UNIVERSIDADE FEDERAL DE SANTA MARIA CENTRO DE CIÊNCIAS DA SAÚDE CURSO DE ODONTOLOGIA DEPARTAMENTO DE ESTOMATOLOGIA

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COMPORTAMENTO CLÍNICO DE RESTAURAÇÕES DE RESINA COMPOSTA EM DENTES DECÍDUOS: ESTUDO RETROSPECTIVO

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Trabalho de Conclusão de Curso apresentado ao curso de Odontologia da Universidade Federal de Santa Maria (UFSM, RS), como requisito parcial para obtenção do grau de Cirurgiã-Dentista.

Orientadora: Profa Dra Tathiane Larissa Lenzi

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RESUMO

COMPORTAMENTO CLÍNICO DE RESTAURAÇÕES DE RESINA COMPOSTA EM DENTES DECÍDUOS: ESTUDO RETROSPECTIVO

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O objetivo deste estudo clínico retrospectivo foi avaliar a sobrevida e os fatores de risco associados com as falhas de restaurações de resina composta realizadas em dentes anteriores e posteriores decíduos. Um total de 212 restaurações em dentes decíduos provenientes dos prontuários de 76 crianças de alto risco de cárie (36 meninas e 40 meninos) atendidas por alunos de graduação na Clínica de Odontopediatria da Universidade Federal de Santa Maria foram incluídas no estudo. A longevidade das restaurações até 6 anos de acompanhamento foi avaliada pelo teste de sobrevida Kaplan-Meier. Análise de regressão multivariada de Cox com fragilidade compartilhada foi usada para avaliar as variáveis clínicas e individuais associadas com as falhas restauradoras (p<0,05). O tempo médio de sobrevida foi de 4,3 anos (95%IC: 4,0-4,6). A sobrevida das restaurações foi de 35,3% até 6 anos de avaliação, com uma taxa de falha anual de 18,8%. Restaurações realizadas em dentes com tratamento endodôntico tiveram 2,16 vezes maior risco de falha do que aquelas feitas em dentes vitais (95% IC: 1,02-4,58; p=0,04). Pacientes que não utilizaram dentifrício fluoretado apresentaram 6,12 vezes maior risco de falha das restaurações (95% IC:1,47-25,49, p=0,01). Restaurações de resina composta realizadas em crianças de alto risco de cárie apresentaram limitada sobrevida após 6 anos de acompanhamento. O uso de dentifrício fluoretado foi um fator de proteção, enquanto que tratamento endodôntico foi um fator de risco para a falha da restauração.

Palavras-chave: Análise de sobrevida. Dente decíduo. Falha de Restauração Dentária. Odontopediatria.

ABSTRACT

CLINICAL PERFORMANCE OF RESIN COMPOSITE RESTORATIONS IN PRIMARY TEETH: RETROSPECTIVE STUDY

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The aim of this clinical retrospective study was to evaluate the survival and risk factors associated with failures of composite resin restorations placed in anterior and posterior primary teeth. A total of 212 restorations in primary teeth from records of 76 high caries risk children (36 girls and 40 boys) attended by undergraduate students in the Pediatric Dentistry Clinic at the Federal University of Santa Maria were included in the study. The restorations' longevity up to 6-year of follow-up was assessed using the Kaplan-Meier survival test. Multivariate Cox regression analysis with shared frailty was used to evaluate the clinical and individual variables associated with failures (p<0.05). Mean survival time was 4.3-year (95%CI: 4.0-4.6). The survival of the restorations reached 35.3% up to 6-year of evaluation, with an overall annual failure rate of the 18.8%. Restorations performed in teeth with pulp treatment had a risk of failure 2.16 times more than restorations placed in vital teeth (95%CI: 1.02-4.58, p=0.04). Patients who didn't use fluoridated toothpaste had 6.12 times more risk of failure in their restorations (95%CI: 1.47-25.49, p=0.01). Composite resin restorations placed in high caries risk children presented limited survival after 6-year of follow-up. The fluoridated toothpaste use was a protection factor while pulp treatment was a risk factor for restoration failure.

Keywords: Survival Analysis. Tooth, Deciduous. Dental Restoration Failure. Pediatric Dentistry

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APRESENTAÇÃO

O presente trabalho está apresentado em formato de artigo científico, de acordo com as normas do periódico *PediatricDentistry* (Qualis CAPES A2, Fator de Impacto 1.774).

ARTIGO

Survival and associated risk factors of composite restorations in primary teeth: a

clinical retrospective university-based study

Short title: Longevity of composite restorations

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Abstract

Purpose: This clinical retrospective university-based study evaluated the survival and risk factors associated with failures of composite resin restorations placed in anterior and posterior primary teeth. *Methods:* A total of 212 restorations in primary teeth from records of 76 high caries risk children (36 girls and 40 boys) were included in the study. The restorations' longevity up to 6-year of follow-up was assessed using the Kaplan-Meier survival test. Multivariate Cox regression analysis with shared frailty was used to evaluate the factors associated with failures (p<0.05). *Results:* Mean survival time was 4.3-year (95%CI: 4.0-4.6). The survival of the restorations reached 35.3% up to 6-year of evaluation, with an overall annual failure rate of the 18.8%.Restorations placed in teeth with pulp treatment had lower survival rate than those in vital teeth (HR 2.16, 95% CI 1.02-4.58). Patients who did not use fluoridated toothpaste had more risk of failure in their restorations (HR 6.12, 95% CI 1.47-25.49). *Conclusion:* Composite resin restorations placed in high caries risk children presented limited survival after 6-year of follow-up. The fluoridated toothpaste use was a protection factor while pulp treatment was a risk factor for restoration failure.

