UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL
FACULDADE DE ODONTOLOGIA

CÁSSIA MENDES DA SILVA

SOBREVIDA E FATORES ASSOCIADOS ÀS FALHAS DE RESTAURAÇÕES ATRAUMÁTICAS EM CRIANÇAS COM CÁRIE NA PRIMEIRA INFÂNCIA: ESTUDO RETROSPECTIVO

Porto Alegre
2019

CÁSSIA MENDES DA SILVA

SOBREVIDA E FATORES ASSOCIADOS ÀS FALHAS DE RESTAURAÇÕES ATRAUMÁTICAS EM CRIANÇAS COM CÁRIE NA PRIMEIRA INFÂNCIA: ESTUDO RETROSPECTIVO

Trabalho de Conclusão de Curso apresentado ao Curso de Graduação em Odontologia da Faculdade de Odontologia da Universidade Federal do Rio Grande do Sul, como requisito parcial para obtenção do título de Cirurgiã-Dentista.

Orientadora: Tathiane Larissa Lenzi.

Porto Alegre

2019

CÁSSIA MENDES DA SILVA

SOBREVIDA E FATORES ASSOCIADOS ÀS FALHAS DE RESTAURAÇÕES ATRAUMÁTICAS EM CRIANÇAS COM CÁRIE NA PRIMEIRA INFÂNCIA: ESTUDO RETROSPECTIVO

Trabalho de Conclusão de Curso apresentado ao Curso de Graduação em Odontologia da Faculdade de Odontologia da Universidade Federal do Rio Grande do Sul, como requisito parcial para obtenção do título de Cirurgiã-Dentista.

Orientadora: Tathiane Larissa Lenzi.

Porto Alegre, 12 de dezembro de 2019.

Tathiane Larissa Lenzi

Universidade Federal do Rio Grande do Sul

Marcia Cançado Figueiredo

Universidade Federal do Rio Grande do Sul

Daniel Demétrio Faustino da Silva

Cirurgião-dentista

AGRADECIMENTOS

Foi um longo período da minha vida até chegar a este momento. E olhando para trás vejo uma trajetória linda com muitos desafios que me fizeram crescer muito e nesse caminho tiveram várias figuras importantes para a minha formação, não só como profissional, mas como pessoa.

Quero começar agradecendo aos meus pais, que sempre me apoiaram em todas as minhas escolhas e que torcem pelo meu sucesso e felicidade como ninguém. Obrigada por serem meu suporte em todos os momentos que precisei, obrigada pela base que vocês me dão, devo tudo isso a vocês. A minha família que sempre torce pela minha felicidade.

Ao meu noivo, não tenho nem palavras que expressem o apoio e amor que me dá, obrigada por nunca me deixar desistir, por ser meu suporte quando tudo parecia que não daria certo. Obrigada por tudo!

Quero muito agradecer ao anjo que entrou na minha vida, minha orientadora, Tathi, que é demais, perfeita, melhor orientadora que alguém pode ter, que tornou todo esse processo de conclusão de curso tão leve e prazeroso, obrigada por tudo. E que profissional és, tenho muito orgulho de poder ter aprendido e convivido com ela mais de perto. Vou levar vários ensinamentos seus na minha vida.

Agradeço a Márcia que é a minha segunda mãe na faculdade, me acolheu no início e nunca mais nos soltamos, obrigada por todos os ensinamentos, por todo apoio nos momentos difíceis, por toda a tua alegria contagiante, obrigada a ensinar a mim e vários alunos que tem o prazer de aprender contigo a pensar de uma maneira mais humanizada, a sair da visão da faculdade, isso com certeza nos torna profissionais diferentes e melhores.

Agradeço também a todos os professores que tive o prazer de aprender tanto, cada um com sua maneira, e que foram muito importantes para o meu processo de formação. Gostaria de agradecer em especial a uma professora que me abriu as portas da odontopediatria logo no início do curso, me permitindo acompanhar a clínica infanto-juvenil e me encantando com seu jeito de atender as crianças, Adriela obrigada por me ensinar tanto.

RESUMO

O objetivo deste estudo retrospectivo foi investigar a sobrevida e os fatores de risco associados às falhas de restaurações atraumáticas em crianças com cárie na primeira infância. Um total de 286 restaurações atraumáticas em molares decíduos provenientes de prontuários de 137 crianças na primeira infância atendidas por alunos de graduação na Bebê Clínica da Faculdade de Odontologia da Universidade Federal de Porto Alegre foram incluídas no estudo. Os procedimentos restauradores foram realizados sem anestesia, sob isolamento relativo, após remoção seletiva de tecido cariado com colheres de dentina e uso de cimento de ionômero de vidro indicado para Tratamento Restaurador Atraumático (ART) (Vitro Molar; DFL, Rio de Janeiro, Brasil). As seguintes variáveis foram coletadas dos prontuários: gênero (feminino ou masculino), nível de escolaridade materna (até 8 anos ou mais de 8 anos), risco de cárie (moderado: dentes cariados, com extração indicada e obturados (ceo-d) até 6 ou alto: ceo-d maior que 6), número de lesões de cárie ativas (até 8 ou mais do que 8), frequência de dieta cariogênica (até 4 vezes ao dia ou acima de 4 vezes), mamadeira diurna (sim ou não), mamadeira noturna (sim ou não), uso de dentifrício fluoretado ($\geq$ 1000 ppm) (sim ou não), frequência de escovação (uma vez ao dia ou duas ou mais), uso de fio dental (sim ou não), tipo de arco (superior ou inferior), tipo de dente (primeiro ou segundo molar) e número de superfícies restauradas (uma ou duas ou mais). Risco de cárie (ceo-d) e número de lesões de cárie ativas foram categorizadas usando a mediana como ponte de corte. Falha foi definida como necessidade de reintervenção na restauração, tratamento pulpar ou extração. A longevidade das restaurações até 1 ano 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 ($p<0,05$). As restaurações atraumáticas realizadas em crianças com alto risco de cárie apresentaram 2,71 vezes mais risco de falha do que aquelas feitas em crianças com risco moderado de cárie na análise bruta ($p=0,03$). No entanto, a associação perdeu significância no modelo ajustado ($p=0,07$). A taxa global de sobrevida das restaurações foi de 85 % após 1 ano de acompanhamento. Com base nos resultados deste estudo, pode-se concluir que as restaurações atraumáticas realizadas em crianças com cárie na primeira infância apresentaram sobrevida satisfatória após 1 ano de acompanhamento.

Palavras-chave: Análise de sobrevida. Dente decíduo. Falha de restauração dentária. Odontopediatria

ABSTRACT

The purpose of this retrospective study was to investigate the survival and risk factors associated with failures of the atraumatic restorations in clidren with early childhood caries. A total of 286 atraumatic restorations in primary molars from records of 137 children in the early childhood attended by undergraduate students at Baby Clinic of the School of Dentistry of the Federal University of Porto Alegre were included in the study. Restorative procedures were performed without anesthesia, under relative isolation, after selective tissue removal with spoon excavators and use of glass ionomer cement indicated for Atraumatic Restorative Treatment (ART) (Vitro Molar; DFL, Rio de Janeiro, Brazil). The following variables were collected from dental records: gender (boys or girls), mother's school level (up to eight years of formal education or more than eight years), caries risk (moderate: decayed, missing and filled - teeth (dmf-t) until six or high: dmf-t higher than six), number of active caries lesions (until eight or more than eight), frequency of cariogenic diet (up to four times daily or more than four times), daytime bottle feeding (yes or no), night bottle feeding (yes or no), use of standard fluoride toothpaste (≥ 1000 ppm) (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 (first or second molar), and number of restored surfaces (one or two or more). Caries experience (dmf-t index) and number of active caries lesions were categorized using the median as the cut- point. Failure was defined as the need for restoration reintervention, pulp treatment or extraction. The restorations' longevity up to 1 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 ($p<0.05$). ART restorations performed in children with high caries risk had 2.71 times more risk of failure than those placed in children with moderate caries risk ($p=0.03$). However, the association has lost significance in the adjusted model ($p=0.07$). The overall survival rate of the restorations was 85% after 1 year of follow-up. Based on the results of this study, it can be concluded that atraumatic restorations performed in children with early childhood caries had a satisfactory survival after 1 year of follow-up.

