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Cleber Paradzinski Cavalheiro

A REDUÇÃO DO TEMPO DE CONDICIONAMENTO ÁCIDO DA DENTINA AUMENTA A SOBREVIDA DE RESTAURAÇÕES EM DENTES DECÍDUOS? ENSAIO CLÍNICO RANDOMIZADO

Santa Maria, RS
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Dissertação de Mestrado apresentada ao 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 a obtenção do título de **Mestre em Ciências Odontológicas**

Orientadora: Profª. Drª. Tathiane Larissa Lenzi

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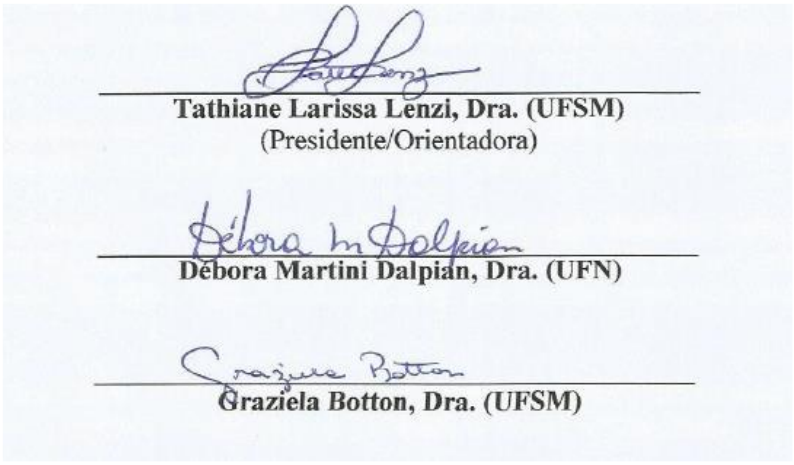

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RESUMO

A REDUÇÃO DO TEMPO DE CONDICIONAMENTO ÁCIDO DA DENTINA AUMENTA A SOBREVIDA DE RESTAURAÇÕES EM DENTES DECÍDUOS? ENSAIO CLÍNICO RANDOMIZADO

AUTOR: Cleber Paradzinski Cavalheiro
ORIENTADORA: Tathiane Larissa Lenzi

Um ensaio clínico randomizado foi conduzido para avaliar a influência da redução do tempo de condicionamento ácido da dentina na sobrevida de restaurações de resina composta em dentes decíduos, após remoção seletiva de tecido cariado. Foram selecionadas crianças com idade entre 5 e 8 anos, que apresentassem pelo menos uma lesão de cárie no terço médio de dentina na superfície oclusal de molares decíduos. Cem molares decíduos foram alocados aleatoriamente em dois grupos de acordo com o tempo de condicionamento do substrato dentinário: tempo recomendado pelo fabricante (15 segundos) ou reduzido (7 segundos). Após aplicação do sistema adesivo (Adper Single Bond 2; 3M ESPE), os dentes foram restaurados com um único incremento de até 4 mm da resina composta (Restaurador Posterior Filtek Bulk Fill; 3M ESPE). Todos os procedimentos clínicos foram realizados na clínica da Disciplina de Odontopediatria da Universidade Federal de Santa Maria por um único operador. As restaurações foram avaliadas após 1, 6, 12 e 18 meses por um examinador treinado e calibrado para a utilização critério proposto pela Federação Dentária Internacional (FDI). Teste de Kaplan-Meier foi usado para estimar a sobrevida das restaurações. Análise de regressão multivariada de Cox com fragilidade compartilhada foi utilizada para avaliar os fatores associados com as falhas restauradoras ($p<0,05$). As diferenças nas taxas de sucesso das restaurações em relação as variáveis relacionadas à criança e ao dente não foram estatisticamente significantes ($p> 0,05$). No entanto, a redução do tempo de condicionamento ácido da dentina teve uma associação *bordeline* ($p = 0,07$), como um fator de proteção para falha das restaurações em comparação aos dentes condicionados pelo tempo recomendado pelo fabricante. As taxas de sobrevida estimadas das restaurações foram de 100%, 97,9%, 94,8% e 84% após 1, 6, 12 e 18 meses, respectivamente. As taxas de sobrevida das restaurações após 18 meses foram 75,7% e 91,4% quando a dentina decídua foi condicionada por 15 e 7 segundos, respectivamente. Em conclusão, o tempo de condicionamento ácido da dentina não influenciou a sobrevida das restaurações de resina composta realizadas em molares decíduos após a remoção seletiva do tecido cariado. No entanto, houve uma tendência para melhor desfecho clínico quando a dentina decídua foi condicionada por 7 segundos.

Palavras-chave: Ataque Ácido Dentário; Dente Decíduo; Ensaio Clínico; Odontopediatria.

ABSTRACT

DOES SHORTENING OF THE ACID ETCHING TIME OF THE DENTIN INCREASE THE SURVIVAL OF RESTORATIONS IN PRIMARY TEETH? RANDOMIZED CLINICAL TRIAL

AUTHOR: Cleber Paradzinski Cavalheiro
ADVISOR: Tathiane Larissa Lenzi

A randomized clinical trial was conducted to evaluate the effect of shortening the dentin acid etching time on the survival of composite resin restorations in primary teeth after selective carious tissue removal. Children aged 5 to 8 years presenting at least one carious lesion in the middle third of the dentin on the occlusal surface of primary molars were selected. One hundred primary molars were randomly allocated into two groups according to the etching time of the dentin substrate: time recommended by the manufacturer (15 s) or reduced time (7 s). After application of the adhesive system (Adper Single Bond Plus; 3M ESPE), the teeth were restored with a single increment of up to 4 mm of composite resin (Filtek Bulk Fill Posterior Restorative; 3M ESPE). All clinical procedures were performed at the Pediatric Dentistry Clinic of the Federal University of Santa Maria by a single operator. The restorations were evaluated after 1, 6, 12, and 18 months by a trained and calibrated examiner as per the World Dental Federation (FDI) criteria. Kaplan-Meier test was used to estimate the survival of the restorations. Cox multivariate regression analysis with shared fragility was used to evaluate the factors associated with restorative failures ($p < 0.05$). Differences in success rates regarding individual and tooth-level variables were not statistically significant ($p > 0.05$). However, the shortening of the acid etching time for dentin had a borderline association ($p=0.07$) as a protective factor for restoration failure when compared to those teeth acid etched by time recommended by manufacturer. Estimated survival rates of the restorations were 100%, 97.9%, 94.8%, and 84% after 1, 6, 12, and 18 months, respectively. The survival rates after 18 months were 75.7% and 91.4% when primary dentin was acid etched for 15 s and 7 s, respectively. In conclusion, the shortening of the dentin acid etching time did not influence survival of composite resin restorations placed in primary molars after selective carious tissue removal. However, there was a tendency for better clinical outcome when primary dentin was acid etched by 7s.

