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LONGEVIDADE E FATORES ASSOCIADOS À FALHA DE
RESTAURAÇÕES ADESIVAS DE DENTES DECÍDUOS

PORTO ALEGRE
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LONGEVIDADE E FATORES ASSOCIADOS À FALHA DE RESTAURAÇÕES
ADESIVAS DE DENTES DECÍDUOS

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Orientador: Prof. Dr. Luciano Casagrande

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ADESIVAS DE DENTES DECÍDUOS

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RESUMO

O objetivo desta tese foi avaliar a longevidade e os fatores associados à falha de restaurações adesivas em dentes decíduos. Para isto, foram desenvolvidos dois estudos retrospectivos. No primeiro, foi feita a análise da longevidade de restaurações realizadas após a remoção seletiva de tecido cariado em dentes decíduos. Foram avaliados os prontuários de pacientes atendidos durante os anos de 2007 a 2012 no ambulatório de Odontopediatria da Universidade Federal do Rio Grande do Sul. Os critérios de inclusão previram a realização de pelo menos um procedimento de restauração com remoção seletiva de tecido cariado, em dente decíduo, e o acompanhamento clínico e/ou radiográfico. A amostra foi composta por 254 dentes de 118 pacientes, com período de acompanhamento de 1 a 50 meses. A sobrevida das restaurações, após 24 meses, foi de 51%, sendo constatada uma associação positiva entre a falha do procedimento e maiores valores do índice de placa visível ($p=0.01$). No segundo estudo, foi realizada uma avaliação da longevidade e dos fatores associados à falha de restaurações em dentes decíduos, após a remoção total e seletiva de tecido cariado. Para isso, foi desenvolvido um estudo retrospectivo, no curso de Odontologia do Centro Universitário Franciscano, com base nos prontuários de pacientes infantis, atendidos durante os anos de 2010 a 2016, que receberam pelo menos uma restauração em dente decíduo e tiveram um acompanhamento mínimo de seis meses. Foram incluídos 123 pacientes e 316 restaurações de resina composta ou cimento de ionômero de vidro. Após 3 anos, as restaurações apresentaram sobrevida de 54,4% e taxa de falha anual de 18,3%. A análise de Log-rank mostrou que a remoção seletiva de tecido cariado ($p=0,03$), o uso de base forradora de hidróxido de cálcio ($p<0,01$) e o cimento de ionômero de vidro ($p=0,04$) como material restaurador, resultaram numa menor sobrevida da restauração. A regressão de Cox ajustada demonstrou que restaurações realizadas com remoção seletiva de tecido cariado apresentam 3,41 (IC 95% 1,37;8,46) vezes maior risco de falha, quando comparadas à remoção total de tecido cariado. Conclui-se, então, que as restaurações em dentes decíduos, realizadas por alunos de graduação, possuem limitadas taxas de sobrevida e que fatores relacionados ao paciente e ao procedimento influenciam no desempenho da restauração.

Palavras-chave: Dente decíduo, cárie dentária, remoção de cárie, resina composta, fatores de risco, análise de sobrevivência

ABSTRACT

The aim of this thesis was to evaluate the longevity and factors associated with failure of adhesive restorations in deciduous teeth. For this, two retrospective studies were carried out. In the first, the longevity of restorations performed after the partial removal of carious tissue in deciduous teeth was analyzed. The records of patients treated during the period from 2007 to 2012 were evaluated at the School of Dentistry, Federal University of Rio Grande do Sul. The inclusion criteria predicted the accomplishment of at least one restoration procedure with partial removal of carious tissue in deciduous tooth and clinical and / or radiographic follow-up. The sample consisted of 254 teeth from 118 patients with follow-up period from 1 to 50 months. The survival rate of restorations after 24 months was 51%, with positive association between procedure failure and higher visible plaque index values ($p=0.01$). In the second study, longevity and factors associated with failure of restorations in deciduous teeth after total and partial removal of carious tissue were evaluated. For that, a retrospective study was developed in the Dentistry course of the Franciscan University Center, based on the records of pediatric patients treated during the period from 2010 to 2016, who received at least one restoration in a deciduous tooth and had minimum follow-up of six months. The study included 123 patients and 316 composite resin or glass ionomer cement restorations. After 3 years, restorations presented survival rate of 54.4% and annual failure rate of 18.3%. The log-rank analysis showed that the partial removal of carious tissue ($p= 0.03$), the use of calcium hydroxide liner ($p<0.01$) and glass ionomer cement ($p=0.04$) as restorative material, resulted in shorter survival rate of restorations. Adjusted Cox regression showed that restorations performed with partial removal of carious tissue were 3.41 (95% CI 1.37-8.46) more likely of presenting greater risk of failure when compared to total removal of carious tissue. It could be concluded that restorations in deciduous teeth performed by undergraduate students have restricted survival rate and that factors related to patient and procedure influenced the performance of restorations.

Keywords: Primary teeth, Dental caries, Caries Removal, Resin composite, Risk factors, Survival analysis.

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INTRODUÇÃO

O tratamento restaurador em Odontopediatria tem por objetivo reparar os danos causados pela doença cárie, proteger e preservar as estruturas dentárias, restabelecer a função adequada, restaurar a estética e proporcionar uma condição que facilite a manutenção de uma boa higiene bucal (MASSARA; REDUA, 2010). A indicação do material restaurador deve ser baseada nessas necessidades individuais dos pacientes, sendo o cimento de ionômero de vidro (CIV) e a resina composta (RC) materiais frequentemente utilizados em dentes decíduos (CASAGRANDE et al., 2013; PINTO et al., 2014). Contudo, ainda são escassas as evidências científicas para que se possa fazer a indicação baseada na longevidade clínica dos materiais restauradores para a dentição decídua (YENGOPAL et al., 2009).

Além disso, a performance das restaurações não é influenciada somente pelo material restaurador (DEMARCO et al., 2012). O desempenho das restaurações pode ser influenciado por uma série de variáveis individuais (paciente) e técnicas, como fatores socioeconômicos, idade, risco à cárie, variáveis clínicas de localização e extensão da cavidade, tipo de remoção de tecido cariado, uso de base forradora, isolamento absoluto, experiência do operador etc. (BUCKER et al., 2014; PINTO et al., 2014; BUCKER et al., 2015; FRANZON et al., 2015; METZ et al., 2015; KAKILETHO et al., 2016; VAN DE SANDE et al., 2016). Embora os ensaios clínicos randomizados forneçam o mais alto nível de evidência, podem não refletir com precisão os procedimentos realizados na prática odontológica rotineira (MJOR et al., 2005).

Ainda, é necessário determinar a efetividade de restaurações em dentes decíduos, quando realizadas no cotidiano dos atendimentos clínicos, em que as variáveis relacionadas ao paciente e ao operador não são controladas nem padronizadas como nos ensaios clínicos randomizados. Dessa forma, esta tese tem por objetivo avaliar a longevidade de procedimentos restauradores em dentes decíduos, quando realizados por estudantes de graduação, e avaliar os fatores individuais e técnicos associados à falha.

ARTIGO 1

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Clinical and radiographic outcomes of partial caries removal restorations performed in primary teeth

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ABSTRACT: Purpose: To analyze the outcomes of partial caries removal (PCR) restorations in primary teeth. **Methods:** The sample of this retrospective study comprised primary teeth that had been treated with PCR by undergraduate students and were selected from the dental records of patients who were receiving treatment at the School of Dentistry, Federal University of Rio Grande do Sul – Brazil (UFRGS), from 2007 to 2012. Records containing clinical and/or radiographic follow-up data of restorations with PCR in primary teeth were included in the analysis. Factors potentially associated with treatment failure were investigated, such as the number of surfaces restored, type of capping material and restorative material used, the presence of visible plaque, and the gingival bleeding index. **Results:** The sample comprised 254 teeth in 118 subjects; the follow-up period ranged from 1 to 50 months. The overall success rate for PCR was 80.3% (204/254). A significant association was found between high final visible plaque index and PCR failure ($P = 0.002$). (*Am J Dent* 2014;27:68-72).

CLINICAL SIGNIFICANCE: Partial caries removal restorations showed high rates of clinical and radiographic success when performed in primary teeth and constitute an important minimal intervention alternative for treatment of acute deep dentin carious lesions. Patients with higher amounts of visible plaque were more prone to experience failure in restorations.