Keywords: adhesive restoration; deciduous tooth; resin composite; survival analysis; pediatric dentistry

Introduction

The occurrence of cavitated carious lesions is still a currentoral health problem and, according to World Health Organization, the prevalence of caries in the primary dentition varies between 60 and 90% worldwide¹. Although the placement of restorations is a frequent approach in the clinical practice, a systematic review has pointed out that there is no sufficient scientific evidence about which is the best filling material for treating caries in primary dentition².

Composite resin has been widely used since fits with concept of Minimally Invasive Dentistry, providing good handling and functional performance besides meeting patients' demands regarding esthetics³. However, the literature reveals few randomized clinical follow-up studies of composite resin restorations in primary dentition⁴⁻⁶.

In this sense, it would be relevant to investigate the longevity of direct composite resin restorations placed in primary teeth in conditions closer to the clinical daily life. A recent retrospective study found that composite resin restorations in primary molars performed better than glass ionomer cement⁷. Since composite restoration survival is affected by several factors such as the cavity size, occlusal risks and tooth type^{7,8}, the longevity of these restorations in anterior primary teeth is still unclear. Furthermore, practice-based clinical retrospective studies provide more solid conclusions than evidence only from patients' records.

Therefore, the aim of this clinical retrospective university-based study was to evaluate the survival and factors associated with failures of composite resin restorations placed in anterior and posterior primary teeth.

Methods

Study characteristics, participants, and study design

The database with clinical records from the Paediatric Dentistry Clinic at the Federal University of Santa Maria was used in the present evaluation. The research protocol (CAAE 48519115.6.0000.5346) was approved by the Local Research Ethics Committee and the parents or guardians have signed a written informed consent. The

personal information of the patients was kept confidential.

The target population consisted of children attended by fourth and five years dental undergraduate students, supervised by specialists in Pediatric Dentistry, during the period between 2008 and 2014. A clinical retrospective study was conducted. To be included in the study, children should have received at least one composite resin restoration placed in vital or non-vital primary teeth. The restorations should have been clinically and/or radiographically followed up for at least 1 year, and patients should have at least one visit at the clinic after the restoration placement. Children with compromised systemic health were excluded from the study. In total, 126 patients were selected through the inspection of clinical and radiographic records and invited to visit the dental office. The recruitment was performed by letters and phone calls, and 76 (60.3%) patients agreed to participate in the clinical evaluations, totalizing 212 evaluations.

Restorative procedures

All procedures were performed under rubber dam isolation. Cavities were prepared with low-speed drills and dentin excavators for caries removal and high-speed carbide burs for removing enamel and unsatisfactory restorations when necessary. Preparation was restricted to total caries removal. In very deep cavities the region close to the pulp was protected with calcium hydroxide cement (Dycal; Dentsply, Petrópolis, RJ, Brazil), followed by a thin layer of glass ionomer cement (VitroFil; DFL, Rio de Janeiro, RJ, Brazil) layer. In moderate deep cavities, only this layer of glass ionomer cement was used. The cavity was conditioned by 37% phosphoric acid gel for 15s. The acid was removed by rinsing with water for 30s, and the cavity was gently dried with air and cotton pellets. The two-step etch-and-rinse adhesive system (Adper Single Bond, 3M ESPE, St. Paul, MN, USA) was used prior to the insertion of the composite resin, using the incremental technique. Composite resins used were: Charisma (Heraeus Kulzer, Hanau, Germany), Filtek Z250 and Z350 (3M ESPE, St. Paul, MN, USA), Opallis (FGM, Joinvile, SC, Brazil) and Evolux (Dentsply, Petrópolis, RJ, Brazil). For the anterior and posterior proximal cavities, a matrix was adapted to the cervical margin. The rubber dam was then removed and the occlusion was checked. For all restorations, finishing and polishing were performed using fine-grained diamond burs, sandpaper strips and siliconized tips.

Data collection

First, the history of the restorations was collected from the patient files. Factors potentially associated with treatment failure were investigated, including individual and clinical characteristics: gender (boys or girls), mother's school level (up to eight years of formal education or more than eight years), income (up to a minimum wage or more than one minimum wage), frequency of cariogenic diet (up to six times daily or more than six times), fluoridated toothpaste use (yes or no), frequency of brushing (once a day or two or more times), flossing use (yes or no), type of arch (upper or lower),type of tooth (anterior or posterior), number of restored surfaces (one or two or more), pulp intervention (yes or no) and capping material (yes or no).

Evaluation of restorations

The restorations were clinically evaluated between October 2015 and April 2016 independently by two trained and calibrated examiners (D.P. and T.L.L.) using dental explorer and mirror, in accordance with World Dental Federation(FDI) criteria⁹, including several items on aesthetic, functional and biological properties. In case of disagreement, the examiners evaluated the restorations jointly, until a consensus was reached. The calibration procedures considered the analysis of some restorations twice, randomly distributed, for Cohen's Kappa calculation (Kappa = 0.87).

For the analysis, different levels of each criterion were simplified according to re-treatment need: no intervention needed (success) and requiring intervention (failed). The restorations were considered as failed in case of replacement (score 5 by FDI) or repair (score 4), and the reason for failure was registered (as judged by the treating clinician). Those patients who presented a treatment need during clinical evaluation were referred for treatment.

A five-point Likert scale was used to assess the functional property "patient view" of FDI criteria in the Pediatric Dentistry. Satisfaction with the treatment was measured from one to five according to the scale: 1=very satisfied; 2 = satisfied; 3 = indifferent; 4 = unsatisfied; 5 = very unsatisfied.