Keywords: Survival analysis. Tooth deciduous. Dental restoration failure. Pediatric dentistry.

SUMÁRIO

1 INTRODUÇÃO

Cárie na primeira infância é definida como a presença de uma ou mais superfícies dentárias cariadas (cavitadas ou não), perdidas (devido à lesão cariosa) ou restauradas em dentes decíduos de crianças até 5 anos de idade (AAPD, 2017; TINANOFF *et al.*, 2019). A cárie dentária em crianças de pouca idade representa um importante problema de saúde pública, uma vez que apresenta maior risco de desenvolvimento de novas lesões cariosas nas dentições decídua e permanente (AL-SHALAN *et al.*, 1997; TINANOFF *et al*., 2019).

Além disso, a cárie na primeira infância pode se manifestar de forma grave, levando à grande destruição dos tecidos dentários em um curto período de tempo e, consequentemente, impactando negativamente na qualidade de vida da criança e seu núcleo familiar (MARTINS-JÚNIOR *et al*., 2013). Na primeira infância, esta doença está intimamente ligada a inadequado hábitos de higiene e fatores dietéticos (RODRIGUES; SHEIHAM, 2000; SEOW *et al*., 2009; TINANOFF *et al.*, 2019), principalmente a alimentação associado ao sono, com produtos que contenham carboidratos fermentáveis, em especial a sacarose (SEOW *et al.*, 2009).

Procedimentos restauradores atrelados à medidas preventivas são rotineiramente realizados na prática clínica visando o controle da rápida progressão da doença e o restabelecimento funcional dos tecidos dentários acometidos por cárie (FINUCANE, 2012). No entanto, o tratamento restaurador é, por vezes, de difícil execução devido às dificuldades de manejo comportamental dos bebês (WAGGONER, 2015).

O Tratamento Restaurador Atraumático (ART) se insere na filosofia de tratamento restaurador definitivo de baixo custo, baseado na Mínima Intervenção. Esta técnica preconiza a remoção seletiva do tecido cariado com o auxílio de instrumentos manuais e o selamento de cavidades rasas e médias e sulcos adjacentes com cimento de ionômero de vidro de alta viscosidade, sob isolamento relativo do campo operatório (FRENCKEN; HOLMGREN, 1999). A relativa simplicidade da técnica permite o controle da dor, tornando desnecessária a utilização de anestesia local. Desta maneira, ocorre redução da ansiedade, favorecendo o bom comportamento dos pacientes durante a realização dos procedimentos clínicos. Além disso, a redução no tempo de trabalho (FRENCKEN; HOLMGREN, 1999) e ausência do barulho referente à utilização do motor também contribuem para o atendimento com menor grau de desconforto (SCHRIKS; VAN AMERONGEN, 2003). Sendo assim, o ART apresenta potencial para ser bem aplicado nos bebês (FRENCKEN *et al*., 2012).

De fato, tem sido reportada alta taxa de sobrevida de restaurações ART em superfícies

oclusais para as dentições decídua e permanente (FRENCKEN *et al.*, 2004; VAN'T HOF *et al.*, 2006) e similar longevidade das restaurações ocluso-proximais realizadas pelas técnicas restauradoras atraumática e convencional em dentes decíduos (TEDESCO *et al.*, 2017). No entanto, esses estudos são focados no comportamento de restaurações atraumáticas em dentes decíduos de crianças em idade escolar.

O nível de cooperação da criança durante o tratamento, o consentimento dos pais, a variabilidade na quantidade de estrutura dentária remanescente e as diferenças em termos de risco de cárie são barreiras para a realização de ensaios clínicos que investiguem a longevidade de restaurações realizadas na primeira infância (WAGGONER, 2015). Assim, estudos retrospectivos podem fornecer dados que refletem a sobrevida dos tratamentos realizados na prática clínica, onde variáveis relacionadas ao operador e ao paciente não são controladas nem padronizadas como em ensaios clínicos randomizados.

A despeito das evidências disponíveis, é incontestável que ainda existe uma lacuna na literatura acerca do comportamento clínico de restaurações na dentição decídua, especialmente na primeira infância. Sendo assim, o objetivo do presente estudo retrospectivo será avaliar a sobrevida e os fatores de risco associados com falhas de restaurações atraumáticas realizadas em crianças com cárie na primeira infância.

2 ARTIGO CIENTÍFICO

Survival and associated risk factors of atraumatic restorative treatment restorations in children with early childhood caries: A retrospective university-based study

Short title: ART survival in the childhood

Cássia Mendes da Silva
Undergraduate Student
Faculty of Dentistry, Department of Surgery and Orthopedics, Federal University of Rio Grande do Sul, Brazil
Ramiro Barcelos 2492, 90035-003, Porto Alegre, RS, Brazil
Contribution to the paper: Performed the methodology and wrote the manuscript

Marcia Cançado Figueiredo
Associate Professor
Faculty of Dentistry, Department of Surgery and Orthopedics, Federal University of Rio Grande do Sul, Brazil
Ramiro Barcelos 2492, 90035-003, Porto Alegre, RS, Brazil
Contribution to the paper: Contributed substantially to discussion and proofread the manuscript

Luciano Casagrande
Associate Professor
Faculty of Dentistry, Post-Graduate Program in Pediatric Dentistry, Federal University of Rio Grande do Sul, Brazil
Ramiro Barcelos 2492, 90035-003, Porto Alegre, RS, Brazil
Contribution to the paper: Consulted on and performed statistical evaluation and proofread the manuscript

Tathiane Larissa Lenzi
Assistant Professor
Faculty of Dentistry, Post-Graduate Program in Pediatric Dentistry, Federal University of Rio Grande do Sul, Brazil
Ramiro Barcelos 2492, 90035-003, Porto Alegre, RS, Brazil
Contribution to the paper: idea and proofread the manuscript.

✉**Corresponding author:**
Tathiane Larissa Lenzi
Faculty of Dentistry, Post-Graduate Program in Pediatric Dentistry, Federal University of Rio Grande do Sul
Ramiro Barcelos 2492, 90035-003, Santa Cecília, Porto Alegre, RS, Brazil
Phone number: +55 51 3308 5493 E-mail: tathilenzi@hotmail.com

Abstract

Purpose: This retrospective university-based study assessed the survival and risk factors associated with failure of atraumatic restorative treatment (ART) restorations placed in children with early childhood caries (ECC). *Methods:* The sample comprised of 286 restorations from records of 137 children attended in a university dental clinic. Date of restoration placement, any re-intervention (failure), and the patient's last check-up were collected. The restorations' longevity up to 1 year of follow-up was assessed by Kaplan-Meier survival test. Multivariate Cox regression analysis with shared frailty was used to evaluate the factors associated with failures ($p<0.05$). *Results:* The mean age of the children was 2.3 years (±0.6), presenting a decayed, missing, and filled teeth (dmft) mean of 6.3 (± 3.2). Mean survival time was 11.1 months (95%CI: 10.8-11.4), with 85.0% of the restorations surviving after 1 year. Caries experience was associated with risk of restoration failure in crude analysis; where ART restorations performed in children with high caries experience had 2.71 times more risk of failure than those placed in children with moderate caries experience ($p=0.03$). However, the association lost its significance in the adjusted model ($p=0.07$). *Conclusion:* ART is a patient-friendly approach to manage ECC that promotes satisfactory restorations' survival after 1 year.

Keywords: atraumatic restorative treatment, baby bottle-fed tooth decay, survival analysis

Introduction

Early childhood caries (ECC) is defined as the presence of one or more decayed (noncavitated 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 highly prevalent worldwide disease that has high costs to society and has a major impact on parents' and children's quality of life[2].

