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AVALIAÇÃO DE RESINAS COMPOSTAS BULK-FILL: ANÁLISE DO DESEMPENHO CLÍNICO EM ODONTOPEDIATRIA

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

Orientadora: Prof.ª Dr.ª Rachel de Oliveira Rocha

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

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Fernando Borba de Araújo, Dr. (UFRGS) (videoconferência)

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(Bíblia Sagrada, Romanos 8:28)

RESUMO

AVALIAÇÃO DE RESINAS COMPOSTAS BULK-FILL: ANÁLISE DO DESEMPENHO CLÍNICO EM ODONTOPEDIATRIA

AUTORA: Mariana Dantas Bellinaso
ORIENTADORA: Rachel de Oliveira Rocha

A presente tese é composta por dois artigos científicos, cujo tema principal são as restaurações em dentes decíduos com resinas compostas do tipo bulk-fill. Artigo 1: Clinical behavior of bulk-fill restorations in primary molars: A systematic review and meta-analysis. O objetivo deste trabalho foi revisar sistematicamente a literatura de ensaios clínicos encontrados nas bases de dados PubMed, Scopus, Web of Science, EMBASE, e Lilacs/BBO, até junho de 2022, a fim de comparar a longevidade de restaurações com resinas compostas bulk-fill e outros materiais restauradores diretos em molares decíduos. De 710 artigos identificados, 10 foram eleitos para leitura de texto completo; e 6, selecionados para revisão sistemática e metanálise. A análise geral da metanálise não apresentou efeito estatisticamente significativo do material na falha das restaurações ($Z = 1.58$; $P = 0.11$). Este estudo mostrou que as resinas compostas bulk-fill podem ser um material restaurador alternativo para a Odontopediatria, por apresentarem longevidade semelhante a outros materiais considerados como controle e menor tempo clínico restaurador. Artigo 2: Enamel instrumentation negatively impacts on the survival of composite restorations after selective removal of carious tissue in primary molars: up to 24-months randomized clinical trial. Este ensaio clínico randomizado, duplo-cego, avaliou a influência da instrumentação do esmalte no desempenho de restaurações de resina composta em molares decíduos submetidos à remoção seletiva de tecido cariado. Cento e trinta e duas lesões de cárie oclusal cavitadas, em dentina profunda, em dentes decíduos, foram selecionadas e alocadas aleatoriamente em dois grupos de intervenção; um, não instrumentado (NIE), e outro, instrumentado (IE; margens de esmalte foram instrumentadas com ponta diamantada antes da restauração). As restaurações foram avaliadas após 3, 6, 12, 18 e 24 meses. As curvas de sucesso e sobrevivência foram criadas e comparadas usando a estimativa de Kaplan-Meier e log-rank. O sucesso clínico geral em 24 meses para restaurações de NIE e IE foi de 93,2% (55/59) e 80,3% (49/61), respectivamente. Foi encontrada diferença estatisticamente significativa apenas entre as taxas de sobrevida ($p = 0,036$), favorecendo o grupo NIE. Dessa forma, o uso de pontas diamantadas no esmalte cavo-superficial em remoção seletiva de tecido cariado, em molares decíduos, portadores de lesões cariosas ativas, cavitas, em dentina profunda, comprometeu o desempenho clínico de restaurações de resina composta bulk-fill, sendo necessário um acompanhamento clínico mais rigoroso.

Palavras-chave: Remoção seletiva de tecido cariado. Esmalte desmineralizado. Resina composta. Resina Bulk-fill. Dente decíduo.

ABSTRACT

EVALUATION OF BULK-FILL COMPOSITE RESINS: ANALYSIS OF CLINICAL PERFORMANCE IN PEDIATRIC DENTISTRY

AUTHOR: Mariana Dantas Bellinaso
ADVISOR: Rachel de Oliveira Rocha

This thesis is composed of two scientific articles, whose main theme is restorations in primary teeth with bulk-fill composite resins. Article 1: Clinical behavior of bulk-fill restorations in primary molars: A systematic review and meta-analysis. The aim of this study was to systematically review the literature of clinical trials found in PubMed, Scopus, Web of Science, EMBASE, and Lilacs/BBO databases, up to June 2022, in order to compare the longevity of bulk-fill restorations and others direct restorative materials in primary molars. From 710 identified studies, 10 were selected for full-text reading and 6 were selected for systematic review and meta-analysis. The overall meta-analysis comparison did not show significant effect of material on restorations failure ($Z = 1.58$; $P = 0.11$). This study showed that bulk-fill composite resins can be an alternative restorative material for Pediatric Dentistry, since it has similar longevity to other considered control materials and a shorter clinical restorative time. Article 2: Enamel instrumentation negatively impacts on the survival of composite restorations after selective removal of carious tissue in primary molars: up to 24-months randomized clinical trial. This randomized, double-blind clinical trial evaluated the influence of enamel instrumentation on the performance of composite resin restorations in primary molars submitted to selective removal of carious tissue. One hundred and thirty-two cavitated occlusal caries lesions, in deep dentin, in primary teeth, were selected and randomly allocated into two intervention groups, a non-instrumented (NIE) and an instrumented (IE; enamel margins were instrumented with a diamond bur before restoration). Composite restorations were evaluated after 3, 6, 12, 18 and 24 months. Success and survival curves were created and compared using Kaplan-Meier estimation and log-rank. The overall clinical success at 24 months from NIE and IE restorations were 93.2% (55/59) and 80.3% (49/61), respectively. A statistically significant difference was found only between the survival rates ($p = 0.036$), favoring the NIE group. Thus, he use of diamond burs in cavosurface enamel for selective removal of carious tissue, in primary molars, with active carious lesions, cavities and in deep dentin, compromised the clinical performance of bulk-fill composite resin restorations, requiring a more rigorous clinical follow-up.

Keywords: Selective caries removal. Demineralized enamel. Composite resin. Bulk-fill resin. Primary tooth.

SUMÁRIO

1 INTRODUÇÃO

A restauração de lesões de cárie com envolvimento dentinário é uma prática rotineira em Odontologia. Em se tratando de Odontopediatria, existe um grande desejo e demanda por utilizar materiais restauradores que apresentem técnicas menos sensíveis e mais rápidas, visto que, quanto menor o tempo necessário para o procedimento, melhor a colaboração da criança. Apesar do uso difundido de resinas compostas, estas ainda apresentam alguns problemas relacionados à contração volumétrica que ocorre durante a polimerização do material. Dessa maneira, as resinas compostas bulk-fill foram desenvolvidas com o objetivo de simplificar a técnica e reduzir o tempo clínico de restaurações em lesões cariosas.

As resinas bulk-fill apresentam monômeros modificados que permitem alta transmissão luminosa, permitindo a utilização de incrementos maiores, sendo possível realizar incrementos únicos em profundidades de até 4-5mm (JUNG; PARK, 2017). Além disso, principalmente as resinas bulk-fill flow, ou seja, de baixa viscosidade, têm apresentado menor estresse de contração e deflexão de cúspides quando comparadas às resinas convencionais, utilizadas na técnica incremental (KIM et al., 2015; MOORTHY et al., 2012).

O desempenho clínico semelhante das resinas bulk-fill e resinas compostas convencionais em restaurações de dentes permanentes, tem sido demonstrado em revisões sistemáticas publicadas nos últimos anos (ABREU et al., 2022; CIDREIRA BOARO et al., 2019; KUNZ et al., 2022; VELOSO et al., 2019). Assumindo que a longevidade das restaurações dentárias depende de fatores relacionados ao paciente (DEMARCO et al., 2012), o comportamento clínico das restaurações de resina composta pode diferir em dentes decíduos (CHISINI et al., 2018), dificultando a extensão direta dos achados de dentes permanentes para decíduos. Dessa forma, um dos artigos desta tese avalia, através de uma revisão sistemática e meta-análise, a longevidade de restaurações de resinas bulk-fill em molares decíduos comparada a outros materiais restauradores utilizados na técnica direta.

Outro fator que pode influenciar na longevidade das restaurações é a condição do esmalte circundante da cavidade. A adesão ao esmalte circundante é um fator importante a ser considerado para o sucesso de restaurações adesivas, pois permite o isolamento do tecido cariado remanescente, intencionalmente deixado, do meio bucal (FALSTER et al., 2002). Quando esse esmalte está desmineralizado, a interface adesiva é afetada negativamente. Estudos laboratoriais (ANTONIAZZI et al., 2016; TEDESCO et al., 2014) constataram que a resistência de união de sistemas adesivos ao esmalte desmineralizado, afetado por cárie, é inferior àquela obtida em esmalte hígido, o que pode ser consequência da menor quantidade de

minerais, superfícies mais porosas e aumento dos espaços intercristalinos (SCHMIDLIN et al., 2004). Dessa forma, faz-se necessário considerar o fato de existir algum esmalte desmineralizado deixado inadvertidamente após o preparo da cavidade. Assim, o segundo artigo apresentado nesta tese é um ensaio clínico randomizado, que avaliou a influência da instrumentação do esmalte cavo-superficial na sobrevida de restaurações de resina composta em molares decíduos, submetidos à remoção seletiva de tecido cariado.

Portanto, o objetivo geral desta tese é revisar sistematicamente a literatura avaliando a longevidade de restaurações de resina composta bulk-fill comparadas a materiais restauradores diretos, bem como avaliar clinicamente a influência do esmalte cavo-superficial na longevidade de restaurações de resina composta bulk-fill em molares decíduos.

