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DESEMPENHO DE UMA RESINA *BULK-FILL* EM RESTAURAÇÕES CLASSE II EM MOLARES DECÍDUOS – ENSAIO CLÍNICO RANDOMIZADO

Santa Maria, RS
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Dissertação apresentada ao Curso de Mestrado do Programa de Pós-Graduação em Ciências Odontológicas, Área de Concentração em Odontologia, ênfase em Odontopediatria, da Universidade Federal de Santa Maria (UFSM, RS), como requisito parcial para obtenção do grau de **Mestre em Ciências Odontológicas.**

Orientadora: Profª. Drª. Rachel de Oliveira Rocha

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RESUMO

DESEMPENHO DE UMA RESINA *BULK-FILL* EM RESTAURAÇÕES CLASSE II EM MOLARES DECÍDUOS – ENSAIO CLÍNICO RANDOMIZADO

AUTORA: Larissa D'Olanda Gindri

ORIENTADORA: Rachel de Oliveira Rocha

Este trabalho é composto por dois artigos acerca do uso de resina *bulk-fill* em lesões ocluso-proximais de molares decíduos, resultantes de um ensaio clínico randomizado. A utilização de resina *bulk-fill* em incrementos de até 4 mm de espessura, proporciona que restaurações em dentes decíduos sejam feitas em incremento único. A redução do número de passos, do tempo restaurador e a praticidade clínica são vantagens desejadas, especialmente na Odontopediatria. É necessário que tais vantagens atribuídas a resina *bulk-fill* sejam comprovadas e que seu desempenho clínico seja avaliado ao longo do tempo. Este estudo teve como objetivo avaliar o desempenho clínico de restaurações ocluso-proximais em dentes decíduos realizadas com duas resinas compostas - resina *bulk-fill* e convencional (técnica incremental) após 6 meses de acompanhamento. Além disso, comparou-se o tempo necessário para a realização das restaurações (desfecho secundário). Cento e quarenta lesões de cárie ocluso-proximais em molares decíduos em 65 crianças com idades entre 5 e 9 anos, foram selecionadas e divididas aleatoriamente em dois grupos: grupo teste - resina *bulk-fill* (Filtek^{TM} Bulk Fill; 3M ESPE, St. Paul, MN, USA) e grupo controle - resina composta convencional (Filtek Z350 XT; 3M ESPE, St. Paul, MN, USA). As restaurações foram realizadas por um único operador treinado, sob anestesia local, isolamento absoluto e remoção seletiva do tecido cariado (dentina firme). As cavidades foram mensuradas quanto a sua profundidade e largura (sentido vestíbulo-lingual), o número de incrementos foi mensurado e o tempo restaurador cronometrado (Artigo I). Um avaliador treinado, calibrado e cego quanto ao material restaurador utilizado, avaliou as restaurações segundo os critérios da Federação Dentária Internacional (FDI) após 3 (baseline) e 6 meses (Artigo II). Os escores obtidos foram analisados considerando o sucesso das restaurações após 6 meses (escores 4 e 5 considerados como falha) e o sucesso incluindo a possibilidade de reparo das restaurações (escore 5 considerado como falha). Os dados relativos ao sucesso, tempo e número de incrementos foram analisados com o teste U de Mann-Whitney. Para todas as análises foi considerado o nível de significância de 5%. Os resultados obtidos mostraram que a resina *bulk-fill* reduziu em aproximadamente 30% o tempo restaurador em comparação a resina composta convencional ($p < 0.0001$). O número de incrementos foi significativamente inferior quando a resina *bulk-fill* foi utilizada (1,1 incremento) ($p<0.0001$) comparado ao uso da resina convencional (2,9 incrementos). A sobrevida da resina *bulk-fill* (94,3%) foi similar ao da resina composta convencional (95,7%) ($p>0.05$) mesmo quando foi considerada a possiblidade de reparo (97,1% de sucesso para as duas resinas compostas; $p>0.05$). A maioria das restaurações recebeu escores que variaram do 1 ao 3 (sucesso clínico). A principal razão de falha (71,4%) foi associada ao parâmetro funcional - adaptação marginal. De acordo com os resultados obtidos, considerando o desempenho clínico e tempo restaurador, é lícito concluir que a resina *bulk-fill* avaliada pode substituir a resina composta convencional na restauração de molares decíduos.

Palavras chave: Clínico, Classe II, Dente decíduo, FDI, Sobrevida.

