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CLEBER PARADZINSKI CAVALHEIRO

O USO DE RESINAS COMPOSTAS FLUIDAS EM CAVIDADES OCLUSO-PROXIMAIS DE DENTES DECÍDUOS E PERMANENTES

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RESUMO

A presente tese de doutorado é composta por três artigos científicos. O primeiro artigo intitulado “Use of flowable resin composite as an intermediate layer in class II restorations: a systematic review and meta-analysis” visou investigar a influência do uso de resinas compostas fluidas como uma camada intermediária em cavidades ocluso-proximais de dentes permanentes em comparação com restaurações de resina composta sem uma camada intermediária, considerando desfechos laboratoriais e clínicos. Uma ampla pesquisa bibliográfica foi realizada nas bases de dados PubMed/MEDLINE, EMBASE, Scopus, LILACS, Web of Science e na plataforma de registros de ensaios clínicos Clinical Trials, a fim de identificar os estudos relacionados com a questão de pesquisa. Dois pesquisadores avaliaram independentemente os artigos selecionados de acordo com os critérios de elegibilidade, realizaram a extração dos dados, avaliaram o risco de viés e a qualidade da evidência dos artigos incluídos na revisão sistemática. Meta-análises usando efeitos fixos foram realizadas no software Review Manager versão 5.3 (Nordic Cochrane Center, Cochrane Collaboration) e as médias, desvios-padrão, riscos relativos (RRs) e os intervalos de confiança de 95% (ICs) foram calculados. De 1.707 estudos potencialmente elegíveis, 140 estudos laboratoriais e 14 estudos clínicos foram selecionados para análise completa do texto e 11 foram incluídos na revisão sistemática, sendo 7 estudos laboratoriais e 4 estudos clínicos. Não houve diferença estatística significativa entre as técnicas restauradoras considerando os desfechos de resistência de união, resistência à fratura e falha clínica. A heterogeneidade foi nula, o risco de viés foi classificado como médio para estudos laboratoriais e incerto para maioria dos estudos clínicos. A qualidade da evidência dos estudos clínicos foi baixa. O segundo artigo intitulado “Is use of flowable resin composite an option for occluso-proximal restorations in primary teeth? A fracture strength analysis” investigou a influência do uso de resinas compostas fluidas em diferentes espessuras de incremento na resistência à fratura de restaurações ocluso-proximais em dentes decíduos. Duas cavidades ocluso-proximais padronizadas foram preparadas nas superfícies mesial e distal de 50 molares decíduos hígidos. Após a aplicação de sistema adesivo universal (Scotchbond Universal; 3M Oral Care) no modo autocondicionante, os dentes foram divididos aleatoriamente em cinco grupos (n=10): 2 mm Filtek Bulk Fill Flowable (3M Oral Care) + Z350 XT (3M Oral Care); 4 mm Filtek Bulk Fill Flowable (3M Oral Care); 2 mm Z350 XT Flow (3M Oral Care) + Z350 XT (3M Oral Care); 4 mm Z350 XT Flow (3M Oral Care) e Z350 XT (3M Oral Care). Todos os dentes restaurados foram submetidos a desafio cariogênico por ciclagem de pH durante 14 dias e depois submetidos ao teste de resistência à fratura. Os dados obtidos foram submetidos à Análise de Variância de um fator e teste Tukey ($\alpha = 0,05$). O padrão de falha foi categorizado como reparável ou irreparável/necessidade de substituição com base nos critérios da Federação Dentária Internacional (FDI). Não houve diferença estatisticamente significatnte na resistência à fratura ($p=0,48$). Uma distribuição semelhante de falhas reparáveis (35-40%) e irreparáveis (60-65%) foi observada entre os grupos. O terceiro artigo intitulado “Fracture strength and cost of different dental manufacturers of flowable bulk-fill resin composites for occluso-proximal restorations in primary teeth” investigou a resistência à fratura de restaurações ocluso-proximais em dentes decíduos

utilizando três diferentes fabricantes de resinas compostas fluidas *bulk-fill* (como camada intermediária ou como único material restaurador) em comparação com resinas compostas convencionais (técnica incremental) e o custo de execução das restaurações. Duas cavidades ocluso-proximais padronizadas foram preparadas nas superfícies mesial e distal de 90 molares decíduos hígidos. Após a aplicação de sistema adesivo universal (Scotchbond Universal; 3M Oral Care) no modo autocondicionante, os dentes foram divididos aleatoriamente em nove grupos (n=10) de acordo com o fabricante (3M Oral Care, Shofu Inc. e FGM) e o número de incrementos de resina composta fluida *bulk-fill* (2 mm – camada intermediária ou 4 mm – único material restaurador) e controle – resina composta convencional (técnica incremental). Todos os dentes restaurados foram submetidos a desafio cariogênico por ciclagem de pH durante 14 dias e depois submetidos ao teste de resistência à fratura. Os dados obtidos foram submetidos à Análise de Variância de um fator e teste Tukey (α = 0,05). O custo foi analisado descritivamente. Não foi encontrada diferença na resistência à fratura entre os grupos (p=1,00). O custo de cada restauração ocluso-proximal variou de 0,99 a 3,94 (US$). O uso de resina composta fluida *bulk-fill* como único material restaurador (4 mm) resultou em menor custo para 3M Oral Care e Shofu Inc. e maior custo para FGM. O uso de resinas compostas fluidas como único material restaurador não compromete a resistência à fratura de restaurações ocluso-proximais em dentes decíduos e reduz o custo, dependendo do fabricante.

Palavras-chave: Dente Decíduo; Restauração Dentária Permanente; Revisão Sistemática; Resinas Compostas.

ABSTRACT

The present doctoral thesis is composed by three scientific articles. The first one article entitled “Use of flowable resin composite as an intermediate layer in class II restorations: a systematic review and meta-analysis” aimed to investigate the influence of the use of flowable resin composites as an intermediate layer in occluso-proximal cavities of permanent teeth compared to composite resin restorations without an intermediate layer, considering laboratory and clinical outcomes. A comprehensive literature search was undertaken in MEDLINE via PubMed, Scopus, LILACS, Embase, Web of Science electronic databases, and the clinicaltrials.gov website in order to identify studies related to the research question. Two authors independently selected the studies according to the eligibility criteria, extracted the data, assessed the risk of bias and the quality of the evidence. Meta-analyses using fixed effects were performed in Review Manager software version 5.3 (Nordic Cochrane Center, Cochrane Collaboration) and means, standard deviations, relative risks (RRs) and 95% confidence intervals (CIs) were calculated. From 1,707 potentially eligible studies, 140 *in vitro* studies and 14 clinical studies were selected for full-text analysis, and 11 were included in the systematic review, being 7 in vitro and 4 clinical studies. There was no statistically significant difference between the restorative techniques considering bond strength, fracture strength and clinical failure outcomes. The heterogeneity found was null. The risk of bias was classified as medium for *in vitro* studies and unclear in most clinical studies. The quality of the evidence of the clinical studies was low. The second article entitled “Is use of flowable resin composite an option for occluso-proximal restorations in primary teeth? A fracture strength analysis” investigated the influence of the use of flowable resin composites in different increment thicknesses on the fracture strength of occluso-proximal restorations in primary teeth. Two standardized occluso-proximal cavities were prepared on mesial and distal surfaces of 50 sound primary molars. After application of a universal adhesive system (Scotchbond Universal; 3M Oral Care) in self-ecth mode, the teeth were randomly assigned into five groups (n=10): 2 mm Filtek Bulk Fill Flowable (3M Oral Care) + Z350 XT (3M Oral Care); 4 mm Filtek Bulk Fill Flowable (3M Oral Care); 2 mm Z350 XT Flow (3M Oral Care) + Z350 XT (3M Oral Care); 4mm Z350 XT Flow (3M Oral Care), and Z350 XT (3M Oral Care). All restored teeth were subjected to cariogenic challenge by pH cycling for 14 days and then submitted to fracture strength test. Fracture strength means were submitted to one-way Analysis of Variance and Tukey’s tests ($\alpha = 0,05$). The failure pattern of each specimen was categorized as reparable or irreparable/need for replacement based on the World Dental Federation (FDI) criteria. There was no difference on fracture strength ($p=0.48$). A similar distribution of reparable (35-40%) and irreparable (60-65%) failures was observed among groups. The third article entitled “Fracture strength and cost of different dental manufacturers of flowable bulk-fill resin composites for occluso-proximal restorations in primary teeth” investigated the fracture strength of occluso-proximal restorations in primary teeth using different dental manufacturers of bulk-fill flowable resin composites (as an intermediate layer or entire cavity) in comparison with conventional resin composite (incremental

technique) and the cost to perform the restorations. Two standardized occluso-proximal cavities were prepared on mesial and distal surfaces of 90 sound primary molars. After application of a universal adhesive system (Scotchbond Universal; 3M Oral Care) in self-ecth mode, the teeth were randomly assigned into nine groups (n=10) according to dental manufacturers (3M Oral Care, Shofu Inc. and FGM) and number of increments of flowable bulk-fill resin composite (2 mm -intermediate layer or 4 mm - entire cavity) and control – conventional resin composite (incremental technique). All restored teeth were subjected to cariogenic challenge by pH cycling for 14 days and then submitted to fracture strength test. Fracture strength means were submitted to one-way Analysis of Variance and Tukey's tests (α = 0,05). The cost was analyzed descriptively. No difference in fracture strength was found among groups (p=1.00). The cost for each occluso-proximal restoration ranged from 0.99 to 3.94 (USD). The use of flowable bulk-fill resin composite entire cavity (4 mm) resulted in the shorter cost for 3M Oral Care and Shofu Inc. and higher cost for FGM. The use of flowable resin composites entire cavity does not jeopardize the fracture strength of occluso-proximal restorations in primary teeth, and reduces the cost, depending of the dental manufacturers.

Keywords: Tooth, Deciduous; Dental Restoration, Permanent; Systematic Review; Composite Resins.

SUMÁRIO

1 INTRODUÇÃO

Lesões de cárie não tratadas ainda representam uma condição prevalente, afetando mais de um terço da população mundial ao considerar as dentições decídua e permanente (WORLD HEALTH ORGANIZATION, 2022). Essas lesões, quando permanecem sem tratamento, podem resultar em dor e na possibilidade de perda do elemento dentário, impactando na qualidade de vida e comprometendo horas em ambiente escolar ou de trabalho e atividades de lazer (CORRÊA-FARIA *et al.*, 2018; GIFT; REISINE; LARACH, 1992). O tratamento restaurador de dentes acometidos por lesões de cárie ainda é um dos principais procedimentos realizados na prática clínica odontológica.

As superfícies proximais e/ou ocluso-proximais são comumente afetadas pela doença cárie em ambas as dentições (DEMARCO *et al.*, 2012; MENDES *et al.*, 2012). Por não se configurarem como superfícies livres e por possuírem difícil acesso a higienização, não estando expostas às ações mastigatórias, as superfícies proximais são mais suscetíveis ao acúmulo de biofilme e, consequentemente, à desmineralização.

A realização de restaurações em superfícies ocluso-proximais representa um grande desafio clínico, especialmente considerando dentes decíduos. As áreas de contato entre os molares decíduos são mais amplas e elípticas que a dos molares permanentes, e situam-se mais próximas ao terço cervical, proporcionado uma maior dificuldade de adaptação cervical do material restaurador (PATEL *et al.*, 2019).

Restaurações diretas de resina composta são populares na prática odontológica entre dentistas e pacientes para restaurar cavidades ocluso-proximais de dentes permanentes (DEMARCO *et al.*, 2023). Em dentes decíduos, o uso de resina composta para restaurar lesões ocluso-proximais tem sido fortemente recomendado (AMERICAN ACADEMY OF PEDIATRIC DENTISTRY, 2022). Resinas compostas proporcionam a realização de preparos cavitários conservadores, de acordo com os princípios da filosofia de mínima intervenção e oferecem estética, resistência e longevidade (CHISINI *et al.*, 2018; DEMARCO *et al.*, 2023).

Entretanto, a técnica restauradora com resina composta convencional pode ser um obstáculo no tratamento de lesões ocluso-proximais. A necessidade de um rigoroso controle da umidade, o correto condicionamento do substrato e múltiplas

etapas, torna a técnica sensível. Além disso, um maior número de superfícies envolvidas no preparo da cavidade está associado a um maior fator de contração de polimerização (FEILZER; DE GEE; DAVIDSON, 1987). Embora a técnica incremental tenha como objetivo minimizar o fator-C, a contração dos incrementos provocada pela polimerização ainda pode comprometer as margens da restauração (SHAHIDI; KREJCI; DIETSCHI, 2017) e facilitar a presença de espaços vazios (DÍAZ *et al.*, 2020), que resultam em falhas restauradoras e aumentam o risco de desenvolvimento de lesões de cárie ao redor das restaurações, quando o controle do biofilme não é possível.

A taxa de falha anual de restaurações ocluso-proximais de resina composta em dentes permanentes varia entre 1,1 e 5,5% (DEMARCO *et al.*, 2023), enquanto em dentes decíduos varia entre 5 e 22,5% (CHISINI *et al.*, 2018). A maioria dos defeitos relacionados à necessidade de reintervenção são lesões de cárie e fraturas, muitas vezes localizados nas margens das restaurações (CHISINI *et al.*, 2018; DEMARCO *et al.*, 2023).

Uma alternativa às resinas compostas convencionais (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 (FRONZA *et al.*, 2015) e, dessa forma, possibilitam realizar restaurações em incrementos únicos de até 4-5 milímetros de espessura, simplificando a técnica restauradora. Tem sido evidenciado que resinas *bulk-fill* condensáveis (*full-body*) apresentam um desempenho clínico semelhante às resinas convencionais utilizadas através da técnica incremental em cavidades ocluso-proximais de dentes permanentes (VELOSO *et al.*, 2019).

Em dentes decíduos, um recente estudo clínico (GINDRI *et al.*, 2022) demostrou que restaurações ocluso-proximais realizadas com resina composta *bulk-fill* condensável apresentam comportamento clínico semelhante ao das resinas convencionais. Além disso, seu uso reduz o tempo clínico em aproximadamente 30%. Todavia, independente da resina composta utilizada, um número significativo de restaurações falharam devido à problemas na adaptação marginal (GINDRI *et al.*, 2022).

Alguns fabricantes têm indicado o uso de resinas compostas fluidas em associação com a técnica incremental, utilizando as resinas compostas fluidas como

primeiro incremento. Resinas compostas fluidas apresentam composições variáveis e, em geral, possuem uma quantidade menor de carga, menor viscosidade, maior elasticidade e, consequentemente, maior fluidez (ATTAR; TAM; MCCOMB, 2003; BAYNE *et al.*, 1998; MURCHISON; CHARLTON; MOORE, 1999). Tais resinas podem se apresentar na forma convencional, permitindo a inserção de incrementos de até 2 milímetros, e na forma *bulk-fill*, em que são possíveis incrementos de até 4 milímetros. Como vantagem, a fluidez das resinas apresentaria melhor capacidade de adaptação ao preparo cavitário, especialmente na parede cervical, podendo reduzir o estresse gerado pela contração de polimerização e também o tempo do procedimento devido a facilidade de inserção (BAROUDI; RODRIGUES, 2015; KWON; KIM; PARK, 2010; PITCHIKA *et al.*, 2016).