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Introduction

Minimally invasive dentistry is considered to be an ideal approach for treating dental diseases, and aims to reduce the potential adverse effects of treatment in patients. Complete caries removal in acute deep dentin lesions results in an increased risk of pulpal exposure and post-operative pulpal symptoms in comparison with the risk after partial caries removal, which is a minimally invasive approach.¹⁻³

The premise of partial caries removal (PCR) relies on modification of the microenvironment of the contaminated dentin under the restoration, thereby arresting the cariogenic process while still preserving the tooth structure and pulp vitality. In PCR techniques, the remaining dentin under the restoration becomes less infected and moist, harder, and darker,^{4,5} allowing the clinician to avoid the pulpal complications related to deep complete caries excavation and reducing the risks and preventing, or delaying, re-treatment.¹⁻³

PCR techniques have been demonstrated to be efficacious in randomized clinical trials, in terms of microbiological, histological, biochemical and clinical-radiographic outcomes,^{6,11} and represent a less invasive alternative for the treatment of primary and permanent teeth with acute cavitated carious lesions. However, long-term randomized clinical trials are scarce and although they provide the highest level of evidence, they may not accurately reflect the survival of treatments in general dental practice.¹² As a result, it is still necessary to determine the effectiveness of PCR restorations when placed in a practice-based clinical environment, where variables such as operator/patient-related factors are not controlled nor standardized as in randomized clinical trials.

This retrospective study analyzed outcomes of PCR techniques performed by undergraduate students in primary teeth.

Materials and Methods

Ethical aspects - This retrospective study was developed at the Children and Youth Dental Clinic, School of Dentistry, Federal University of Rio Grande do Sul (UFRGS), Porto Alegre, Brazil. The protocol of this study was submitted to and approved by the Research Committee (n. 23489) and the local Ethics Committee (n. 08913112.2.0000.5347).

Sample collection - The sample was composed of dental records from patients who were receiving treatment at the School of Dentistry, Federal University of Rio Grande do Sul (UFRGS), from 2007 to 2012. The Children and Youth Dental Clinic of the UFRGS attends to an estimated population of 100 children and adolescent patients per semester, mainly from low socioeconomic backgrounds. A search was conducted to identify primary teeth that had received PCR restorations performed by fourth-year dental students. Data were retrieved for procedures performed by two trained individuals.

The records were selected if subjects met the following inclusion criteria:

- No medically compromised children;
- Reported PCR restorations in primary teeth;
- Involved clinical follow-up of PCR (records of first clinical examination and patient follow-up) and/or radiographic exams, including diagnostic and follow-up examinations of the tooth that underwent the PCR procedure;
- Informed consent forms were properly completed and signed by the legal guardian of the patient;
- Patients had been regularly attending the dental clinic (every 6 months).

All the procedures were performed under the supervision of senior faculty at the clinics (pediatric dentistry specialists), and

Table 1. Status of the restorations according to clinical and demographic characteristics (n = 254 restorations).

Variables	n (%) of restorations	Success (%)	Failure (%)
Sex			
Boys	123 (48.4)	105 (85.4)	18 (14.6)
Girls	131 (51.6)	99 (75.6)	32 (24.4)
Teeth			
1 st molar	135 (53.1)	113 (83.7)	22 (16.3)
2 nd molar	119 (46.9)	91 (76.5)	28 (23.5)
Surfaces			
Single	110 (43.3)	91 (82.7)	19 (17.3)
Multi-surface	144 (56.7)	113 (78.5)	31 (21.5)
Restorative material			
GIC	34 (13.4)	26 (76.5)	8 (23.5)
Resin	220 (86.6)	178 (80.9)	42 (19.1)
Capping material			
CaOH	110 (43.3)	88 (80.0)	22 (20.0)
GIC	24 (9.5)	19 (79.2)	5 (20.8)
Adhesive system	120 (47.2)	97 (80.8)	23 (19.2)
Visible plaque			
Baseline (Mean [SD])	38.7 (30.0)	38.7 (30.8)	38.5 (26.8)
Follow-up (Mean [SD])	27.4 (24.8)	24.9 (22.5)	37.1 (30.8)
Gingival bleeding			
Baseline (Mean [SD])	24.7 (27.8)	24.9 (28.2)	23.8 (26.5)
Follow-up (Mean [SD])	16.4 (17.6)	15.4 (16.3)	20.5 (21.5)

included clinical, radiographic, diagnostic, and interventional treatments. Briefly, the patients were anesthetized, and rubber dam isolation was performed by quadrants. Caries was removed completely from the cavosurface margins and all lateral walls of the cavity preparation with carbide burs at low speed. Caries removal at the site of "risk for pulp exposure" was performed with a dentin excavator. Remaining carious tissue was clinically evaluated (color and hardness), and then the cavity was thoroughly rinsed with phosphate-buffered saline (pH 7.4). In cases with deep caries near the pulp, a calcium hydroxide liner (Dycal) was placed prior to etching and/or restoration. In the composite restorations, the total-etch technique was performed by applying 37% phosphoric acid gel for 15 seconds to the cavity. The acid was removed by rinsing with water for 30 seconds and the cavity was gently dried with air and cotton pellets. Single Bond adhesive system was applied to the entire cavity as instructed by the manufacturer. The cavities were filled with resin composite (Filtek Z350[®]) using the incremental technique. For the glass-ionomer cement (Vitremer[®], GIC) the primer was applied for 30 seconds in the entire cavity, dried using an air syringe and then light cured for 20 seconds. The material was mixed in 1:1 (2 scoops of powder and 2 drops of liquid) ratio and placed into the cavity using a syringe system and then light-cured with a power of 550 mw/cm² for 40 seconds. For the restoration of the Class II cavities, a metal matrix was adapted to the cervical margin with an interproximal wedge. The rubber dam was then removed and the occlusion checked.

Data collection - Histories of PCR procedures were extracted from the dental records. Factors potentially associated with treatment failure were investigated. Two reviewers analyzed the records. Data collected included the following information: (1) patient age (years); (2) gender (boy/girl); (3) Aimano & Bay¹³ gingival bleeding and visible plaque index (GBI – initial/final; VPI – initial/final); (4) tooth location (first or second molars); (5) type of cavity (one surface or multiple surfaces);

(6) pulp capping material (calcium hydroxide cement, GIC, or adhesive system); (7) restorative material (GIC, or resin composite - RC); (8) monitoring period (measured in months until the last clinical and/or radiographic evaluation).

The outcomes of the PCR restorations were determined by clinical and/or radiographic evaluation. Clinical failure was measured after the procedure if there was presence of restorative failure, fistula, edema, abscess, increased mobility, or pain. All re-interventions were registered as failure due to either replacement or repair.

The radiographic criteria of success were as follows: no radiolucency in the furcation or periapical region, no increase in the periodontal space, absence of internal resorption, and absence of any other signs suggesting pulp involvement. The examiners were trained for diagnostic reproducibility, and this was determined by assessing 10% of the radiographs on two different occasions.

Data analysis - The descriptive distribution provides summary statistics of success rates according to the independent variables and demographic and clinical characteristics named, which, in this case, included gender (boy/girl), teeth (first/second molar), number of surfaces (single/multiple), type of capping material (calcium hydroxide cement/GIC/adhesive system), restorative material (GIC or RC), mean number of surfaces with visible plaque and the mean number of sites with gingival bleeding. Survival rates for PCR restoration longevity were calculated using the Kaplan-Meier method. The multivariate Cox regression analysis was performed to identify significant factors associated with failure. In this analysis, we calculated the hazard ratio between comparison groups and their respective 95% confidence intervals (HR; 95%CI). A backward stepwise procedure was used to select covariates in the fitting of the model. Only those variables presenting P-values < 0.2 in the unadjusted assessment were selected for the multivariate analysis. A significance level of 5% was considered for the final model. Data analyses were performed with STATA^b software 12.0.

Results

The sample comprised 254 restorations placed in 118 subjects (60 boys and 58 girls), with an average age of 5.5 years (SD: 1.9). The follow-up period ranged from 1 to 50 months. Among these 254 restorations, 128 (50.4%) were evaluated for 6 months; 62 (24.4%) for 12 months; and 64 (25.2%) for over 24 months. Table 1 shows the distribution of PCR procedures and their rates of "success" based on the demographic and clinical characteristics of the sample. Among the PCR procedures considered in the analyses, 131 (51.6%) were performed in girls. Multi-surface restorations were more common (56.7%) than single-surface restorations (43.3%), and those performed in first molars (53.1%) were more numerous than those in second molars (46.9%). Resin composites were the restorative material used most frequently (86.6%), while adhesive systems were the capping material of preference (47.2%), followed by calcium hydroxide (43.3%). The overall clinical and radiographic success rate was 80.3% (204/254). Failures (19.7%) were mainly due to restoration failures in 33 (13%) teeth and due to signs and symptoms of pulp necrosis in 17 (6.7%) teeth. The Kappa coefficient in the radiographic reproducibility evaluation was 0.89.

