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Larissa D'Olanda Gindri

ESTRATÉGIAS RESTAURADORAS SIMPLIFICADAS PARA DENTES DECÍDUOS: REDUÇÃO DO TEMPO DE CONDICIONAMENTO DA DENTINA E USO DE RESINA DE INCREMENTO ÚNICO (*BULK-FILL*)

Santa Maria, RS
2023

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Tese de Doutorado apresentada ao Programa de Pós-Graduação em Ciências Odontológicas da Universidade Federal de Santa Maria (UFSM, RS), como requisito parcial para a obtenção do título de **Doutora em Ciências Odontológicas com ênfase em Odontopediatria**.

Orientadora: Profª. Drª Rachel de Oliveira Rocha

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Larissa D'Olanda Gindri

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Aprovada em 17 de julho de 2023.

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Rachel de Oliveira Rocha, Dra. (UFSM)
(Presidente/Orientadora)

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Andressa Cargnelutti Follak Miotti, Dra. (UFSM)

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Graziela Botton, Dra. (UFSM)

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2023

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Acredite em milagres**,** mas não dependa deles.

(Immanuel Kant)

RESUMO

ESTRATÉGIAS RESTAURADORAS SIMPLIFICADAS PARA DENTES DECÍDUOS: REDUÇÃO DO TEMPO DE CONDICIONAMENTO DA DENTINA E USO DE RESINA DE INCREMENTO ÚNICO *(BULK-FILL)*

AUTORA: Larissa D'Olanda Gindri
ORIENTADORA: Rachel de Oliveira Rocha

A presente tese é composta por dois artigos científicos, que avaliaram duas estratégias simplificadas para a restauração de dentes decíduos. O primeiro artigo, trata-se de uma revisão sistemática com meta-análise, que investigou a influência da redução do tempo de condicionamento ácido e da aplicação do *primer* acídico na resistência de união de sistemas adesivos à dentina de dentes decíduos. A busca foi realizada nas bases de dados PubMed, Web of Science e Scopus. Oito estudos foram incluídos na revisão sistemática e sete na meta-análise. A redução do tempo de condicionamento da dentina não influenciou a resistência de união imediata de sistemas adesivos com condicionamento ácido prévio (Z=0,07, p=0,95) ou autocondicionantes (Z=0,41, p=0,69). A resistência de união após envelhecimento foi superior quando o tempo de condicionamento ácido foi reduzido (Z=2,01, p=0,04). O risco de viés foi considerado alto para todos os estudos. Com base nos resultados obtidos, pode-se concluir que a redução do tempo de condicionamento da dentina através da aplicação do ácido ou do *primer* acídico não prejudica a adesão em dentes decíduos e ainda, a redução do tempo de condicionamento ácido favorece a estabilidade da união ao longo do tempo. O segundo estudo, trata-se de um ensaio clínico randomizado, que objetivou comparar a performance clínica e o tempo necessário para restaurar lesões ocluso-proximais em molares decíduos, utilizando uma resina de incremento único (*bulk-fill;* Filtek™ Bulk-fill, 3M ESPE*)* e uma resina convencional (Filtek Z350 XT, 3M ESPE). 140 restaurações ocluso-proximais em molares decíduos de 65 participantes realizadas em ordem aleatória, sendo 70 com cada uma das duas resinas foram avaliadas por um único examinador calibrado, utilizando o critério da Federação Dentária Internacional (FDI), nos tempos imediato (*baseline),* após 6 e 12 meses. O tempo clínico foi mensurado com o uso de cronômetro digital, considerando o tempo desde a inserção até a fotoativação final da resina. O sucesso e a sobrevida das restaurações foram avaliados pelas estimativas de Kaplan-Meier e comparadas pelo teste de *log-rank*. A diferença no tempo clínico restaurador foi comparada usando o teste U de Mann-Whitney. O nível de significância foi de 5%. Após 12 meses, 115 restaurações foram avaliadas e a probabilidade de sucesso foi de 88,7% para as restaurações realizadas com a resina convencional e 85,9% para resina *bulk-fill*. A estimativa de sobrevida foi de 90% e 93,7%, respectivamente para as restaurações com as resinas convencional e *bulk-fill*. Não foram encontradas diferenças significativas entre as curvas de sucesso (p=0,62) e sobrevida (p=0,51). A principal causa de falha das restaurações foi relacionada a problemas na adaptação marginal. A resina *bulk-fill* exigiu 30% menos tempo do que a resina convencional (p<0,001). A resina *bulk-fill* apresenta desempenho clínico semelhante ao da resina convencional, com redução do tempo clínico restaurador, sendo assim, uma opção para a restauração de lesões ocluso-proximais em molares decíduos.

Palavras-chave: Adesivos Dentinários. Dente Decíduo. Longevidade. Resinas Compostas. Falha de Restauração Dentária.

ABSTRACT

SIMPLIFIED RESTORATIVE STRATEGIES FOR PRIMARY TEETH: REDUCED DENTIN ETCHING TIME AND USE OF BULK-FILL COMPOSITE RESIN

AUTHOR: Larissa D'Olanda Gindri
ADVISOR: Rachel de Oliveira Rocha

This thesis is composed of two scientific articles, which evaluated two simplified adhesive strategies used in primary teeth. The first study investigated, by a systematic review and meta-analysis, the influence of reduced dentin etching (acid-etching or acidic primer) time on the bond strength of adhesive systems to primary teeth. The search was performed in PubMed, Web of Science, and Scopus databases. Eight studies were included in the systematic review and seven in the meta-analysis. The shortening etching time did not influence the immediate dentin bond strength for etch-and-rinse ($Z=0.07$, $p=0.95$) or self-etch systems ($Z=0.41$, $p=0.69$). After aging, however, the shorting etching time improved the bond strength for etch-and-rinse adhesives ($Z=2.01$, $p=0.04$). All studies presented a high bias risk. In conclusion, the reduction of dentin etching time does not jeopardize the adhesion in primary teeth for etch-and-rinse or self-etch adhesives, and the reduction of acid-etching time contributed to resin-dentin bonding stability over time. The second study is a randomized clinical trial, which aimed to compare the clinical performance and the time required to restore occlusal-proximal lesions in primary molars, using a bulk-fill resin (FiltekTM Bulk-fill, 3M ESPE) and a conventional resin (Filtek Z350 XT, 3M ESPE). 140 occlusal-proximal restorations in primary molars of 65 participants performed in random order, 70 with each of the two resins were evaluated by a single calibrated examiner, using the criteria of the World Dental Federation (FDI), in the immediate (baseline), after 6 and 12 months. The clinical time was measured using a digital timer, considering the time from insertion to the final photoactivation of the resin. The success and survival of the restorations were evaluated using Kaplan-Meier estimates and compared using the log-rank test. The difference in clinical restorative time was compared using the Mann-Whitney U test. The significance level was 5%. After 12 months, 115 restorations were evaluated and the probability of success was 88.7% for restorations performed with conventional resin and 85.9% for bulk-fill resin. Survival estimates were 90% and 93.7%, respectively, for restorations with conventional and bulk-fill resins. No significant differences were found between the success ($p=0.62$) and survival ($p=0.51$) curves. The main cause of failure of restorations was related to problems in marginal adaptation. The bulk-fill resin required 30% less time than the conventional resin ($p<0.001$). Bulk-fill resin presents similar clinical performance to that of conventional resin, with reduced clinical restorative time, thus being an option for restoring occlusal-proximal lesions in primary molars.

Keywords: Dentin-Bonding Agents. Tooth, Deciduous. Longevity. Composite Resins. Dental Restoration Failure.

SUMÁRIO

1. INTRODUÇÃO

O tratamento restaurador de dentes decíduos acometidos por lesões de cárie ainda é um dos principais procedimentos realizados na prática clínica em odontopediatria (CHINISI et al., 2018; RICKETTS et al., 2013;). Frente a tantas opções de materiais restauradores, o uso combinado de sistemas adesivos e resinas compostas parece ser o protocolo mais usual para restaurar lesões cariosas em molares decíduos (RICKETTS et al., 2013; SANTOS et al., 2016). Isso porque as resinas compostas permitem preparos conservadores, de acordo com a filosofia de mínima intervenção, oferecem estética, resistência e longevidade (CHINISI et al., 2018; PINTO et al., 2014).

Ainda assim, o uso de sistemas adesivos e resinas compostas exigem rigoroso controle da umidade, correto condicionamento do substrato e múltiplas etapas, o que torna a técnica sensível e denota tempo clínico (CHINISI et al., 2018; FERRANCE, 2008). Por isso, alcançar as condições ideais pode ser um desafio no atendimento infantil, visto que a colaboração do paciente é limitada e o seu comportamento pode dificultar a obtenção de restaurações adequadas e assim, comprometer o desempenho clínico do material ao longo do tempo (CHINISI et al., 2018; JAMALI et al., 2018). Neste cenário, o desenvolvimento de estratégias restauradoras simplificadas torna-se desejável em odontopediatria.

Um dos fatores que pode influenciar a longevidade das restaurações em resina composta é a capacidade do sistema adesivo em estabelecer adesão estável ao longo do tempo. Entre os fatores que influenciam a resistência de união entre o sistema adesivo e os substratos dentários, é o correto condicionamento da dentina, em especial quando do uso de sistemas que exigem a aplicação de ácido fosfórico (sistemas *etch-and-rinse)* como primeiro passo operatório (PERDIGAO, 2010). Nos dentes decíduos, a adesão à dentina é ainda mais desafiadora que em dentes permanentes. Isto porque a dentina de dentes decíduos tem maior densidade tubular, maior diâmetro tubular e menor conteúdo mineral (ANGKER et al., 2004), tornando este substrato mais sensível ao condicionamento ácido (NOR et al., 1996). Uma desmineralização mais profunda da dentina, dificulta a penetração dos monômeros resinosos, formando uma zona de fibrilas colágenas desprotegidas, considerada fraca e susceptível a degradação enzimática e hidrolítica ao longo do tempo (HASHIMOTO et al., 2003; PIOCH et al., 1998).

Em busca de melhores resultados na adesão à dentina de dentes decíduos, alterações nos protocolos adesivos têm sido propostas, entre elas, a redução do tempo de condicionamento ácido quando do uso de sistemas *etch-and-rinse,* assim como, do tempo de aplicação do *primer*

acídico (em sistemas adesivos autocondicionantes) (NOR et al., 1997; SANABE et al., 2009). Os resultados de estudos laboratoriais, entretanto, não são unânimes em comprovar o benefício da redução do tempo de condicionamento da dentina decídua (AGUILERA et al., 2012; LENZI; BARGA; RAGGIO, 2014; SANABE et al., 2009). Portanto, avaliar e revisar sistematicamente a literatura existente sobre o assunto é justificada.

A *American Academy of Pediatric Dentistry* (AAPD) recomenda o uso da resina composta como material restaurador para lesões oclusais e ocluso-proximais tanto em dentes permanentes quanto em dentes decíduos (American Academy of Pediatric Dentistry, 2022). Entretanto, a necessidade de inserção da resina composta em incrementos de até 2 mm de espessura, para controlar a contração volumétrica que ocorre durante a polimerização e suas consequências, implica em múltiplas etapas e torna a técnica restauradora sensível e demorada (ABBAS et al., 2003; CAMPOS et., 2014). Uma alternativa às resinas compostas convencionais (resinas que exigem o uso em técnica incremental) são as resinas de incremento único, denominadas *bulk-fill* que, por meio de alterações em sua formulação, apresentam uma menor contração de polimerização (FLURY; PEUTZFELDT; LUSSI, 2014; FRONZA et al., 2015) e, dessa forma, possibilitam realizar restaurações em incrementos únicos de até 4 ou 5 mm de espessura, simplificando a técnica restauradora.

Recentes revisões sistemáticas e meta-análises têm demonstrado que as resinas *bulk-fill* apresentam comportamento clínico semelhante ao das resinas convencionais (ABREU et al., 2022; CIDREIRA BOARO et al., 2019; KUNZ et al., 2022; VELOSO et al., 2019). Entretanto, esses resultados foram obtidos com base em estudos conduzidos principalmente em dentes permanentes, e não podem ser extrapolados diretamente para os dentes decíduos, uma vez que existem diferenças morfológicas e funcionais entre os dentes permanentes e dentes decíduos (ANGKER et al., 2004; LENZI et al., 2013; UESUKA et al., 2006). Além disso, em odontopediatria, os fatores relacionados ao paciente, entre eles o comportamento durante o procedimento é um dos fatores que pode influenciar a qualidade da restauração (CHINISI et al., 2018).

Seis ensaios clínicos randomizados avaliando o comportamento de resinas *bulk-fill* em dentes decíduos são encontrados na literatura (AKMAN; TOSUN, 2020; EHLERS et al., 2019; LARDANI et al., 2022; OTER; DENIZ; CEHRELI, 2018; MASSA et al., 2022; SARAPULTSEVA; SARAPULTSEV, 2019). Considerando que, nestes estudos, as restaurações oclusais, ocluso-aproximais ou ambas, realizadas com resinas *bulk-fill* foram comparadas com materiais restauradores diferentes das resinas compostas convencionais (AKMAN; TOSUN, 2020; EHLERS et al., 2019; LARDANI et al., 2022; MASSA et al., 2022;

SARAPULTSEVA; SARAPULTSEV, 2019) e que diferentes critérios de avaliação foram considerados, estudos clínicos randomizados que avaliem as restaurações de resina *bulk-fill* realizadas em dentes decíduos são necessários a fim de assegurar o emprego deste material em diferentes situações restauradoras em odontopediatria.

Em odontopediatria, a avaliação de estratégias restauradoras simplificadas é de suma importância. Procedimentos restauradores mais fáceis e simples, reduzem o tempo clínico, a chance de erros e contribuem com a cooperação do paciente, o que pode influenciar na longevidade das restaurações. Portanto, o objetivo geral desta tese é avaliar duas estratégias restauradoras simplificadas possíveis de serem utilizadas em odontopediatria. O primeiro estudo avaliou, por meio de uma revisão sistemática com meta-análise, a influência da redução do tempo de condicionamento da dentina decídua na resistência de união de sistemas adesivos. Já o segundo estudo trata-se de um ensaio clínico randomizado que avaliou a performance clínica de uma resina *bulk-fill* na restauração de lesões ocluso-proximais em molares decíduos.