2 ARTIGO 1 - CLINICAL BEHAVIOR OF BULK-FILL RESTORATIONS IN PRIMARY MOLARS: A SYSTEMATIC REVIEW AND META-ANALYSIS

Este artigo será submetido ao periódico *International Journal of Paediatric Dentistry*; ISSN: 1365-263X; Fator de impacto = 3.264; Qualis A1. O artigo está de acordo com as normas desse periódico, que estão descritas no Anexo A.

Article type: Systematic review and meta-analysis

Clinical behavior of bulk-fill restorations in primary molars: A systematic review and meta-analysis

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Authors' contributions:

R.O.R conceived the idea and study design. R.O.R and F.Z.S analyzed the data. M.D.B and R.O.R led the writing.

Running title: Bulk-fill composite similar to control materials

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Clinical behavior of bulk-fill restorations in primary molars: A systematic review and meta-analysis

ABSTRACT

Background: The similar clinical performance of bulk-fill resins and incremental composite resins in restorations of permanent teeth has been shown in systematic reviews published in recent years.

Aim: To investigate the longevity of bulk-fill composite resin restorations in primary molars compared to direct restorative materials.

Design: An electronic search including the databases PubMed, Scopus, Web of Science, EMBASE, and Lilacs/BBO with no date or language restrictions were applied. The records were cross-checked in an electronic spreadsheet to eliminate duplicates and analyze the inclusion and exclusion of studies. The inclusion criteria were clinical trials assessing bulk-fill restorations in primary molars that compared bulk-fill restorations with any other direct restorative materials and provided data as restoration failure or success.

Results: Out of 710 articles, after title and abstract screening, 635 records could not be included. Ten full-text articles were reviewed, and 6 eligible studies were included in the systematic review and meta-analysis. The overall meta-analysis comparison did not show statistically significant effect of material on restorations failure ($Z = 1.58$; $P = 0.11$).

Conclusion: Restorations placed with bulk-fill composite resins present similar longevity to other considered control materials, being suitable for occlusal and occlusal-proximal restorations in primary molars. (CRD 42021289288)

Keywords: Bulk-fill resin. Composite resin. Dental restoration. Primary tooth.

INTRODUCTION

Resin composite materials are traditionally used to restore dentin carious cavities in primary molars, mainly for their adhesive, esthetic, and relatively easy handling properties[1]. Other adhesive materials, such as glass ionomer cement (GIC), resin-modified glass ionomer cement (RMGIC), and compomers, are also frequently used in Pediatric Dentistry and comply with the concept of Minimally Invasive Dentistry. The choice of material depends much more on the operator's personal issues than on the material's performance, considering that there is no superiority among restorations longevity between RMGIC, compomer, and composite resin in primary molars[2–4].

Bulk-fill composite resins, presented as a full-body material, enable the restoration of the whole cavity using a single increment (at approximately 4-mm thickness) due to their higher translucency, allowing deeper light penetration[5]. A less time-consuming restorative procedure is always advisable in the treatment of children. Full-body bulk-fill resins require a shorter restorative time to perform restorations in permanent posterior teeth than composite resins used in an incremental technique (incremental composite resins)[6]. Thus, bulk-fill resins are now also being used in Pediatric Dentistry for posterior teeth restorations in vital[7,8] and non-vital primary teeth[9].

The similar clinical performance of bulk-fill resins and conventional composite resins used in incremental technique in restorations of permanent teeth has been shown in systematic reviews published in recent years[10–13]. One systematic review also pointed out that there is no difference between restorations with bulk-fill and incremental composite resins in primary molars[14]. However, only two clinical trials were included, and failure data were analyzed regardless of primary or permanent teeth. Assuming that the longevity of dental restorations depends on patient-related factors[15], child behavior management problems during dental appointments could also affect the quality of restoration; thus, the clinical behavior of

composite resin restorations may differ in primary teeth[16], hindering direct extension of the findings from permanent to primary teeth. Thus, this systematic review aimed to investigate the longevity of bulk-fill composite resin restorations in primary molars compared to direct restorative materials. The hypothesis was that there is no difference in the clinical performance among materials between bulk-fill composite resins and the other restorative materials.

MATERIAL AND METHODS

This meta-analysis was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement[17], and the study protocol was previously registered at PROSPERO (CRD 42021289288). The research PICO question was: "Does the clinical behavior of bulk-fill restorations similar to other direct restorative materials in primary molars?"; in which primary molars were the population; bulk-fill restorations were the intervention; direct restorative materials were the control, and the outcome was the clinical behavior, expressed through of restoration failures.

Search strategy

Two independent authors conducted an electronic search, including the databases PubMed, Scopus, Web of Science, EMBASE, and Lilacs/BBO. The search strategy used in PubMed combined controlled vocabulary (Mesh terms) and free terms as follows: "((((((((((((((((((((((((Composite resins[MeSH Terms]) OR Composite resins) OR Composite resin*) OR Composite restorative material*) OR Resin composit*) OR Resin composite restoration*) OR Posterior composite restoration*) OR Resin-based composite*) OR Dental composite*) OR Direct posterior composite*) OR Composite restoration*) OR Direct composite resin*) OR Direct resin composite restoration*) OR Direct composite restoration*) OR Direct restoration*) OR Direct resin composit*) OR Direct composit*) OR Class I restoration*) OR Class II restoration*) OR Occlusal restoration*) OR Proximal restoration*)))

AND (((((((Bulk Fill) OR Bulk-Fill) OR BulkFill) OR Bulk-Fill composite*) OR Bulk Fill composite*) OR Bulk Fil*))) AND ((((((((((((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)))". The searches for other databases were adapted from the PubMed strategy (Supplementary Table 1). No date or language restrictions were applied. The search time was June 2022. The records of the five databases were cross-checked in an electronic spreadsheet (Numbers 11.1, Apple Inc, Cupertino, CA, USA) to eliminate duplicates and analyze the inclusion and exclusion of studies. The same two reviewers individually evaluated the titles and abstracts of retrieved articles to assess their eligibility. A search in the references of included studies was further performed to identify any non-included relevant study.

Eligibility criteria

Studies were eligible for inclusion if they met the following criteria: (1) consisted of a clinical trial study assessing bulk-fill restorations in primary molars; (2) had compared bulk-fill restorations with any other direct restorative materials; (3) provided data as restoration failure or success. Studies were excluded if, after reading the text in its entirety: (1) used bulk-fill composite resin covered with an incremental resin; (2) used bulk-fill composite resin to repair of existing restoration; (3) were a research protocol or a review; and (4) full-text was unavailable. Disagreements between reviewers were decided by consensus together with a third reviewer.

Data Extraction

Data were extracted by two reviewers and compiled into a predefined spreadsheet, including study characteristics (year of publication, country of the first author, population,

sample size, restorative materials, operators, evaluation criteria, examiners) and study results (restoration failure, drop-out rate). Corresponding authors were contacted by email to obtain unclearly or not reported data. Unanswered information made the study excluded. All information was registered precisely as described in the study.

Assessment of risk of bias

The potential risk of bias for each study was examined independently by two examiners using the Cochrane Collaboration risk of bias tool (RoB 2)[18], considering the domains: randomization process, deviations from the intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Any disagreements between the reviewers were resolved via consensus. The risk of bias assessment was summarized in a "traffic light" figure using a *web app*[19].

Meta-analysis

The meta-analysis were conducted using the Review Manager software (RevMan version 5.4; Cochrane Collaboration, London, UK). The pooled risk ratio was calculated using the Mantel-Haenszel method, with a random-effects model, and a significance level of 5%. The heterogeneity was quantified using Cochran's and I^2 values. Values higher than 50% were considered heterogeneous[20].

RESULTS

Study selection

The literature search yielded 710 results in all databases, and one study was identified through manual search, with 75 duplicates. After title and abstract screening, 635 records could not be included, mainly for the reasons: out of review scope, laboratory study, restorations

performed only in permanent teeth, restorations in anterior teeth, with hypomineralization or non-carious cervical lesions, restoration repair, no bulk-fill composite resin restorations, and research protocol or review articles. Ten full-text articles were reviewed, and 6 eligible studies were identified and included in the systematic review and meta-analysis. Figure 1 depicts the PRISMA flowchart for the study selection process.

Descriptive analysis of included studies

Included studies were published in English, and reported from 2018 to 2022. Two studies were from Turkey,[21,23] and the others four studies were from Russia,[24] Germany, [22] Italy,[8] and Brazil.[7] The studies were described as prospective university-based parallel-group study[21], clinical study[22], preliminary data of a randomized single blind clinical trial[23], a prospective case-control split-mouth study[24], blinded and split mouth study[8], and a two-arm parallel randomized clinical trial[7].

The six selected studies included 276 participants, ages between 4 and 10 years old, and 798 restorations, of which 399 were bulk-fill restorations. At the final follow-up, 687 restorations were evaluated, being 344 bulk-fill restorations. Four studies considered 12 months follow-up[8,21–23], one study considered 18 months of follow-up[7] and one study completed the follow-up at 24 months[24].

Restorations were placed on both jaws in the first and second primary molars. Two studies included only occlusal cavities[23,24], two studies considered only occluso-proximalI[21,22], and both occlusal and occluso-proximal cavities were restored in two studies[7,8].

Five commercial brands of bulk-fill composite resins were compared with two incremental composite resin brands, one compomer, one resin-modified glass ionomer cement (RMGIC), and one high-viscosity glass-ionomer (HVGIC). Three studies used a universal adhesive system applied using the self-etch mode[22,23] or selective enamel acid etching[7,8], a two-

step self-etch system was used in one trial[21], and a one-step self-etch system with selective enamel acid-etching was applied in one trial[24].