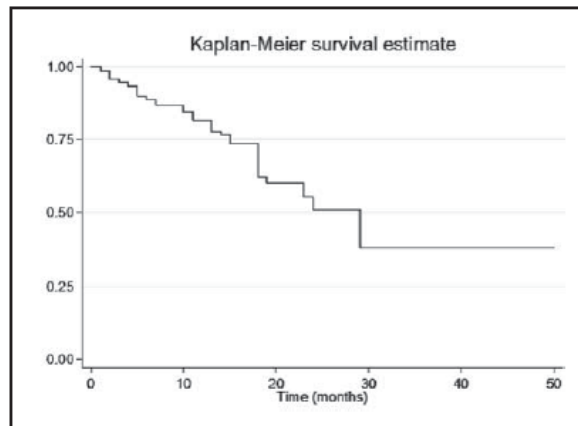


Figure. Kaplan-Meier survival curve of restorations over 50 months.

The cumulative PCR procedure survival estimate is shown in the Figure. Mean survival time was 29.5 months (95%CI: 16.7-17.7), with 50% of the restorations surviving after 29 months of evaluation (median survival time: 29 months). Survival rates of the restorations were 98%, 89%, 82%, and 51% at 1, 6, 12, and 24 months of follow-up, respectively.

Table 2 shows the unadjusted and adjusted hazard ratios (HR) for failures according to independent variables. The unadjusted analysis demonstrated that except for the mean number of surfaces showing visible plaque in the last period of evaluation, the relationship between differences in survival rates and clinical and demographic characteristics was not statistically significant. After the adjustment, teeth restored with resin composites had a borderline association ($P < 0.07$) with a protective factor for treatment failure, when compared to teeth restored with GIC. In addition, patients with a higher number of surfaces with visible plaque were more likely to experience failure after the PCR procedure. For every additional surface with visible plaque, the risk of failure increased by 2% (HR: 1.2).

Discussion

The results of our study showed that PCR restorations presented with a good survival rate in primary molars in periods up to 51 months. We also observed that patients with a higher amount of visible plaque after treatment and during the recall periods were more prone to exhibit treatment failure.

According to a survey¹⁴ performed in 191 undergraduate programs in Brazilian dental schools, indirect pulp capping with PCR is the most commonly taught procedure to treat deep carious lesions in dentin. The main goal of PCR is to avoid pulp exposure and pulp therapy, making it a less technique-sensitive and time-consuming treatment with superior results in comparison with traditional, conservative endodontic treatments such as direct pulp capping and pulpotomy.¹⁵

This practice-based retrospective study evaluated PCR restorations performed by undergraduates in their fourth clinical year, when they provide dental care to children and adolescents. The degree of operator experience may be an important factor in successful treatment, as well as the ability to best treat pediatric patients.^{16,17} During their fourth clinical year, dental students have already been in clinical practice for more than 2 years, and so have the ability to perform PCR

Table 2. Unadjusted and adjusted hazard ratios (HR: 95%CI) for failure of the restorations according to clinical and demographic characteristics. Cox regression model.

Variables	HR _{crude} (95%CI)	P-value	HR _{adjusted} (95%CI)	P-value
Sex		0.11		
Boys	1			
Girls	1.61 (0.9-2.9)			
Teeth		0.24		
1 st molar	1			
2 nd molar	1.40 (0.8-2.5)			
Surfaces		0.22		0.34
Single	1		1	
Multi-surface	1.43 (0.8-2.5)		1.33(0.7-2.4)	
Restorative material		0.39		0.07
GIC	1		1	
Resin	0.72 (0.3-1.5)		0.32(0.1-1.1)	
Capping material		0.45		0.11
CaOH	1		1	
GIC	1.39 (0.5-3.7)		0.60 (0.1-2.5)	
Adhesive system	1.45 (0.8-2.6)		1.74 (0.9-3.3)	
Visible Plaque				
Baseline	1.00 (0.9-1.1)	0.57	-	
Follow-up	1.01 (1.01-1.02)	0.01	1.01(1.01-1.02)	0.01
Gingival bleeding				
Baseline	0.99 (0.9-1.0)	0.57		
Follow-up	1.00 (0.9-1.0)	0.66		

treatment adequately. Additionally, the students perform all procedures under the supervision of instructors and professors, who check each step of the treatment. Students at the same level (fourth year) from public Brazilian dental schools are able to produce high-quality anterior and posterior composite restorations.¹⁸

The sample was composed of dental records from 118 patients from low socioeconomic backgrounds, and with a high caries risk profile. It comprised 254 primary molar teeth that underwent PCR techniques. A low socioeconomic level and higher level of caries prevalence may have a significant detrimental effect on posterior restoration survival.¹⁹ Patients with a higher caries risk have a higher chance of exhibiting posterior resin composite failure.²⁰ Therefore, the patients included in this sample were already at a higher risk of presenting with failure after PCR treatment. However, having said this, it is important to highlight that pediatric patients under care at public dental schools in Brazil receive treatment free of charge, and after oral rehabilitation, they are included in a therapeutic program that is based on oral health instruction and programmed recall intervals, as determined by the caries risk assessment. This environment of health promotion helps to overcome the disadvantages faced by these patients with regard to their initial oral health status, when compared to patients with better socioeconomic conditions.¹⁸

Retrospective analysis showed that the majority of PCR restorations were made in deep dentin by using a one-step PCR procedure, which involved many surfaces of primary molars, and was performed under anesthesia and rubber dam isolation. Over the demineralized dentin, an adhesive system (47.2%) was used most frequently as the capping material, followed by calcium hydroxide (43.3%). No difference in outcomes was observed among the capping materials used. In fact, this was also observed in past RCTs that compared the influence of different capping materials on the arrestment of deep carious lesions under the restoration.^{6,8-10} Interestingly, even with the

placement of an inert material, such as gutta-percha, it was possible to observe the arrest of active carious lesions.⁴ Carious lesions may act as a “pulp capping inducer” once the dentin matrix contains growth factors and cytokines that are sequestered during dentinogenesis²¹ and released by acids with other extracellular matrix components, inducing reactionary or reparative dentinogenesis.²²

In Brazil, resin composite and GIC are the most used materials to restore primary teeth. Their indications are not based solely on their physical and chemical properties, but also regarding the dental care needs of the child, such as degree of dental destruction, functional and esthetic sequelae caused by caries as well as the child’s behavior. According to Bücher et al.,²³ composite restorations are a long lasting, high quality treatment option in pediatric patients with early childhood caries (ECC). The success rate achieved was 81.5%, and the average retention time was 23.6 months, with an annual failure rate of 4.2%. The main reasons for failure were caries (44%) and complete restoration loss (46.4 %).²³

In the present retrospective study, most of the teeth were restored with resin composite (86.6%), while others were restored with GIC (13.4%). When evaluating treatment success, a borderline association ($P < 0.07$) was found with composite restorations being a protective factor against restoration failure. It was speculated that if another sample containing more teeth restored with GIC was evaluated, significant differences could be observed between resin composite and GIC. In fact, while a high survival rate can be observed with different resin composites in long-term function, the success of conventional GIC in posterior primary teeth may be lower than that observed for composite restorations; thus, in studies with longer clinical follow-up periods, the lower mechanical properties could compromise the performance of posterior restorations of conventional GIC.^{16,24} However, the same argument may not be used for resin-modified GIC (RMGIC), especially when placed in primary teeth. In an RCT that evaluated the clinical performance of resin composite and RM-GIC placed in 132 primary molars, the type of restorative material, number of restored surfaces, and caries removal technique (completed or incomplete) did not influence the longevity of the restorations. The restorations were clinically and radiographically followed up at 6-month intervals for up to 18 months, using the USPHS modified criteria. The overall success rate reached 87.1%.²⁵

The patient records’ analysis showed a high rate of clinical and radiographic success (80.3%), which corroborates with the findings of RCTs of IPT with incomplete caries removal performed in primary teeth.^{4,6-9,11} Overall, the failure rate was low in this retrospective study. Restoration failure was the reason for most of the unsuccessful outcomes observed (13%), followed by dental pulp complications (6.7%) such as fistula, edema, swelling, necrosis, and radiolucency at the interdental and/or periapical regions, as determined by periapical radiographs.

In the present study the Kaplan-Meier estimator, which measures the fraction of the restorations with PCR surviving after the follow-up period, to calculate the survival rate, was used. Mean survival time was 29.5 months (95% CI: 16.7–17.7); the survival rates of the restorations were 98%, 89%, 82%, and 51% at 1, 6, 12, and 24 months of follow-up, respec-

tively. Although the failure rate at 24 months appears to be high, it is important to note that the estimator takes into account the censored data, i.e., those restorations that have not yet reached the 24-month evaluation in this retrospective analysis. This explains the low estimated survival rate (51%) of restorations at 24 months, which may be underestimating the actual performance of the restorative procedures during this period.