Keywords: Acid Etching; Tooth, Clinical Trial Dental; Deciduous; Pediatric Dentistry.

SUMÁRIO

1 INTRODUÇÃO

A ocorrência de lesões de cárie cavitadas representa ainda um problema atual e de difícil resolução em muitos países e de acordo com Organização Mundial de Saúde, a prevalência de lesões de cárie na dentição decídua varia entre 60 e 90% em todo o mundo (PETERSEN et al. 2005). A resina composta tem sido amplamente utilizada para restaurar dentes decíduos acometidos por lesões de cárie, 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 e, portanto, a maior aceitação pelos pacientes e responsáveis (KILPATRICK & NEUMANN, 2007).

Embora a seleção do tipo de resina composta pareça não influenciar expressivamente a sobrevida das restaurações (DEMARCO et al. 2017), tem sido evidenciado que sistemas adesivos convencionais ainda são a melhor opção para restaurar dentes decíduos (LENZI et al., 2016). Tradicionalmente, o conhecimento adquirido sobre dentes permanentes é transferido aos decíduos, visto que o mesmo protocolo de aplicação de sistemas adesivos tem sido indicado para ambos os substratos, apesar das diferenças microestruturais entre a dentina decídua e permanente.

A dentina de dentes decíduos apresenta menor área de dentina intertubular em decorrência da maior densidade tubular (SUMIKAWA et al., 1999; LENZI et al., 2013), além de menor conteúdo mineral (ANGKER et al., 2004). Essa última característica tem sido associada a uma maior reatividade do substrato a ácidos e, consequentemente, uma maior desmineralização quando o mesmo tempo de condicionamento utilizado em dentes permanentes é empregado em dentes decíduos.

A maior desmineralização do substrato dentinário e a subsequente incompleta infiltração dos monômeros resinosos na dentina desmineralizada poderiam interferir nas propriedades mecânicas da interface adesiva, acarretando em menores valores de resistência de união à dentina decídua (SENAWONGSE et al., 2004; UEKUSA et al., 2006; CAN-KARABULUT et al., 2009). Estudos baseados na análise morfológica também demonstraram que a camada híbrida formada em dentina de dentes decíduos é 25-30% mais espessa em comparação à camada híbrida de dentes permanentes, quando da utilização do mesmo protocolo adesivo (NÖR et al., 1996; OLMEZ et al., 1998). Além disso, as fibrilas colágenas expostas na base da camada híbrida, desprovidas de proteção mineral e/ou monomérica, permitem a nanoinfiltração (SANO et al., 1995), criando zonas suscetíveis à degradação hidrolítica e

enzimática com o passar do tempo, culminado com a falência funcional das restaurações (HASHIMOTO et al., 2000).

Neste contexto, a redução do tempo de condicionamento ácido poderia beneficiar a impregnação do adesivo na dentina desmineralizada em dentes decíduos, uma vez que a profundidade de desmineralização seria menor. Pesquisas laboratoriais tem demonstrado que a redução do tempo de condicionamento ácido da dentina de dentes decíduos em aproximadamente metade do tempo recomendado para dentes permanentes não interfere negativamente na resistência de união imediata de sistemas adesivos (SARDELLA et al., 2005; SANABE et al., 2009; OSÓRIO et al., 2010), assim como, favorece a estabilidade da união resina-dentina (SANABE et al., 2009). Apesar de promissores, os resultados foram obtidos sobre dentina hígida.

Com o advento da filosofia de Mínima Intervenção, a possibilidade de remoção seletiva do tecido cariado vem ganhando destaque na Odontologia Restauradora. Em lesões profundas, quando há o risco de exposição pulpar, a manutenção da vitalidade deve ser priorizada. Nesse sentido, preconiza-se a remoção seletiva de tecido cariado à dentina macia. Por outro lado, em lesões rasas e moderadas, a remoção de tecido cariado à dentina firme deve ser realizada, com o intuito de preservar estrutura dentária, sem comprometer a longevidade das restaurações (SCHWENDICKE et al., 2016).

A dentina afetada por cárie possui uma zona de dentina intertubular com menor conteúdo mineral (WANG; SPENCER; WALKER, 2007; YOSHIYAMA et al., 2000) e cristais de cálcio e fosfato resistentes à dissolução ácida no interior dos túbulos dentinários (NAKAJIMA et al., 2000). Ao mesmo tempo em que o menor conteúdo mineral proporciona uma maior profundidade de desmineralização, a obliteração dos túbulos dentinários limita a infiltração dos monômeros resinosos e a formação de *tags* de resina (YOSHIYAMA et al., 2000).

Tais características influenciam diretamente o desempenho dos materiais adesivos, resultando em menores valores de resistência de união em relação à dentina hígida (NAKAJIMA et al., 2000; YOSHIYAMA et al., 2000; NAKORNCHAI et al., 2005; MARQUEZAN et al., 2010), formação de camadas híbridas mais espessas (ERHARDT et al., 2008; PEREIRA et al., 2006; WANG; SPENCER; WALKER, 2007) e maior exposição da zona de dentina desmineralizada na base da camada híbrida (WANG; SPENCER; WALKER, 2007). Assim, é de se esperar que a redução no tempo de condicionamento exerça um efeito

benéfico quando as restaurações adesivas são realizadas após remoção seletiva de tecido cariado.

De fato, um recente estudo demonstrou que a redução do tempo de condicionamento ácido melhora a estabilidade da união de sistema adesivo convencional à dentina hígida e afetada por cárie de dentes decíduos (LENZI et al., 2014). No entanto, enquanto as pesquisas laboratoriais apresentam a vantagem de avaliar, inicialmente, uma variável de interesse com menos vieses (HEINTZE & ZIMMERLI, 2011; BAYNE 2012), os resultados obtidos não podem ser diretamente extrapolados para as situações clínicas, uma vez que as interfaces adesivas são constantemente sujeitas às condições impostas pela cavidade bucal, tais como, variação de temperatura, forças mastigatórias, processos biológicos e reações químicas (DE MUNCK et al., 2003).

Desde que estudos laboratoriais são limitados em predizer o sucesso clínico dos materiais restauradores, estudos clínicos representarem o método mais eficiente na avaliação de protocolos adesivos ou modificações destes para utilização em dentes decíduos. Assim, deve-se considerar que o desenvolvimento e acompanhamento de um ensaio clínico randomizado e controlado, avaliando a influência do tempo de condicionamento ácido da dentina no comportamento clínico de restaurações de resina composta em dentes decíduos, após remoção seletiva de tecido cariado, poderá esclarecer lacunas existentes acerca deste assunto, além de servir como referência para o avanço da prática clínica baseada em evidências.

