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ODONTOLÓGICAS

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**SOBREVIDA E FATORES DE RISCO ASSOCIADOS À FALHAS
DE RESTAURAÇÕES DE RESINA COMPOSTA EM CRIANÇAS
COM CÁRIE DE ACOMETIMENTO PRECOCE:
ESTUDO CLÍNICO RETROSPECTIVO**

DISSERTAÇÃO DE MESTRADO

Santa Maria, RS
2017

Pâmela Campagna

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Dissertação apresentada ao Curso de Mestrado do Programa de Pós-Graduação em Ciências Odontológicas, Área de Concentração em Odontologia, ênfase em Odontopediatria, da Universidade Federal de Santa Maria (UFSM, RS), como requisito parcial para obtenção do grau de **Mestre em Ciências Odontológicas**

Orientadora: Profa. Dra. Marta Dutra Machado Oliveira

Santa Maria, RS

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Aprovada em 17 de Julho de 2017

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2017

DEDICATÓRIA

À meus pais pelo amor, incentivo e apoio incondicional.

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(Autor desconhecido)

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“Há pessoas que marcam a nossa vida, que despertam algo especial em nós, que abrem nossos olhos de modo irreversível e transformam a nossa maneira de ver o mundo.”

(Autor desconhecido)

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RESUMO

SOBREVIDA E FATORES DE RISCO À FALHAS DE RESTAURAÇÕES DE RESINA COMPOSTA EM CRIANÇAS COM CÁRIE DE ACOMETIMENTO PRECOCE

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No tratamento restaurador de cárie precoce da infância a resina composta tem sido amplamente utilizada, porém, ainda existe uma lacuna na literatura acerca do comportamento clínico deste material na dentição decídua, especialmente na primeira infância. O objetivo deste estudo clínico retrospectivo foi avaliar a sobrevida e fatores de risco associados à falhas de restaurações de resina composta realizadas em crianças com cárie de acometimento precoce atendidas na Clínica de Bebês da Universidade Federal de Santa Maria, RS. Um total de 78 restaurações em dentes decíduos de registros de 24 crianças com risco elevado de cárie (9 meninas e 15 meninos) foram incluídas no estudo. Dentes anteriores e posteriores foram aceitos, desde que a restauração tenha sido realizada à no mínimo um ano anteriormente as avaliações e tenha seguido os preceitos e técnicas preconizados na instituição (UFSM). Dois dentistas foram treinados para avaliar as restaurações sendo o índice de concordância intra examinador de 0,80 a 0,87 e o inter examinador 0,81. A longevidade das restaurações, até 30 meses de seguimento, foi avaliada utilizando o teste de sobrevivência de Kaplan-Meier. A análise de regressão Cox multivariada com fragilidade compartilhada foi utilizada para avaliar os fatores associados às falhas ($p < 0,05$). O tempo médio de sobrevivência foi de 26 meses (IC 95%: 24,5-26,7). A sobrevida das restaurações atingiu 34,8% até 30 meses, com uma taxa de falha anual global de 20,0%. As restaurações que envolveram duas ou mais superfícies apresentaram 2,50 vezes mais risco de falha do que as restaurações de uma única superfície ($p = 0,03$). As restaurações realizadas em dentes vitais apresentaram menor risco de falha do que às realizadas em dentes submetidos à intervenção pulpar (FC: 0,25 IC 95%: 1,00-0,65; $p = 0,00$). Os pacientes com índice de placa maior que 20% tiveram mais risco de falha em suas restaurações (HR: 3,63; IC 95%: 1,29-10,2; $p = 0,01$). As restaurações de resina composta realizadas em pacientes com cáries da primeira infância representaram uma sobrevivência restrita após 30 meses de seguimento. As variáveis clínicas, como o número de superfícies restauradas, terapia pulpar e o controle do biofilme, podem desempenhar um papel importante na sobrevivência das restaurações de resina composta realizadas em crianças mais jovens com alto risco de cárie.

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

ABSTRACT

Survival and associated risk factors of composite restorations in children with early childhood caries

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In the restorative treatment of early childhood caries composite resin has been widely used, however, there is still a gap in the literature about the clinical behavior of this material in the deciduous dentition, especially in early childhood. The aim of this retrospective clinical study was to evaluate the survival and risk factors associated with failure of composite resin restorations performed in children with early-onset caries treated at the Baby Clinic of the Federal University of Santa Maria, RS. A total of 78 restorations in primary teeth from records of 24 high caries risk children (9 girls and 15 boys) were included in the study. Previous and subsequent teeth have been accepted, provided that the restoration has been performed at least a year before the evaluations and has followed the precepts and techniques recommended in the institution (UFSM). Two dentists were trained to evaluate the restorations with the intra-examiner concordance index of 0.80 to 0.87 and the inter-examiner 0.81. The restorations longevity up to 30 months 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 ($p < 0.05$). Mean survival time was 26 months (95%CI: 24.5-26.7). The survival of the restorations reached 34.8% up to 30 months, with an overall annual failure rate of the 20.0%. Restorations involving two or more surfaces had 2.50 times more risk of failure than restorations placed in cavities involving single surface ($p = 0.03$). Restorations performed in vital teeth had a lower risk of failure than those performed in teeth underwent pulp intervention (HR: 0.25; 95%CI: 1.00-0.65; $p = 0.00$). Patients with plaque index more than 20% had more risk of failure in their restorations (HR: 3.63; 95% CI 1.29-10.2; $p = 0.01$). Resin composite restorations placed in patients with early childhood caries presented restricted survival after 30 months of follow-up. Clinical variables such as number of restored surfaces, pulp therapy and poor biofilm control may play an important role in the survival of composite restorations performed in younger children with high caries risk.

Keywords: Pediatric Dentistry. Restoration Failure. Survival Analysis. Tooth decay.

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1 INTRODUÇÃO

A dentição decídua contribui no desempenho das funções mastigatórias, de articulação, fonação e oclusão, sendo portanto, indispensável preservá-la em estado de saúde até seu período normal de esfoliação (ALENCAR;CAVALCANTI; BEZERRA, 2007). No entanto, a perda prematura destes dentes é um problema frequente, sendo a cárie a causa principal (PERES et al., 2013).

Embora a prevalência da doença cárie tenha diminuído no Brasil, os índices encontrados para os primeiros anos de vida merecem uma atenção especial. O estudo de ROSENBLATT e ZARZAR, 2004, avaliou 468 crianças de 12 a 36 meses e através de exame clínico encontrou lesões de cárie precoce da infância em 133 crianças. Segundo a Academia Americana de Odontopediatria (AAPD), cárie precoce na infância é caracterizada como a presença de um ou mais dentes decíduos cariados (lesões cavitadas ou não), perdidos (devido à cárie) ou restaurados antes dos 71 meses de idade (BÜCHER et al., 2013). Outros profissionais denominam a cárie da primeira infância como uma epidemia silenciosa, já que dados nacionais sugerem que mais de 50% dos pré-escolares são acometidos pela doença (BRASIL, 2012). Além disso, as lesões cariosas são de natureza aguda e progressiva, sendo sua evolução capaz de causar grande destruição dentária, ou até mesmo sua perda. Tal condição pode causar complicações locais, sistêmicas, psicológicas e sociais, exigindo assim, tratamento imediato, restaurador e preventivo (LOSSO et al., 2009).

A Organização Mundial da Saúde propõe metas para estimular países em desenvolvimento a adotarem medidas para melhorar seus indicadores em saúde bucal. A meta para 2010 era que 90% dos indivíduos de 05 anos de idade estivessem livres de cáries no Brasil. Todavia, dados de um levantamento epidemiológico realizado no Brasil em 2010 apontam que aos 05 anos de idade, somente 46,6 % das crianças estavam livres de cárie. Segundo este mesmo levantamento,

uma criança brasileira de 05 anos possui, em média, 2,43 dentes com experiência de cárie, com predomínio do componente cariado, que é responsável por mais de 80% do índice (Brasil, 2012). Além disso, outros estudos realizados no Brasil indicam que a prevalência de cárie precoce na infância varia de 12 a 46%, sendo a faixa etária entre 01 e 03 anos, a mais acometida (BÖNECKER, 2002).