Data analyses were performed with STATA software 12.0 (Stata Corp., College Station, TX, USA). The descriptive analysis provides the distribution summary according to the independent variables. The annual failure rate (AFR) of the restorations was calculated according to the formula: $(1-y)^z = (1-x)$, in which "y" expresses the mean AFR and "x" the total failure rate at "z" years. Survival analysis was performed to assess factors associated with the longevity of the restorations, and data was censored at 6-year of follow-up. Survival curves of the restorations were assessed through the Kaplan-Meier method.

Multivariate Cox regression models with shared frailty were performed to identify factors associated with failure of the restorations. These models consider that observations within the same group (the patient) are correlated, sharing the same frailty, being analogous to multilevel regression models with random effects. Hazard ratios and their respective 95 % confidence intervals (HR; 95 % CI) were obtained. 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 significant level of 5% was considered for the final model.

Results

Two hundred and twelve restorations placed in 76 patients (36 girls and 40 boys) were included in the analysis. The mean age of the children was 7.9 years (± 1.7), presenting a dmf-t mean of 6.3 (\pm 3.2). The follow-up period ranged from 1 to 6-year with a mean of 2.6 years (± 1.0).

Table 1 shows the distribution of restorations and their rates of "success" according to individual and clinical-level variables. Among all restorations considered in the analysis, 110 (51.9%) were placed in boys. Posterior restorations were more common (86.3%) than anterior ones (13.7%), as well as those performed in lower arch (53.8%) when compared with upper arch (46.2%). In the most restorations (96.2%) none capping material was used. Composite resin restorations placed on vital teeth were more common (91.5%) than those teeth with pulp treatment (8.5%). The majority of restorations were placed in children that did not use dental floss (75.2%), ingested sugar

up to six times daily (80.7%) and brushed their teeth two or more times daily (81.1%). The overall success rate was 66.0% (140/212).

Table 2 shows the unadjusted and adjusted Hazard Ratios (HR) for failures according to independent variables. The adjusted model showed that restorations performed in teeth with pulp treatment had a risk of failure 2.16 times more than restorations placed in vital teeth (p=0.04). Patients who didn't use fluoridated toothpaste had 6.12 times more risk of failure in their restorations (p = 0.01).

The cumulative restoration survival estimate is shown in Figure 1. Mean survival time was 4.3-year (95%CI: 4.0-4.6), with 44.7% of the restorations surviving after 4-year of evaluation. The overall AFR after 6-year follow-up was 18.8%.

The distribution of the restorations according to the FDI criteria is summarized in Table 3. Overall, fracture, marginal adaptation and caries recurrence were the main reasons for composite restorations failures.

Discussion

This clinical retrospective university-based study provides valuable information regarding the survival of composite resin restorations placed in anterior and posterior primary teeth and the associated risk factors for failure in a high caries risk children. Presence of pulp treatment and non-use of fluoridated toothpaste were associated with restoration failures.

Mean survival time was 4.3-year (95%CI: 4.0-4.6) and the survival rate of the restorations reached 35.3% after 6-year follow-up. For survival analyses, the Kaplan-Meier estimator was used. Although the survival rate at 6-year appears to be low, it is important to highlight that the estimator takes into account the censored data, i.e., those restorations that have not yet achieved the 6-year evaluation in this retrospective analysis. This explains the low estimated survival rate of restorations when compared to clinical success (66.0%), when only the failures were considered (140/212), irrespective of the function time. Moreover, students have lower ability than professionals to perform dental restorations, and such aspect could contribute to a lower survival rate. On the other hand, restoration longevity found in this study could be satisfactory considering the shorter biological cycle of the primary dentition.

The overall AFR after 6-year follow-up was 18.8%. A previous retrospective

study¹⁰ found an overall success rate of 81.5% after a mean time of 30.7-month for composite restorations in children with early childhood caries, with a AFR of 4.2%. Other investigation found an AFR of 9.5% for composite filling in primary molars up to 4 years of follow-up⁷. However, in these studies, the information about restoration failure was just collected from patients' records, which may overestimate the performance of the restorative procedures.

Study design, population profile, sample size, tooth type and criteria for failure applied also can influence on the survive rates. This is the first study that assessed the longevity of restorations in primary teeth using the FDI criteria. It has been found that FDI is more sensitive than the USPHS criteria, especially for the criteria marginal staining and marginal adaptation¹¹.

Systematic reviews had pointed out that the posterior composite restorations AFR was 2.4% after 10-year ¹² while for anterior ones the AFRs ranged from 0.6% to 4.1% ¹³ in permanent teeth. Bücher et al. reported a cumulative failure rate of 17.2% after 8-year for composite fillings performed in children with high caries risk, with ARF of 10.0%. Moreover, incisors showed a significantly lower survival compared to molars ⁸. In our study, the type of tooth was not associated to restoration failure. It was speculated that if another sample containing more restorations in anterior primary teeth was evaluated, significant differences could be observed.

Whereas secondary caries and fracture are the main reasons for failure in posterior composite restorations in permanent teeth¹², anterior restorations are likely more prone to replacement due aesthetic qualities (color, anatomical form, surface stain) and retention loss¹³. In our study, staining and brightness loss were related to failure of anterior restorations, but the major reason for failure in both anterior and posterior restorations was caries recurrence followed by fracture and marginal adaptation. In primary dentition, the esthetic demand from the patient may be not a factor determining for restoration replacing as in adult population. It is important to note that, in this retrospective study, only individuals with high caries risk were included in the sample. Thus, these patients were more likely to present resin composite failure¹⁴. Secondary caries has frequently described as the main reason for replacing filling in these populations^{15,16}.