2. ARTIGO 1 - ETCHING TIME AND BONDING OF ADHESIVE SYSTEMS TO DENTIN OF PRIMARY TEETH: A SYSTEMATIC REVIEW AND META-ANALYSIS

Artigo publicado no periódico *International Journal of Paediatric Dentistry*, ISSN 1365-263X, Fator de impacto: 1.993; Qualis CAPES A1.

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Etching time and bonding of adhesive systems to dentin of primary teeth: A Systematic Review and Meta-Analysis

Larissa D'Olanda Gindri[a], Tatiana Tambara Fröhlich[a], Carolina Ramos Rosso[b], Rachel de Oliveira Rocha[c]

[A] Dental Science Graduate Program, Federal University of Santa Maria, Santa Maria, RS, Brazil.
[B] School of Dentistry, Federal University of Santa Maria, Santa Maria, RS, Brazil.
[C] Department of Stomatology, Federal University of Santa Maria, Santa Maria, RS, Brazil.

Running title: Effect of shorter etching time in primary dentin

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Ethics statement

No ethical approval will be needed because data from previous published studies in which ethical consent was obtained by primary investigators will be retrieved and analyzed.

Correspondence address:

Dr. Rachel de Oliveira Rocha
Department of Stomatology, Pediatric Dentistry
Federal University of Santa Maria, Santa Maria, RS, Brazil
Av. Roraima, 1000, Prédio 26 F, Cidade Universitária, Santa Maria, RS, Brazil
Phone: +55 55 3220 9266
Corresponding author fax: +55 55 3220 9266
E-mail: rachelrocha@smail.ufsm.br

ABSTRACT

Background: Due to the chemical and morphological differences between primary vs. permanent teeth, the time reduction of the acid-etching or acidic primer can result in higher values of bond strength.

Aim: To assess through a systematic review and meta-analysis the influence of the reducing etching (acid-etching or acidic primer) time on the bond strength of adhesive systems to primary dentin.

Design: A systematic search was carried out in 3 databases: PubMed, Web of Science and Scopus. Studies that evaluated the effect of reducing the etching time on the bond strength of adhesive systems to primary dentin were included. Meta-analyses were performed using a random-effects model, with subgroups for etch-and-rinse and self-etching adhesives, with a significance level of $p < 0.05$. The risk of bias and heterogeneity between studies (Cochrane and I^2 tests) were assessed.

Results: Eight studies were included in the systematic review and seven in the meta-analyses. The shortening etching time did not influence the immediate dentin bond strength for etch-and-rinse ($Z=0.07$, $p=0.95$) and self-etching adhesives ($Z=0.41$, $p=0.69$). After aging, however, the shorting etching time improved the bond strength for etch-and-rinse adhesives ($Z=2.01$, $p=0.04$). All studies presented high bias risk.

Conclusions: Reducing the acid etching time to primary dentin improves the long-term bond strength to this substrate.

Key-words: adhesive system, bond strength, dental etching, primary dentin.

INTRODUCTION

Aesthetic and conservative restorations render adhesive systems essentials for Pediatric Dentistry. However, there are no protocols firmly established by manufacturers for using it in primary teeth, as the same adhesive protocol is assigned to permanent and primary teeth, disregarding the chemical and morphological differences between these dentin substrates.[1,2] Primary dentin has a higher tubular density, with a larger diameter in peritubular and intertubular dentin and the lower mineral content,[2,3] turning this substrate more reactive to acid conditioners.[4] Therefore, an increased demineralization occurs in primary dentin, producing a thicker hybrid layer and lower bond strength values[4-6] when submitted to the same etching time used for dentin in permanent teeth.[4]

The deeper demineralization of primary dentin jeopardizes the adhesion by the collapse of collagen fibrils, calcium phosphate crystals precipitation, and thus, less penetration of resin monomers occurs into the demineralized dentin.[7,8] The unprotected collagen fibrils zone formed at the base of the hybrid layer is considered the weakest area within the adhesive interface,[8,9] which is highly susceptible to both hydrolytic and enzymatic long-term deterioration.[8]

To improve the adhesion to primary dentin, some authors have proposed the reduction of the etching time.[1,4,5] A reduced etching time for primary dentin would yield the formation of a more homogeneous hybrid layer,[5,6] and increase the bond strength values. However, the results of the studies that proposed a reduction in etching time are not unanimous. Higher bond strength values are found when the acid etching agent is applied for shorter times than indicated by the manufacturers,[11,12] but these findings were not found in studies with the same scope,[13,14] neither for self-etching adhesives systems.[15] So, there is a need to appraise and systematically review the existing literature. Although randomized controlled trials are traditionally the gold standards for judging the benefits of treatments,[21] laboratory studies evaluating the bond strength values may be considered useful as screening tools for new adhesive approaches, as

reducing the etching time for primary dentin.[22] Similarly, a systematic review synthesizing the evidence on the outcome 'bond strength' may also promote evidence-based achievements to predict the clinical effectiveness of adhesive systems.

This systematic review and meta-analysis aimed to investigate the influence of reducing the etching (acid-etching or acidic primer) time on the bonding of etch-and-rinse and self-etching adhesive systems to dentin of primary teeth. The tested null hypothesis was that the bond strength of adhesive systems to primary dentin was not affected by reduced acid etching time.

METHODS

This systematic review was conducted following the recommendations of the Cochrane Handbook and structured according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[18] The addressed focused question was: “Does the reduced acid etching time impact on the bond strength between adhesive systems and primary dentin?” The research question was developed based on the acronym PICO (participant, intervention, comparator, and outcome), in which, primary dentin was the “participant”; the reduced acid etching time was the “intervention”; acid etching time according to manufacturers' instructions was the “control, and the "outcome" was the bond strength.

Search strategy

A comprehensive literature search was undertaken through the PubMed/MEDLINE, Scopus and Web of Science databases for identification of studies published by May 25, 2020. The search was conducted with no publication time or language restrictions. The search strategy for the PubMed / MEDLINE database was formulated with the combination of MeSH terms and free terms as follows: ((((((((((((tooth, deciduous[MeSH Terms]) OR tooth, deciduous) OR deciduous tooth) OR deciduous dentition*) OR primary dentition*) OR milk tooth) OR

milk teeth) OR deciduous teeth) OR primary teeth) OR primary tooth) OR baby tooth) OR baby teeth)) AND ((((((dentin bonding agents[MeSH Terms]) OR dentin bonding agents) OR dental bonding[MeSH Terms]) OR dental bonding) OR adhesive system*) OR bond*). This strategy was adapted to search the Scopus, as follows: (TITLE-ABS-KEY (“adhesive systems”) AND TITLE-ABS-KEY (“deciduous teeth”) OR TITLE-ABS-KEY (“primary teeth”)) and Web of Science - TOPIC: (ADHESIVE SYSTEM) AND TOPIC: (DECIDUOUS TEETH) OR TOPIC: (PRIMARY TEETH) AND TOPIC: (BOND STRENGTH) databases. The results of searches of various databases were cross-checked to locate and eliminate duplicates.

Study selection

In the first phase, titles and abstracts were screened independently by two authors (C.R.R. and L.D.G.) to identify potentially eligible studies. The inclusion criteria were: a) laboratory studies that have evaluated the bond strength of adhesive systems to primary dentin, and b) have included reducing the etching time before using adhesive systems. The studies selected in the first phase were subjected to a full-text reading for the definitive inclusion in the systematic review, and two exclusion criteria were considered: a) bond strength values within 24 hours not presented, b) absence of a control group (acid etching time according to manufacturers' instructions). Disagreements between the two authors regarding eligibility were resolved by a consensus with a third reviewer (R.O.R.). The reference lists of all included studies were hand-searched to retrieve all potentially relevant studies.

Data extraction

Extracted data from included studies were registered by one researcher (R.O.R.) in a standardized form (Microsoft Office Excel 2016, Microsoft Corporation, Redmond, WA, USA). For each study, the publication's data (title, authors, year of publication and the first author origin), methodology details (the type of primary teeth, number of teeth per group, adhesive systems, mechanical test and storage time), intervention (acid etching time according

manufacturers' instruction and reduced time), and the outcome (bond strength values) were recorded. For studies that did not clearly report the bond strength values or had presented the results in graphs or figures, corresponding authors were contacted by email (at least twice). If no information was provided, the study was not included in the meta-analysis.

Assessment of risk of bias

The risk of bias in each study was assessed based on the criteria described in a previous systematic review,[19] and adapted for the present review, considering the items: sample size calculation, the same number of teeth in all experimental groups, a random sequence of performance the adhesive procedures, evaluation of the failure mode, adhesive procedures performed by a single operator and blinding of the responsible operator for performing the mechanical test. For each identified item a 'YES' was assigned and for each missing information, a 'NO' was assigned. The risk of bias was classified according to the sum of the number of items that received 'YES', as follows: 1 to 3 = high risk of bias; 4 to 5 = medium risk of bias; 6 to 7 = low risk of bias.

Data analysis

Standardized mean differences were evaluated, through a random-effects model, between experimental (reduced acid etching time) and control groups (acid etching time according to the manufacturers). Subgroups meta-analysis were conducted considering the etching strategy (etch-and-rinse adhesive systems, and self-etching adhesive systems). Moreover, meta-analyses were performed considering the aging (water storage time) on the bond performance (including studies that had a storage time for at least 6 months). For studies that evaluated more than one adhesive system, the bond strength means (standard deviations) were combined to one mean (standard deviation) using a predefined formula (Cochrane Statistical Guidelines).[10] Statistical heterogeneity among studies was considered using the Cochran Q test, and the inconsistency I^2 test (>50% indicates high heterogeneity).[10] Meta-

analyses were conducted using Review Manager (RevMan version 5.3; Cochrane Collaboration, London, UK) with the significance level at 5%.

RESULTS

Study selection

The study selection process is presented in a PRISMA flowchart (Figure 1).[18] A total of 1625 potentially eligible studies was found in the researched databases. After excluding duplicates, 1330 studies were evaluated regarding the inclusion criteria. Most of these studies (1323 studies) did not perform a bond strength test and/or did not include a reduced acid etching time. Seven studies were selected for full-text screening. Another one study was identified from the reference list of selected studies, so eight studies were included in qualitative analysis. One study could not be included in the meta-analysis because the standard deviation values were not provided, even after requesting the authors. So, seven studies were considered in the quantitative analysis. An inter-examiner agreement was obtained during study selection (Cohen's Kappa, 0.84).

Descriptive analysis

The main descriptive data are summarized in Tables 1. All studies were conducted by researchers from Brazil[12,13,15,16,20] and Spain.[11,14,17] All studies were published in English, and their publication years ranged from 2006 through 2014.

The microtensile test was applied in all studies for bond strength assessment. Six studies considered sound dentin[11-14,17,20] as a bonding substrate, and two studies also considered caries-affected dentin.[15,16] Three studies evaluated the reduced acid etching time[14,16,20] and five evaluated both the reduction of acid etching time and primer application time.[11-13,15,17] In only two studies,[13,15] the bond strength was also evaluated after water storage of 12 months.

Among the etch-and-rinse adhesive systems, most of the studies used Single Bond/Adper Single Bond 2 (3M ESPE).[11-13,15,17,20] The adhesives Excite (Ivoclar/Vivadent)[14] and Prime & Bond NT (Dentsply Sirona)[16] were used by one study each. All studies that evaluated the bond strength using self-etching adhesive system used Clearfil SE Bond (Kuraray Noritake),[11-13,15,17] and two studies also included the adhesive One-Up Bond F (Tokuyama)[11,17]

Meta-analysis

According to the overall meta-analysis (Figure 2), reduced time of acid etching or primer application did not impact on the immediate bond strength values, as no significant differences were found between experimental (reduced time) and control (acid etching or primer application time according manufacturers) groups (Z = 0.33, p = 0.74), as well as, the subgroup meta-analysis considering etch-and-rinse adhesive systems (Z = 0.07, p = 0.95) or self-etching adhesives (Z = 0.41, p = 0.69), separately. The data were not heterogeneous (I^2=0; Chi^2 p = 0.80). The reduced acid etching time resulted in greater bond strength values (Z=2.01, p=0.04) when specimens were tested after 12 months of water storage. However, the overall meta-analysis of long-term bond strength values reveled no significant differences between control and experimental groups (Z = 0.76; p = 0.45), as the subgroup meta-analysis considering only self-etching adhesives (Z = 0.63; p = 0.53), as depicted in Figure 3. No significant heterogeneity was observed in overall (I^2=44%, Chi^2 p=0.15,) and subgroups meta-analysis (I^2= 6 %, Chi^2 p = 0.30, and I^2= 0 %, Chi^2 p = 0.46, respectively for etch-and-rinse and self-etch adhesive systems).

Quality and risk of bias of the studies

All included studies have a high risk of bias (Table 2). No study informed the sample size calculation, if a single operator performed all adhesive procedures, and if the operator of test machine was blinded to experimental groups.

DISCUSSION

This systematic review is the first to compile data from laboratory studies that evaluated the reduced time of acid-etching or acidic primer for the use of adhesive systems applied to primary teeth. The concern with the performance of adhesive systems on primary teeth has long been described, justified by the histological and mineral content differences compared to permanent teeth and which result in lower bond strength values.[5,6] Besides, commercially available adhesives do not recommend a specific protocol for their use on primary teeth, considering the particularities of this substrate.

The hypothesis tested in this review - the reduction of acid etching or acidic primer time influences the bond strength to dentin of primary teeth - can be partially accepted, because of the reduced time of acid etching increased the dentin bond strength of adhesive systems to primary dentin only after aging. However, the reduced time of the primer application of self-etching adhesives did not influence the bond strength, regardless of the water storage time. The reduction of the acid-etching time seems to decrease the degradation that occurred during water storage. Water degradation is more pronounced for etch-and-rinse systems, as previously pointed by a systematic review and meta-analysis of in vitro studies,[33] a superior immediate performance was observed for etch-and-rinse adhesives, however after aging, the bond strength values were similar, regarding the etching strategy.