O tratamento das lesões de cárie na infância envolve o controle da doença e a reversão dos sinais clínicos nos seus estágios iniciais. Já em casos que as lesões atingem dentina, apresentando ou não cavitação, há necessidade de tratamento operatório associada à medidas preventivas, a fim de modificar as condições que levaram ao desenvolvimento da doença cárie (LOSSO et al., 2009), principalmente nesta faixa etária, em que as crianças estão estabelecendo hábitos que perpetuarão pela vida inteira.

A resina composta tem sido amplamente utilizada como material restaurador na clínica odontopediátrica, entre outras razões, por ser um material com propriedades adesivas, permitindo maior preservação da estrutura dentária, restringindo o preparo à remoção do tecido cariado. Também tem como vantagem a estética (KILPATRICK; NEUMANN 2007) e portanto, a maior aceitação pelos pacientes e responsáveis.

Lesões de cárie precoce na infância possuem peculiaridades no tratamento no que diz respeito às questões comportamentais e de condicionamento. O atendimento nesta faixa etária exige uma maior habilidade do cirurgião dentista devido à reduzida capacidade de cooperação das crianças, o que pode influenciar negativamente na longevidade dos procedimentos restauradores (BÜCHER et al., 2013). Uma das dificuldades encontradas está na realização de alguns procedimentos obrigatórios no uso da resina composta, como por exemplo, o isolamento absoluto.

Assim, o uso de intervenções anestésicas como sedação ou anestesia geral, tem sido recomendado para realização de tratamento restaurador em crianças com cárie de acometimento precoce (AAPD, 2016). A dificuldade de manejo comportamental nessa faixa etária também acaba inviabilizando a realização de ensaios clínicos controlados

e randomizados que avaliem o comportamento clínico de restaurações realizadas em dentes decíduos durante a primeira infância (WAGGONER, 2014).

Neste contexto, a realização de pesquisas baseadas na prática clínica parece ser uma boa estratégia para avaliar a longevidade das restaurações o mais próximo das situações reais (OPDAM et al., 2010). No entanto, poucos estudos retrospectivos investigaram a sobrevivência de restaurações de resina composta realizadas em crianças com cárie de acometimento precoce (BUCHER et al., 2014; AMIN et al., 2016).

A sobrevivência de diferentes tratamentos restauradores realizados, sob anestesia geral, em crianças com cárie de acometimento precoce foi investigada considerando um total de 818 pacientes. Destas, 32,9% foram submetidos à reintervenção de algum tratamento restaurador durante os 03 anos de acompanhamento. Coroas de aço e restaurações de amálgama apresentam maior taxa de sobrevivência em comparação com as restaurações de resina composta (AMIN et al., 2016).

Por outro lado, alta taxa de sucesso clínico de restaurações de resina composta realizadas, sob anestesia geral, na primeira infância tem sido relatada na literatura. O estudo retrospectivo de BUCHER et al., 2014, avaliou 1.017 restaurações de resina composta realizadas em crianças com cárie precoce da infância em tratamentos sob anestesia geral. O tempo médio de acompanhamento foi de 30,9 meses com taxa de sucesso de 81,5%. Considerando que em muitos países, como o Brasil, os procedimentos restauradores em bebês geralmente são realizados sem emprego de abordagens farmacológicas para manejo comportamental, os resultados obtidos nos estudos supracitados não podem ser diretamente extrapolados. Apesar das evidências disponíveis, é incontestável que ainda existe uma lacuna na literatura acerca do comportamento clínico de restaurações de resina composta na dentição decídua, especialmente na primeira infância. Sendo assim, a realização de um estudo retrospectivo para avaliar o comportamento clínico de restaurações de resina composta em crianças com cárie de acometimento precoce se faz necessária.

2 PROPOSIÇÃO

O objetivo desta dissertação é apresentar um artigo científico abordando a sobrevida e os fatores associados com as falhas de restaurações de resina composta em crianças com cárie de acometimento precoce.

3 ARTIGO

Esta dissertação está baseada nas normativas da Universidade Federal de Santa Maria. Por se tratar de pesquisa envolvendo seres humanos, o projeto de pesquisa deste trabalho foi submetido à apreciação do Comitê de Ética em Pesquisa da Universidade Federal de Santa Maria, tendo sido aprovado (ANEXO A). Sendo assim, esta dissertação é composta por um artigo que foi enviado para publicação na revista *Pediatric Dentistry*.

“ Survival and associated risk factors of composite restorations in children with early childhood caries: a clinical retrospective study ”

Campagna P, Pinto LT, Lenzi TL, Ardenghi TM, Rocha RO, Oliveira MDM.

3.1 Title Page

Survival and associated risk factors of composite restorations in children with earlychildhood caries: a clinical retrospective study

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Abstract

Purpose: This clinical retrospective cohort university-based study assessed the survival and risk factors associated with failures of resin composite restorations placed in patients with early childhood caries.

Methods: A total of 78 restorations in primary teeth from records of 24 high caries risk children (9 girls and 15 boys) were included in the study. The restorations' longevity up to 30 months 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 26 months (95%CI: 24.5-26.7). The survival of the restorations reached 34.8% up to 30 months, with an overall annual failure rate of the 20.0%. Restorations involving two or more surfaces had 2.50 times more risk of failure than restorations placed in cavities involving single surface ($p = 0.03$). Restorations performed in vital teeth had a lower risk of failure than those performed in teeth underwent pulp intervention (HR: 0.25; 95%CI: 1.00-0.65; $p = 0.00$). Patients with plaque index more than 20% had more risk of failure in their restorations (HR: 3.63; 95% CI 1.29-10.2; $p = 0.01$).

Conclusion: Resin composite restorations placed in patients with early childhood caries presented restricted survival after 30 months of follow-up. Clinical variables such as number of restored surfaces, pulp therapy and poor biofilm control may play an important role in the survival of composite restorations performed in younger children with high caries risk.

Keywords: baby bottle-fed tooth decay; deciduous tooth; dental restoration; failure; survival analysis

Introduction

Early childhood caries (ECC) is defined as the presence of one or more decayed (non cavitated or cavitated lesions), missing (due to caries), or filled tooth surfaces in any primary tooth in a child under the age of six.¹ ECC remains a significant public health problem, since it results in higher risk of new caries lesions in both primary and permanent dentitions² besides negatively impacts on oral health-related quality of life.^{3,4}

Restorative therapy is routinely performed in daily Pediatric clinic for treating rapid and extensive destruction of primary teeth promoted by ECC.⁵ However, restorative treatment may be a great challenge for the practitioners due to difficulties with behavior management of infants or toddlers. Moreover, anterior teeth are frequently affected by ECC. In this sense, small teeth dimensions, large carious lesions and, consequently, reduced area for bonding⁶ may jeopardize the longevity of the restorations.

Resin-based composites have been generally used for restoring primary teeth, providing good handling and functional performance besides meeting patients' demands regarding esthetics.⁷ There is a lack of supporting clinical data regarding the restoration of primary teeth of very young children. Child's level of cooperation during treatment, parental consent, variability in the amount of remaining tooth structure, and differences in caries risk are barriers to obtaining good clinical data on restorative options.⁶ Thus, retrospective studies may provide relevant data about the longevity of resin-based composite restorations placed in primary dentition.