Restorative therapy is regularly performed in daily Pediatric clinic for treating rapid and extensive destruction of primary teeth caused by ECC[3]. Nevertheless, management of ECC is particularly challenging for dental practitioners because of difficulties with behavior management in infants[4]. Atraumatic restorative treatment (ART) is a patient-friendly approach that simplifies the restorative procedure through the exclusive use of hand instruments, followed by the application of high-viscous glass ionomer cement[5]. Furthermore, ART is less painful and anxiety-inducing than conventional restorative treatments and rarely requires local anesthesia[6].

Although ART was originally developed for use in underserved communities, its use has now been extended to private practice in developed countries[7]. The rationale for its widespread use lies in the fact that the principles of ART fit well with minimal intervention dentistry[6]. The current scientific evidence suggests that ART is an appropriate procedure to treat occlusal and occluso-proximal cavities in primary teeth[8,9]. These findings, however, are focused on the survival rates of ART in primary teeth in school children. A recent 1-year pragmatic randomized controlled trial[10] reported that fewer children with ECC treated with ART approach were referred for specialist pediatric dental treatment in comparison with conventional treatment performed under general anesthesia, leading to cost saving of 63%[11].

It has been shown that the presence of enamel defects and high levels of mutans streptococci are strongest risk factors associated with ECC[12]. Additionally, presence of

dentinal caries, frequent consumption of sweetened foods, poor oral hygiene, and presence of visible plaque are significant risk factors[12]. To the best of our knowledge, no previous study has investigated the individual and tooth related factors that may dictate the survival time of ART in children with ECC.

Therefore, this retrospective university-based study aimed to evaluate the survival and risk factors associated with failure of ART restorations placed in children with ECC.

Methods

Ethical aspects

The local Research Ethics Committee approved the research protocol. For the collection of data, the parents or guardians signed written informed consent. The personal information of the patients was kept confidential. Present observational study conforms to the STROBE statement.

Sample collection

This retrospective university-based study was conducted at the Baby Clinic of the School of Dentistry, Federal University of Rio Grande do Sul, Brazil. The convenience sample comprised of children (0-3 years old) treated during the period 2010-2018 by fourth and fifth year undergraduate dental students, supervised by professors (pediatric dentistry specialists). To be included in the study, children should have received at least one ART restoration in primary molars. Moreover, patients should have at least one visit at the clinic after the restoration placement. Children with compromised systemic health were excluded from the study.

Of a total of 1,002 clinical records, 164 had ART restorations in primary teeth. Six patients were excluded because they did not return to dental clinic after restoration was

performed. Additionally, 21 records presented incomplete data, hence, were excluded from the study. Thus, 137 children were included in the study.

Restorative procedures

The clinical approach followed the ART guidelines proposed by Frencken and Holmgren[5]. No local anesthesia was used during treatment. The plaque was removed, and an enamel hatchet was used to access underlying softened dentin when necessary. All procedures were performed under relative isolation of the operatory field with cotton rolls. Hand excavators compatible with the size of the carious cavity were used to perform selective carious tissue removal up to firm dentin[13]. Visual and tactile clinical criteria were used to guide to selective carious tissue removal up to firm dentin on the pulp floor. Excavation was stopped when hardened, dried dentin with a leathery consistency (resistant to hand excavator) was achieved[13]. Complete carious tissue removal was performed from the cavosurface margins and lateral walls. Conditioning of the cavity was done with 11.5% polyacrilic acid solution (DFL, Rio de Janeiro, Brazil) for 10 s, followed by rinsing with water and drying with cotton pellets. Moisture control was done with cotton rolls. The cavity was restored with glass ionomer cement (Vitro Molar; DFL, Rio de Janeiro, Brazil). The material was hand mixed according to the manufacturer instructions (powder/liquid ratio 1:1), and inserted into the cavity with a #1 spatula. A thin layer of petroleum jelly was rubbed over the index finger and the restoration was pressed for 20 s. For occluso-proximal cavities, an adapted matrix strip with a wooden wedge was used to maintain it in place, providing appropriate contour to the restoration.

After the initial set (approximately 5 min), occlusion was checked and if necessary, sharp hand instruments were used for adjustments. A new layer of petroleum jelly was applied to the restoration and parents or guardians were instructed to not offer solid food to

children for at least 1 hour after restorative treatment.

Data collection

The restoration history was collected from the patient records. The 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), caries experience (moderate: decayed, missing, and filled teeth (dmft) until six or high: dmf-t higher than six), number of active caries lesions (until eight or more than eight), frequency of cariogenic dietary carbohydrate - mainly sugar intake (up to four times daily or more than four times), daytime bottle feeding (yes or no), nighttime bottle feeding (yes or no), use of standard fluoride toothpaste (≥ 1000 ppm) (yes or no), frequency of brushing (once a day or twice or more times), flossing use (yes or no), type of arch (upper or lower), type of tooth (first or second molar), and cavity type (occlusal or occluso-proximal). Caries experience (dmft index), and number of active caries lesions of the patients at the first appointment were categorized using the median as the cutoff point.

Date of restoration placement and any re-intervention as well as the patient's last check-up were considered to calculate the longevity of restorations. When no intervention was necessary on the restoration until the last check-up (date of censoring), the restoration was considered satisfactory. A restoration was considered a failure if it was replaced or repaired, or if another treatment affecting the restoration was necessary (endodontic treatment or tooth extraction).

Statistical analysis

The descriptive distribution provides summary statistics according to the independent variables. Survival analysis was performed to assess factors associated with the restorations' longevity, and data were censored at 1 year of follow-up. Survival curves of the restorations

were assessed through the Kaplan-Meier method. Curves were also adjusted by individuals to take into account clustering of data (more than one restoration per subject).

Multivariate Cox regression models with shared frailty were performed to identify factors associated with failure of 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 $p < 0.20$ were selected to be included in the final model. A significance level of 5 % was considered significant. Data analyses were performed with STATA software 12.0 (Stata Corp., College Station, TX, USA).

Results

Two hundred and eighty-six atraumatic restorations placed in 137 patients were included in the analysis. The mean age of the children was 2.3 years (±0.6), presenting a decayed, missing, and filled teeth (dmft) mean of 6.3 (± 3.2).

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, 163 (53.0%) were placed in girls. Most restorations were placed in children who did not use dental floss (93.0%) and had their teeth brushed twice or more times per day (87.8%) with a standard fluoride toothpaste (80.1%). Additionally, the restorations were more common in children who were bottle fed during the daytime (89.5%) and nighttime (87.8%), and who ingested sugar up to four times daily (79.4%). The majority of the restorations (82.9%) were placed in first primary molars. Occlusal restorations were more frequent (93.0%) than occluso-proximal

ones (7.0%) as well as those performed in the lower arch (54.2%) when compared with the upper arch (45.8%). The overall success rate was 89.9% (257/286).

Table 2 shows the unadjusted and adjusted HR for failures according to independent variables. Caries experience was associated with risk of restoration failure in crude analysis, where ART restorations performed in children with high caries experience had 2.71 times more risk of failure than those placed in children with moderate caries experience (p=0.03). However, the association lost its significance in the adjusted model (p=0.07).

The cumulative restoration survival estimate is shown in Figure 1. Mean survival time was 11.1 months (95%CI: 10.8-11.4), with 85.0% of the restorations surviving after 1 year of evaluation.

Discussion

This is the first retrospective study that investigated the survival and factors associated with failures of the ART restorations performed in infants with ECC. The overall survival rate of the restorations was 85.0% after 1 year of follow-up.

A recent systematic review[14] reported that the survival rate of single- and multiple-surfaces ART restorations in primary teeth over the first 2 years were 94.3% and 65.4%, respectively. It is important to highlight that these findings are based on restorations placed in school children by trained and experienced operators. The reduced ability to manage a younger child's behavior in association with the limited technical experience of the students could contribute to the subtle low survival of restorative treatment found in our study.

