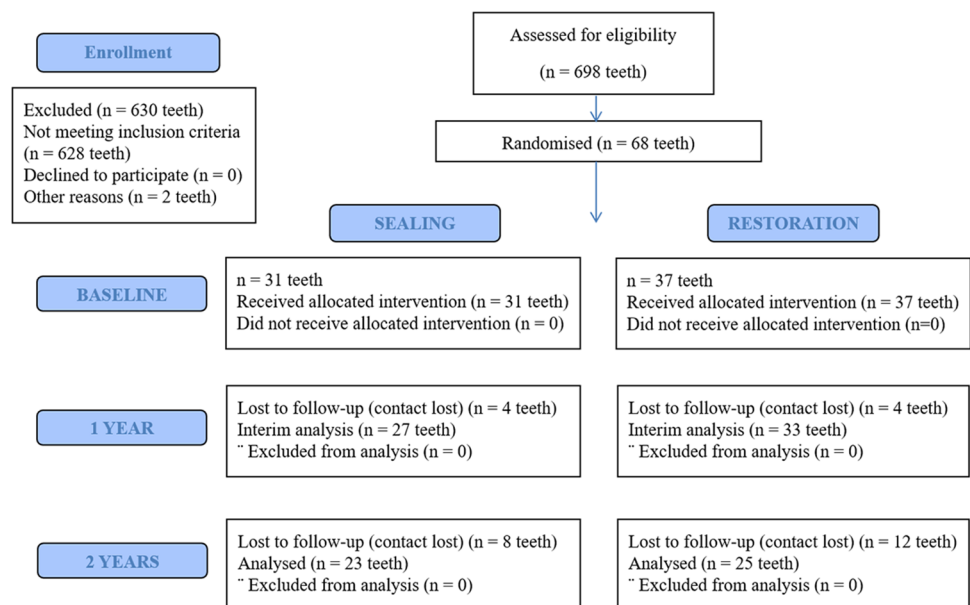
rates were 47.8% (n = 12 failures) in the sealing group and 76.0% in the restoration group (n = 6 failures). According to the USPHS criteria, three failures in the restoration group were classified as I (retention) and three as IX (secondary caries). In the sealing group, 10 failures were classified as I (retention) and two as IX (secondary caries). Because III status (marginal integrity) was observed in two sealed teeth, a re-intervention was performed. No child reported postoperative sensitivity (VII). Kaplan–Meier survival curves are shown in Fig. 2. The log-rank test was significant (p < 0.001) only at the two-year follow-up. Cox regression (Table 3) showed no significant association with failure (p < 0.05).

Over the follow-up period, no radiographic lesion progression was observed.

Discussion

This study showed that sealing a cavity using RMGIC can arrest cavitated carious lesions in the dentine (ICDAS 5) of deciduous molars, regardless of lesion depth and extent. Although more failures related to retention, marginal integrity and secondary caries (caries adjacent to the material) were observed in the sealing group than in the restoration one, the results show that no radiographic lesion progression occurred in either group. Therefore, the null hypothesis was partially accepted. Additionally, to our knowledge, this was the first randomised controlled clinical trial on the sealing of cavitated dentine carious lesions with two years of follow-up in which lesion depth and extent were measured. In this study, instead of just defining the cavity design based on the number (one) and location (occlusal) of surfaces involved, the cavity was quantitatively measured in millimetres with

