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Survival and Associated Risk Factors of Selective Caries Removal Treatments in Primary Teeth: A Retrospective Study in a High Caries Risk Population

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Keywords
Dental plaque · High caries risk · Longevity · Primary teeth · Selective caries removal

Abstract
Objective: The aim of this retrospective study was to analyze the survival probability of selective caries removal (SCR) treatments in the primary teeth of children with high caries experience and factors potentially associated with treatment failure. ***Methods:*** The sample included SCR treatments conducted in anterior and posterior teeth without sedation or general anesthesia among children attending a university dental service. Kaplan-Meier survival analysis was used to estimate the longevity of restorations and multivariate Cox regression with shared frailty was used to assess risk factors. ***Results:*** A total of 284 SCR treatments in 88 children (aged 5.2 ± 1.91 years) with high caries experience (mean dmft/DMFT = 11.1 ± 5.04) were analyzed. The 3-year survival reached 48.8%, with an annual failure rate of 21.2%. Restorative failures ($n = 60$) were found more frequently compared to pulp complications ($n = 12$). SCR performed in anterior primary teeth were more prone to failure (hazard ratio = 3.6, 95% CI: 1.94; 6.71). Patients with a higher amount of visible plaque experienced more failures in SCR treatments (hazard ratio 3.0, 95% CI:1.27; 7.07). ***Conclusions:*** In this retrospective study, SCR showed restricted survival when compared to other prospective clinical trials. Patient-related factors, especially the young age and high caries experience of the children, may represent a challenge for restoration survival. Regardless of the caries removal technique or restorative material, cariogenic biofilm has a negative effect on the survival of restorations, probably by acting directly on material deterioration and, particularly, on the development of new caries lesions of rapid progression.

The contemporary approach to the management of caries lesions recommends that in deep lesions of vital teeth, preserving pulpal health should be prioritized [Schwendicke et al., 2016]. Selective caries removal (SCR)

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is indicated for the treatment of deep caries lesions in primary and permanent teeth [American Academy of Pediatric Dentistry, 2012]. The technique involves selective removal to soft dentin over the pulp site to avoid its exposure, while the cavity margins (i.e., peripheral dentin) are left hard (scratchy) [Schwendicke et al., 2016].

Studies have demonstrated that complete caries removal in deep caries lesions of primary and permanent teeth increased the risk of pulp exposure and the postoperative symptoms in comparison with SCR [Maltz et al., 2012; Ricketts, 2013; Schwendicke et al., 2013a; Franzon et al., 2015]. Recently, an RCT demonstrated high rates of clinical and radiographic success of selective and complete caries removal in primary teeth with deep carious lesions, which did not differ significantly. However, as an additional advantage, 1-step incomplete excavation (selective) requires less treatment time and results in lower levels of discomfort for the patients, which is especially important when treating children [Franzon et al., 2014].

In fact, there is sound scientific evidence that demonstrates the good results of SCR [Pinto at al., 2006; Casagrande et al., 2009; Maltz et al., 2012]. However, a great proportion of dentists still prefer to remove all the carious dentin. One of the reasons for clinicians avoiding SCR is the fear of caries progression under the restoration. A survey among German dentists showed that 72% of the respondents said that they agreed with the statement "cariogenic microorganisms need to be removed completely, since caries might progress otherwise." Moreover, 73% of them agreed with the statement "caries should always be removed completely," since residual caries is a risk for the vitality of the pulp." Dentists also reported preferring more invasive treatment to improve the longevity of the restoration, even at the risk of compromising pulp vitality [Schwendicke et al., 2013b].

Similarly, less invasive strategies for managing deep lesions have not widely entered clinical practice in France. The behavior, attitudes, and beliefs of French, German, and Norwegian dentists regarding deep carious lesion management demonstrated that most of the dentists from Germany and France thought complete removal was required to avoid lesion progression and were uncertain whether remaining sealed bacteria would harm the pulp [Schwendicke et al., 2017]. These studies reinforce the fact that the concern of clinicians is more focused on the technique itself, instead of on other patient factors that can also influence the performance of the restorations.