In five trials, all restorations were carried out by a single operator[8,21–24]. Only three studies reported the experience or training of the operator[7,8,22]. The restorative procedure was carried out with rubber dam isolation in only two included studies[7,8]. In four studies, slow-speed tungsten carbide burs and hand instruments were used for caries removal[7,8,21,23]. Only one study reported on selective caries tissue removal[7].

Modified United States Public Health Service criteria (USPHS) was used in three studies[21,23,24], and FDI criteria was adopted by the other three studies[7,8,23]. Restorations were considered failed if a score Charlie and scores 4 or 5 were assigned for the modified USPHS and FDI, respectively. Examiners were trained for evaluation criteria in five studies[7,8,21–24], and one study did not inform the examiners' training[24]. Recall rate was 100% after 12[8] and 24-months[24], 99%[22], 84%[7], 83,7%[21], and 62.5% after 12-months[23]. The characteristics of each included study are listed in Table 1.

Assessment of risk of bias

The risk of bias assessment is summarized in Figure 2[19]. Four studies were classified as having a low risk of bias in the overall judgment[7,8,21,23]. Nevertheless, the majority of the domains received a low risk of bias. 'Some concerns' was assigned for the domain 'Bias arising from the randomization process' for three studies[21–23]; and for 'Bias in the measurement of outcome' for two studies[7,22], because the evaluators were not blinded to restorative materials. Regarding the domain 'Bias in the selection of the reported result', one study[24] was classified as a serious risk of bias because outcomes were described in different ways.

Meta-analysis

The data of the six included studies were analyzed. The overall meta-analysis comparison did not show statistically a significant effect of material on restorations failure (Z = 1.58; P = 0.11). In the subgroups comparisons, there were also no difference between bulk-fill and incremental resin restorations (Z = 0.38; P = 0.71), high-viscosity GIC restorations (Z = 1.10; P = 0.27), and RMGIC restorations (Z = 1.64; P = 0.10). No failures were observed in the comparison between bulk-fill and compomer restorations, so the effect could not be estimated. The overall meta-analysis resulted in no heterogeneity (I^2 = 0%). (Figure 3)

DISCUSSION

This meta-analysis explored the clinical performance of bulk-fill restorations compared to incremental composite resin, compomer, and high-viscosity and resin-modified GIC restorations in primary molars. Pooled effect sizes across the clinical outcome showed that bulk-fill restorations present similar performance compared to considered control materials in primary molars after 12[8,21–23], 18[7], and 24 months[24]. The considered hypothesis that there is no difference in the clinical performance among bulk-fill and other restorative materials could not be rejected.

The clinical effectiveness of bulk-fill resin has been pointed out as similar to conventional incremental resin[13] in permanent teeth. Although a previous systematic review[14] considered restorations in primary teeth, only two studies[21,23] were included. Four more studies[7,8,22,24] were considered in the present systematic review. Bulk-fill composite resins seem attractive for use in pediatric dentistry, mainly by being applied in a single increment, requiring a shorter restorative time to perform restorations in posterior teeth than conventional composite resins[6]. Thus, comparing the clinical performance of bulk-fill and incremental composite resins

through a systematic review is essential to support their routine clinical use. However, critical points must be considered.

In general, the longevity of occluso-proximal restorations is worse compared to occlusal restorations[16]. Included studies evaluated restorations involving only one[23,24] or two[21,22] surfaces, and two studies included restorations in both one and two surfaces[7,8]. It was not possible to compare failures in occlusal and occluso-proximal restorations separately, however, only two surfaces restorations failed in the Akman, Tosun study[21], whereas the number of restored surfaces did not influence the restoration's survival, according to Massa et al.[7] It is worth noting that bulk-fill resins were compared to others direct restorative materials[7,8,22] besides incremental composite resin in both occlusal and occluso-proximal restorations. Compomer, RMGIC, and incremental composite resin are usually used to restore primary molars with no advantage among them regarding the clinical performance[2], and therefore, were considered, in the present systematic review, as control materials. Five brands of bulk-fill resins were considered in the six included studies. These studies included only restorations completely composed of bulk-fill resin with no capping layer. Several in vitro studies highlighted the negative effects of composite resin polymerization shrinkage and the generated stress on restoration margins that may impact secondary caries development[25]. Also, polymerization shrinkage and generated stress depend, among other factors, on the composite resin composition and properties[26]. Therefore, considering that secondary caries has been pointed out as the main reason for failure in restorations in primary teeth[16], the use of bulk-fill covered with an incremental composite resin was not considered in the present systematic review.

Although there is no clinical evidence concerning adhesive systems strategies, the in vitro literature suggests a superior performance of etch-and-rinse adhesives compared with self-etch systems in primary teeth[27], except for universal adhesives, that can be used in both etching strategies[28]. In two included studies, a universal adhesive was used with selective enamel acid

etching[7,8], and with self-etch system[24]. The other three studies, a self-etch system[21] and a universal system in a self-etch mode[22,23] were used. It is noteworthy to consider that in only two studies the restorations were placed using rubber-dam isolation, despite the evidence that restorations placed in primary teeth under rubber-dam showed a greater success rate, independently of the restorative material[16].

Few restoration failures were observed in the included studies, and caries recurrence was only described as a failure reason in two studies[7,24]. This is probably related to the short follow-up time and the non-inclusion of children with poor[21], inadequate[24], or extremely poor oral hygiene[23]. Besides, individual caries risk was only mentioned by one study[7]. Marginal discoloration, anatomic form, marginal adaptation, and the fracture was pointed as the reason for bulk-fill restorations failures[7,8]. Pulpal outcomes were not considered a restoration failure by the included studies, although two pulp failures have been reported in two studies[8,21].

The evaluation criteria used in the included studies were FDI[7,8,22] or modified USPHS[21,23,24], considering scores 4 and 5 or Charlie as a failure. Both FDI as modified USPHS criteria have been considered appropriate to clinical trials on restorations longevity[29], and besides being the most often used, enable comparisons among investigations. Although trained and calibrated evaluators are imperative, only two studies described the examiners' training and calibration[7,21], and it can severely impact studies' results. In addition, one study also included a grading, considering esthetic, functional, and biological properties together[22].

Although all included studies have been described as randomized trials[7,8,21–24], only one[7] cited the Consolidated Standards of Reporting Trials (CONSORT) statement, an important tool to improve the quality of randomized clinical trials. Adherence to the CONSORT guidelines seems crucial for complete reporting, especially regarding the methods. The included studies did not clearly describe some informations. As already stated, individual caries risk was only recorded by one study[7], as well as, and only two studies[7,22] informed on the management of

dentine carious lesions before restoration. Selective carious tissue removal may increase the risk of experiencing restoration failure in primary teeth[30], thus, reporting the carious tissue management is imperative. Nevertheless, the overall the risk of bias in the four included studies was low[7,8,21,23]. One study was classified as having some concerns[22], and only one study was classified as high risk of bias on account of bias in reporting results[24]. Even so, the quality of the studies may not have strongly impacted the estimated effect. Despite being an important factor to be considered in pediatric dentistry, none of the articles included in this systematic review compared the restorative time for bulk-fill or conventional resins.

It is important to highlight that the low number of studies included and the follow-up time are important limitations of the present review. However, considering the fact that bulk-fill resins suitable to complete the whole restoration have gained popularity in recent years, it is probable that clinical trials are ongoing. The follow-up time in clinical trials regarding restorations in primary teeth is always a matter of concern, however, one must consider that a long follow-up time would require the recruitment of young children, probably with non-cooperative behavior. Including school-aged children, on the other hand, limits the follow-up time by tooth exfoliation. Even so, currently results can assist dentists in choosing a restorative material that offers adequate clinical performance, and is being user-friendly and time-saving.

The results of this systematic review allow concluding that restorations placed with bulk-fill composite resins present similar longevity to other considered control materials, being suitable for occlusal and occluso-proximal restorations in primary molars.

Why this paper is important to paediatric dentists

Bulk-fill composite resins can be a chosen restorative material for Paediatric Dentistry, since it has a shorter clinical restorative time with similar longevity to other considered control materials.

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Figure legend

Figure 1. PRISMA flowchart for the study selection process.

Figure 2. Risk of bias assessment.

Figure 3. Overall meta-analysis.

Figure 1. PRISMA flowchart for the study selection process.