Fig. 1 CONSORT flow diagram of the study selection process



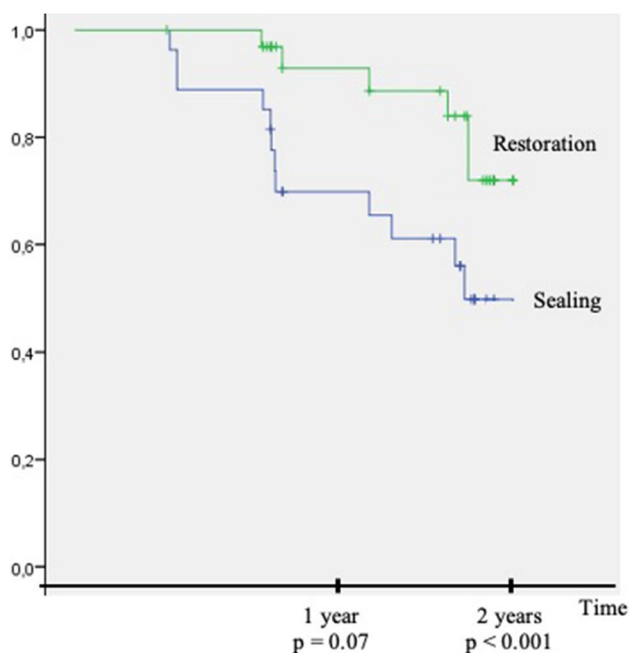


Fig. 2 Survival curves and log-rank test results at one- and two-year follow-ups

a probe. This is also the first study in which dentin occlusal caries lesion extent and depth were not used as exclusion criteria and were instead statistically analysed separately, which differs from the protocols of other studies that only included lesions with a cavity opening limited to 1.5 mm [5] and 3 mm [4]. This is a methodology that has not been used previously. By analysing the results of the interim analysis (performed at one year of follow-up), cavities measuring less than 2 mm in mesiodistal extent were found to be less prone to fail. Therefore, cavity size had a significant influence on treatment success, indicating that small lesions on teeth that will remain in the mouth for only a short period should preferably be sealed. Additionally, survival rates were not different at this point in the analysis, supporting this approach.

Concerning sealing cavitated lesions, Hesse et al. [4] reported a success rate of 64% for resin-based pit and fissure sealants placed over dentine lesions after 18 months, while the present study found a rate of 47.8% after two years. This reduction is to be expected since more failures might occur progressively over time. Moreover, the present study included not only cavities with outer dentine caries lesions but also deeper lesions, in contrast to the study protocol of Hesse et al. [4].

An overall success rate of 60.4% after two years was recorded for RMGIC, considering survival as the main outcome, and a dropout rate of 29.4%, which was exactly the expected sample loss. However, when comparing the survival rates of both groups, the restoration group showed better performance than the sealing group (per the survival

curve). This fact might be due to the lack of caries removal in the sealing group, which might have influenced the adhesion of the material to the lateral cavity walls, as the main difference between the two groups was carious tissue removal. This hypothesis is further supported by the dominant type of failure observed in the sealing group, which was related to retention. In the study of Dias et al. [5], three clinical failures in each group (sealing and restoration) were observed after 24 months, albeit without a significant difference between the two groups. Although these authors did not present survival curves per group, the small number of failures they reported can be considered a positive and expected result since resin-based materials used under rubber dams usually perform well, mainly in small carious lesions. The study conducted by Hesse et al. [4] also demonstrated that the sealed group experienced significantly greater clinical failures ($n=6$ teeth at 18 months) compared to the restoration group. In our study, cotton rolls were used instead of a rubber dam, with no anaesthesia in either group, which can be considered a patient-friendly procedure for children.

Notably, the fact that failures were observed over time does not necessarily indicate that a re-intervention is needed, i.e. material repair or substitution, mainly in primary teeth. Close monitoring of the patient is recommended to assess other clinical outcomes, signs and symptoms. Our main concern remains that postoperative pain and/or radiographic caries progression should also be considered in the decision-making process to repair or replace a dental material.

This study found no differences between the two groups in terms of caries arrestment or radiographic caries progression, a result that is similar to that of other published studies [4, 5]. Both the trials by Hesse et al. [4] and Dias et al. [5] also evaluated the efficacy of sealing occlusal caries but only assessed the outer half of dentine for caries progression. Additionally, both trials used a flowable resin as sealing material instead of restoring using a composite resin after selective caries removal, which differs from our protocol. The study conducted by Hesse et al. [4] also demonstrated that both treatments had similar efficacy in arresting caries progression after 18 months.

It is important to highlight that a direct comparison between the results of our study and those just mentioned is not straightforward, as they used different materials and included only superficial lesions reaching up to the outer half of the dentine. Moreover, no information about the size of the cavity was provided. Therefore, it is not possible to claim without a doubt that the higher number of failures observed after two years in our study was related to the type of material used. The depth and extent of the lesions included herein should also be considered, although cavity size was not necessarily associated with failure. This means that in both treatment groups, sealing and restoring had the potential to fail after two years regardless of cavity size.