A previous retrospective study⁸ found an overall success rate of

81.5% after a mean time of 30.7 months for composite restorations placed under general anesthesia in children with early childhood caries. However, anesthesiologic interventions, such as sedation or general anesthesia, are not a common approach in many countries for treatment of infants or toddlers. In this sense, dental treatment supported by non-pharmacological behavior guidance techniques may reflect conditions closer to the clinical daily life.

Therefore, the aim of this clinical retrospective cohort university-based study was to evaluate the survival and factors associated with failures of resin composite restorations in patients with ECC.

Methods

Ethical aspects and study design

A retrospective longitudinal study was conducted. The research protocol was approved by the Local Research Board and the parents or guardians signed a written informed consent. The personal information of the children was kept confidential.

Sample collection

The convenience sample comprised children (0-3 years old) who underwent restorative treatment in Pediatric Dentistry Clinic at the Federal University of Santa Maria during the period between April 2013 and December 2015. Graduate students, supervised by specialists in Pediatric Dentistry, attended the children. Most patients have high risk of caries. To be included in the study, children should have received at least one resin-based composite restoration in 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, 34 patients were selected through the inspection of clinical and radiographic records and invited to visit the dental office. The recruitment was performed by phone calls, and 24 (70.6%) patients agreed to participate in the clinical evaluations. Three teeth were lost to exfoliation four were extracted, leaving 78 restorations available for examination.

Restorative procedures

All procedures were performed under rubber dam isolation. Cavities were prepared with low-speed handpieces and dentin excavators were used for carious tissue removal; high-speed carbide burs were used for removing enamel and unsatisfactory restorations when necessary. Preparation was restricted to carious tissue removal. In deep and moderate cavities, a thin layer of calcium hydroxide cement (Dycal; Dentsply, Petrópolis, RJ, Brazil) was used. The cavity was conditioned by 37 % phosphoric acid gel for 15 s. The acid was removed by rinsing with water for 30 s, 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 incremental insertion of resin composite (Filtek Z250 or Z350, 3M ESPE, St. Paul. MN, USA). 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

The history of the restorations was collected from the patient records. 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), household income (up to one Brazilian minimum wage (BMW) – nearly corresponded to 273 US dollars during the period of data gathering or more than one BMW), 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 pulp capping material (yes or no).

Training and calibration of evaluators

Two dentists (P.C. and M.D.M.O) underwent a total of 8 h of specific training session involving theoretical explanations, discussion and assessment of 20 photographs on World Dental Federation (FDI) criteria.⁹ FDI criteria include several items on aesthetic, functional and biological properties. Each criterion of FDI can be expressed with five scores, three for acceptable (1. clinically very good; 2. clinically good; 3. clinically sufficient/satisfactory) and two for non-acceptable (4. clinically unsatisfactory – repairable restoration; 5. clinically poor – restoration replacement). The responsible for training session was a benchmark examiner (T.L.L.) who has been trained and calibrated for using the criteria. The examiners' calibration procedures considered two examinations of 10 restorations, randomly distributed in both periods to avoid memory bias, for Cohen's Kappa calculation (Kappa = 0.81).

Evaluation of restorations

The children's restorations were clinically evaluated between December 2016 and March 2017 independently by two trained and calibrated examiners using a dental probe and plane buccal mirror, in accordance with FDI criteria. In case of disagreement, the examiners evaluated the restorations jointly, until a consensus was reached.

For the statistical analysis, the worst grading among all parameters of both criteria was considered. 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 clinician).

The visible plaque index (Ainamo and Bay) was used to evaluate the routine of plaque control by children.¹⁰ For the calculation of these indexes, the number of dental surfaces was divided by the surfaces with visible plaque or gingival bleeding. For the analysis, the values of these two indexes were dichotomized. A satisfactory biofilm control was considered when the visible plaque index was less than 20 %.¹¹ Those patients who presented treatment need during clinical evaluation were referred for treatment.

Statistical analysis

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 30 months 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 (HR) and their respective 95% confidence intervals (CI) were obtained. A backward stepwise procedure was used to select covariates in the fitting of the model. Only those variables presenting *P*-values less than 0.2 in the unadjusted assessment were selected for the multivariate analysis. A significant level of 5% was considered for the final model.

Results

Seventy and eight restorations placed in 24 patients (9 girls and 15 boys) were included in the analysis. The mean age of the children after follow-up was 5.4 years (± 0.8), presenting a decayed, missing and filled -teeth (dmf-t) mean of 7.8 (± 4.0). The follow-up period ranged from 15 to 30 months with a mean of 24 months (± 5.1).

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, 56 (71.8%) were placed in boys. Most restorations (67.9%) were performed in children with visible plaque index more than 20% in the follow-up. Posterior restorations were more frequent (51.3%) than anterior ones (48.7%) as well as those performed in

upper arch (73.1%) when compared with lower arch (26.9%). Resin-based composite restorations placed on vital teeth were more common (80.8%) than those teeth with pulp treatment (19.2%) as well as those involving two or more surfaces (64.1%) in comparison with single surface (35.9%). In the majority of the restorations (93.6%) no pulp capping material was used. The overall success rate was 47.4%(37/78). Table 2 shows the unadjusted and adjusted HR for failures according to independent variables.

The adjusted model showed that restorations involving two or more surfaces had 2.50 times more risk of failure than restorations placed in cavities involving only one surface ($p=0.03$). Restorations performed in children with visible plaque index more than 20% had 3.63 times more risk of failure compared to patients with good biofilm control ($p=0.01$). The results also demonstrated that restorations placed in vital teeth had a lower risk of failure than those performed in teeth underwent pulp treatment (HR: 0.25;95%CI: 1.00-0.65; $p = 0.00$).

The cumulative restoration survival estimate is shown in Figure 1. Mean survival time was 26 months (95%CI: 24.5-26.7), with 34.8% of the restorations surviving after 30 months of evaluation. The overall AFR after 24 months follow-up was 20.0%. The distribution of the restorations according to the FDI criteria is summarized in Table 3. Marginal adaptation, fracture and caries recurrence were the main reasons for need of intervention (repair or replacement) in the resin-based composite restorations.

Discussion

This cohort study involved the clinical evaluation of resin-based composite restorations performed in patients with ECC by undergraduate students and the factors associated with restoration failures. The overall survival rate of the restorations was 34.8% after 30 months of follow-up. Although the survival rate was low, it is important to note that the Kaplan Meier estimator takes into account the censored data, i.e., those restorations that have not yet reached the 30-month evaluation in this retrospective analysis. In addition, the reduced ability to manage a child's behavior in association with lack of technical experience of the students could contribute to the restricted survival of restorative treatment.

The overall AFR was 20.0%. A previous investigation⁸ found an ARF of 4.2% for composite restorations performed in children with ECC under general anesthesia. In our study, all procedures were made in association with non-pharmacological behavior guidance techniques, which could explain the higher AFR. Moreover, only individuals with high caries risk were included in the sample. It has been evidenced that these patients are more likely to present resin composite restoration failure.¹²

In this sense, it would be interesting to consider other restorative treatment options such as fillings with materials less technically sensitive and zirconia or stainless steel crowns.^{13,14} A retrospective study¹³ showed that stainless steel crowns and amalgam restorations placed under general anesthesia for ECC had better survival than resin composite restorations over three-year follow-up. Furthermore, zirconia crowns have been shown clinically satisfactory and very acceptable by parents.¹⁴ Glass ionomer cements are widely used in Brazil to restore primary teeth

due several advantages such as ease of the technique, which reduces chair time, being mainly important for treatment of uncooperative and very young children.¹⁵ Further studies evaluating the survival of resin-modified glass ionomer cement restorations in infants are required. In our study, the number of restored surfaces also had a detrimental effect over the longevity of the restorations. Teeth presenting two or more restored surfaces presented more failures when compared to one restored surface (HR 2.50; 95%CI: 1.08-5.78). It has been reported that a higher number of surfaces enrolled in cavity preparations can decrease the tooth resistance to fracture,¹⁶⁻¹⁸ even in primary teeth that had lower occlusion loading compared than permanent ones.¹⁹