There is strong evidence that daily use of fluoride toothpaste has a significant caries-preventive effect in children ^{17–19}. It has been evidenced that the use fluoridated

toothpaste is effective in caries control in children even younger than 6 years-old ^{20,17}. In our study, patients who did not use fluoridated toothpaste had 6.12 times more risk of failure in their restorations. This reinforces the anti-caries effect of fluoride toothpastes and the need to support their use by children, regardless of the age, since this approach can increase significantly the lifetime of restorations. Also, this effect seems to be boosted by supervised tooth brushing, brushing frequency more than once daily and use of toothpastes containing fluoride concentrations of 1000 ppm and above ¹⁷. The frequency of brushing was not associated to restoration failure in this study, probably because the most children brushed the teeth twice or more daily.

The longevity of the restorations was not influenced by the flossing use. The natural spaces among primary teeth may facilitate proximal biofilm control, reducing the chances of restoration failure. Furthermore, there is no evidence that the self-flossing had a positive effect in reducing interproximal caries risk in children ²¹. In line with prior retrospectives studies ^{7,15,22}, we found that the composite resin restorations placed in teeth with pulp treatment teeth had a risk of failure 2.16 times more than those performed in vital teeth. It has been shown that less than 20.0% of the restorations in endodontically treated teeth survived after 10-year. Additionally, the AFRs were 11.0% and 4.7% for restorations placed in non vital and vital teeth, respectively²². Endodontically treated teeth seemed to be more at risk for re-intervention because reduction in tooth structure affecting fracture resistance ²³ and failure risk ²⁴.

The number of restored surfaces did not influence survival, which is in accordance with some reports^{7,25}. However, it has been shown that a higher number of surfaces enrolled in cavity preparations can decrease the permanent posterior restoration survival¹⁶. The comparison of cavity size, class type, and number of restored surfaces may not correctly reflect how is compromised the tooth structure¹⁵. Moreover, primary teeth had a lower occlusion loading compared than permanent ones ²⁶.

Given randomized clinical trials as the gold standard design for longitudinal restoration analysis, the results of this study should be viewed considering their possible methodological limitations. The retrospective design results in an obvious lack of standardization of indication and treatment protocols. On the other hand, clinical practice-based studies seem to be a good strategy to determine the survival of restorations in nearest to real-life situations ²⁷.

Conclusion

This clinical retrospective university-based study showed limited survival of composite resin restorations placed in high caries risk children after 6-year of follow-up. Pulp intervention and non-use of fluoridated toothpaste jeopardized the restoration longevity.

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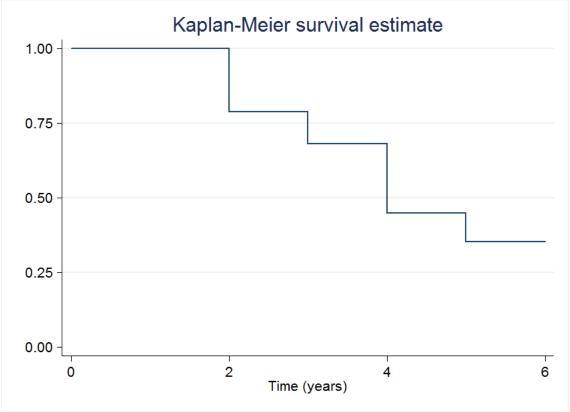


Figure 1. Kaplan-Meier survival curve of restorations over 6-year.

Table 1. Status of the restorations according to clinical and demographic characteristics (n=212 restorations)

Variables	n (%) of restorations	Success (%)	Failure (%)
Gender			
Boys	110 (51.9)	78 (70.9)	32 (29.1)
Girls	102 (48.1)	62 (60.8)	40 (39.2)
Mother's education			
Up to eight years	110 (51.9)	73 (66.4)	37 (33.6)
More than eight years	102 (48.1)	67 (65.7)	35 (34.3)
Income			
Up to a minimum wage	94 (44.3)	62 (66.0)	32 (34.0)
More than the minimum wage	118 (55.7)	78 (66.1)	40 (33.9)
Frequency of cariogenic diet			
Up to six times daily	171 (80.7)	111 (64.1)	60 (35.1)
More than six times	41 (19.3)	29 (70.7)	12 (29.3)
Fluoridated toothpaste use			
Yes	195 (92.0)	125 (64.1)	70 (35.9)
No	17 (8.0)	15 (88.2)	2 (11.8)
Frequency of brushing			
Once a day	40 (18.9)	23 (57.5)	17 (42.5)
Two or more times	172 (81.1)	117 (68.0)	55 (32.0)
Flossing use			
Yes	52 (24.8)	36 (69.2)	16 (30.8)
No	158 (75.2)	102 (64.6)	56 (35.4)
Type of arch			
Upper	98 (46.2)	68 (69.4)	30 (30.6)
Lower	114 (53.8)	72 (63.2)	42 (36.8)
Type of tooth			
Anterior	29 (13.7)	20 (69.0)	9 (31.0)
Posterior	183 (86.3)	120 (65.6)	63 (34.4)
Number of restored surfaces			
One	105 (49.5)	73 (69.5)	32 (30.5)
Two or more	107 (50.5)	67 (62.6)	40 (37.4)
Pulp intervention			
No	194 (91.5)	130 (67.0)	64 (33.0)
Yes	18 (8.5)	10 (55.6)	8 (44.4)
Capping material			
No	204 (96.2)	137 (67.2)	67 (32.8)
Yes	8 (3.8)	3 (37.5)	5 (62.5)