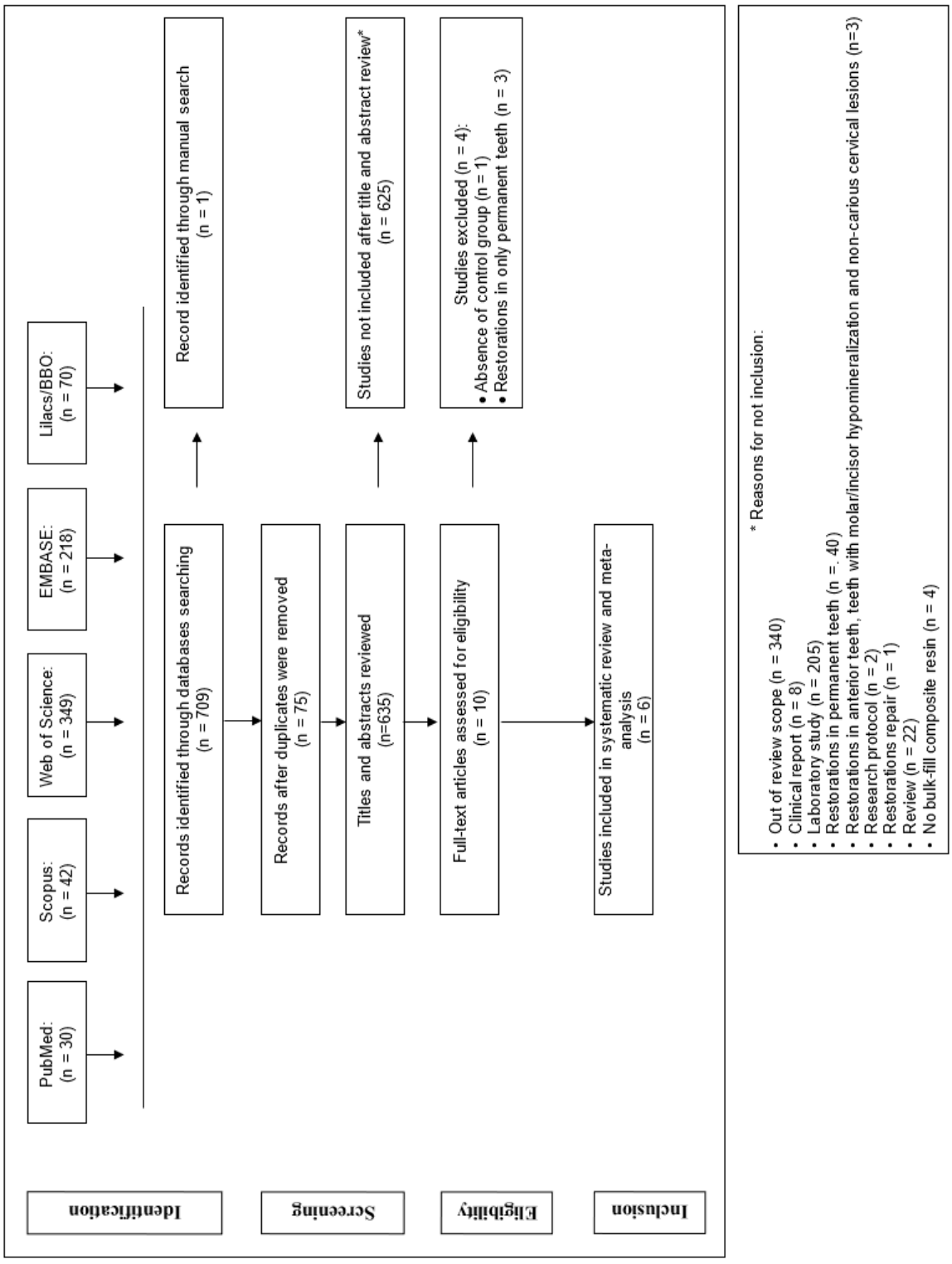

Figure 2. Risk of bias assessment.

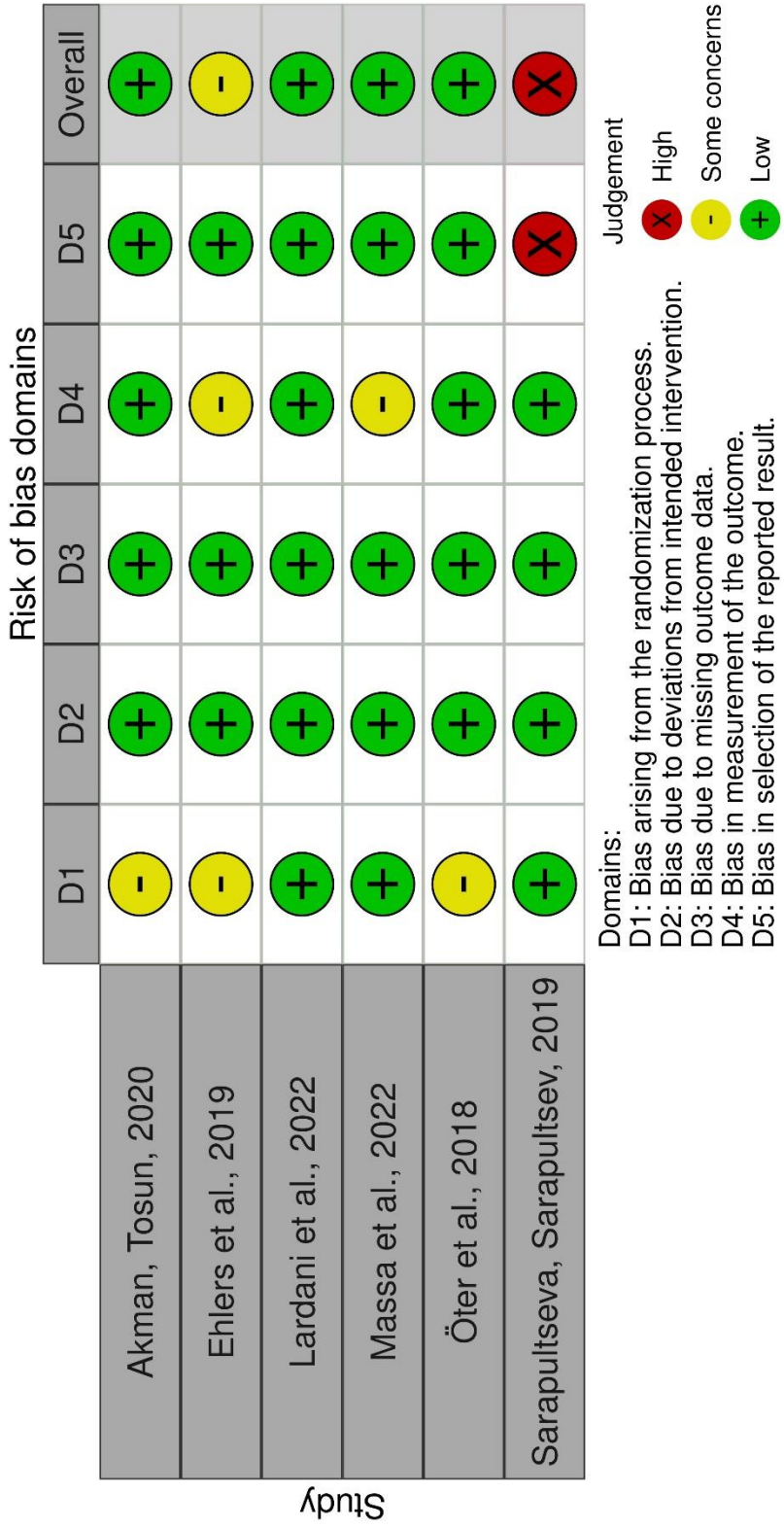

Figure 3. Overall meta-analysis.

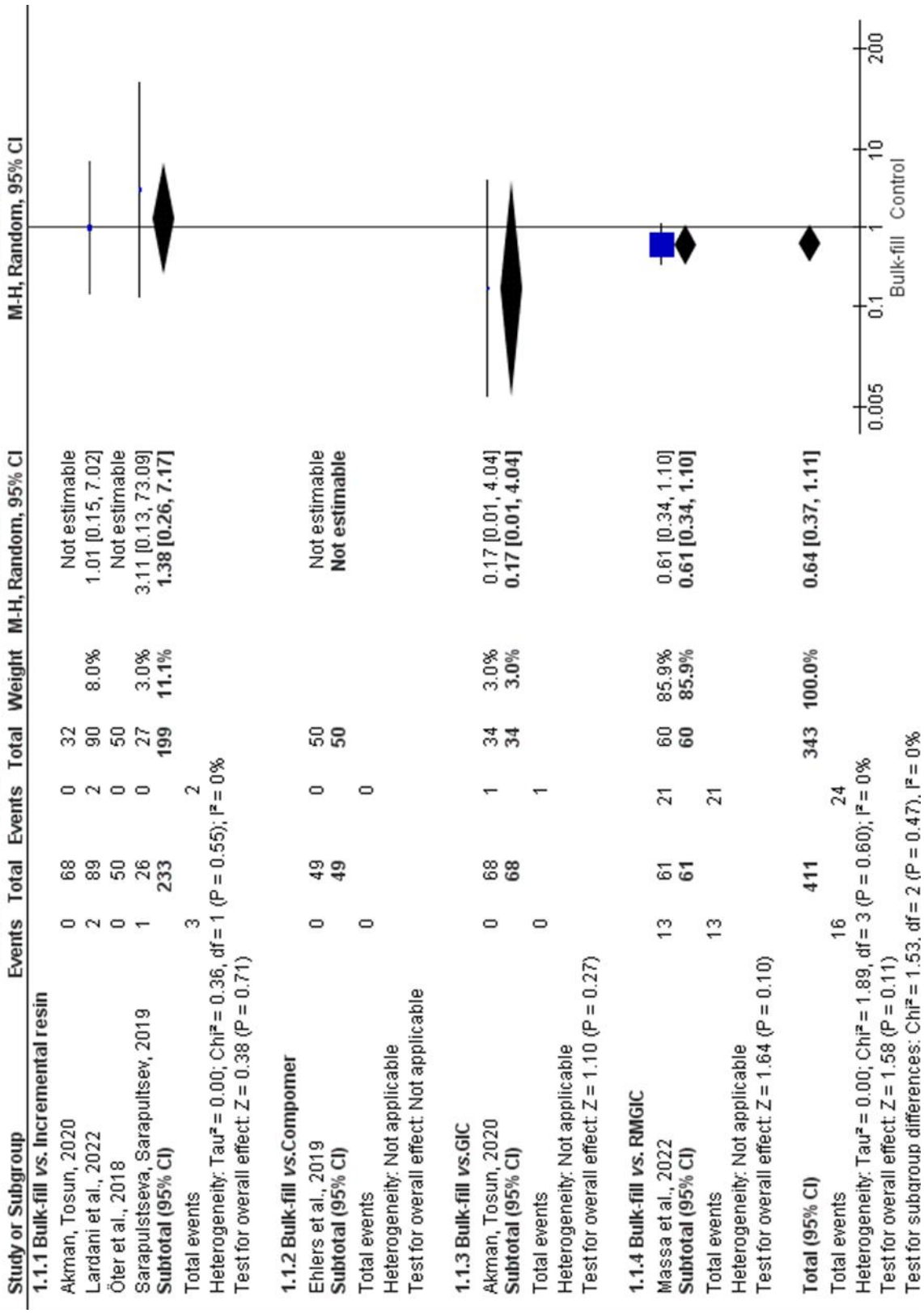

Table 1. Characteristics of included studies in systematic review and meta-analysis.

