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Pulp Vitality and Longevity of Adhesive Restorations Are Not Affected by Selective Carious Removal: A Multicenter Clinical Trial

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Keywords
Composite resin · Dental restoration · Multicenter study · Pulp vitality · Selective caries removal · Survival analysis

Abstract
The aim of this multicenter randomized clinical trial was to evaluate the pulp vitality and survival rate of adhesive restorations performed on posterior deciduous teeth after non-selective (NSCR) or selective (SCR) carious tissue removal over 33 months. One hundred and seven children (average age 4–8 years, SD 1.4) with at least two active moderate cavitated lesions in dentin were included. Teeth were randomized and submitted to NSCR or SCR before composite resin restoration. Restorations were clinically and radiographically assessed at baseline, 6, 12, 18, 24, and 33 months by a blinded, trained, and calibrated operator in each center. The characteristics of the restorations were recorded according to FDI criteria and were considered as restorative failures when scores 4 or 5 were presented. Pulp vitality was measured by clinical and radiographic examinations, and those teeth that presented any signs or symptoms of irreversible pulpitis or pulp necrosis were considered as failure. Data were analyzed by a Cox regression model with shared frailty, considering two outcomes: pulp and restorative. A total of 278 restorations (137 after NSCR and 141 after SCR) were performed at baseline in four different centers and there was no loss in the follow-up period. Survival rate was 97.1 and 87.1% for pulp and for restorative outcome, respectively. The overall annual failure rate was 7%. There were no differences in the failure risk according to the treatment group, center, and all the clinical and demographic variables, regardless of outcome. Composite restorations of active moderate deep carious lesions performed on posterior primary teeth show satisfactory survival for restorative and pulp outcome after a 33-month follow-up, regardless of the technique executed for carious tissue removal.

Introduction

Modern concepts about caries, from its prevention and etiology to the early and accurate lesion diagnosis, offer more conservative treatment options for deciduous

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and permanent teeth, within a minimal intervention philosophy [Ericson, 2007; Innes et al., 2016]. Once moderate or deep dentine lesions are established, non-selective removal of carious tissue (NSCR) is no longer indicated, due to a higher pulp exposure risk and pulp tissue damage, both for primary and permanent teeth [Ricketts et al., 2013; Schwendicke et al., 2016; Ricketts et al., 2018]. The technique indicated in the literature is selective carious tissue removal (SCR), which recommends that all carious tissue should be removed from the lateral cavity walls, while carious dentin of the pulp wall is removed until leathery consistency in cases in which there is no apparent clinical risk of pulpal exposure, or until softened dentin when there is a risk of pulp exposure [Ricketts et al., 2013; Schwendicke et al., 2016; Ricketts et al., 2018].

Although scientific evidence through clinical, radiographic, and microbiological outcomes demonstrates the success of the SCR technique in primary teeth [Dalpian et al., 2012; Bressani et al., 2013; Casagrande et al., 2013; Singhal et al., 2016], recent studies have demonstrated lower survival rates for the restorations performed after SCR [Dalpian et al., 2014; Franzon et al., 2015]. In primary teeth, a retrospective study showed that restorative failures were the main cause of SCR failures (13%), and failures related to pulpal signs and symptoms were present only in 6.7% of the cases [Dalpian et al., 2014]. A randomized clinical trial demonstrated that restorations performed after SCR showed lower survival rate (66%) when compared to restorations after NSCR (86%). However, a greater number of pulp exposures were observed when NSCR technique was executed [Franzon et al., 2015].

In this context, the divergences in the literature and the reduced number of studies with external validity demand more research with higher methodological quality. Thus, this multicenter study aimed to compare the pulp vitality and survival rate of adhesive restorations performed on posterior deciduous teeth after NSCR or SCR over 33 months. We hypothesized that there is no difference among treatments with regard to restoration survival and pulp vitality over time.

Materials and Methods

This study is reported according to CONSORT (Consolidated Standards of Reporting Trials) guidelines for the elaboration of randomized controlled trials and registered on the website www.ensaiosclinicos.gov.br (trial: RBR-7JY2F7).