The lowest mineral content of primary dentin and the highest density and tubular diameter[2,3,6] appear to be responsible for thicker hybrid layers[4] and lower bond strength values obtained in primary dentin.[6] Thick demineralized dentin layers impair the complete infiltration by resin monomers, especially at their base.[8,9] The hybrid layers with poorly or non-infiltrated demineralized dentin zones offer a pathway for nanoleakage and interface degradation over time.[7,13] The etch-and-rinse adhesives appear to be less resistant to degradation than self-etching,[13,28] probably because of the higher demineralization ability of phosphoric acid than

acidic primers. The reduction of the acid-etching time results in thinner,[11,12,15,17] and a more infiltrated hybrid layers.[11,17] More homogeneous hybrid layers seem not to influence the immediate bond strength; however, it may be related to bond stability, represented by the higher bond strength values in the group that reduced the acid-etching time.

The acid primers application for shorter times than those recommended by the self-etching systems manufacturers, however, did not impact the bond strength values,[2,4,12,13,15] regardless of evaluation time (immediate or after aging). The demineralization ability of acidic monomers is lighter compared to phosphoric acid etch as a separate step, preventing the excessive dentin mineral loss. The simultaneous demineralization and monomers infiltration decrease the collapse of the demineralized dentin; therefore, fewer potential discrepancies and gap formations may be observed.[4,24] Irrespective of the application time (10 or 20 seconds), the acidic primers were able to partially dissolve the smear layer and leaving hydroxyapatite remnants available for chemical interaction with the adhesive monomers.[7,8,15] Sanabe *et al.*[13] observed in SEM analysis, hybrid layers with indistinguishable morphological characteristics when the primer was applied for the time recommended by the manufacturer or by half the time. Laboratory studies also demonstrate the stability of self-etching adhesives over time.[7,26,28] Both studies[13,15] that evaluated the bond strength over time used the adhesive Clearfil SE Bond, which is considered a 'gold-standard' for self-etching adhesives.[27] This adhesive system contains MDP (10-methacryloxydecyl dihydrogen phosphate) as an acidic polymerizable monomer. Due to its mild aggressiveness, MDP causes minimal dissolution of the smear plugs and limited opening of tubules,[25] leaving hydroxyapatite remnants available for chemical interaction with a functional monomer.[13] These precipitates prevent the loss of calcium from the dentinal matrix.[26] The less defective hybrid layers and intense chemical adhesion to hydroxyapatite[23] may contribute to the stability of bonded interfaces over time.[13,15]

The dentin condition (sound or caries-affected) impacts on the bonding performance of adhesive systems. Caries-affected dentin (CAD) presents less of mineral content and higher intertubular porosity, which results in a deeper demineralized layer.[31] The intratubular mineral obliteration decreases the monomer infiltration and resin tag formation,[29] with lower bond strength values to CAD than sound dentin.[29-31] Additionally, selective caries removal has been strongly recommended, based on minimal intervention concept;[32] therefore, CAD is a clinically relevant substrate. Only one study[15] presents the necessary data for CAD quantitative analysis; thus, a meta-analysis comparing the reduced etching time on CAD cannot be performed, and this is a limitation of this systematic review. Future studies evaluating the immediate and long-term bond strength are necessary to prove the effects of the reduced etching time on caries-affected dentin. The electronic search of our systematic review included only the databases PubMed/MEDLINE, Web of Science, and Scopus, which is also a limitation. However, the inclusion of other databases could not add to the present outcome, and grey literature can result in a higher number of incomplete data, having an unclear impact on meta-analysis results in medical research.

All included studies were classified as having a high risk of bias. The absence or incomplete description of the parameters as sample size calculation, random sequence of specimen preparation, and blinding of the operator responsible for carrying out the mechanical test should be considered in future studies. Nevertheless, all meta-analyses did not present heterogeneity. This result is uncommon, as in general, meta-analyses of laboratory studies show high heterogeneity[33,36,37] primarily due to the methodological variations, as the use of specific guidelines for conducting and reporting in vitro studies is not widespread. Some factors may be associated with non-heterogeneity, as the single mechanical test used in all studies (microtensile bond strength test), besides, the included studies were carried out either in Brazil or in Spain, even by the same research group, contributing for similar methodologies.

The methodological limitations of this in vitro study do not permit a direct extrapolation to the clinical situation, because the relation between the bond strength evaluations with the clinical performance is hard to establish.[34] However, the adhesive ability of a material is an indicator of the longevity of restorations, superior laboratory performance are indicative of better clinical performance.[35] Whereas the main reasons for restoration failures is secondary caries and fracture, achieving higher values of bond strength, especially in the long-term to predict the clinical performance of this material/technique.[36] Therefore, conducting laboratory studies is necessary even before clinical studies.

The reduction of the acid etching time to primary dentin improved the long-term bond strength of etch-and-rinse adhesives; however, this result should be interpreted with caution, because only two studies could be included in the meta-analysis. Ideally, our results should be confirmed by randomized clinical trials. Currently, there is one randomized clinical trial evaluating the reduction of acid-etching time of primary dentin, showing a trend, not statistically significant, but clinically relevant, of better clinical outcome, after 18 months, with reduced acid-etching time for etch-and-rinse adhesive systems.[38] For self-etching adhesive system, there is no literature with clinical methodology. So, our findings encourage future randomized clinical trials with sufficiently long follow-up time.

The present systematic review and meta-analysis showed that the reduction in the acid-etching and acidic primer application time did not jeopardize the immediate bond strength to primary dentin. Moreover, reduced acid-etching time promoted higher bond strength values after aging, even if only two studies were included.[13,15] The reduced application time of self-etching primers did not impact the dentin bond strength. These results are valuable, considering the reduction in clinical time, without affecting the performance of the adhesive system or improving it.

CONCLUSION

Based on the findings of this systematic review, it can be concluded that reducing the acid-etching time to primary dentin improves the long-term bond strength of etch-and-rinse adhesives to this substrate.

Why this paper is important to paediatric dentists

- The reduction in the conditioning time of primary dentin for etch-and-rinse and self-etch adhesives did not jeopardize immediate adhesion.
- The reduction of acid-etching time contributed to resin-dentin bonding stability over time.
- It is necessary to develop specific adhesive protocols for primary teeth.

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TABLES

Table 1. Descriptive data and bond strength values of the included studies.

(continua)

Study	Country	Tipe of teeth	N&	Mechanical test	Adhesive system#	Etching-time (seconds)	Immediate bond strength (24 hours)	Long-term bond strength (12 months)
Aguilera et al., 2013	Spain	Molars	n=6	Microtensile	Single Bond (3M ESPE)	15 7*	29.4 (11.5)^{A} 42.0 (17.1)^{A}	-
					Clearfil SE Bond (Kurakay)	20 10*	29.3 (10.1)^{A} 27.4 (7.3)^{A}	
					One-Up Bond F (Tokuyama)	20 10*	10.7 (3.7)^{A} 18.0 (7.4)^{A}	
Bolanos-Carmona et al., 2006	Spain	Molars	n=3	Microtensile	Excite (Ivoclar/Vivadent)	15 5*	3.8 (1.3)^{A} 3.3 (1.2)^{A}	-
Lenzi et al., 2013	Brazil	Molars	n=6	Microtensile	Adper Single Bond 2 (3M ESPE)	15 7*	44.2 (6.8)^{A} 40.9 (3.2)^{A}	21.6 (6.1)^{A} 30.1 (5.5)^{A}
					Clearfil SE Bond (Kuraray)	20 10*	41.0 (6.5)^{A} 41.2 (5.1)^{A}	36.4 (4.6)^{A} 33.6 (4.3)^{A}
Osorio et al., 2010	Spain	N.I.	n=2	Microtensile	Adper Single Bond (3M ESPE)	15 7*	29.3 (11.5)^{A} 42.0(17.1)^{A}	-
					Clearfil SE Bond (Kuraray)	20 10*	29.3 (13.1)^{A} 27.4 (15.3)^{A}	
					One Up Bond F (Tokuyama)	20 10*	11.7 (3.7)^{A} 17.8 (13.4)^{A}	

Table 1. Descriptive data and bond strength values of the included studies.

(conclusão)

							49.0 (12.9)^{A}	30.4 (5.6)^{A}
					Adper Single Bond (3M ESPE)	15	46.9 (15.1)^{A}	36.0 (13.6)^{A}
						7*		
Sanabe at al., 2009	Brazil	Molars	n=10	Microtensile				
						20	52.9 (13.1)^{A}	42.4 (16.6)^{A}
					Clearfil SE Bond (Kuraray)	10*	51.7 (12.9)^{A}	41.9 (18.6)^{A}
						15	47.5 (14.4)^{A}	
					Adper Single Bond (3M ESPE)	7*	59.4 (13.1)^{A}	
								-
Sardella et al., 2005	Brazil	Molars	n=4	Microtensile				
						20	30.2 (8.6)^{A}	
					Clearfil Se Bond (Kuraray)	10*	31.6 (6.6)^{A}	
						15	25.7 (15.3-36.3)^{B}	
					Prime & Bond NT (Dentsply Sirona)	10*	30.5 (24.3-37.5)^{B}	-
						5*	30.3 (25.8-.34.7)^{B}	
Scheffel et al. 2013	Brazil	Molars	n=4	Microtensile				
						15	8.8 (3.0)^{A}	
					Single Bond (3M ESPE)	10*	7.8 (4.5)^{A}	-
Torres et al. 2007	Brazil	Molars	N=10	Microtensile				
						5*	10.0 (3.3)^{A}	

&: Number of teeth per group. N.I.: not informed or unclear describe in the study. #: According to described in the study. *: reduced acid etching or acidic primer application time. A: Mean and standard deviation (MPa). B: median and percentile (MPa).

Table 2. Risk of bias

Study	Random sequence	Sample size calculation	Same number of teeth per group	Failure mode evaluation	Single operator	Blinded operator	Risk of bias
Aguilera et al., 2013	No	No	?	No	No	No	High
Bolanos-Carmona et al., 2006	Yes	No	No	Yes	No	No	High
Lenzi et al., 2013	Yes	No	Yes	Yes	No	No	High
Osorio et al., 2010	No	No	?	Yes	No	No	High
Sanabe at al., 2009	Yes	No	Yes	Yes	No	No	High
Sardella et al., 2005	No	No	Yes	Yes	No	No	High
Scheffel et al, 2013	No	No	Yes	Yes	No	No	High
Torres et al, 2007	Yes	No	Yes	Yes	No	No	High

?: Unclearly described in the study.

FIGURES

Figure 1: Flowchart diagram of studies selection according to PRISMA statement.

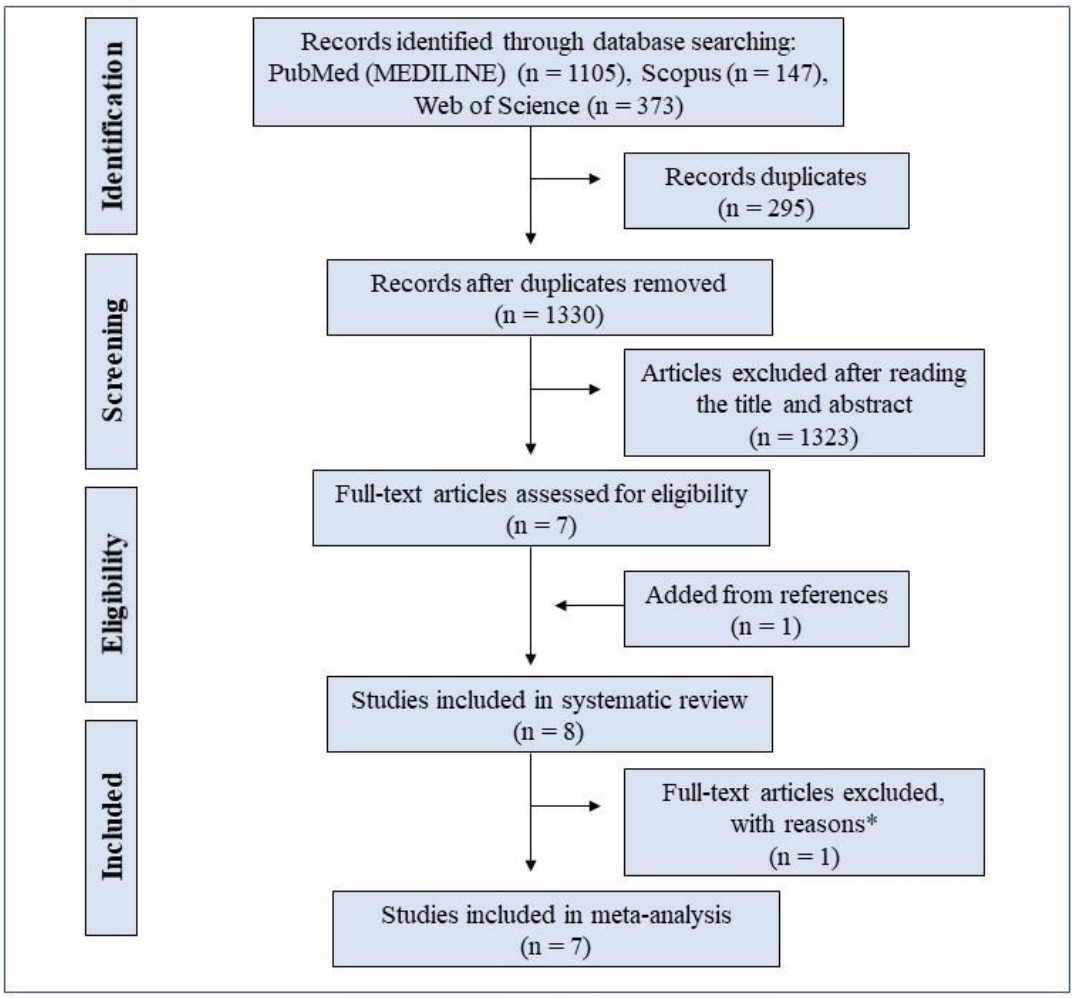


Figure 2: Results of reducing etching time meta-analyses, using random effect model.