It is well established in the scientific literature that dental biofilm is a marker for oral health patterns. A birth cohort study demonstrated that the lifetime exposure to dental biofilm might be a risk factor in cumulative dental diseases, such as caries, failure of restorative treatments, and tooth loss.²⁰ Our results showed that patients presenting more sites with visible plaque (IPV >20 %) had 3.63 times more risk of failure in their restorations. Although gingival bleeding index is the clinical parameter more faithful reference from oral hygiene routine, this evaluation was not made because difficulties when applied in infant patients.²¹ Children with a history of pulpal intervention also presented higher risk of failure. Few studies have assessed the influence of endodontic treatment on restoration survival,^{22,23} however these reports also detected increased risk for failure in teeth with pulp intervention. This is probably due to reduction in tooth structure affecting fracture resistance²⁴ and

consequently, decreasing the restoration survival.²⁵

Fracture, marginal adaptation, anatomic form and caries were the main reasons for failure of the restorations. However, most restorations could be repaired due fracture and marginal adaptation. This is friendly-patient approach for treating defective restorations in order to improve the restoration survival and diminish chair time.²⁶

With regard to the limitations of this study, it must be considered in practice-based retrospective studies, patients are not specifically selected. A convenience sample of children attending a dental clinic was followed by a relatively short-term clinical and the sample size was small; so the findings presented here should be considered with caution. On the other hand, this study provides valuable information for clinicians and researches about clinical factors associated with failures of composite restorations performed in children with ECC.

Conclusion

Resin composite restorations placed in patients with ECC presented restricted survival after 30 months of follow-up. Clinical variables such as number of restored surfaces, pulp therapy and poor biofilm control may play an important role in the survival of composite restorations performed in younger children with high caries risk.

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Figure 1. Kaplan-Meier survival curve of restorations over 30 months.

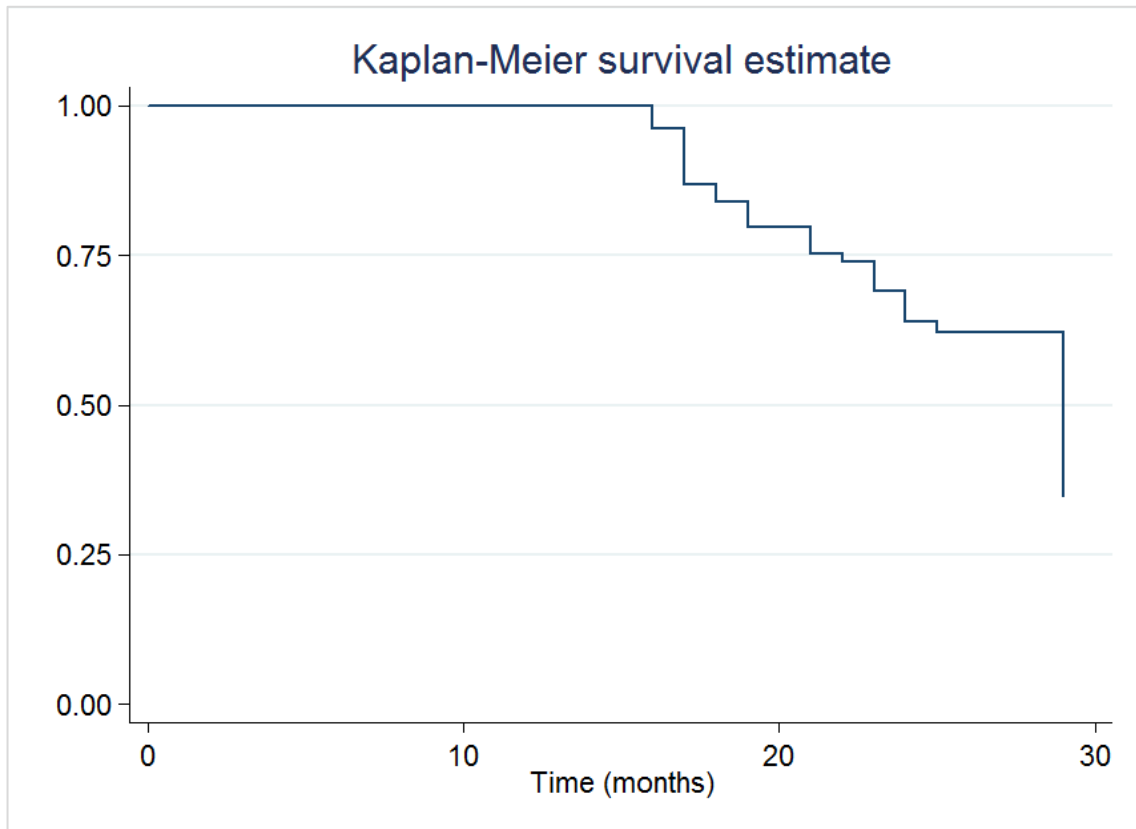


Table 1. Status of the restorations according to clinical and demographic characteristics (n=78 restorations)

Variables	n (%) of restorations	Success (%)	Failure (%)
Gender			
Boys	56 (71.8)	26 (46.4)	30 (53.6)
Girls	22 (28.2)	11 (50.0)	11 (50.0)
Mother's education			
Up to eight years	36 (46.2)	17 (47.2)	19 (52.8)
More than eight years	42 (53.8)	20 (47.6)	22 (52.4)
Income			
Up to one minimum wage	40 (51.3)	22 (55.0)	18 (45.0)
More than one minimum wage	38 (48.7)	15 (39.5)	23 (60.5)
Visible plaque index (follow-up)			
Up to 20%	25 (32.1)	12 (48.0)	13 (52.0)
More than 20%	53 (67.9)	23 (43.4)	30 (56.6)
Type of arch			
Upper	57 (73.1)	27 (47.4)	30 (52.6)
Lower	21 (26.9)	10(47.6)	11 (52.4)
Type of tooth			
Anterior	38 (48.7)	17 (44.7)	21 (55.3)
Posterior	40 (51.3)	20 (50.0)	20 (50.0)
Number of restored surfaces			
One	28 (35.9)	17 (60.7)	11 (39.3)
Two or more	50 (64.1)	20 (40.0)	30 (60.0)
Pulp intervention			
Yes	15 (19.2)	5 (33.3)	10 (66.7)
No	63 (80.8)	32 (50.8)	31 (49.2)
Pulp capping material			
Yes	5 (6.4)	2 (37.5)	3 (62.5)
No	73 (93.6)	35 (48.0)	38 (52.0)

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		0.84		
Boys	1			
Girls	1.08 (0.47-2.55)			
Mother's education		0.43		
Up to eight years	1			
More than eight years	1.50 (0.72-3.12)			
Income		0.28		
Up to one minimum wage	1			
More than one minimum wage	1.08 (0.68-1.74)			
Visible plaque index (follow-up)		0.05		0.01
Up to 20%	1		1	
More than 20%	2.57 (1.02-6.47)		3.63 (1.29-10.2)	
Type of arch				
Superior	1	0.53		
Inferior	0.79 (0.38-1.65)			
Type of tooth		0.78		
Anterior	1			
Posterior	0.86 (0.45-1.67)			
Number of restored surfaces		0.04		0.03
One	1		1	
Two or more	2.17 (1.03-4.54)		2.50 (1.08-5.78)	

Pulp intervention		0.00		0.00
Yes	1		1	
No	0.22 (0.09- 0.53)		0.25 (0.10- 0.65)	
Pulp capping material		0.28		
Yes	1			
No	0.51 (0.15- 1.73)			