Um estudo laboratorial avaliou a utilização de um incremento de 4 milímetros de uma resina composta fluida *bulk-fill* como camada intermediária em restaurações ocluso-proximais de pré-molares hígidos extraídos através dos testes de microtração e resistência à fratura. Em ambas análises não houve diferença na comparação com restaurações realizadas com apenas resina composta convencional (técnica incremental) (DE ASSIS *et al.*, 2016). Taxas de sobrevida semelhantes entre a utilização de uma camada intermediária de 1 a 1,5 milímetros de resina composta fluida e restaurações realizadas somente com resina composta convencional de cavidades ocluso-proximais em dentes posteriores permanentes também foram encontradas após 7 anos de acompanhamento clínico considerando parâmetros estéticos, biológicos e funcionais (VAN DIJKEN; PALLESEN, 2011). Sendo assim, a utilização de resinas compostas fluidas poderia ser uma alternativa para simplificar o procedimento, podendo minimizar o número de passos, uma vez que estes materiais possuem uma ponteira aplicadora, facilitando sua inserção na cavidade, especialmente na parede cervical, sem a necessidade de uma espátula.

Usualmente, as resinas compostas fluidas requerem uma camada final de cobertura com resina composta convencional devido à baixa resistência ao desgaste, principalmente em superfícies de estresse oclusal. No entanto, considerando que dentes decíduos recebem menor carga oclusal e ciclo biológico mais curto, bons resultados clínicos têm sido observados para a realização de restaurações ocluso-proximais em dentes decíduos usando apenas resina composta fluida, através da inserção de incrementos de até 2 milímetros. Não houve diferença

significativa na durabilidade clínica após 2 anos de restaurações para resina composta fluida e restaurações de cimento de ionômero de vidro modificado por resina (ANDERSSON-WENCKERT; SUNNEGÅRDH-GRÖNBERG, 2006). Recentemente, o uso apenas de resina composta fluida *bulk-fill*, em incremento único de 4 milímetros, apresentou desempenho clínico semelhante ao de restaurações em compômero em cavidades ocluso-proximais de molares decíduos após 1 ano de acompanhamento (EHLERS *et al.*, 2019).

Nesse sentido, o uso de resinas compostas fluidas em dentes permanentes (como camada intermediária) e decíduos (como camada intermediária ou como único material restaurador) poderiam ser opções restauradoras para cavidades ocluso-proximais. Todavia, há a necessidade da compilação dos dados disponíveis na literatura para dentes permanentes acerca desta abordagem restauradora. Além disso, nenhum estudo laboratorial investigou o uso de resinas fluidas em cavidades ocluso-proximais de dentes decíduos considerando o desfecho de resistência à fratura em comparação com restaurações com resina composta convencional (técnica incremental).

Diante do exposto, no presente trabalho serão apresentados os artigos oriundos de três investigações científicas. O primeiro, intitulado “Use of flowable resin composite as an intermediate layer in class II restorations: a systematic review and meta-analysis” avaliou sistematicamente a literatura científica para investigar o uso de resinas compostas fluidas em cavidades ocluso-proximais de dentes permanentes considerando desfechos laboratoriais (resistência de união e resistência à fratura) e clínico (falha restauradora). O segundo, intitulado “Is use of flowable resin composite an option for occluso-proximal restorations in primary teeth? A fracture strength analysis” comparou a resistência à fratura de diferentes espessuras de resina composta fluida (utilização como camada intermediária e como único material restaurador) em cavidades ocluso-proximais de dentes decíduos. O terceiro, intitulado “Fracture strength and cost of different dental manufacturers of flowable bulk-fill resin composites for occluso-proximal restorations in primary teeth” comparou a resistência à fratura de resinas compostas fluidas *bulk-fill* de três diferentes fabricantes em cavidades ocluso-proximais de dentes decíduos, descrevendo o custo dos materiais testados.

2 ARTIGO 1 – Use of flowable resin composite as an intermediate layer in class II restorations: a systematic review and meta-analysis.

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Use of flowable resin composite as an intermediate layer in Class II restorations: A systematic review and meta-analysis

Cleber Paradzinski Cavalheiro[1] ORCID:0000-0001-9402-1811

Helena Scherer[2] ORCID:0000-0002-9074-338X

José Carlos Pettorossi Imparato[3] ORCID:0000-0002-1990-2851

Fabrício Mezzomo Collares[4] ORCID:0000-0002-1382-0150

Tathiane Larissa Lenzi[1] ORCID: 0000-0003-3568-5217

[1]School of Dentistry, Post-Graduate Program in Pediatric Dentistry, Federal University of Rio Grande do Sul, Rua Ramiro Barcelos, 2492, 90035-003, Porto Alegre, Rio Grande do Sul, Brazil.

[2]School of Dentistry, Federal University of Rio Grande do Sul, Rua Ramiro Barcelos, 2492, 90035-003, Porto Alegre, Rio Grande do Sul, Brazil.

[3]School of Dentistry, Department of Orthodontics and Pediatric Dentistry, University of Sao Paulo, Avenida Prof. Lineu Prestes, 2227, São Paulo, São Paulo, Brazil.

[4]School of Dentistry, Department of Materials Laboratory, Federal University of Rio Grande do Sul, Rua Ramiro Barcelos, 2492, 90035-003, Porto Alegre, Rio Grande do Sul, Brazil.

✉**Corresponding Author**

Tathiane Larissa Lenzi

E-mail: tathiane.lenzi@ufrgs.br

Telephone/Fax: +55 51 3308 5027

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Authors' contributions

Conceptualization/Idea: Cleber Paradzinski Cavalheiro and Tathiane Larissa Lenzi; **Investigation:** Cleber Paradzinski Cavalheiro, Helena Scherer, José Carlos Pettorossi Imparato and Tathiane Larissa Lenzi; **Methodology/ Literature Search:** Cleber Paradzinski Cavalheiro, José Carlos Pettorossi Imparato and Tathiane Larissa Lenzi; **Formal analysis/ Data Analysis:** Cleber Paradzinski Cavalheiro, José Carlos Pettorossi Imparato and Tathiane Larissa Lenzi; **Roles/Writing - original draft:** Cleber Paradzinski Cavalheiro; **Writing - review & editing:** Helena Scherer, José Carlos Pettorossi Imparato, Fabrício Mezzomo Collares and Tathiane Larissa Lenzi

Abstract

Objective: To investigate the influence of an intermediate layer of a flowable resin composite in class II resin composite restorations. **Materials and Methods:** The authors searched MEDLINE via PubMed, Scopus, LILACS, Embase, Web of Science electronic databases, and the clinicaltrials.gov website to identify laboratory and clinical studies that evaluated class II cavities with resin composite restorations with or without an intermediate layer of flowable resin composite. Two authors independently selected the studies, extracted the data, assessed the risk of bias and the quality of the evidence. Meta-analyses were performed using RevMan5.3 with fixed effects model comparing bond strength (Mpa), fracture strength (Newton), and clinical (number of failures) outcomes between restorative techniques (with or without flowable resin composite as an intermediate layer). **Results:** From 1,707 potentially eligible studies, 140 in vitro studies and 14 clinical studies were selected for full-text analysis, and 11 were included in the systematic review, being 7 in vitro and 4 clinical studies. There was no statistically significant difference between the restorative techniques considering the outcomes evaluated. The heterogeneity found was null. The risk of bias was classified as medium for in vitro studies and unclear in most clinical studies. The quality of the evidence of the clinical studies was low. **Conclusion:** The use of flowable resin composite as an intermediate layer does not improve the effectiveness of the Class II restorations based on laboratory and clinical outcomes. **Clinical Relevance:** Flowable resin composite as an intermediate layer may be used for Class II restorations; however, this technique does not improve the effectiveness of the Class II restorations.

Keywords: Direct restoration, Resin composite, Dental restoration, Class II restoration, Flowable resin composite, Systematic review

Introduction

Direct resin composite restorations are popular in dental practice among dentists and patients for restoring posterior teeth. The main reasons for failure in posterior teeth are recurrent caries and fracture. [1] Overall, class II cavities appear to be more common than other configurations, and patients who receive restorations with a larger number of surfaces experience a significantly higher risk of failure. [2] It has been shown that cavity features such as the number of restored walls, and resin composite volume may dictate the service time of the restorative approach. [1]

Although there is no consensus regarding the best restorative technique in adhesive dentistry, polymerization of a resin composite can be a challenge due to shrinkage stress, [3] resulting in gaps in the bonded interface. The presence of voids [4] and marginal deterioration [5] are among the problems reported. In this view, cavities with a larger number of surfaces involved in the restoration can be an even more significant challenge. They are associated with a high C-factor [6], lower bond strength, and higher shrinkage stress. [7]

In this sense, some manufacturers have indicated the use of an intermediate layer of flowable resin composite placed in the cervical part of the proximal box of Class II resin composites. This material presents higher flow, low-viscosity, greater elasticity, and less filler loading in their formulation, [8–10] besides provide easier insertion into cavity and better marginal adaptation. The use of an intermediate layer of flowable resin composite would be an option to reduce the total stiffness, making the restoration able to compensate for the shrinkage stress. [11]

On the one hand, it has been shown that the use of flowable resin composite as an intermediate layer may reduce marginal defects; [12] on the other hand, this technique seems not to reduce polymerization shrinkage stress by cuspal deflection

analysis. [13] Despite the widespread use in the general practice of this technique of placing flowable resin composite as an intermediate layer in Class II cavities, a systematic quantitative evaluation of the available scientific evidence has never been undertaken to the best of our knowledge. Therefore, we systematized data from laboratory studies and clinical trials that investigated the use of flowable resin composite as an intermediate layer for restoring Class II cavities.

Materials and methods

This systematic review was conducted according to the Cochrane Handbook, [14] reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement, [15] and we focused on making a strict process that evaluates the available studies and meta-analyzing only similar design studies.

The following research question was formulated to address the literature and outline the search strategy: Does the use of flowable resin composite (conventional or bulk-fill) as an intermediate layer in Class II cavities improve laboratory and clinical outcomes in comparison with resin composite restorations without this layer? The population/problem, intervention, comparison, and outcome of the study were established according to the PICO question. In this respect, the population consisted of patients or extracted human teeth with direct resin composite Class II (MO, OD or MOD) restorations in permanent teeth. The intervention was the use of flowable resin composite (conventional or bulk-fill) as an intermediate layer in Class II cavities, and a comparison was the use of resin composite without an intermediate layer. The outcomes evaluated were bond strength or fracture strength for laboratory studies and restoration failure for clinical studies.

Search strategy

A comprehensive literature search was performed using the MEDLINE via PubMed, Scopus, LILACS, Embase, and Web of Science databases to identify studies related to the research question and published up to September 2020. The search was conducted with no publication year or language limits. The following search steps were performed: computer search of databases, review of reference lists of all included studies, and contact with authors. For the subject search, we used a combination of controlled vocabulary and text words based on the search strategy for the MEDLINE via PubMed database:

((((((((((occlu* proximal) OR class II cavities) OR class II) OR approximal lesion) OR proximal lesion*) AND composite resins[MeSH Terms]) OR composite resin*) OR resin* composite) OR conventional composite resin*)) AND ((((((((((occlu* proximal) OR class II cavitie*) OR class II) OR approximal lesion) OR proximal lesion*) AND flowable hybrid composite[MeSH Terms]) OR flowable hybrid composite) OR flowable composite) OR flow line) OR flowable resin*)

A sensitive search strategy was adapted for the Scopus, LILACS, Embase, and Web of Science databases. To reduce the publication bias, the ClinicalTrials.gov website was checked for unpublished documents. The results of searches of various databases were cross-checked to locate and eliminate duplicates.

Eligibility criteria

Firstly, titles and abstracts were reviewed independently by two authors (C.P.C. and T.L.L.) and selected for further review if they met the inclusion criteria: *in vitro* or clinical studies that investigated the use of an intermediate layer of a flowable resin composite in Class II (MO, OD or MOD) restorations performed in permanent teeth. The calculation of inter-examiner agreement (Kappa = 1.00) indicated

excellent agreement. Full-text versions of articles selected in the previous step were retrieved and reviewed independently by two authors (C.P.C. and T.L.L.) considering the exclusion criteria:

For *in vitro* studies: (1) did not evaluate methacrylate-based resin composite restorations, (2) did not present a control group (without an intermediate layer of flowable resin composite), (3) did not use the same adhesive system protocol in both groups, (4) did not use same resin composite in both groups, (5) sample containing teeth that received endodontic treatment prior to the restorative treatment, (6) did not specify the amount of flowable resin composite used, and (7) did not consider bond strength or fracture strength as outcomes.

For clinical studies: (1) did not evaluate methacrylate-based resin composite restorations, (2) did not present a control group (without intermediate layer of flowable resin composite), (3) did not use the same adhesive system protocol in both groups, (4) did not use the same resin composite in both groups, (5) sample containing teeth that received endodontic treatment prior to the restorative treatment, (6) follow-up lower than six months, (7) dropout rate ≥ 30%, (8) absence of similar follow-up for patients in both groups evaluated in the same way, and (9) did not evaluate restoration failure as outcome.

Disagreements were firstly resolved by discussion between the reviewers (C.P.C. and T.L.L.). If discrepancies remained, a third author (J.C.P.I.) was consulted.

Data extraction

Two authors (C.P.C. and T.L.L.) collected the data using a standardized sheet in Microsoft Office Excel 2013 (Microsoft Corporation, Redmond, WA, USA). For

each paper, the following data were systematically extracted: publication details (authors, year, country, and design study), methodology (sample size, commercial brands and manufacturers of the restorative materials, localization of the cavity margins, amount of flowable resin composite used, number of operators and evaluators, and only for *in vitro* studies - cavity dimensions and thermocycling cycles), and outcomes information (means and standard deviations for *in vitro* studies and follow-up, dropout, restorative failures and clinical criteria for evaluating restorations for clinical studies).

Form to avoid overlapping data, when there were multiple reports of the same study (i.e., reports with different follow-ups), only the longest follow-up study was considered.

Assessment of risk of bias and quality of evidence

The reviewers (C.P.C. and T.L.L.) also independently assessed the risk of bias of *in vitro* studies based on and adapted from previous systematic reviews [16, 17] and the risk of bias of clinical studies using the Cochrane tool [14]. The following criteria were considered:

for *in vitro* studies: the same type of teeth, randomization of the teeth for experimental groups, sample size calculation, teeth free of caries, standardization of the size of the cavities, materials used according to manufacturers' instructions, restorations performed by a single operator, and blinding of the operator machine. If the authors reported the parameter, the study had a Y (yes) on that specific parameter; if it was not possible to find the information, the paper received an N (no). Articles that reported 1 to 3 items were classified as high risk of bias, 4 to 6 as medium risk, and 7 or 8 as low risk.

for clinical studies: selection bias (sequence generation, allocation concealment), performance and detection bias (blinding of participants, operators, outcome assessment), attrition bias (incomplete outcome data), and reporting bias (selective outcome reporting). Studies were evaluated by means of rating each domain as having low, high, or unclear (either lack of information or uncertainty over the potential for bias) risk of bias.

For the final classification of risk of bias, the reviewers resolved disagreements via consensus.

The quality of evidence of the clinical studies for the outcome effect estimate was assessed according to the guidelines of the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) [18].