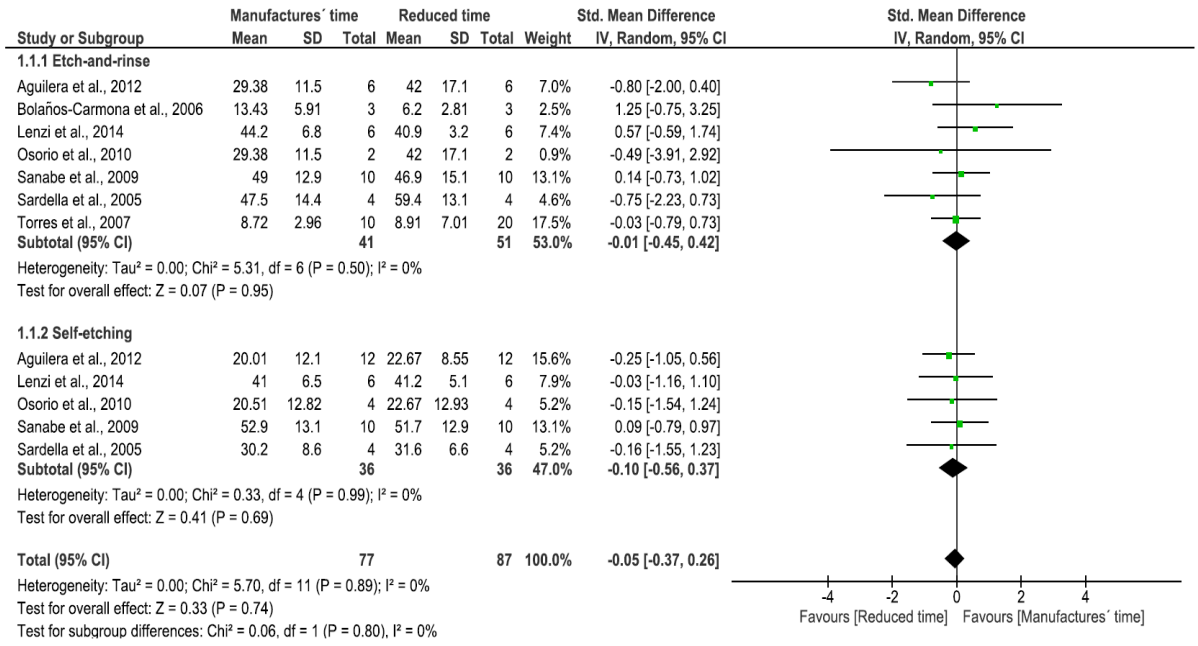
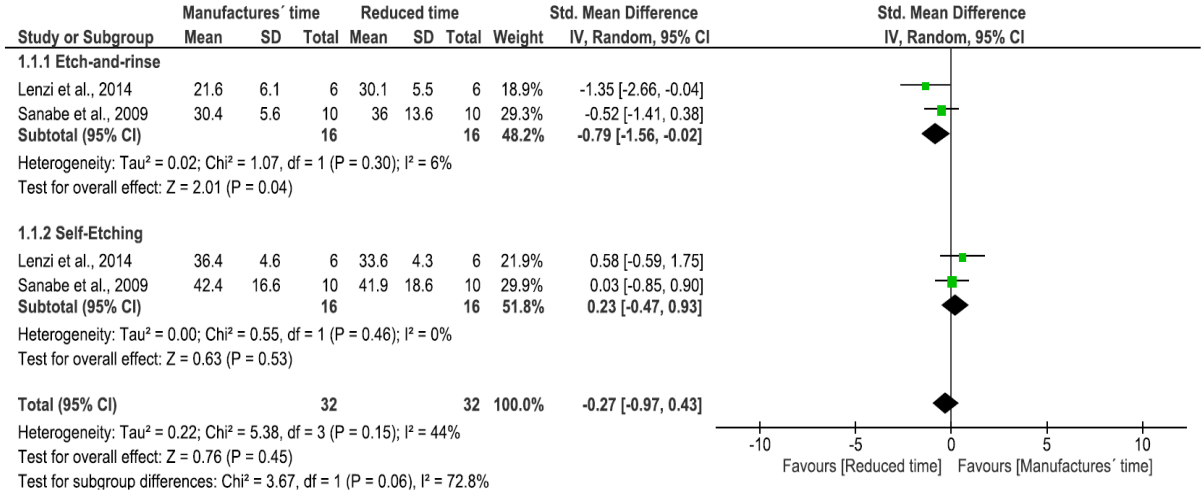


Figure 3: Results of reducing etching time meta-analyses after aging, using random effect model.



3. ARTIGO 2 - ONE-YEAR CLINICAL EVALUATION OF CLASS II BULK-FILL RESTORATIONS IN PRIMARY MOLARS: A RANDOMIZED CLINICAL TRIAL

Artigo publicado no periódico *Brazilian Dental Journal*, ISSN 0103-6440, Fator de impacto: 1.686; Qualis CAPES A2.

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Artigo formatado conforme as diretrizes para autores do periódico (Anexo B).

One-year clinical evaluation of class II bulk-fill restorations in primary molars: randomized clinical trial

Short title: Bulk-fill resin in primary molars

Larissa D'Olanda Gindri[1], Igor Perlin Cassol[2], Tatiana Tambara Fröhlich[1], Rachel de Oliveira Rocha[1]

[1] Department of Stomatology, Federal University of Santa Maria, Santa Maria, RS, Brazil

[2] Federal University of Santa Maria, Santa Maria, RS, Brazil

Correspondence:

Larissa D'Olanda Gindri

Dental Science Graduate Program, Federal University of Santa Maria, Santa Maria, RS, Brazil.

Av. Roraima, 1000, Prédio 26 F, Cidade Universitária, Santa Maria, RS, Brazil.

Phone: +55 55 999018273

E-mail: larigindri@gmail.com

ABSTRACT

This double-blind, randomized clinical trial aimed to compare the clinical performance and clinical time to restore occluso-proximal cavities in primary molars with *bulk-fill* resin and conventional resin. A total of 140 class II restorations in primary molars of 65 participants (mean age of 6.7 + 1.5) were placed in two random groups: *bulk-fill* and conventional resin. The restorations were evaluated using FDI criteria at the baseline, 6-month, and one year by a single calibrated examiner, and the clinical restorative time was measured with a digital timer. The success and survival of the restorations were evaluated with Kaplan-Meier graphs. The log-rank test compared the curves. Differences in restorative clinical time were compared using the Mann-Whitney U test. The level of significance was 5%. After one year, 115 restorations were evaluated. The success probability was 88.7% for Filtek Z350 XT and 85.9% for Filtek™ Bulk-fill, and the survival probability, Filtek Z350 XT presented 90%, and Filtek™ Bulk-fill presented 93.7%. No significant difference was found between the success and survival curves ($p=0.62$), ($p=0.51$). The main reason for failure was marginal adaptation. *Bulk-fill* resin required 30% less time than the conventional resin ($p<0.001$). *Bulk-fill* resin presented similar clinical performance to the conventional resin and required less restorative clinical time. It is an option to restore class II lesions of primary molars.

Key Words: criteria, survival, longevity, class II, primary teeth.

INTRODUCTION

The restoration of carious lesions is the most common procedure performed in primary teeth (1,2). The composite resins have become very popular for direct posterior restorations of primary teeth due to their main advantages as conservative preparations, aesthetic characteristics and their good clinical performance (2). However, composite resins are a very sensitive and time-consuming technique (2,3), so bulk-fill resins are an attractive choice for restoring primary teeth.

Bulk-fill resin gained space because of the option to build increments up to 4-5 mm. Therefore, single-increment restorations are possible, decreasing the technical sensitivity and chair time inherent to the incremental technique of conventional resins. The polymerization shrinkage stress is reported as the main limitation of monomeric materials like composite resins (4). It is associated with gap formation, cusp deflection, poor marginal adaptation, postoperative sensitivity, and secondary caries (4). *Bulk-fill* resins contain stress-relieving monomers and pre-polymerized particles that reduce polymerization shrinkage even when inserted in larger increments than the conventional 2 mm recommended by conventional resin manufacturers (5). Likewise, the efficiency of polymerization is also a concern regarding the longevity of restorations, as inefficient polymerization compromises the material's mechanical properties (6). For efficient polymerization, *bulk-fill* resins improve translucency, using specific polymerization modulators and more potent initiator systems (7).

The results of the clinical performance of bulk-fill composite resins are promising (8-10). In a systematic review and meta-analysis of randomized clinical trials that compared *bulk-fill* resins and conventional resins, the materials showed similar clinical performance, with follow-up for one to ten years (8). However, these findings mainly come from studies on permanent teeth, and the results cannot be extrapolated to primary teeth, as there are morphological and chemical differences between them (11). There is a lack of literature about the clinical performance of *bulk-fill* resin in primary teeth; few studies (12-14) seem to indicate a similar performance of *bulk-fill* resin and other restorative materials such as conventional resin and compomer. However, more randomized clinical trials are needed to indicate the use of *bulk-fill* resin in posterior primary teeth.

Whereas composite resins are the most common direct restorative material used in posterior primary teeth, bulk-fill resins offer technical simplification, which is very useful in pediatric dentistry, especially for non-cooperative children. Therefore, the aim of this double-blind, randomized clinical trial was to compare the clinical behavior of a *bulk-fill* and a

conventional resin for a follow-up period of 1 year and compare the clinical time required to restore occlusal-proximal cavities in primary molars. The null hypothesis tested was that there is no difference in the clinical performance of occlusal-proximal restorations in primary teeth placed with these materials.

MATERIAL AND METHODS

Ethical approval

This study was reviewed and approved by the Ethics Committee of the Federal University of Santa Maria (UFSM; Santa Maria, Brazil) (81118217.7.0000.5346). The participants and their parents or legal guardians were informed about the objectives and procedures of the study and agreed to participate by signing a statement of informed consent. The study was registered in the Brazilian Clinical Trials Registry (REBEC; RBR-329pyp) and is reported following the recommendations of the CONSORT statement (15).

Trial design, settings and location of data collection

A double-blind (patient and evaluator), randomized controlled trial was performed with two parallel groups - the intervention group: *bulk-fill* composite resin, and the control group: conventional composite resin. The study was conducted in the pediatric dentistry clinic of the Federal University of Santa Maria, Rio Grande do Sul, Brazil, from March to November 2018.

Eligibility criteria

One trained examiner through clinical examination and bitewing radiography recruited eligible patients who sought dental care at the local university. Children aged 5 to 9 years old and presenting at least one primary molar with a moderately deep dentin occlusal-proximal caries lesion, without signs of irreversible pulp pathologies or necrosis, were invited to participate in the study. The lesions should be restricted to the occlusal and proximal surfaces without involving the buccal and lingual walls to standardize the preparations. The presence of the previous restoration in the selected tooth, root resorption over 2/3, children with an adverse medical history, parents who were not available for periodic follow-up, and teeth that it was not possible to use rubber dam isolation were not included in this study.

Sample size calculation

The success rates of a previous study comparing the survival of restorations placed with the bulk-fill flow and conventional composite resin were used for the sample calculation of the

present study (16). The parameters considered were: α = 5%, power of 80%, considering the outcome binary (success/failure), and equivalence study, with a limit of 10%. The number of restorations was increased to consider the 20% possible drop-out of participants; the minimal sample size was 70 restorations in each group. The sample calculation was performed using a freely available online website (www.sealedenvelope.com).

Randomization and allocation concealment

The randomization process was carried out on a website (www.sealedenvelope.com) by a researcher (ROR) who did not participate in the operative procedures or the evaluation of the restorations. One hundred and forty cavities were randomized; 70 were assigned to the test group (bulk-fill resin) and 70 to the control group (conventional resin) by a randomization list defining the order of the composite resin placement.

The randomization list was generated and transferred into opaque, sealed, and numbered envelopes. The operator only had access to the envelope at the time of insertion of the composite resin into the cavity (after completing the adhesive protocol).

Blinding

The participants (children) and their caregivers were blind to the restorative material used. The evaluator (TTF) was also blinded and evaluated the restorations without information about which group the restoration was allocated. Blinding of the operator was not possible due to differences in the application of restorative materials. In order to minimize possible biases, the operator only opened the allocation envelope after completing the adhesive protocol, which was the same for all restorations.

Interventions: restorative treatment

A single operator placed all restorations. The operator was trained by a professor and restored the equivalent of 10% of the sample (14 restorations) before the study started to train the differences between the restorative materials, bulk-fill technique, and incremental technique.

The operator anesthetized the teeth (lidocaine 2% with epinephrine 1:100:000) and performed rubber dam isolation, including at least one tooth adjacent to the occlusal-proximal caries lesion. The cavity design was restricted to access and extension of the caries lesion; the operator did not prepare any additional retention or bevel. The removal of caries tissue followed a selective caries removal up to firm dentine, following coloration and texture parameters (17) and complete carious tissue removal from the cavosurface margins and all

lateral walls with a slow-speed round bur in a low-speed handpiece and hand instruments. If necessary, access to carious dentine was obtained using a spherical diamond bur mounted in a high-speed handpiece. Before starting the adhesive protocol, cavities dimensions (depth and buccal-lingual distance) were measured with a periodontal millimeter probe. A metallic matrix was placed with wooden wedges, and the cavities were cleaned by thoroughly rinsing with water. All teeth received the same adhesive protocol. The total-etch technique was performed with a 37% phosphoric acid gel (Condac 37, FGM, Joinville, SC, Brazil) for 15 seconds, rinsed for 20 seconds, and gently air-dried. The adhesive system (Scotchbond^{TM} Universal, 3M ESPE, St. Paul, MN, USA) was applied actively to the entire surface for 20 seconds. Next, direct a gentle air stream over the adhesive for 5 seconds and light cured for 10 seconds using a light-curing unit (QHL 75 Curing Light, Dentsply Sirona, Milford, DE, USA) with an intensity of 650 mW/mm2. Only at this point, the assistant defined the composite resin to be used by opening the allocation envelope.

In the groups assigned for conventional composite resin (control group), the cavities were filled with Filtek Z350 XT (3M ESPE St. Paul, MN, USA, shade A2D and A2E), using an oblique layering technique in 2-mm increments, each increment was light cured for 20 seconds individually. In the experimental group (bulk-fill composite resin), cavities were filled with Filtek^{TM} Bulk Fill (St. Paul, MN, USA, shade A2), in one increment up to 4 mm, light cured for 60 seconds. If the cavity exceeded 4 mm depth, it was filled with two increments, light cured individually for the same time. The occlusion was checked using articulating paper, and the restoration was finished using diamond burs (fine grain diamond burs #3118F; KG Sorensen, São Paulo, SP, Brazil); final polishing was performed with polishing tips (KG Sorensen, Cotia, São Paulo, Brazil). The materials used in this study and the technical sequence are listed in Table 1.