* *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	Surfaceluster	51 (65.4)	9 (11.5)	2 (2.6)	-	16 (20.5)
	Surface staining	38 (48.7)	24 (30.8)	-	-	16 (20.5)
	Marginal staining	18 (23.1)	42 (53.8)	2 (2.6)	-	16 (20.5)
	Translucency and color stability	17 (21.8)	26 (33.3)	17 (21.8)	1 (1.3)	17 (21.8)
	Anatomic form	12 (15.4)	20 (25.6)	22 (28.2)	5 (6.4)	19 (24.4)
Functional properties	Fracture	36 (46.1)	7 (9.0)	6 (7.7)	10 (12.8)	19 (24.4)

	Marginal Adaptation	5 (6.4)	28 (35.9)	11 (14.1)	15 (19.2)	19 (24.4)
Biological properties	Caries recurrence	45 (57.7)	5 (6.4)	2 (2.6)	4 (5.1)	22 (28.2)

4 CONSIDERAÇÕES FINAIS

Com base neste estudo retrospectivo clínico, observou-se uma limitada sobrevida de restaurações de resina composta em pacientes acometidos por cárie precoce de infância. Tais resultados são decorrentes das dificuldades no manejo comportamental desses pacientes, associado ao padrão de destruição da estrutura dentária acometida pela doença cárie nesta faixa etária. Variáveis clínicas relacionadas ao número de superfícies restauradas, presença de intervenção pulpar e deficiente controle de biofilme foram associadas às falhas restauradoras. Ademais, a maioria das crianças apresentaram baixo nível socioeconômico e alto risco de cárie, fatores sociais determinantes e individuais que afetam diretamente a qualidade das restaurações adesivas (Demarco et al., 2013; Correa et al., 2012). Sendo assim, fica evidente que o principal desafio do Odontopediatra é o sucesso na implementação de medidas preventivas e de promoção de saúde a fim de postergar ou evitar a necessidade de intervenção invasiva.

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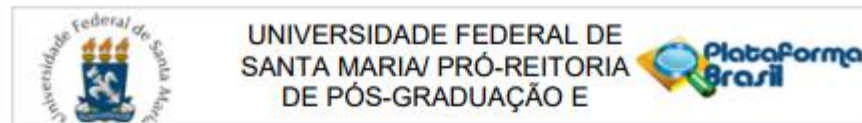
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Anexo A –Aprovação do Comitê de Ética em Pesquisa da UFSM



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Longevidade das Restaurações Realizadas na Clínica de Bebês da UFSM - Estudo Retrospectivo

Pesquisador: Marta Dutra Machado Oliveira

Área Temática:

Versão: 2

CAAE: 63123516.8.0000.5346

Instituição Proponente: Departamento de Estomatologia

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.930.775

Apresentação do Projeto:

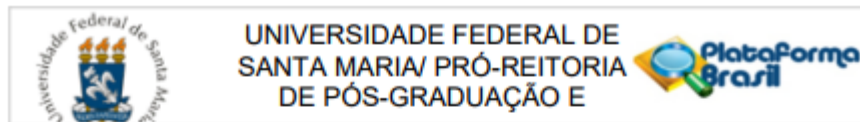
Trata-se de um projeto de dissertação de mestrado vinculado ao Programa de Pós-Graduação em Ciências Odontológicas. Será um estudo longitudinal retrospectivo. Os prontuários dos pacientes atendidos na Clínica de Bebês do Curso de Odontologia da Universidade Federal de Santa Maria serão avaliados. Os pacientes que apresentarem restaurações de resina composta em dentes decíduos realizadas a mais de um ano serão selecionados e seus dados transcritos para uma ficha elaborada para o presente estudo. Após a tabulação dos dados, os pacientes em questão serão convidados a retornarem a Universidade Federal de Santa Maria para avaliação das restaurações. O contato com os pacientes será realizado por telefone pelo pesquisador.

Os pesquisadores irão se responsabilizar pelos custos do presente projeto.

Objetivo da Pesquisa:

OBJETIVO GERAL: avaliar as condições clínicas e a longevidade de restaurações de resina composta realizadas em dentes decíduos na Clínica de Bebês do Curso de Odontologia da Universidade Federal de Santa Maria.

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



Continuação do Parecer: 1 610 775

OBJETIVOS ESPECÍFICOS

- Verificar a longevidade clínica de restaurações de resina composta em dentes deciduos anteriores;
- Verificar a longevidade clínica de restaurações de resina composta em dentes deciduos posteriores;
- Comparar a longevidade clínica de restaurações entre dentes deciduos anteriores e posteriores;
- Avaliar a influência de materiais intermediários na longevidade de restaurações de resina composta em dentes deciduos;
- Averiguar o risco de cárie e cárie recidivante na longevidade das restaurações de resina composta em dentes deciduos;
- Correlacionar a remoção parcial e a remoção total de tecido cariado com a durabilidade das restaurações.

Avaliação dos Riscos e Benefícios:

Sobre riscos e benefícios consta no TCLE: "Esta pesquisa não apresenta grandes riscos aos pacientes, apenas algum desconforto por ficar de boca aberta, ou um pouco de sensibilidade ao jato de ar/água que são colocados sobre o dente durante a avaliação. Estes incômodos serão minimizados por pausas na avaliação, para que o paciente descanse fechando a boca, e jatos de ar/água moderados e espaçados."

Riscos estão descritos de maneira adequada e coerente nos documentos.

Sobre os benefícios consta: "Quanto as vantagens, os participantes e seus responsáveis receberão instruções de higiene oral, além de outras explicações sobre saúde bucal, ficando os avaliadores disponíveis para responder dúvidas."

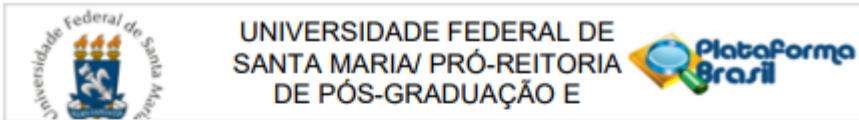
Benefícios estão descritos de maneira adequada e coerente nos documentos.

Comentários e Considerações sobre a Pesquisa:

O projeto esta muito bem apresentado e possui tema relevante.

Os pesquisadores justificaram o tamanho da amostra (37), por ser o número de pacientes que preenchem os critérios de inclusão e exclusão apresentados no projeto.

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DE PÓS-GRADUAÇÃO E

Continuação do Parecer: 1.930.775

Considerações sobre os Termos de apresentação obrigatória:

Todos os termos estão apresentados de maneira adequada.

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:

O projeto não apresenta pendências ou inadequações e pode ser aprovado.

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

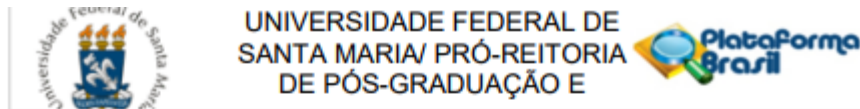
Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_838179.pdf	25/01/2017 19:29:02		Acelto
Projeto Detalhado / Brochura Investigador	Projeto_Pamela_revisado.pdf	25/01/2017 19:28:39	Marta Dutra Machado Oliveira	Acelto
Outros	projeto_integra_Pamela.pdf	19/12/2016 00:32:04	Marta Dutra Machado Oliveira	Acelto
Outros	Termo_confidencialidade_Pamela.pdf	06/12/2016 20:56:26	Marta Dutra Machado Oliveira	Acelto
Declaração de Instituição e Infraestrutura	Termo_autorizacao_institucional_Pamela.pdf	06/12/2016 20:55:53	Marta Dutra Machado Oliveira	Acelto
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Pamela.pdf	06/12/2016 20:55:14	Marta Dutra Machado Oliveira	Acelto
Folha de Rosto	Folha_rosto_Pamela.pdf	06/12/2016 20:54:21	Marta Dutra Machado Oliveira	Acelto