ABSTRACT

PERFORMANCE OF A *BULK-FILL* COMPOSITE IN CLASS II CAVITIES IN PRIMARY MOLARS - RANDOMIZED CLINICAL TRIAL

AUTHOR: Larissa D'Olanda Gindri

ADVISOR: Rachel de Oliveira Rocha

This study consists of two studies on the use of *bulk-fill* resin in occluso-proximal lesions of primary molars. The use of *bulk-fill* resin in increments up to 4 mm thick, provides that restorations on primary teeth can be made with a single increment. Reduction on the number of steps, restorative time, and technical simplification are desired advantages, especially in Pediatric Dentistry. It is necessary that such advantages attributed to *bulk-fill* resin are proven and that its clinical performance is evaluated longitudinally. The aim of this study was to compare the clinical behavior of bulk fill resin and conventional resin (incrementally applied) in occluso-proximal cavities in deciduous molars after 6-month. Moreover, the time spent to restore the occluso-proximal cavities (secondary outcome). One hundred forty occluso-proximal cavities in deciduous molars in 65 participants (mean age of 6.7 $\pm$ 1.5) were randomized in two groups, according to composite resin: *bulk-fill* (Filtek^{TM} Bulk Fill; 3M ESPE, St. Paul, MN, USA) and conventional composite resin (Filtek Z350 XT; 3M ESPE, St. Paul, MN, USA). All restorations were made by a single trained operator, under local anesthesia, rubber dam isolation, and the removal of carious tissue followed parameters of selective carious removal to firm dentin. The cavities were measured for their depth and, buccolingual distance, and the restorative time was registered (data used in article I). A trained, calibrated, and blind examiner evaluated the restorations according to the International Dental Federation (IDF) criteria within 3 (baseline) and 6 months after restorative procedures (data used in article II). The obtained scores were analyzed considering restoration success (scores 4 and 5 as failure) or success and repair (only score 5 as failure). All data were analyzed with the Mann-Whitney U test. A significance level of 5% was considered in all analysis. The results showed that *bulk-fill* resin reduces restorative time by approximately 30% compared to conventional composite resin ($p < 0.0001$). Moreover, while most of the restorations that used *bulk-fill* resin received a single increment, the restorations of the control group required on average, 3 increments ($p < 0.0001$). Thus, the reduction of clinical time and the number of steps that *bulk-fill* resin offers in occluso-proximal lesions of deciduous molars has been demonstrated. The *bulk-fill* resin demonstrated satisfactory and similar clinical performance to the conventional composite resin. Most restorations received scores ranging from 1 to 3 (clinical success). The success rate of the *bulk-fill* resin was 94.3%, and the conventional resin was 95.7% ($p = 0.7$). Seven restorations failed in the evaluation of 6 months, 4 of *bulk-fill* resin and 3 of conventional resin. Marginal adaptation was the main cause of clinical failure (5 restorations). According to the results, *bulk-fill* resin presented similar clinical behavior to the conventional resin. It is an option to restore occluso-proximal lesions of deciduous molars.

Keywords: Clinical, Class II, Deciduous teeth, FDI, Survival.

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1. INTRODUÇÃO GERAL

O conceito de Odontologia Minimamente Invasiva trouxe novas condutas para o tratamento restaurador dos dentes decíduos. A remoção seletiva de tecido cariado passou a ser utilizada como rotina e as resinas compostas tornaram-se a principal escolha para restaurar molares decíduos acometidos por cárie (RICKETTS et al., 2013; SANTOS et al., 2016).

No entanto, a necessidade de inserção em incrementos de até 2 mm de espessura, na tentativa de reduzir os efeitos da contração de polimerização (ABBAS et al., 2013; CAMPOS et., 2014), em especial as tensões geradas nesse processo, implica em maior tempo clínico e maior sensibilidade técnica. Esse fator é crítico no atendimento infantil, principalmente no caso de crianças não-colaboradoras, e pode influenciar negativamente na obtenção de restaurações adequadas e ainda, comprometer seu desempenho clínico ao longo do tempo (CHISINI et al., 2018). Ainda assim, as resinas compostas têm apresentado as menores taxas de falhas anuais em restaurações em molares decíduos (CHISINI et al., 2018; PINTO et al., 2014) comparadas aos outros materiais disponíveis.

As resinas *bulk-fill* foram desenvolvidas com a proposta de menor contração de polimerização, dispensando a inserção pela técnica incremental. As alterações em sua formulação e o aumento da translucidez (FRONZA et al., 2015), permitem a inserção em incrementos de até 4 ou 5 mm de profundidade (FLURY et al., 2014), com a possibilidade da realização de restaurações em incremento único. Com isso, o procedimento restaurador é simplificado e as desvantagens decorrentes do número de passos operatórios inerentes a técnica incremental, como a formação de espaços e o risco de contaminação entre as camadas de resina são minimizadas (KUMAGAI et al., 2015). Ademais, o tempo clínico restaurador pode ser reduzido (GÜLER et al., 2014; DE PINHO et al., 2017) e assim, a utilização das resinas *bulk-fill* pode ser vantajosa em Odontopediatria.

O desempenho clínico dessas resinas parece ser similar ao das resinas convencionais quando empregadas na restauração de dentes permanentes (VELOSO et al., 2018) ou decíduos (ÖTER et al., 2018; EHLERS et al., 2019). No entanto, os dados disponíveis para dentes decíduos provêm de apenas dois ensaios clínicos randomizados, com 12 meses de acompanhamento, Öter et al. (2018), avaliou apenas restaurações envolvendo superfícies oclusais (ÖTER et al., 2018) e Ehlers et al. (2019) comparou apenas a resina *bulk-fill* flow ao compômero (EHLERS et al., 2019). Assim, ainda são necessários estudos que assegurem as vantagens das resinas *bulk-fill* para uso em dentes decíduos, dado que a escolha de técnicas e

materiais para o atendimento infantil deve considerar as diferenças estruturais e morfológicas dos dentes decíduos - menor conteúdo mineral, menor espessura de esmalte, câmaras pulpares mais volumosas, distância mésio-distal maior que a cérvico-incisal e superfícies de contato amplas e achatadas (OLIVEIRA et al., 2010), além da necessidade de atendimento rápido, devido a menor tolerância inerente a faixa etária, sem que isso comprometa a qualidade e a técnica.