Study Design and Participants

This international multicenter randomized controlled double-blind clinical trial included 278 restorations performed between 2013 and 2015. Treatments were evaluated up to 33 months and were executed at 4 centers – Federal University of Rio Grande do Sul (UFRGS), São Paulo University (USP), Peruvian University Cayetano Heredia (UPCH), and International University of Ecuador (UIE) – by 4 dentists (specialists in pediatric dentistry) working at the Universities.

Sample selection (September 2013 to February 2015) was performed by examining patients enrolled in the pediatric services in the clinics or by active search. Children aged 4–8 years with at least two primary molars with active moderate carious lesions in dentine were eligible. The inclusion criteria were: (1) primary molars presenting moderate active caries lesions (reaching ≥1/2 of the dentin and up to 1 mm separating the lesion from the pulp on interproximal radiographic examination); (2) occlusal contact with the antagonist and proximal contact (in cases of occlusal-proximal restorations) at baseline; (3) lesions limited to the occlusal and occlusal-proximal surfaces (presence of enamel in the cervical region at the end of carious tissue removal); (4) absence of clinical and radiographic diagnosis of irreversible pulpitis or pulp necrosis. Patients were excluded if they presented severe clinical signs of bruxism, erosion, fluorosis, and/or hypoplasia or motor systemic problems.

Sample Size

Samples were estimated based on the difference in survival rate between treatments (66% [SCR] and 86% [NSCR] at 2-year follow-up) at $\alpha = 5\%$, with a power of 90%; this resulted in 94 treatments per group [Franzon et al., 2015]. A dropout rate of 25% was estimated based on a study carried out with a similar population with 36 months of follow-up [Franzon et al., 2007], thus increasing the number of restorations to 118 per group.

Interventions

All dentists were updated and trained by an expert researcher of the UFRGS. The training involved a 3-day immersion within the base institution (UFRGS). First, a theoretical class was taught about the techniques for removing decayed tissue and the criteria for clinical and radiographic evaluation. Subsequently, there was a practical demonstration in vitro and in vivo of each protocol to be followed in the test (SCR) and control (NSCR) groups. Afterward, each operator selected in the centers to be involved in the study reproduced the techniques for removing carious tissue (in vitro and in vivo) under the supervision of the coordinator in a clinical setting. After all these steps, the study operators were considered trained to perform the procedures in their institutions.

The participants underwent the following procedures: after local anesthesia and rubber dam isolation, the lesion was accessed, when necessary, with a diamond bur operated at high speed under water-cooling and tooth was randomized and allocated on the test (SCR) or control group (NSCR). First, a complete carious removal from cavity lateral walls was performed with dentin excavators (Dentsply Maillefer, Ballaigues, Switzerland) and low-speed burs – No. 1, 2, 4, 6, and 8 (KG Sorensen, Cotia, Brazil) according to the hardness-tactile criteria (hardness to probe) – and then, according to randomization, SCR (only disorganized dentin was removed on the pulp wall until a leathery consistency was achieved, performed by manual and low-speed bur instruments) or NSCR (all carious dentin was removed from the pulp wall, with the same instruments, until reaching hard dentin) was executed. If dental pulp exposure occurred at the time the techniques were performed,

tooth was properly treated and included in the pulp outcome assessment. The proposed treatment in these cases was ferric sulfate pulpotomy [Fernandes et al., 2013; Junqueria et al., 2018] and subsequent restoration with composite resin.

The cavity was washed with distilled water and dried. Both groups received dentin-pulp complex protection with calcium hydroxide cement (Dycal; Dentsply, Rio de Janeiro, RJ, Brazil) [Fernandes et al., 2013], followed by 37% phosphoric acid etching of enamel for 30 s and dentine for 15 s. Finally, the cavity was flushed with air/water spray and dried carefully with sterile cotton. All cavities were then restored with composite resin (Filtek Z350 XT; 3M ESPE, Sumaré, SP, Brazil) after hybridization with adhesive system (Adper Single Bond; 3M ESPE) according to the manufacturer's instructions. Rubber dam was removed and occlusion was adjusted. Seven to 30 days after the procedures, the restorations were submitted to the finishing and polishing, finalizing with baseline radiographic and clinical examination. All patients' treatment needs were provided throughout the study, as a strict program of recall for consultations and a program of oral health maintenance.