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

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Continuação do Parecer: 1.930.775

Não

SANTA MARIA, 17 de Fevereiro de 2017

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

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 *Interpretations 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
<i>Meta-Analyses/ Systematic Reviews</i>	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
<i>Scientific Studies</i>	200 words, structured	3,500 words	40	4	3	
<i>Case Reports</i>	150 words, unstructured	1,850 words	20	4	3	
<i>Literature Reviews (JDC only)</i>	150 words, unstructured	2,500 words	0	0	4	
<i>Brief Communications</i>	150 words, structured	2,000 words	20	2	2	
<i>Letters to the Editor</i>	none	350 words	8	0	0	
<i>Editorials</i>	none	1,000 words	40	2	2	Invited by the Editor-in-Chief

Editorials

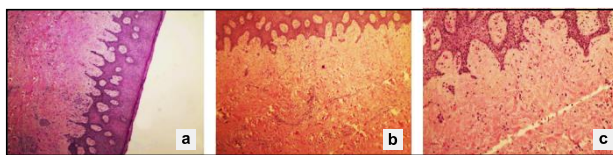
Full-length manuscript not to exceed 1,000 words; excluding *References* and *Figure Legends*.

Maximum Figures: 2 • Maximum Tables: 2

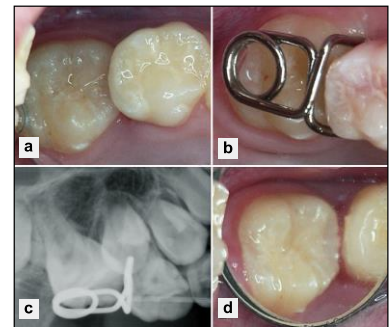
Brief Communications

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.

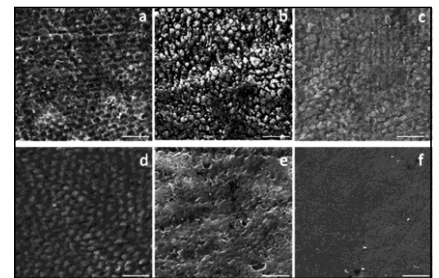
Authors desiring to have more Figures or Tables MUST agree to electronic publication of their manuscript, and must select this preference. Each separate chart, graph or photograph will be counted as a separate figure. Figures grouped together will be counted as their individual parts. See samples below:



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 to 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.

American Academy of Pediatric Dentistry. AAPD Publications. Available at: "<http://www.aapd.org/publications/>". Accessed: 2015-03-20. (Archived by WebCite® at: "<http://www.webcitation.org/6XAypVwds>")

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.

Authors should avoid citing 'personal communication' unless it provides essential information not available from a public source. Personal communications should not be numbered, but should be cited in the text as follows: (*G. Seale, DDS, oral communication, March 2015*). Authors should obtain written permission and confirmation of accuracy from the source of a personal communication; this permission should be uploaded in ScholarOne as a supplementary document at the time of manuscript submission. Authors should verify the accuracy of all references and are responsible for ensuring that no cited reference



contains material that was retracted or found to be in error subsequent to its publication.

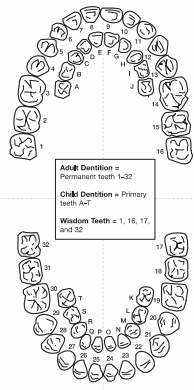
Editorial Style

Text formatting:

- Manuscripts should be submitted as Office 2010 Microsoft Word format (.docx); Word .doc files are also accepted. No paper copy will be accepted.
- Double space all text.
- Use basic fonts such as Arial, Courier, Helvetica no smaller than 11 points.

Units of measure: Authors should express all quantitative values in the International System of Units (SI units) unless reporting English units from a cited reference. Figures and tables should use SI units, with any necessary conversion factors given in legends or footnotes. For most cases spell out numbers under 10, and use numerals for numbers 10 and above — this applies to all ages, days of the month, degrees of temperature, dimensions, percentages; proportions, scores, serial numbers, speeds, sums of money, time of day, and percent values. Numbers beginning a sentence should be spelled out. Report percentages to one decimal place (i.e., XX.X percent) when sample size is ≥ 200 . Laboratory data values should be rounded to the number of digits that reflects the precision of the results and the sensitivity of the measurement procedure.

Statistical tests: The results of all statistical comparisons should be reported to include the statistical test value and the associated *P*-value and confidence interval, if appropriate. Except when one-sided tests are required by study design, such as in non inferiority trials, all reported *P*-values should be two-sided. In general, *P*-values larger than 0.01 should be reported to two decimal places, those between 0.01 and 0.001 to three decimal places. Actual *P*-values should be expressed unless $P < .001$, in which case they should be so designated. Results in the abstract and the paper generally should include estimates of effect size and 95 percent confidence intervals, not just *P*-values or statements that a difference was statistically significant.



Tooth names: The complete names of individual teeth should be given in full in the text of articles using the following convention: [(primary/permanent), (maxillary/mandibular), (right/left), (central/lateral or first/second/third), (tooth type)]. Examples: 'primary maxillary right first molar', 'permanent mandibular first molars', but 'mandibular right second pre-molar'. In tables these names may be abbreviated by the Universal system (A-T for primary teeth, 1-32 for permanent teeth).

Commercially-produced materials: Any mention of commercially produced materials, instruments, devices, software, etc., must be followed by the name of the manufacturer and the manufacturer's location in parentheses. Example: '... in an Excel spreadsheet (Microsoft, Inc, Redmond, Wash., USA).'

Abbreviations: Abbreviations should be used to make manuscripts more concise. The first time an abbreviation appears, it should be placed in bold in parentheses following the full spelling of the term [e.g., "...permanent first molars (**PFMs**)..."]

Permissions: For materials taken from other sources, a written statement from the authors and publisher giving permission to Pediatric Dentistry for reproduction must be provided. Waivers and statements of informed consent must accompany the manuscript when it is submitted for review. Waivers must accompany any photograph showing a human subject unless the subject's features are sufficiently blocked to prevent identification.

Human and animal subjects: Review of research involving human subjects is required by federal law. Federal laws and regulations regarding research on human subjects have specific requirements for Institutional Review Board (IRB) and study administration. The IRB must review research that involves the following areas, among others: medical and administrative record data; research that uses leftover tissues (eg. extracted teeth); health services research; survey research; behavioral research; biomedical and other clinical research. An official IRB-approval letter **in English dated prior to the initiation of the research** must be included with the submission. If the IRB has exempted the research from review, a copy of the letter of exemption must accompany the submission. Please state your IRB status on the title page. If applicable, the manuscript must state in the *Methods* section that the study was approved by an IRB or other institutional research ethics committee and identify the name and location of the institution housing the committee. When human subjects have been used, the text should indicate that informed consent was obtained from all participating adult subjects, and parents or legal guardians of minors or incapacitated adults. If required by the authors' institution, informed assent must have been obtained from participating children at or above the age specified by the institution. The cover letter for the manuscript must contain a statement similar to the following: "The procedures, possible discomforts or risks, as well as possible benefits were explained fully to the human subjects involved, and their informed consent was obtained prior to the investigation."

Figures: Image resolution, after cropping to the area of interest, should be 300-600 dpi. Figures should be submitted individually as .jpg or .tif files. Each separate chart, graph or photograph will be counted as a separate figure. Figures grouped together will be counted as their individual parts. Photomicrographs must include a scale labeled with a convenient unit of length (e.g., 50 μ m). Figures should be numbered in Arabic numerals in the order of the first citation in the text. Legends for each figure must be printed on a separate page. Include a key for symbols or letters used in the figures. Figures should be



saved and submitted as a separate file. Figure legends should be understandable without reference to the text. A key for any symbols or letters used in the figure should be included. Abbreviations should be explained in a footnote to the figure. If illustrations, tables, or other excerpts are included from copyrighted works, the author is responsible for obtaining written permission from the copyright holder prior to submitting the final version of the paper. Full credit must be given to such sources with a superscript reference citation in the figure legend. Reference citations in figure legends or captions should follow numerically the reference number in the text immediately preceding mention of the figure. Figures take up additional page space and should be limited to those that add value to the text.