Considerando que as resinas *bulk-fill* possibilitam a simplificação do protocolo restaurador e redução do tempo clínico, desejáveis especialmente em Odontopediatria e que, restaurações envolvendo mais de uma superfície (ocluso-proximais), apresentam maior risco de falha comparadas a restaurações envolvendo apenas uma superfície (SANTOS et al., 2010; OPDAM et al., 2014), justifica-se a realização do presente estudo. Este trabalho foi realizado em dois artigos, o primeiro com o objetivo de comparar o tempo clínico e o número de incrementos necessários na realização das restaurações ocluso-proximais em molares decíduos e o segundo com o objetivo de avaliar o desempenho clínico da resina resina *bulk-fill*.

2.1 ARTIGO I – IS THE CLINICAL TIME SHORTER WHEN A *BULK-FILL* RESIN IS USED TO RESTORE OCCLUSO-PROXIMAL CAVITIES IN PRIMARY MOLARS? PRELIMINARY FINDINGS OF A RANDOMIZED CONTROLLED CLINICAL TRIAL

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TITLE PAGE

Article type: Short-communication

Is the clinical time shorter when a *bulk-fill* resin is used to restore occluso-proximal cavities in primary molars? Preliminary findings of a randomized controlled clinical trial

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LDG and IPC carried out the clinical trial; TTF carried out the restorations evaluation; LDG and ROR conceived and planned the clinical trial. All authors provided critical feedback and helped shape the research, analysis and manuscript.

Running title: Clinical time using *bulk-fill* resin

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ABSTRACT

Background. Shorter clinical time is a desire in pediatric dentistry. *Bulk-fill* resins could be a good option in restoration in primary molars.

Aims and Methods. This short communication aims to present the preliminary findings regarding the clinical time required to restore occluso-proximal cavities in primary molars using a *bulk-fill* and a conventional composite resin.

Results. *Bulk-fill* resin composite required less restorative clinical time than conventional composite to filled occluso-proximal cavities in primary molars ($p<0.0001$) as fewer number of increments used ($p<0.0001$).

Conclusion. *Bulk-fill* composite resin is indicated in the restoration occluso-proximal lesions of primary molars, when the aim is to reduce the clinical time and the number of steps.

Introduction

Bulk-fill resin composites were introduced on the market as a faster and easier material to restore occlusal and occluso-proximal cavities, enabling restorations in a single increment (up to 4- or 5-mm thick increments)[1] with lower polymerization induced shrinkage stress[2] and technique sensitivity[3] than conventional layering resin composites. These characteristics are ideally suited in Paediatric Dentistry, particularly in case of young or uncooperative children. Although the clinical performance and the longevity of *bulk-fill* resins seem to be similar to traditional layering composites in permanent teeth, as pointed in previous clinical trials[4-6], there is no information about the reduction of the clinical time required to restore primary molars using *bulk-fill* resins. The question "is the clinical time shorter when a *bulk-fill* resin composite is used to restore occluso-proximal cavities in deciduous molars?" remains unclear. Thus, this short communication aims to present the preliminary findings regarding the clinical time required to restore occluso-proximal cavities in primary molars using a *bulk-fill* and a conventional resin composite.

Materials and Methods

This study is part of an ongoing double-blind, randomized controlled clinical trial, parallel groups, for assessing the performance of a *bulk-fill* resin composite in class II cavities in primary molars (Local Research Board, CAAE 81118217.7.0000.5346; Brazilian Clinical Trials Registry (ReBEC), RBR-329pyp). It was conducted at the Paediatric Clinic of the School of Dentistry, Federal University of Santa Maria, after obtaining guardian's and children's agreement and signed terms of informed and consent (appendices A and B). March to November 2018, 140 primary molars with occluso-proximal lesions were selected from 65 healthy children aged 5 to 9 years. The sample size was calculated for the primary outcome (restoration survival), based on previously published data[4], considering an $\alpha = 0.05$; $\beta = 80\%$;

adding 20% for possible loss of follow-up, 140 resin composite restoration were necessary, 70 for each group. All teeth were detected by visual inspection (dentinal lesions) and interproximal radiography, with no clinical and radiographic signs or symptoms of pulp involvement, and be able to receive a rubber dam.