In the present study, the outcome of PCR was not influenced by the position of the tooth in the arch. It seems that tooth position in the arch is associated more with failure when the restoration is placed in a permanent tooth. In a previous study, a higher risk of fracture was found for mandibular molars compared to premolars.²⁶

Moreover, there was no significant difference in outcome between teeth with one and many restored surfaces. It has been found that a higher number of surfaces involved in cavity preparation can significantly decrease the success rate of posterior composite restorations in permanent teeth.^{16,19} However, in primary teeth there is much less occlusal loading compared to that in permanent teeth, which reduces the influence of proximal site involvement in cavity preparation on the outcome of treatment. In addition, when evaluating permanent teeth, the presence of proximal boxes in posterior teeth is a challenge with regard to oral hygiene, but this may be less critical in primary molars.

A significant association was found between final visible plaque index (VPI) and the failure of PCR procedures ($P = 0.002$). Dental plaque is a marker for oral health patterns.²⁷ While evaluating the trajectory of dental plaque from childhood until adult life in a birth cohort (Dunedin, New Zealand), investigators observed three different dental plaque trajectories: low, medium, and high. A lifetime exposure to dental biofilms may be a key risk factor in cumulative dental diseases, caries experience, and tooth loss due to caries,²⁸ and individuals exhibiting high levels of dental plaque throughout their lives had a higher chance of tooth loss due to caries.

IPT with PCR was the technique most widely performed by the dental students for acute deep dentin carious lesions, and was executed in one appointment. This observation corroborates with the profile of teaching pulp therapy in primary teeth by Brazilian dental schools, where the majority of respondents (98%) indicated one appointment for IPC procedures.¹⁴ This result was consistent with scientific evidence showing that re-intervention of the treated tooth is not necessary,^{4,11} since the remaining carious dentin becomes arrested and thus stalls the progression of the lesion under restorations.^{4,30} According to a recent systematic review, one-step complete excavation, step-wise excavation, or two-step incomplete caries removal increases the risk of pulp exposure when compared to one-appointment incomplete caries removal.¹

Moreover, in a cost-effectiveness study of one- and two-step incomplete and complete excavations, in which a model was used to simulate treatment of a molar tooth with a deep caries lesion in a 15-year-old patient, it was observed that one-step PCR reduces costs and keeps teeth vital for longer. On the other hand, complete excavation of deep caries lesions raises the risk of pulp damage and often initiates a cascade of re-intervention, which ultimately leads to untimely tooth extraction.³

The results from this practice-based retrospective study show that patient related-factors definitely impact the survival of restorative treatments. Thus, it is assumed that PCR failures in primary teeth are related more to individual caries risk as well as a high visible plaque index rather than to the intentional retention of demineralized dentin under a restoration.

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ARTIGO 2

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Longevity and factors associated with failure of adhesive restorations in primary teeth performed by undergraduate dental students - a retrospective study in a high caries risk population

Short title: Survival of primary teeth restorations

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ABSTRACT

Objective: To evaluate longevity and factors associated with failures in adhesive restorations of primary teeth. **Methods:** In this retrospective University-based study, sample was comprised of restorations placed in primary teeth by dental students. Clinical records and radiographic images of each patient were screened in order to find whether restored teeth were re-treated (restoration repair or replacement, pulp therapy or extraction), or presented any defective restorations or adjacent caries, which were considered as failures. The following individual and treatment factors, potentially associated with restoration failure, were considered: gender, age, caries experience, visible plaque and gingival bleeding indexes, tooth position, use of rubber dam, type of caries excavation, type of cavity, presence of liner material and type of restorative material. Statistical analysis was performed by the Kaplan-Meier survival and Multivariate Cox-regression with shared frailty. **Results:** A total of 123 high caries risk patients ($10.3 \pm 4 \text{ dmft}$) with 316 restorations were included. The three-year survival reached 54.4%, with annual failure rate of 18.3%. Log-rank test showed that the selective caries removal ($p=0.03$), use of calcium hydroxide liner ($p<0.01$) and Glass Ionomer Cement as restorative material ($p=0.04$) presented lower survival rates. Multivariate Cox regression showed that restorations placed in teeth after selective caries removal showed 3.41 (95% CI 1.37-8.46) times higher risk of failure compared with restorations performed over complete caries removal. **Conclusion:** Restorations performed by undergraduate students in high caries risk patients have limited survival rates, as some treatment-related factors may influence the restoration performance.

Clinical Relevance: Some treatment-related factors may influence the survival rate of adhesive restorations performed in high caries risk patients. Hence, clinicians should schedule their recall appointments to monitor these restored primary teeth even more frequently.

INTRODUCTION

Caries is still one of the major reasons for tooth loss worldwide. There is a paradigm shift in dentistry toward non-invasive and minimally invasive approaches, which account for a continuum update in daily practice. Hence, some researchers have drawn their attention on reasons for restoration failures regarding patient-related or tooth/treatment-related factors^{1,2}. Although some studies reported higher survival rates of unrestored carious primary teeth until exfoliation^{3,4} or even restored teeth with defective restoration left untreated⁵, in deep carious

lesions one must provide long-lasting restorative treatment options to reduce pain and further minimize more invasive approaches (pulp therapy), especially in young patients.

Selective caries removal (SCR), which is based on the microenvironment modification of contaminated dentin intentionally left on the pulp floor, decreases the risk of pulp exposure and post-operative symptoms in adhesive restorations of deep carious lesions^{6,7}. However, most dentists aiming to improve restoration longevity still prefer to perform complete caries removal (CCR) even for deep lesions, as they thought complete removal is required to avoid lesion progression, and were also uncertain whether the bacteria left would harm the pulp or not^{8,9}. Moreover, there is a lack of consensus in both techniques regarding the material choice for such restorations in pediatric patients. Some authors have reported similar survival rates for glass ionomer cements and composite restorations¹⁰, whereas different results pointing out higher risks of failure for glass ionomer cements are observed¹¹.

Clinical trials indeed provide strong evidence on decision making regarding different treatments. Nevertheless, such controlled settings provide high internal validity but low external validity, which make difficult extrapolation of those results to the daily clinical practice¹². Hence, despite its limitations, retrospective studies based on clinical practice are very useful to provide information and guidance for dentists in relation to restoration longevity and risk factors associated with failures in daily practice. There are few retrospective studies^{10,11,13,14} in primary teeth that evaluate restoration longevity and patient-related factors, but none have compared different restorative approaches (SCR and CCR). Therefore, we aimed to evaluate longevity and factors associated with failure of primary teeth restorations in a high caries risk population under a University practice-based clinical setting. Our null hypothesis was that none of the individual- or treatment-related factors would influence the restoration longevity of primary teeth.

MATERIALS AND METHODS

Study design and Ethical Aspects

This retrospective University-based study was developed at the Pediatric Dentistry Unit, School of Dentistry, Franciscan University Center, Santa Maria, Brazil. The research protocol was conducted in accordance with ethical standards of the National Council on Ethics in Research (n. 466/2012) and was approved by the Local Ethics Committee (CAAE: 54711016.7.0000.53061). All clinical records included in the study had informed consent forms

properly completed and signed by patient's legal guardian authorizing dental treatment and use of registered data for research. Patients' personal information was kept confidential. Present observational study conforms to the STROBE guideline.

Participants and data collection

The population participating in this research was composed of all children treated by undergraduate dental students during the period between 2010 and 2016, supervised by clinical instructors, who are specialists in Pediatric Dentistry. Treatments had low cost to patients in the University Clinic, which attracted many children from families with limited income and low socioeconomic status.

To be eligible for the study, children should have received at least one restoration (Glass Ionomer Cement – GIC; Composite Resin – CR) in vital primary teeth due to caries lesion. Restorations should have been clinically and/or radiographically monitored for at least 6 months.

Two examiners (DMD/CSG) collected data from patients' files. The following individual- and treatment-related factors potentially associated with restoration failure were considered: (1) gender, (2) age, (3) caries experience (dmft+DMFT index – at first appointment), (4) visible plaque and gingival bleeding indexes (VPI and GBI – at first appointment and in the last check-up), (5) tooth position (anterior or posterior), (6) use of rubber dam, (7) type of caries excavation (SCR; CCR), (8) type of cavity (one or multiple surfaces), (9) presence of liner material (calcium hydroxide cement) and (10) type of restorative material (GIC; CR).