Data analyses

Conventional meta-analyses were performed using fixed effects models in the Review Manager Software version 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark), considering a p-value ≤ 0.05 as statistically significant (Z-test). Pooled mean differences between Class II resin composite restorations with or without an intermediate layer of flowable resin composite were calculated for *in vitro* studies considering bond strength and fracture strength, relative risk (RRs), and 95% confidence intervals (CIs) for clinical studies. Analyses were performed according to the thickness of flowable resin composite (until 2 mm or higher than 2 mm), considering fracture strength as outcome. Statistical heterogeneity among studies was assessed via the Cochrane Q test and inconsistency (I^2).

Only one study [19] compared the microtensile bond strength of both restorative techniques, considering an increment of flowable resin composite until 2

mm. The others [20–22] used more than 2 mm. Thus, this study did not include in the meta-analysis, and only a descriptive analysis was performed.

Results

Study selection

The search strategy identified 1,707 potentially relevant studies, excluding 253 duplicates. After the screening of titles and abstracts, 154 studies were assessed for more detailed information. Of these, 133 laboratory and 10 clinical studies were excluded after a review of the full-text articles. Finally, 7 *in vitro* and 4 clinical studies met the eligibility criteria and were included in the systematic review. Figure 1 presents a flowchart of the study selection process and the reasons for exclusions.

Characteristics of the included studies

For *in vitro* studies

Table 1 shows descriptive extracted data from the included studies in the systematic review. All studies were published in English between 2005 and 2019 and conducted in Brazil [19–22] and Turkey. [23–25] Four studies [19–22] considered bond strength as outcome. Of these, three studies [20–22] used more than 2mm of flowable resin composite as an intermediate layer, and all performed microtensile bond strength (μTBS) test. Four studies [20, 23–25] considered fracture strength as outcome, but only one [24] conducted thermocycling cycles before the fracture resistance test.

For clinical studies

Table 2 shows descriptive extracted data from the included studies in the systematic review. All studies were published in English between 2003 and 2017.

One study [26] was performed in Germany, and three studies [27–29] were performed in Sweden. All had a parallel design and included molars and premolars. One [26] reported using a rubber dam in part of the sample. Two studies [26, 27] used a cavity liner for pulp protection in deep cavities. Only one [29] used a bulk flowable resin composite as an intermediate layer.

Assessment of risk of bias and quality of evidence

For *in vitro* studies

From 7 included studies, all were considered as having a medium risk of bias (Table 3). The items that most frequently received "no" were sample calculation and blinding of the testing machine operator. All studies included the same type of teeth, teeth free of caries, standardized the size of the cavities, and applied the materials according to manufacturers' instructions.

For clinical studies

The final assessment of the risk of bias in the included studies is summarized in Table 4. The risk of bias was unclear in most studies (46.4% of all items across studies). No study described the method used to generate the randomization sequence, leading to an unclear risk of bias. Moreover, three studies [26–28] had high risk of bias regarding the allocation concealment. Only one study [29] reported blinding of the participants, and three studies reported blinding of the examiner, being classified as low risk of bias. A low quality of evidence was judged according to the GRADE (Table 5).

Meta-analyses

Meta-analysis with 3 data sets [20–22] was performed considering bond strength as outcome. There was no statistically significant difference between groups (Effect size: -0.08 95% CI -3.55; 3.39, p= 0.96, I^2=0%) (Figure 2). From 4 studies included in the meta-analysis considering fracture strength as outcome, 2 data sets [23, 24] used until 2 mm of flowable resin composite as an intermediate layer (p=0.47, I^2=10%) and 2 data sets [20, 25] tested more than 2mm of flowable resin composite (p=0.24, I^2=0%). Irrespective of the flowable resin composite thickness, there was no statistically significant differences between groups (Effect size: 0.25 95% CI -0.43; 0.93, I^2=0%) (Figure 3).

Meta-analysis with 4 data sets [26–29] was performed considering clinical failure as outcome. Also, there was no significant difference between restorative approaches (RR 1.00 95% CI 0.52; 1.92, p=0.99, I^2=0) (Figure 4).

Descriptive analysis

One study [19] found no statistically significant difference in bond strength of Class II resin composite restorations with and without an intermediate layer of flowable resin composite until 2 mm.

Discussion

This is the first systematic review investigating if the use of an intermediate layer of flowable resin composite improves laboratory and clinical outcomes of Class II resin composite restorations. Restorative technique modifications should be tested in the laboratory before being implemented in clinical practice. In the selection process, 133 *in vitro* studies were excluded after full reading because most of them evaluated microleakage as outcome. Although the use of flowable materials in class

II cavities has been widely researched [30–32] across microleakage tests, the large variability between the methodologies difficult the data interpretation. Furthermore, overestimated data can be found because of small amounts of dyes that can capture a penetration in any marginal discrepancy. [33] Thus, studies that evaluated microleakage as an outcome should not be considered since they don't present a minimum threshold level for acceptance and may predict incorrect results. [33, 34]

Bond strength tests are encouraged to predict clinical behavior of adhesive systems, [35] and critical areas such as the gingival wall of Class II cavities can be adequately assessed through microtensile tests. [33] Moreover, extensive preparations make teeth progressively weaker, resulting in lower values when axial walls are not present in fracture resistance tests. [36] Therefore, we considered relevant to evaluate data about bond strength and fracture strength.

We did not restrict the amount of flowable resin composite used as an intermediate layer as an eligibility criterion; however, for statistical purposes considering fracture strength as outcome, we considered two cut-off points for the thickness of flowable resin composite (until 2 mm or higher than 2 mm) because they were common in most included studies. Furthermore, all studies that evaluated bond strength as outcome included in the meta-analysis used the microtensile bond strength test and considered the use of more than 2 mm of flowable resin composite. These aspects may explain the null heterogeneity found in both analyses.

The use of an intermediate layer of flowable resin composite did not influence on the bond strength values (Effect size: -0.08 95% CI -3.55; 3.39, p= 0.96) neither fracture strength, considering the use of until 2 mm (Effect size: 0.25 95% CI -0.43; 0.93, p= 0.47) or more than 2 mm of flowable layer thickness (Effect size: 101.90 95% CI -69.31; 273.11, p= 0.24). Since the use of an intermediate layer of flowable

resin composite did not negatively influence the laboratory outcome, it could help clinical practice, facilitating the filling of the cavity, mainly on the cervical margins. It has been shown that marginal defects without visible evidence of dentin on the wall or the base can result in caries adjacent to restorations and should be constantly monitored. [37]

All included clinical studies evaluated the restorations using modified USPHS criteria [38] and had a small number of failures. Meta-analysis showed that also there was no significant difference between restorative approaches (RR 1.00 95% CI 0.52; 1.92, p=0.99, I^2=0). The following parameters were assessed: anatomical form, marginal adaptation, color match, marginal discoloration, surface roughness, and caries. Specific parameters for class II restorations, such as approximal contact areas, approximal excess of material, periodontal or mucosal response, and fracture of material, were not covered by the studies.

It is important to highlight that most restorations were performed with cotton rolls and suction, and only one study [26] performed a rubber dam isolation in part of the sample. Non-use rubber dam to perform restorations does not seem to influence restorations' survival, considering that number of failures were similar in both groups. Furthermore, it has been evidenced that restorations' longevity is not influenced by operative field isolation technique. [39] Two studies [26, 27] evaluated the restorations after 2 years, a follow-up relatively short to detect differences between restorative techniques using the same material. We included studies that used conventional and flowable bulk-fill resin composites. The SDR flowable bulk-fill resin composite was used in *in vitro* [20–22, 25] and clinical [29] studies. It has been reported that SDR flowable bulk-fill resin composite presented lower shrinkage stress after polymerization when compared with other flowable materials, nano-hybrid, and

micro-hybrid resin composites. [40] However, the type of flowable resin composite did not influence the results found in this systematic review. Previous systematic reviews also found similar clinical performance between conventional resin composite and full-body bulk-fill resin composite or base/flowable bulk-fill resin composite. [41, 42] Although the use of flowable resin composite has other advantages such as shorter clinical time, no study evaluated this outcome.

The effect of the underlying quality of evidence of the findings must be emphasized. Most *in vitro* studies did not perform sample calculation and blinding of the operator of the testing machine. No clinical study described the method used to generate randomization sequence, and most studies [26–28] did not perform allocation concealment, leading to a high risk of bias. Moreover, only one study [29] reported the sample size calculation.

Finally, we must address that the small number of included studies, and the small sample size, mainly in clinical studies, might have influenced the absence of significant differences among restorative techniques found in this review. The quality of primary studies is of paramount importance to increase the knowledge translation to clinical practice. Therefore, there is a need for further well-designed and well-reported randomized controlled clinical investigations assessing Class II restorations' clinical performance with and without an intermediate flowable resin composite.

Conclusion

The use of flowable resin composite as an intermediate layer does not improve the effectiveness of the Class II restorations based on laboratory and clinical outcomes. Further studies are required before definitive conclusions can be drawn.

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Table 1. Main characteristics of data sets from *in vitro* selected studies from systematic review.

Study	Coun-try	Number Cavities per Group / Type of Human Tooth	Flowable Resin Composite / Resin Composite Commercial Brand	Amount of Flowable Resin Composite as intermediate layer	Outcome	Thermo-cycling	Test	Cervical Margins
Assis et al. 2016 [20]	Brazil	10 and 15 / Maxillary premolars	Surefill SDR Flow (Dentsply) / Spectrum TPH3 (Dentsply)	4mm	Bond strength and Fracture strength	-	µTBS* and Fracture Resistance	1mm below CEJ‡
Barros et al. 2019 [21]	Brazil	10 / Maxillary premolars	Surefill SDR Flow (Dentsply) / Spectrum TPH3 (Dentsply)	3.5 to 4mm	Bond strength	-	µTBS	1mm below CEJ
Güray Efes et al. 2013 [24]	Turkey	8 / Third molars	Filtek Supreme XT Flowable (3M ESPE) / Filtek Supreme XT (3M ESPE)	1mm	Fracture strength	5000 cycles	Fracture Resistance	1mm below CEJ
Kumagai et al. 2015 [22]	Brazil	11 / Third molars	SureFil SDR Flow (SDR) / Filtek Z350 XT (3M ESPE)	4mm	Bond strength	-	µTBS	Dentin
Oz, Ergin, Gurgan 2018 [25]	Turkey	12 / Maxillary molars	SDR posterior bulk-fill flowable (SDR) / CeramX Duo (Dentsply)	3 to 4mm	Fracture strength	-	Fracture Resistance	1mm above CEJ
Özgünaltay, Görücü 2005 [23]	Turkey	12 / Mandibular molars	Filtek Flow (3M ESPE) / Filtek Z250 (3M ESPE) and Filtek P60 (3M ESPE)	1mm	Fracture strength	-	Fracture Resistance	Enamel
Vidal et al. 2012 [19]	Brazil	12 / Premolars	Filtek Supreme Plus Flowable Restorative (3M ESPE) / Filtek Supreme Plus Universal Restorative (3M ESPE)	1.5mm	Bond strength	-	µTBS	1mm below CEJ

Abbreviations: µTBS*: microtensile, CEJ ‡: cement-enamel junction

Table 2. Main characteristics of data sets from clinical selected studies from systematic review.

Study	Country	Study Design	Number of restorations (per group) / Type of Tooth	Number of Patients / Mean Age of Patients	Flowable Resin Composite / Resin Composite Commercial Brand	Amount of Flowable Resin Composite as intermediate layer	Follow-up time / Drop-Out	Criteria Evaluation	Cavity Liner	Field Isolation	Substrate Margins
Ernst et al. 2003 [26]	Germany	Parallel	116 (58) / Premolars and Molars	52 / 42.5±15.4 years	Revolution (Kerr) / Prodigy Condensable (Kerr)	A thin layer	2 years / 4.3%	USPHS	Glass ionomer cement base in 53%	Rubber dam in 70%	Enamel and Dentin
Stefanski, van Dijken 2010 [27]	Sweden	Parallel	108 (54) / Premolars and Molars	48 / 39.2 years	Filtek Flow Supreme XT (3M ESPE) / Filtek Supreme XT (3M ESPE)	1 to 1.5mm	2 years / 14.8%	USPHS	Calcium hydroxide base was only placed in pulpal close cavity parts (<0.5 mm)	Cottons pellets	Enamel and Dentin
van Dijken, Pallesen 2011 [28]	Sweden	Parallel	118 (59) / Premolars and Molars	48 / 57 years	Tetric Flow (Ivoclar Vivadent) / Tetric Ceram (Ivoclar Vivadent)	1 to 1.5mm	7 years / 3.4%	USPHS	None	Cottons pellets	Enamel and Dentin
van Dijken, Pallesen 2017 [29]	Sweden	Parallel	76 (38) / Premolars and Molars	38 / 55.3 years	SDR Flow (Dentsply) / Ceram X mono (Dentsply)	4mm	6 years / 5.3%	USPHS	None	Cottons pellets	-

Table 3. Risk of bias from *in vitro* selected studies for systematic review.

Study	The same type of teeth	Teeth Rando-mization	Sample size calcu-lation	Teeth free of caries	Standar-dized the size of the cavities	Materials used according to manufacturers' instructions	Restorations preparation performed by a single operator	Blinding of the operator machine	Risk of bias
Assis et al. 2016 [20]	Y	N	N	Y	Y	Y	Y	N	Medium
Barros et al. 2019 [21]	Y	Y	N	Y	Y	Y	Y	N	Medium
Güray Efes et al. 2013 [24]	Y	N	N	Y	Y	Y	N	N	Medium
Kumagai et al. 2015 [22]	Y	Y	N	Y	Y	Y	N	N	Medium
Oz, Ergin, Gurgan 2018 [25]	Y	Y	N	Y	Y	Y	N	N	Medium
Özgünaltay, Görücü 2005 [23]	Y	Y	N	Y	Y	Y	Y	N	Medium
Vidal et al. 2012 [19]	Y	Y	N	Y	Y	Y	N	N	Medium

Table 4. Risk of bias from clinical selected studies for the systematic review.

Study	Random sequence generation	Allocation concealment	Blinding of Participants	Blinding of personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting
Ernst et al. 2003 [26]	Unclear	High	Unclear	Unclear	Low	Low	Low
Stefanski, van Dijken 2010 [27]	Unclear	High	Unclear	Unclear	Unclear	Low	Low
van Dijken, Pallesen 2011 [28]	Unclear	High	Unclear	Unclear	Low	Low	Low
van Dijken, Pallesen 2017 [29]	Unclear	Unclear	Low	Unclear	Low	Low	Low

Table 5. A summary of GRADE's approach to rating quality of evidence.

Certainty assessment							№ of restorations		Effect	Certainty	Importance
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Without Flowable Layer**	**With Flowable Layer**	**Relative (95% CI)**		
4	Clinical trials	Serious[a]	Not serious	Not serious	Serious[b]	-	195	194	RR 1.00 [0.52, 1.92]	⊕⊕◯◯ LOW	IMPORTANT

CI: confidence interval; RR: Risk Ratio

a. Problems with the form of randomization, allocation concealment, blinding of participants and blinding of operators were detected.

b. Few studies and few restorations assessed.

GRADE Working Group grades of evidence **High quality:** Further research is very unlikely to change our confidence in the estimate of effect. **Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low quality:** We are very uncertain about the estimate.