Two groups were defined according to the restorative material: a conventional resin composite (Filtek Z350 XT resin; 3M ESPE, St. Paul, MN, USA), and a *bulk-fill* resin composite (Filtek^{TM} Bulk Fill, 3M ESPE, St. Paul, MN, USA). The allocation of the teeth to each group was determined by a randomized sequence generated in an online tool (Sealed Envelope; https://www.sealedenvelope.com). The concealment of randomization was maintained with the use of opaque and sealed envelopes. Randomization and concealment were performed by a researcher who was not related to restorative procedures (ROR). An assistant opened the envelops at the time of restoration.

Clinical procedures were performed by a single trained investigator following the same protocol: local anesthesia using 2% lidocaine and 1:100.000 epinephrine, rubber dam isolation, and selective caries removal (dentin excavator and round burs in low speed)[7]. Cavities dimensions (depth and buccal-lingual distance) were measured with a WHO model millimeter probe. All teeth received the same adhesive protocol, according to the manufacturer's instructions; after the adhesive protocol, the assistant opened the envelope that determined the composite resin used.The cavities were filled according to the designed group resin composite, and restorations received occlusal adjustments (3118F fine grain diamond bur; KG Sorensen, São Paulo, SP, Brazil) and polishing (polishing tips; KG Sorensen, Cotia, São Paulo, Brazil). The restorative steps are described in Table 1. The clinical restorative time was considered the time spent from the opening of the allocation envelope until the end of the resin composite light polymerization and was measured with a digital timer by an assistant, who also registered the number of increments of composite used in each cavity.

Descriptive statistics for cavities dimensions (depth and buccal-lingual distance), the number of increments and clinical restorative time were calculated and are presented as the mean and standard deviation. The differences in restorative clinical time, cavities dimensions (depth and buccal-lingual distance), and the number of increments between the *bulk-fill* and conventional resin composite groups were compared using Mann-Whitney U-test, as the data was not normality distributed (Anderson-Darling test, $p<0.005$). The possible correlations of restorative clinical time and the number of increments or cavities dimensions were determined by Spearman correlation test. The probability level for statistical significance was $\alpha = 0.05$. Statistical analyses were carried out using Minitab Express software (version 1.5.2, Minitab Inc., State College, PA, USA).

Results

A total of one hundred and forty restorations were filled in deciduous molars, seventy with conventional composite resin and seventy with *bulk-fill* resin. Table 2 presents the results for clinical restorative time, number of increments and cavity dimensions for *bulk-fill* and conventional resin composites. *Bulk-fill* resin composite required less restorative clinical time than conventional composite to filled occluso-proximal cavities in primary molars ($p<0.0001$) as fewer number of increments used ($p<0.0001$). No statistically significant differences were found between the composites concerning the cavity dimensions ($p=0.113$, and $p=0.255$ to depth and buccal-lingual distance, respectively). Spearman correlation reveals that restorative clinical time has a moderate correlation with cavities depth ($rho= 0.41$; $p<0.0001$); buccal-lingual distance ($rho = 0.33$; $p<0.0001$), and number of increments ($rho = 0.57$; $p<0.0001$).

Discussion

The results of this study revealed that *bulk-fill* resin composite required shorter

restorative clinical time ($p < 0.0001$) than conventional composite. Thus, the clinical restorative time using a *bulk-fill* resin was almost 30% shorter, corresponding to approximately 2 minutes faster. Moreover, the number of increments used in *bulk-fill* restorations was also lower than layering restorations (conventional composites). This is the first clinical study that investigated the clinical time and the number of increments required for filling occluso-proximal cavities in primary molars using a *bulk-fill* resin composite. Previous *in vitro* studies[8,9] also found that the use of a *bulk-fill* resin composite reduced the restorative time compared to conventional resin incrementally placed. However, the restorative time may be different in real clinical situations, as the present study, unlike those found in laboratory conditions, but even so, the reduction of he restorative clinical time seems to be an advantage of *bulk-fill* resins.

A moderate correlation could be found between the size of the cavity (depth and labio-lingual distance) and the number of increments with the restorative clinical time. Considering that the dimensions of the cavities were similar in both experimental groups, shorter clinical time using *bulk-fill* resins must undoubtedly be a consequence of easier and faster placement in a single increment, in almost all cavities. Only four of 70 cavities required more than one increment, due to their depth greater than 4 mm.

According to recent published systematic reviews of clinical studies[10,11], *bulk-fill* resin composites could be an alternative for direct restorations in posterior teeth, as statistically significant differences in the failure rate between *bulk-fill* and conventional resin restorations were not found. Therefore, the choice of *bulk-fill* resins over conventional ones can be made considering factors such as cost-benefit, operator's ability and reduced working time. The evidence that emerged from this study may support this assumption. The significant reduction of restorative clinical time when a *bulk-fill* resin was used to filled occluso-proximal cavities in primary molars represents an advantage over conventional resins, especially in pediatric clinic practice, where reduced chair time is essential for better child cooperation.

Why this paper is important to paediatric dentistry?

This study shows that a *bulk-fill* resin composite reduced the restorative clinical time compared to a conventional resin.

This study enhances the evidence for the *bulk-fill* resins and recommends it as a straightforward and faster option to fill occluso-proximal cavities in primary molars.

Conflict of interest: The authors declare no conflict of interest.