Date of restoration placement and any re-intervention (repair, replacement, endodontic treatment, extraction), as well as the last patient's check-up were considered to calculate the restoration survival.

Clinical procedures

All clinical procedures were performed by 3rd year dental students supervised by the clinical staff. Treatment procedures followed recommendations of the current guidelines and policies of the American Association of Pediatric Dentistry¹⁵.

After clinical examination, diagnostic radiographs were obtained to visualize the depth of caries lesions and the furcation/periapical regions. Caries lesions were located in the dentin and they must not present any symptom or sign suggesting irreversible pulp involvement. The decision about using rubber dam isolation, liner and restorative material, was made by clinical instructors. In superficial and middle lesions, caries was removed completely from the cavosurface margins and all lateral walls, including the pulp floor of the cavity preparation. In deep carious lesions, if complete excavation led to the risk of pulp exposure, selective caries removal was performed. The restorative materials were used according to the manufacturer's instructions [Vitrofil - DFL, Rio de Janeiro / RJ, Brazil; Acid Gel 37% - Villevie, Joinville / SC, Brazil; Magic Bond DE - Coltene, Rio de Janeiro, Brazil; Llis - FGM, Joinville / SC, Brazil; Opallis - FGM, Joinville / SC, Brazil].

For the management of caries activity, patients also received non-invasive treatments such as oral hygiene, dietary advices, prophylaxis and fluoride therapy; and were registered in an individual preventive program consisting of dental hygiene monitoring (VPI/GBI).

Outcomes

The restoration survival was the main outcome of this study and it was described as the period between the restorative procedure and the last dental check-up (=censoring date) without the tooth suffering any re-intervention. Clinical records and radiographic images of each patient were screened in order to find whether restored teeth were re-treated (restoration repair or replacement, pulp therapy or extraction), or presented any defective restorations or adjacent caries, which was considered as failures. The examiners were trained for diagnostic reproducibility, and this was determined by assessing 10% of the radiographs on two different occasions. The Kappa coefficient in the radiographic reproducibility evaluation was 0.90.

Data analysis

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

Restoration survival was assessed by Kaplan–Meier Estimator. Differences on survival rates according to the clinical and demographic characteristics were tested by the Log-rank test and the significance level was set at 5%. The annual failure rate (AFR) was calculated using

the formula: $(1 - y)z = (1 - x)$, where “y” is the mean AFR and “x” is the total failure rate at “z” years.

Test of proportional-hazards assumption was performed for each independent variable before including them in the Multivariate Cox regression model. Only variables with proportional-hazards ($p > 0.05$) were included in the regression. Analysis with shared frailty was performed to identify factors associated with restoration failure. This method takes into account the clustering effect, i.e., considers that observations within the same patient are correlated, as systemic and behavioral factors can interfere with the individual's response to treatment. Variable selection followed a stepwise backward method. Only variables showing $p < 0.40$ were included in the final adjusted model. Hazard ratios (HR) and their 95% confidence intervals were estimated. This study adopted 5% significance level.

RESULTS

Initial screening included all 1137 clinical records of children who attended the Franciscan University Center. After analyzing the inclusion criteria of having at least one restored primary tooth and 6 months of follow-up, 316 eligible restorations were included in the analysis (Figure 1). This corresponded to 123 patients (68 boys and 55 girls) with mean age of 6.4 years (SD 2.1), mostly from low socioeconomic families and high caries experience (10.3 ± 4.0 dmft+DMFT mean). The mean VPI and GBI values at the first visit were 22.0% (± 16.9) and 19.6% (± 19.7), respectively. At the last check-up appointment, the mean VPI value was 19.3% (± 19.8) and GBI reached 12.1% (± 12.5).

Table 1 shows the distribution of restorations in primary teeth according to the individual- and treatment-related variables. Regarding the restorations, composite resin was the most frequently used material (87.3%) and, in 16.8% of cases, calcium hydroxide liner was used as indirect pulp capping. A total of 99 failures were observed during the 36 months of follow-up in which 61 were due to restorative failure, 33 to secondary caries and 5 to pulp involvement.

The mean observation time was 22.3 months. Figure 2 shows the Kaplan-Meier survival curves over 36 months. The three-year survival reached 54.4%, with AFR of 18.3%. The Log-

rank test showed that the selective caries removal ($p=0.03$), use of calcium hydroxide liner ($p<0.01$) and GIC as restorative material ($p=0.04$) presented lower survival rates.

Table 2 shows the crude and adjusted Cox regression analyses for independent variables and restoration failure. The adjusted model showed that restorations placed in teeth after selective caries removal showed 3.41 times higher risk of failure compared with restorations performed over complete caries removal (95% CI).

DISCUSSION

The results of this retrospective study demonstrated a limited survival rate (54.4%) of adhesive restorations placed in primary teeth of high caries risk children. AFR was 18.3% up to 3 years of follow-up. The null hypothesis was rejected, as some treatment-related factors influenced the restoration longevity of primary teeth. Restorations placed over selective caries removal, use of calcium hydroxide liner and performed with GIC as restorative material showed lower survival rates. The multivariate Cox regression showed that restorations with SCR presented 3.41 times higher risk of failure compared to total carious removal.

AFR of restorations in primary teeth evaluated by retrospective studies ranges from 4.2% to 11.7%^{11,13,14}. One factor that may explain the higher AFR in our study is related to the population profile, which was composed of high caries risk children, with average dmft + DMFT of 10.3, twice as high as that observed in others retrospective studies^{11,13}. This factor may have contributed to the result, since the survival rate of restorations is significantly lower in primary teeth of children with high caries experience^{14,16}.

Socioeconomic characteristics of the individual play an important role in restoration failures. Low socioeconomic conditions and low maternal educational level were associated with unsatisfactory survival rate of restorations¹⁷. In Brazil, dental treatments in university centers are provided at low cost, which usually attracts population from low socioeconomic level. Thus, it was expected that the survival rate of restorations evaluated in this study would be influenced by the socioeconomic conditions of the population. In addition, the operator's experience and ability may influence the quality and longevity of restorations^{13,18}. Despite of being supervised by the clinical staff, procedures were carried out by unskilled 3rd year undergraduate dental students. Hence, we speculate that the operator's experience might also have accounted for the lower survival rates observed in our study. Noteworthy, other

retrospective studies have shown long lasting restorations in children when experienced professionals perform the restorative procedures^{13,14}.

Defective restorations (fracture, wear, partial loss) were the most frequent reason for failure, followed by adjacent caries lesions and pulp involvement. Another retrospective study with primary teeth also reported defective restorations as the main reason for failure, in which 46.4% of cases were due to total loss of restoration and 9.6% due to fractures¹⁴. In the present study, adjacent caries was responsible for failure in 33.3% of the cases. A review has shown that the main reasons for short-term restorative failures are fractures of teeth or restorations and, in the long term, secondary caries¹⁹.

SCR is indicated for the treatment of deep caries lesions and involves selective removal to soft dentin over the pulp site to avoid its exposure, while the cavity margins (i.e., peripheral dentine) are left hard (scratchy)⁹. The remaining carious tissue becomes more hardened, darkened and less contaminated, regardless of the use of calcium hydroxide liner²⁰⁻²². In our study, the use of a calcium hydroxide liner in deep cavities may have constituted a confounding factor that could have influenced the shorter survival of restorations. The reduced area for adhesion and the significantly lower integrity margin of composite restorations may have a detrimental effect on restoration survival²³. Moreover, there are some difficulties with calcium hydroxide handling, especially in children, considering the reduced size of the cavity and the limited ability to cooperate, which reinforce the need to rethink this indication, as it not essential to promote remineralization of the remaining tissue. Current evidence does not support cavity liners to maintain pulpal vitality after excavating caries lesions and before restoring cavities of primary teeth²⁴. On the contrary, the synthesized data suggests potential advantages of not using liners before filling the cavity²⁴. Although restorations with calcium hydroxide presented lower survival than those without the liner material, this variable was not included in the regression model because only variables with proportional hazards were included in the analysis.

In vitro studies have shown that the adhesion to demineralized dentin are lower when compared to sound dentin, and that teeth restored after SCR have reduced resistance to fracture, suggesting that this may compromise the restoration performance^{25,26}. In this study, it was observed that primary teeth with SCR were 3.41 times more likely to present restoration failure. This is in accordance with a randomized clinical trial that evaluated deep carious lesions restored after SCR and CCR. The authors observed that restored teeth after SCR were 2.9 times more likely to present restoration failure than CCR²⁷.