Clinical evaluation

A single examiner performed the evaluation of the restorations using the World Dental Federation (FDI) criteria (18). The examiner was trained about the FDI criteria. In the first moment, the evaluated criteria were presented with photographic images of restorations and discussed. Afterward, the examiner evaluated a random sequence of restoration images two times with an interval of 7 days, and the assigned scores were compared to those assigned by a reference examiner ('gold standard'). Cohen's kappa test demonstrated a kappa value <0.85 intra-examiner.

The restorations were evaluated at the baseline (until one month), six-month, and one-year after being placed. The following items were evaluated: 1) functional properties - fracture of restorative material/restoration retention, and marginal adaptation; 2) aesthetic properties - surface gloss, surface staining, marginal staining, and anatomical form; 3) biological properties - recurrence of caries. These items were ranked according to the scores: 1) clinically very good; 2) clinically good; 3) clinically satisfactory; 4) clinically unsatisfactory (but can be repaired), and 5) clinically poor (should be replaced) (18). In each time evaluated, visible plaque index and gingival bleeding index evaluations were performed, and professional plaque removal. In addition, guidance about oral hygiene and dietary habits was reinforced for parents and patients.

Statistical analysis

The primary outcome was the restoration failure according to the resin composite after a one-year follow-up. The restorations with FDI scores 4 and 5 (clinically unsatisfactory and clinically poor, respectively) and teeth that required endodontic treatment were considered as failure in the success analysis. Exfoliated teeth during the follow-up period without symptoms were considered a clinical success. In the survival analysis, only restorations classified in score 5 were considered as failures (19). The success and survival of the restorations concerning composite resin were evaluated with survival tables and Kaplan-Meier graphs. The log-rank test compared the success and survival curves.

Cavities dimensions (depth and buccal-lingual distance) and clinical restorative time were calculated and are presented as the mean and standard deviation. The differences in restorative clinical time and cavities dimensions (depth and buccal-lingual distance) between the bulk-fill and conventional resin composite groups were compared using the Mann-Whitney U test, as the data was not normality distributed (Anderson-Darling test).

The data were analyzed using Minitab software, version 19 (Minitab Inc., State College, PA, USA), with a significance level of 5%.

RESULTS

A total of 140 restorations were placed in 65 children (39 boys - 26 girls) with a mean age of 6.7 + 1.5 (SD), presenting a decayed, missing, and failed primary teeth (dmft) index mean of 5.8 + 2.4. Table 2 shows the socioeconomic, demographic, and clinical variables of patients according to experimental group. At the baseline and 6-month follow-up, 140

restorations were evaluated according to the summarized FDI criteria. After one year, 5 teeth were lost due to physiological exfoliation, 7 patients who received 16 restorations did not return (drop-out 11.4%), and 4 teeth needed endodontic treatment. Finally, 115 restorations were evaluated after follow-up (Figure 1).

The success probability after 12 months was 88.7% for Filtek Z350 XT and 85.9% for Filtek^{TM} Bulk-fill. The mean success time for Filtek Z350 XT restorations was 11.7 and for Filtek Bulk-fill was 11.6 months. There was no significant difference in the success curves after 12 months (p=0.62) (Figure 2). Considering the survival probability, Filtek Z350 XT presented 90%, and Filtek Bulk-fill presented 93.7% after 12 months. The mean survival time was 11.8 for both composites. No significant difference was found between the survival curves (p=0.51) (Figure 2).

Table 3 summarized the distribution of the restorations according to the evaluated parameters of the FDI criteria. Twelve restorations, 7 of *bulk-fill* resin, and 5 of conventional resin, received scores 4 or 5 at the end of one-year follow-up and needed intervention. Marginal adaptation was the main cause of failure (5 of Filtek Bulk-fill and 2 of Filtek Z350 XT), followed by fracture/retention (1 of Filtek Bulk-fill resin and 2 of Filtek Z350 XT) and the recurrence of caries (1 restoration in each group). Among the 5 failure restorations placed with conventional resin, only the restoration that failed due to marginal adaptation can be repaired (score 4); the other 4 restorations required replacement (score 5). Among the 7 failed restorations placed with *bulk-fill* resin, 5 received repairs (4 failed due to marginal adaptation and 1 failed due to recurrence of pathology), and 2 needed to be replaced. No restoration required intervention due to aesthetic parameters; only minor changes were observed during the 12-month follow-up. A total of 4 teeth required endodontic treatment - 2 restored with conventional resin and 2 with *bulk-fill* resin.

The results for clinical restorative time, number of increments, and cavity dimensions for *bulk-fill* and conventional resin composites are presented in table 4. The clinical restorative time using a bulk-fill resin was almost 30% shorter, corresponding to approximately 2 minutes faster ($p<0.001$) as fewer increments were used ($p<0.001$). No statistically significant differences were found between the composites concerning the cavity dimensions (p=0.113, and p=0.255 to depth and buccal-lingual distance, respectively).

DISCUSSION

In the present study, the clinical performance of two composite resins in class II restorations placed on primary molars was compared, and similar clinical performance between bulk-fill and conventional composite resin was demonstrated; thus, the null hypothesis that there is no difference between the restorations was accepted. Furthermore, this study also evaluated the clinical time required to place conventional resin restorations using the incremental technique and bulk-fill resin in a single increment. Restorations placed with *bulk-fill* resin were significantly faster than restorations placed with conventional resin.

Several clinical studies available on the clinical performance of *bulk-fill* resin, including meta-analyses, have shown its good performance (8-10,16,20); however, in primary teeth, there are still few randomized clinical trials (12-14), especially those that compare conventional resin and *bulk-fill* resin (12-14). The main advantage attributed to *bulk-fill* resin concerns clinical time, in which its reduction is significant in pediatric dentistry. When the material of choice is composite resin, patient-related factors, especially in the case of non-cooperative children, can affect the performance of the restoration due to the sensitive technique (2). The reduction of clinical time can minimize these adversities. This study is the first to evaluate both clinical performance and clinical time of the use of *bulk-fill* resin in primary teeth, and the compilation of results - similar clinical performance and shorter clinical time of *bulk-fill* restorations - showed an advantage the use of *bulk-fill* resin in the care of children compared to conventional resins.

Only a few recent randomized clinical trials evaluated *bulk-fill* resin in primary teeth (9-11). Ehlers et al. (13) compared class II restorations placed with *flowable bulk-fill* resin *vs.* a compomer. Öter et al. (12) used class I restorations to compare *bulk-fill* resin and conventional composite resin, and Akman et al. (14) evaluated a glass ionomer restorative system, two *bulk-fill* resins, and a conventional resin in class II restorations. All studies follow-up the restorations for one year and the *bulk-fill* resin showed similar clinical behavior to other restorative materials in all studies, except for glass ionomer cement, which was statistically less successful in marginal adaptation and retention criteria (14). The difference in restorative materials (compomer, *flowable bulk-fill*, regular *bulk-fill*, conventional resin, and glass ionomer cement), and the type of lesion (class I or class II) used in the studies do not allow the results to be compared. Our results are comparable to those of Akman et al. (14), which also compared the *bulk-fill* resin and the conventional resin in occlusal-proximal cavities in primary molars. Both studies showed similar clinical performance between *bulk-fill* resin and conventional resin. The

most encouraging result found in RCTs that evaluated *bulk-fill* in primary molars is that the clinical performance of *bulk-fill* resin is comparable to conventional resin and compomer.

After a one-year clinical follow-up, 115 restorations were evaluated according to the FDI criteria, and 12 restorations required some reintervention. The success rates of restorations were 88.7% for conventional resin and 85.9% for bulk-fill resin. Despite the number of failures in a short follow-up period, the materials tested in the study were two composite resins, so the results were expected to be similar to the composite resin in other clinical studies that evaluated the clinical behavior of direct posterior restorations in primary teeth (21,22). Sengul and Gurbuz (18) evaluated class II restorations placed with composite resin, compomer, GIC, and RMGIC. The estimative success rate of composite resin restorations was 85% and 79.5% at one-year and 2-year follow-up, similar to our findings. Bektas et al. (22) also found similar estimative success rates for conventional resin in class II restorations, 85% and 80.6% at one-year and 18-month follow-up, respectively.

Only class II cavities were included in the sample. Occlusal-proximal restorations have a trend for more failure than restorations restricted to the occlusal surface (2,23). The challenges in class II cavities are related to the size of the cavity and the depth, especially in primary molars. Due to the shape of the proximal surfaces of the primary molars, large proximal cavities result in preparations with limited mechanical retention (24). Even so, the dimensions of the cavities were similar in depth and buccal-lingual distance between the cavities restored with conventional and bulk-fill resin; thus, the technical difficulty was the same regardless of the restorative material.

To the best of our knowledge, this is the first randomized clinical trial that tested bulk-fill resin in primary molar under selective caries removal. An in vitro study evaluated the cusp deflection, presence of enamel cracks, and fracture resistance of class II restorations placed with bulk-fill resin in permanent molars. The results showed that the selective caries removal did not influence the biomechanical behavior of restorations (25). Selective caries removal has been strongly recommended as being less invasive, reducing the risks of pulp exposure and postoperative sensitivity (17). Nevertheless, it may increase the risk of restoration failure (26). In addition, in class II cavities, the technique becomes more complex, so achieving adequate sealing in the proximal margins of the restoration is challenging (24-26). Still, minimally invasive approaches like selective caries removal should be preferable to total caries removal, and patients should be recalled at shorter intervals so that restorations can be repaired before needing replacement (26).

The decision to use the FDI criteria was based on the possibility of considering a restoration classified as clinically unacceptable (score 4) to be repairable (18). Therefore, the success analysis (scores 1, 2, 3) and survival analysis (scores 1, 2, 3, 4) were performed (19). In the survival analysis, restorations that only needed repair were considered acceptable (18); thus, the survival rate of the restorations was higher than the success rate, as half of the restorations that failed needed only repairs. It is essential to highlight that the bulk-fill restorations success rate was 85.9% and increased to 93.7% in the survival analysis, with 7 failures of the bulk-fill resin, five considered as repairable, and only 2 needing replacement. Although there is no significant difference between the materials, this result may still be clinically relevant. Restoration repair increases the survival of restorations, which is especially important for primary teeth, as repair is less invasive, comfortable, and inexpensive than restoration replacement (18,26).

Stress due to polymerization shrinkage and inadequate polymerization may lead to the debonding of material from the cavity walls and subsequent micro-gaps formation (4). A recent systematic review and meta-analysis (8) compared bulk-fill and conventional resins in terms of their physical-mechanical properties, and clinical performance pointed out that bulk-fill resins have less polymerization shrinkage stress, cusp deflection, and microhardness than conventional composites, and both materials presented similar marginal quality, flexural strength, and fracture strength. Despite these in vitro results, the clinical performance of bulk-fill and conventional resins was similar in randomized clinical trials. However, a meta-analysis in permanent teeth performed by Kruly et al. (20) found better results for marginal adaptation after 12 months in conventional resin restorations than low polymerization shrinkage composite resin, including bulk-fill resins. In our study, marginal adaptation and fracture/retention was the main reasons for failures, for both groups.

This study included 65 children who received 140 restorations. These patients belong to a low socioeconomic level, having a high caries risk. Factors related to the patient, such as socioeconomic status, caries risk, and oral hygiene, were shown to influence the failure of restorations (2,24). A retrospective study assessed the potential factors associated with treatment failure of selective caries removal in the primary teeth of children with high caries experience. It demonstrated the association between high dmft and biofilm accumulations and a higher risk of treatment failure (27). Despite the characteristics of the sample, recurrence of caries was the reason for failure in only two restorations, probably due to all children being included in a program of periodic recalls, reinforcing oral hygiene care and dietary habits. On the other hand, 4 restorations required endodontic intervention. These patients already had

previous endodontic treatments or extractions due to caries disease; the endodontic outcome is probably not related to the restorative material but factors related to the patient.

As previously described, the cavities presented similar buccal-lingual dimensions and depth. Thus, the technical difficulty was the same in the groups. Even so, the bulk-fill resin showed a shorter restorative clinical time. This result shows that filling the cavity in a single increment is easier to handle and more straightforward than the conventional incremental technique.

In this study, factors influencing restorations' longevity were minimized. All restorations were performed under local anesthesia and a rubber dam, minimizing the influence of the child's behavior (2). All cavities received the universal adhesive system Scotchbond Universal^{TM} in etch-and-rinse mode, which is recommended to restore primary molars after selective caries removal (28). Even so, shorter restorative clinical time in the bulk-fill group should be associated with technical simplification and easy handling.

The limitations of this study are the short follow-up period (one year); however, in primary teeth, physiological exfoliation hinders more extended periods of follow-up, so the period of 1-year follow-up becomes relevant. In addition, due to the inability to introduce a blind operator, to minimize bias, the cavity was only allocated to one of the experimental groups, after completing the adhesive protocol. Drop-outs are usually common complications in longitudinal studies, especially those involving children. Finally, this study was conducted at a university; all restorations were placed in ideal conditions, resulting in high internal validity; however, it may not reflect clinical practice.

Bulk-fill resin and conventional resin showed similar clinical performance after one year. Furthermore, both composite resins showed good clinical behavior. The significant reduction of restorative clinical time when a bulk-fill resin was used represents an advantage over conventional resins, especially in pediatric and non-cooperative patients. Therefore, the bulk-fill resin is recommended to restore occlusal-proximal lesions in primary molars.