A higher number of surfaces included in cavity preparations can decrease the tooth resistance to fracture [15–17], even in primary teeth that have lower occlusal loading compared to permanent ones [18]. Furthermore, there is a greater failure when proximal surface is involved due to recurrent caries in the cervical wall[19]. This is more critical in primary teeth considering the anatomical characteristics, such as lower height of crowns and contact area between

molars nearer to cervical region. In our study, the number of restored surfaces was not associated with risk of restoration failure, probably because most ART restorations (93.0%) were restricted to the occlusal surface.

ART restorations performed in children with high caries experience had 2.71 times more risk of failure than those placed in children with moderate caries experience in crude analysis. However, the association lost its significance in the adjusted model (p=0.07). It is relevant to note that sample presented a decayed, missing, and filled teeth (dmft) mean of 6.3 (± 3.2), i.e., considerably high[20]. Moreover, the restorations were similarly distributed between infants categorized as having a high and moderate caries experience.

It has been shown that sweetened food consumption more than once per day and tooth brushing less than once daily are significant factors associated with ECC[12]. In our study, the survival of the restorations was not influenced by frequency of cariogenic dietary carbohydrate and brushing. Although ART restorations were more common in children who ingested sugar up to four times daily, the majority of the infants had their teeth brushed two or more times per day with standard fluoride toothpaste. There is strong evidence that only toothpaste at fluoride concentrations of 1000 ppm and above has a significant caries-preventive effect in children, even younger than six years[21,22].

Few children received breastfeeding for more than 6 months in our sample. Thus, we evaluated only if bottle feeding had a detrimental effect on restoration survival. Both daytime and nighttime bottle feeding were not associated with risk for restoration failure. In line with current scientific literature, no association of nighttime bottle feeding with risk factor for ECC has been shown[12]. However, the evidence level is insufficient for definitive conclusions about this question.

Bottle feeding has, however, been associated with caries in molars[23], corroborating our findings. The majority of the active and cavitated caries lesions were observed in primary

molars. It is important to highlight that infants were included in a periodic recall program at the Baby Clinic based on guidance and intensive counselling with parents according to individual caries risk factors. Additionally, information related to alimentary practices was collected before treatment data. We believe that, in most cases, a reduction in frequency of bottle-feeding practice, especially at night, as well as, sugar consumption occurred.

The high viscous glass ionomer cement is the material of choice for ART[6] because it has good biocompatibility, favorable setting time, release of fluoride, and formation of a chemical bond with enamel and dentin[24,25]. Nevertheless, the relatively high cost of these materials jeopardizes their use, either in public health or private practice in low-income populations.

In an attempt to overcome this problem, low-cost Brazilian brands of glass ionomer cements were developed such as Vitro Molar (DFL, Rio de Janeiro, Brazil). Although this material is not high viscous glass ionomer cement, manufacturers recommend it for ART. This material has been frequently used in low-income communities, not only in Brazil. A recent study[26] found similar clinical performance between Vitro Molar and high-viscous glass ionomer cement (Ketac Molar Easy Mix; 3M ESPE, St. Paul, USA) in occlusal ART restorations in primary molars after 4 years of follow-up.

Regarding the limitations of this study, it must be considered that, in practice-based retrospective studies, neither patients nor operators were not specifically selected. However, this study could reflect the real clinical situation, where the lack of controlled settings may provide higher external validity, making extrapolation of results more reliable to daily practice.

A previous study[27] found an annual rate failure (ARF) of 20.0% for composite resin restorations performed in children with ECC after 2 years of follow-up, while our study showed an ARF of 15.0% for ART restorations after 1 year. Based on these findings and

considering that ART is a more patient-friendly approach than conventional restorative treatment with composite resin, clinicians may opt for ART to restore primary molars, mainly in young and uncooperative patients.

Conclusion

Based on the results of this study, the following conclusion can be made:

Atraumatic restorative treatment restorations placed in children with ECC presented satisfactory survival after 1 year of follow-up.

Conflict of interest

The authors declare no conflict of interest.

References

1. American Academy of Pediatric Dentistry (AAPD). Policy on early childhood caries (ECC): Classifications, consequences and preventive strategies. Ped Dent 2016;38:26-17.

2. Tinanoff N, Baez RJ, Diaz Guillory C, Donly KJ, Feldens CA, McGrath C, et al. Early childhood caries epidemiology, aetiology, risk assessment, societal burden, management, education, and policy: Global perspective. Int J Paediatr Dent 2019;29:238-248.

3. Finucane D. Rationale for restoration of carious primary teeth: a review. Eur Arch Paediatr Dent 2012;13:281-292.

4. Waggoner WF. Restoring Primary Anterior Teeth: Updated for 2014. Pediatr Dent 2015;37:163-170.

5. Frencken JE, Holmgren CJ. How effective is ART in the management of dental caries?

Community Dent Oral Epidemiol. 1999;27:423-430.

6. Frencken JE. The state-of-the-art of ART restorations. Dent Update 2014;41:218-224.

7. Holmgren CJ, Roux D, Doméjean S. Minimal intervention dentistry: part 5. Atraumatic restorative treatment (ART) – a minimum intervention and minimally invasive approach for the management of dental caries. Br Dent J 2013;214:11-18.

8. Mickenautsch S, Yengopal V, Banerjee A. Atraumatic restorative treatment versus amalgam restoration longevity: a systematic review. Clin Oral Investig. 2010;14:233-240.

9. Tedesco TK, Calvo AFB, Lenzi TL, Hesse D, Guglielmi CA, Camargo LB, et al. ART is an alternative for restoring occlusoproximal cavities in primary teeth – evidence from an updated systematic review and meta-analysis. Int J Paediatr Dent 2017;27:201-209.

10. Arrow P, Klobas E. Minimum intervention dentistry approach to managing early childhood caries: a randomized control trial. Community Dent Oral Epidemiol 2015;43:511-520.

11. Tonmukayakul U, Arrow P. Cost-effectiveness analysis of the atraumatic restorative treatment-based approach to managing early childhood caries. Community Dent Oral Epidemiol 2017;45:92-100.

12. Kirthiga M, Murugan M, Saikia A, Kirubakaran R. Risk Factors for Early Childhood Caries: A Systematic Review and Meta-Analysis of Case Control and Cohort Studies. Pediatr Dent 2019;41:95-112.

13. Schwendicke F, Frencken JE, Bjørndal L, Maltz M, Manton DJ, Ricketts D, et al. Managing Carious Lesions: Consensus Recommendations on Carious Tissue Removal.

Adv Dent Res 2016;28:58-67.

14. de Amorim RG, Frencken JE, Raggio DP, Chen X, Hu X, Leal SC. Survival percentages of atraumatic restorative treatment (ART) restorations and sealants in posterior teeth: an updated systematic review and meta-analysis. Clin Oral Investig 2018;22:2703-2725.

15. Demarco FF, Corrêa MB, Cenci MS, Moraes RR, Opdam NJ. Longevity of posterior composite restorations: not only a matter of materials. Dent Mater 2012;28:87-101.

16. Correa MB, Peres MA, Peres KG, Horta BL, Barros AJ, Demarco FF. Do socioeconomic determinants affect the quality of posterior dental restorations? A multilevel approach. J Dent 2013;41:960-967.

17. Da Rosa Rodolpho PA, Donassollo TA, Cenci MS, Loguercio AD, Moraes RR, Bronkhorst EM. 22-Year clinical evaluation of the performance of two posterior composites with different filler characteristics. Dent Mater 2011;27:955-963.

18. Hickel R, Kaaden C, Paschos E, Buerkle V, García-Godoy F, Manhart J. Longevity of occlusally-stressed restorations in posterior primary teeth. Am J Dent 2005;18:198-211.

19. Pinto GS, Oliveira LJ, Romano AR, Schardosim LR, Bonow ML, Pacce M, et al. Longevity of posterior restorations in primary teeth: Results from a paediatric dental clinic. J Dent 2014;42:1248-1254.