However, the worse performance of SCR restorations compared to CCR must be interpreted with caution. The indication bias (restorative protocol) could have interfered directly the results and constitutes a limitation of this study. In our clinical protocol, CCR is recommended for superficial and middle cavities while SCR is indicated for deep cavities to prevent pulp exposure. Thus, the greater failure risk of SCR may also be related to the cavity depth, which was not measured in this study. The literature indicates that deeper and more extensive cavities are factors associated with restorative failure^{13,14,27}.

The results of this study should not discourage the indication of SCR in a population at high caries risk/experience. On the contrary, a high-risk population could be benefited by minimal invasive techniques as SCR. In a micro-simulation study that aimed to compare the costs-effectiveness of different excavations in low- and high-risk patients, the cost-effectiveness advantages of selective excavation were more pronounced in high-risk groups when compared to stepwise and complete excavation²⁸. Additionally, one-step SCR reduces patient pain and is a less time-consuming technique, considering the increased risk of pulp exposure of complete caries removal²⁹.

Regarding the type of restorative material, GIC accounted for the lower survival rates. Similar results were observed in a retrospective study carried out by undergraduate students, where teeth restored with CR presented better performance than GICs¹¹. On the other hand, in a randomized clinical trial assessing primary molars restored with CR and resin-modified glass ionomer cement no difference in the performance of restorations were observed after 18 months of follow-up³⁰.

GIC has favorable properties for use in children, such as the absorption and release of fluoride and reduced sensitivity to moisture when compared to composite, but it has lower mechanical properties³¹. Generally, GIC is used in more complex clinical situations, such as in children with negative behavior and difficulty to perform rubber dam isolation, which can lead to worse prognosis, regardless of the chosen material. Thus, an indication bias may have occurred, since in more complicated clinical cases, GIC was indicated.

The limitations of this investigation are related to the retrospective design. Data regarding child's behavior during consultation, depth of caries lesions and others clinical characteristics, such as bruxism, were not available in our records. The confounding factors in this study include the unequal distribution of SCR and CCR, comparison of different cavity depths and the use of calcium hydroxide liner. Nevertheless, retrospective studies could reflect the real clinical situation, where not controlled settings provide high external validity making

more reliable extrapolation to the daily practice. Hence, the results may be extrapolated to high caries risk patients with limited income and low socioeconomic status, in which CCR and composite restorations present higher longevity if compared to CIGs.

CONCLUSIONS

Considering the limitations of the present study, it is possible to conclude the following:

1. Restorations performed by undergraduate students in high caries risk patients have limited survival rates,
2. Treatment-related factors may influence the restoration performance in primary teeth,
3. Restorations performed with composite resin after complete carious removal and without calcium hydroxide liner (procedures performed on superficial and medium lesions) present higher survival rates.

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Table 1. Distribution of restorative treatments in primary teeth according to the individual and tooth-level variables (123 children, 316 restorations).

Variables	n (%) of restorations	Success (%)	Failure (%)
<i>Gender</i>			
Male	185 (58.5)	128(69.2)	57(30.8)
Female	131 (41.5)	89(67.9)	42(32.1)
<i>Age</i>			
< 3 years	16 (5.1)	9 (56.3)	7 (43.8)
> 3 years	300 (94.9)	208 (69.3)	92 (30.7)
<i>DMF-t</i>			
< 5	33 (10.4)	20 (60.6)	13 (39.4)
> 5	283 (89.6)	197 (69.6)	86 (30.4)
<i>VPI follow-up</i>			
< 20%	218 (68.9)	155(71.1)	63(28.9)
> 20%	98 (31.1)	62(63.3)	36(36.7)
<i>GBI follow-up</i>			
< 20%	247 (78.2)	167(67.6)	80(32.4)
> 20%	69 (21.8)	50(72.5)	19(27.5)
<i>Type of teeth</i>			
Posterior	259 (82.0)	178 (68.7)	81 (31.3)
Anterior	57 (18.0)	39 (68.4)	18 (31.6)
<i>Rubber dam</i>			
yes	247 (78.2)	180 (72.9)	67 (27.1)
no	69 (21.8)	37 (53.6)	32 (46.4)
<i>Caries removal</i>			
Complete	263 (83.2)	182 (69.2)	81 (30.8)
Selective	53 (16.8)	35 (66.0)	18 (34.0)
<i>Liner material</i>			
no	263 (83.2)	193 (73.4)	70 (26.6)
yes	53 (16.8)	24 (45.3)	29 (54.7)
<i>Restored surfaces</i>			
1	139 (44.0)	97 (69.8)	42 (30.2)
2 or more	177 (56.0)	120 (67.8)	57 (32.2)
<i>Restorative Material</i>			
Composite Resin	276 (87.3)	200 (72.5)	76 (27.5)
GIC	40 (12.7)	17 (42.5)	23 (57.5)

Table 2. Crude (^c) and adjusted (^a) Hazard Ratios (HR) for independent variables (123 children, 316 restorations) and failure of restorative treatments in primary teeth (Cox regression with shared frailty models).

Independent variables	HCR^c(95% CI)	p-value	HR^a(95% CI)	p-value
<i>Gender</i>				
Male	1.00	0.977	-	-
Female	1.01 (0.36;2.82)			
<i>VPI follow-up</i>				
< 20%	1.00	0.379	1.00	0.306
> 20%	1.62 (0.55;4.81)		1.01 (0.98;1.04)	
<i>Type of teeth</i>				
Posterior	1.00	0.979	-	-
Anterior	1.01 (0.53;1.90)			
<i>Caries removal</i>				
Complete	1.00	0.015	1.00	0.008
Selective	2.68 (1.21;5.94)		3.41 (1.37;8.46)	
<i>Restored surfaces</i>				
1	1.00	0.545	-	-
2 or more	1.16 (0.71;1.90)			

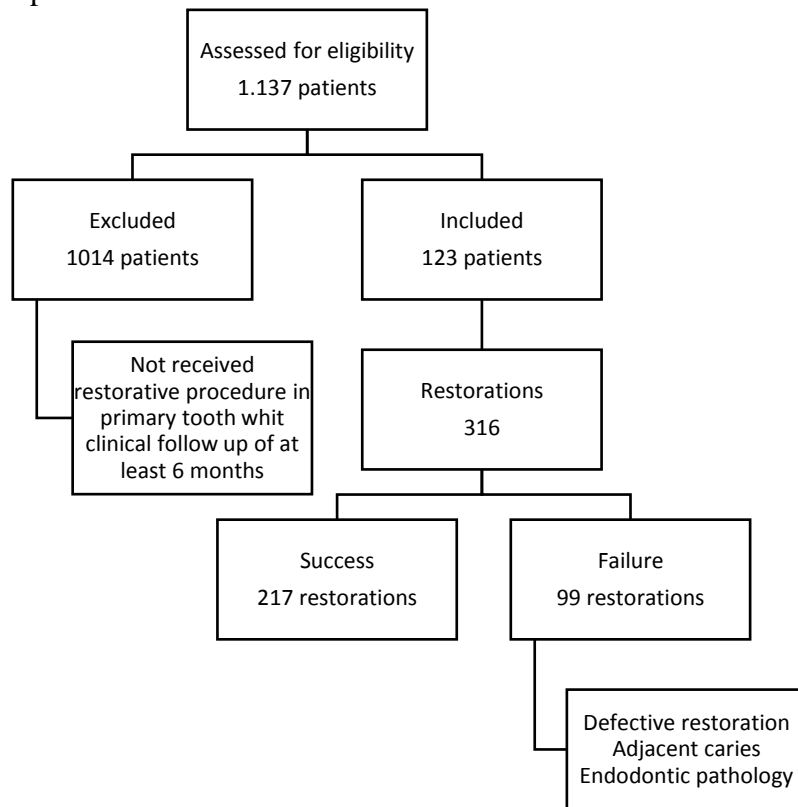
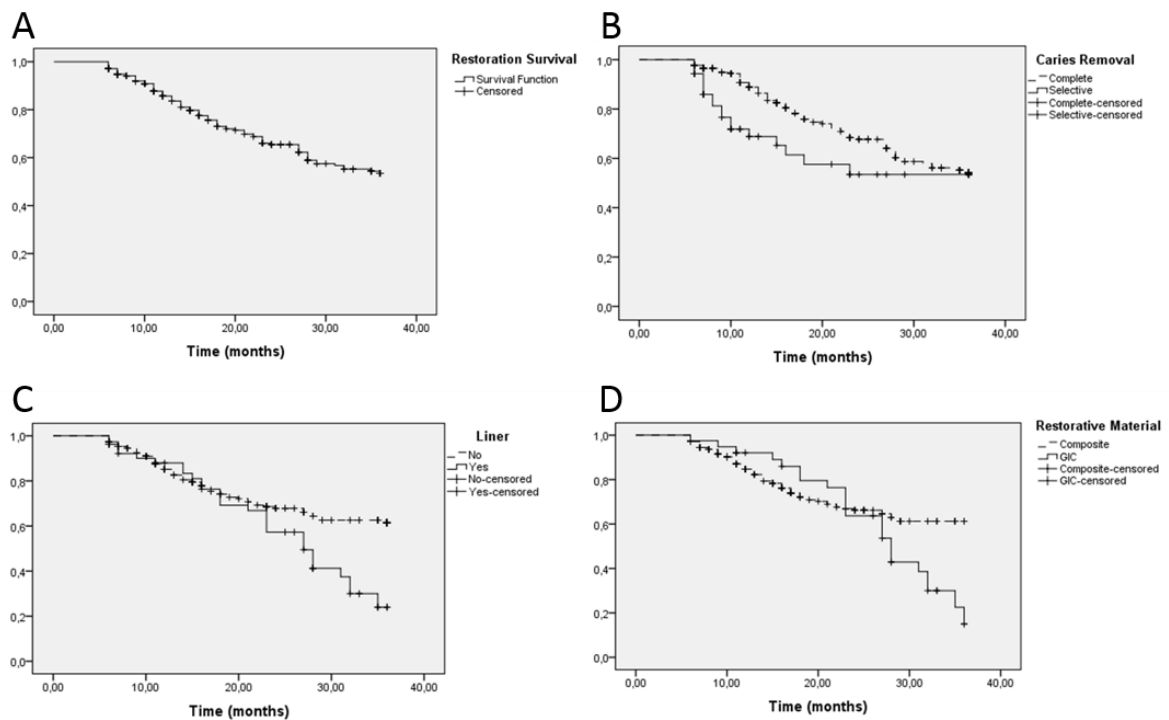
Figure 1. Sample selection flowchart