RESUMO

Este ensaio clínico randomizado, duplo-cego objetivou comparar a performance clínica e tempo clínico para restaurar cavidades ocluso-proximais em molares decíduos, restauradas com resina bulk-fill e resina convencional. Um total de 140 restaurações classe II em molares decíduos de 65 participantes (média de idade 6.7 + 1.5) foram realizadas dividas em dois grupos randomizados: resina bulk-fill e resina convencional. As restaurações foram avaliadas conforme o critério da FDI no baseline, após 6 meses e 1 ano, por um único examinador calibrado e o tempo clínico restaurador foi mensurado por um cronômetro digital. O sucesso e a sobrevida das restaurações foram avaliados através dos gráficos de Kaplan-Meier. O teste de log-rank comparou as curvas. A diferença no tempo clínico restaurador foi comparada usando o teste U de Mann-Whitney. O nível de significância foi de 5%. Após 1 ano, 115 restaurações foram avaliadas. A probabilidade de sucesso foi de 88,7% para Filtek Z350 XT e 85.9% para Filtek^{TM} Bulk-fill e quanto a probabilidade de sobrevivência, Filtek Z350 XT apresentou 90% e Filtek^{TM} Bulk-fill apresentou 93,7%. Não foi encontrada diferença significativa entre as curvas de sucesso e sobrevida (p=0,62), (p=0,51). A principal causa de falha foi a adaptação marginal. A resina bulk-fill exigiu 30% menos tempo do que a resina convencional (p<0,001). A resina bulk-fill apresentou desempenho clínico semelhante ao da resina convencional e necessitou menor tempo clínico restaurador. Dessa forma, é uma opção para restaurar lesões classe II em molares decíduos.

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TABLES

Table 1. Characteristics and application mode of the materials used in this study

Material/ Manufacturer	Composition	Mode of application
Condac 37 FGM, Joinville, SC, Brazil.	Phosphoric acid 37%, thickener, pigment, deionized water.	1. Apply on enamel and dentin for 15s; 2. Wash with water; 3. Removal excess with cotton balls.
Scotchbond Universal Adhesive* 3M ESPE, St. Paul, MN, USA.	Bond: MDP, HEMA, dimethacrylate resins, methacrylate-modified polyalkenoic acid copolymer ethanol, water, filler, initiator, silica.	1. Apply the adhesive actively to the entire surface for 20s. If necessary, rewet the disposable applicator; 2. Direct a gentle air stream over the adhesive for 5s or until it no longer moves and the solvent is completely evaporated; 3. Light cure for 10s.
Filtek Z350 XT** 3M ESPE St. Paul, MN, USA Shade A2D and A2E	UDMA, Bis-GMA, Bis-EMA,TEGDMA, zirconia, silica.	1. Insert incrementally in 2-mm increments; 2. Light cure each increment for 20s with a light-curing unit (QHL 75 Curing Light, Dentsply Sirona, Milford, DE, USA) with an intensity of 650 mW/mm^2.
Filtek^{tm} Bulk Fill 3M ESPE St. Paul, MN, USA Shade A2	Bis-GMA, UDMA, Bis-EMA, procrylate resins Ytterbium trifluoride, zirconia, silica.	1. Insert single increment up to 4 mm thick; 2. Light cure for 60s. If the cavity exceeded 4 mm depth, insert two increments and light cure for 60s each one with a light-curing unit (QHL 75 Curing Light, Dentsply Sirona, Milford, DE, USA) with an intensity of 650 mW/mm^2.

Abbreviations: bis-GMA, bisphenol-A diglycidyl dimethacrylate; UDMA, urethane dimethacrylate; TEGDMA, triethylene glycol dimethacrylate; bis-EMA, ethoxylated bisphenol A dimethacrylate.* Also known as Single Bond Universal in some countries.
** Also known as Filtek Supreme Plus in some countries.

Table 2. Baseline characteristics of the subjects included into the study groups

Characteristics of sample	Conventional resin (Filtek Z350 XT) (Nr = 70)	*Bulk-fill* resin (Filtek™ Bulk Fill) (Nr = 70)
Age (years) – Mean (SD)	6,9 ± 1,5	6,5 ± 1,5
*Dmft** – Mean (SD)	5,9 ± 2,6	5,6 ± 2,2
Sex – n (%)		
Female	24 (34)	27 (39)
Male	46 (66)	43 (61)
Teeth – n (%)		
First molar	39 (56)	36 (51)
Second molar	31 (44)	34 (49)
Arch – n (%)		
Upper	36 (51)	30 (43)
Lower	34 (49)	40 (57)
Mother education level – n (%)		
Primary school	30 (43)	22 (31)
High school	38 (54)	42 (60)
Graduate	2 (3)	6 (9)
Family income – n (%)**		
≤ 2 BMW	41 (59)	41 (59)
> 2 BMW	29 (41)	29 (41)
Skin color – n (%)		
White	42 (60)	51 (73)
Not white	28 (40)	19 (27)
VPI*** – n (%)		
< 10%	22 (31)	20 (29)
≤10% - ≥ 30%	44 (63)	47 (67)
> 30%	4 (6)	3 (4)
GBI*** – n (%)		
< 10%	31 (44)	26 (37)
≤10% - ≥ 30%	38 (54)	42 (60)
> 30%	1 (1)	2 (3)

Nr = number of restorations; **dmft* = decayed, missing, and filled deciduous teeth index; ** measured through the Brazilian Minimum Wage (BMW) (1 BMW corresponded to approximately USD 250 during the period of data collection), all families of children included in the study received less than 3 BMW. ***Index collected in the last evaluation.

Table 3. Evaluation of the restorations according to FDI criteria used in this study

	Conventional resin (Filtek Z350 XT)			*Bulk-fill* resin (Filtek™ Bulk Fill)		
	Baseline	6-month	1 year	Baseline	6-month	1 year
Surface gloss (1/2/3/4/5)	40/30/0/0/0	33/34/0/0/0	17/33/1/0/0	46/24/0/0/0	37/29/0/0/0	25/26/0/0/0
Surface staining (1/2/3/4/5)	70/0/0/0/0	67/0/0/0/0	51/0/0/0/0	69/1/0/0/0	65/1/0/0/0	49/2/0/0/0
Marginal staining (1/2/3/4/5)	70/0/0/0/0	65/2/0/0/0	49/2/0/0/0	68/2/0/0/0	63/3/0/0/0	48/3/0/0/0
Anatomical form (1/2/3/4/5)	49/21/0/0/0	46/21/0/0/0	27/21/3/0/0	58/12/0/0/0	50/16/0/0/0	33/17/1/0/0
Fracture/ retention (1/2/3/4/5)	70/0/0/0/0	67/0/0/0/1	51/0/0/0/2	70/0/0/0/0	65/1/0/0/1	51/0/0/0/1
Marginal adaptation (1/2/3/4/5)	70/0/0/0/0	67/0/0/1/1	49/2/0/1/1	69/1/0/0/0	62/4/0/2/1	49/2/0/4/1
Recurrence of caries (1/2/3/4/5)	70/0/0/0/0	67/0/0/0/0	51/0/0/0/1	70/0/0/0/0	66/0/0/0/0	51/0/0/1/0

The numbers separated by slash represent the number of evaluated restorations that received the respective score: 1. clinically very good; 2. clinically good; 3. clinically satisfactory; 4. clinically unsatisfactory; 5. clinically poor.

Table 4. Means and standard deviations considering restorative time, number of increments and other variables for filling occluso-proximal cavities in primary molars

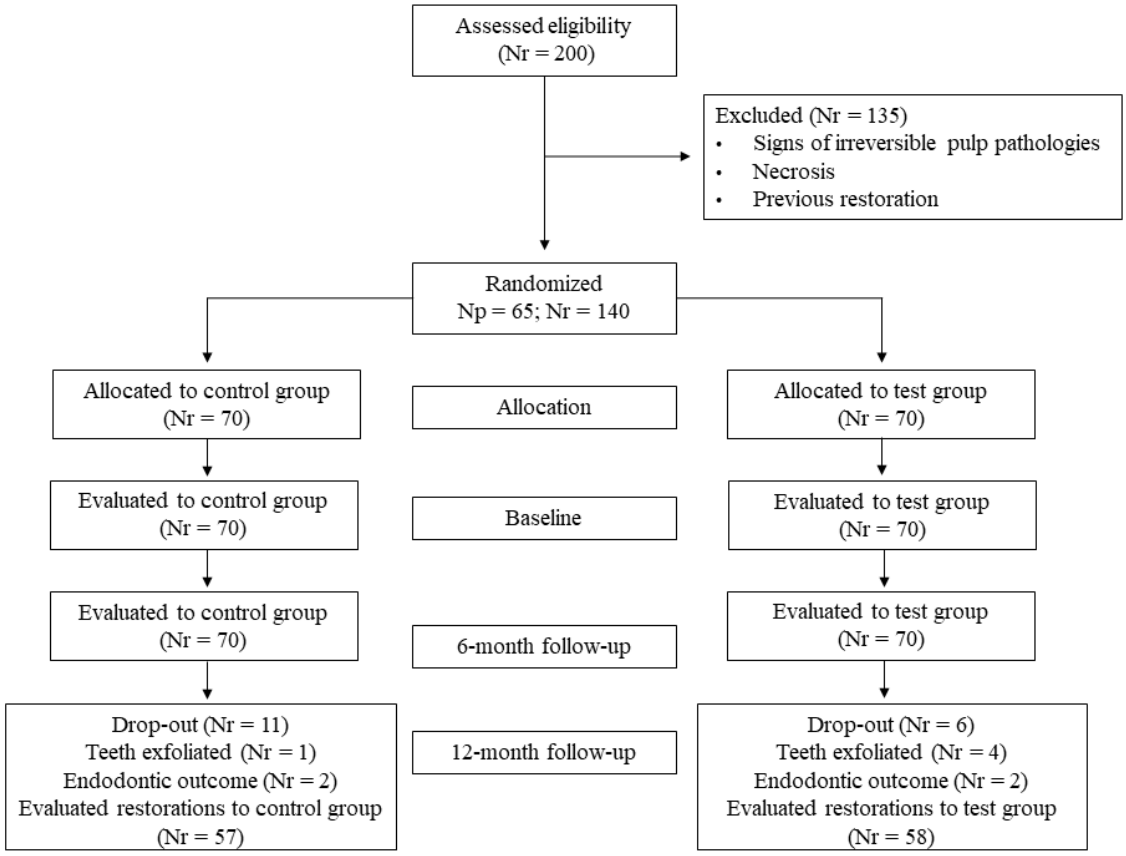
	Conventional resin (Filtek Z350 XT)	*Bulk-fill* resin (Filtek™ Bulk Fill)	Significance Mann-Whitney U-test
Clinical restorative time*	6.1 (3.2)	4.4 (2.2)	p<0.0001
Depth**	2.7 (0,9)	2.4 (0.9)	p=0.1133
Buccal-lingual distance**	2.7 (0.9)	2.9 (0.9)	p=0.255

* minutes
** mm

FIGURE LEGENDS

Figure 1. CONSORT flowchart of the participants ’progress through the trial phases.

Figure 2. Success (A) and survival (B) curves (Kaplan-Meier) for Bulk-fill and conventional resin restorations over one-year, log-rank p = 0,62 (A) and p = 0,51 (B).



Np = number of participants; Nr = number of restorations.

Figure 1

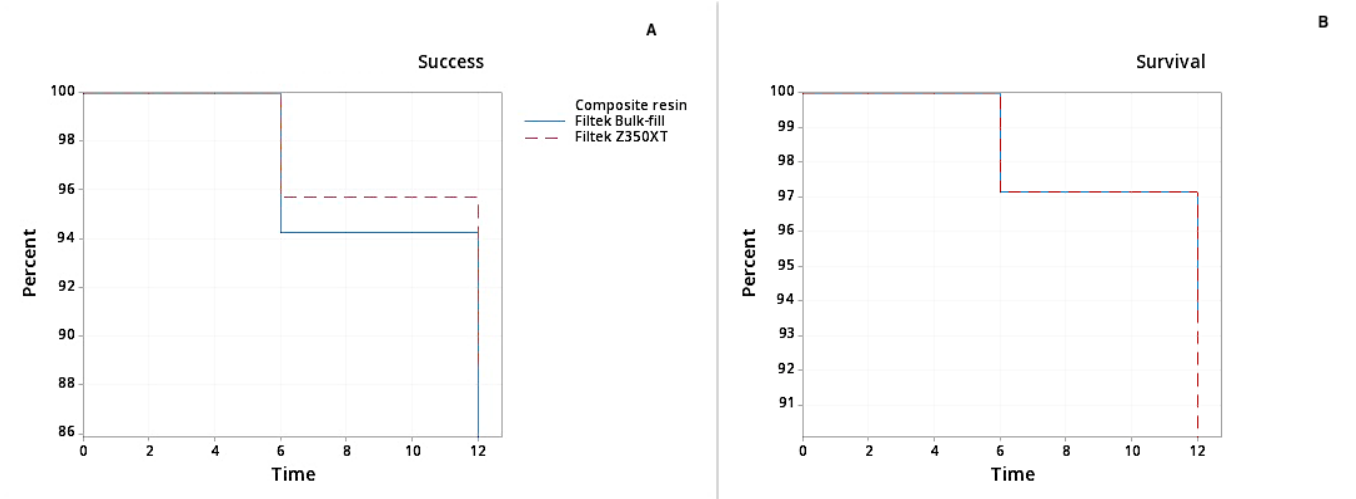


Figure 2

4. DISCUSSÃO

O surgimento dos materiais adesivos revolucionou a odontologia, uma vez que possibilitaram a prática clínica baseada em procedimentos minimamente invasivos, que tem por objetivo a máxima preservação da estrutura dental. Somente com o desenvolvimento de materiais restauradores adesivos que abordagens conservadoras, como realizar o preparo cavitário limitado ao acesso a lesão cariosa e a remoção seletiva do tecido cariado, tornaram-se possíveis e encorajadas (ERICSON, 2007; MURDOCH-KINCH; MCLEAN, 2003; TIRLET et al., 2014).

Assim, a tendência da odontologia adesiva caminha em busca da simplificação técnica, da redução na sensibilidade técnica e de uma melhor performance dos sistemas adesivos e dos materiais restauradores. Na odontopediatria, o engajamento por estratégias adesivas simplificadas torna-se ainda mais interessante, já que tem sido demonstrado que a colaboração da criança durante o procedimento restaurador é um dos fatores que pode levar a falha restauradora (CHINISI et al., 2018). Os dois artigos que compõe essa tese, buscaram avaliar duas estratégias restauradoras simplificadas utilizadas em dentes decíduos. O primeiro estudo, uma revisão sistemática com meta-análise acerca de uma modificação no protocolo adesivo, demonstrou que a redução no tempo de condicionamento ácido da dentina de dentes decíduos promove valores de resistência de união superiores ao longo do tempo. Já o segundo estudo, que avaliou uma resina *bulk-fill* em restaurações ocluso-proximais em molares decíduos, encontrou um comportamento clínico semelhante ao da resina convencional, e ainda com menor tempo clínico restaurador.