20. Petersen PE, Bourgeois D, Ogawa H, Estupinan-Day S, Ndiaye C. The global burden of oral diseases and risks to oral health. Bull World Health Organ 2005;83:661-669.

21. Walsh T, Worthington H V, Glenny A-M, Appelbe P, Marinho VC, Shi X. Fluoride toothpastes of different concentrations for preventing dental caries in children and

adolescents. Cochrane database Syst Rev 2010;(1):CD007868.

22. Dos Santos APP, Nadanovsky P, De Oliveira BH. A systematic review and meta-Analysis of the effects of fluoride toothpastes on the prevention of dental caries in the primary dentition of preschool children. Community Dent Oral Epidemiol 2013;41:1-12.

23. Kato T, Yorifuji T, Yamakawa M, et al. Association of breast feeding with early childhood dental caries: Japanese population-based study. BMJ Open 2015;5:e006982.

24. Croll TP, Nicholson JW. Glass ionomer cements in pediatric dentistry: review of the literature. Pediatr Dent 24:423-429.

25. Mickenautsch S. How well are GIC product labels related to current systematic review evidence? Dent Update 2011;38:634-638, 641-642, 644.

26. Faustino-Silva DD, Figueiredo MC. Atraumatic restorative treatment—ART in early childhood caries in babies: 4 years of randomized clinical trial. Clin Oral Investig doi:10.1007/s00784-019-02800-8.

27. Campagna P, Pinto LT, Lenzi TL, Ardenghi TM, de Oliveira Rocha R, Oliveira MDM. Survival and Associated Risk Factors of Composite Restorations in Children with Early Childhood Caries: A Clinical Retrospective Study. Pediatr Dent 2018;40:210-214.

Table 1. Status of the restorations according to clinical and demographic characteristics (n=286 restorations)

Variables	n (%) of restorations	Success (%)	Failure (%)
Gender			
Girls	163 (57.0)	151 (92.6)	12 (7.4)
Boys	123 (43.0)	106 (86.2)	17 (13.8)
Mother's education			
Up to eight years	143 (50.4)	129 (90.2)	14 (9.8)
More than eight years	142 (49.6)	127 (89.4)	15 (10.6)
Caries experience			
Moderate	161 (51.3)	149 (92.6)	12 (7.4)
High	125 (48.7)	108 (86.4)	17 (13.6)
Number of active caries lesions			
Up to 8 lesions	154 (53.8)	137 (89.0)	17 (11.0)
More than 8 lesions	132 (46.2)	120 (90.9)	12 (9.1)
Frequency of brushing			
Once a day	35 (12.2)	34 (97.1)	1 (2.9)
Twice or more times	251 (87.8)	223 (88.8)	28 (11.2)
Standard fluoridated toothpaste use (≥ 1000 ppm F)			
Yes	229 (80.1)	205 (89.5)	24 (10.5)
No	57 (19.9)	52 (91.2)	5 (8.8)
Flossing use			
Yes	20 (7.0)	17 (85.0)	3 (15.0)
No	266 (93.0)	240 (90.2)	26 (9.8)
Frequency of cariogenic diet			
Up to four times daily	227 (79.4)	206 (90.8)	21 (9.2)
More than four times	59 (20.6)	51 (86.4)	8 (13.6)
Daytime bottle feeding			
Yes	256 (89.5)	229 (33.3)	27 (66.7)
No	30 (10.5)	28 (93.3)	2 (6.7)
Nighttime bottle feeding			
Yes	251 (87.8)	227 (90.4)	24 (9.6)
No	35 (12.2)	30 (85.7)	5 (14.3)
Type of arch			
Upper	131 (45.8)	116 (88.6)	15 (11.4)
Lower	155 (54.2)	141 (91.0)	14 (9.0)
Type of tooth			
First molar	237 (82.9)	212 (89.4)	25 (10.6)
Second molar	49 (17.1)	45 (91.8)	4 (8.2)
Cavity type			
Occlusal	266 (93.0)	239 (89.9)	27 (10.1)
Occluso-proximal	20 (7.0)	18 (90.0)	2 (10.0)

Table 2. Unadjusted and adjusted Hazard Ratios (HR; 95%CI) for failure of the restorations according to clinical and demographic characteristics. Cox regression model with shared frailty.

Variables	HR_{crude} (95%CI)	p-value	$HR_{adjusted}$ (95%CI)	p-value
Gender				
Girls	1	0.05	1	0.05
Boys	2.25 (0.99 – 5.11)		2.25 (0.99-5.14)	
Mother's education				
Up to eight years	1	0.42		
More than eight years	1.44 (0.58-3.59)			
Caries experience				
Moderate	1	0.03	1	0.07
High	2.71 (1.11-6.61)		2.11 (0.93-4.78)	
Number of active caries lesions				
Up to 8 lesions	1	0.90		
More than 8 lesions	0.95 (0.39-2.32)			
Frequency of brushing				
Once a day	1	0.18	1	0.15
Twice or more times	4.18 (0.51-34.50)		4.50 (0.58-35.01)	
Standard fluoridated toothpaste use (≥ 1000 ppm F)				
Yes	1	0.36		
No	1.68 (0.55-5.08)			

Flossing use				
Yes	1	0.53		
No	1.61 (0.37-7.04)			
Frequency of cariogenic diet				
Up to four times daily	1	0.19	1	0.20
More than four times	2.03 (0.71-5.85)		1.82 (0.73-4.56)	
Daytime bottle feeding				
No	1	0.33		
Yes	2.27 (0.43-11.89)			
Nighttime bottle feeding				
Yes	1	0.57		
No	0.67 (0.19-2.48)			
Type of arch				
Upper	1	0.41		
Lower	0.72 (0.32-1.59)			
Type of tooth				
First molar	1	0.62		
Second molar	0.75 (0.24-2.33)			
Cavity type				
Occlusal	1	0.86		
Occluso-proximal	0.92 (0.36-2.37)			

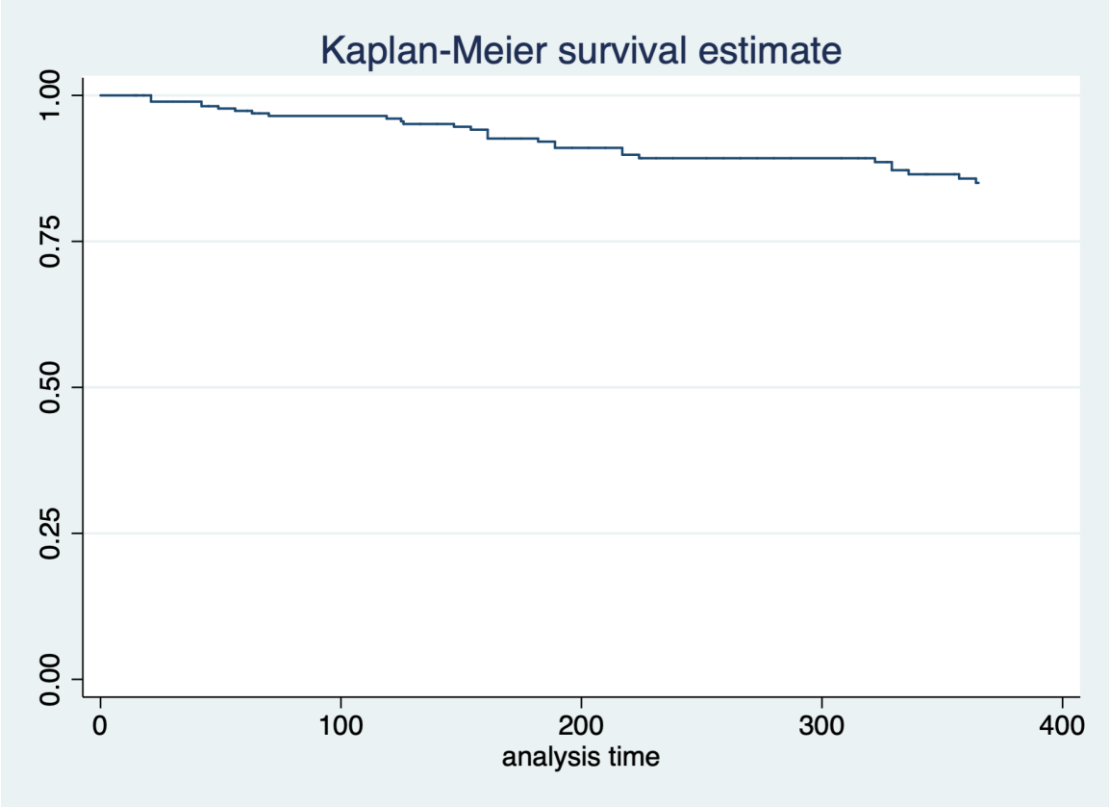


Figure 1. Kaplan-Meier survival curve of ART restorations over 1 year.