Figure 2. Figure 2 – Kaplan–Meier survival curves of restorative treatments over 36 months of clinical and radiographic follow-up. (A) Overall survival probability rate of adhesive restorations placed in anterior and posterior primary teeth (54.4%). (B) Restorations placed over selective caries removal presented lower survival ($p=0.03$); (C) The use of a calcium hydroxide liner reduced the survival of restorations ($p<0.01$); (D) GIC restorations showed lower survival compared to Composite restorations ($p=0.04$).



CONSIDERAÇÕES FINAIS

Nesta tese, são apresentados dois estudos retrospectivos sobre procedimentos restauradores em dentes decíduos, realizados por alunos de graduação. A longevidade das restaurações, observada no primeiro estudo, foi de 51% em 24 meses e, no segundo, foi de 54,4% em 36 meses. A sobrevida das restaurações foi limitada e especula-se que vários fatores podem ter influenciado esse resultado. A sobrevida do procedimento restaurador é menor quando realizado por profissionais com pouca experiência clínica (METZ et al., 2015; BUCKER et al., 2015). Os procedimentos nos dois estudos foram realizados por alunos de graduação; assim sendo, operadores com pouca experiência.

O perfil dos pacientes também pode estar relacionado com os resultados encontrados. Pelo baixo custo do atendimento, a população atendida em clínicas de graduação é principalmente de baixo nível socioeconômico. A literatura indica que esse nível do paciente interfere na longevidade dos procedimentos restauradores (CORREA et al., 2013), assim como o maior risco à cárie também está relacionado com a menor sobrevida das restaurações (BUCKER et al., 2014; KAKILETHO et al., 2016). A média de cpo-d/CPO-D das crianças incluídas nos estudos foi elevada e pode ter influenciado o resultado.

Além da longevidade, avaliaram-se os fatores associados à sobrevida das restaurações. No primeiro estudo, uma associação significativa foi encontrada entre o índice de placa visível e a falha dos procedimentos restauradores com remoção seletiva de tecido cariado (RSTC). Pacientes com maiores quantidades de placa visível foram mais propensos a experimentar falhas em restaurações. Destaca-se, assim, a importância de reforçar e enfatizar o tratamento não invasivo, concomitante ao tratamento invasivo. A manutenção periódica preventiva do paciente, associada a um programa de promoção da saúde, torna-se fundamental para o sucesso do tratamento.

A restauração com RSTC realizada em dentes decíduos, constitui-se numa importante alternativa para tratamento de lesões cariosas em dentina profunda. Entretanto, a RSTC apresentou risco de falha 3,41 (IC95% 1.37;8.46) vezes maior em comparação com restaurações realizadas com remoção total de tecido cariado. Apesar do maior risco de falha do procedimento restaurador, é importante destacar que a RSTC apresenta as vantagens de diminuir os riscos de exposição pulpar, ser realizada em menor tempo, além de apresentar índices de sucesso superior aos demais tratamentos conservadores da polpa (FAROOQ et al., 2000; SCHWENDICKE et al., 2013; FRANZON et al., 2014). Desta forma, considerando os riscos e benefícios, a RSTC

ainda deve ser a primeira escolha de remoção de tecido para cavidades profundas em dentes decíduos.

Os resultados também evidenciaram uma menor sobrevida das restaurações, quando utilizada base forradora de hidróxido de cálcio, e o CIV como material restaurador. O CIV possui propriedades mecânicas inferiores em relação à RC, o que pode comprometer o seu desempenho (PINTO et al., 2014). Entretanto, deve-se considerar as limitações do estudo. O hidróxido de cálcio é indicado para o capeamento pulpar indireto em cavidades muito profundas. Desta forma, a extensão e profundidade da cavidade podem ser um fator de confusão, visto que cavidades maiores possuem menor sobrevida (BUCKER et al., 2014; PINTO et al., 2014; BUCKER et al.; 2015, METZ et al.; 2015; FRANZON et al., 2015). O mesmo raciocínio pode ser utilizado para o tipo de remoção de tecido cariado, considerando a indicação de RSTC somente em cavidades profundas, para assim prevenir uma exposição pulpar. Por fim, segue a indicação de material restaurador. Na prática clínica, considerando a menor sensibilidade do CIV à umidade e simplicidade da técnica, este é utilizado em situações clínicas mais complexas, como em crianças com comportamento negativo, dificuldade de isolamento absoluto e dúvida sobre o diagnóstico pulpar, que podem ocasionar um pior prognóstico, independentemente do material escolhido. Associada a estes fatores, também observamos uma distribuição desigual do material restaurador, no primeiro estudo, e do tipo de remoção de tecido cariado e uso de base forradora, no segundo estudo.

Assim sendo, as avaliações apresentaram algumas limitações de mensuração de dados, distribuição da amostra e vieses de indicação de técnica e material restaurador. Porém, apesar das limitações, estes apresentam a vantagem de refletir o desempenho de restaurações em dentes decíduos, quando realizadas no cotidiano dos atendimentos clínicos, em que as variáveis relacionadas ao paciente, operador e tratamento não são controladas nem padronizadas como nos ensaios clínicos randomizados. Os resultados desta tese podem ser generalizados para uma população de baixo nível socioeconômico, alto risco à cárie e atendida por profissionais com pouca experiência clínica.

Em frente ao exposto, é possível concluir que restaurações adesivas, em dentes decíduos, realizadas por estudantes de graduação em crianças de alto risco à cárie, possuem limitadas taxas de sobrevida, e que fatores relacionados ao paciente e ao procedimento estão associados à falha do procedimento restaurador.

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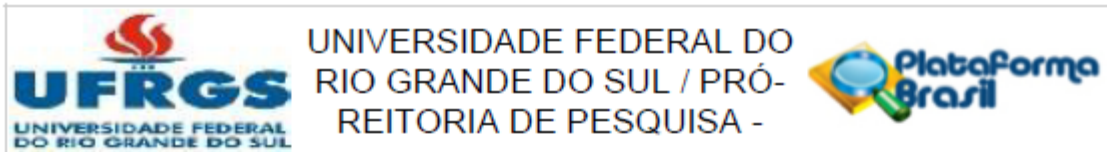
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VAN DE SANDE F.H, COLLARES K, CORREA M.B, CENCI M.S, DEMARCO F.F, OPDAM N. Restoration Survival: Revisiting Patients' Risk Factors Through a Systematic Literature Review. **Oper Dent**, v.41, n.S7, p.S7-S26, 2016.