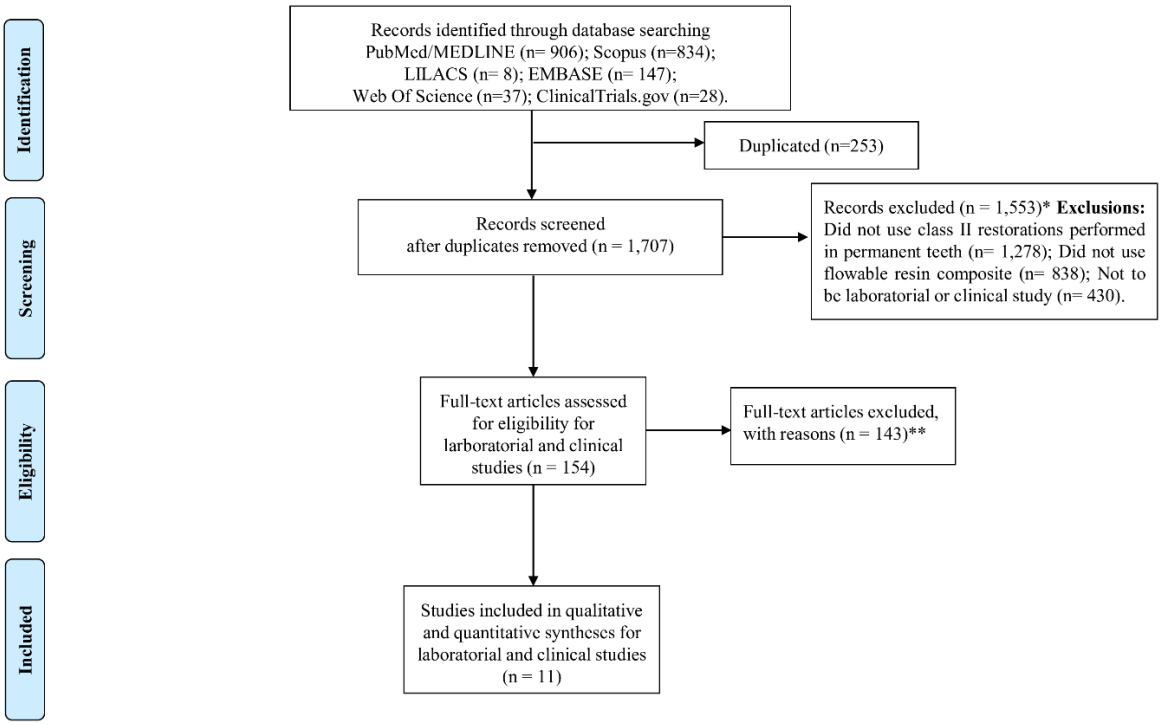

Figure 1: Flowchart diagram of study selection according to the PRISMA statement.

Full-text in vitro articles excluded, with reasons (n = 133)** Exclusions: (1) did not evaluate direct methacrylate-based resin composite restorations (n=2); (2) did not present a control group (without an intermediate layer of flowable resin composite) (n=16); (3) did not use the same adhesive system protocol in both groups (n=10); (4) did not use same resin composite in both groups (n=9); (5) sample containing teeth that received endodontic treatment prior to the restorative treatment (n=6); (6) did not specify the amount of flowable resin composite used (n=7); and (7) did not consider bond strength or fracture strength as outcomes (n=124).

Full-text clinical articles excluded, with reasons (n = 9)** Exclusions: (1) did not evaluate direct methacrylate-based resin composite restorations (n=0); (2) did not present a control group (without intermediate layer of flowable resin composite) (n=2); (3) did not use the same adhesive system protocol in both groups (n=2); (4) did not use the same resin composite in both groups (n=3); (5) sample containing teeth that received endodontic treatment prior to the restorative treatment (n=1); (6) follow-up lower than six months (n=2); (7) dropout rate ≥ 30% (n=1); (8) absence of similar follow-up for patients in both groups evaluated in the same way (n=0); and (9) did not evaluate restoration failure as an outcome (n=2).

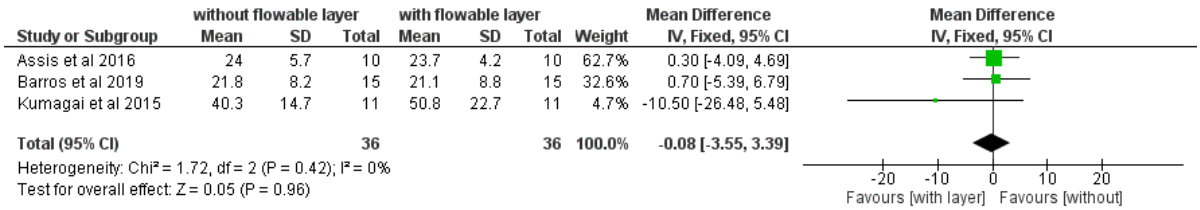

Figure 2: Meta-analysis comparing the bond strength (Mpa) of Class II restorations with and without an intermediate layer of flowable resin composite.

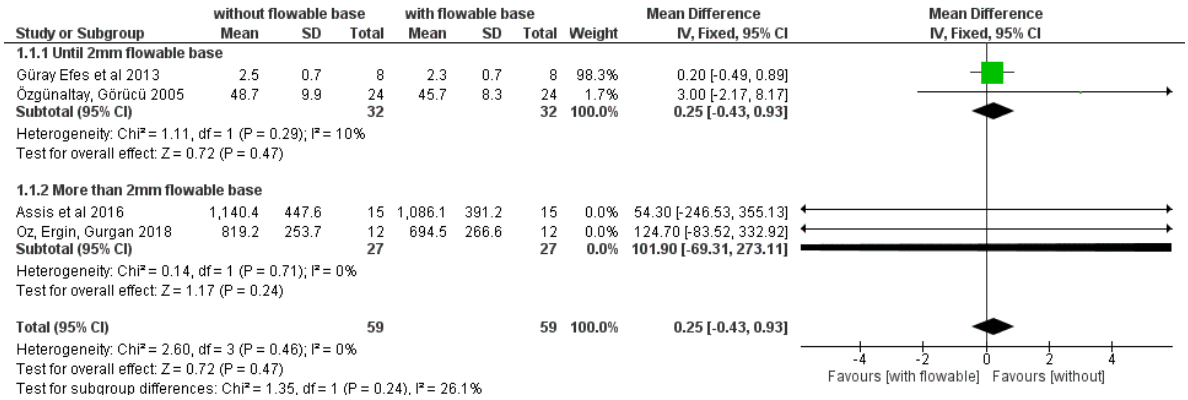

Figure 3: Meta-analysis comparing the strength fracture (Newton) of Class II restorations with and without an intermediate layer of flowable resin composite, considering the thickness of flowable resin composite as subgroups (until 2 mm or higher than 2 mm).

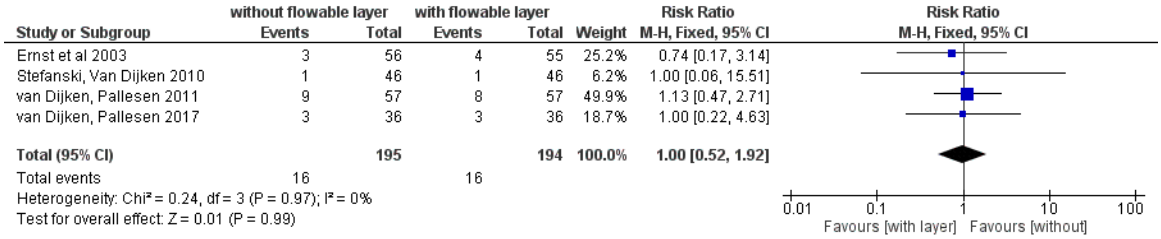

Figure 4: Meta-analysis comparing the risk of failure of Class II restorations with and without an intermediate layer of flowable resin composite.

3 ARTIGO 2 – Is use of flowable resin composite an option for occluso-proximal restorations in primary teeth? A fracture strength analysis

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Is use of flowable resin composite an option for occluso-proximal restorations in primary teeth? A fracture strength analysis

Short Tittle: Flowable resin composite in primary teeth

Cleber Paradzinski Cavalheiro
School of Dentistry, Post-Graduate Program in Dentistry, Federal University of Rio Grande do Sul, Porto Alegre, RS, Brazil
clebe.r@hotmail.com ORCID: 0000-0001-9402-1811

Carolina Lopes da Silva
School of Dentistry, Post-Graduate Program in Dentistry, Federal University of Rio Grande do Sul, Porto Alegre, RS, Brazil
silvacarollopes@gmail.com ORCID: 0000-0001-6843-8605

Vicente Castelo Branco Leitune
School of Dentistry, Post-Graduate Program in Dentistry, Federal University of Rio Grande do Sul, Porto Alegre, RS, Brazil
vicente.leitune@ufrgs.br ORICID: 0000-0002-5415-1731

Fernando Borba de Araujo
School of Dentistry, Post-Graduate Program in Dentistry, Federal University of Rio Grande do Sul, Porto Alegre, RS, Brazil
fernando@odontofernandoaraujo.com.br ORCID: 0000-0003-2892-3256

José Carlos Pettorossi Imparato
School of Dentistry, Department of Pediatric Dentistry and Orthodontics, University of São Paulo, São Paulo, SP, Brazil
jimparato@usp.br ORCID: 0000-0002-1990-2851

Tathiane Larissa Lenzi
School of Dentistry, Post-Graduate Program in Dentistry, Federal University of Rio Grande do Sul, Porto Alegre, RS, Brazil
tathiane.lenzi@ufrgs.br ORCID: 0000-0003-3568-5217

✉**Corresponding author:**
Tathiane Larissa Lenzi
School of Dentistry, Post-Graduate Program in Dentistry, Federal University of Rio Grande do Sul
Ramiro Barcelos 2492, 90035-003, Santa Cecília, Porto Alegre, RS, Brazil
Phone number: +55 55 3308 5493
E-mail: tathiane.lenzi@ufrgs.br

Author contributions

C.P.C. wrote the manuscript, performed the methodology and performed statistical evaluation, C.L.S performed the methodology and performed statistical evaluation, V.B.C.L. contributed substantially to the methodology, F.B.A. contributed substantially to discussion and proofread manuscript, J.C.P.I. contributed substantially to discussion and proofread manuscript, and T.L.L. conceived the idea, performed the methodology, contributed substantially to discussion and proofread manuscript.

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Abstract

Aim: To investigate the fracture strength of occluso-proximal restorations in primary teeth using different flowable resin composites (as an intermediate layer or entire cavity) and a conventional resin composite (incremental technique). **Design:** Two standardized occluso-proximal cavities were prepared on mesial and distal surfaces of fifty sound primary molars. The teeth were randomly assigned into five groups (n=10): 2mm Filtek Bulk Fill Flow + Z350 XT; 4mm Filtek Bulk Fill Flow; 2mm Z350 XT Flow + Z350 XT; 4mm Z350 XT Flow, and Z350 XT inserted by incremental technique. All restored teeth were subjected to cariogenic challenge and then submitted to fracture strength test. The failure pattern of each specimen was categorized as reparable or irreparable/need for replacement based on the World Dental Federation (FDI) criteria. Fracture strength means were submitted to one-way ANOVA and Tukey's *post-hoc* tests. Failure pattern was analyzed descriptively. **Results:** There was no statistically significant difference on fracture strength among groups (p=0.48). A similar distribution of reparable (35-40%) and irreparable (60-65%) failures was observed among groups. **Conclusion:** Based on a laboratorial setting, the use of different flowable resin composites (as an intermediate layer or entire cavity) may be an option to restore occluso-proximal cavities in primary molars.

Keywords: Class II, primary teeth, flowable resin composite, fracture strength, occluso-proximal

Introduction

Restorative treatment of primary teeth compromised by cavitated dentinal carious lesions remains one of the main procedures performed in daily Paediatric Dentistry practice. Overall, proximal surfaces presented a greater risk of caries, mainly because of limited salivary access, the absence of chewing forces, and difficult cleaning techniques.[1,2] Restoring the occluso-proximal cavities in primary teeth is a challenging task because of the broad contact area, difficulty in matrix band placement, and reduced enamel dentin thickness which implies in a less retentive cavity,[3] besides the children cooperation for the treatment.

Resin composites are widely used in occluso-proximal primary molars cavities,[4] because of their advantages, such as conservative preparations, aesthetics, and mechanical resistance. Conversely, resin composites are highly sensitive[4,5] and time-consuming, and the polymerization of monomeric materials can be challenging because of shrinkage stress, which results in gaps in the bonded interface.[6] From this perspective, cavities with a substantial number of surfaces involved can be an even more significant challenge in the restoration owing to the high C-factor,[7] and higher shrinkage stress.[6]

The use of an intermediate layer of flowable resin composites placed in the cervical part of the proximal box, in association with the final capping layer of a conventional resin composite, has been suggested by some manufacturers for occluso-proximal cavities. Contemporary flowable resin composites are characterized by higher flow, lower viscosity, and variable filler loading in their formulation,[8] which could facilitate their insertion into the cavity, improve cervical adaptation, and reduce the risk of marginal defects.[9] Furthermore, the use of an intermediate layer of flowable resin composite could reduce the total stiffness, allowing the shrinkage

stress of the restoration to be compensated.[10] Flowable resin composites are available in two groups: conventional that are inserted in increments of up to 2 mm in thickness or bulk-fill that due composition modifications (such high translucency and presence of additional or more efficient photoinitiators for achieve deeper polymerization) can be inserted in increments of up to 4–5 mm in thickness.[8,10]

The use of flowable resin composites without a final capping layer is a rarely reported restorative technique, mainly on stress-bearing surfaces, due the lower wear strength.[8] However, good outcomes in terms of the clinical durability of occluso-proximal restorations in primary molars using only flowable conventional resin composites have been reported.[11] This approach may be an attractive option for restoring primary teeth with lower occlusal load and shorter biological cycle. Furthermore, the use of a single increment of flowable bulk-fill resin composite to restore small occluso-proximal cavities in primary molars is desirable in the clinical practice due to technical facility and reduced chair time. Nevertheless, the comparison of the fracture strength of flowable conventional and bulk-fill resin composites in primary teeth has never undertaken.

Therefore, this laboratory study aimed to investigate the fracture strength of occluso-proximal restorations in primary teeth using different flowable (conventional or bulk-fill) resin composites (as an intermediate layer or entire cavity) and a conventional resin composite (incremental technique).

Materials and methods

This laboratory-based study followed the RoBDEMAT[12] Guideline.

Sample Calculation

The sample size calculation was performed using software available at www.sealedenvelope.com. The means and standard deviations of fracture strength of occluso-proximal cavities in permanent teeth using convention resin composite inserted by incremental technique (1,140.4 ± 447.6) and flowable bulk-fill resin composite as an intermediate layer followed by a final layer of conventional resin composite (1,086.1 ± 391.2) were considered for the calculation.[13] In order to detect a difference of 40 Newton among the groups, using a 5% significance level and 80% power, the minimum sample size was 9 teeth and 18 cavities per group.

Teeth selection and preparation

Fifty sound exfoliated primary molars (twenty-five first primary molars and twenty-five second primary molars) were obtained in accordance with the Declaration of Helsinki from the patients' informed consent after study protocol approval by the ethics committee (protocol number 4.573.690). The teeth were disinfected in 0.5% aqueous chloramine, and subsequently, they were individually fixed 1 mm below the cementoenamel junction in PVC rings embedded with self-curing acrylic resin[13] (JET Clássico, São Paulo, SP, Brazil) to facilitate the restorative procedures.