3 CONCLUSÃO

Com base nos resultados do presente estudo retrospectivo, pode-se concluir que as restaurações atraumáticas realizadas em crianças com cárie na primeira infância apresentaram sobrevida satisfatória após 1 ano de acompanhamento. Sendo assim, o Tratamento Restaurador Atraumático é uma boa opção para manejo de cárie na primeira infância em associação com a identificação e abordagem individualizada dos fatores de risco à cárie.

REFERÊNCIAS

AL-SHALAN, T. A.; ERICKSON, P. R.; HARDIE, N. A. Primary incisor decay before age 4 as a risk factor for future dental caries. **Pediatric Dentistry**, v. 19, n. 1, p. 37–41, 1997.

AMERICAN ACADEMY OF PEDIATRIC DENTISTRY (AAPD). Policy on early childhood caries (ECC): Classifications, consequences and preventive strategies. **Pediatric Dentistry**, v. 39, n.6, p. 59-61, 2017.

FINUCANE, D. Rationale for restoration of carious primary teeth: a review. **European Archives of Paediatric Dentistry**, v. 13, n. 6, p. 281–92, 2012.

FRENCKEN, J. E.; HOLMGREN, C. J. How effective is ART in the management of dental caries? **Community Dentistry and Oral Epidemiology**, v. 27, n. 6, p. 423–30, 1999.

FRENCKEN, J. E. et al. Effectiveness of single-surface ART restorations in the permanent dentition: a meta-analysis. **Journal of Dental Research**, v. 83, n. 2, p. 120–3, 2004.

FRENCKEN, J. E.; LEAL, S.C.; NAVARRO, M.F. Twenty-five-year atraumatic restorative treatment (ART) approach: a comprehensive overview. **Clinical Oral Investigations**, v. 16, n. 5, p. 1337–46, 2012.

MARTINS-JÚNIOR, P. A. et al. Impact of Early Childhood Caries on the Oral Health-Related Quality of Life of Preschool Children and Their Parents. **Caries Research**, v. 47, n. 3, p. 211–218, 2013.

RODRIGUES, C. S.; SHEIHAM, A. The relationships between dietary guidelines, sugar intake and caries in primary teeth in low income Brazilian 3-year-olds: a longitudinal study. **International Journal of Paediatric Dentistry**, v. 10, n. 1, p. 47–55, 2000.

SCHRIKS, M. C. M.; VAN AMERONGEN, W. E. Atraumatic perspectives of ART: psychological and physiological aspects of treatment with and without rotary instruments. **Community Dentistry and Oral Epidemiology**, v. 31, n. 1, p. 15–20, 2003.

SEOW, W. K. *et al.* Case-Control Study of Early Childhood Caries in Australia. **Caries Research**, v. 43, n. 1, p. 25–35, 2009.

TEDESCO, T. K. *et al*. ART is an alternative for restoring occlusoproximal cavities in primary teeth – evidence from an updated systematic review and meta-analysis. **International Journal of Paediatric Dentistry**, v. 27, n. 3, 2017.

TINANOFF, N., *et al*. Early childhood caries epidemiology, aetiology, risk assessment, societal burden, management, education, and policy: Global perspective. **International Journal of Paediatric Dentistry**, v. 29, n.3, p.238-48, 2019.

VAN 'T HOF, M. A., *et al*. The atraumatic restorative treatment (ART) approach for managing dental caries: a meta-analysis. **International Dental Journal**, v. 56, n. 6, p. 345–51, 2006.

WAGGONER, W.F. Restoring Primary Anterior Teeth: Updated for 2014. **Pediatric Dentistry**, v.37, n.2, p.163-70, 2015.

ANEXO A – Aprovação do Comitê de Ética em Pesquisa

UFRGS - PRÓ-REITORIA DE PESQUISA DA UNIVERSIDADE FEDERAL DO RIO GRANDE DO

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: SOBREVIDA E FATORES ASSOCIADOS ÀS FALHAS DE RESTAURAÇÕES ATRAUMÁTICAS EM CRIANÇAS COM CÁRIE DA PRIMEIRA INFÂNCIA: ESTUDO CLÍNICO RETROSPECTIVO

Pesquisador: Tathiane Larissa Lenzi

Área Temática:

Versão: 3

CAAE: 89678418.5.0000.5347

Instituição Proponente: Faculdade de Odontologia

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.809.294

Apresentação do Projeto:

O projeto de pesquisa "Sobrevida e fatores associados às falhas de restaurações atraumáticas em crianças com cárie de primeira infância: estudo clínico retrospectivo" é coordenado pela Profa Tathiane Larissa Lenzi, da Faculdade de Odontologia, e conta com a participação de Luciano Casagrande e de Márcia Cançado Figueiredo e da acadêmica Cássia Mendes da Silva, da Faculdade de Odontologia da UFRGS. Os pesquisadores solicitaram que fosse mantido sigilo
na íntegra do projeto de pesquisa, até a publicação dos resultados.

Objetivo da Pesquisa:

O objetivo da pesquisa será investigar a sobrevida de restaurações atraumáticas em crianças com cárie da primeira infância realizadas por alunos do curso de Graduação em Odontologia da Universidade Federal do Rio Grande do Sul e os fatores relacionados aos insucessos clínicos.

Avaliação dos Riscos e Benefícios:

RISCOS: Apresentados de forma adequada. Segundo os autores os riscos são mínimos e referem-se, principalmente, aos de um exame odontológico inicial. Durante os procedimentos, o participante da pesquisa poderá sentir desconforto ou cansaço por ficar com a boca aberta pelo tempo do procedimento. Para minimizar os riscos relacionados à quebra de sigilo e confidencialidade, os pesquisadores assumem o compromisso de preservar a confidencialidade dos dados mediante a identificação dos indivíduos por meio de código numérico no banco de

Endereço: Av. Paulo Gama, 110 - Sala 317 do Prédio Anexo 1 da Reitoria - Campus Centro
Bairro: Farroupilha **CEP:** 90.040-060
UF: RS **Município:** PORTO ALEGRE
Telefone: (51)3308-3738 **Fax:** (51)3308-4085 **E-mail:** etica@propesq.ufrgs.br

dados.

BENEFÍCIOS: O participante e seus pais/responsáveis receberão orientação de higiene oral e esclarecimentos sobre a condição de saúde bucal da criança como benefícios decorrentes da sua participação. Ainda, será oferecido suporte aos participantes do estudo que necessitem de tratamento odontológico, durante todo o período do estudo. O tratamento odontológico será realizado por alunos cursando a Disciplina Eletiva Bebê Clínica. Os procedimentos do estudo fazem parte do de acompanhamento clínico ao qual os participantes da pesquisa já estão inseridos.