Study: Author, year	Akman, Tosun, 2020[21]	Ehlers et al., 2019[22]	Lardani et al., 2022[8]	Massa et al., 2022[7]	Öter et al., 2018[23]	Sarapultseva, Sarapultsev, 2019[24]
Country	Turkey	Germany	Italy	Brazil	Turkey	Russia
Study design [§]	Randomized, prospective university-based parallel-group design	Randomized clinical trial	Blinded and split mouth design study	Two-arm, parallel, randomized clinical trial	Randomized, single-blind, prospective clinical trial	Randomized, split-mouth clinical trial
Participants (n)	30	32	45	62	80	27
Age range at baseline (years)	6 to 10	4 to 9	5 to 9	3 to 8	7,41(1.8) [†]	3 to 6
Restorations per group (n) [‡]	40	50	90	72	80	27
Number of surfaces	Occluso-proximal	Occluso-proximal	Occlusal and occluso-proximal	Occlusal and occlusal-proximal	Occlusal	Occlusal
Follow-up time (months)	12	12	12	18	12	24
Restorative material [§]						
Control	Filtek Z550 (3M ESPE, St Paul, MN, USA) Equia Fil (GC Corporation, Japan)	Dyract eXtra (Dentsply, Germany)	Activa™ BioActive-Restorative (Pulpdent Corp., Watertown, MA, USA)	Vitremer (3M Oral Health, St. Paul, NM, USA)	Filtek Z550 (3M ESPE, St Paul, MN, USA)	Ceram X mono (Dentsply, Konstanz, Germany)
Bulk-fill	SonicFill (Kerr Corporation, Orange, CA, USA) X-tra fil (Voco, Cuxhaven, Germany)	Venus Bulk-fill (Hereaus Kulzer, Hanau, Germany)	SDR Bulk-fill (Dentsply, Konstanz, Germany)	Filtek Bulk-Fill Posterior Restorative (3M Oral Health, St. Paul, NM, USA)	Filtek Bulk-fill (3M ESPE, St Paul, MN, USA)	SDR (Dentsply, Konstanz, Germany)

Study: Author, year	Akman, Tosun, 2020[21]	Ehlers et al., 2019[22]	Lardani et al., 2022[8]	Massa et al., 2022[7]	Öter et al., 2018[23]	Sarapultseva, Sarapultsev, 2019[24]
Adhesive system	Clearfil SE Bond (Kuraray, Tokyo, Japan)	Scotchbond Universal (3M Oral Care, St Paul, MN, USA)	Scotchbond Universal (3M ESPE, Maplewood, MN, USA)	Scotchbond Universal (3M Oral Health, St. Paul, NM, USA)	Single Bond Universal (3M ESPE, St Paul, MN,)	Prime and bond NT (Dentsply, Germany)
Use of rubber dam	No	No	Yes	Yes	No	No
Operator	One	One	One	Two	One	One
Criteria	USPHS	FDI	FDI	FDI	USPHS	USPHS
Examiner	Two	Two	One	One	One	Two

† average
‡ At the baseline
§ As described in the study

Supplementary Table 1. Search strategy adapted from PubMed for the other databases

Scopus
(TITLE-ABS-KEY (bulk-fill) AND TITLE-ABS-KEY (primary) OR TITLE-ABS-KEY (deciduous))
Web of Science
#2 AND #1 (ALL=(DECIDUOUS)) OR ALL=(PRIMARY) (ALL=(BULK FILL)) OR ALL=(BULK-FILL)
EMBASE
(Bulk-fill AND clinical)
LILACS
BULK FILL [Palavras] or BULK-FILL [Palavras]

3 ARTIGO 2 - ENAMEL INSTRUMENTATION NEGATIVELY IMPACTS ON THE SURVIVAL OF COMPOSITE RESTORATIONS AFTER SELECTIVE REMOVAL OF CARIOUS TISSUE IN PRIMARY MOLARS: UP TO 24-MONTHS RANDOMIZED CLINICAL TRIAL

Este artigo será submetido ao periódico *International Journal of Paediatric Dentistry*; ISSN: 1365-263X; Fator de impacto = 3.264; Qualis A1. O artigo está de acordo com as normas desse periódico, que estão descritas no Anexo A.

Article type: Randomized clinical trial

Enamel instrumentation negatively impacts on the survival of composite restorations after selective removal of carious tissue in primary molars: up to 24-months randomized clinical trial

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Authors' contributions:

R.O.R conceived the idea and study design. M.D.B and T.T.F collected the data. R.O.R and F.Z.S analyzed the data. M.D.B and R.O.R led the writing.

Running title: Enamel instrumentation influences restorations

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Clinical trial registration number: RBR-8bwz7r

Enamel instrumentation negatively impacts on the survival of composite restorations after selective removal of carious tissue in primary molars: up to 24-months randomized clinical trial

ABSTRACT

Background: In vitro studies found that the bond strength of adhesive systems to demineralized enamel is lower than that obtained in sound enamel.

Aim: This randomized, double-blind clinical trial evaluated the influence of enamel instrumentation on the performance of composite resin restorations in primary molars submitted to selective removal of carious tissue.

Design: One hundred and thirty-two occlusal caries lesions in primary teeth were selected in 68 children (mean age 5,5 years) and were randomly allocated into two intervention groups, a non-instrumented (NIE) and an instrumented (IE; enamel margins were instrumented with a diamond bur previously restoration). Composite restorations were evaluated after 3, 6, 12, 18, and 24 months. Success (FDI scores 4 and 5 as failure) and survival (only FDI score 5 as failure) curves were created and compared using the Kaplan-Meier estimation, and log-rank.

Results: The overall clinical success for restorations from NIE and IE were 93.2% (55/59) and 80.3% (49/61), respectively. A statistically significant difference was found only between the survival rates ($p = 0.036$). No statistically significant influence was found for clinical and sociodemographic variables on restorations survival.

Conclusion: Enamel margins instrumentation negatively impacts the survival of composite restorations in primary teeth submitted to selective removal of carious tissue. (RBR-8bwz7r).

Keywords: Clinical trial. Dental caries. Selective caries removal. Demineralized enamel. Composite resin. Primary tooth.

INTRODUCTION

Restoration of dentin carious lesions is a routine practice in dentistry. The complete removal of decayed dentin in deep lesions can result in a higher risk of pulp exposure and postoperative pulpal symptoms, requiring more complex treatments such as pulpotomy or pulpectomy[1,2] . On the other hand, studies show that the maintenance of the affected dentin under the restoration in the selective removal of decayed tissue does not influence pulp vitality, suggesting a more conservative treatment[3,4] . The selective removal of carious tissue requires the complete carious enamel and dentin removal from cavity walls, while the pulpal wall should be excavated to soft, leathery, or firm dentin[5,6].

Dentin hardening or pulp vitality is often the usual outcome in clinical studies[2–4], and pulpal vitality maintenance and stopping caries progression are associated with selective removal of caries tissue. However, there are still few clinical studies considering factors related to the longevity of restorations, such as the condition of the surrounding enamel after caries excavation. Bonded enamel margins play a substantive role in adhesive restorations success, avoiding post-operative sensibility, marginal staining, and secondary caries. Furthermore, adequate enamel margins sealing is of paramount value to arrest the residual lesion[6,7].

Adhesion to enamel is usually more simplified and predictable than to dentin[8]. However, demineralized enamel negatively affects the adhesive interface. In vitro studies[9,10] found that the bond strength of adhesive systems to demineralized enamel is lower than that obtained in sound enamel, which may be a consequence of the lower amount of minerals, surfaces more porous, and increased intercrystalline spaces[11]. These changes can lead to an unsatisfactory conditioning pattern and less infiltration of monomers, which would result in low bond strength, and it is necessary to consider the fact that there is some demineralized enamel left inadvertently after cavity preparation[9].

Thus, this randomized clinical trial aimed to evaluate the influence of enamel margins instrumentation on the performance of composite resin restorations in primary molars submitted to selective removal of carious tissue.

MATERIALS AND METHODS

Study design and ethics

A randomized, double-blind (patient and examiner) controlled trial was conducted. The study protocol was approved by the institutional ethics committee (CAAE 62645316.4.0000.5346) and registered on the Brazilian Registry of Clinical Trials (RBR-8bwz7r). The study was reported according to the CONSORT guidelines[12] .