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

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

* According manufacturers.
Abbreviations: bis-GMA, bisphenol-A diglycidyl dimethacrylate; UDMA, urethane dimethacrylate; TEGDMA, triethylene glycol dimethacrylate; bis-EMA, ethoxylated bisphenol A dimethacrylate.

Table 2. Means and standard deviations considering restorative time, number of increments and other variables for filling occluso-proximal cavities in primary molars.

	Bulk-fill resin composite (Filtek™ Bulk Fill)	Conventional resin composite (Filtek Z350 XT)	Significance Mann-Whitney U-test
Clinical restorative time**	**4.4 (2.2)**	**6.1 (3.2)**	**p<0.0001**
Number of increments	**1.1 (0.4)**	**2.9 (1.0)**	**p<0.0001**
Depth*	2.4 (0.9)	2.7 (0.9)	p=0.1133
Buccal-lingual distance*	2.9 (0.9)	2.7 (0.9)	p=0.255

*mm
** minutes

2.2 ARTIGO II – SIX-MONTH FOLLOW-UP OF OCCLUSO-PROXIMAL *BULK-FILL* COMPOSITE RESTORATIONS IN PRIMARY MOLARS: RANDOMIZED CLINICAL TRIAL

Artigo formatado conforme as diretrizes para autores do periódico International Journal of Paediatric Dentistry (ANEXO 1).

TITLE PAGE

Article type: Randomize clinical trial

Six-month follow-up of occluso-proximal *bulk-fill* composite restorations in primary molars: randomized clinical trial

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LDG and IPC carried out the clinical trial; TTF carried out the restorations evaluation; LDG and ROR conceived and planned the clinical trial. All authors provided critical feedback and helped shape the research, analysis and manuscript.

Running title: Performance of *bulk-fill* resin in deciduous molars.

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ABSTRACT

Background. *Bulk-fill* composite resins can be used in a single increment (4-5 mm), allowing the reduction of the number of restorative steps and the technical sensitivity, which are especially desirable in paediatric dentistry.

Aim: This double-blind, randomized clinical trial aimed to compare the clinical behavior of bulk fill composite resin and conventional composite resin in occluso-proximal cavities in primary molars after 6-month.

Design. One hundred forty occluso-proximal cavities in primary molars in 65 participants (mean age of 6.7 ± 1.5) were randomized in two groups, according to composite resin: *bulk-fill* and conventional composite resin. The restorations were evaluated at baseline and after 6-month, by a single experienced and calibrated examiner using the FDI criteria. Statistical analyses were performed using the Mann-Whitney U test (α=0.05).

Results. After the 6-month follow-up, the success rate of the *bulk-fill* resin was similar to conventional resin (94.3% and 95.7%, respectively) ($p>0.05$). Seven restorations failed after six months, 4 of *bulk-fill* and 3 of conventional composite resin. Marginal adaptation was the main reason for clinical failure (5 restorations).

Conclusion. *Bulk-fill* resin presented similar clinical behavior to the conventional resin. It is an option to restore occluso-proximal lesions of deciduous molars.

Key-words: FDI criteria, survival, class II, primary teeth.

Introduction

The approach of minimally invasive dentistry has brought new approaches to the restorative treatment of deciduous teeth. The composite resins have become very popular in posterior restorations of deciduous teeth due to their main advantages as conservative preparations, aesthetic characteristics, and their good clinical performance[1-5]. However, it is recommended that the conventional resin composites be applied in the incremental technique to obtain an adequate depth of cure, minimize the polymerization shrinkage stress and its consequences, making their use very sensitive and time-consuming technique[6,7].

Bulk-fill composite resins have been designed as a simplified option to incremental technique. The incorporation of reactive photoinitiators, higher translucency allowing the light dissipation through the material[8], and monomers that reduce the polymerization shrinkage[9], enable their application in increments of 4-5 mm thick[10,11], and thus, restorations can be built-up with a single increment. The simplification of the operative procedures by reducing the number of steps also decreases the technical sensitivity and the risk of voids between composite resin layers[12,13]. The simplified filling technique can also lead to reduced clinical time[13,14], one of the most claimed advantages of the *bulk-fill* composite resins, that is particularly interesting for Paediatric Dentistry, mainly for young and non-collaborating children.

The clinical performance of *bulk-fill* composite resins has been described as comparable to conventional resins in posterior restorations[15], both in Class I and II[16-21] although the failure rate is higher for restorations including more than one surface[15], the same was observed for conventional resin restorations[22,23]. The reasons for restoration failures, pointed in a recent systematic review comparing *bulk-fill* and conventional composite resins, were secondary caries, tooth and resin fractures, post-operative sensitivity, anatomical shape and poor marginal adaptation, marginal discoloration, and retention[15].

The longevity of restorations is related to the operative technique and restorative

material, patients' and cavity characteristics[19], and, as well as the adhesive materials, often behave differently in deciduous and permanent teeth[24], because of their structural and morphological differences[25]. In this respect, the described results are concerning *bulk-fill* composite resin restorations in permanent teeth, and only two clinical studies so far have examined the use of *bulk-fill* composites as restorations in deciduous teeth. Nevertheless, Öter et al. (2019) only included Class I restorations[26] and Ehlers et al. (2019) compared only a flowable *bulk-fill* composite to compomer[27]. Even so, in both studies[26-27], *bulk-fill* composite resins also performed successfully in deciduous teeth, which encourages further studies to confirm the good performance of the *bulk-fill* composite resins.