Cavity preparation

A trained operator performed all the cavity preparations. Two cavities were prepared on the occluso-mesial and occluso-distal surfaces of each tooth using a #2068 truncated cone diamond bur (Fava, São Paulo, SP, Brazil) at high rotation (KaVo, Joinvile, SC, Brazil) under constant cooling. Each cavity measured 4 mm in cervico-occlusal height, 4 mm in bucco-lingual/palatal width, and 2 mm in disto-

mesial width. Cavity dimensions were measured using a digital pachymeter (Absolute Digimatic, Mitutoyo, Tokyo, Japan).

Randomization

The widest bucco-lingual/palatal and disto-mesial dimensions of each tooth crown were measured and recorded using a digital caliper (Absolute Digimatic, Mitutoyo, Tokyo, Japan). The sum of these two dimensions was used in the distribution of specimens among the groups[14] considering five first primary molars and five second primary molars to ensure uniformity of tooth size in each group. A staff member who was not involved in other laboratory study phases performed the randomization. The teeth were allocated to five experimental groups (n = 10) using Random.org (Randomness and Integrity Services Ltd., Dublin, Ireland) program to generate a random coded list according to the type of resin composite and the number of increments, as follows (Figure 1):

Group 1: 2 mm of flowable bulk-fill resin composite as an intermediate layer (Filtek Bulk Fill Flowable; 3M Oral Care, St. Paul, MN, USA) + two increments of conventional resin composite (Filtek Z350 XT; 3M Oral Care, St. Paul, MN, USA) inserted by incremental technique;

Group 2: 4 mm (single increment) of flowable bulk-fill resin composite (Filtek Bulk Fill Flowable; 3M Oral Care, St. Paul, MN, USA);

Group 3: 2 mm of flowable conventional resin composite as an intermediate layer (Filtek Z350 XT Flow; 3M Oral Care, St. Paul, MN, USA) + two increments of conventional resin composite (Filtek Z350 XT; 3M Oral Care, St. Paul, MN, USA) inserted by incremental technique;

Group 4: 4 mm (two increments) of flowable conventional resin composite (Filtek Z350 XT Flow; 3M Oral Care, St. Paul, MN, USA);

Group 5 - Control: Four increments of conventional resin composite (Filtek Z350 XT; 3M Oral Care, St. Paul, MN, USA) inserted by incremental technique.

Restorative procedure

All restorations were performed by a single trained operator and the anatomical aspects were reproduced in all experimental groups. The materials used in this study are listed in Table 1. A Tofflemire matrix retainer (TDV, Pomerode, SC, Brazil) and metallic matrix band (Golgran, São Caetano do Sul, SP, Brazil) were applied to the tooth. The first restored cavity was the occluso-mesial, followed by the occluso-distal cavity. All cavities were treated with universal adhesive (Scotchbond Universal, 3M Oral Care, St. Paul, MN, USA) in the self-etch mode[15] according to the manufacturer's instructions. Restorative procedures were performed according to the allocation group following the manufacturer's instructions. The resin composite increments were measured with a millimeter probe (Golgran, São Caetano, SP, Brazil) and light curing with a light-emitting diode curing unit (Radii-cal, SDI, Victoria, AUS) with the light source in contact with the coronal edge of the metallic matrix band, and an irradiance of 1200 mW/cm^2 was checked using the built-in radiometer of the light curing. Polishing was performed using rubber points (Astropol, Ivoclar Vivadent, Schaan, Liechtenstein) one day after restoration.

Cariogenic challenge

All restored teeth were submitted to cariogenic challenge by pH-cycling. The demineralizing solution was composed of 2.2 mM $CaCl_2$, 2.2 mM NaH_2PO_4, and 50 mM acetic acid adjusted to pH of 4.8, and the remineralizing solution was composed

of 1.5 mM $CaCl_2$, 0.9 mM NaH_2PO_4, and 0.15 M KCl adjusted to a pH of 7.0. Each tooth was cycled individually in 15mL of both solutions for 8h in the demineralizing solution and 16h in the remineralizing solution. This procedure was carried out for 14 days at room temperature without agitation, and the solutions were renewed daily[16].

Fracture strength

Each restored tooth was coded according to the randomization to ensure blinding of the testing machine operator. The teeth were individually mounted in a universal testing machine (EZ-SX series, Shimadzu Corp., Kyoto, Japan) and subjected to a compressive axial load applied to the center of each occluso-proximal restoration, parallel to the long axis of the tooth, using a round-end steel device (6 mm in diameter) at a crosshead speed of 1 mm/min. A compressive force was applied until the specimen fractured and the machine automatically stopped operating. The load required to fracture the specimens was expressed in Newton (N).

Fracture pattern

A single trained examiner evaluated the fracture patterns. Each occluso-proximal restoration was categorized as reparable when the failure covered up to half of the restoration (partially loose/lost restoration) or irreparable/needed replacement when the failure involved more than half of the restoration, complete loss of the restoration, or multiple fractures.[17]

Statistical analysis

The tooth was the experimental unit. Thus, the fracture strength values from each occluso-proximal cavity from the same tooth were calculated for statistical analysis. The fracture strength mean for each experimental group was expressed as

the average of 10 tooth used for group.

The normal distribution of the data was confirmed using a Kolmogorov-Smirnov test. The fracture strength means were analyzed by one-way ANOVA and Tukey's *post-hoc* tests. Statistical significance was defined at $p < 0.05$. Statistical analysis was performed using Minitab-18 software (Minitab Inc., State College, PA, USA). Failure pattern was analyzed descriptively.

Results

The fracture strength means and standard deviations for all experimental groups are shown in Table 2. There was no statistically significant difference on fracture strength among groups (p=0.48).

The distribution of the failure pattern for the five experimental groups is summarized in Table 3. A similar overall distribution of reparable (ranged of 35 to 40%) and irreparable/need for replacement (ranged of 60 to 65%) failures was observed.

Discussion

This is the first study, to the best of our knowledge, to evaluate the fracture strength of occluso-proximal restorations in primary teeth using different flowable (conventional or bulk-fill) resin composites (as an intermediate layer or entire cavity) and a conventional resin composite (incremental technique). A recent systematic review[18] found that the use of a flowable resin composite as an intermediate layer did not negatively influence the effectiveness of class II restorations performed in permanent teeth based on laboratory, including fracture strength and clinical outcomes. In this study, the use of flowable bulk-fill resin composite (1,293 ± 535N) or flowable conventional resin composite (1,225 ± 445N) as an intermediate layer

resulted in a similar fracture strength of occluso-proximal restorations in primary molars compared with the use of conventional resin composite (layering technique) (1,289 ± 409N). Since the use of an intermediate layer of flowable resin composite did not negatively influence the fracture strength means, especially on the cervical margins cervical margins. In addition, this layer could reduce the restoration stiffness and enamel cracks incidence.[10,19]

The first generation of flowable materials commonly had a low filler content composition, demanding a final capping layer of a conventional resin composite owing to their minor wear resistance. However, acceptable clinical results have been reported for occluso-proximal restorations using flowable conventional resin composite in primary teeth[11]. The cumulative failure rate at 2 years was 13.6%, with recurrent caries as the main reason for failure. No difference in functional failure (marginal adaptation and fracture) was found between the flowable conventional resin composite and resin-modified glass ionomer cement restorations.[11] In this study, the use of a single increment of flowable bulk-fill resin composite (1,230 ± 539N) and two increments of flowable conventional resin composite (1,565 ± 420N), without the final capping layer of conventional resin composite also resulted in fracture strength values similar to those obtained using the conventional restorative technique.

This finding is interesting because the use of a resin composite with low viscosity and higher flow into the cavity could combine the advantages of ease of insertion, usually with an applicator tip, and agility during the procedure, mainly considering a single 4-5 mm increment of flowable bulk-fill resin composite to restore primary teeth. However, it is important to highlight that the type of filler and its apparent viscosity significantly influence the wear resistance of flowable resin

composites.[20] In this study, both flowable materials tested had high filler contents (Filtek Z350 XT Flow; 3M Oral Care - 65% in weight and 46% in volume, and Filtek Bulk Fill Flowable; 3M Oral Care – 64.5% in weight and 42.5% in volume), which may explain the results.

On the other hand, the utilization of conventional resin composites following the incremental technique requires sculptability, demands higher operator sensitivity for correct adaptation in the cervical part of the proximal box, and carries an implicit risk of incorporating impurities or air bubbles between layers, which could cause functional failures.[21,22] In addition, this restorative approach requires more chair time,[23] which may influence the child's behavior during treatment and, consequently, impact the restoration quality.

Although previous literature indicates that the use of a flowable resin composite promotes better stress distribution,[24] significantly reducing the cuspal deflection in the occluso-proximal cavities of permanent teeth in comparison to conventional resin composite restorations using an incremental filling technique,[25] no difference regarding the fracture pattern was observed in this study. Evaluation of the fracture pattern demonstrated a similar distribution of reparable and irreparable restorations among the groups, although a higher frequency of restorations (60-65%) requiring replacement was observed.

A previous study[13] evaluating the fracture strength of occluso-proximal restorations performed in permanent teeth categorized the failure pattern as reparable when the failure was 2 mm above the cemento-enamel junction and irreparable when the failure occurred 2 mm below the cemento-enamel junction, that is, subgingivally. Since reintervention of defective restorations at the subgingival level is not an approach for primary teeth, the fracture pattern in this study was

categorized as reparable when the failure covered up to half of the restoration (partially loose/lost restoration) and irreparable when the failure involved partial (more than half of the restoration) or complete loss of the restoration, or multiple fractures based on the revised World Dental Federation criteria.[17]

Since large cavities, with extensive preparations, make the teeth progressively weaker, producing a reduction fracture strength means when proximal walls are absent,[26] and the mechanical stability of resin composites is one of the prerequisites for the long-term clinical success of restorations,[27] we considered it relevant to evaluate different flowable (conventional and bulk-fill) resin composites in occluso-proximal cavities through fracture strength test. Although mechanical testing, such as fracture strength are not common in primary teeth, especially considering occluso-proximal restorations,[28] this methodology remains an important experimental method for the evaluation of restorative techniques, before being implemented in clinical practice.

This *in vitro* study had some limitations. To perform the mechanical test, a compressive axial loading parallel to the long axis was applied to each occluso-proximal restoration. An appropriate contact area is recommended to prevent food impaction, patient discomfort and allow for interdental papilla to fill the interproximal space.[17] In this sense, the contact point reproduction and lateral forces considering wear effect and fatigue loading should also be considered clinically.[29] All restorations were subjected to a cariogenic challenge before the fracture strength test to simulate the conditions of the oral environment that may impact on the restoration performance. It has been shown that combined aging treatments and pH-cycling alone negatively affect adhesive bond strength.[30] Thus, pH-cycling may be useful in predicting the longevity of restorations.[30]

In conclusion, the use of flowable (conventional or bulk-fill) resin composites as an intermediate layer or entire cavity present similar fracture strength means of conventional resin composite (incremental technique) in occluso-proximal restorations in primary teeth. However, these findings cannot be directly extrapolated to clinical practice and are limited to materials tested and methodological design. Randomized clinical trials are necessary to investigate the effect of flowable resin composites in occluso-proximal restoration survival in primary teeth.

Why this paper is important to paediatric dentists:

Flowable resin composites are characterized by easy insertion and agility during the restorative procedures. Based on fracture strength data, the use of flowable (conventional or bulk-fill) resin composite as an intermediate layer or entire cavity may be an interesting option to restore occluso-proximal cavities in primary molars.

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Table 1. Main composition and manufacturers' recommendations protocol of the materials used.

Material	Manufacturers' recommendations protocol	Batch number	Main composition
Scotchbond Universal adhesive system (3M Oral Care, St. Paul, MN, USA)	Self-etch mode Apply the adhesive for 20 s with vigorous agitation Gentle air thin for 5 s Light cure for 10 s	2210200175	MDP Phosphate Monomer, Dimethacrylate resins, HEMA, Vitrebond Copolymer, Filler, Ethanol, Water, Initiators, Silane
Resin composite Z350 XT, A2B Shade (3M Oral Care, St. Paul, MN, EUA)	Insert in 2 mm increments Light cure for 20s each increment	2032400481	Bis-GMA, UDMA, TEGDMA, Bis-EMA, non-agglomerated/non-aggregated 20 nm silica filler, non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, and aggregated zirconia/silica cluster filler Fill content: 78.5% in weight and 63.3% in volume
Flowable resin composite Z350 XT Flow, A2 Shade (3M Oral Care, St. Paul, MN, EUA)	Insert in 2 mm increments Light cure for 20s each increment	2207500254	Bis-GMA, TEGDMA, Procrylat resins, non-agglomerated/non-aggregated surface-modified 20 nm silica filler, non-agglomerated/ non-aggregated 75 nm silica filler, and aggregated zirconia/silica cluster filler Fill content: 65% in weight and 46% in volume
Flowable resin composite Filtek Bulk Fill Flowable, A2 Shade (3M Oral Care , St. Paul, MN, EUA)	Insert in 4 mm increments Light cure for 20s each increment	2201700296	Bis-GMA, UDMA, Bis-EMA, Procrylat resins, 0.1 to 5 μ ytterbium trifluoride filler and 0.01 to 3.5 μ zirconia/silica cluster filler Fill content: 64.5% in weight and 42.5% in volume

MDP: 10-methacryloyloxydecyl-dihydrogen-phosphate; Bis-GMA: bisphenyl-glycidyl methacrylate; HEMA: 2-hydroxyethyl methacrylate; TEGDMA: triethylene glycol dimethacrylate; Bis-EMA: ethoxylated bisphenol-A dimethacrylate; UDMA: urethane dimethacrylate

Table 2. The fracture strength means (Newton) and standard deviations for all experimental groups.

Group	Fracture strength
Flowable bulk-fill resin composite as an intermediate layer	1,293 ± 535^{A}
Flowable bulk-fill resin composite entire cavity	1,230 ± 539^{A}
Flowable conventional resin composite as an intermediate layer	1,225 ± 445^{A}
Flowable conventional resin composite entire cavity	1,565 ± 420^{A}
Conventional resin composite (incremental technique)	1,289 ± 409^{A}

*Equal capital superscript letters indicate no statistically significance difference among groups ($p>0.05$).

Table 3. Distribution of the fracture pattern for all experimental groups.