The study was conducted at a pediatric service in a university setting from March 2017 to March 2020.

Sample size calculation

Sample size estimation was performed based on the success rates of composite resin restorations in primary molars submitted to total or partial removal of decayed dentin[5]. Considering the success rates after 24 months of follow-up, 80% power, and 5% significance level, a minimum of 55 restorations in each group were required. Considering a 20% sample loss rate over the study period, 66 restorations were needed in each experimental group, totaling 132 restorations.

Patient and tooth selection

The inclusion criteria were the following: children with at least one active moderate occlusal cavitated carious lesion in primary molar; no previous restorations in the selected tooth, no clinical or radiographic signs of irreversible pulpitis or pulp necrosis. Children who

refused or did not cooperate with the clinical procedure were excluded.

Participants were selected through clinical and radiographic examination by one examiner, from the school screening clinic, from March 2017 to June 2018. Children who met the eligibility criteria were invited to participate, and legal guardians signed the free and informed consent term. The operator enrolled and assigned the participants for interventions.

Randomization and allocation concealment

The randomization sequence was generated by a collaborator who was not involved in this study, using a website. Allocation concealment was maintained using opaque, sealed, and serially numbered envelopes. Carious lesions were randomized in two experimental groups, according to the enamel instrumentation. If the participant presented more than one carious lesion, each one received a number according to the randomization list. The sealed envelopes were opened immediately before the restorative procedure. Blinding of the operator who performed the restorations was not possible; participants and their legal guardians, and clinical examiner were blinded to the experimental group.

Study groups

Teeth were assigned randomly to two groups: non-instrumented enamel (NIE) during selective removal of carious dentin; and instrumented enamel (IE) with a diamond bur after selective carious dentin removal.

Interventions

A single trained operator, experienced in pediatric dentistry, performed all restorative procedures. The operator was experienced in selective carious dentin removal and had been updated and instructed during an one-hour training session towards the used materials and how to employ them. All restorative materials were used strictly according to the manufacturers'

instructions.

Restorative procedures were performed after dental prophylaxis, local anesthesia (lidocaine 2% with epinephrine 1:100:000), and rubber dam isolation. Complete removal of carious tissue from cavity walls was performed using rotary instruments in low speed and selective carious dentin removal until firm dentine from pulpal wall were performed using dentin excavators. After selective carious dentin removal, the allocation envelope was opened to define the experimental group. A cylindrical diamond bur (#1090, KG Sorensen, São Paulo, SP, Brazil) at high speed, under water-cooling, was used in the instrumented enamel group.

The same restorative procedure was performed for the two experimental groups. Enamel and dentin were etched with a 37% phosphoric acid (Condac 37, FGM, Brazil) for 15 seconds, followed by rinsing with water-air spray for 30 s. A sterile cotton pellet was used to remove excess water from the dentin, to obtain a moist surface, and protect the dentin substrate from rigorous drying of the enamel with compressed air jets. Afterward, the Single Bond Universal adhesive (3M ESPE, St. Paul, MN, USA) was applied actively to the entire preparation, followed by a gentle stream of air for 5 seconds and light-cured for 10 seconds (Emmiter C, Schuster, Santa Maria, RS, Brazil).

The composite resin (Filtek Bulk Fill, 3M ESPE, St. Paul, MN, USA) was applied in a single increment with a maximum of 4mm, light-cured for 20 seconds. After removing the rubber dam isolation, possible occlusal interferences were checked, and, when necessary, occlusal adjustment was performed with fine-grid diamond bur (#3118F; KG Sorensen, São Paulo, SP, Brazil) at high speed, under water-cooling. Restorations were polished with abrasive points (Enhance kit; Dentsply Sirona, Milford, DE, USA).

Clinical assessment

One examiner trained and calibrated (intra-examiner kappa value greater than 0.8),

blinded to the experimental groups assessed the restorations after 3, 6, 12, 18, and 24 months.

The modified FDI criteria[13] was used to evaluate the restorations, considering the following domains: surface gloss/luster and roughness, surface staining, marginal staining, color stability and translucency, anatomic form, fracture/retention, marginal adaptation, and recurrence of pathology. For the recall evaluation, previous dental prophylaxis was performed to remove bacterial biofilm and debris that could influence the clinical evaluation of the restorations. In all evaluation recall, data on visible plaque index, gingival bleeding index, and clinical dental examination were also collected.

The primary outcome was the restoration success and survival. Success was considered when restoration, at the time of the follow-up evaluation, was classified as clinically acceptable (FDI scores 1 to 3). Survival was considered including restorations classified as acceptable (FDI scores 1 to 3) and repairable (FDI score 4, clinically unsatisfactory - repairable restoration). On survival analysis, only restorations that received an FDI score of 5 were considered failures.

Statistical analysis

Descriptive statistics were used to describe the sample characteristics. Statistical analysis was conducted considering the survival and success rates of restorations. Success and survival curves were created using the Kaplan-Meier estimation, and the curves from groups were compared using the log-rank test (Minitab 19, Minitab, State College, PA, USA). Cox regression model to assess the relationship of predictors and the restorations' survival rates was performed, and the hazard ratio (95% confidence interval) was calculated (Statistica for Windows 12.0, StatSoft Inc., Tulsa, OK, USA). All analysis were performed by a researcher blinded to the experimental groups, using the pre-set level of significance at 5%.

RESULTS

One hundred and twenty restorations in 62 children were evaluated, 59 from the non-instrumented enamel group and 61 from the instrumented enamel group, from a total of 132 restorations, according to Figure 1. Demographic and clinical characteristics of children and restored teeth are described in Table 1. The loss of follow-up was because children moved to another city, changed the mobile phone numbers, or missed the assessment appointments.

The overall clinical success of occlusal restorations were 93.2% (55/59) and 80.3% (49/61), respectively for NIE and NI groups. Considering the restorations needing repair (score 4) as no failed restorations, thus overall survival was 100% (59) for the non-instrumented enamel group and 91.8% (56/61) for the instrumented enamel group. The estimated success probability at 24 months were 88.5% (95% CI 77.6 - 99.7) and 71.3% (95% CI 57.2 - 85.5) for NIE and IE, respectively. The estimated success probability was similar between groups (p=0.056). Log-Rank test showed a significant difference in the comparisons of survival rates (p = 0.036), considering NIE (no failure) and IE (88.5% (95% CI 78.6-98.3). No statistically significant influence was found for clinical and sociodemographic variables on restorations survival, as present in Table 2.

DISCUSSION

This randomized clinical trial evaluated the effect of enamel instrumentation on the success and survival of composite restorations up to twenty-four months of clinical service in primary molars. Twelve restorations (19.7%) failed when enamel was previously instrumented, and four restorations (6.8%) failed when enamel was not instrumented. All failed restorations from the non-instrumented enamel group were considered as likely to be repaired (survival rate of 100%), while restoration replacement was indicated for five restorations placed in cavities with instrumented enamel (survival rate of 91.8%). Therefore, the estimated survival

probability at 24 months was higher for restorations placed in cavities with no-instrumented enamel.

Selective removal of carious tissue has been strongly recommended during primary and permanent teeth restorations to avoid pulpal exposure, preserving pulp health[1–4]. The use of diamond burs to access the cavity is not always necessary, and in many situations, the carious dentin is removed with manual instruments or low-speed rotary instruments[5]. Laboratory studies, however, pointed out that demineralized enamel can jeopardize the bonding of adhesive systems, suggesting that the demineralized enamel surrounding carious cavities may compromise the longevity of the restoration[9,10]. Lower mineral content, higher porosity, and enlarged inter-crystalline spaces[11] might explain the lower bond strength values on demineralized enamel, as the resin-monomer infiltration can be impaired. Therefore, considering that the longevity of dentin bonding and the effective marginal sealing are dependent on the enamel bonding integrity, it has been suggested that demineralized enamel be removed, thus providing a sound enamel for bonding.

Unlike the results of in vitro studies, a lower survival rate was found in previously instrumented enamel restorations. Considering that the removal of dental tissue on cavity preparations impairs the resistance to fracture[14], the intention of using a diamond bur at high-speed was only to access non-cavitated carious lesions in dentin, removing only the surrounding enamel, enough to access the carious dentin. We can infer that this minimal instrumentation of the enamel may have exposed the subsurface enamel, less mineralized, and thus, less favorable for adhesion. Although laboratory and clinical studies suggest beveling the cavosurface enamel to expose a more favorable substrate[15], increasing the enamel area[16], reducing the marginal staining[17], the use of a bevel preparation on enamel is not a consensus. Therefore, in the present study, enamel instrumentation was restricted to access carious dentin, removing only the surrounding enamel, as suggested in the previous studies[9,10].

The fracture with partial or total restoration loss was the reason for failures in the non-instrumented enamel group; whereas, recurrent caries, associated or not with restoration fracture, were observed in eight of twelve failed restorations from instrumented enamel group. It is essential to consider that, although all restorations were placed in children with high caries risk, recurrent caries were only observed in restorations from instrumented enamel group. Margin defects, as interfacial gaps, can be associated with secondary caries, allowing the biofilm penetration into the adhesive interface[18]. Surrounding enamel removal with diamond burs may have led to imperfections in marginal adaptation, favoring interfacial gaps creation, explaining the occurrence of recurrent lesions only in the instrumented enamel group, even though all the patients were at high caries risk. It is worth considering that recurrent caries lesions have been identified as the main reason for restoration failure in primary teeth[19] . Failure due to endodontic reasons also only occurred in the instrumented enamel group. This failure may be more related to a diagnostic failure, but it was still considered a failure in the evaluation criteria.