Recently, it was recommended that the assessment of patient factors, such as socioeconomic status, caries risk/activity/severity, and oral hygiene (among others), should become part of clinical studies investigating restoration survival, since several of these factors were shown to influence the failure of restorations [van de Sande et al., 2016]. A recent retrospective study comparing "complete" and "selective" caries removal in young permanent molars demonstrated that, regardless of caries removal technique, the restorations showed a restricted survival in patients with high caries activity and gingivitis [Casagrande et al., 2016]. Thus, the aim of this retrospective study was to analyze the survival probability and factors (patient and treatment-related) associated with failure of SCR treatments in the primary teeth of children with high caries experience.

Subjects and Methods

Study Design and Ethical Aspects

This university-based retrospective study was developed at the Pediatric Dentistry Specialization Course, Faculty of Dentistry, Federal University of Rio Grande do Sul (UFRGS), Porto Alegre, Brazil. The study was conducted in accordance with ethical standards of the Resolution of the National Council on Ethics in Research (No. 466/2012) and the Helsinki Declaration (2008). The research protocol had approval from the local ethics committee (No. 36799714.1.0000.5347). All the clinical records included in the study had informed consent forms properly completed and signed by the legal guardians of the patients, authorizing dental treatment and use of registered data for research.

Sample and Data Collection

The sample consisted of SCR treatments conducted in anterior and posterior primary teeth, due to primary caries lesions, that included a clinical and radiographic follow-up of at least 6 months. The SCR treatments were selected from the dental records of children aged 3–10 years, without medical problems, who regularly visited the university clinic (at least once a year) between 2005 and 2013. One trained dentist (X.C.M.) collected the clinical and radiographic data from the patient files.

Factors potentially associated with SCR survival were also retrieved from the records: (1) patient age; (2) gender; (3) caries experience (dmft/DMFT index – at first appointment); (4) visible plaque and gingival bleeding indexes (VPI and GBI – at first appointment and at the last check-up); (5) tooth position (anterior or posterior); (6) type of cavity (1 or multiple surfaces); (7) presence of a liner material (calcium hydroxide cement); and (8) restorative material applied (composite resin or resin-modified glass ionomer cement – RMGIC). The values of VPI and GBI were dichotomized, considering that the patient had a satisfactory plaque control when these indexes were less than 20% [Lang and Tonetti, 2003].

Clinical Procedures

All clinical procedures were performed by dentists who attended a postgraduate course in Pediatric Dentistry at the UFRGS and were supervised by clinical instructors (specialists in pediatric dentistry with over 15 years of clinical experience in treating children).

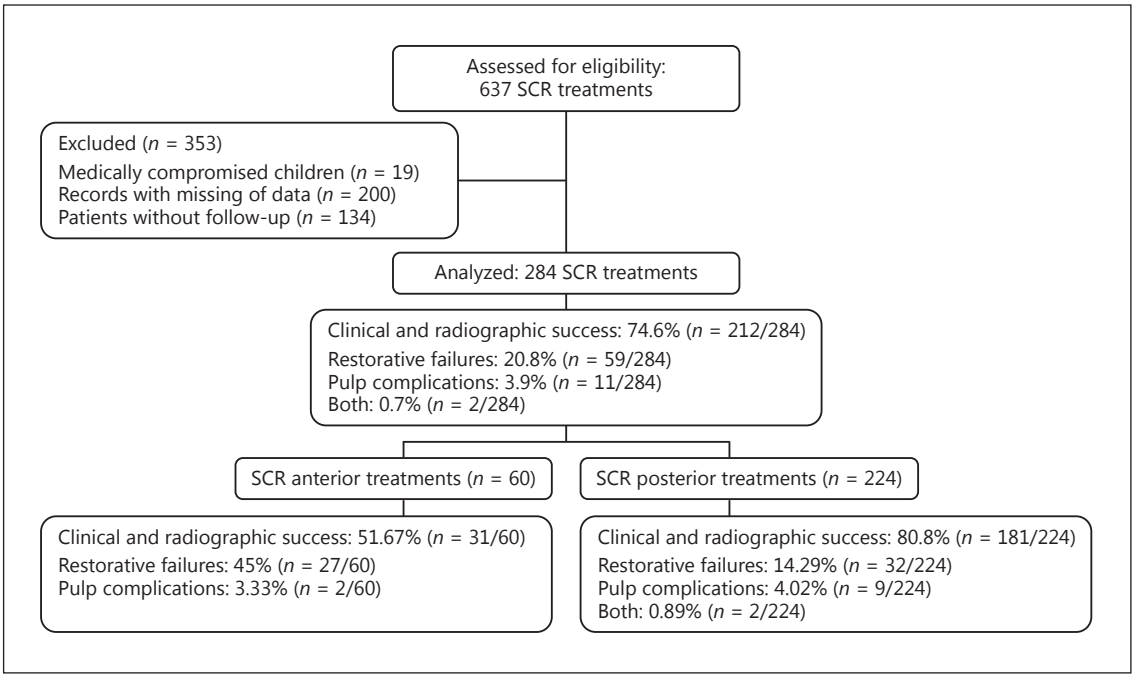

Fig. 1. Flowchart of the study. SCR, selective caries removal.