2 ARTIGO - Shortening of the acid etching time for dentin as recommendation of new adhesive protocol to restore primary teeth: An 18 months randomized clinical trial

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Shortening of the acid etching time for dentin as recommendation of new adhesive protocol to restore primary teeth: An 18 months randomized clinical trial

Short title: Shortening the etching time for primary dentin

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Abstract

Purpose: To evaluate the influence of shortening of etching time for dentin on the restoration survival after selective carious tissue removal in primary molars. *Methods:* This two-arm randomized clinical trial included sixty-two subjects (5-8 year-old) and 100 primary molars presenting moderate dentin carious lesions on occlusal surface. The sample was randomly assigned into groups previously to adhesive application (Adper Single Bond 2; 3M ESPE): etching time recommended by manufacturer (15 s) or reduced (7 s). Composite resin (Filtek Bulk Fill Posterior Restorative; 3M ESPE) was inserted in a single increment for all restorations. Restorations were evaluated at 1, 6, 12, and 18 months using FDI criteria. Survival estimates for restorations' longevity were evaluated with Kaplan-Meier method. Multivariate Cox regression analysis with shared frailty was used to assess the factors associated with failures ($p < 0.05$). *Results:* The etching time did not influence the restorations' longevity (p=0.07; 75.7% and 91.4% with 15 and 7s of etching, respectively). *Conclusion:* After 18 months of follow-up, the etching time of primary dentin did not influence the clinical behavior of adhesive restorations in primary molars after selective carious tissue removal. However, there was a tendency for better clinical outcome when using etching time of 7s.

Trial registration: ClinicalTrials.gov Identifier: NCT02969538

Keywords: deciduous teeth; clinical trial; etching time

Introduction

Composite resin has been widely used to restore decayed primary teeth because of its superior esthetics and lesser removal of sound tissue as compared to conventional treatments, thus allowing minimal intervention approaches such as selective carious tissue removal. Even though this material has shown satisfactory properties, a significant number of failures have been reported[1,2]. Factors associated with children such as caries risk[3], oral hygiene[4], age[3,4], and behavior, as well as cavity-related features such as number of restored surfaces[3,5] and presence of endodontic treatment[1] could affect the survival of the restoration.

Although the choice of the type of composite material seems to have a minor effect on restoration service time[6], etch-and-rinse adhesives are still the better option for restoring primary teeth[7], being the most used by clinicians. However, it has been known that chemical[8] and microstructural[9] differences between primary and permanent dentin may jeopardize the adhesion in this substrate[10,11].

Greater tubular density and larger diameter[9] result in a reduced area of intertubular dentin available for bonding. Chemically, the lower mineral content[8] reduces the buffering capacity and increases the reactivity of primary tooth dentin to acidic solutions. This is more critical while performing restorative procedures in cavity preparations involving residual carious tissue due to lesser mineral content in this substrate[12].

Deeper demineralization of the dentinal substrate and subsequent incomplete penetration of resin monomers into the demineralized area results in a non-impregnated zone at the bottom of the hybrid layer, which creates sites more prone to degradation over time[13]. Therefore, a reduced acid etching time for primary dentin has been suggested to maintain adequate long-term adhesion.

A previous *in vitro* study[14] stated that acid etching for half the time recommended by

the manufacturer improves the bond stability with sound and carious primary dentin when etch-and-rinse adhesives are employed. Unfortunately, there is a lack of clinical evidence for the same.

Since randomized clinical trials provide the necessary support to clinicians in an evidence-based decision-making process, the aim of this study was to investigate whether shortening the acid etching time for dentin increases the restoration survival after selective caries removal in primary molars.

Methods

Study design and ethical concern

This was a two-arm, parallel, randomized clinical trial that followed the CONSORT (Consolidated Standards of Reporting Trials) guidelines, and the study has been registered on the website www.clinicaltrials.gov (#NCT02969538). The local Ethics Committee on Investigations Involving Human Subjects of the Federal University of Santa Maria reviewed and approved the protocol and consent form for this study. Written informed consent was obtained from the guardians of the participants prior to starting the treatment. The study was carried out in the Pediatric Dentistry Clinic of the School of Dentistry, Federal University of Santa Maria, Santa Maria, Rio Grande do Sul, Brazil, from December 2015 to June 2018. The participants and their guardians received detailed information about the survey, but they were not aware of the treatment provided by the specific restoration under evaluation.

Sample calculation

The sample size calculation was performed with the help of the website www.openepi.com. As there was no clinical information regarding the reduced etching time, the sample size calculation was based on a previous laboratory study that reported 44.2 ± 6.8 MPa and 40.9 ± 3.2 MPa (bond strength mean ± standard deviation) for experimental

groups[15], with significance level of 5% and power of 80%. An additional 20% was added to the sample size to compensate for possible loss to follow-up, and the required sample size was 50 restorations per group. The experimental unit was the tooth.

Sample selection

A total of 130 children (aged 5-8 years) were examined by two dentists (R.O.R. and T.M.A.) check the inclusion and exclusion criteria (Figure 1). The participants were recruited in the order that they attended the screening appointment. The clinical evaluations were performed using a plane buccal mirror and a ballpoint probe (Hu-Friedy Manufacturing Co., Chicago, USA). Children presenting good general health with cooperative behavior and at least one primary molar with a moderate occlusal dentinal carious lesion were included in the study. The depth of the lesions was confirmed by bitewing radiographic examinations, i.e., the caries lesions should involve the middle third of dentin radiographically. Moreover, the inclusion criteria also required that the participants presented teeth with the following clinical and radiographic features: absence of sensitivity and/or spontaneous pain, swelling, fistula, and mobility incompatible with the root resorption stage, and absence of any radiographic signs suggesting pulp necrosis. Participants requiring any other dental treatment were referred to the Dental School of the University. All individuals received dietary and oral hygiene instructions. Based on the pre-established criteria, 62 volunteers were selected for this study (Figure 1).

Training and calibration

One examiner (D.P.) underwent 8 h of specific training session involving theoretical explanations, discussion, and assessment of 20 representative photographs of each score of the World Dental Federation (FDI) criteria[16]. After these procedures, the examiner evaluated restorations in 10 children and repeated the evaluations after two weeks to determine intra-examiner agreement. Additionally, a benchmark examiner (T.L.L.) performed examinations

to calculate the inter-examiner reliability. Intra and inter-examiner weighted kappa values were 0.87 and 0.84, respectively. The operator (C.P.C.) was a graduate dental student, specialist in Pediatric Dentistry, and underwent training to perform the restorations. The operator was assisted by a dental assistant (P.S.S.).