Tables: Tables should be double-spaced, appear on separate pages, and should be titled and numbered in Arabic numerals in the order of the first citation in the text. Short headings should appear at the top of each column. Explanatory matter should be placed in captions, not in the title. For footnotes, use the following symbols in this sequence: *, **, †, ‡, §. Tables should be understandable without alluding to the text. Due to space limitations, only tables adding value to the text should be included.

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The following categories constitute the editorial actions that may be taken on a manuscript:

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Acceptance: When the reviewers and Editor have determined the revision is acceptable the author receives a letter of acceptance specifying an approximate time frame for anticipated publication. Once a manuscript is accepted, it enters the production phase of publication. At this point, no further changes can be made by the author other than those suggested by the copy-editor.

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Apêndice A - Termo de Consentimento Livre e Esclarecido

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Universidade Federal de Santa Maria
 Centro de Ciências da Saúde
 Curso de Odontologia

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Título do projeto: Longevidade das Restaurações Realizadas na Clínica de Bebês da UFSM- Estudo Retrospectivo-

Pesquisadora responsável: Profa. Dra. Marta Dutra Machado Oliveira.

Departamento: Estomatologia

Telefone para contato: (55) 3220 9266

Garantia de acesso: Em qualquer etapa do estudo, você terá acesso à pesquisadora responsável pela pesquisa para esclarecimento de eventuais dúvidas.

As informações contidas neste documento foram fornecidas pela cirurgiã-dentista Pâmela Campagna (CRO-23328) a fim de esclarecimentos e consentimento da sua participação voluntária na presente pesquisa.

O objetivo deste estudo será avaliar a longevidade e o comportamento clínico de restaurações de resina composta ("massinha branca") em dentes decíduos (de leite) realizadas por alunos do curso de Odontologia da Universidade Federal de Santa Maria. Neste estudo, vamos observar qual o tempo de duração das restaurações e as condições destas (cor, resistência, recorrência de cárie, manchamento,) além de avaliarmos a satisfação e sensibilidade dos pacientes após o tratamento.

Aceitando participar desta pesquisa, um aluno da graduação e uma pós graduanda, ambos da Odontologia da UFSM, irão realizar em ~~seu~~(a) filho(a) um exame clínico convencional(que será uma avaliação inicial das condições dentais), sendo que ambos serão orientados por um professor. Se for necessário realizar algum

Se você tiver alguma consideração ou dúvida sobre a ética da pesquisa, entre em contato com o endereço abaixo das páginas.

Comitê de Ética em Pesquisa - CEP-UFSM

Av. Roraima, 1000 - Prédio da Reitoria - 7º andar - Campus Universitário - 97105-900 - Santa Maria-RS - tel.:

(55) 32209362 - e-mail: ~~www~~ comiteeticapesquisa@small.ufsm.br. Web: www.ufsm.br/cep

procedimento, será oferecido tratamento gratuito pelos pesquisadores ou encaminhado para as clínicas da UFSM.

Esta pesquisa não apresenta grandes riscos aos pacientes, apenas algum desconforto por ficar de boca aberta, ou um pouco de sensibilidade ao jato de ar/água que são colocados sobre o dente durante a avaliação. Estes incômodos serão minimizados por pausas na avaliação, para que o paciente descanse fechando a boca, e jatos de ar/água moderados e espaçados. Quanto às vantagens, os participantes e seus responsáveis receberão instruções de higiene oral além de outras explicações sobre saúde bucal, ficando os avaliadores disponíveis para responder dúvidas.

Este estudo é de grande valia para a população em geral, visto que o uso do amálgama ("massinha preta") diminuiu consideravelmente, e a resina composta ("massinha branca") é o material mais utilizado atualmente, necessitando de estudos para seu aperfeiçoamento. Importante ressaltar que aceitando ou não participar desta pesquisa, os voluntários chamados terão direito a tratamento odontológico nas clínicas da UFSM, ambos com a mesma agilidade, sendo que sua não participação não terá nenhum prejuízo. Do mesmo modo, se houver a vontade de retirar-se do estudo, este direito é garantido sem qualquer penalidade.

Todas as informações obtidas deste estudo serão analisadas pelos avaliadores com garantia de sigilo da identificação dos voluntários, sendo que estes terão o direito de informações sobre os resultados da pesquisa.

Os participantes não terão despesas relacionadas ao estudo, e também não há compensação financeira pela sua participação. Se existir qualquer despesa adicional, ela será absorvida pelo orçamento da pesquisa. Em casos de danos, comprovadamente decorrentes da participação na pesquisa, há garantia de indenização.

Você está recebendo uma cópia deste documento, sendo que outra cópia fica de posse do pesquisador.

Eu, _____ acredito ter sido suficientemente informado a respeito das informações que li ou que foram lidas para mim, descrevendo o estudo "Longevidade das Restaurações Realizadas na Clínica de Bebês UFSM- Estudo Retrospectivo". Eu discuti com a pesquisadora Pâmela Campagna sobre a minha decisão de autorizar a participação de meu (minha) filho(a) nesse estudo. Ficaram claros para mim quais são os propósitos do estudo, os procedimentos a serem realizados, seus desconfortos e riscos, as

Se você tiver alguma consideração ou dúvida sobre a ética da pesquisa, entre em contato com o endereço abaixo das páginas.

Comitê de Ética em Pesquisa - CEP-UFSM

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garantias de confidencialidade e de esclarecimentos permanentes. Ficou claro também que a participação é isenta de despesas. Concordo voluntariamente na participação do _____ (a) _____ neste estudo e poderei retirar o meu consentimento a qualquer momento, antes ou durante o mesmo, sem penalidades ou prejuízo ou perda de qualquer benefício que possa ter adquirido.

Santa Maria, _____ de _____ de 2016.

Assinatura do responsável legal

Número do documento de identidade

Assinatura da pesquisadora responsável

Prof. Dra. Marta Dutra Machado Oliveira

Se você tiver alguma consideração ou dúvida sobre a ética da pesquisa, entre em contato com o endereço abaixo das páginas.

Comitê de Ética em Pesquisa - CEP-UFSM

Av. Roraima, 1000 - Prédio da Reitoria - 7ª andar - Campus Universitário - 97105-900 - Santa Maria-RS - tel.:

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Apêndice B – Termo de confidencialidade

TERMO DE CONFIDENCIALIDADE

Universidade Federal de Santa Maria
 Centro de Ciências da Saúde
 Curso de Odontologia

TERMO DE CONFIDENCIALIDADE

Título do projeto: Longevidade das Restaurações Realizadas na Clínica de Bebês da UFSM - Estudo Retrospectivo-

Pesquisador responsável: Prof. Dra. Marta Dutra Machado Oliveira
 Instituição/Departamento: Departamento de Estomatologia

Telefones para contato: (55) 3220 9266

Todos os participantes desta pesquisa terão sua privacidade preservada, sendo que os dados serão coletados pelos pesquisadores através de exame clínico e fichas clínicas de atendimentos realizados na clínica de Odontopediatria da Universidade Federal de Santa Maria. Todas as informações coletadas neste estudo serão utilizadas, única e exclusivamente, para execução do presente projeto.

As informações somente poderão ser divulgadas de forma anônima e serão mantidas na UFSM - Rua Marechal Floriano Peixoto, 1184, CEP - 970 15372 - Santa Maria - RS, por um período de cinco anos, sob a responsabilidade da Prof. Dra. Marta Dutra Machado Oliveira. Após este período os dados serão destruídos.