Treatments were delivered at a low charge to the patients in the university clinic; this attracted many children from families with limited income and low social economic status. The treatment procedures followed the recommendations of the current guidelines and policies of the American Association of Pediatric Dentistry [American Academy of Pediatric Dentistry, 2012].

After clinical examination, diagnostic radiographs were obtained to visualize the depth of caries lesions and the furcation/periapical regions. Caries lesions should be located in the inner half of dentin and there must not be any symptom or sign suggesting irreversible pulp involvement for SCR treatment.

Patients were given local anesthetics and treatment was performed under rubber dam isolation. If necessary, high-speed diamond burs under water coolant were used to access the lesion. Caries removal was undertaken by using low-speed stainless steel burs or hand excavators. Peripheral enamel and dentin were prepared to the level of hard dentin (scratchy). At the site of "risk for pulp exposure," selective removal to soft dentin was performed using visual and tactile criteria (confirmed by using a blunt-tipped probe).

In some cases, a calcium hydroxide liner (Dycal; Dentsply Caulk, Milford, DE, USA) was placed prior to the restoration based on the clinician's judgement of lesion depth. For proximal lesions, a matrix and wedge were placed. The cavities were filled with RMGIC (Vitremer; 3M ESPE, Saint Paul, MN, USA) or composite resin (Filtek Z350; 3M ESPE) using the etch-and-rinse adhesive system (Adper Single Bond; 3M ESPE) according to the manufacturer's instructions. The choice for RMGIC or composite resin was at the discretion of the dental team.

Composite resin and RMGIC were light-cured using a power of approximately 550 mW/cm^2 (Elipar Highlight; 3M ESPE). After curing, the rubber dam was removed and the occlusion was checked. After 1 week, patients visited the clinic for finishing and polishing of the restorations.

All patients selected also received preventive noninvasive treatments, such as oral hygiene and dietary advice, prophylaxis, and fluoride therapy, and all invasive procedures that they needed.

Outcomes

Survival of the SCR treatments was the main outcome of the study and it was described as the period between the time SCR was conducted and the last dental check-up appointment (censoring date) without the tooth having suffered any reintervention. Clinical records and radiographic images of each patient were screened in order to find whether the teeth with SCR treatment needed reintervention (restoration repair or replacement, pulp therapy, or extraction), which was considered as failure.

Data Analysis

Data were analyzed using Stata 11.2 software (College Station, TX, USA) and censored at 36 months of follow-up.

Survival of the SCR treatments was assessed by Kaplan-Meier estimator. The annual failure rate (AFR) was calculated using the following formula: $(1 - y)z = (1 - x)$, where "y" is the mean AFR and "x" is the total failure rate at "z" years.

Multivariate Cox regression models with shared frailty were performed to identify factors associated with failure of SCR treatments. This test takes into account the effect of clustering (i.e., considers that observations within the patient are correlated), as systemic and behavioral factors can interfere with the individual's response to treatment. Only variables presenting a $p < 0.30$ were included in the final adjusted model. Hazard ratios and their 95% CI were estimated. A level of 5% significance was considered.

Table 1. Distribution of SCR treatments in primary teeth according to the individual and tooth-level variables (88 children, 284 restorations)