Comentários e Considerações sobre a Pesquisa:

- Introdução e justificativa: adequadas. Há uma lacuna na literatura acerca do comportamento clínico de restaurações na dentição decídua, especialmente na primeira infância.
- Desenho experimental: estudo observacional com etapas retrospectiva e prospectiva.
- Tamanho amostral: 430 participantes, que corresponde ao número estimado de pacientes atendidos na Bebê Clínica da Faculdade de Odontologia da UFRGS entre os anos de 2010 e 2017.
- Critérios de inclusão: bebês com dentes decíduos anteriores ou posteriores restaurados pela técnica atraumática, com no mínimo 1 ano, e que tenham retornado pelo menos uma vez às consultas de reavaliação.
- Critérios de exclusão: prontuários com dados incompletos sobre os procedimentos restauradores realizados, pacientes cujos dentes decíduos selecionados para a pesquisa esfoliaram, pacientes com necessidades especiais e crianças com condição de saúde geral comprometida.
- Forma de recrutamento dos participantes: contato telefônico com os responsáveis pelos pacientes.
- Procedimentos experimentais: seleção dos prontuários (obtenção dos dados de contato dos participantes); treinamento e calibração do examinador; contato com os responsáveis pelos participantes; coleta dos dados dos prontuários (relacionados ao participante e às restaurações que foram executadas); avaliação clínica das restaurações; análise de dados.

a) Os pesquisadores indicaram que o tempo médio para a realização de uma avaliação clínica é de 30 minutos (conforme Item 3.6 do Projeto de Pesquisa).

b) Indicou-se que o participante será avaliado por pesquisador que participou de aula teórica, seguido da análise de imagens. Nessa etapa, o pesquisador em treinamento irá avaliar 10 participantes, duas vezes, em dois momentos distintos (concordância intra-examinador). Nestas duas consultas, o participante será também avaliado por um examinador de referência. O tempo

estimado para o exame nesta etapa não foi apresentado. Considerando-se que o tempo estimado para um exame é de 30 minutos (conforme indicado no item 3.6 do Projeto de Pesquisa), o tempo total será de 1 hora.

Considerações sobre os Termos de apresentação obrigatória:

- Folha de Rosto: adequada.
- Termo de Compromisso para Uso de Dados - Adequado, estando assinado por todos os pesquisadores.
- Termo de Consentimento Livre e Esclarecido - Adequado.
- Termo de Assentimento para o Paciente menor de idade: não se aplica, pois os participantes são bebês.
- Documento de aprovação pela COMPESQ-Odontologia: presente.
- Cronograma: adequado. O início da seleção dos prontuários será em setembro de 2018, enquanto que as avaliações clínicas dos participantes ocorrerão a partir de maio de 2019.
- Termo de concordância do responsável pelo arquivo de prontuários para que se tenha acesso aos dados: presente, assinado pela Profa Márcia Figueiredo, coordenadora da ação de extensão.
- Termo de concordância do responsável pela Clínica onde ocorrerá a avaliação dos participantes: presente, assinado pela Profa Márcia Figueiredo, coordenadora da ação de extensão.
- Formulários para coleta de dados: Foi incluído formulário onde serão registrados os dados demográficos e os relativos à avaliação das restaurações clínicas.
- Orçamento: o projeto será realizado com financiamento próprio, sob a responsabilidade da pesquisadora responsável, com custo total de R$ 1.105,50. Não foi previsto o custeio do transporte dos participantes e responsáveis, uma vez que os pesquisadores indicaram que os procedimentos de acompanhamento fazem parte da rotina da clínica.

Conclusões ou Pendências e Lista de Inadequações:

Após a análise do projeto de pesquisa, o mesmo pode ser aprovado quanto aos aspectos éticos de pesquisa em humanos, considerando-se as resoluções 466/2012 e 510/2016, do Conselho Nacional de Saúde.

PENDÊNCIAS ENCAMINHADAS NO ÚLTIMO PARECER:

- O termo pacientes foi substituído por participantes da pesquisa em todos os documentos do projeto.

- É necessário que os pesquisadores revisem a alocação dos participantes. Há um Grupo "Treinamento e Calibração" (n=10) e Grupo "Tratamento restaurador atraumático" (n=410), considerando o total de pacientes que foram atendidos no período indicado pelos pesquisadores. Modificar esta informação no projeto e também no Formulário de Submissão à Plataforma Brasil (Item "Grupos em que serão divididos os participantes da pesquisa neste centro").
O grupo “Treinamento e Calibração” foi incluído no formulário de submissão à Plataforma Brasil.

- Os pesquisadores indicaram que os custos de transporte não são previstos na pesquisa pois as consultas de retorno fazem parte da rotina de atendimento dos pacientes no serviço. Porém, os 10 participantes que integram o Grupo "Treinamento e Calibração" deverão retornar uma semana após o exame inicial. Este retorno está previsto na rotina de acompanhamento? Em caso de resposta negativa, os custos do transporte devem ser previstos no orçamento.
Os participantes da pesquisa selecionados para serem incluídos no grupo “Treinamento e Calibração” serão bebês com restaurações e atividade de cárie em atendimento na Bebê Clínica que deverão retornar semanalmente. Portanto, o retorno está previsto na rotina de acompanhamento. Essa informação foi incluída no projeto.

- Os pesquisadores incluíram a descrição completa dos "Riscos" no Formulário de Submissão à Plataforma Brasil.

- Revisar o Apêndice C, Item "Dados de identificação". Por favor incluir espaço para codificação alfa-numérica, com o intuito de garantir sigilo e confidencialidade, uma vez que constam informações que identificam o participante.
O espaço para codificação alfa-numérica foi inserido no Apêndice C.

- Conforme o "Termo de Autorização para Acesso aos Prontuários" a acadêmica Cássia Mendes da Silva irá participar da equipe de pesquisa. Assim, por favor incluir seu nome no formulário de submissão à Plataforma Brasil, como membro da equipe.
A acadêmica foi incluída como participante da equipe da pesquisa na Plataforma Brasil.

- Descrever todas as etapas do projeto no TCLE, inclusive a eventual possibilidade de retorno para acompanhamento. As etapas do projeto foram incluídas no TCLE.

Considerações Finais a critério do CEP:

Aprovado.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1137078.pdf	18/07/2018 11:48:23		Aceito
Outros	RESPOSTA.docx	18/07/2018 11:45:17	Tathiane Larissa Lenzi	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	18/07/2018 11:44:31	Tathiane Larissa Lenzi	Aceito
Projeto Detalhado / Brochura Investigador	PROJETO_CORRIGIDO.pdf	18/07/2018 11:43:55	Tathiane Larissa Lenzi	Aceito
Outros	FICHA_COLETA_DADOS.pdf	18/07/2018 11:40:15	Tathiane Larissa Lenzi	Aceito
Outros	TERMO_COMPROMISSO_DADOS.pdf	18/07/2018 11:38:40	Tathiane Larissa Lenzi	Aceito
Outros	FICHA_CLINICA.docx	18/07/2018 11:32:42	Tathiane Larissa Lenzi	Aceito
Outros	AUTORIZACAO_FICHAS.pdf	25/06/2018 17:25:32	Tathiane Larissa Lenzi	Aceito
Declaração de Instituição e Infraestrutura	AUTORIZACAO_CLINICA.pdf	25/06/2018 17:25:06	Tathiane Larissa Lenzi	Aceito
Folha de Rosto	Folha.pdf	16/05/2018 10:27:22	Tathiane Larissa Lenzi	Aceito
Outros	COMPESQ.pdf	15/05/2018 19:51:07	Tathiane Larissa Lenzi	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

PORTO ALEGRE, 09 de Agosto de 2018

Assinado por:
MARIA DA GRAÇA CORSO DA MOTTA
(Coordenador)

Endereço: Av. Paulo Gama, 110 - Sala 317 do Prédio Anexo 1 da Reitoria - Campus Centro
Bairro: Farroupilha **CEP:** 90.040-060
UF: RS **Município:** PORTO ALEGRE
Telefone: (51)3308-3738 **Fax:** (51)3308-4085 **E-mail:** etica@propesq.ufrgs.br

ANEXO B – Normas do periódico Journal of Dentistry for Children

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

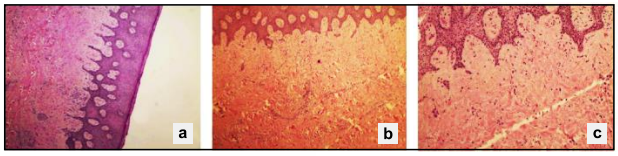
Editorials

Full-length manuscript not to exceed 1,000 words; excluding *References* and *Figure Legends.*
Maximum Figures: 2 • Maximum Tables: 2

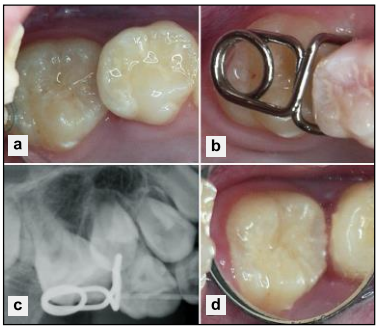
Brief Communications

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.