Randomization, allocation and blinding

The randomization was performed by a staff member (D.P.R.) who was not involved in any of the clinical trial phases. Teeth were randomly allocated to each group according to a sequence obtained using the appropriate software (Random Allocation 1.0, Isfahan, Iran). The allocation concealment was guaranteed by the use of opaque and numbered individual envelopes. The envelopes were opened after the selective carious tissue removal procedure. Although the operator was not blinded to group assignment when performing the interventions, the participants were blinded. Furthermore, the examiner, who did not take part in the restoration phase, was blinded.

Treatment procedures

The two groups of interventions were defined according to the acid etching time of primary dentin: recommended by manufacturer (15 s) or reduced (7 s). After dental prophylaxis, local anesthesia and rubber dam isolation were performed. Hand excavators were used for selective carious tissue removal up to firm dentin[17], and carbide burs at low speed (Nº. 2) were used for complete carious tissue removal from the cavosurface margins and all lateral walls. Dentinal carious lesions were accessed when necessary using a spherical diamond bur (Nº. 1011; KG Sorensen, São Paulo, Brazil) operated at high speed under water-cooling. Visual and tactile clinical criteria were used to guide selective carious tissue removal up to firm dentin on pulpal floor. Excavation was stopped when hard and dried dentin with a leathery consistency (resistant to hand excavator) was reached[17].

After removing carious tissue, each cavity was washed with water spray until it was

visually clean and then dried. The margins of the enamel cavity of teeth of both groups were etched with 35% phosphoric gel acid (Scotch Etchant, 3M ESPE, St. Paul, USA) for 15 s, while the dentin was acid etched for 15 s or 7 s. The etching time was measured using a digital stopwatch. Cavities were flushed with air/water spray, and dried with sterilized absorbent papers leaving a slightly glistening appearance. Two layers of the adhesive system (Adper Single Bond Plus; 3M ESPE, St. Paul, USA) were actively applied on the entire preparation in both groups according to the manufacturer's recommendations. This was followed by gentle air thinning for 5 s and light curing (Radii-cal; SDI, Victoria, AUS) for 10 s. Composite resin (Filtek Bulk Fill Posterior Restorative, shade A1; 3M ESPE, St. Paul, USA) was inserted as a single increment of approximately 4 mm and light cured for 20 s on each surface of the tooth. The occlusion was checked by using articulating paper, and the restorations were finished immediately using fine diamond burs (KG Sorensen, São Paulo, Brazil). Polishing was performed using rubber points one week after restoration (Astropol, Ivoclar Vivadent, Schaan, Liechtenstein).

Evaluation

The restorations were evaluated according to the FDI criteria by a calibrated evaluator after 1, 6, 12, and 18 months of the restoration. The patients were recalled for follow-up by telephone contact, and the evaluations were performed in dental chair using artificial dental light, triple syringe, plane buccal mirror, and ballpoint probe. All parameters during the evaluation were recorded using a standardized manual case report form. FDI criteria[16] were categorized into three groups: esthetic (marginal staining), functional (fracture and marginal adaptation), and biological (caries recurrence). The worst score among all evaluated parameters was considered. Each criterion of FDI was evaluated for five scores, of which three scores indicated acceptable restorations (1: clinically very good; 2: clinically good; 3: clinically sufficient/satisfactory) and two scores indicated non-acceptable restorations (4:

clinically unsatisfactory, repairable restoration; 5: clinically poor, restoration replacement required). The restorations were recorded as failed if they scored 4 or 5 of the FDI criteria.

Statistical analysis

Distribution of success rates of restorations was calculated according to the independent variables of the following demographic and clinical characteristics: sex (male/female), tooth type (first/second molar), arch (upper/lower), dentin etching time (15 s/7 s), presence of visible plaque (no/yes), and gingival bleeding (no/yes) at the site of the restoration after follow-up. Restoration longevity was assessed by Kaplan-Meier estimator. Differences on survival rates according to the clinical variables were tested by the log-rank test and the significance level was set at 5%. The annual failure rate (AFR) was calculated using the formula: $(1 - y)z = (1 - x)$, where "y" is the mean AFR and "x" is the total failure rate at "z" years.

Survival estimates for restorations' longevity were evaluated using 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, and are analogous to multilevel regression models with random effects. Test of proportional-hazards assumption was performed for each independent variable before including them in the regression analysis. 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 $p < 0.20$ were selected for inclusion in the final model. The significance level was set at 5%. Data analyses were performed using the STATA 12.0 software (Stata Corp., College Station, Texas, USA).

Results

The sample comprised of 100 restorations in 62 subjects (24 boys and 38 girls) with an average age of 7.1 years (± 1.5 years). The follow-up period ranged from 1 to 18 months. Dropouts included three participants (4.8%) and four (4%) restorations. Physiological exfoliation was seen for 1 tooth and 11 teeth at 12 and 18 months, respectively. Finally, 84 restorations were evaluated after follow-up (Figure 1).

The distribution of restorations in primary molars according to individual and tooth-level variables is shown in Table 1. Among the restorations analyzed, 50 (52.1%) belonged to girls participants. Restorations performed in second molars were more common (68.7%) than those performed in first molars (31.3%), and there were more restorations in the lower arch (64.6%) than in the upper arch (35.4%). The majority of the restorations had visible plaque (76.0%) on the site after follow-up.

Table 2 shows the unadjusted and adjusted HR for failures according to independent variables. Differences in success rates regarding clinical and demographic characteristics of individual and tooth-level variables were not statistically significant ($p > 0.05$). However, the shortening of the acid etching time (7 s) for dentin showed a borderline association ($p = 0.07$) as a protective factor against restoration failure as compared to the acid etching time recommended by the manufacturer (15 s).

Mean estimated time of survival was 17.6 months (95% CI, 17.2-17.9). Estimated survival rates of the restorations were 100%, 97.9%, 94.8%, and 84% at 1, 6, 12, and 18 months of follow-up evaluations, respectively. The survival rates at the 18-month follow-up were 75.7% and 91.4% (AFR: 16.9% and 5.7%) when primary dentin was acid etched for 15 and 7 s, respectively (Figure 2).

Discussion

Dentin etching is a crucial step to attain effective bonding. Application time, concentration, composition, and pH of acid solution affect the depth of intertubular dentin demineralization[10]. Furthermore, the substrate type may interfere with bonding effectiveness, and consequently affect the longevity of the restoration.