Variables	Restorations, *n* (%)	Success, *n* (%)	Restorative failure, *n* (%)	Endodontic failure, *n* (%)	Both failures, *n* (%)
Gender					
Male	158 (55.63)	123 (77.85)	29 (18.35)	4 (2.53)	2 (1.27)
Female	126 (44.37)	89 (69.84)	30 (24.60)	7 (5.56)	0 (0)
VPI (follow-up)					
≤20%	168 (59.2)	133 (79.17)	27 (16.07)	6 (3.57)	2 (1.19)
>20%	116 (40.8)	79 (67.24)	32 (28.45)	5 (4.31)	0 (0)
GBI (follow-up)					
≤20%	180 (63.4)	139 (77.22)	33 (18.33)	6 (3.33)	2 (1.12)
>20%	104 (36.6)	73 (69.23)	26 (25.96)	5 (4.81)	0 (0)
Number of surfaces					
1	115 (40.5)	86 (74.78)	28 (24.35)	1 (0.87)	0 (0)
2 or more	169 (59.5)	126 (73.97)	31 (18.93)	10 (5.92)	2 (1.18)
Type of teeth					
Anterior	60 (21.1)	31 (51.67)	27 (45.00)	2 (3.33)	0 (0)
Posterior	224 (78.9)	181 (80.36)	32 (14.73)	9 (4.02)	2 (0.89)
Capping material					
Adhesive system	176 (62)	131 (74.43)	39 (22.16)	6 (3.41)	0 (0)
Calcium hydroxide	108 (38)	81 (74.08)	20 (19.44)	5 (4.63)	2 (1.85)
Restorative material					
Composite resin	249 (87.68)	188 (75.10)	51 (20.88)	10 (4.02)	0 (0)
RMGIC	35 (12.32)	24 (68.57)	8 (22.86)	1 (2.86)	2 (5.71)

SCR, selective caries removal; VPI, visible plaque index; GBI, gingival bleeding index; RMGIC, resin-modified glass ionomer cement.

Results

The clinical records retrieved included 637 SCR treatments. After the exclusion of medically compromised children, records with missing data, and patients without follow-up, 284 SCR treatments remained and were included in the analysis (Fig. 1). These corresponded to 88 patients (45 boys and 43 girls) with a mean age of 5.2 ± 1.9 years (mode = 4.75; median = 4.83), mostly from low socioeconomic backgrounds and with high caries experience (mean dmft/DMFT = 11.1 ± 5.0; mode = 11; median = 11.0). The mean VPI and GBI at the first visit were 46.6 ± 33.4 and 40.9 ± 35.3%, respectively. At the last check-up appointment, the mean of VPI was 22.2 ± 18.0% and GBI reached 18.0 ± 15.8%.

Table 1 shows the distribution of SCR treatments in primary teeth according to the individual and tooth-level variables. Regarding the restorations, composite resin was the material most frequently used (87.7%) and, in 38% of the cases, a calcium hydroxide liner was used over the remaining carious dentin. Overall, 72 failures were observed: 59 due to restoration reasons (replacement/repair), 11 due to pulp complications (fistula/abscess), and 2 due to the combination of both (restorative and endodontic problems). The mean observation time was 15.8 months. No teeth exfoliated during the evaluation period.

In Figure 2, the survival rate probability for all fillings over 36 months is depicted. The AFR calculated was 21.2% after 3 years. The AFR for anterior and posterior SCR treatments were 26.7 and 18.8%, respectively. Composite fillings presented 21.7% of AFR, while RMGIC showed 18.5%.

Table 2 shows the crude and adjusted Cox regression analyses for independent variables and failure of SCR treatments. The adjusted model showed that patients with VPI above 20% at the recall period had 3 times more chance of failure than children with VPI up to 20%. Re-