Randomization and Blinding

The randomization unit was the tooth (at least two for each participant) and the randomization procedure was performed as follows: number corresponding to each tooth of the eligible participant for the study was printed on paper and stored in a dark envelope, as well as the treatment group. First, a paper was selected from the envelope by the patient and the tooth was first selected. After anesthesia and rubber dam, a second paper of the treatment envelope was selected by a person other than the operator, and the treatment indicated was executed (test/control). The second tooth selected automatically received the opposite treatment (control/test). If there was a third tooth, the treatment was randomized again and if there was a fourth tooth, it received the opposite treatment of the third and so on. The patient/caregiver and clinical evaluator of the restorations were also blinded, kept unaware of the groups they have been assigned to.

Objectives and Outcomes

The primary survival outcome was the restoration survival evaluated by clinical examination. Radiographs and restorations were clinically assessed at baseline and after 6, 12, 18, 24, and 33 months by a blinded, trained, and calibrated operator from each center. The characteristics of the restorations were recorded according to an adaptation of the FDI criteria [Hickel et al., 2010] in relation to the following criteria: staining (I); fracture of material and retention (II); marginal adaptation (III); postoperative sensibility (IV); and recurrence of caries (V). Scores 1, 2, and 3 (1 = clinically very good; 2 = clinically good; 3 = clinically sufficient/satisfactory) were recorded as clinical success and scores 4 and 5 (4 = clinically unsatisfactory; 5 = clinically poor) as clinical failure. After the training and calibration phase, the weighted kappa coefficient intra and inter examiners for FDI ranged from 0.62 to 0.72 and 0.72 to 0.90, respectively.

Pulpal exposure during caries removal was also included in the analysis and was considered a second outcome. Pulp failure was assessed by the following criteria: pulp exposure (during removal of decayed tissue), presence of mobility not compatible with rhizolysis, presence of edema, presence of fistula, report of spontaneous pain, and presence of palpation sensitivity. The absence of any of these signs and symptoms was considered pulp success. Radiographs and restorations were also clinically assessed at baseline and after 6, 12, 18, 24, and 33 months.

Some variables were considered and included: data such as institution, age (dichotomized on average), sex, type of surfaces restored (occlusal or occlusal-proximal), household income, and oral health measures. Household income was a sum of all forms of income in a month (salary, wages, pensions, and rental income). It was collected in Reais (Brazilian currency, BRL 5.05 equivalent to USD 100, approximately) and transformed in tertiles for each assessment: T1 (lowest): <BRL 1,000.00, T2: BRL 1,000.00 to <BRL 1,500.00, and T3 (highest): BRL 1,500+. Sociodemographic data were collected through a questionnaire answered by legal guardians in the baseline assessment. Clinical variables were assessed in all evaluations. Dental caries was assessed according to the number of decayed, missing, or filled teeth (DMFT index) [Word Health Organization, 1997]. Visible plaque and gingival bleeding were also evaluated (number of dental surfaces with plaque and gingival bleeding) [Ainamo and Bay, 1975].

Statistical Analysis

Data analyses were performed with STATA 14 (StataCorp. 2014, Stata Statistical Software: Release 14.1, StataCorp LP, College Station, TX, USA). Survival estimates for restoration longevity and pulp vitality were evaluated using the Kaplan-Meier method. We also estimated the annual failure rate (AFR) of the restorations and of the pulp vitality according to the following formula: $(1 - y)\ z = (1 - x)$, in which y expresses the mean AFR and x the total failure rate at z years. Cox regression model with shared frailty with clustering data for patients with multiple restorations was performed to assess differences in survival rates of the restoration and pulp vitality according to the intervention treatment, institution, and clinical and demographic characteristics of the sample. In this analysis, we calculated the hazard ratio (HR) and its respective 95% confidence interval (CI).