Group	Reparable	Irreparable/Need for replacement
Flowable bulk-fill resin composite as an intermediate layer	7 (35%)	13 (65%)
Flowable bulk-fill resin composite entire cavity	8 (40%)	12 (60%)
Flowable conventional resin composite as an intermediate layer	7 (35%)	13 (65%)
Flowable conventional resin composite entire cavity	8 (40%)	12 (60%)
Conventional resin composite (incremental technique)	7 (35%)	13 (65%)

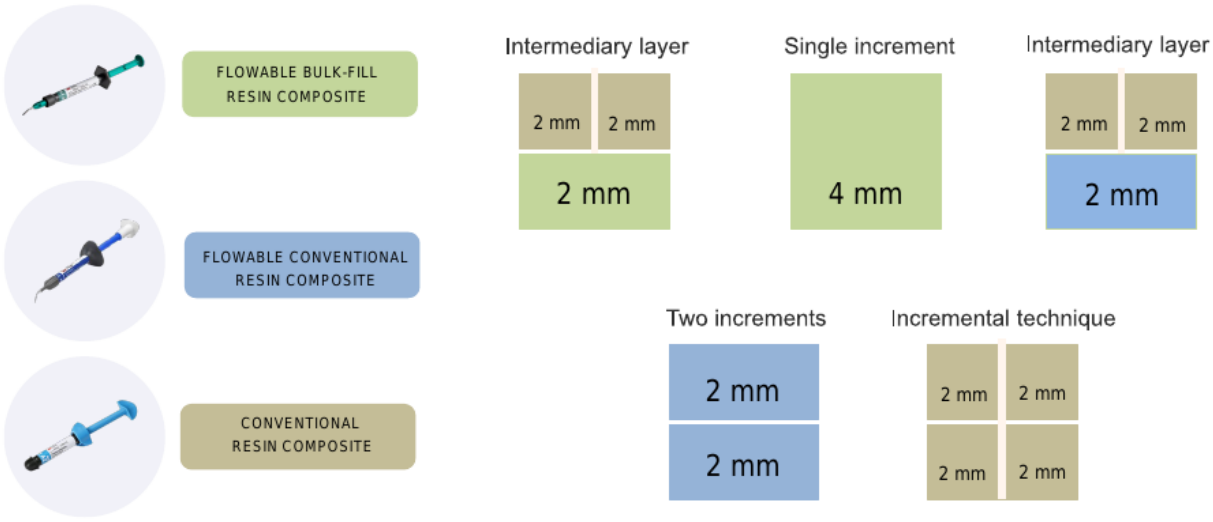

Figure 1. Illustration of the experimental groups.

4 ARTIGO 3 – Fracture strength and cost of different dental manufacturers of flowable bulk-fill resin composites for occluso-proximal restorations in primary teeth

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Fracture strength and cost of different dental manufacturers of flowable bulk-fill resin composites for occluso-proximal restorations in primary teeth

Short Tittle: Flowable bulk-fill resin composites restorations

Cleber Paradzinski Cavalheiro
DDS, MSc, PhD Student
School of Dentistry, Post-Graduate Program in Dentistry, Federal University of Rio Grande do Sul, Ramiro Barcelos 2492, 90035-003, Porto Alegre, RS, Brazil +55 51 3308 5493 clebe.r@hotmail.com

Carolina Lopes da Silva
DDS, MSc, PhD Student
School of Dentistry, Post-Graduate Program in Dentistry, Federal University of Rio Grande do Sul, Ramiro Barcelos 2492, 90035-003, Porto Alegre, RS, Brazil +55 51 3308 5493 silvacarollopes@gmail.com

Clara Cavagnoli Mendes
DDS Student
School of Dentistry, Federal University of Rio Grande do Sul, Ramiro Barcelos 2492, 90035-003, Porto Alegre, RS, Brazil
+55 51 3308 5493 clara.cavagnoli@hotmail.com

José Carlos Pettorossi Imparato
DDS, MSc, PhD, Associate Professor
School of Dentistry, Department of Pediatric Dentistry and Orthodontics, University of São Paulo, Avenida Prof. Lineu Prestes 2227, 05508-000, São Paulo, SP, Brazil +55 11 3091-7418 jimparato@usp.br

Tathiane Larissa Lenzi
DDS, MSc, PhD, Assistant Professor
School of Dentistry, Post-Graduate Program in Pediatric Dentistry, Federal University of Rio Grande do Sul, Ramiro Barcelos 2492, 90035-003, Porto Alegre, RS, Brazil
+55 51 3308 5493 tathiane.lenzi@ufrgs.br
✉**Corresponding author:**
Tathiane Larissa Lenzi
School of Dentistry, Post-Graduate Program in Dentistry, Federal University of Rio Grande do Sul
Ramiro Barcelos 2492, 90035-003, Santa Cecília, Porto Alegre, RS, Brazil
Phone number: +55 55 3308 5493
E-mail: tathiane.lenzi@ufrgs.br

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Abstract

Purpose: To investigate the fracture strength of occluso-proximal restorations in primary teeth using different dental manufacturers of bulk-fill flowable resin composites (as an intermediate layer or entire cavity) in comparison with conventional resin composite (incremental technique) and the cost to perform the restorations. **Methods:** Two standardized occluso-proximal cavities (4 mm cervico-occlusal height, 4 mm bucco-lingual/palatal width and 2 mm disto-mesial width) were prepared in ninety sound primary molars. After application of a universal adhesive system in the self-etch mode, the teeth were randomly assigned into nine groups (n=10) according to dental manufacturers – 3M Oral Care™, Shofu Inc.© and FGM Dental Group®, number of increments of flowable bulk-fill resin composite – 2 mm (intermediate layer) or 4 mm (entire cavity) and control – conventional resin composite (incremental technique). All restored teeth were subjected to cariogenic challenge by pH cycling for 14 days prior to fracture strength test. Fracture strength means were submitted to one-way ANOVA and Tukey's *post-hoc* tests (α=5%). The cost was analyzed descriptively. **Results:** No difference in fracture strength was found among groups (p=1.00). The cost for each occluso-proximal restoration ranged from 0.99 to 3.94 (USD). The use of flowable bulk-fill resin composite entire cavity (4 mm) resulted in the shorter cost for 3M Oral Care™ and Shofu Inc.© and higher cost for FGM Dental Group®. **Conclusions:** The use of flowable bulk-fill resin composites entire cavity does not jeopardize the fracture strength of occluso-proximal restorations in primary teeth, and reduces the cost, depending of the dental manufacturers.

Keywords: occluso-proximal, primary teeth, bulk-fill flowable resin composite, fracture strength.

Introduction

Occluso-proximal cavities are more common than other cavity configurations.[1] Although consensus regarding the best restorative technique is lacking, resin composites have been strongly recommended for occluso-proximal cavities in primary molars because of their advantages such as conservative preparation, mechanical resistance, and esthetics.[2,3] However, conventional resin composites are highly sensitive and time-consuming, and polymerization shrinkage stress, which is associated with gap formation, poor marginal adaptation, cusp deflection, and caries around the restorations, is the primary limitation.[4,5]

Therefore, bulk-fill resin composites are an attractive choice for primary-tooth restoration. Single-increment restorations (thickness ≤ 4–5 mm) are possible owing to the improved translucency and use of specific polymerization modulators and more potent initiator systems.[6] Bulk-fill resin composites can be classified into two groups: low-viscosity or flowable and high-viscosity or full-body bulk-fill resin composites. A recent clinical study[7] on occluso-proximal restorations in primary teeth showed that compared with conventional resin composites, full-body bulk-fill resin composites demonstrated similar clinical performance and required 30% less time.

Bulk-fill flowable resin composites contains less filler loading in their formulation, presenting higher flow, low viscosity, and greater elasticity,[8–10] which facilitate their insertion into the cavity, improve cervical adaptation, and reduce the risk of marginal defects.[11] The use of a bulk-fill flowable resin composite entire cavity has rarely been reported; however, bulk-fill flowable resin composites have shown excellent clinical performance in the occluso-proximal cavities of primary molars, similar to that of compomers.[12] Therefore, bulk-fill flowable resin composites may be an interesting alternative for clinical use in primary teeth that present a lower occlusal

load and a shorter biological cycle. Considering that several options for bulk-fill resin composites with variable formulations and technologies are available in the market, cost analyses are important because they provide dental practitioners with crucial information that helps them make decisions about treatment planning, management, and health promotion.

Therefore, this in vitro study aimed to compare the fracture strengths of occluso-proximal restorations in primary teeth using different dental manufacturers of bulk-fill flowable resin composites (as an intermediate layer or entire cavity) in comparison with conventional resin composite (incremental technique) and the cost of performing restorations.

Methods

This laboratory-based study followed the CRIS Guidelines[13] for in vitro studies.

Sample Calculation

The sample size calculation was performed using software available at www.sealedenvelope.com The means and standard deviations of fracture strength of occluso-proximal cavities in permanent teeth restored with conventional resin composite inserted by incremental technique (1,140.4 ± 447.6) and flowable bulk-fill resin composite as an intermediate layer followed by a final layer of conventional resin composite (1,086.1 ± 391.2) were considered for the calculation.[14] In order to detect a difference of 40 Newton between the groups, using a 5% significance level and 80% power, the minimum sample size was 9 teeth and 18 cavities per group.

Selection and tooth preparation

Ninety sound exfoliated primary molars (forty-five first primary molars and

forty-five second primary molars) were obtained from a pool after the approval of the study protocol by the Ethics Committee of the Federal University of Rio Grande do Sul, Brazil (protocol number 4.573.690). The teeth were disinfected in 0.5% aqueous chloramine, and subsequently, they were individually fixed 1 mm below the cementoenamel junction in PVC rings embedded with self-curing acrylic resin[14] (JET Clássico, São Paulo, SP, Brazil) to facilitate the restorative procedures.

Cavity preparation

A trained operator performed all cavity preparations. Two cavities were prepared on occluso-mesial and occluso-distal surfaces of each tooth using a #2068 truncated cone diamond bur (Fava, São Paulo, SP, Brazil) at high rotation (KaVo, Joinvile, SC, Brazil) under constant cooling. Each cavity measured 4 mm cervico-occlusal height, 4 mm bucco-lingual/palatal width width and 2 mm disto-mesial width. Cavity dimensions were confirmed using a digital pachymeter (Absolute Digimatic, Mitutoyo, Tokyo, Japan).

Randomization

The widest bucco-lingual/palatal and disto-mesial dimensions of each tooth crown were measured and recorded using a digital caliper (Absolute Digimatic, Mitutoyo, Tokyo, Japan). The sum of these two dimensions was used in the distribution of specimens among the groups[15] considering five first primary molars and five second primary molars to ensure uniformity of tooth size in each group. Randomization was performed by a staff member who was not involved in any of the laboratory study phases. The teeth were assigned to nine experimental groups (n = 10) using a program to generate a random number list (Random.org—Randomness

and Integrity Services Ltd., Dublin, Ireland) according to the type of resin composite and the number of increments, as follows (Figure 1):

3M Oral Care™:

2 mm of flowable bulk-fill resin composite (Filtek Bulk Fill Flowable; 3M Oral Care™, St. Paul, MN, USA) as an intermediate layer + conventional resin composite (Filtek Z350 XT; 3M Oral Care™, St. Paul, MN, USA) inserted by incremental technique;

4 mm (single increment) of flowable bulk-fill resin composite (Filtek Bulk Fill Flowable; 3M Oral Care™, St. Paul, MN, USA);

Conventional resin composite (Filtek Z350 XT; 3M Oral Care™, St. Paul, MN, USA) inserted by incremental technique.

Shofu Inc.©:

2 mm of flowable bulk-fill resin composite (Beautifil Bulk Flowable; Shofu Inc.©, Kyoto, Honshu, Japan) as an intermediate layer + conventional resin composite (Beautifil II; Shofu Inc.©, Kyoto, Honshu, Japan) inserted by incremental technique;

4 mm (single increment) of flowable bulk-fill resin composite (Beautifil Bulk Flowable; Shofu Inc.©, Kyoto, Honshu, Japan);

Conventional resin composite (Beautifil II; Shofu Inc.©, Kyoto, Honshu, Japan) inserted by incremental technique.

FGM Dental Group ®:

2 mm of flowable bulk-fill resin composite (Opus Bulk Fill Flow APS; FGM Dental Group ®, Joinville, SC, Brazil) as an intermediate layer + conventional resin composite (Opallis; FGM Dental Group®, Joinville, SC, Brazil) inserted by incremental technique;

4 mm (single increment) of flowable bulk-fill resin composite (Opus Bulk Fill Flow APS; FGM Dental Group®, Joinville, SC, Brazil);

Conventional resin composite (Opallis; FGM Dental Group®, Joinville, SC, Brazil) inserted by incremental technique.

Restorative procedure

All restorations were performed by a single trained operator and the anatomical aspects were reproduced in all experimental groups. The materials used in this study are listed in Table 1. A Tofflemire matrix retainer (TDV, Pomerode, SC, Brazil) and metallic matrix band (Golgran, São Caetano do Sul, SP, Brazil) were applied to the tooth. The first restored cavity was the occluso-mesial, followed by the occluso-distal cavity. All cavities were treated with universal adhesive (Scotchbond Universal, 3M Oral Care™, St. Paul, MN, USA) in the self-etch mode according to the manufacturer's instructions. Restorative procedures were performed according to the allocation group following the manufacturer's instructions. The resin composite increments were measured with a millimeter probe (Golgran, São Caetano, SP, Brazil) and light curing with a light-emitting diode curing unit (Radii-cal, SDI, Victoria, AUS), and an irradiance of 1200 mW/cm^2 was checked using the built-in radiometer of the light curing unit. Polishing was performed using rubber points (Astropol, Ivoclar Vivadent, Schaan, Liechtenstein) one day after restoration.

Cariogenic challenge

All teeth were subjected to cariogenic challenge by pH cycling prior to fracture strength test. The demineralizing solution contained 2.2 mM $CaCl_2$, 2.2 mM NaH_2PO_4, and 50 mM acetic acid adjusted to pH of 4.8, and the remineralizing solution contained 1.5 mM $CaCl_2$, 0.9 mM NaH_2PO_4, and 0.15 M KCl adjusted to a pH of 7.0. Each tooth was cycled individually in 15mL of both solutions for 8h in the demineralizing solution and 16h in the remineralizing solution. This procedure was carried out for 14 days at room temperature without agitation, and the solutions were renewed daily.[16]

Fracture strength

Each restored tooth was numbered according to the randomization sequence to ensure blinding of the testing machine operator. The teeth were individually mounted in a universal testing machine (EZ-SX series, Shimadzu Corp., Kyoto, Japan) and subjected to a compressive axial load applied to the center of each occluso-proximal restoration, parallel to the long axis of the tooth, using a round-end steel device (6 mm in diameter) at a crosshead speed of 1 mm/min. A compressive force was applied until the specimen fractured and the machine automatically stopped operating. The load required to fracture the specimens was expressed in Newton (N).

Estimation of costs

Costs for each experimental group were estimated using a microcosting approach, accounting only for the resin composites used to restore the occluso-proximal cavities (payer's perspective). For this estimation, the operator registered the manufacturers of materials in a specific form. The average price from three

different Brazilian dental-material suppliers, calculated based on the results of a survey conducted in October 2023, was used to determine the material costs. Further, the quantities used during each restorative procedure were registered, determining the number of milligrams per increment available in each syringe. Then, the cost to perform each occluso-proximal restoration considering the different dental manufacturers was obtained. All costs were calculated in Brazilian Reals (R$) and converted to US Dollars (USD) using purchasing-power-parity values for October 2023 (1 USD = 5.03 R$).

Statistical analysis

The experimental unit in the current study was the tooth. Thus, the fracture strength values from each occluso-proximal cavity from the same tooth were averaged for statistical analysis. The fracture strength mean for every experimental group was expressed as the average of 10 tooth used for group.

The normal distribution of the data was confirmed using a Kolmogorov-Smirnov test. The fracture strength means were analyzed by one-way ANOVA and Tukey's *post-hoc* tests. Statistical significance was defined at $p < 0.05$. Statistical analysis was performed using Minitab-18 software (Minitab Inc., State College, PA, USA). The cost required to performer each occluso-proximal restoration considering the different dental manufacturers was analyzed descriptively.

Results

The fracture strength means and standard deviations for all experimental groups are shown in Table 2. No statistically significant difference on fracture strength was observed among experimental groups (p= 1.00).

The cost descriptions for all experimental groups are summarized in Table 3.