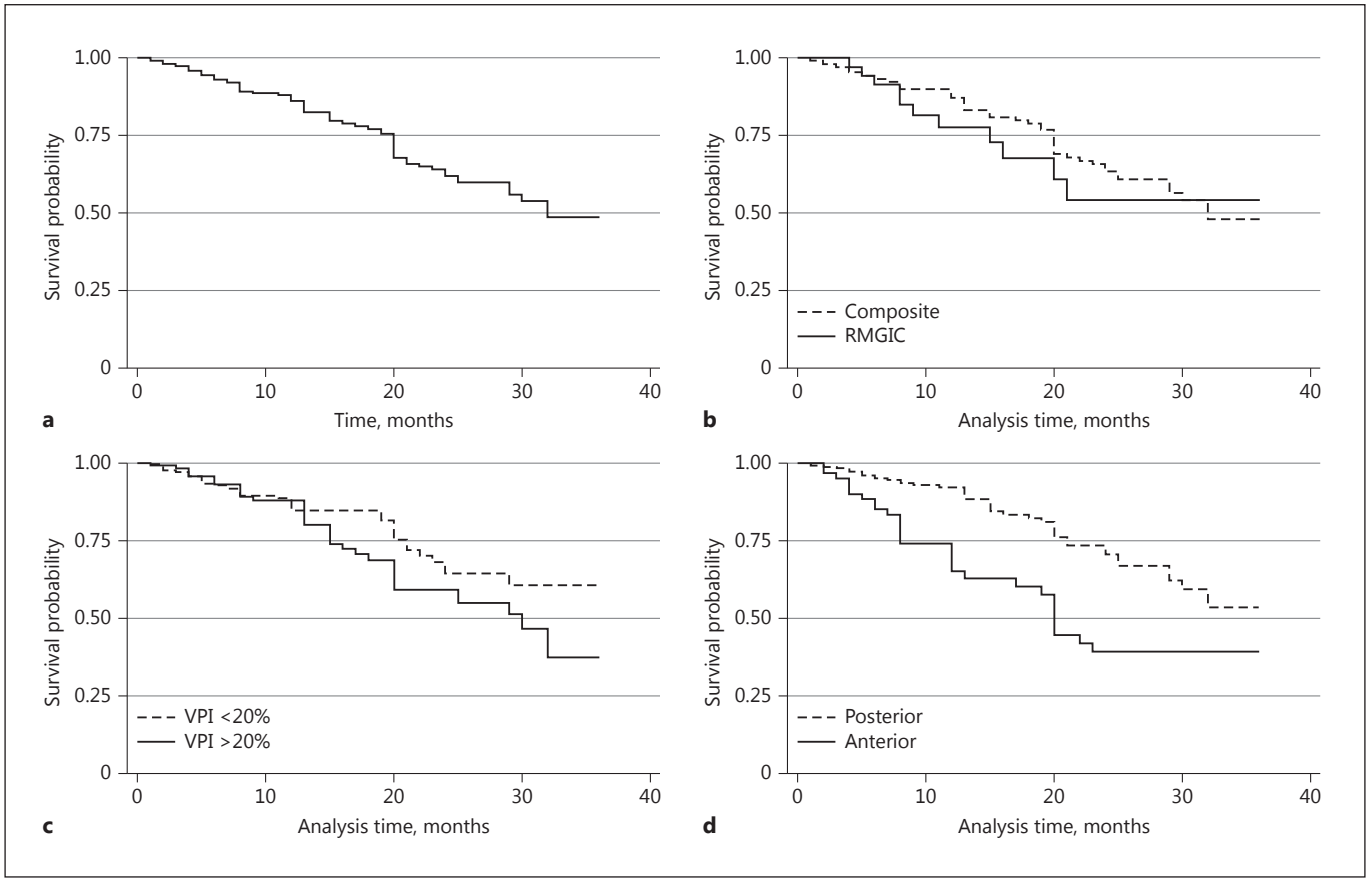

Fig. 2. Kaplan-Meier survival curves of selective caries removal (SCR) treatments over 36 months of clinical and radiographic follow-up. **a** Survival of minimally invasive restorations: overall survival probability rate of adhesive restorations placed in anterior and posterior primary teeth after SCR (48.8%). **b** Restorative material: resin-modified glass ionomer cement (RMGIC) and composite presented similar survival. **c** Visible plaque index (VPI): patients with a higher amount of visible plaque experienced more failures in SCR treatments. **d** Primary teeth: SCR treatments performed in anterior primary teeth presented more failures.

garding the position of teeth in the arch, anterior teeth had 3.6 times higher risk of failure in SCR treatment in comparison with posterior teeth.

Discussion

The results from this retrospective study showed that SCR treatments performed in the primary teeth of children with high caries experience resulted in a limited survival rate. The Kaplan-Meier estimator showed that the survival of restorations reached 48.8%, with an AFR of 21.2% after 3 years of follow-up. Risk factors for failure of SCR treatments were identified as anterior teeth and deficient oral hygiene.

Recently, it has been suggested that patient factors, such as age, caries experience, and socioeconomic status, have a decisive influence on the survival of restorations. Studies have already shown that "older" children [Bücher et al., 2015; Metz et al., 2015], with severe decay [Bücher et al., 2014], from low income [Demarco et al., 2012; Correa et al., 2013; van de Sande et al., 2013, 2016; Metz et al., 2015] had significantly lower survival probabilities in their restorations.

The population enrolled in this retrospective study constitutes a challenge for treatment survival, representing the worse scenario. The very high caries experience (mean dmft = 11.1 ± 5.0), associated with lack of oral hygiene (biofilm accumulation) and low income (patient risk factors), had a detrimental influence on the treatment longevity. The age of patients presented no association with the outcome, probably because the sample was basically composed of young children (mean age = 5.2 ± 1.9 years; mode = 4.75; median = 4.83).