Results

The sample comprised 278 restorations (137 after NSCR and 141 after SCR) placed in 107 subjects (see www.karger.com/doi/10.1159/000510698 for online suppl. Fig. 1). All subjects and restorations were evaluated in 6, 12, 18, 24, and 33 months of follow-up. Regarding demographic characteristics of the sample, 51.4% were girls and the mean age was 5.9 years (SD 1.4). In addition, 22.4% of the children were from the lowest socioeconomic tertile. According to clinical aspects, the mean of the DMFT and the surfaces with gingival bleeding were 8.12 (SD 3.42) and 38.25 (SD 21.00), respectively (Table 1).

Table 2 presents the survival of restorative and pulp outcome according to sample characteristics. Mean survival time was 29.7 months (95% CI 28.8–30.1) and the overall AFR was 7%. According to restorative outcome and pulp outcome, the overall clinical survival was 87.1% (242/278) and 97.1% (270/278), respectively. Estimated

Table 1. Characteristics of the sample according to sociodemographic and clinical variables at baseline (n = 107)

Variables	Total subjects
Research institution, *n* (%)	
UFRGS	27 (25.2)
USP	19 (17.8)
UPCH	30 (28.0)
UIE	31 (29.0)
Sex, *n* (%)	
Girls	55 (51.4)
Boys	52 (48.6)
Age, *n* (%)	
≤5 years old	48 (44.9)
>5 years old	59 (55.1)
Family income in BRL, *n* (%)	
1st tertile	24 (22.4)
2nd tertile	49 (45.8)
3rd tertile	34 (31.7)
Surfaces, *n* (%)	
Occlusal	62 (57.9)
Occlusal-proximal	45 (42.1)
Treatment, *n* (%)	
NSCR	51 (47.7)
SCR	56 (52.3)
DMFT, mean (SD)	8.12 (3.42)
Visible plaque, mean (SD)	45.78 (25.56)
Gingival bleeding, mean (SD)	38.25 (21.00)

BRL, Brazilian real (BRL 5.05 was equivalent to USD 1.00, approximately); NSCR, non-selective caries removal; SCR, selective caries removal; SD, standard deviation.

survival rates of the restoration were similar between treatment groups (NSCR and SCR). Among the restorative procedures, 34.5% were performed at UIE, 27% at UPCH, 23% at the coordinating institution (UFRGS), and 15.5% at USP. Single-surface restorations were more common (58.3%) and restorations were similarly distributed between the NSCR (49.3%) and SCR groups (50.7%).

Restorative failures were distributed equally among the FDI criteria evaluated and between treatment groups (Table 3). In relation to non-repairable failures (FDI scores 4 and 5), 4 were related to postoperative sensitivity (2 in each group) and 13 were due to caries recurrence (53.8% in the NSCR group and 46.2% in the SCR group). Regarding pulp outcome, pulp exposure occurred in 3 teeth allocated to the NSCR group and in 2 allocated to the SCR group ($p > 0.05$). Considering pulp failure after 33 months, in the SCR group there was 1 fistula, 1 root resorption, and 1 episode of edema ($p > 0.05$). Total pulp failures were distributed in the UIE (n = 2) and UPCH (n = 6) centers. The other symptoms (pain and tenderness) did not occur in any treatment.

Table 4 shows the HR for restorations and pulp failures according to the treatment strategy, institution, and clinical and demographics variables. Regarding restorative outcome, there were no differences in the risk of failure according to the treatment group (HR 0.86; 95% CI 0.46–1.59) and institution (USP: HR 0.28; 95% CI 0.06–1.19; UPCH: HR 0.87; 95% CI 0.30–2.52; UIE: HR 1.21; 95% CI 0.46–3.18). Analogous observations were found regarding all the clinical and sociodemographic variables ($p >$ 0.05). Regarding pulp outcome, there were also no differences in the risk of failure according to the treatment group (HR 1.64; 95% CI 0.39–6.94), institution, and all the clinical and sociodemographic variables ($p > 0.05$).

Discussion

This randomized controlled double-blind multicenter clinical trial evaluated the survival rate of composite restorations conducted after two different carious tissue removal techniques (NSCR and SCR) in primary molars with moderate active carious lesions over 33 months. After clinical follow-up, restorations performed over both treatments presented similar survival rate, although NSCR yielded more pulp exposures as a complication of the technique.