Table 3 Univariate^a and multivariate^b Cox regression results at one- and two-year follow-ups

Risk factors	Relative risk ^a	p-value	Relative risk ^b	p-value	Relative risk ^a	p-value	Relative risk ^b	p-value
1 year				2 years				
Sex		0.08		0.02		0.22	-	-
Male	1.00		1.00		1.00		-	-
Female	2.22 (0.90–5.44)		3.15 (1.109–8.30)		1.81 (0.70–4.69)		-	-
Age (years)		0.40	-	-		0.86	-	-
≤ 5.8	1.00				1.00			
> 5.9	1.48 (0.59–3.72)				1.08 (0.43–2.68)			
VPI		0.44	-	-		0.79	-	-
> 10%	1.00				1.00			
≤ 10%	1.41 (0.57–3.49)				0.79 (0.10–5.76)			
GBI		0.08		0.14		0.54	-	-
> 10%	1.00		1.00		1.00			
≤ 10%	2.21 (0.88–5.54)		2.05 (0.78–5.53)		0.74 (0.29–1.90)			
dmf-t		0.39	-	-		0.53	-	-
> 4	1.00				1.00			
≤ 3	1.55 (0.56–4.32)				0.53 (0.07–4.01)			
Group		0.08		0.14		0.04		0.89
Sealing	1.00		1.00		1.00		1.00	
Restoration	2.19 (0.89–5.38)		2.08 (0.78–5.56)		2.68 (1.02–6.53)		1.04 (0.53–2.03)	
BL extent		0.29	-	-		0.23	-	-
> 3 mm	1.00				1.00			
≤ 2 mm	0.62 (0.25–1.52)				1.76 (0.69–4.48)			
MD extent		0.05		0.03		0.05		0.97
> 3 mm	1.00		1.00		1.00		1.00	
≤ 2 mm	0.40 (0.15–1.05)		0.23 (0.05–0.92)		2.67 (0.97–7.37)		0.98 (0.51–1.88)	
Lesion depth		0.53	-	-		0.34	-	-
> 3 mm	1.00				1.00			
≤ 2 mm	0.67 (0.19–2.31)				2.03 (0.46–8.79)			
Volume		0.23	-	-		0.23	-	-
> 70 mm ³	1.00				1.00			
≤ 69 mm ³	3.40 (0.45–25.7)				3.40 (0.45–25.7)			
Jaw side		0.83	-	-		0.95	-	-
Right	1.00				1.00			
Left	1.10 (0.44–2.71)				0.97 (0.39–2.38)			
Jaw		0.42	-	-		0.64	-	-
Upper	1.00				1.00			
Lower	1.45 (0.57–3.66)				1.23 (0.50–3.03)			
Molar		0.44	-	-		0.74	-	-
First	1.00				1.00			
Second	0.70 (0.29–1.72)				0.86 (0.35–2.11)			

Conversely, in terms of controlling caries progression, both sealing and restoring procedures using RMGIC showed a success rate of 100% since no progression was observed. Therefore, our results suggest that sealing cavitated dentine lesions with RMGIC without anaesthesia, rubber dam placement or caries removal might be a good option for treating such lesions in children at high risk of caries, where the preventive effect of RMGIC is fully desirable. Furthermore, the decision-making process for choosing between sealing and restoring a cavitated carious lesion should consider the need to monitor the treated teeth over time. GI sealants may often fail over cavities and may need to be repaired, so preventive periodic maintenance is required. Therefore, it is important to consider both cavity size and the time it will take a tooth to exfoliate when opting for sealing an ICDAS grade 5 lesion.

Conclusions

Sealing ICDAS grade 5 occlusal carious lesions of deciduous molars using RMGIC achieved lower survival rates than restorations after two years. However, both sealing and restorative procedures were effective in controlling caries progression over the said period.

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Declarations

Conflict of interest The authors declare no competing interests.

Ethics approval and consent to participate This study was approved by the Research Ethics Committee of the Federal University of Rio Grande do Sul, Brazil (CAAE no. 63778617.6.0000.5347) and registered in the Brazilian Registry of Clinical Trials database (registration no. RBR-225n35). All parents or guardians signed a written informed consent form for data collection.

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