Instead, the patient caries-risk has been associated with restorations failure in permanent teeth[20]; in the present study, no clinical or sociodemographic variable has impacted significantly on restorations survival. It was expected, however, that sociodemographic factors such as low maternal education level and income, as well as, the clinical variables, active caries lesion, and the presence of antagonist tooth could be associated with restoration failure. There is no evidence in the literature that adhesive restoration survival rates can be influenced by selective removal of carious dentin[21]; the teeth from both experimental groups were subjected to selective removal of carious dentin, nevertheless, endodontic failures occurred only in the instrumented enamel group. Moreover, a decrease in the annual failure rates was observed in a previous systematic review when restorations were placed using a rubber dam[19]. This factor was not considered in the regression analysis as all restorations were performed with a rubber dam.

Regarding the restorative materials, all restorations were performed using a universal adhesive in the etch-and-rinse approach. Currently, it seems to be a consensus that bonding to the enamel of permanent teeth requires prior phosphoric-acid etching[22]. For primary teeth, it is valid for conventional adhesives[23], but not for universal systems[24,25]. Although these findings refer to bonding to sound enamel, one might expect the same to be true for demineralized enamel[26] ; thus, justifying the use of phosphoric-acid etching in the present study, even in presumably demineralized enamel. It is unlikely, however, that the restoration failures might be associated with the adhesive system, or even the composite resin, as the same restorative materials were used in both experimental groups.

The evaluation of restorations was conducted using the FDI criteria as in previous studies in primary teeth[21,24]. Besides being more sensitive than the USPHS criteria[27], FDI criteria allows to classify a failed restoration as repairable (score 4)[28], and, therefore the data was analyzed as success (including as failure all restorations classified as scores 4 and 5) and survival (only restorations identified as score 5 were considered as failure)[29] . The value of this analysis is based on the fact that the restoration repair increases the restoration longevity, preserves the dental structure, and reduces the treatment costs[29] . Besides, repair seems to be more patient-friendly, as it is easier and faster than restoration replacement[30].

The limitations of this study are related to the controlled settings, as a single trained operator performing all restorations, inherent to randomized clinical trials. Besides that, the two-year follow-up should be considered a short clinical time, mainly compared to the follow-up time of restorations in permanent teeth. Even so, this study provides useful data for helping clinicians in a daily practice routine. Sociodemographic variables were almost homogenous, as all participants were selected among the patients enrolled in a university-based clinic, also representing a study limitation. Further studies considering a low caries-risk population and clinical dentists are suggested to confirm the results of this study. Even though; the results of

this study showed a low survival rate for composite restorations placed in cavities with instrumented enamel.

CONCLUSION

Based on the results of this randomized double-blind controlled clinical trial, it can be concluded that enamel instrumentation negatively impacts the survival of composite restorations in primary teeth.

Why this paper is important to paediatric dentists

The use of diamond burs to access carious lesions can jeopardize the survival of composite restorations in primary teeth.

When the enamel will be instrumented before restoration, the clinical follow-up must be more rigorous.

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Figure legend

Figure 1. Flow chart of the study design.

Figure 1. Flow chart of the study design.

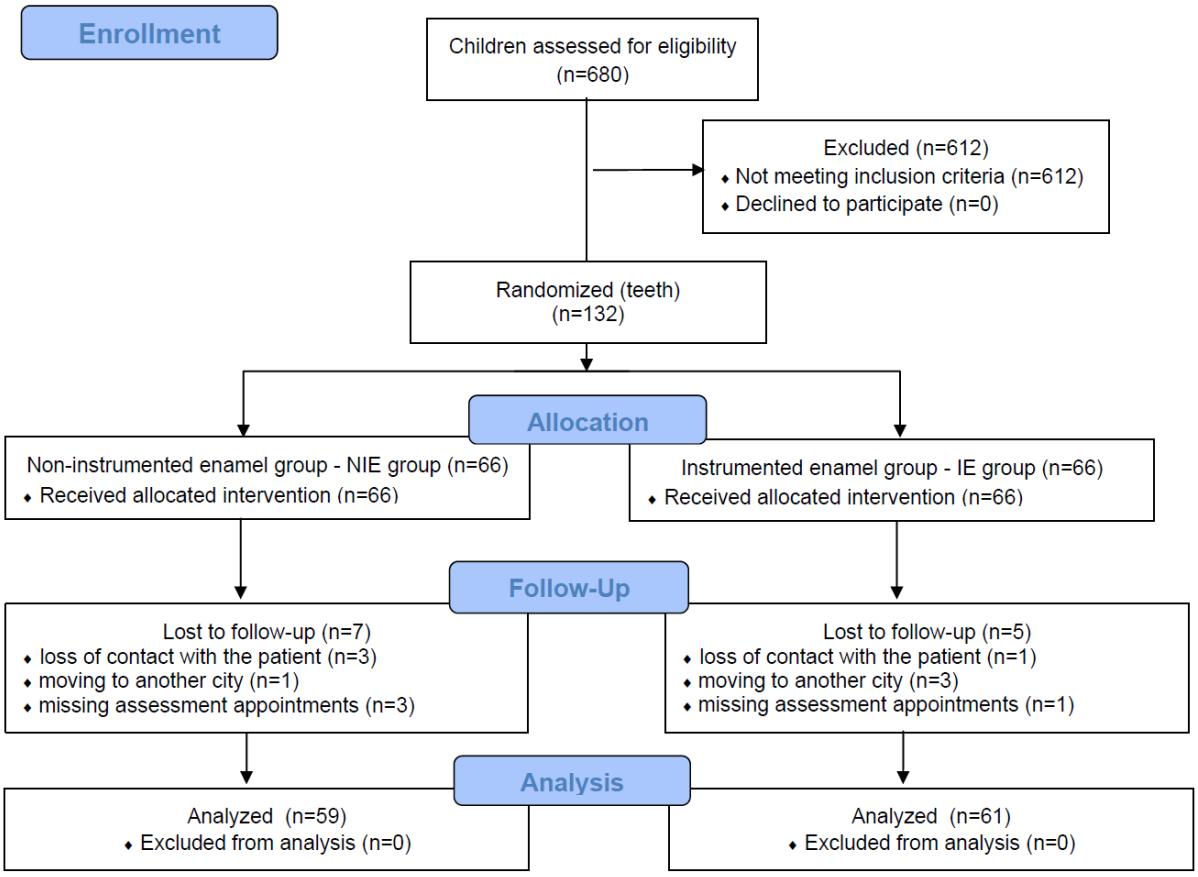

Table 1. Initial sample characteristics.

	NIE group (%)	IE group (%)
Gender		
Male	28 (23.33)	34 (28.33)
Female	31 (25.83)	27 (22.50)
Age (average)	5.86	6.00
Maternal education level†		
Incomplete primary education	16 (13.33)	12 (10.00)
Primary education	3 (2.50)	7 (5.83)
Lower secondary education	11 (9.17)	12 (10.00)
Upper secondary education	26 (21.67)	26 (21.67)
Incomplete bachelor's or equivalent	1 (0.83)	1 (0.83)
Bachelor's or equivalent	2 (1.67)	3 (2.50)
Family income (R$)‡		
< BRL 1.100.00	17 (14.17)	16 (13.33)
> BRL 1.100.00	42 (35.00)	45 (37.50)
Tooth type		
54	5 (4.17)	4 (3.33)
55	4 (3.33)	11 (9.17)
64	6 (5.00)	4 (3.33)
65	6 (5.00)	6 (5.00)
74	0 (0.00)	7 (5.83)
75	16 (13.33)	9 (7.50)
84	6 (5.00)	5 (4.17)
85	16 (13.33)	15 (12.50)
Lesion activity		
Active	48 (40.00)	50 (41.67)
Inactive	11 (9.17)	11 (9.17)
Presence of antagonist tooth		
Yes	59 (49.17)	59 (49.17)
No	0 (0.00)	2 (1.67)

† According to The International Standard Classification of Education, 2011.
‡ BRL, Brazilian real (BRL 5.46 was equivalent to USD 1.00, approximately, on April 26, 2021).

Table 2. Results for the Cox regression, as Hazard ratios (HR 95% CI) according to sociodemographic and clinical variables.

		HR (95% CI)	P value
Sex			
	Boys	1.00	
	Girls	0.89 (0.40-1.95)	0.77
Maternal education level†			
	Incomplete primary education	1.12 (0.19 - 6.61)	0.53
	Primary education	0.39 (0.03 - 4.96)	0.55
	Lower secondary education	0.33 (0.03 - 3.75)	0.24
	Upper secondary education	1.24 (0.26 - 6.12)	0.86
	Incomplete bachelor's or equivalent	3.26 (0.24 - 44.81)	0.33
	Bachelor's or equivalent	1.00	
Family income ‡			
	< BRL 1.100.00	1.83 (0.42 - 7.91)	0.42
	> BRL 1.100.00	1.00	
Lesion activity			
	Active	0.93 (0.39 - 2.25)	0.88
	Inactive	1.00	
Presence of antagonist tooth			
	Yes	0.61 (0.09 - 4.21)	0.62
	No	1.00	

† According to The International Standard Classification of Education, 2011.
‡ BRL, Brazilian real (BRL 5.46 was equivalent to USD 1.00, approximately, on April 26, 2021).