A inexistência de um protocolo adesivo específico para os dentes decíduos, que considere as diferenças químicas e morfológicas existentes entre esses e os dentes permanentes (ANGKER et al., 2004) é um fator a ser considerado em odontopediatria. A adesão à dentina dos dentes decíduos apresenta menores valores de resistência de união quando comparada à dentina dos dentes permanentes (PIRES et al., 2018). Assim, tempos de condicionamento reduzidos para a dentina decídua parecem proporcionar a formação de uma camada híbrida mais homogênea e funcional (NOR et al., 1996; HANASUBA et al., 2012), resultando em maiores valores de resistência de união. A revisão sistemática e meta-análise "*Etching time and bonding of adhesive systems to dentin of primary teeth: A Systematic Review and Meta-Analysis"*, demonstrou que a redução do tempo de condicionamento ácido ou da aplicação do *primer* acídico não influenciou a resistência de união imediata de sistemas adesivos *etch-and-rinse* e autocondicionantes. E, após o envelhecimento, o tempo de condicionamento ácido

reduzido melhorou a resistência de união para os adesivos convencionais (*etch-and-rinse*). Esse resultado reforça a necessidade de estabelecer protocolos adesivos específicos para os dentes decíduos, buscando melhorar a performance dos sistemas adesivos a esse substrato.

Reconhecemos a limitação da evidência produzida a partir de estudos laboratoriais, sendo que os resultados obtidos não podem ser extrapolados diretamente para o ambiente clínico. Entretanto, quando novos materiais/técnicas surgem, devem primeiramente ser testados através de estudos laboratoriais, antes de serem submetidos ao ambiente clínico (VAN MEERBEEK et al., 2010). Apenas um ensaio clínico randomizado avaliou a redução do tempo de condicionamento ácido à dentina dos dentes decíduos de adesivos convencionais (CAVALHEIRO et al., 2020). No estudo, os autores não encontraram diferença estatisticamente significativa após 18 meses de acompanhamento, mas consideraram que houve uma tendência clinicamente relevante, de melhor resultado clínico para o grupo que reduziu o tempo de condicionamento ácido (CAVALHEIRO et al., 2020). Para os sistemas adesivos autocondicionantes, não existem estudos clínicos que avaliaram a redução de tempo do *primer* acídico. Assim, o resultado do presente estudo é a principal evidência do efeito da redução do tempo de aplicação do *primer* acídico na dentina decídua quando do uso de adesivos autocondicionantes (*self-etch*).

Com a compilação dos resultados de estudos laboratoriais através da presente revisão sistemática e meta-análise, a expectativa é de que sejam conduzidos outros ensaios clínicos randomizados, que avaliem restaurações realizadas com sistemas adesivos *etch-and-rinse* e autocondicionantes em protocolos específicos para dentes decíduos, por períodos de tempo suficientemente longos para detectar diferenças estatisticamente significativas, se elas existirem. Além disso, a dentina afetada por cárie é um substrato relevante que deve ser considerado tanto em estudos laboratoriais quanto clínicos. Em estudos laboratoriais, a adesão a dentina afetada produz valores de resistência de união inferiores aos da dentina hígida (MARQUEZAN et al., 2010; NAKAJIMA et al., 1995; YOSHIYAMA et al., 2002). Além disso, a remoção seletiva do tecido cariado é fortemente recomendada (SCHWENDICKE et al., 2016), logo os sistemas adesivos precisam ser avaliados no condicionamento desse substrato. No estudo conduzido por Cavalheiro et al. (2020), os dentes acometidos por lesões cariosas foram submetidos a remoção seletiva de tecido cariado, e novos estudos clínicos também deveriam ser conduzidos em dentes submetidos a essa abordagem.

A longevidade das restaurações é dependente de diversos fatores, entre eles, as propriedades do material restaurador, a experiência do profissional, as condições do dente afetado, o risco de cárie do paciente e a colaboração do paciente (DEMARCO et al., 2012).

Este último fator é atribuído como o responsável pela grande variação na taxa de falha das restaurações em resina composta (CHINISI et al., 2018). Visto que, apesar das resinas compostas atenderem a demandas importantes como estética, resistência e longevidade (CHINISI et al., 2018; PINTO et al., 2014), a necessidade de inserção do material em incrementos torna a técnica sensível e demorada, o que pode ser desafiador na gestão do comportamento infantil. O artigo "*One-year clinical evaluation of class II bulk-fill restorations in primary molars: a randomized clinical trial"* buscou comparar o desempenho de uma resina convencional ao de uma resina *bulk-fill*, que tem ganhado destaque por permitir a inserção do material em incrementos únicos de até 4 ou 5 mm de espessura, podendo ser uma opção vantajosa na escolha do material restaurador para os dentes decíduos.

Os ensaios clínicos randomizados em dentes decíduos comparando a resina *bulk-fill* a outros materiais restauradores foram publicados entre 2018 e 2022. Os estudos apresentam diferenças metodológicas, como a inclusão de restaurações somente oclusais, ocluso-proximais, ou ambas, diferentes materiais restauradores considerados como controle, bem como critérios de avaliação distintos. Ainda assim, os resultados desses estudos parecem evidenciar que, independente das diferenças metodológicas, as resinas *bulk-fill* se comportam de maneira semelhante a outros materiais adesivos como os cimentos de ionômero de vidro modificados por resina, compômero e resina composta convencional (AKMAN; TOSUN, 2020; EHLERS et al., 2019; LARDANI et al., 2022; OTER; DENIZ; CEHRELI, 2018; MASSA et al., 2022; SARAPULTSEVA; SARAPULTSEV, 2019).

No presente estudo, uma resina *bulk-fill* foi comparada a uma resina convencional, em lesões ocluso-proximais submetidas a remoção seletiva de tecido cariado. Até o presente momento, nenhum outro ensaio clínico randomizado apresentou as mesmas peculiaridades. As restaurações ocluso-proximais tendem a falhar mais do que as cavidades restritas a face oclusal, principalmente quando há contato com o dente antagonista (DA FRANCA; COLARES; VAN AMERONGEN, 2011; OPDAM et al, 2014). Da mesma forma, as restaurações realizadas em dentes submetidos a remoção seletiva de tecido cariado apresentam maior risco de falha (FRANZON et al., 2015; PEDROTTI et al., 2019). Ainda assim, esse ensaio clínico randomizado, optou por incluir abordagens conservadoras e atuais, que estão de acordo com a filosofia de mínima intervenção, principalmente porque a remoção seletiva de tecido cariado diminui o risco de exposições pulpares (SCHWENDICKE et al., 2016). Além disso, as restaurações foram avaliadas pelo critério da FDI, que considera o reparo das restaurações defeituosas, também considerado uma abordagem conservadora (HICKEL et al., 2007).

A inserção da resina composta em incrementos maiores possibilita que as restaurações sejam realizadas com um incremento único (ZORZIN et al, 2015) e, com isso, espera-se que o tempo clínico restaurador também seja reduzido. A redução do tempo já foi demonstrada em estudos laboratoriais (BELLINASO; SOARES; ROCHA, 2019; MOSHARRAFIAN; HEIDARI; RAHBAR, 2017; DE PINHO et al., 2017), porém, em condições clínicas, esse foi o primeiro estudo, conduzido em dentes decíduos, que mensurou o tempo clínico e demonstrou uma redução de aproximadamente 30% quando a resina *bulk-fill* foi utilizada. Para validar esse resultado, as cavidades foram mensuradas previamente e apresentaram dimensões semelhantes, atribuindo a redução no tempo restaurador a simplificação da técnica. O desempenho clínico semelhante das resinas *bulk-fill* e convencional, aliado a redução do tempo clínico restaurador beneficiam a escolha da resina *bulk-fill* para a restauração dos molares decíduos.

5. CONCLUSÃO

Através desta tese foi demonstrado que a redução no tempo de condicionamento ácido da dentina decídua favorece a estabilidade da união ao longo do tempo, exaltando ainda a necessidade de desenvolver protocolos adesivos específicos para os dentes decíduos. Também foi demonstrado que a resina *bulk-fill* apresenta desempenho clínico semelhante ao da resina convencional em restaurações ocluso-proximais em molares decíduos e requer menor tempo clínico restaurador, sendo uma opção de material restaurador para molares decíduos.

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ANEXO A – NORMAS PARA PUBLICAÇÃO NO PERIÓDICO INTERNATIONAL JOURNAL OF PAEDIATRIC DENTISTRY

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Divided into: Summary, Introduction, Material and methods, Results, Discussion, Bullet points, Acknowledgements, References, Figure legends, Tables and Figures arranged in this order.

- **Summary** should be structured using the following subheadings: Background, Hypothesis or Aim, Design, Results, and Conclusions and should be less than 200 words.
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- **Results** should clearly and concisely report the findings, and division using subheadings is encouraged. Double documentation of data in text, tables or figures is not acceptable. Tables and figures should not include data that can be given in the text in one or two sentences.
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- **Bullet Points:** Authors will need to provide no more than 3 'key points 'that summarise the key messages of their paper to be published with their article. The key points should be written with a practitioner audience in mind under the heading:
  *Why this paper is important to paediatric dentists.

References: Maximum 30.

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May be invited by the Editor.

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Twetman S, Axelsson S, Dahlgren H et al. Caries-preventive effect of fluoride toothpaste: a systematic review. Acta Odontologica Scandivica 2003; 61: 347-355.

Paulsson L, Bondemark L, Söderfeldt B. A systematic review of the consequences of premature birth on palatal morphology, dental occlusion, tooth-crown dimensions, and tooth maturity and eruption. Angle Orthodontist 2004; 74: 269-279.

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- the **Case report** itself (a brief description of the patient/s, presenting condition, any special investigations and outcomes);

- a **Discussion** which should highlight specific aspects of the case(s), explain/interpret the main findings and provide a scientific appraisal of any previously reported work in the field.
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iv. The author's institutional affiliations where the work was conducted, with a footnote for the author's present address if different from where the work was conducted;
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Journal article
1. King VM, Armstrong DM, Apps R, Trott JR. Numerical aspects of pontine, lateral reticular, and inferior olivary projections to two paravermal cortical zones of the cat cerebellum. J Comp Neurol 1998;390:537-551.

Book
2. Voet D, Voet JG. Biochemistry. New York: John Wiley & Sons; 1990. 1223 p.

Internet document
3. American Cancer Society. Cancer Facts & Figures 2003.
http://www.cancer.org/downloads/STT/CAFF2003PWSecured.pdf Accessed March 3, 2003

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Instruções aos autores

Escopo e política

O Brazilian Dental Journal é um periódico científico revisado por pares (sistema duplo-cego) que publica Documentos Originais Completos, Comunicações Curtas, Relatórios de Casos e Críticas Convidadas, tratando os diversos campos da Odontologia ou áreas relacionadas, com acesso aberto. Serão considerados para publicação apenas artigos originais. Na submissão de um manuscrito, os autores devem informar em carta de encaminhamento que o material não foi publicado anteriormente e não está sendo considerado para publicação em outro periódico, quer seja no formato impresso ou eletrônico.

ENDEREÇO ELETRÔNICO PARA SUBMISSÃO

SERÃO CONSIDERADOS APENAS TRABALHOS REDIGIDOS EM INGLÊS. Autores cuja língua nativa não seja o Inglês, devem ter seus manuscritos revisados por profissionais proficientes na Língua Inglesa. **Os trabalhos aceitos para publicação serão submetidos à Revisão Técnica, que compreende revisão lingüística, revisão das normas técnicas e adequação ao padrão de publicação do periódico. O custo da Revisão Técnica será repassado aos autores. A submissão de um manuscrito ao BDJ implica na aceitação prévia desta condição.** A decisão de aceitação para publicação é de responsabilidade dos Editores e baseia-se nas recomendações do corpo editorial e/ou revisores "*ad hoc*". Os manuscritos que não forem considerados aptos para publicação receberão um e-mail justificando a decisão. Os conceitos emitidos nos trabalhos publicados no BDJ são de responsabilidade exclusiva dos autores, não refletindo obrigatoriamente a opinião do corpo editorial.

Todos os manuscritos serão submetidos a revisão por pares. Autores e revisores serão mantidos anônimos durante o processo de revisão. Os artigos aceitos para a publicação se tornam propriedade da revista.

Brazilian Dental Journal é um jornal de acesso aberto, o que significa que todos os artigos publicados estão disponíveis gratuitamente na Internet imediatamente após a publicação.

O Brazilian Dental Journal manterá os direitos autorais e editoriais de todos os artigos publicados, incluindo traduções. Os usuários podem usar, reutilizar e construir sobre o material publicado na revista, mas apenas para fins não comerciais e desde que a fonte seja claramente e adequadamente mencionada.

A Revista adota sistema para identificação de plagiarismo (AntiPlagiarist - ACNP Software).

O Brazilian Dental Journal está indexado na base de dados DOAJ para acesso público.

Registro e publicação de Erratas

Errata são correções de erros identificados em um artigo ou outro tipo de documento já publicado. A publicação de uma errata é necessária quando o(s) autor(es) do artigo ou editor, identificam um ou mais erros no artigo já publicado. O procedimento para publicação de errata segue a orientação das bases internacionais e visa preservar o registro original do manuscrito informando, todavia sobre eventuais correções. As correções devem ser identificadas e informadas ao Editor-chefe da Brazilian Dental Journal através do e-mail sousanet@forp.usp.br. Em seguida, o editor-chefe iniciará o processo de publicação no SciELO informando sobre o erro localizado em um artigo já publicado.