The results of the study revealed a satisfactory overall survival rate of restorations. In total, the survival rate was 87.1% after 33 months (85.4% for NSCR and 88.7% for SCR). A lower survival rate for composite resin performed after SCR (66%) was observed in another clinical trial with the same outcome. Restorations after NSCR showed similar survival rate compared to our study (86%) [Franzon et al., 2015]. We can infer that the difference in results between studies related to the SCR technique are due to aspects such as the amount of carious dentin tissue remaining under the composite, mainly in cervical-proximal wall, and the fact that the previous study had a significantly larger number of occlusal-proximal lesions than occlusal ones. In the present study, there were no differences in outcome between occlusal and occlusal-proximal restorations.

Retrospective studies and a systematic review that evaluated the longevity of restorations performed on deciduous teeth showed success rates similar to those in our findings [Pinto et al., 2014; Bücher et al., 2015; Santos et al., 2016]. Although this methodological option clarifies the performance of treatments executed in the day-to-day

Table 2. Success rate of restorative and pulp outcome according to the research center, type of intervention, and clinical and sociodemographic characteristics of the sample (n = 278 restorations)

Variables	Total of restorations	Restorative outcome		Pulp outcome	
		success	failure	success	failure
Research institution, *n* (%)					
UFRGS	64 (23.0)	59 (92.2)	5 (7.8)	62 (96.9)	2 (3.1)
USP	43 (15.5)	39 (90.7)	4 (9.3)	43 (100.0)	0 (0.0)
UPCH	75 (27.0)	67 (89.3)	8 (10.7)	71 (94.7)	4 (5.3)
UIE	96 (34.5)	77 (80.2)	19 (19.8)	94 (97.9)	2 (2.1)
Sex, *n* (%)					
Girls	137 (49.3)	119 (86.9)	18 (13.1)	135 (98.5)	2 (1.5)
Boys	141 (50.7)	123 (87.2)	18 (12.8)	135 (95.7)	6 (4.3)
Age, *n* (%)					
≤5 years old	123 (44.2)	111 (90.2)	12 (9.8)	118 (95.9)	5 (4.1)
>5 years old	155 (55.8)	131 (84.5)	24 (15.5)	152 (98.1)	3 (1.9)
Family income in BRL, *n* (%)					
1st tertile	169 (63.1)	147 (87.0)	22 (13.0)	164 (97.0)	5 (3.0)
2nd tertile	21 (7.8)	20 (95.2)	1 (4.8)	21 (100.0)	0 (0.0)
3rd tertile	78 (29.1)	67 (85.9)	11 (14.1)	75 (96.2)	3 (3.8)
Treatment, *n* (%)					
NSCR	137 (49.3)	117 (85.4)	20 (14.6)	134 (97.8)	3 (2.2)
SCR	141 (50.7)	125 (88.7)	16 (11.3)	136 (96.5)	5 (3.5)
Surfaces, *n* (%)					
Occlusal	162 (58.3)	144 (88.9)	18 (11.1)	158 (97.5)	4 (2.5)
Occlusal-proximal	116 (41.7)	98 (84.5)	18 (15.5)	112 (96.5)	4 (3.5)
DMFT, mean (SD)	278 (100)	8.10 (3.4)	8.28 (3.7)	8.14 (3.4)	7.62 (3.77)
Visible plaque, mean (SD)	278 (100)	38.09 (21.3)	39.36 (19.1)	37.9 (21.2)	47.6 (8.1)
Gingival bleeding, mean (SD)	278 (100)	45.1 (25.7)	50.7 (24.8)	45.5 (25.7)	54.7 (20.2)
Follow-up period, *n* (%)					
0–6 months	14 (5.0)	14 (100)	0 (0.0)	13 (92.9)	1 (7.4)
7–12 months	33 (11.9)	28 (84.5)	5 (15.5)	33 (100.0)	0 (0.0)
13–24 months	200 (71.9)	171 (85.5)	29 (14.5)	194 (97.0)	6 (3.0)
25–33 months	31 (11.2)	29 (93.5)	2 (6.5)	30 (96.8)	1 (3.2)

BRL, Brazilian real (BRL 5.05 was equivalent to USD 1.00, approximately); NSCR, non-selective caries removal; SCR, selective caries removal; SD, standard deviation.

routine of dentistry, they usually use data from treatments performed by undergraduate students, which makes it difficult to extrapolate the findings to clinical dentists in general, since there is strong evidence that the experience of the operator interferes with the longevity of restorative treatments [Opdam et al., 2007; Bücher et al., 2015]. However, even with a different study design, our results were quite similar regarding restoration survival of other studies.