Primary tooth dentin has greater tubular density and larger diameter than that of permanent tooth dentin[18]. Since the penetration of acids occurs primarily along the tubules, it could be possible that denser and larger diameter tubules could result in deeper penetration of the acidic conditioner. Primary tooth dentin also seems to be more reactive to acid etching due to a reduced degree of mineralization[8].

Nowadays, selective carious tissue removal to firm dentin is the treatment of choice for moderately deep cavitated dentinal lesions in order to maximize the longevity of the restorations by sufficient removal to soft dentin[17]. Although enough infected dentin is removed, the demineralized dentin, which can be remineralized, is maintained on the pulpal floor. This substrate presents a higher number of porosities in intertubular dentin, facilitating the diffusion of the inorganic conditioners, while the buffering action of the mineral phase of dentin is compromised by reduced mineral content. As consequence, a deeper demineralized layer forms thicker hybrid layers than those produced in sound dentin[19]. Therefore, an acid etching time reduced by approximately 50% for etch-and-rinse adhesive systems could reduce the occurrence of an unprotected dentin zone along the bottom of hybrid layers, mainly in a carious substrate.

It has been demonstrated that shortening of the dentin acid etching time is not detrimental to immediate bond strength[15], and reduces the degradation of bond strength created by etch-and-rinse adhesive systems in sound and carious primary dentin[14]. This is the first double-blind randomized clinical trial that assessed the effect of reduced acid etching

time for dentin on the survival of the restoration after selective carious tissue removal in primary molars.

A satisfactory survival rate of composite resin restorations was achieved during the 18 months follow-up period, irrespective of the dentin acid etching time. Evaluation of the treatment success showed a borderline association ($p = 0.07$) with shorter acid etching time (7 s) of the primary dentin as a protective factor against restoration failure when compared to the teeth etched as per the time recommended by the manufacturer (15 s).

Estimated survival rates of the restorations performed with the shortening of the acid etching time were 100%, 98%, 96% and 91.4 % at one, 6, 12 and 18 months of evaluations, while the restorations performed with etching time recommended by manufacturer reached survival rates of 100%, 97.8%, 93.4%, and 75.7% in the respective follow-up periods. It is important to highlight that our sample was estimated by laboratory parameter[15] (differences between bond strength means and standard deviations) and the clinical primary endpoint was measured at 18 months.

In our study, specific parameters related to adhesive protocol were considered for evaluation of the restorations, including marginal staining, fracture, marginal adaptation, and caries recurrence. The main reasons for failure of the restorations were related to marginal adaptation and fracture, especially when dentin was acid etched as per the time recommended by manufacturer (15 s). Therefore, shortening of the acid etching time could promote better adhesion in primary teeth, minimizing the occurrence of functional failures.

Moreover, only occlusal cavities were included in our study to avoid the influence of other variables on the outcome. A reduced survival of occluso-proximal restorations in primary molars than occlusal restorations has been reported[20]. Large proximal cavities result in preparations with boxes with limited retention due to the shape of primary molars.

Failures due caries recurrence were similar between both the experimental groups.

Furthermore, failures were not associated with individual and tooth-level variables such as sex, tooth type (first/second molar), arch (upper/lower), presence of gingival bleeding, or visible plaque at the restoration site.

The sample consisted of 100 primary molars from 62 children, who had undergone restorative procedures. These patients belonged to a low socioeconomic level and were at a high caries risk. Thus, children included in the sample were more likely to experience restorative failures[21]. Conversely, it is important to highlight that children were included in a periodic recall program at the University, which explains the low dropout and failure rates. Survival rate was calculated using the Kaplan-Meier estimator, which measures the fraction of the restorations surviving after the follow-ups. The estimator takes into account the censored data (i.e., restorations that were lost from the sample before the outcome occurred, exfoliated teeth, and/or those restorations not assessed in the 18-month evaluation), which can underestimate the real success rate of the restorative procedures during this period. Nevertheless, a high estimated survival rate (84%) was found in this study.

Shortening of the acid etching time for dentin by half the recommended by manufacturer (7s) is a simple strategy and clinically applicable for minimizing the discrepancy between the depth of demineralization and infiltration of the resin monomers, as well as improving the survival of adhesive restorations in primary teeth. Since there was a tendency for better clinical outcome with etching time reduced to approximately half of the manufacturer's recommended time, this new adhesive protocol for etch-and-rinse systems should be used in pediatric dentistry (enamel etching time remains at 15 s).

Conclusion

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

1. The shortening of the acid etching time of primary dentin did not influence the clinical

behavior of adhesive restorations placed in primary molars after selective carious tissue removal.

2. There was a tendency for better clinical outcome with 7 s of acid etching time.

Conflict of interest

The authors declare no conflict of interest.

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Table 1. Status of the restorations according to clinical and demographic characteristics (n=96 restorations).

Variables	n (%) of restorations	Success (%)	Failure (%)
Sex			
Girls	50 (52.1)	43 (86.0)	7 (14.0)
Boys	46 (47.9)	39 (84.8)	7 (15.2)
Teeth			
1st molar	30 (31.3)	22 (73.3)	8 (26.7)
2nd molar	66 (68.7)	60 (90.9)	6 (9.1)
Arch			
Upper	34 (35.4)	30 (88.2)	4 (11.8)
Lower	62 (64.6)	52 (83.9)	10 (16.1)
Gingival bleeding on the site			
No	52 (54.2)	47 (90.4)	5 (9.6)
Yes	44 (45.8)	35 (79.5)	9 (20.5)
Visible plaque on the site			
No	23 (24.0)	19 (82.6)	4 (17.4)
Yes	73 (76.0)	63 (86.3)	10 (13.7)

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

Variables	HR_{crude} (95%CI)	p-value	$HR_{adjusted}$ (95%CI)	p-value
Sex		0.94		
Girls	1			
Boys	1.04 (0.37-2.97)			
Teeth		0.07		
1st molar	1			
2nd molar	0.98 (0.96-1.00)			
Arch		0.71		
Upper	1			
Lower	1.25 (0.39-3.97)			
Gingival bleeding on the site		0.22		0.20
No	1		1	
Yes	1.97 (0.66-5.88)		2.04 (0.68-6.10)	
Visible plaque on the site		0.46		
No	1			
Yes	0.64 (0.20-2.05)			
Dentin etching time		0.08		0.07
Recommended by manufacturer (15s)	1		1	
Reduced etching time (7s)	0.36 (0.11-1.14)		0.35 (0.11-1.11)	