Table 2. Crude and adjusted hazard ratios (HR) for independent variables (88 children, 284 restorations) and failure of SCR treatments in primary teeth (Cox regression with shared frailty models)

Independent variables	Crude HR (95% CI)	*p* value	Adjusted HR (95% CI)	*p* value
Gender		0.780		–
Male	1.00		–	
Female	0.90 (0.44; 1.85)			
Age		0.134		0.336
<3 years	1.00		1.00	
>3 years	0.43 (0.14; 1.29)		0.51 (0.18; 1.78)	
Dmft/DMFT		0.568	–	–
<5	1.00			
>5	1.29 (0.52; 3.19)			
Number of surfaces		0.755		–
1	1.00		–	
2 or more	1.10 (0.61; 1.97)			
Capping material		0.513		–
Adhesive system	1.00		-	
Calcium hydroxide	0.82 (0.46; 1.47)			
Restorative material		0.344		–
Composite resin	1.00		-	
RMGIC	1.46 (0.67; 3.21)			
GBI		0.256		0.425
≤20%	1.00		1.00	
>20%	1.52 (0.74; 3.16)		0.69 (0.27; 1.71)	
VPI		0.003		0.012
≤20%	1.00		1.00	
>20%	2.94 (1.45; 5.97)		3.00 (1.27; 7.07)	
Type of teeth		<0.001		0.000
Posterior	1.00		1.00	
Anterior	3.49 (1.96; 6.22)		4.07 (1.94; 6.71)	

SCR, selective caries removal; VPI, visible plaque index; GBI, gingival bleeding index; RMGIC, resin-modified glass ionomer cement.

The history of dental plaque accumulation from childhood until adult life may be a key risk factor in cumulative dental problems, such as caries experience, failure in restorative procedures, and tooth loss [Broadbent et al., 2011]. In the present study, it was found that high levels of VPI (>20%) were significantly associated with restoration failure. On the contrary, low GBI (<20%) was not associated with a longer survival of the restorations, maybe because gingivitis in children has been shown to be less severe compared to adults when similar amounts of dental plaque deposition are found [Jenkins and Papapanou, 2000].

All children and adolescents treated at the Pediatric Dentistry Clinic (UFRGS) are included in a preventive program in which maintenance appointments are programmed and education for oral health is carried out, according to the individual risk. This approach had a positive impact in terms of oral health promotion, since a general reduction of VPI and GBI was observed. However, patients who maintained a high dental plaque percentage experienced more failures in their restorations. Similar results were found in another retrospective university-based study of minimally invasive restorations performed in primary molars. The multi-level analysis showed that patients with high caries experience with a higher amount of visible dental plaque after treatment were more prone to restoration failure. The overall survival rates of SCR

restorations performed by 4th-year dental students reached 51% at the 24-month follow-up [Dalpian et al., 2014].

Due to the great variability in study designs and population characteristics, data on longevity of restorations placed in primary teeth are difficult to compare [Qvist et al., 2010; Casagrande et al., 2013; Dalpian et al, 2014; Pinto et al., 2014; Franzon et al., 2015; Bücher et al., 2015]. Although it has been demonstrated that treatment-related variables, such as the use of capping material [Demarco et al., 2012; Pallesen et al., 2013], number of restored surfaces [Van Nieuwenhuysen et al., 2003; Opdam et al., 2007; Da Rosa et al., 2011], and type of restorative materials [Bücher et al., 2015; Do, 2012], can influence restoration survival, those variables were not associated with failure in the present study.

In the present study, the decision related to the use of a capping material over the remaining carious dentin was made by the clinical instructors at the time of the procedure. Based on a recent meta-analysis of 3 RCT with primary teeth, current evidence does not advocate cavity liners to maintain pulpal vitality after excavating caries lesions and before restoring cavities. On the contrary, the synthesized data suggest potential advantages of not using liners before filling the cavity [Schwendicke et al., 2015].