Therefore, the aim of this double-blind, randomized clinical trial was to compare the clinical behavior of a *bulk-fill* and a conventional resin composites in occluso-proximal cavities in deciduous molars. The null hypothesis tested was that the composite resin does not influence on the performance of occluso-proximal restorations in deciduous teeth.

Materials and Methods

Ethical approval

The Ethics Committee of the Federal University of Santa Maria (UFSM; Santa Maria, Brazil) reviewed and approved this study 81118217.7.0000.5346). All participants (children) and their caregivers were informed about the objectives and procedures of the study and agreed to participate in the study by signing a statement of informed consent. The study was registered in the Brazilian Clinical Trials Registry (REBEC; RBR-329pyp) and is reported following the recommendations of the CONSORT statement[28].

Study design

This was a double-blind (evaluator and participants), randomized controlled trial with two groups (*bulk-fill* composite resin - intervention; and conventional composite resin - control)

with an equal allocation ratio.

Settings and eligibility criteria for participants

The study was conducted from March to November 2018, in a University setting at the pediatric dentistry clinic of the School of Dentistry from Federal University of Santa Maria, Rio Grande do Sul, Brazil.

Children who attended care in the clinic of the local university and met the eligibility criteria were invited to participate in the study. The eligibility criteria were as follows: children with (1) age ranging from five to nine years, (2) at least one deciduous molar with occluso-proximal caries lesión involved dentin, (3) absence of signs of irreversible pulp pathologies or necrosis, and (4) absence of previous restoration in the selected tooth. Children with an adverse medical history, not able to receive rubber dam isolation and a not good likelihood of availability for follow-up were not included in this study. One trained clinician carried out the clinical and preoperative bitewing radiographic assessments.

Sample size calculation, randomization, and allocation concealment

The success rates of a previous study[16] that compared one flowable *bulk-fill* and one conventional composite resin was considered as a parameter for the sample size calculation. A sample size calculation was performed using a freely available online website (www.sealedenvelope.com) with the parameters: α = 5%, power of 80%, considering the outcome binary (success/failure) and equivalence study, with a limit of 10%. Considering the probability of losing about 20% participant, the minimal sample sized was 70 restorations in each group.

The randomization was also performed using the website (www.sealedenvelope.com) by a researcher who was not involved in any experimental procedures. The randomization

sequence was generated and transferred into opaque, sealed, and numbered envelopes. The group assignment sequence remained unknown until the moment of the restorative intervention. Cavities were randomized in two groups, according to restorative material (*bulk-fill* composite resin or conventional composite resin) by a randomization list defining the order of the composite resin placement.

Operatory procedures

The restorative procedures were performed by a single operator, trained previously by one experienced professor. Fourteen restorations (10% of the sample) that were not included in the study were performed before to the start of the study to train the operator regarding differences in the use of conventional and *bulk-fill* composite resin. The materials used in this study are detailed in Table 1. All materials were used according to the manufacturer's instructions.

All participants had the tooth anesthetized (lidocaine 2% with epinephrine 1:100:000), and received the rubber dam isolation, including at least one teeth adjacent to the occluso-proximal caries lesion. The cavity design was restricted to the selective caries removal to firm dentine, following coloration and texture parameters[29] with a slow-speed round bur in a low-speed hand-piece and hand instruments. If necessary, the access to carious dentine was obtained using a spherical diamond bur mounted in a high-speed hand-piece. A metallic matrix was placed with wooden wedges and the cavities were cleaned by thoroughly rinsing with water. All teeth received the same adhesive protocol. The total-etch technique was performed with a 37% phosphoric acid gel (Condac 37, FGM, Joinville, SC, Brazil) for 15 seconds, rinsed for 20 seconds, and gently air-dried. The adhesive system (ScothUniversal, 3M ESPE, St. Paul, MN, USA) was applied actively to the entire surface for 20 seconds. Direct a gentle air stream over the adhesive for 5 seconds and curing for 10 seconds (Table 1). Curing the adhesive and

composite resins was performed with a light-curing unit (QHL 75 Curing Light, Dentsply Sirona, Milford, DE, USA) with an intensity of 650 mW/mm^2.

The operator was not blinded to the composite resin group. However, only at this point, the assistant defined the composite resin to be used by opening the allocation envelope.

In the groups assigned for conventional composite resin (control group), the cavities were filled with 2-mm increments, using an oblique layering technique, each increment was curing for 20 seconds individually. In the experimental group (*bulk-fill* composite resin), cavities were filled with one increment up to 4 mm, the increment was cured for 60 seconds. If the cavity exceeded 4 mm depth, cavities were filled with two increments, cured individually for the same time. After occlusal adjustments and contouring (fine grain diamond burs #3118F; KG Sorensen, São Paulo, SP, Brazil) final polishing was performed with polishing tips (KG Sorensen, Cotia, São Paulo, Brazil).