4 DISCUSSÃO

As resinas compostas têm sido tradicionalmente utilizadas como material restaurador em molares decíduos, principalmente por suas características adesivas, estéticas e seu fácil manuseio (DHAR et al., 2015), porém, ainda apresentando dificuldades relacionadas à contração volumétrica que ocorre durante a polimerização do material, sendo necessário utilizá-las na técnica incremental. As resinas compostas bulk-fill permitem a restauração de toda a cavidade em um único incremento (de aproximadamente 4 mm de espessura) devido à presença de monômeros para aliviar o estresse de contração e fotoiniciadores específicos, permitindo uma penetração mais profunda da luz (VAN ENDE et al., 2017; ILIE; HICKEL, 2011).

A performance clínica das resinas bulk-fill parece ser semelhante às convencionais em restaurações de dentes posteriores, como mostrado por revisões sistemáticas (KRULY et al., 2018; VELOSO et al., 2019). Além disso, as resinas bulk-fill de alta viscosidade requerem um tempo restaurador menor em dentes permanentes posteriores quando comparadas às resinas compostas utilizadas na técnica incremental (BELLINASO; SOARES; ROCHA, 2019). Essa característica é aconselhável no tratamento restaurador em Odontopediatria, visto que, quanto mais rápido o procedimento, melhor a colaboração dos pacientes. Dessa forma, as resinas bulk-fill têm sido amplamente utilizadas nessa especialidade (LARDANI et al., 2022; MASSA et al., 2022; OLEGÁRIO et al., 2022).

Assim, mostrou-se necessário também avaliar o comportamento clínico em dentes decíduos. Na revisão sistemática *Clinical behavior of bulk-fill restorations in primary molars: A systematic review and meta-analysis*, foram avaliados ensaios clínicos a fim de encontrar evidências referentes à longevidade de restaurações com resinas compostas bulk-fill em molares decíduos. Os resultados mostraram que as restaurações com resinas bulk-fill apresentam performance similar quando comparadas a materiais considerados controle, como compômeros, ionômeros de vidro modificados por resina (RMGIC) e resina composta incremental, em molares decíduos aos 12 (AKMAN; TOSUN, 2020; EHLERS et al., 2019; LARDANI et al., 2022; OTER; DENIZ; CEHRELI, 2018), 18 (MASSA et al., 2022) e 24 meses (SARAPULTSEVA; SARAPULTSEV, 2019).

A longevidade das restaurações dentárias também depende de fatores relacionados ao paciente (DEMARCO et al., 2012), pois problemas de gestão do comportamento infantil durante as consultas odontológicas podem afetar a qualidade da restauração. Já a escolha do material depende muito mais de questões pessoais do operador do que do desempenho do material, considerando que não há superioridade entre a longevidade das restaurações em

RMGIC, compômero e resina composta em molares decíduos (ORTIZ-RUIZ et al., 2020; PIRES et al., 2018; SANTOS et al., 2016). Dessa forma, com os resultados desta revisão sistemática, percebemos que as resinas bulk-fill conciliam fatores importantes para o atendimento clínico pediátrico, apresentando longevidade semelhante a outros materiais restauradores diretos e tendo a vantagem da diminuição do tempo clínico.

Para o tratamento restaurador, uma técnica que tem sido amplamente difundida em Odontopediatria é a remoção seletiva de tecido cariado. Nesta técnica, é realizada a remoção total da dentina nas paredes laterais, com brocas de baixa rotação, e remoção parcial na parede pulpar, com colheres de dentina (FRANZON et al., 2015; SANTAMARIA et al., 2015), evitando assim o alto risco de sintomas pulpares pós-operatórios e exposição pulpar, o que levaria a tratamentos mais radicais, como a pulpotomia ou pulpectomia (RICKETTS et al., 2013; SCHWENDICKE et al., 2016).

Durante esse preparo da cavidade e ponderando uma maior longevidade da restauração, é importante considerarmos o fato de existir algum esmalte desmineralizado deixado inadvertidamente, visto que estudos in vitro (ANTONIAZZI et al., 2016; TEDESCO et al., 2014) nos mostram que a resistência de união de sistemas adesivos é inferior em esmalte desmineralizado quando comparado a esmalte hígido. Essa diferença na resistência de união pode ser consequência da menor quantidade de minerais, superfícies mais porosas e aumento dos espaços intercristalinos (SCHMIDLIN et al., 2004), podendo levar a um padrão de condicionamento insatisfatório e menor infiltração de monômeros, o que resultaria em baixa resistência de união.

Dessa forma, o segundo artigo desta tese, intitulado *Enamel instrumentation negatively impacts on the survival of composite restorations after selective removal of carious tissue in primary molars: up to 24-months randomized clinical trial*, avaliou a influência da instrumentação do esmalte cavo-superficial na sobrevida de restaurações de resina composta em molares decíduos submetidos à remoção seletiva de tecido cariado. Foi observado que o sucesso clínico para restaurações do grupo sem instrumentação e com instrumentação do esmalte foi de 93,2% (55/59) e 80,3% (49/61), respectivamente.

Ao contrário dos resultados dos estudos in vitro, uma menor taxa de sobrevivência foi encontrada em restaurações de esmalte previamente instrumentado. A intenção de usar uma broca diamantada em alta rotação foi apenas para remover o esmalte circundante, suficiente para acessar o tecido cariado. Essa mínima instrumentação do esmalte pode ter exposto a camada subsuperficial, menos mineralizada e, portanto, menos favorável à adesão. Embora alguns estudos sugiram chanfrar o esmalte cavo-superficial para expor um substrato mais

favorável (OPDAM et al., 1998), aumentando a área do esmalte (PATANJALI et al., 2019) e reduzindo o manchamento marginal (COELHO-DE-SOUZA et al., 2012), este preparo chanfrado ainda não é um consenso.

Defeitos de margem, como gaps interfaciais, podem estar associados ao desenvolvimento de cárie secundária, permitindo a penetração do biofilme na interface adesiva (SCHWENDICKE et al., 2020). Embora todas as restaurações tenham sido feitas em crianças com alto risco de cárie, lesões de cárie recorrentes foram observadas apenas em restaurações do grupo de esmalte instrumentado. A remoção do esmalte circundante com pontas diamantadas pode ter levado a imperfeições na adaptação marginal, favorecendo a criação de gaps interfaciais, explicando essa ocorrência apenas no grupo de esmalte instrumentado, embora todos os pacientes apresentassem alto risco de cárie.

Portanto, nesta tese, podem ser obtidas algumas considerações importantes a respeito do uso de resinas bulk-fill em molares decíduos. Podemos sugerir que as resinas bulk-fill são um bom material de escolha para restaurações em Odontopediatria pela sua longevidade, porém, necessitando alguns cuidados no preparo da cavidade a ser restaurada, visto que, quando o esmalte circundante for instrumentado, será preciso um acompanhamento clínico mais rigoroso.

5 CONCLUSÃO

Com esta tese, foi possível verificar que restaurações de resinas compostas bulk-fill apresentam longevidade semelhante a outros materiais considerados de controle, sendo adequadas para restaurações em molares decíduos, apresentando como vantagem ter um menor tempo restaurador. Também pode-se sugerir que o uso de pontas diamantadas para acessar lesões de cárie pode comprometer a sobrevivência de restaurações de resina composta em dentes decíduos, sendo assim, o acompanhamento clínico deve ser mais rigoroso quando o esmalte for instrumentado antes da restauração.

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

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Sections

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International Journal of Paediatric Dentistry publishes papers on all aspects of paediatric dentistry including: growth and development, behaviour management, diagnosis, prevention, restorative treatment and issue relating to medically compromised children or those with disabilities. This peer-reviewed journal features scientific articles, reviews, case reports, short communications and abstracts of current paediatric dental research. Analytical studies with a scientific novelty value are preferred to descriptive studies. Case reports illustrating unusual conditions and clinically relevant observations are acceptable but must be of sufficiently high quality to be considered for publication; particularly the illustrative material must be of the highest quality.

3. MANUSCRIPT CATEGORIES AND REQUIREMENTS

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Divided into: Abstract, Introduction, Material and methods, Results, Discussion, Bullet points, Acknowledgements, References, Figure legends, Tables and Figures arranged in this order. 3500 word limit, with an exception of qualitative papers which allow a 5000 word limit.

Abstract should be structured using the following subheadings: Background, Aim, Design, Results and Conclusion and should be less than 200 words.

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Material and methods should be clearly described and provide enough detail so that the observations can be critically evaluated and, if necessary repeated. Use section subheadings in a logical order to title each category or method. Use this order also in the results section. Authors should have considered the ethical aspects of their research and should ensure that the project was approved by an appropriate ethical committee, which should be stated. Type of statistical analysis must be described clearly and carefully.

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.

Discussion section presents the interpretation of the findings. This is the only proper section for subjective comments and reference to previous literature. Avoid repetition of results, do not use subheadings or reference to tables in the results section.

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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We consider publishing systematic reviews if the manuscript has comprehensive and unbiased sampling of literature and covering topics related to Paediatric Dentistry.

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criteria (language, type of studies i.e. randomized controlled trial or other, duration of studies and chosen endpoints, c) evaluation of papers and level of evidence. For examples see:

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.

iv. Short Communications

Brief scientific articles or short case reports may be submitted, which should be no longer than three pages of double-spaced text and include a maximum of three illustrations. They should contain important, new, definitive information of sufficient significance to warrant publication. They should not be divided into different parts and summaries are not required.

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

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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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