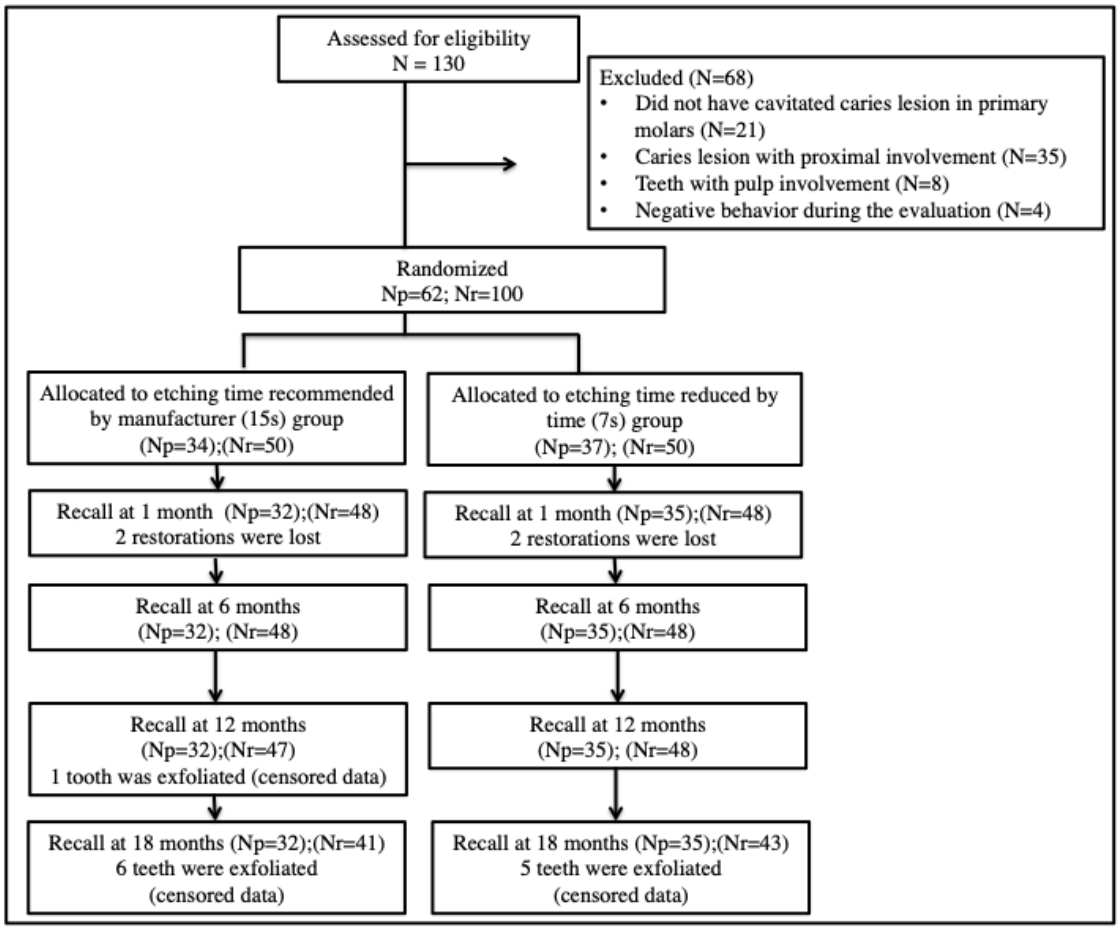

Figure 1. Flowchart of the study.
Np=number of patients; Nr=number of restorations

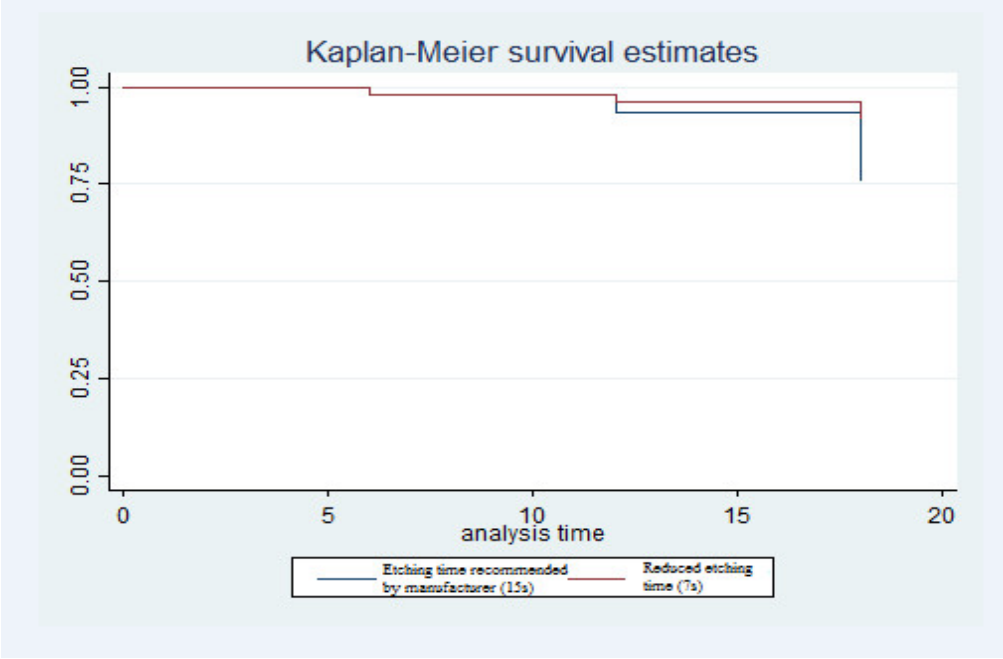

Figure 2. Adjusted Kaplan-Meier survival curves. Similar performance was observed in terms of restorations' longevity when primary dentin was acid etching by 15 and 7s.

3 CONCLUSÃO

A qualidade da união resina-dentina é um fator crítico para o sucesso de restaurações adesivas. A produção de vias de difusão a partir da remoção do conteúdo inorgânico tecidual pela aplicação de um agente condicionador ácido é um passo fundamental dentro dos protocolos de adesão à dentina. Idealmente, após o condicionamento da dentina, toda a zona desmineralizada deveria ser infiltrada por monômeros resinosos no processo de formação da camada híbrida, a fim de promover o selamento efetivo deste substrato. Entretanto, a literatura é unânime em afirmar que a profundidade de desmineralização da dentina e sua subsequente infiltração monomérica é discrepante (HASHIMOTO et al., 2000), resultando em interfaces adesivas mais suscetíveis à biodegradação imposta pela cavidade bucal (DE MUNCK et al., 2003).