The costs of the Filtek Z350 XT, Beautifil II, and Opallis syringes were 56.27, 55.87 and 14.07 (USD), whereas the costs for Filtek Bulk Fill Flow, Beautifil Bulk Flowable, and Opus Bulk Fill Flow APS syringes were 36.75, 60.63 and 30.91 (USD), respectively. The cost of each occluso-proximal restoration ranged from 0.99 to 3.94 (USD). Regarding 3M Oral Care™ and Shofu Inc.© products, single-increment restorations using flowable bulk-fill resin composites resulted in lower costs (USD 2.38 and 3.38, respectively) compared to those of restorations using a conventional resin composite inserted using an incremental technique (USD 3.94 and 3.47, respectively). Costs were lower when materials from the FGM Dental Group® were used, and the least expensive restoration was achieved using conventional resin composite with the incremental technique (0.99 USD).

Discussion

This is the first study that investigated the fracture strength of occluso-proximal restorations in primary teeth using bulk-fill flowable resin composites (as an intermediate layer or entire cavity) in comparison with conventional resin composite (incremental technique) from three different manufacturers (3M Oral Care™, Shofu Inc©, and FGM Dental Group®). All restorative approaches demonstrated similar fracture strengths, independent of the dental manufacturers of the materials tested.

Laboratory tests are useful for evaluating new restorative techniques and materials before they are applied clinically.[17] In this study, the cavity size was standardized, and all preparations had cervical enamel because the absence of cervical enamel areas affects the performance of occluso-proximal resin-composite restorations.[18] Furthermore, all restorations were subjected to a cariogenic challenge to simulate the oral conditions.[19] Additionally, because bulk-fill low-viscosity resin

composites have variable compositions and filler contents, which can influence their ability to flow, elastic modulus, and capacity to compensate for the stresses generated during polymerization,[20] we considered it relevant to evaluate three different manufactures, widely used in clinical practice, of bulk-fill flowable resin composites through fracture strength test.

Simplification of operative procedures is desirable in pediatric dental practice. Bulk-fill materials allow agility and have good adaptation to the cavity walls in primary teeth.[21] Therefore, the fracture-strength results in this study are promising. The fracture strength of restorations with bulk-fill flowable resin composite as an intermediate layer followed by incremental insertion of conventional resin composite (3M Oral Care™ - 1,293 ± 535; Shofu Inc.© - 1,221 ± 533; FGM Dental Group® - 1,202 ± 364) was similar to that of conventional resin composite restorations (layering technique) (3M Oral Care™ - 1,289 ± 409; Shofu Inc.© - 1,200 ± 397; FGM Dental Group® - 1,201 ± 244). This restorative approach has been recommended for occluso-proximal cavities in permanent teeth based on laboratory[14] and clinical[22] outcomes.

Recently, the use of bulk-fill flowable resin composites alone (without a cover layer) has been suggested for restoring primary molars. The clinical performance of occluso-proximal restorations perfomed using flowable bulk-fill resin composite (Venus Bulk Fill, Heraeus Kulzer®, Hanau, Germany) is similar to that of compomer restorations in primary molars at the 1-year follow-up[12]. In the present study, the use of flowable bulk-fill resin composite entire cavity (3M Oral Care™ - 1,230 ± 539; Shofu Inc.© - 1,286 ± 438; FGM Dental Group® - 1,207 ± 429) resulted in a similar fracture strength to layering technique with conventional resin composite, which could suggest satisfactory clinical results such as those found for Venus Bulk Fill.

The use of flowable bulk-fill composites can provide several advantages in pediatric dentistry, such as reduction in treatment time due to the one-step application, ease of material insertion using an applicator tip, reduced risk of contamination, and application in children with a limited attention span.

It is important to highlight that all flowable bulk-fill resin composites tested have high filler content (Filtek Bulk Fill Flow; 3M Oral Care™ – 64.5% in weight and 42.5% in volume, Beautifil Bulk Flowable; Shofu Inc.© - 73% in weight and 60% in volume, and Opus Bulk Fill Flow APS; FGM Dental Group® - 68% in weight), similar to that of the flowable bulk-fill resin composite tested in the aforementioned clinical study[12] (Venus Bulk Fill; Heraeus Kulzer® – 65% in weight and 38% in volume). Although different types of flowable bulk-fill resin composites exhibit different physical and mechanical characteristics,[23] it has been demonstrated that Filtek Bulk Fill Flow and Beautifil Bulk Flowable presents adequate elastic modulus[23]. The elastic modulus is affected by the filler content: a higher filler content leads to a higher elastic modulus, which means that the material has a greater ability to resist deformation and can be used in stress-bearing areas.[24] This could explain the satisfactory fracture strengths of the flowable bulk-fill resin composites evaluated in this study.

Evaluation of the cost minimization of restorative materials through linear regression was planned a priori to investigate the relationships between the cost per occluso-proximal restoration and fracture strength, considering three different dental manufacturers (3M Oral Care™, Shofu Inc.©, and FGM Dental Group®). Because there was no statistically significant difference in the fracture strength, only a descriptive analysis was performed. The costs ranged from 0.99 to 3.94 (USD).

Overall, lower costs were obtained with materials from the FGM Dental

Group®. However, regarding this dental manufacturers, the use of conventional resin composite (incremental technique) (Opallis) resulted in lower costs (0.99 USD), and the use of flowable bulk-fill resin composite entire cavity (Opus Bulk Fill Flow APS) resulted in a more expensive restoration (2.00 USD). This result should be interpreted with caution, since the Opus Bulk Fill Flow APS (30.91 USD) syringe costs approximately twice as much as the Opallis (14.07 USD) syringe, probably because it presents the Advanced Polymerization System (APS), which enhances the polymerization components and allows a reduction in camphorquinone concentration, that according to the FGM Dental Group®, ensures a higher degree of conversion and longer handling time under ambient light compared to conventional systems based on camphorquinone.[25] Moreover, the incremental technique requires sculptability, demanding more chair-time[7], which may influence the child's behavior and in turn impact the restoration quality and overall cost of treatment.

Regarding materials from 3M Oral Care™ and Shofu Inc.©, the use of flowable bulk-fill resin composite entire cavity was the restorative strategy with a lower cost (Filtek Bulk Fill Flow - 2.38 USD and Beautifil Bulk Flowable - 3.38 USD), whereas the use of conventional resin composites with the incremental technique resulted in a higher cost (Z350 XT – 3.94 USD and Beautifil II – 3.47 USD). Compared to the FGM Dental Group®, 3M Oral Care™ and Shofu Inc.© sell resin composites with a smaller cost variation between versions (Z350 XT – 56.27 USD; Filtek Bulk Fill Flow – 36.65 and Beautifil II – 55.87; Beautifil Bulk Flowable – 60.63 USD). In addition to simplifying the technique, the use of flowable bulk-fill resin composites without a cover layer reduces the treatment cost, depending on the dental manufacturers.

The most expensive flowable bulk-fill resin composite in the Brazilian dental

market is from Shofu Inc.© (60.63 USD), probably because this material uses Giomer technology. This technology is characterized by the presence of surface-prereacted glass ionomer filler particles incorporated into the resin matrix that release ions (fluoride, sodium, silicate, aluminum, borate, and strontium) that provide biological functions.[26,27] In addition, the syringe contains 2.4 g of material, whereas the 3M Oral Care™ and FGM Dental Group® syringes contain 2 g, which may have also contributed to the higher cost.

Finally, the limitations of this in vitro study must be mentioned. These findings cannot be directly extrapolated to clinical practice and are limited to the materials tested. To perform the mechanical test, a compressive axial load parallel to the long axis was applied to each occluso-proximal restoration. For clinical application, lateral forces and fatigue loading should also be considered.[28] In addition, other costs related to treatment, such as the length of treatment, dentist fees, and equipment wear and tear, were not considered.

Conclusions

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

1- The use of flowable bulk-fill resin composites entire cavity does not jeopardize the fracture strength of occluso-proximal restorations in primary teeth.
2- The use of flowable bulk-fill resin composites entire cavity reduces the cost to perform occluso-proximal restorations, depending of the dental manufacturers.

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Table 1. Main composition and manufacturers' recommendations protocol of the materials used.

Material	Manufacturers' recommendations protocol	Quantity per package and syringe	Batch number	Main composition
Scotchbond Universal adhesive system (3M Oral Care™, St. Paul, MN, USA)	Self-etch mode Apply the adhesive for 20 s with vigorous agitation Gentle air thin for 5 s Light cure for 10 s	5 milliliter	2210200175	MDP Phosphate Monomer, Dimethacrylate resins, HEMA, Vitrebond Copolymer, Filler, Ethanol, Water, Initiators, Silane
Resin composite Z350 XT, A2B Shade (3M Oral Care™, St. Paul, MN, EUA)	Insert the resin composite in 2 mm increments Light cure for 20 s each increment	4 grams	2032400481	Bis-GMA, UDMA, TEGDMA, Bis-EMA, non-agglomerated/non-aggregated 20 nm silica filler, non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, and aggregated zirconia/silica cluster filler Fill content: 78.5% in weight and 63.3% in volume
Flowable resin composite Filtek Bulk Fill Flowable, A2 Shade (3M Oral Care™, St. Paul, MN, EUA)	Insert the flowable resin composite in 4 mm increments Light cure for 20 s each increment	2 grams	2201700296	Bis-GMA, UDMA, Bis-EMA, Procrylat resins, 0.1 to 5 μ ytterbium trifluoride filler and 0.01 to 3.5 μ zirconia/silica cluster filler Fill content: 64.5% in weight and 42.5% in volume
Resin composite Beautifil II, A20 Shade (Shofu Inc.©, Kyoto, Honshu, Japan)	Insert the resin composite in 2 mm increments Light cure for 20 s each increment	4.5 grams	052143	Bis-GMA, TEGDMA, aluminum oxide, silica, Aluminofluoro-borosilicate glass filler, pre-reacted glass-ionomer filler, camphoroquinone Fill content: 83.3% in weight and 68.8% in volume

Flowable resin composite Beautifil Bulk Flowable, Universal Shade (Shofu Inc.©, Kyoto, Honshu, Japan)	Insert the flowable resin composite in 4 mm increments Light cure for 20 s each increment	2.4 grams	082157	Bis-GMA, UDMA, Bis-MPEPP, TEGDMA, S-PRG filler based on fluoboroalumino-silicate glass Fill content: 73% in weight and 60% in volume
Resin composite Opallis, DA2 Shade (FGM Dental Group®, Joinville, SC, Brazil)	Insert the resin composite in 2 mm increments Light cure for 20 s each increment	4 grams	140921	Bis-GMA, BisEMA, TEGDMA, UDMA, camphorquinone, co-initiator and silane, silanized barium-aluminum silicate glass, pigments and silicas Fill content: 78.5 to 79.8% in weight and 57 to 58% in volume
Flowable resin composite Opus Bulk Fill Flow APS, A2 Shade (FGM Dental Group®, Joinville, SC, Brazil)	Insert the flowable resin composite in 4 mm increments Light cure for 40 s each increment	2 grams	210921	Bis-GMA, BisEMA, TEGDMA, UDMA, camphorquinone, antioxidant, co-initiator, photoinitiator, stabilizers and pigmentssilanized silica, stabilizers Fill content: 68% in weight and NR% in volume

MDP: 10-methacryloyloxydecyl-dihydrogen-phosphate; Bis-GMA: bisphenyl-glycidyl methacrylate; HEMA: 2-hydroxyethyl methacrylate; TEGDMA: triethylene glycol dimethacrylate; Bis-EMA: ethoxylated bisphenol-A dimethacrylate; UDMA: urethane dimethacrylate; Bis-MPEPP: bisphenol-A polyethoxy-dimethacrylate; EDMAB: ethyl 4-dimethyl aminobenzoate; S-PRG: surface prereacted glass ionomer. NR: Not Reported.

Table 2. The fracture strength means (Newton) and standard deviations.

Group	Fracture strength
Flowable bulk-fill resin composite as an intermediate layer – 3M Oral Care™	1,293 ± 535[A]
Flowable bulk-fill resin composite entire cavity – 3M Oral Care™	1,230 ± 539[A]
Conventional resin composite (incremental technique) – 3M Oral Care™	1,289 ± 409[A]
Flowable bulk-fill resin composite as an intermediate layer – Shofu Inc.©	1,221 ± 533[A]
Flowable bulk-fill resin composite entire cavity – Shofu Inc.©	1,286 ± 438[A]
Conventional resin composite (incremental technique) – Shofu Inc.©	1,200 ± 397[A]
Flowable bulk-fill resin composite as an intermediate layer – FGM Dental Group®	1,202 ± 364[A]
Flowable bulk-fill resin composite entire cavity – FGM Dental Group®	1,207 ± 429[A]
Conventional resin composite (incremental technique) – FGM Dental Group®	1,201 ± 244[A]

*Equal capital superscript letters indicate no statistically significance difference among groups ($p>0.05$).

Table 3. The cost description (USD) for each experimental group.

Group	Cost for each occluso-proximal restoration
Flowable bulk-fill resin composite as an intermediate layer – 3M Oral Care™	3.16
Flowable bulk-fill resin composite entire cavity – 3M Oral Care™	2.38
Conventional resin composite (incremental technique) – 3M Oral Care™	3.94
Flowable bulk-fill resin composite as an intermediate layer – Shofu Inc.©	3.38
Flowable bulk-fill resin composite entire cavity – Shofu Inc.©	3.28
Conventional resin composite (incremental technique) – Shofu Inc.©	3.47
Flowable bulk-fill resin composite as an intermediate layer – FGM Dental Group®	1.50
Flowable bulk-fill resin composite entire cavity – FGM Dental Group®	2.00
Conventional resin composite (incremental technique) – FGM Dental Group®	0.99

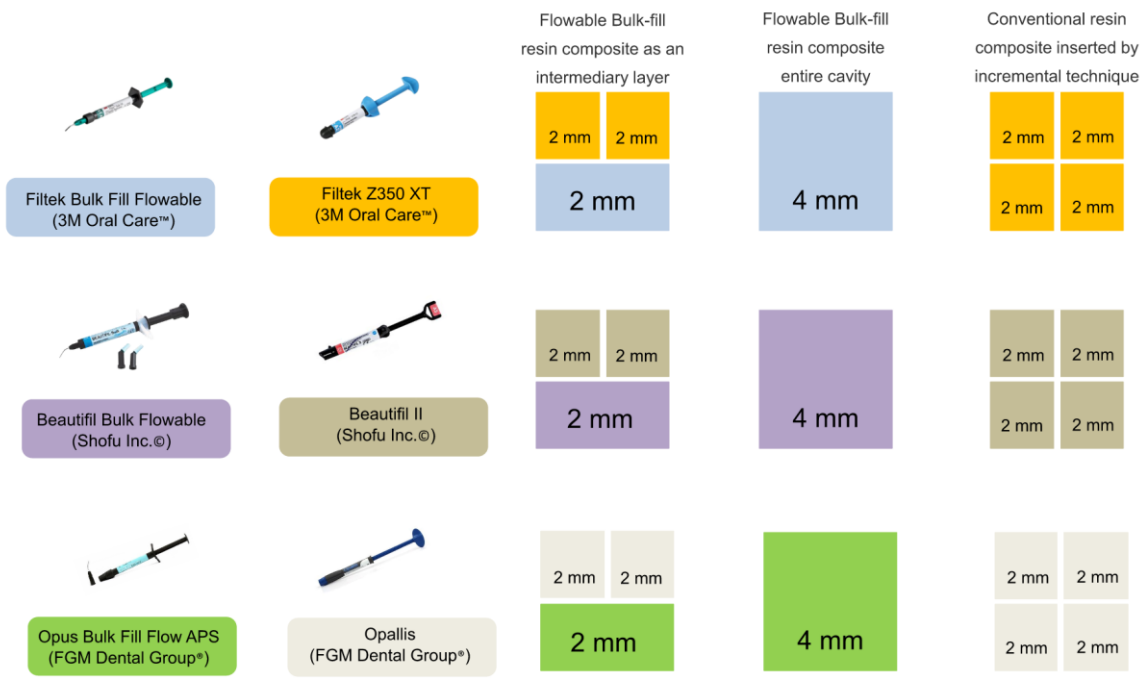

Figure 1. Illustration of the nine experimental groups.