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
Gender		0.06	*	
Boys	1			
Girls	0.32(0.14-0.72)			
Mother's education		0.56		
Up to eight years	1			
More than eight years	1.14 (0.72-1.82)			
Income		0.73		
Up to a minimum wage	1			
More than the minimum wage	1.08 (0.68-1.74)			
Frequency of cariogenic diet		0.87		
Up to six times daily	1			
More than six times	1.05 (0.56-1.97)			
Fluoridated toothpaste use		0.01		0.01
Yes	1		1	
No	6.78 (1.64-28.07)		6.12 (1.47-25.49)	
Frequency of brushing		0.12	*	
Once a day	1			
Two or more times	0.65 (0.38-1.12)			
Flossing use		0.89		
Yes	1			
No	1.04 (0.59-1.82)			
Type of arch				
Superior	1	0.94		
Inferior	1.02 (0.63-1.63)			
Type of tooth		0.78		
Anterior	1			
Posterior	1.11 (0.55-2.23)			

Number of restored surfaces		0.29	*	
One	1			
Two or more	1.28 (0.80-2.05)			
Pulp intervention		0.02		0.04
No	1		1	
Yes	2.46 (1.15-4.5.24)		2.16 (1.02-4.58)	
Capping material		0.33		
No	1			
Yes	1.57 (0.63-3.92)			

^{*} P-values > 0.05 in the adjusted model.

Table 3.Clinical evaluation of the restorations according to the World Dental Federation (FDI) criteria.

General evaluated criteria	Specific evaluated criteria	1	2	3	4	5
Esthetics properties	Superficial brightness	79 (37.3)	66 (31.1)	40 (18.9)	1 (0.5)	26 (12.3)
	Surface staining	161 (75.9)	23 (10.8)	2 (0.9)	-	26 (12.3)
	Marginal staining	100 (47.2)	73 (34.4)	13(6.1)	-	26 (12.3)
	Translucency and color stability	133(62.7)	38 (17.9)	14 (6.6)	-	27 (12.7)
	Anatomic form	97 (45.7)	34 (16.0)	39 (18.4)	11 (5.2)	31(14.6)
Functional properties	Fracture	116 (54.7)	19 (9.0)	12 (5.7)	26 (12.3)	39 (18.4)
	Marginal Adaptation	35 (16.5)	87 (41.0)	25 (11.8)	26 (12.3)	39 (18.4)
	Patient view*	82 (38.7)	93 (43.9)	34 (16.0)	3 (1.4)	-
Biological properties	Caries recurrence	129 (60.8)	26 (12.3)	7 (3.3)	14 (6.6)	36 (17.0)
	Postoperative sensitivity	186 (87.7)	-	-	-	26 (12.3)

^{*} Adapted for Pediatric Dentistry by five-point Likert scale.

ANEXO A - Aprovação do Comitê de Ética em Pesquisa



UNIVERSIDADE FEDERAL DE SANTA MARIA/ PRÓ-REITORIA DE PÓS-GRADUAÇÃO E



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: COMPORTAMENTO CLÍNICO DE RESTAURAÇÕES DE RESINA COMPOSTA EM

DENTES DECÍDUOS: ESTUDO RETROSPECTIVO

Pesquisador: Tathiane Larissa Lenzi

Área Temática: Versão: 2

CAAE: 48519115.6.0000.5346

Instituição Proponente: Departamento de Estomatologia

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.286.506

Apresentação do Projeto:

Estudo de caracter longitudinal retrospectivo tem como objetivo avaliar o comportamento clínico de restaurações de resina composta em dentes decíduos, investigando a longevidade das restaurações e os fatores relacionados aos insucessos dos procedimentos restauradores em dentes anteriores e posteriores. Serão selecionados os prontuários odontológicos das crianças atendidas na Clínica de Odontopediatria da UFSM entre os anos de 2013 e 2015, que apresentem restauração de resina composta em dentes decíduos com pelo menos 1 ano em função na cavidade bucal. As restaurações serão avaliadas por dois examinadores previamente treinados, levando-se em consideração parâmetros estéticos, funcionais e biológicos. Os dados serão submetidos a análise estatística apropriada.

Objetivo da Pesquisa:

O objetivo geral será avaliar o comportamento clínico restaurações de resina composta em dentes decíduos realizadas por alunos do curso de Graduação em Odontologia da Universidade Federal de Santa Maria, investigando a longevidade das restaurações e os fatores relacionados aos insucessos dos procedimentos restauradores em dentes anteriores e posteriores.

Endereço: Av. Roraima, 1000 - prédio da Reitoria - 2º andar

Bairro: Camobi CEP: 97.105-970

UF: RS Município: SANTA MARIA

Telefone: (55)3220-9362 E-mail: cep.ufsm@gmail.com



UNIVERSIDADE FEDERAL DE SANTA MARIA/ PRÓ-REITORIA DE PÓS-GRADUAÇÃO E



Continuação do Parecer: 1.286.506

Objetivos específicos

Investigar a longevidade clínica de restaurações de resina composta em dentes anteriores;

Avaliar a longevidade clínica de restaurações de resina composta em dentes posteriores;

Investigar a longevidade clínica de restaurações diretas confeccionadas em resina composta, com e sem a utilização de materiais restauradores intermediários;

Verificar o efeito de diferentes tipos de resina composta na longevidade das restaurações;

Analisar o impacto da remoção de tecido cariado (parcial vs. total) na durabilidade das restaurações; Investigar a influência do risco de cárie na longevidade das restaurações anteriores e posteriores.