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ANEXOS

Parecer CEP artigo 1



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Remoção Parcial de Tecido Cariado - Estudo Retrospectivo em Clínica de Graduação

Pesquisador: Luciano Casagrande

Área Temática:

Versão: 3

CAAE: 08913112.2.0000.5347

Instituição Proponente: UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL/COMITÊ DE ÉTICA EM

DADOS DO PARECER

Número do Parecer: 184.151

Data da Relatoria: 10/01/2013

Apresentação do Projeto:

A remoção parcial de tecido cariado (RPTC) está inserida numa proposta minimamente invasiva, para lesões cáries agudas em dentina profunda, visto que, ao conservar um remanescente de tecido cariado, preserva-se a estrutura dentária e mantém-se a vitalidade pulpar. Além disso, apresenta outras vantagens como a diminuição do tempo clínico de trabalho, com resultados superiores se comparada com tratamentos endodônticos conservadores tradicionais, como o capeamento pulpar direto e a pulpotomia. Contudo, existe a necessidade de verificar se o sucesso relatado nos estudos é observado na rotina dos atendimentos clínicos.

Objetivo da Pesquisa:

Objetivo Geral

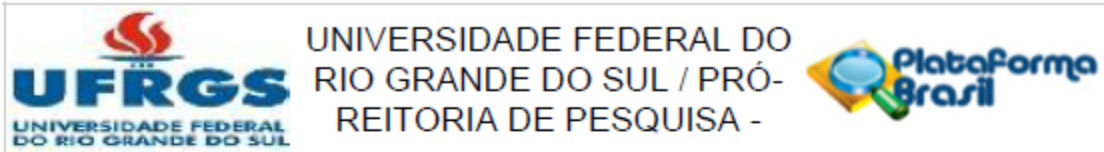
Avaliar a evolução clínica de técnicas de RPTC quando utilizada por alunos de graduação Clínica Infanto-juvenil - UFRGS, através da avaliação de prontuários clínicos de pacientes atendidos no Ambulatório da Clínica Infanto-Juvenil da Faculdade de Odontologia da UFRGS, que realizaram procedimento de remoção parcial de tecido cariado em dentes decíduos, a fim de verificar se os bons resultados encontrados em estudos clínicos controlados (eficácia) possuem reprodutibilidade clínica (efetividade).

Objetivos secundários

- Determinar o número de procedimentos com remoção parcial de tecido cariado realizados na clínica Odontológica Infanto-Juvenil da UFRGS.

-Relatar o sucesso clínico e radiográfico dos procedimentos com remoção parcial de tecido cariado

Endereço: Av. Paulo Gama, 110 - 2º andar do Prédio da Reitoria - Campus Centro
Bairro: Farroupilha **CEP:** 90.040-080
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Telefone: (51)3308-3738 **Fax:** (51)3308-4085 **E-mail:** etica@propesq.ufrgs.br



realizados na clínica Odontológica Infanto-Juvenil da UFRGS.

- Descrever os tipos de insucesso dos procedimentos com remoção parcial de tecido cariado realizados na clínica Odontológica Infanto-Juvenil da UFRGS.

- Avaliar os fatores associados ao insucesso dos procedimentos com remoção parcial de tecido cariado realizados na clínica Odontológica Infanto-Juvenil da UFRGS.

Avaliação dos Riscos e Benefícios:

Foram adequados conforme sugestão.

Comentários e Considerações sobre a Pesquisa:

O estudo envolve a consulta a prontuários para verificar o resultado da utilização de uma técnica para tratamento de cárie dentária que já é utilizada como protocolo da disciplina de Odontopediatria. O estudo prevê intervenções em pacientes, apenas acesso a dados e reinterpretação de exames radiográficos.

Considerações sobre os Termos de apresentação obrigatória:

Foi incluído termo de compromisso na utilização de dados conforme recomendação.

Recomendações:

Frente a adequação dos aspectos que estavam pendentes, recomenda-se aprovação.

Conclusões ou Pendências e Lista de Inadequações:

Frente a adequação dos aspectos que estavam pendentes, recomenda-se aprovação.

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

Encaminhe-se.

PORTO ALEGRE, 10 de Janeiro de 2013

Assinador por:
José Artur Bogo Chies
(Coordenador)

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Parecer CEP artigo 2



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Restaurações adesivas em dentes decíduos ζ estudo retrospectivo

Pesquisador: Débora Martini Dalpian

Área Temática:

Versão: 1

CAAE: 54711016.7.0000.5306

Instituição Proponente: Centro Universitário Franciscano - UNIFRA

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.478.981

Apresentação do Projeto:

Os materiais atualmente utilizados para procedimentos restauradores em ontopediatria são o cimento de ionômero de vidro, cimento de ionômero de vidro resinoso e resina composta. Entretanto são escassos os estudos de acompanhamento clínico de restaurações adesivas em dentes decíduos e não existe evidência suficiente para que se possa fazer alguma recomendação no que tange qual o material com melhor performance para a dentição decídua. Além disto, ainda é importante determinar a eficácia de restaurações em dentes decíduos, quando realizadas no cotidiano

dos atendimentos clínicos, onde as variáveis relacionadas ao paciente e operador não são controlados nem padronizados como em ensaios clínicos randomizados. Desta forma, o objetivo deste projeto é avaliar o comportamento de procedimentos restauradores em dentes decíduos quando realizados por estudantes de graduação do Centro Universitário Franciscano. Será desenvolvido um estudo retrospectivo com avaliação dos prontuários das crianças atendidas nas clínicas de graduação do curso de Odontologia do Centro Universitário Franciscano. Os Critério de Inclusão serão os prontuários que apresentem - relato de procedimento restaurador em dente decíduo;- presença de exame clínico anterior e posterior a data do procedimento restaurador;- prontuários corretamente preenchidos e assinados pelo responsável do paciente, bem como, pelo

professor orientador. Os critério de exclusão:Prontuários sem assinatura do responsável no campo

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Continuação do Parecer: 1.478.981

de autorização de exames e imagens.

Objetivo da Pesquisa:

Segunda a pesquisadora:

Objetivo Primário:

Avaliar o comportamento de procedimentos restauradores em dentes decíduos quando realizados por estudantes de graduação do Centro Universitário Franciscano.

Objetivo Secundário:

Descrever os procedimentos restauradores realizados por estudantes de graduação do Centro Universitário Franciscano. Relatar o sucesso clínico dos procedimentos restauradores em dentes decíduos quando realizados por estudantes de graduação do Centro Universitário Franciscano. Comparar o sucesso clínico de diferentes materiais restauradores quando realizados por estudantes de graduação do Centro Universitário Franciscano. Avaliar os fatores associados ao sucesso dos procedimentos restauradores em dentes decíduos quando realizados por estudantes de graduação do Centro Universitário Franciscano.

Avaliação dos Riscos e Benefícios:

Riscos:

Os riscos potenciais seriam a divulgação dos dados dos pacientes. Entretanto, os autores assumem o compromisso de preservar a confidencialidade dos dados mediante a assinatura do termo de compromisso na utilização dos dados (anexo) e pela identificação dos indivíduos por meio de código numérico no banco de dados.

Benefícios:

O benefício é a otimização do ensino da referida técnica caso seja identificado que os alunos não a estão realizando da forma adequada.

Comentários e Considerações sobre a Pesquisa:

O projeto analisado apresenta elementos necessários para o desenvolvimento de um trabalho final de graduação.

Considerações sobre os Termos de apresentação obrigatória:

O projeto apresenta todos os Termos e documentos preconizados pela Resolução CNS nº466/12.

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Recomendações:

Não há.

Conclusões ou Pendências e Lista de Inadequações:

Este protocolo encontra-se aprovado.

Considerações Finais a critério do CEP:

Toda e qualquer alteração do Projeto, assim como os eventos adversos graves, deverão ser comunicados imediatamente a este Comitê. O pesquisador deve apresentar relatório final da pesquisa, ao CEP/UNIFRA, via Plataforma Brasil, no mês de AGOSTO/2016, conforme determinação do CONEP.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_683299.pdf	31/03/2016 13:29:48		Aceito
Projeto Detalhado / Brochura Investigador	projeto.pdf	31/03/2016 13:28:34	Débora Martini Dalpian	Aceito
Folha de Rosto	folharosto.pdf	28/03/2016 11:30:47	Débora Martini Dalpian	Aceito
Declaração de Instituição e Infraestrutura	autorizacaolocal.pdf	28/03/2016 11:30:36	Débora Martini Dalpian	Aceito
Declaração de Pesquisadores	TCUD.pdf	20/03/2016 10:36:39	Débora Martini Dalpian	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	20/03/2016 10:36:11	Débora Martini Dalpian	Aceito

Situação do Parecer:

Aprovado

SANTA MARIA, 05 de Abril de 2016

Necessita A

Não

Assinado por:
 Maria do Carmo dos Santos Araujo
 (Coordenador)

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