No statistically significant difference was found relating occlusal and occlusal-proximal restorations to the risk of failure. Similar results were observed in another study that evaluated the use of adhesive restorations with composite on carious remaining dentine in primary molars [Ribeiro et al., 1999]. However, the literature is not unanimous about this relation. A retrospective study on

Table 3. Number of failures for each FDI criterion over the 33-month follow-up

FDI variables[a]	NSCR, *n* (%)	SCR, *n* (%)	*p* value*
I – Staining	6 (54.5)	5 (45.5)	0.69
II – Fracture of material and retention	7 (53.8)	6 (46.2)	0.70
III – Marginal adaptation	7 (50.0)	7 (50.0)	0.93
IV – Postoperative sensibility	2 (50.0)	2 (50.0)	0.96
V – Recurrence of caries	7 (53.8)	6 (46.2)	0.70
Total	29 (52.7)	26 (47.3)	

[a] Scores 1, 2, and 3 were recorded as clinical success and scores 4 and 5 as clinical failure. * Chi square test – comparison between groups considering the cluster of teeth within children. NSCR, non-selective caries removal; SCR, selective caries removal.

Table 4. Hazard ratios (HR 95% CI) according to the type of intervention, research center and clinical and sociodemographic characteristics of the sample. Cox regression model with shared fragility

Variables	Restorative outcome		Pulp outcome	
	HR (95% CI)	*p* value	HR (95% CI)	*p* value
Research institution				
UFRGS	1.00		1.00	
USP	0.44 (0.94–2.09)	0.30	–	–
UPCH	0.92 (0.26–3.19)	0.89	2.19 (0.19–24.3)	0.52
UIE	1.39 (0.45–4.28)	0.56	0.79 (0.05–10.70)	0.86
Sex				
Girls	1.00		1.00	
Boys	0.74 (0.31–1.77)	0.50	2.96 (0.45–19.33)	0.256
Age				
≤5 years old	1.00		1.00	
>5 years old	0.40 (0.12–1.27)	0.12	0.28 (0.04–1.77)	0.18
Family income in BRL				
1st tertile	1.00		1.00	
2nd tertile	0.34 (0.03–3.13)	0.34	–	
3rd tertile	0.81 (0.31–2.09)	0.67	1.12	0.91
Treatment				
NSCR	1.00		1.00	
SCR	0.75 (0.38–1.46)	0.40	1.64 (0.39–6.94)	0.49
Surfaces				
Occlusal	1.00		1.00	
Occlusal-proximal	1.20 (0.57–2.56)	0.62	2.05 (0.40–10.3)	0.38
DMFT	0.98 (0.85–1.10)	0.61	1.35 (0.20–9.00)	0.75
Visible plaque	1.00 (0.99–1.02)	0.57	0.63 (0.09–4.24)	0.64
Gingival bleeding	1.00 (0.98–1.02)	0.90	8.10 (1.20–11.5)	0.75

BRL, Brazilian real (BRL 5.05 was equivalent to USD 1.00, approximately); HR, hazard ratio; CI, confidence interval; NSCR, non-selective caries removal; SCR, selective caries removal.

the longevity of restorations in primary molars showed that in crude analysis, class II restorations demonstrated lower survival rate than class I restorations, but lost significance after adjustments [Pinto et al., 2014]. Furthermore, a systematic review about the longevity of posterior composite restorations performed in permanent teeth demonstrated a higher failure risk for restorations with higher number of surfaces [Opdam et al., 2014].

The most common failure observed in the study was the marginal adaptation, followed by fracture of material and retention, recurrence of caries, staining, and postoperative sensibility, in descending order, with no differences between the SCR and NSCR groups. The low number of failures and high survival rates of restorations found in our study may be related to a rigorous control of consultations scheduling and the cut-off point of the clinical criteria (FDI) used to evaluate restorative performance [Hickel et al., 2010].