Verificar o efeito da intervenção pulpar no desempenho clínico das restaurações;

Avaliar a influência de fatores demográficos e socioeconômicos na longevidade das restaurações.

Avaliação dos Riscos e Benefícios:

Adequados.

Comentários e Considerações sobre a Pesquisa:

.

Considerações sobre os Termos de apresentação obrigatória:

Todos presentes e adequados.

Recomendações:

Veja no site do CEP - http://w3.ufsm.br/nucleodecomites/index.php/cep - na aba "orientações gerais", modelos e orientações para apresentação dos documentos. Acompanhe as orientações disponíveis, evite pendências e agilize a tramitação do seu projeto.

Conclusões ou Pendências e Lista de Inadequações:

As pendências apontadas no parecer anterior foram resolvidas de modo satisfatório.

Considerações Finais a critério do CEP:

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Bairro: Camobi CEP: 97.105-970

UF: RS Município: SANTA MARIA

Telefone: (55)3220-9362 E-mail: cep.ufsm@gmail.com



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Continuação do Parecer: 1.286.506

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas	PB_INFORMAÇÕES_BÁSICAS_DO_P	12/10/2015		Aceito
do Projeto	ROJETO_572003.pdf	22:13:35		
Declaração de	Autorizacao.pdf	12/10/2015	Tathiane Larissa	Aceito
Instituição e		22:10:53	Lenzi	
Infraestrutura				
Outros	Termo.docx	12/10/2015	Tathiane Larissa	Aceito
		21:49:34	Lenzi	
Outros	TCF.doc	12/10/2015	Tathiane Larissa	Aceito
		21:45:28	Lenzi	
Projeto Detalhado /	Protocolo_de_pesquisa.docx	12/10/2015	Tathiane Larissa	Aceito
Brochura	i i	21:44:34	Lenzi	
Investigador				
TCLE / Termos de	TCLE_corrigido.docx	12/10/2015	Tathiane Larissa	Aceito
Assentimento /		21:44:11	Lenzi	
Justificativa de				
Ausência				
Outros	Registro_GAP.pdf	24/08/2015	Tathiane Larissa	Aceito
		12:04:11	Lenzi	
Recurso Anexado	CEP.docx	20/08/2015	Tathiane Larissa	Aceito
pelo Pesquisador		09:10:05	Lenzi	
Folha de Rosto	Folha.pdf	19/08/2015	Tathiane Larissa	Aceito
		12:39:31	Lenzi	

Situadad do Parecer	ituação do	Parecer
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Aprovado

Necessita Apreciação da CONEP:

Não

SANTA MARIA, 19 de Outubro de 2015

Assinado por: CLAUDEMIR DE QUADROS (Coordenador)

Endereço: Av. Roraima, 1000 - prédio da Reitoria - 2º andar

Bairro: Camobi CEP: 97.105-970

UF: RS Município: SANTA MARIA

ANEXO B – Normas do periódico *Pediatric Dentistry*

AAPD Instructions for Authors

Pediatric Dentistry

Pediatric Dentistry is the official publication of the American Academy of Pediatric Dentistry, the American Board of Pediatric Dentistry and the College of Diplomates of the American Board of Pediatric Dentistry. It is published bi-monthly and is internationally recognized as the leading journal in the area of pediatric dentistry. The journal promotes the practice, education and research specifically related to the specialty of pediatric dentistry. This peer-reviewed journal features scientific articles, case reports, and abstracts of current pediatric dental research.

Journal of Dentistry for Children

Acquired after the merger between the American Society of Dentistry for Children and the American Academy of Pediatric Dentistry in 2002, the *Journal of Dentistry for Children (JDC)* is an internationally renowned journal whose publishing dates back to 1934. Published three times a year, *JDC* promotes the practice, education and research specifically related to the specialty of pediatric dentistry. It covers a wide range of topics related to the clinical care of children, from clinical techniques of daily importance to the practitioner, to studies on child behavior and growth and development. *JDC* also provides information on the physical, psychological and emotional conditions of children as they relate to and affect their dental health.

Introduction

Manuscripts that are selected for publication promote the practice, education and research for the specialty of pediatric dentistry. Manuscripts are considered for publication only if the article, or any part of its essential substance, tables or figures have not been or will not be published in another journal or are not simultaneously submitted to another journal.

The statements, opinions, and advertisements are solely those of the individual authors, contributors, editors, or advertisers, as indicated. Published manuscripts do not necessarily represent the views of the editor, the AAPD Communications Department, or the American Academy of Pediatric Dentistry organization.

Types of Manuscripts

Type of manuscript must be one of the following: Meta-Analyses/Systematic Reviews, Scientific Studies, Case Reports, or Literature Reviews (JDC only), Letters to the Editor, Editorials and Brief Communications.

Meta-Analyses / Systematic Reviews

Authors of systematic reviews must adhere to Preferred Reporting Items for Systematic Reviews and Meta-Analyses, available at: 'http://www.prisma-statement.org/statement.htm'.

Structured Abstracts for systematic reviews are recommended. Headings should include: Research Question, Research Protocol, Literature Search, Data Extraction, Quality Appraisal, Data Analysis and Results, and Intrepretations of Results.