Retratação de artigos publicados

A retratação é um instrumento público para registrar problemas em artigo publicado (Retratação Parcial) ou comunicar o seu cancelamento (Retratação Total) e é parte integral do sistema de comunicação científica. O procedimento de registro de retratação de um artigo publicado pela Brazilian Dental Journal é iniciado após o recebimento de comunicação formal ao Editor-chefe da revista, através do e-mail sousanet@forp.usp.br, que comunicará a SciELO. A comunicação deve vir acompanhada do texto de retratação informando os motivos pelos quais o artigo sofrerá retratação. O artigo retratado não será suprimido do veículo onde foi originalmente publicado. Na versão XML para os casos de retratação total, ficará publicada somente o texto da retratação com a justificativa encaminhada pelo editor e os dados básicos do artigo, como: título, autor, afiliação e resumo. Para retratação parcial, apenas será suprimido a parte na qual se identificou o problema. Em ambos os casos, o PDF original é mantido, mas com o texto da retratação agregado antes do texto completo original e com tarjas de marca d'água que o identificam como artigo retratado.

Publicação de Adendo

A publicação de um Adendo é realizada nos casos em que não há correções de texto ou ativos digitais, mas quando ocorre a inclusão de informação sobre um documento já publicado. Os adendos não contradizem a publicação original e não são usados para corrigir erros, devem ser utilizados quando a adição da informação for benéfica para a compreensão do leitor sobre uma parte significativa da contribuição publicada. Os adendos podem ser revisados por pares, de acordo com a política editorial da revista. Todos os adendos são vinculados com link ao artigo publicado ao qual se relacionam. Neste caso as informações adicionadas não são inseridas efetivamente no documento já publicado como ocasionalmente ocorre com a errata, por exemplo. O procedimento para publicação de adendo segue a orientação das bases internacionais e visa preservar o registro original do manuscrito informando, todavia sobre eventuais adições. O processo de publicação de um adendo pode ser iniciado por uma comunicação ao Editor-chefe da revista Brazilian Dental Journal, através do e-mail sousanet@forp.usp.br, que comunicará a SciELO informando sobre a necessidade do adendo em um artigo já publicado.

Guia de boas práticas para o fortalecimento da ética na publicação científica

A Brazilizan Dental Journal segue o guia de boas práticas para o fortalecimento da ética na publicação científica padrão para todos os periódicos das coleções da Rede SciELO. O programa SciELO segue normas e recomendações de padrões de ética e responsabilidade na comunicação científica estabelecidas pelas instituições nacionais e internacionais, entre as quais se destacam: COPE, CSE, Equator Network, ICMJE, CNPq, Fapesp e o Manual de Boas Práticas para o Fortalecimento da Ética na Publicação Científica do SciELO. Este guia promove a integridade e transparência no processo de avaliação de manuscritos e na reprodutibilidade da pesquisa, sobre a ocorrência de manipulação ou invenção de dados, a cópia não referenciada de dados ou do texto de outro autor, a duplicidade da publicação do mesmo texto ou de pesquisa, conflitos de interesse ou de autoria. Tudo o que é publicado no periódico, assim como as ações corretivas que se façam necessárias, são de responsabilidade do editor chefe. Nesse sentido, este guia explicita conceitos e ações que promovem a integridade no processo de publicação e encaminhamentos em casos de suspeita ou de comprovação de má conduta. Maiores informações podem ser obtidas através do contato formal com o Editor-chefe da revista, através do e-mail: sousanet@forp.usp.br.

Forma e preparação de manuscritos

AS NORMAS DESCRITAS A SEGUIR DEVERÃO SER CRITERIOSAMENTE SEGUIDAS.

Geral

- Submeter o manuscrito em Word e em PDF, composto pela página de rosto, texto, tabelas, legendas das figuras e figuras (fotografias, micrografias, desenhos esquemáticos, gráficos e imagens geradas em computador, etc).
- O manuscrito deve ser digitado usando fonte Times New Roman 12, espaço entrelinhas de 1,5 e margens de 2,5 cm em todos os lados. **NÃO UTILIZAR** negrito, marcas d'água ou outros recursos para tornar o texto visualmente atrativo.
- As páginas devem ser numeradas seqüencialmente, começando no *Summary*.
- Trabalhos completos devem estar divididos sequencialmente conforme os itens abaixo:

1. Página de Rosto
2. Summary e Key Words
3. Introdução, Material e Métodos, Resultados e Discussão
4. Resumo em Português (obrigatório apenas para os autores nacionais)
5. Agradecimentos (se houver)
6. Referências
7. Tabelas
8. Legendas das figuras
9. Figuras

- Todos os títulos dos capítulos (Introdução, Material e Métodos, etc) em letras maiúsculas e sem negrito.
- Resultados e Discussão **NÃO** podem ser apresentados conjuntamente.
- Comunicações rápidas e relatos de casos devem ser divididos em itens apropriados.

- Produtos, equipamentos e materiais: na primeira citação mencionar o nome do fabricante e o local de fabricação completo (cidade, estado e país). Nas demais citações, incluir apenas o nome do fabricante.
- Todas as abreviações devem ter sua descrição por extenso, entre parênteses, na primeira vez em que são mencionadas.
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Página de rosto

- A primeira página deve conter: título do trabalho, título resumido (*short title*) com no máximo 40 caracteres, nome dos autores (máximo 6), Departamento, Faculdade e/ou Universidade/Instituição a que pertencem (incluindo cidade, estado e país). **NÃO INCLUIR** titulação (DDS, MSc, PhD etc) e/ou cargos dos autores (Professor, Aluno de Pós-Graduação, etc).
- Incluir o nome e endereço **completo** do autor para correspondência **(informar e-mail, telefone e fax)**.
- A página de rosto deve ser incluída em arquivo separado do manuscrito.

Manuscrito

- A primeira página do manuscrito deve conter: título do trabalho, título resumido (*short title*) com no máximo 40 caracteres, sem o nome dos autores.

Summary

- A segunda página deve conter o *Summary* (resumo em Inglês; máximo 250 palavras), em redação contínua, descrevendo o objetivo, material e métodos, resultados e conclusões. Não dividir em tópicos e não citar referências.
- Abaixo do *Summary* deve ser incluída uma lista de Key Words (5 no máximo), em letras minúsculas, separadas por vírgulas.

Introdução

- Breve descrição dos objetivos do estudo, apresentando somente as referências pertinentes. Não deve ser feita uma extensa revisão da literatura existente. As hipóteses do trabalho devem ser claramente apresentadas.

Material e métodos

- A metodologia, bem como os materiais, técnicas e equipamentos utilizados devem ser apresentados de forma detalhada. **Indicar os testes estatísticos utilizados neste capítulo**.

Resultados

- Apresentar os resultados em uma seqüência lógica no texto, tabelas e figuras, enfatizando as informações importantes.
- Os dados das tabelas e figuras não devem ser repetidos no texto.
- Tabelas e figuras devem trazer informações distintas ou complementares entre si.
- Os dados estatísticos devem ser descritos neste capítulo.

Discussão

- Resumir os fatos encontrados sem repetir em detalhes os dados fornecidos nos Resultados.

- Comparar as observações do trabalho com as de outros estudos relevantes, indicando as implicações dos achados e suas limitações. Citar outros estudos pertinentes.
- Apresentar as conclusões no final deste capítulo. Preferencialmente, as conclusões devem ser dispostas de forma corrida, isto é, evitar citá-las em tópicos.

Resumo (em Português) - Somente para autores nacionais

O resumo em Português deve ser **IDÊNTICO** ao resumo em Inglês (Summary). OBS: **NÃO COLOCAR** título e palavras-chave em Português.

Agradecimentos

- O Apoio financeiro de agências governamentais deve ser mencionado. Agradecimentos a auxílio técnico e assistência de colaboradores podem ser feitos neste capítulo.

Referências

- As referências devem ser apresentadas de acordo com o estilo do **Brazilian Dental Journal (BDJ)**. É recomendado aos autores consultar números recentes do BDJ para se familiarizar com a forma de citação das referências.
- As referências devem ser numeradas por ordem de aparecimento no texto e citadas entre parênteses, sem espaço entre os números: (1), (3,5,8), (10-15). **NÃO USAR SOBRESCRITO**.
- Para artigos com dois autores deve-se citar os dois nomes sempre que o artigo for referido. Ex: "According to Santos **and** Silva (1)...". Para artigos com três ou mais autores, citar apenas o primeiro autor, seguido de "et al.". Ex: "Pécora et al. (2) reported that..."
- Na lista de referências, os nomes de TODOS OS AUTORES de cada artigo devem ser relacionados. Para trabalhos com 7 ou mais autores, os 6 primeiros autores devem ser listados seguido de "et al."
- A lista de referências deve ser digitada no final do manuscrito, em seqüência numérica. Citar **NO MÁXIMO** 25 referências.
- A citação de abstracts e livros, bem como de artigos publicados em revistas não indexadas deve ser evitada, a menos que seja absolutamente necessário. **Não citar referências em Português**.
- Os títulos dos periódicos devem estar abreviados de acordo com o Dental Index. O estilo e pontuação das referências devem seguir o formato indicado abaixo:

Periódico
1. Lea SC, Landini G, Walmsley AD. A novel method for the evaluation of powered toothbrush oscillation characteristics. Am J Dent 2004;17:307-309.
Livro
2. Shafer WG, Hine MK, Levy BM. A textbook of oral pathology. 4th ed. Philadelphia: WB Saunders; 1983.
Capítulo de Livro
3. Walton RE, Rotstein I. Bleaching discolored teeth: internal and external. In: Principles and Practice of Endodontics. Walton RE (Editor). 2nd ed. Philadelphia: WB Saunders; 1996. p 385-400.

Tabelas

- As tabelas com seus respectivos títulos devem ser inseridas após o texto, numeradas com algarismos arábicos; **NÃO UTILIZAR** linhas verticais, negrito e letras maiúsculas (exceto as iniciais).
- O título de cada tabela deve ser colocado na parte superior.
- Cada tabela deve conter toda a informação necessária, de modo a ser compreendida independentemente do texto.

Figuras

- **NÃO SERÃO ACEITAS FIGURAS INSERIDAS EM ARQUIVOS ORIGINADOS EM EDITORES DE TEXTO COMO O WORD E NEM FIGURAS EM POWER POINT**;
- Os arquivos digitais das imagens devem ser gerados em Photoshop, Corel ou outro software similar, com extensão TIFF e resolução mínima de 300 dpi. Apenas figuras em PRETO E BRANCO são publicadas. Salvar as figuras no CD-ROM.
- Letras e marcas de identificação devem ser claras e definidas. Áreas críticas de radiografias e fotomicrografias devem estar isoladas e/ou demarcadas.
- Partes separadas de uma mesma figura devem ser legendadas com letras maiúsculas (A, B, C, etc). Figuras simples e pranchas de figuras devem ter largura mínima de 8 cm e 16 cm, respectivamente.

As legendas das figuras devem ser numeradas com algarismos arábicos e apresentadas em uma página separada, após a lista de referências (ou após as tabelas, quando houver).

Políticas sobre Conflito de Interesses, Direitos Humanos e Animais, e Consentimento Livre e Esclarecido

CONFLITO DE INTERESSES

O Brazilian Dental Journal reafirma os princípios incorporados na Declaração de Helsínquia e exige que toda a investigação envolvendo seres humanos, no caso de publicação nesta revista, seja conduzida em conformidade com tais princípios e outros especificados nos respectivos comites de ética da instituição dos autores. No caso de estudos com animais, os mesmos princípios éticos devem também ser seguidos.
Quando foram utilizados procedimentos cirúrgicos em animais, os autores devem apresentar, na secção Metodologia, provas de que a dose de uma substância é adequada para produzir anestesia durante todo o procedimento cirúrgico.

Todos os estudos realizados em humanos ou animais devem acompanhar uma descrição, na secção de Metodologia, dizendo que o estudo foi aprovado pelo respectivo Comitê de Ética da afiliação dos autores e fornecer o número de aprovação do protocolo. Além disso, devem conter a aprovação do Comitê de Ética como material suplementar obrigatório. O certificado do Comitê de Ética, redigido em diferentes línguas do inglês, espanhol e português, deve ser traduzido na íntegra para inglês.

Todos os autores e co-autores são obrigados a revelar qualquer potencial conflito de interesses ao submeter o seu artigo (por exemplo, emprego, honorários de consultoria, contratos de investigação, propriedade de acções, licenças de patentes, filiações de aconselhamento, etc.). Se o artigo for

subsequentemente aceito para publicação, esta informação deve ser incluída na secção final.

DIREITOS HUMANOS E DOS ANIMAIS

Toda a investigação deve ter sido conduzida de acordo com quadro ético apropriado. Se houver suspeita de que o trabalho não foi realizado dentro de um quadro ético apropriado, os editores poderão rejeitar o manuscrito, e/ou contactar o comité de ética do(s) autor(es). Em raras ocasiões, se o Editor tiver sérias preocupações sobre a ética de um estudo, o manuscrito pode ser rejeitado por razões éticas, mesmo que tenha sido obtida a aprovação de um comité de ética.

- Os artigos que realizem qualquer estudo animal ou clínico devem conter uma declaração em de aprovação do comitê de ética animal e humana.
- A investigação deve ser realizada de forma a que os animais não sejam desnecessariamente afetados.
- O registo é exigido para todos os ensaios clínicos.

CONSENTIMENTO INFORMADO

No Brazilian Dental Journal, os pacientes têm um direito à privacidade que não deve ser violado sem consentimento informado. As informações de identificação, incluindo nomes, iniciais, ou números de hospitais, não devem ser publicadas em descrições escritas, fotografias, ou pedigrees, a menos que a informação seja essencial para fins científicos e o paciente (ou pai ou tutor) dê o seu consentimento informado por escrito para publicação.

O consentimento informado para este fim exige que o manuscrito a publicar seja mostrado a um paciente identificável. Os autores devem revelar a estes pacientes se algum material potencialmente identificável pode estar disponível através da Internet, bem como em versão impressa após a publicação. O consentimento do paciente deve ser escrito e arquivado ou com a revista, os autores, ou ambos, conforme ditado pelos regulamentos ou leis locais. Os pormenores de identificação não essenciais devem ser omitidos. O consentimento informado deve ser obtido se houver qualquer dúvida de que o anonimato pode ser mantido. Quando o consentimento informado tiver sido obtido, deve ser indicado no artigo publicado.