Regarding the pulp outcome, the number of pulp exposures was approximate between the groups; however, in the NSCT group there was more exposure, in accordance with previous studies [Franzon et al., 2015; Li et al., 2018]. However, there was no significant difference in pulp success according to the technique used. Thus, the efficacy of SCR appears comparable to that of NSCR, with similar pulpal symptoms and failure; yet, SCR may result in a low incidence of pulpal exposure [Li et al., 2018]. In addition, pulp survival rate was high and similar to previous studies [Junqueira et al., 2018; Lin et al., 2020].

This study has some limitations. The presence of moderate lesions may have hindered the clinical differentiation in the SCR and NSCR. However, all lesions were in the inner half of dentin and, to evaluate restoration success, it was a good choice to test in moderately deep cavities. Further, we considered as failure only those restorations that needed a major repair or total replacement of the restoration. However, this more conservative ap-

proach is based on an attempt to minimize damage to dental tissue and avoid the repetitive restorative cycle [Ericson, 2007]. Moreover, the results could be even better if the repairs were not considered as failures, since a practice-based study about the longevity of repaired restorations showed that repairs can enhance the longevity of dental restorations considerably [Opdam et al., 2012].

Unlike most studies found in the literature, no statistical difference was found in this study between clinical and demographic characteristics and the main outcome [Opdam et al., 2014; Pinto et al., 2014; Casagrande et al., 2017; Collares et al., 2018]. Studies designed to evaluate the risk factors that could influence the longevity of the restorations show that high caries risk, high index of gingival bleeding, and restorations with more than one surface reduce the restorations survival [Opdam et al., 2014; Pinto et al., 2014; Casagrande et al., 2017]. An explanation for our findings may be the homogeneity of the sample; in general, all patients were at high risk for caries, as well as having high indices of visible plaque and gingival bleeding at baseline.

It is important to emphasize the external validity of the data obtained through this multicenter research. The operators of the international institutions that participated in the study did not use the SCR technique in their clinical and institutional practice. However, an effective discussion and training on the technique of SCR allowed them to perform it with the same survival rates as the traditional NSCR technique. Although there is increasing evidence supporting less invasive carious tissue removal strategies [Ricketts et al., 2013; Schwendicke et al., 2016; Ricketts et al., 2018], they are still treated over-invasively, with complete removal of carious tissue, compromising tooth structure and the health of the dental pulp [Schwendicke et al., 2013]. The reasons underlying this failure to translate evidence into clinical practice are many and complex [Innes et al., 2016; Schwendicke et al., 2016].

Finally, composite restorations of active moderate carious lesions performed on posterior primary teeth show satisfactory survival rates of 87.1% (restorative outcome) and 97.1% (pulp outcome) after 33 months of follow-up, regardless of the technique performed for carious tissue removal. The findings of this study indicated the technique of SCR, supporting a minimal intervention philosophy. Thus, the NSCR of deep lesions should not be considered an option, submitting the patient to a non-justifiable risk.

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Statement of Ethics

The study was approved by the Ethics Committees (EC) from the Federal University of Rio Grande do Sul (protocol No. 806.674), by the EC from the Peruvian University Cayetano Heredia (CARFE-DPE-SM-0888-2013, acceptance letter), and by the EC from the International University of Ecuador (acceptance letter). All individuals and their legal guardians were informed about the study's aim and consented to participate.

Conflict of Interest Statement

The authors have no conflicts of interest in relation to the products or methods mentioned herein. They certify that they have no affiliation with or financial involvement in any organization or entity with a direct financial or personal interest in the subject matter or materials discussed in this paper.

Author Contributions

J.T.P. and F.B.A. conceived the study. F.B.A. trained and calibrated the examiners. J.T.P., F.B.A., J.C.P.I., I.C.O., R.A.M.H., and A.C.A.V. organized and performed the data collection of all phases of the study. J.T.P. and T.M.A. analyzed the data and interpreted the results. J.T.P. and J.K.K. drafted the paper and critically reviewed the manuscript. All authors read and approved the final version of the manuscript.

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