Evaluation

The restorations were evaluated after 3 months (baseline) and 6 months after placement by a single trained and calibrated examiner, blinded for composite resin groups. The training was based on the presentation and discussion of the clinical criteria for evaluation of restorations according to the FDI criteria[30], illustrated with photographic images of restorations. Afterwards, the examiner evaluated at two times intervals of 7 days, a random sequence of restoration images and the assigned scores were compared to those assigned by a reference examiner ('gold standard'). Cohen's kappa test demonstrated a kappa value <0.85 intra-examiner.

Before evaluation, the patients were submitted to visible plaque index and gingival bleeding index evaluations and professional plaque removal. The restorations were evaluated according to FDI (World Dental Federation) criteria, modified for the study (Table 2 and Table

3). The following items were considered: 1) functional properties: fracture of restorative material and restoration retention, and marginal adaptation; 2) aesthetic properties: surface gloss/luster and roughness, surface and marginal staining, and aesthetic anatomical form; 3) biological properties: recurrence of caries. These items were ranked according to the scores: 1) clinically very good; 2) clinically good; 3) clinically satisfactory; 4) clinically unsatisfactory, and 5) clinically poor [30].

Statistical analysis

The primary outcome was the restoration failure according to the resin composite after 6-month follow-up. The restorations with FDI scores 4 and 5 (clinically unsatisfactory and clinically poor, respectively) were considered as failure in the survival analysis and only the score 5 (clinically poor) were considered as failure in the repair analysis. The characteristics of the restorations were described by descriptive statistics using cumulative relative frequency distribution of the FDI scores. The experimental and control groups were compared with the Mann-Whitney U test (α=0.05). Analyses were performed using Minitab 18 statistical software (Minitab Inc., State College, PA, USA) with a significance level of 5%.

Results

A total of 140 restorations were placed in 65 children (39 boys - 26 girls) with a mean age of 6.7 $\pm$ 1.5 (SD) presenting a decayed, missing, and filled primary teeth (dmft) index mean of 5.8 $\pm$ 2.4. The demographic and clinical characteristics are detailed in Table 4. All restorations were evaluated at the baseline and after 6 months (Figure 1).

The majority of restorations presented FDI scores among 0 to 3, classified as a success after 6 months, regardless of the composite resin (Table 5). The survival rate of restorations at the end of 6 months was 95.7% and 94.3% for conventional and *bulk-fill* composite resins,

respectively (Table 5). The Mann-Whitney U test indicated no significant differences between the success/failure for the evaluated composite resins ($p = 0.7$). In the repair analysis, the success was identical for two resin composite (97.1%). The distribution of FDI scores according to the evaluated parameters are described in Table 6 and Table 7. Seven restorations failed after 6 months; 4 from *bulk-fill* composite resin group and 3 from conventional composite resin group. Irrespective of the composite resin, failures were observed in the functional parameter of the FDI criteria, marginal adaptation, fracture of restorative material and restoration retention.

Marginal Adaptation

The main reason for failure after 6-month follow-up was marginal adaptation, which was verified in 5 failed restorations, three of *bulk-fill* and two of conventional composite resin groups. Among the three failed *bulk-fill* restorations, two could be repaired (score 4) and one should be replaced. In conventional composite resin restorations, one could be repaired, and one should be replaced.

Fracture of restorative material and restoration retention

One restoration failed by fracture of the composite resin and one was lost after 6 months, in conventional composite resin group and *bulk-fill* composite resin group, respectively. Both restorations were classified as clinically poor (score 5), and need to be replaced.

Other Parameters

The aesthetic parameters - surface gloss/luster and roughness, surface and marginal staining, and aesthetic anatomical form; and biological properties - recurrence of caries were

considered as clinical success in all restorations.

Discussion

This study is the first to compare high-viscosity *bulk-fill* composite resin in occluso-proximal restorations of deciduous teeth to conventional composite resin. This study is also notable for the use of selective caries removal in all restorations and the use of the FDI criterion for evaluation. In the present study, similar clinical behavior was found for a *bulk-fill* and a conventional resin composite in occluso-proximal restorations in deciduous molars. The null hypothesis of no difference was therefore accepted.

The results of the present study are in line with previous clinical studies published in permanent[16-21] and deciduous teeth[26,27]. However, in the previous studies that evaluated *bulk-fill* resins in deciduous molars, two meaningful differences need to be clarified. While Öter et al. (2019) confirm that *bulk-fill* composite resin can be used similarly to the conventional resin to restore deciduous teeth, considering only Class I cavities[26], Ehlers et al. (2019) compared a flowable *bulk-fill* resin to a compomer in Class II cavities of deciduous teeth[27].

Even with a short follow-up period (6 months), three *bulk-fill* restorations with marginal defects were considered clinically poor (failure) as one *bulk-fill* restorations that were fractured or lost. While conventional resin composite presented better results than low polymerization shrinkage composite resin, including *bulk-fill* resins, considering marginal adaptation after 12-months[31], no differences were found between groups in the present study. Moreover, two of the three failed restorations were classified as clinically unsatisfactory, but that could be repaired. A longer follow-up period would be required to corroborate this evidence.