Este projeto de pesquisa foi revisado e aprovado pelo Comitê de Ética em Pesquisa da UFSM em __/__/____, e recebeu o número CAAE _____.

Santa Maria, ____ de _____ de 2016.

 Pesquisador responsável

Telefone para contato: (55) 8148 3220

Se você tiver alguma consideração ou dúvida sobre a ética da pesquisa, entre em contato com o endereço abaixo das páginas.
 Comitê de Ética em Pesquisa - CEP-UFSM
 Av. Roraima, 1000 - Prédio da Reitoria - 7º andar - Campus Universitário - 97105-900 - Santa Maria-RS - tel.: (55) 32209362 - e-mail: comiteeticapesquisa@small.ufsm.br Web: www.ufsm.br/cep

Apêndice C – Ficha Clínica utilizada na Clínica de Bebês da UFSM

Ministério da Educação
 Universidade Federal de Santa Maria
 Centro de Ciências da Saúde
 Departamento de Estomatologia
 Disciplina de Clínica de Bebês

PPGCO
Programa de Pós-graduação em Ciências Odontológicas -
 Área de Especialização em Odontopediatria - UFSM

DATA: ___/___/___
 ALUNOS: _____

PACIENTE:
 Data de Nascimento: _____
 Nome do pai: _____
 Nome da mãe: _____
 Endereço: _____
 Telefones(s): _____
 Naturalidade: _____

Local de nascimento: () Hospital () Outro
 Pré-natal: () Sim () Não Tipo de parto: () C () N
 Tempo: () Prematuro () A termo
 Tem acompanhamento pediátrico: () Sim () Não _____

Comentários adicionais relevantes de saúde progressiva:

Uso de chupeta: () Sim () Não
 Introdução () Nascimento (1^o dias) () Antes de 6 meses () Após 6 meses
 Complemento () Mel () Açúcar () Medicamento () Chá
 Frequência () Menos de 2 horas/dia () de 2 a 6 horas/dia
 () Mais de 6 horas/dia () Mais de 12 horas/dia
 Sucção digital () Sim () Não
 () Polegar () Indicador

Erupção do 1º dente () Ao nascimento () Antes 6 meses () Entre 6 e 8 meses
() Entre 9 e 12 meses () Após 12 meses

Indicação do 1º grupo () II () IS

Sintomas () Irritabilidade () Choro () Salivação aumentada
() Febre () Diarréia () Sonolência

Dieta

Introdução de açúcar. Quando? _____

Alimentação materna exclusiva até 6 meses? () Sim () Não

Introdução mamadeira. Quando? _____

Conteúdo () Leite bovino () Leite ovino () Leite caprino
() Leite soja () Leite arroz () Suco natural
() Suco industrial () Chá () Gelatina
() Café () Refrigerante () Leite em pó

Adicionais () Açúcar branco () Açúcar mascavo () Mel
() Farináceos () Aveia () Acheocolatados

Frequência () - de 3x () de 3 a 6x () + de 6x

Uso de copinho () Sim () Não

Alimentos sólidos () Frutas () Biscoitos () Bolos () Guloseimas

Alergias Manifestadas () Pó () Mofo () Alimentos () Modificação de temperatura
() Medicamentos

Especificações: _____

Sintomas: () Respiração Bucal () Ronco () Bruxismo
() Respiração Mista () Coriza () Tosse
() Adenóide hipertrofica (diagnóstico médico)
() Amígdala hipertrofica (diagnóstico médico)

Escovação () 1x ao dia () 2x ao dia () 3x ou mais
() Mãe () Pai () Responsável () Criança
() Escova manual () Escova elétrica

Creme dental → _____

História de Traumatismo → _____

EXAME CLÍNICO

	V	P/L	M	D	O
55					
54					
53					
52					
51					
61					
62					
63					
64					
65					
75					
74					
73					
72					
71					
81					
82					
83					
84					
85					

OBSERVAÇÕES CLÍNICAS

55	
54	
53	
52	
51	
61	
62	
63	
64	
65	
75	
74	
73	
72	
71	
81	
82	
83	
84	
85	

ICDAS	Características
0	Superfície lisa
1	MB visível com sondagem
2	MB visível sem sondar
3	Microcavidade em esmalte
4	Sombreamento em dentina
5	Cavidade em dentina (até 1/2 de superfície)
6	Cavidade em dentina (destruição coronária)

* Ativa (x) ou Inativa ()

**PERFIL DO PACIENTE
DOENÇA CÁRIE**

- Livre de cárie
 Sem fatores etiológicos
 Com fatores etiológicos
- Com experiência de cárie
 Sem atividade
 Com atividade
- Sem necessidades invasivas
 Com necessidades invasivas

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Este termo tem como objetivo informar, esclarecer e solicitar autorização para a participação de seu/sua filho (a) no projeto Clinica da Bebê a ser desenvolvido nas Clínicas do curso de Odontologia - UFSM pelos mestrandos e demais acadêmicos, sob orientação da professora Dra. Maria Dulce Machado Oliveira. A realização dos procedimentos tem como objetivo prevenção e os tratamentos necessários a fim de preservar a saúde e apoiar desenvolvimento da criança.

É necessário ressaltar que poderão ocorrer alguns desconfortos relacionados às técnicas e que são listados a seguir:

- . Sensibilidade no momento da aplicação;
- . Desconforto devido a sensação agradável;
- . Reação adversa causando choro em função do aparelho utilizado nos procedimentos utilizados;
- . Sensação de pressão do gampo do isolamento elástico;
- . Cansaço relativo em função dos procedimentos com maior durabilidade;
- . Sensibilidade pós aplicação;
- . Possibilidade de inervação das técnicas realizadas pela persistência de algumas vezes.

Para minimizar ou solucionar os possíveis riscos serão efetuados os seguintes procedimentos:

- . Serão empregadas todas as recursos para a diminuição do desconforto no ato anestésico, tais como: aplicação de anestésico tópico, aquecimento do gel, injeção lenta, utilização de mucosa;
- . A duração do efeito poderá ser de algumas horas após o atendimento, sendo para seu filho(a) não morder lábios, bochechas ou língua, se tiver mais dúvidas procure orientação;
- . Se seu filho(a) chorar isso deve ser encarado de maneira normal, pois nesta fase da vida existe insegurança e medo;
- . Em caso de sensibilidade devido ao gampo do isolamento absoluto, poderá ser recitado analgésico (remédio para alívio da dor) já na saída do atendimento, solucionando algumas questões de sensibilidade de uma forma geral;
- . Como em qualquer tratamento clínico, é possível que o tratamento não dê certo, embora os procedimentos sejam realizados dentro do rigor técnico, por profissional treinado.

Caso não tenha entendido qualquer informação citada neste termo, peça ao profissional que explique de novo.

Os pacientes participantes terão assistência na clínica de odontologia e, além disso, serão realizadas orientações periódicas sobre saúde bucal, o que contribuirá para a qualidade de vida de toda sua família. Todas as dados de seu/sua filho(a) serão mantidos em sigilo.

Eu, _____, RG _____, abaixo assinado, autorizo a participação de meu/minha filho/filha, _____, como paciente no projeto Clinica da Bebê. Declaro que fui suficientemente informado a respeito das informações que li ou que foram lidas para mim. Ficaram claros quais os procedimentos a serem realizados, seus desconfortos, as garantias de confidencialidade e de esclarecimentos permanentes.

Local e data:

Nome e Assinatura do sujeito ou responsável:

Declaro que obtive de forma apropriada e voluntária o Consentimento Livre e Esclarecido deste representante legal para a participação do paciente.

Santa Maria, ____ de _____ de 201__.

Aluno operador responsável _____