Considerando que a zona de desmineralização da dentina não impregnada por adesivo em sua totalidade é mais pronunciada em dentes decíduos (NÖR et al., 1996), a redução do tempo de condicionamento poderia limitar tais efeitos nesse substrato. Ademais, a condição biológica do substrato pode afetar diretamente a qualidade da união resina-dentina. Atualmente, a remoção seletiva de tecido cariado tem sido fortemente recomendada, independente da profundidade da lesão, com o intuito de preservar ao máximo estrutura dentária (SCHWENDICKE et al., 2016).

No presente estudo, o tempo de condicionamento da dentina decídua não influenciou no comportamento clínico das restaurações adesivas realizadas em molares decíduos após a remoção seletiva de tecido cariado. Entretanto, houve uma tendência ($p=0,07$) para um melhor resultado clínico quando a dentina decídua foi condicionada por aproximadamente metade do tempo recomendado pelo fabricante (7 segundos).

A tendência observada corrobora os resultados obtidos em um estudo laboratorial (LENZI et al., 2014) em que a redução do tempo de condicionamento ácido melhorou a estabilidade da união de sistema adesivo convencional à dentina hígida e afetada por cárie de dentes decíduos. No presente estudo, a taxa de sobrevida foi de 75,7% e 91,4% para as restaurações realizadas após condicionamento ácido da dentina por 15 segundos e 7 segundos, respectivamente. Vale ressaltar que as restaurações foram avaliadas até 18 meses de acompanhamento e uma provável diferença estatisticamente significante entre os tempos de condicionamento ácido da dentina poderia ser encontrada com um tempo de acompanhamento clínico maior.

Considerando que a redução do tempo de condicionamento é um passo simples e

viável de ser aplicado clinicamente e, que não influencia negativamente na longevidade das restaurações adesivas, os clínicos deveriam optar por realizar o condicionamento com ácido fosfórico inicialmente em esmalte durante 8 segundos e, em seguida, proceder ao condicionamento do substrato dentinário por 7 segundos, totalizando 15 segundos de condicionamento do esmalte, quando da utilização de um adesivo convencional.

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ANEXO A – Aprovação do Comitê de Ética em Pesquisa

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

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: EFEITO DA REDUÇÃO DO TEMPO DE CONDICIONAMENTO ÁCIDO NO COMPORTAMENTO CLÍNICO DE RESTAURAÇÕES DE RESINA COMPOSTA EM DENTES DECÍDUOS

Pesquisador: Rachel de Oliveira Rocha

Área Temática:

Versão: 2

CAAE: 50648315.9.0000.5346

Instituição Proponente: Universidade Federal de Santa Maria/ Pró-Reitoria de Pós-Graduação e

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.320.844

Apresentação do Projeto:

É uma pesquisa vinculada ao Programa de Pós-Graduação em Ciências Odontológicas do CCS da UFSM que trata da "Redução do Tempo de Condicionamento Ácido no Comportamento Clínico de Restaurações de Resina Composta em Dentes Decíduos".

É um estudo clínico randomizado e controlado conforme orientações do Consolidated Standards of Reporting of Trials (CONSORT). Pacientes de ambos os gêneros, com idade entre 7 e 10 anos, apresentando lesões de cárie oclusas, em metade externa de destina, serão alocados aleatoriamente de acordo com o tempo de condicionamento ácido da destina: aplicação de gel de ácido fosfórico durante 15 ou 7 segundos, após remoção parcial. Restaurações de resina composta (Adper Single Bond 2 +Z250) serão avaliadas por dois examinadores previamente calibrados pelo critério USPHS após 6, 12 e 18 meses. Os dentes esfoliados serão submetidos ao teste de microtração para correlação dos achados clínicos com os valores de resistência de união. O n amostral calculado foi de 20 pacientes. Por questões de risco de perda e recusas, serão selecionados 30 pacientes por grupo e convidados a participar do estudo, totalizando 60 pacientes. Os procedimentos clínicos serão realizados na Clínica Odontológica da Universidade Federal de Santa Maria. Os pacientes serão selecionados por meio de exame clínico e radiográfico.

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UF: RS **Município:** SANTA MARIA
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As tomadas radiográficas serão padronizadas pelo uso de posicionadores de radiografia interproximal infantil. Todas as tomadas radiográficas serão realizadas com o uso de aventais e colares plumbíferos, com o objetivo de reduzir a exposição de radiação secundária nos órgãos reprodutores, tórax, abdome e glândulatireóide. Os critérios de inclusão envolverão a presença de um ou mais molares decíduos com pequena lesão de cárie oclusal, detectável radiograficamente como limitada à metade externa da dentina, ou seja, cavidade rasa ou média. Além disso, os dentes selecionados não deverão apresentar restaurações ou lesões de cárie em superfícies que interfiram com a lesão a ser tratada e acompanhada. Os critérios de exclusão serão: crianças que se recusarem ou não colaborarem com a realização do procedimento clínico, presença de hábitos parafuncionais, dentes sem antagonista, lesões cariosas que envolvam mais de uma superfície ou, que ao exame radiográfico, envolvam metade interna de dentina e presença de sintomatologia dolorosa ou sinais de alteração pulpar.

Os dados obtidos serão submetidos à análise estatística apropriada a fim de comparar os diferentes tempos de condicionamento ácido da dentina, analisar a sobrevida, comparar a resistência de união entre as diferentes épocas de esfoliação dos dentes decíduos e correlacionar os valores de resistência de união e o critério USPHS.

O custo do estudo será de R$ 1.670,00 custados pelas pesquisadoras.

Apresenta cronograma respeitando o período de apreciação do CEP.

Objetivo da Pesquisa:

Objetivo geral: avaliar a influência da redução tempo de condicionamento ácido no comportamento clínico de restaurações de resina composta em dentes decíduos, após remoção parcial do tecido cariado.

Objetivos específicos:

1) Investigar o efeito da redução no tempo de condicionamento nos valores de resistência de união à dentina de dentes decíduos;

2) Avaliar o desempenho clínico de restaurações adesivas após 18 meses de acompanhamento;

3) Correlacionar os valores de resistência de união e o desempenho clínico das restaurações

adesivas.

Avaliação dos Riscos e Benefícios:

Riscos: durante os procedimentos a criança poderá sentir desconforto por ficar com a boca aberta pelo tempo do procedimento, pelo procedimento de anestesia e pelo uso do equipamento odontológico que provoca vibração e ruído. Eventual sangramento decorrente da adaptação do grampo de isolamento absoluto poderá ocorrer e será mostrado aos pais/responsáveis, e as orientações necessárias serão fornecidas. A criança será exposta a radiação para a realização de radiografias, mas os riscos serão minimizados com o uso de avental e colar pumblífero. A dose de exposição será mínima e a radiografias serão feitas sem repetição acentuada, especialmente para exame inicial.