Each color represents one material tested (Blue: Filtek Bulk Fill Flowable - 3M Oral Care™, Orange: Filtek Z350 XT - 3M Oral Care™, Violet: Beautifil Bulk Flowable - Shofu Inc.©, Brown: Beautifil II - Shofu Inc.©, Green: Opus Bulk Fill Flow APS - FGM Dental Group® and, Gray: Opallis - FGM Dental Group®).

Each colored square represents one resin composite increment (mm).

5 CONCLUSÃO

Com base nos resultados dos estudos contemplados na presente tese, pode-se concluir que:

O uso de resinas fluidas como camada intermediária em cavidades ocluso-proximais de dentes permanentes apresenta valores de resistência de união, resistência à fratura e falha restauradora similares à utilização de apenas resinas compostas convencionais. No entanto, a certeza da evidência é baixa.

Com base em valores de resistência à fratura, o uso de resina composta fluida como único material restaurador parece ser uma opção interessante para restaurar cavidades ocluso-proximais em molares decíduos, uma vez que este material é caracterizado pela fácil inserção e agilidade durante os procedimentos restauradores.

Além disso, os valores de resistência à fratura foram similares ao comparar resinas compostas fluidas *bulk-fill* em cavidades ocluso-proximais de molares decíduos de três diferentes fabricantes amplamente utilizados na prática clínica em Odontopediatria. Em alguns casos, dependendo do fabricante, a utilização de apenas resina composta fluida *bulk-fill* reduz o custo do procedimento restaurador.

Vale destacar que estudos clínicos randomizados que avaliem a sobrevida de restaurações ocluso-proximais de dentes decíduos com resinas compostas fluidas *bulk-fill* em comparação com restaurações realizadas com resinas compostas convencionais e/ou *bulk-fill* condensáveis (*full-body*) são necessários para o estabelecimento de um novo protocolo clínico e desfechos secundários relevantes como tempo clínico e custo-eficácia devem ser realizados.

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ANEXO A – Aprovação do Comitê de Ética em Pesquisa

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

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Uso de resinas fluidas em cavidades ocluso-proximais de dentes decíduos: estudo in vitro e avaliação de custo-minimização

Pesquisador: Tathiane Larissa Lenzi

Área Temática:

Versão: 2

CAAE: 42463121.3.0000.5347

Instituição Proponente: Faculdade de Odontologia

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 4.573.690

Apresentação do Projeto:

O presente projeto de pesquisa, intitulado "Uso de resinas fluidas em cavidades ocluso-proximais de dentes decíduos: estudo in vitro e avaliação de custo-minimização", é de responsabilidade da profa. Tathiane Larissa Lenzi, da FO-UFRGS, e conta com a participação dos alunos Carolina Lopes da Silva e Cleber Paradzinski Cavalheiro.

O resumo do projeto é apresentado como:

"O objetivo deste estudo será investigar o uso de resinas fluidas (convencional ou bulk-fill) na resistência à fratura de cavidades ocluso-proximais em dentes decíduos. Serão selecionados 240 segundos molares decíduos hígidos e duas cavidades ocluso-proximais (MO e DO) serão preparadas com uma ponta diamantada esférica #1090 em alta rotação, medindo 4mm de altura no sentido cérvico-oclusal, 3mm de largura no sentido vestíbulo-lingual e 2mm de profundidade no sentido mésio-distal. Em seguida, o sistema adesivo universal (Single Bond Universal, 3M ESPE) será utilizado no modo convencional. Os dentes serão envolvidos por uma matriz metálica do tipo Tofflemire, adaptada com um porta matriz de Tofflemire e, em seguida, incrementos de resina composta serão inseridos nas cavidades de acordo com seu respectivo grupo e fotoativados por 20 segundos. Os grupos de alocação serão: 2mm Filtek Bulk Fill Flow + Z350 XT, 4mm Filtek Bulk Fill

Endereço: Av. Paulo Gama, 110 - Sala 311 do Prédio Anexo 1 da Reitoria - Campus Centro
Bairro: Farroupilha **CEP:** 90.040-060
UF: RS **Município:** PORTO ALEGRE
Telefone: (51)3308-3738 **Fax:** (51)3308-4085 **E-mail:** etica@propesq.ufrgs.br

Flow + Z350 XT, 4mm Filtek Bulk Fill Flow, 2mm Z350 XT Flow + Z350 XT, 4mm Z350 XT Flow + Z350 XT, 4mm Z350 XT Flow, 3mm Z350 XT Flow + Z350 XT, Z350 XT, 2mm Beautifil Bulk Flowable + Beautifil II, 4mm Beautifil Bulk Flowable + Beautifil II, 4mm
Beautifil Bulk Flowable, Beautifil II, 2mm Opus Bulk Fill Flow + Opallis, 4mm Opus Bulk Fill Flow + Opallis, 4mm Opus Bulk Fill Flow e Opallis. Todos os dentes serão armazenados em água destilada a 37o C por 24 horas. Metade da amostra será submetida ao teste de resistência à fratura imediatamente e a outra metade submetida a envelhecimento através de 5000 ciclos de termociclagem entre 5ºC –55ºC. Os dados obtidos serão submetidos à Análise de Variância ou teste de Kruskal-Wallis e teste de Tukey, dependendo da distribuição da normalidade.
Também será determinado o custo-minimização do material através de regressão linear, mensurando a relação entre custo por incremento do material e suas propriedades."

Local de realização: Disciplina de Clínica Infanto-Juvenil e Laboratório de Materiais Dentários (LAMAD), ambos na Faculdade de Odontologia da UFRGS.

Objetivo da Pesquisa:
Objetivo Geral: O presente estudo terá como objetivo investigar o uso de resinas fluidas (convencional ou bulk-fill) na resistência à fratura de cavidades ocluso-proximais em dentes decíduos.

Objetivos Específicos:
- Comparar a resistência à fratura de resinas compostas fluidas convencionais e bulk-fill;
- Comparar a resistência à fratura de diferentes espessuras de resina fluida desde a utilização como camada intermediária até o preenchimento total da cavidade ocluso-proximal;
- Comparar a resistência à fratura de resinas fluidas de diferentes marcas comerciais;
- Investigar o custo-minimização dos diferentes materiais testados.

Avaliação dos Riscos e Benefícios:
Riscos:
No formulário da P, TCLE e projeto (pág 7) os riscos são apontados como:
"Possível contaminação da amostra doada, destruição da amostra por uso de máquinas de testes, manipulação dos dentes alterando sua estrutura original por instrumentos e materiais odontológicos e quebra confidencialidade no uso de dados, esta última minimizada pela codificação dos dentes para posterior utilização.".

Benefícios:

Também no formulário PB, TCLE e projeto (pág 7) os benefícios são descritos como: "Benefícios indiretos relacionados à contribuição para o avanço de pesquisas e desenvolvimento do conhecimento sobre materiais dentários em dentes decíduos.".

Comentários e Considerações sobre a Pesquisa:

O presente projeto de pesquisa refere-se a uma investigação in vitro, com uso de 240 dentes molares decíduos extraídos/esfoliados, afim de investigar a resistência a fratura de 2 resinas fluídas utilizadas no preenchimento de cavidades ocluso-proximais.

Assim, o envolvimento de seres humanos no estudo se refere à cessão de dentes. Os dentes decíduos hígidos (esfoliados ou extraídos por motivos terapêuticos) a serem utilizados no estudo serão coletados a partir da cessão dos mesmos por pacientes com dentição decídua ou mista (de 4 a 12 anos) atendidos na disciplina de Clínica Infanto-Juvenil da FO-UFRGS. Todos os participantes serão convidados verbalmente a cederem os dentes decíduos extraídos/esfoliados. Os pacientes que concordarem com a cessão assinarão Termo de Assentimento Livre e Esclarecido (TALE), e os responsáveis o Termo de Consentimento Livre e Esclarecido (TCLE) bem como um Termo de Cessão de Material Biológico.

"O tamanho da amostra foi calculado através do software disponível no endereço eletrônico www.sealedenvelope.com. A resistência à fratura para o uso da resina composta convencional utilizada pela técnica incremental em cavidades ocluso-proximais de dentes permanentes foi considerada para o cálculo. De acordo com a literatura, a resistência a fratura apresenta médias de 49.02 Newton e a diferença de ±7.65 no desvio padrão entre os grupos analisados (resina composta convencional versus resina fluida + resina composta convencional)24. Afim de

detectar diferença entre os grupos, foi estabelecido uma diferença de 10 Newton entre os valores. Usando a significância de 5% e o poder de 80, o valor mínimo para a amostra seria de 10 dentes (20 cavidades) por grupo. Assim, para cada subprojeto, 20 cavidades serão utilizadas para cada grupo experimental. Nesse sentido, incluindo os dentes que serão utilizados no piloto, serão necessários 240 dentes para contemplar os 3 subprojetos.". (projeto, pág 7-8).

Demais procedimentos do estudo, serão conduzidos laboratorialmente, com os dentes cedidos, e sem envolvimento de participantes. Carta de anuência do Laboratório de Materiais Dentários

(LAMAD) foi anexada ao projeto.
A pesquisadora responsável é professora atuante na disciplina na qual os pacientes serão abordados e convidados para a cessão dos dentes decíduos.

Considerações sobre os Termos de apresentação obrigatória:
Os seguintes termos foram apresentados:
- Projeto de pesquisa;
- Termo de Consentimento Livre e Esclarecido (TCLE) aos pais/responsáveis;
- Termo de Assentimento Livre e Esclarecido (TALE);
- Carta de anuência do LAMAD;
- Cronograma: o estudo foi previsto para ser desenvolvido ao longo de 12 meses, considerando as devidas aprovações éticas. A previsão de coleta dos dentes decíduos é 01/03/2021.
- Orçamento: informados como no valor de R$ 6.410,40. "Os materiais serão custeados pela pesquisadora responsável."(projeto, pág 15).

Conclusões ou Pendências e Lista de Inadequações:
Na análise da versão 1 do projeto de pesquisa, as seguintes pendências foram observadas e necessitam de atenção:

Pendência 1) Ajustes no TCLE aos pais/responsáveis:
- Remover a informação sobre o Programa de Pós-Graduação em Odontologia e o telefone de contato com o mesmo – removido;
- Deve ser escrito na forma de convite - ajustado;
- Adequar todo texto de forma a deixar claro que o participante é o filho(a)/menor de idade, e não o pai/responsável (p.ex.: "Caso aceite participar..." deve ser adequado para "Caso você concorde com a participação do seu filho(a)") - ajustado;
- Mencionar, claramente, os objetivos do estudo, e os riscos (p.ex: "Os objetivos da pesquisa são testar laboratorialmente 2 marcas comerciais de resinas fluídas em dentes de leite, e, para tanto, estamos convidado o seu filho(a) a ceder o dente decíduo esfoliado/extraído para ser utilizado na presente pesquisa. A participação no estudo envolverá apenas a cessão do dente."; "Os riscos decorrentes da participação de seu filho(a) na pesquisa são mínimos, e relacionados a possível contaminação do dente, e sua destruição (...)".) - ajustado;
- Incluir a informação sobre o benefício indireto ao participante - ajustado;
- Mencionar que os dados do estudo ficarão armazenados por pelo menos 5 anos, sob

responsabilidade da pesquisadora principal - ajustado;
- Informar que os dentes cedidos serao utilizados somente na presente pesquisa. Caso haja possibilidade de uso futuro, o consentimento será novamente solicitado ao responsável e participante - ajustado;
- Substituir o termo “doação” por “cessão”, uma vez que o dente é de posse do participante, o qual pode remover seu consentimento a qualquer momento, sem precisar justificar - ajustado;
- O campo para coleta do RG do responsável deve ser removido - removido.
Resposta V2: Todas as alterações solicitadas foram realizadas em acordo. PENDÊNCIA ATENDIDA.

Pendência 2) O termo de doação de material biológico pode ser suprimido, uma vez que as informações sobre o estudo já estão presentes no TCLE/TALE, e que o estudo irá formar um biorrepositório. Caso seja mantido, os mesmos ajustes sugeridos na Pendência 1 deverão ser realizados no referido termo.
Resposta V2: O Termo de Cessão de Material Biológico foi suprimido do projeto. PENDÊNCIA ATENDIDA.

Pendência 3) Ajustes no TALE:
- Remover a informação sobre o Programa de Pós-Graduação em Odontologia e o telefone de contato com o mesmo - removido;
- Adequar texto sobre riscos, conforme aqueles apresentados nos demais documentos do projeto e linguagem de fácil entendimento à faixa etária (atualmente, consta: “Enquanto seu dente doado estiver incluído na pesquisa
ele pode ser testado junto com outros dentes doados e pode sofrer alterações na sua forma, tamanho
ou dimensões em decorrência do uso dos materiais que usamos para tratar os dentes.”) – ajustado;
- Mencionar, brevemente, os demais aspectos do assentimento conforme o TCLE: a participação envolve a cessão do dente esfoliado/extraaído; ausência de ônus financeiro ou valor a receber; possibilidade de retirar o consentimento a qualquer momento, sem prejuízo ao atendimento, etc – informações adicionadas.
Resposta V2: Todas as alterações no TALE foram realizadas em acordo. PENDÊNCIA ATENDIDA.

Todas as pendências foram atendidas, estando a presente versão do projeto (versão 2) em acordo com as resoluções CNS/MS nos. 466/2012 e 510/2016. Pela aprovação.

Os pesquisadores deverão encaminhar ao CEP relatórios parcial e final do projeto.

Considerações Finais a critério do CEP:
APROVADO.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1692193.pdf	19/02/2021 15:03:54		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_novo.docx	19/02/2021 15:03:19	Tathiane Larissa Lenzi	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TALE_novo.docx	19/02/2021 15:03:11	Tathiane Larissa Lenzi	Aceito
Outros	Resposta_CEP.docx	19/02/2021 15:03:01	Tathiane Larissa Lenzi	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_novo.docx	19/02/2021 14:45:19	Tathiane Larissa Lenzi	Aceito
Folha de Rosto	Folha_de_rosto.pdf	19/02/2021 14:42:28	Tathiane Larissa Lenzi	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

Continuação do Parecer: 4.573.690

PORTO ALEGRE, 04 de Março de 2021

Assinado por:
José Artur Bogo Chies
(Coordenador(a))

Endereço: Av. Paulo Gama, 110 - Sala 311 do Prédio Anexo 1 da Reitoria - Campus Centro
Bairro: Farroupilha **CEP:** 90.040-060
UF: RS **Município:** PORTO ALEGRE
Telefone: (51)3308-3738 **Fax:** (51)3308-4085 **E-mail:** etica@propesq.ufrgs.br