Usually, the use of RMGIC was preferred in cases where there was no clinical time for restoration with composite resin and in noncooperative children. Indication bias is most likely; however, the statistical analysis employed in this study is considered as the most suitable for the retrospective design. The multivariate Cox regression (with shared frailty) showed that, both in crude and multivariable analyses, the RMGIC presented similar longevity compared to the composite resin. Also, the use of a liner material under the restoration had no significant effect on the survival estimation (crude and adjusted analyses). This may be explained by the clinical profile of the patients (very high caries experience), resulting in SCR treatments failing in a short time.

From data collected in the clinical records it was not possible to state whether the failures in restorations occurred due to fractures, loss of retention, or secondary caries lesions. However, we speculate that young children with caries in anterior primary teeth are likely to represent a very high caries risk population, in which the trajectory of biofilm accumulation may have a negative effect on restoration survival, acting directly on material deterioration [Spencer et al., 2014; Hashemikamangar et al., 2015] and, especially, on the development of new caries lesions of rapid progression [Bücher et al., 2014].

The poor performance observed in the restorations of anterior teeth may also be associated with the treatment-related variables involved in SCR. The smallest area available for adhesion on the sidewalls, the difficulty of controlling the depth of caries removal (since it is not possible to verify the depth of the lesion by anterior periapical radiograph), and the esthetic appeal of these teeth (which are often darkened by the remaining caries under the restoration) may explain the higher number of failures/reinterventions in the anterior segment. Moreover, small pigmentation in the restoration margins that would be tolerated in posterior teeth is mostly unwanted in the anterior teeth and often requires repair or replacement.

Regarding the caries removal technique itself, this is a noncontrolled retrospective study in a population with high caries experience. It was not "controlled" (complete caries removal group) because partial (selective) caries removal is taught as a clinical protocol in our undergraduate and graduate program since the mid-1990s, for primary and permanent teeth presenting deep dentin lesions. According to the recent International Caries Consensus Collaboration, regarding the recommendations on carious tissue removal, the main goal of SCR is to avoid the risk of pulp exposure and more invasive interventions. Recently, our group investigated the survival of adhesive restorations placed in permanent molars of high caries risk children. In this retrospective study, the survival and risk factors of "complete caries removal" were compared to "selective caries removal" restorations. Both treatments presented a restricted survival in patients with high caries activity and gingivitis, but complete caries removal yielded more pulp exposures. Patients who controlled the biofilm routinely (less gingivitis) experienced longer survival in their treatments. Regardless of the technique used, the control of the cariogenic biofilms and caries activity of patients was more relevant than the technique itself [Casagrande et al., 2016].

With regard to the limitations of this study, given its retrospective design, indication bias is most likely, due to the limited traceability of the real volume and depth of the cavities where the liner material was used, as well as the distribution among the used materials (composite resin and RMGIC). Moreover, other specific details, such as the reason for restoration failure, influence of bruxism, and behavior of children during treatment, were not available in the patients' records. However, the statistical analysis employed in this study is considered as the most suitable for the retrospective design, which provides ad-

equate external validity for a high caries risk population. The results were assessed using multivariate Cox regression with shared frailty, which considers that observations of the same patient are correlated, sharing the same frailty.

Although the results have demonstrated a restricted treatment survival, it does not discourage the indication of SCR in a population at high caries risk/experience. On the contrary, in a micro-simulation study (tooth-level Markov model) that aimed to compare the cost-effectiveness of different excavations in low- and high-risk patients, selective excavation was more effective and less costly than both alternatives (stepwise and complete excavation), regardless of an individual's risk. Moreover, the cost-effectiveness advantages of selective excavation were more pronounced in high-risk groups [Schwendicke et al., 2014]. Additionally, 1-step SCR reduces patient pain and is a less time-consuming technique, considering the increased risk of pulp exposure of complete caries removal [Franzon et al., 2014], reducing costs and keeping teeth vital for longer [Schwendicke et al., 2013c].

Within the limitations of this study, it was demonstrated that patient-related factors, such as oral hygiene and caries experience, may play an important role in the survival of minimally invasive SCR treatments in primary teeth. Patients who successfully followed an oral health program focusing on education and motivation of the patients showed a better restoration survival.

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Disclosure Statement

The costs of this retrospective study were funded by the researchers. The authors declare that they have no conflicts of interest.

Author Contributions

The experiments were conceived and designed by X.C.M., R.F., F.B.A., and L.C. The data collection was performed by X.C.M. The data were analyzed by N.J.M.O., M.B.C., F.F.D., and L.C. The paper was written by X.C.M., N.J.M.O., M.B.C., R.F., F.F.D., F.B.A., and L.C.

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