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, além do tratamento dos dentes envolvidos na pesquisa. Os responsáveis pelo paciente serão orientados a procurar assistência odontológica caso seja observado algum outro problema durante o exame do mesmo e em caso de dor, será oferecido tratamento de urgência pela pesquisadora.

Comentários e Considerações sobre a Pesquisa:

.

Considerações sobre os Termos de apresentação obrigatória:

Projeto na íntegra, folha de rosto, registro no GAP, Autorização institucional, TCLE, termo de confidencialidade, Informações básicas do projeto e termo de doação de dentes.

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.

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

Continuação do Parecer: 1.320.844

Conclusões ou Pendências e Lista de Inadequações:

Não existem pendências ou inadequações.

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_616569.pdf	10/11/2015 19:55:51		Aceito
Outros	TCF_NOVO.doc	10/11/2015 19:55:21	Rachel de Oliveira Rocha	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_NOVO.docx	10/11/2015 19:54:40	Rachel de Oliveira Rocha	Aceito
Outros	Registro_GAP.pdf	30/10/2015 15:19:32	Rachel de Oliveira Rocha	Aceito
Folha de Rosto	FOLHA_DE_ROSTO.pdf	30/10/2015 15:19:05	Rachel de Oliveira Rocha	Aceito
Outros	TERMO_DOACAO_DENTES_HUMANOS.docx	27/10/2015 22:10:11	Rachel de Oliveira Rocha	Aceito
Outros	AUTORIZACAO.pdf	27/10/2015 22:09:43	Rachel de Oliveira Rocha	Aceito
Projeto Detalhado / Brochura Investigador	PROJETO.docx	27/10/2015 22:05:49	Rachel de Oliveira Rocha	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

SANTA MARIA, 12 de Novembro de 2015

Assinado por:
CLAUDEMIR DE QUADROS
(Coordenador)

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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

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. This peer-reviewed journal features scientific articles, case reports, and abstracts of current pediatric dental research.

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*. Authors submitting manuscripts are expected to follow these instructions before submissions will be accepted for review consideration.

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 or viceversa.

Randomized Clinical Trials

Studies that are *Randomized Clinical Trials* should review and consider CONSORT guidelines and checklist available at: "www.consort-statement.org".

Maximum Figures: 4 • Maximum Tables: 3 or viceversa.

Cohort Studies

Studies that are observational cohort, case-controlled and cross-sectional studies must include submission of STROBE checklist addressing the guidelines available at: "www.strobe-statement.org/index.php?id=avao;ab;e-checklists")

Maximum Figures: 4 • Maximum Tables: 3 or viceversa.

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	4*	4*	Inclusion of large tables or more figures will be at the Editor-in-Chief's discretion and may require electronic publication
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	
LTEs & Responses to the LTE	None	1,000 words	8	0	0	
Editorials	None	1,000 words	40	2	2	Invited by the Editor-in-Chief

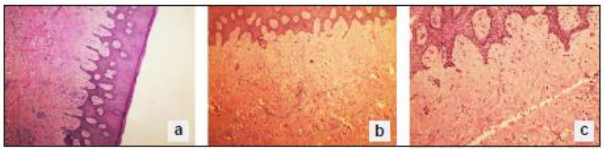
Case Reports

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 or viceversa.

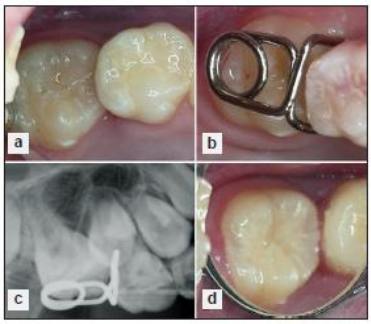
Literature Reviews (JDC only)

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

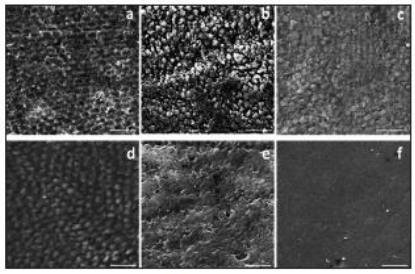
*** Authors desiring to have more figures or tables than provided in the Table above MUST agree to electronic publication of their manuscript, and must select this preference. Each separate chart, graph or photograph will be counted as a separate figure. Figures grouped together will be counted as their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



Example of 3 Figures



Example of 4 Figures



Example of 6 Figures

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Letters to the Editor & Responses to the Letter to the Editor

Full-length manuscript not to exceed 1000 words; excluding References.

Editorials

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

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. The scope of this style submission is for concise scientific studies and not intended to be a substitute for literature review.

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. 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 has significant intellectual contribution to the submission. 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 for each author (fill in the blanks): The responsibility of _____ was to _____.

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.

Author and institution blinded submissions will be selected by the Editor or Section Editors to be sent to at least two reviewers. The corresponding author may submit the names and email addresses of up to four qualified potential reviewers for their manuscript. These individuals (as well as requests to exclude reviewers) will be considered by the editorial membership. 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 (in the text as well as the Title page. The title page of the manucript must provide the following data of the contents complying with the criteria for specific types of submissions as described:

- Abstract: number of words _____.
- Body of text (excluding *Abstract*, *Acknowledgments*, *References,* Figures and Tables): number of words _____.
- Number of tables: _____.
- Number of figures: _____.

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. Each table and figure should have a number (if more than one) and title included with appropriate footnotes (and figure legend for figures). 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.

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World Wide Web

All websites and web articles (**URLs**) must be archived in WebCite® and listed in the reference section at the end of the manuscript— do not include links to websites in the text. To WebCite® a web link 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, as well as the WebCite® link and an access date. For example:

> American Academy of Pediatric Dentistry. AAPD Publications. Available at: "http://www.aapd.org/publications/". Accessed: February 3, 2019. (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.

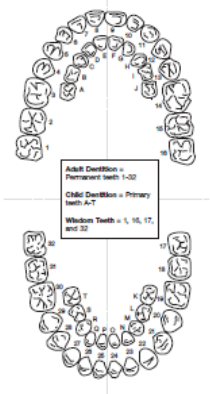
Authors should avoid citing 'personal communication' unless it provides essential information not available from a public source. Personal communications should not be numbered, but should be cited in the text as follows: (*G. Seale, DDS, oral communication, January 2019*). Authors should obtain written 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.



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- ❑ As appropriate, includes whether providers and participants were blinded.
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