Scientific Studies

Full-length manuscript not to exceed 3,500 words (including structured Abstract, Introduction, Methods, Results, Discussion,

Conclusions, and Acknowledgments; excluding References and Figure Legends). The structured abstract should be no longer than 200 words and contain the following sections: Purpose, Methods, Results, and Conclusions. The Introduction section should include only pertinent references. The Methods section should be sufficiently detailed to replicate the study. The Results section should include only results and not discussion of the data. The Discussion section should discuss the results, of the present study and compare them to the existing knowledge base. The Conclusions section should consist of succinct, numbered statements that are supported by the results of the study. They should not repeat the Results section.

Maximum Figures: 4 • Maximum Tables: 3

Case Reports

Full-length manuscript not to exceed 1,850 words (including unstructured Abstract, brief Introduction, Description of Case, Discussion, Acknowledgments (if any), and References (if any). The unstructured Abstract should be no longer than 150 words.

Maximum Figures: 4 • Maximum Tables: 3

Literature Reviews (JDC only)

Full-length manuscript not to exceed 2,500 words (including unstructured *Abstract, Introduction*, the *Review of the Literature* with appropriate subheading, *Discussion, Conclusions*, and *Acknowledgments*; excluding *References*). The unstructured Abstract should be no longer than 150 words.

Maximum Tables: 4

Letters to the Editor

Full-length manuscript not to exceed 350 words; excluding References.



Type of article	Abstract maximum length & type	Maximum text length	Maximum references	Maximum no. of figures	Maximum no. of tables	Notes
Meta-Analyses/ Systematic Reviews	200 words, structured	3,500 words	No limit	No limit	No limit	Inclusion of figures and tables will be at the Editor-in-Chief's discretion
Scientific Studies	200 words, structured	3,500 words	40	4	3	
Case Reports	150 words, unstructured	1,850 words	20	4	3	
Literature Reviews (JDC only)	150 words, unstructured	2,500 words	0	0	4	
Brief Communications	150 words, structured	2,000 words	20	2	2	
Letters to the Editor	none	350 words	8	0	0	
Editorials	none	1,000 words	40	2	2	Invited by the Editor-in-Chief

Editorials

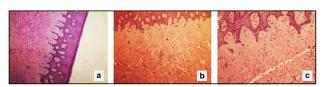
Full-length manuscript not to exceed 1,000 words; excluding References and Figure Legends.

Maximum Figures: 2 • Maximum Tables: 2

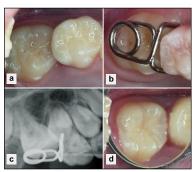
Brief Communications

Full-length manuscript not to exceed 2,000 words (including structured *Abstract*; excluding *References* and *Figure legends*). The structured Abstract should be no longer than 150 words.

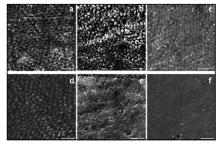
Authors desiring to have more Figures or Tables MUST agree to electronic publication of their manuscript, and must select this preference. Each separate chart, graph or photograph will be counted as a separate figure. Figures grouped together will be counted as their individual parts. See samples below:



3 Figures



4 Figures



6 Figures



Manuscript Submission

All new manuscripts must be submitted to AAPD's online submission and review website, ScholarOne Manuscripts; *Pediatric Dentistry* at: "http://mc.manuscriptcentral.com/pediadent"; *JDC* at: "http://mc.manuscriptcentral.com/jdentchild". Authors who do not yet have an account on the website should click the 'Create Account' link on the upper right-hand corner of the welcome page and follow the step-by-step process to open an account. On the dashboard page, authors should select the Author Center. In the Author Center, they should click the 'Click here to submit a new manuscript' link.

If you already have an account, enter your user ID and password and log in.

Manuscript submission guidelines for *Pediatric Dentistry* follow the 'uniform requirements for manuscripts submitted to biomedical journals' which have been developed by the International Committee of Medical Journal Editors (ICMJE). Please visit the ICMJE website at: "http://www.icmje.org/manuscript_1prepare.html" for more information.

Author Information

The author must include each author's name, earned academic degrees, professional title (such as 'associate professor', 'chair'), work affiliations, complete address, telephone and fax numbers, and email address. In addition, each author should provide a statement of responsibility detailing what he or she contributed to the manuscript. These can be uploaded to the site as a Microsoft Word Document (it is recommended that statements from all authors be placed in a single document). No honorary designations such as 'FRCS', 'FICD', 'Diplomate', should be listed.

A submission with more than one author implies that each author contributed to the study or preparation of the manuscript. Only individuals who have made a significant contribution to the study or manuscript should be listed as authors. Contributors who do not meet the criteria for authorship, such as individuals who provided only technical help or writing assistance, should be listed in the *Acknowledgments* section at the end of the manuscript. The corresponding author should submit the following statement: "All authors have made substantive contribution to this study and/or manuscript, and all have reviewed the final paper prior to its submission."

Authors (including authors of letters to the editor) are responsible for disclosing all financial and personal relationships that might bias their work. If such conflicts exist, the authors must provide additional detail in the appropriate text box during online submission. Funding sources for the work being submitted must be disclosed in the *Acknowledgments* section of the manuscript.

Authors should express their own findings in the past tense and use the present tense where reference is made to existing knowledge, or where the author is stating what is known or concluded. Footnotes should be avoided and their content incorporated into the text. The editors reserve the right to revise the wording of papers in the interest of the journal's standards of clarity and conciseness.

The corresponding author will be asked to submit the names and email addresses of four preferred reviewers for their manuscript. Preferred reviewers should not be colleagues at the contributors' institution or present or former research partners.