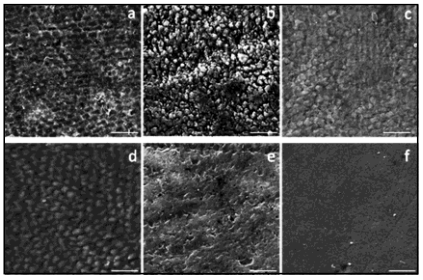
Authors desiring to have more Figures or Tables MUST agree to electronic publication of their manuscript, and must select this preference. Each separate chart, graph or photograph will be counted as a separate figure. Figures grouped together will be counted as their individual parts. See samples below:



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 refered 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 (**URL**s) 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.

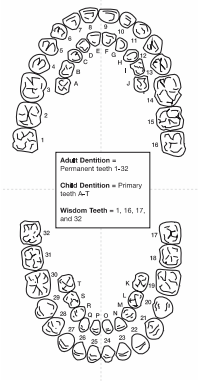
Editorial Style

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 µm). 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.

Copyright: All authors must agree to the terms of copyright transfer as indicated during the online manuscript submission process. The American Academy of Pediatric Dentistry owns the copyright for all content published in the journal. The AAPD and its licensees have the right to use, reproduce, transmit, derivate, publish, and distribute the content, in the journal or otherwise, in any form or medium. Authors will not use or authorize the use of the contribution without the AAPD's written consent, except as may be permitted as 'fair use' under U.S. copyright law. Authors represent and warrant to the AAPD that: the submitted manuscript is the authors' own original work; authors have the full right and power to make this copyright transfer; the work does not violate any copyright, proprietary, intellectual property or personal rights of others; the work is factually accurate and contains no matter defamatory or otherwise unwise unlawful; authors have not previously in any manner disposed of by sale or assignment any of the rights granted to the AAPD nor previously granted any rights adverse to or inconsistent with this copyright transfer; and that there are no rights outstanding which would diminish, encumber or impair the full enjoyment of the copyright transfer granted to the AAPD.

National Institutes of Health (NIH) Funded Manuscripts: Authors of studies funded by the NIH whose manuscripts are accepted for publication in either *Pediatric Dentistry* or the *Journal of Dentistry for Children* will have their final accepted version deposited to PubMed Central (PMC) by the publisher AAPD on behalf of the authors.

Actions Taken on a Manuscript

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

Rejection: The flaws that lead to this decision generally center on substantive or methodological issues. A manuscript is usually rejected because: it is outside the area of coverage of the journal; it contains serious flaws of design, methodology, analysis, or interpretation; or it is judged to make only a limited novel contribution to the field.

Revision: Manuscripts may have publication potential but are not yet ready for final publication. The study as presented may not merit acceptance as is but may warrant consideration after substantive revision (e.g., reorganizing the conceptual structure, conducting additional experiments, or modifying analyses). The action editor will give the author an invitation to revise and resubmit for another round of reviews (usually with the same reviewers). An editor cannot guarantee acceptance of a revised manuscript, but authors who respond flexibly and attend closely to suggested revisions enhance their chances for an acceptance. Authors must include a detailed cover letter outlining their responses to the revisions. Revisions **must be submitted using Track Changes** so the original with the sections deleted can be seen along with the new text.

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.

New scholars who wish to learn more about the editorial and peer review process as it operates with AAPD should e-mail the AAPD Headquarters Office at *rgillmeister@aapd.org*.

AAPD Manuscript Submission Checklist

This checklist applies specifically to original research articles but much of it will apply to submission of other manuscript types, as well. Please see the section 'Types of Manuscripts' in the Instructions for Authors for complete information.

Submission Documents

- ❑ Submit manuscript in *.doc* or *.docx* format.
- ❑ Manuscript is double spaced.
- ❑ Used basic fonts such as Arial, Courier, Helvetica no smaller than 11 points.
- ❑ Two versions of the manuscript are be uploaded, one version containing all the author information and one version without any information identifying the authors or their institutions (blinded).
- ❑ Tables 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).
- ❑ IRB approval, informed consent (verbal or written), HIPAA compliance (if from the United States), and/or animal care committee must be included with the submission.
- ❑ IRB approval letters must be in English, on official IRB letterhead, and over an official signature of the IRB approval agent.

Short Title

- ❑ A brief but comprehensive phrase summarizing the paper.

Keywords

- ❑ Five words that appear in the title/abstract, and searchable in PubMed.

Abstract

- ❑ The *Abstract* is brief, providing the reader with a concise but complete summary of the paper.
- ❑ Date range of study should be given.
- ❑ Number of patients/animals (including age and gender, if appropriate) should be given.
- ❑ Various groups, including controls, described.
- ❑ Procedures performed should be described.
- ❑ Specifics of evaluation should parallel the results portion of the abstract.
- ❑ *Abstract* results parallel abstract methods.
- ❑ *Abstract* results contain quantitative data along with statistical significance.
- ❑ *Abstract* conclusions can be drawn from the results of the study.

Introduction

- ❑ Provides context for the article.
- ❑ Provides objective of the study.
- ❑ Provides a clear purpose/hypothesis.
- ❑ Does not exceed two or three paragraphs.

Methods

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

Results

- ❑ Clearly mirrors methods; used subtitles if needed. Check for consistency in data in text, tables, and figures.
- ❑ Report the results of the statistical analysis for all variables collected and analyzed, not just for those which exhibited statistical or near statistical significance.
- ❑ Text and Tables must stand alone.

Continued on next page

Discussion

- ❑ State pertinent new findings, but do not repeat results.
- ❑ How did your results differ from other relevant literature?
- ❑ Do not cite tables or figures in the discussion. These should be introduced in the methods and results sections.
- ❑ Do not cite new results not previously reported in the Results. All results the author wishes to discuss must have first been presented in the Results section of the manuscript.
- ❑ Describe limitations of your study in the paragraph just before your Conclusions. Include itemization of limitations of any incomplete data.
- ❑ Describe the type of future studies needed, if appropriate.

Conclusions

- ❑ Synthesis of key points.
- ❑ List and number using Arabic numerals.
- ❑ *Conclusions* should be supported by data.
- ❑ Numbered succinct statements.

References

- ❑ Call out references in order they appear in text.
- ❑ Adhere to AAPD guidelines.
- ❑ Verify accuracy of your references.
- ❑ Archive each and all references in WebCite®.

Tables

- ❑ Adhere to AAPD Maximum requirements according to Type of Manuscript.
- ❑ Include title for each table.
- ❑ Numbers correspond to numbers in text.
- ❑ Define abbreviations below each table.

Figures

- ❑ Adhere to AAPD Maximum requirements according to Type of Manuscript.
- ❑ Image resolution, after cropping to the area of interest, should be a minimum 300-600 *dpi*.
- ❑ Figures should be submitted individually as *.jpg* or *.tif* files.
- ❑ 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.
- ❑ Figure legends should clearly define findings on each figure, with labels mentioned in the caption if they are used in the figure.
- ❑ If based on individual subject, caption should include subject age and gender.

***NOTE*: Authors desiring to have more Figures or Tables MUST agree with the 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 examples on page 2.**