Manuscripts will be published in English, using American spelling. Manuscripts must be submitted with proper English grammar, syntax, and spelling. Before submitting a manuscript for consideration authors may consider using a professional editing service such as: 'http://www.journalexperts.com'. AAPD does not endorse such service and use of such service has no relation with acceptance of a manuscript for publication.

Two versions of the manuscript must be uploaded, one version containing all the author information and one version without any information identifying the authors or their institutions. Tables should appear at the end of the main document, while photos, photomicrographs and graphs are to be submitted as separate files (.jpg or .tif format only). Do not embed tables, photos, figures or graphics in the text of the manuscript. Prior to submission, the corresponding author must guarantee that the article has not been published and is not being considered for publication elsewhere.

Manuscript Preparation

Authors are advised to review several recently published articles to familiarize themselves with proper format and requirements.

Title: Titles should be as brief as possible while clearly conveying the main point or purpose of the article. The manuscript title is limited to 20 words or less, and a short title limited to five words or less must also be submitted. All submissions, including titles and subheads, are subject to change during the editing process.

Short Title: Also referred as a 'Running Head', must be a brief but comprehensive phrase of what the paper is all about, or a brief version of the title of the paper. not to exceed 50 characters.

Keywords: A maximum of five keywords must be submitted. Authors should ensure that the keywords appear in the title and/or abstract and that they are PubMed searchable.

Abstract: All submissions must include an Abstract. An Abstract should be brief, providing the reader with a concise but complete summary of the paper. Generalizations such as 'methods were described' should not be used. Meta-analyses/Systematic Reviews and Scientific Studies should have a structured abstract of no more than 200 words with the following sections: Purpose, Methods, Results and Conclusions. Case Reports, Literature Reviews (JDC only) and Brief Communications should have an unstructured abstract of no more than 150 words.

Introduction: The introduction should provide the context for the article, the objective of the study, and should state the hypothesis or research question (purpose statement), how and why the hypothesis was developed, and why it is important. It should generally not exceed two or three paragraphs.

Methods: The Methods section should include as appropriate, a detailed description of the study design or type of analysis and dates and period of study; condition, factors, or disease studied; details of sample (eg study participants and the setting from which they were drawn); method of random sequence generation in detail (coin flip, random table, etc.); method of allocation concealment in detail (opaque envelopes, sequential numbered drug containers, etc); description of treatment providers; whether providers and participants were blinded; inclusion and exclusion criteria; intervention(s), if any; outcome measures; method of blinding of outcome assessors; method of standardization and calibration of outcome assessors, including kappa statistics; and statistical analysis.

Results: The results reported in the manuscript should be specific and relevant to the research hypothesis. Characteristics of the study participants should be followed by presentation of the results, from the broad to the specific. The *Results* section should not include implications or weaknesses of the study, but should include validation measures if conducted as part of the study. Results should not discuss the rationale for the statistical procedures used.

Discussion: The *Discussion* section should be a formal consideration and critical examination of the study. The research question or hypothesis should be addressed in this section, and the results should be compared to and contrasted with the findings of other studies. New results not previously reported in the *Results* cannot appear first in the Discussion. (Note: A lengthy reiteration of the results should be avoided.) The study's limitations and the generalizability of the results should be discussed, as well as mention of unexpected findings with suggested explanations. The type of future studies needed, if appropriate, should be mentioned.

Conclusion: The *Conclusion* should help the reader understand why the research should matter to them after they have finished reading the paper. Conclusions should be numbered, succinct statements that are supported by the results of the study. They should not repeat the Results section.

Acknowledgment: Funding and other sources of support must be disclosed in the Acknowledgment section. Personal acknowledgments should be limited to appropriate professionals who have contributed intellectually to the paper but whose contribution does not justify authorship.

References: References are a critical element of a manuscript and serve three primary purposes—documentation, acknowledgment, and directing or linking the reader to additional resources. Authors bear primary responsibility for all reference citations. References should be numbered consecutively with superscript Arabic numerals in the order in which they are cited in the text. A list of all references should appear at the end of the paper in numeric order as they are cited in the text. Journal abbreviations are those used by Index Medicus. The reference style to use is the recent edition of the American Medical Association Manual of Style.

The following are sample references:

Journal

For journals, list all authors when there are six or fewer; when there are seven or more, list the first three, then 'et al.' Page numbers should be included where possible. For example: 12-8, 191-5, 347-51.

Bogert TR, García-Godoy F. Effect of prophylaxis agents on the shear bond strength of a fissure sealant. Pediatr Dent 1992;14(1):50-1.

Book

Bixler D. Genetic aspects of dental anomalies. In: McDonald RE, Avery DR, eds. Dentistry for the Child and Adolescent. 5th ed. Philadelphia: CV Mosby Co; 1987:90-116.

Article, report, or monograph issued by a committee, institution, society, or government agency

Medicine for the public: Women's health research Bethesda, Md.: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health; 2001. DHHS publication 02-4971.

World Wide Web

Websites and Web articles (URLs) should be cited as 'webcited'' references in the reference section at the end of the manuscript—do not include links to websites in the text. To webcite' a web reference means to take a snapshot of the cited document and to cite the archived copy (WebCite' link) in addition to the original URL. AAPD requires that authors use the free WebCite' technology (www.webcitation.org) to archive all cited web references first before they cite them. Provide the original URL, the WebCite' link and an access date.

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Authors should provide direct references to original sources whenever possible. Avoid using abstracts or literature reviews as references. If possible, avoid references to papers accepted but not yet published. If such a citation is necessary, these papers should be cited as being 'In press', and verification that they have been accepted for publication must be provided. Where possible, references of easily accessible material are preferable to dissertations, theses, and other unpublished documents.

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