Differently from previous studies, which related secondary caries as the main reason for failures of *bulk-fill* restorations in permanent teeth[16]. Although secondary caries is associated with high caries risk of patients[32] and Class II restorations, as the children participant of this

study local failures as contamination with saliva during the restorative procedures were also related to secondary caries[19]. Similarly, the use of rubber dam isolation, as in the present study, may lead to a lower failure rate of the restorations, compared to cotton roll usage[33]. All participants received oral hygiene instruction and polish at a baseline and 6-month follow-up, being motivated for oral health care, and thus, no restoration failed because of caries recurrence.

The clinical procedures employed in this study were determined to control possible factors influencing the restorative outcome. Local anesthesia and rubber dam were used in all restorations to avoid contamination by oral fluids, and reduce anxiety levels[34], minimizing the influence of the child's behavior. In the present study, all cavities were subjected to selective removal of carious tissue, eliminating the risk of endodontic intervention, as previously suggested[1,35]. Even though selective carious tissue removal may increase the risk of experiencing restoration failure in deciduous teeth[36], only one failure by retention loss was found in the present study, can still not associated with it. Actually, in the present study, the restorations were performed after selective carious tissue removal to firm, not to soft dentine and it was shown that the selective removal of carious tissue did not influence the biomechanical behavior of class II *bulk-fill* resin restorations[37].

Due to its high translucency[11,38], the main disadvantage attributed to *bulk-fill* resins is aesthetics. Our results showed, however, no esthetic impairment of the restorations, regardless of composite resin. The use of single increment to restore Class II cavities seems to have favored the anatomical form compared to the incremental technique, whereas 51 *bulk-fill* restorations were classified as clinically excellent (score 1), 39 restorations performed with conventional resin were considered as excellent. It is worth mentioning that 6 *bulk-fill* restorations worsened their anatomical form (from score 1 to scores 2 or 3), while only two restorations had their scores changed. Even so, no restoration was considered unsatisfactory regarding the surface gloss/luster and roughness, surface and marginal staining, aesthetic

anatomical form or recurrence of caries.

The decision to use the FDI criteria, despite the limited number of studies using it to evaluate restorations in deciduous teeth[27,39,40] was because it is more detailed and more sensitive than the USPHS criteria[41]. Moreover, using FDI criteria, it was possible to consider a restoration classified as clinically unacceptable (score 4) as repairable[30], preserving tooth structure, increasing restoration longevity, and reducing treatment costs[42]. In our study, three of the seven failed restorations could be repaired and not replaced.

The short follow-up period (6-month) represents the main limitation of this study. Long periods of observation, more than 10 years for restorations in permanent teeth, are essential[15], however, considering deciduous teeth, clinical failures could be observed from 6 to 12 months[3,43]. Also, maintaining the participants over longer periods is hugely challenging, even in a university setting, as in the present study.

Based on the 6-month clinical data, it can be concluded that the evaluated *bulk-fill* composite resin presented successfully clinical performance, similar to conventional composite resin, in occluso-proximal restorations in deciduous teeth.

Why this paper is important to paediatric dentistry?

This study shows that the *bulk-fill* composite resin restorations performed similarly to conventional resin, but offers practicality and easy clinical management.

This study shows that a *bulk-fill* resin composite is an option as a restorative material to be used in deciduous teeth.

Conflict of interest: The authors declare no conflict of interest.

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Table 1. Resin composites and adhesive system used in the study.

Material	Manufacturer	Composition
Condac 37	FGM, Joinvile, SC, Brazil.	Phosphoric acid 37%, thickener, pigment, deionized water.
Scotchbond Universal Adhesive*	3M ESPE, St. Paul, MN, USA.	MDP, HEMA, dimethacrylate resins, methacrylate-modified polyalkenoic acid copolymer ethanol, water, filler, initiator, sílica.
Filtek Z350 XT**	3M ESPE, St. Paul, MN, USA.	UDMA, Bis-GMA, Bis-EMA,TEGDMA, zirconia, silica.
Filtek^{tm} Bulk Fill	3M ESPE, St. Paul, MN, USA.	Bis-GMA, UDMA, Bis-EMA, procrylate resins Ytterbium trifluoride, zirconia, silica.

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

Table 2. World Dental Federation (FDI) Criteria Used for Clinical Evaluation: Aesthetic properties.

Aesthetic properties	1. Surface luster	2. Surface staining	3. Marginal staining	4. Anatomic form
1. Clinically excellent / very good	1.1. Luster comparable to enamel.	2.1. No surface staining.	3.1. No marginal staining.	4.1. Form is ideal.
2. Clinically good	1.2. Slightly dull, not noticeable from speaking distance.	2.2. Minor staining, easily removable.	3.2. Minor staining, easily removable.	4.2. Form is only slightly affected.
3. Clinically sufficient / satisfactory	1.3. Dull surface but acceptable if covered with film of saliva.	2.3. Moderate surface staining, also present on other teeth, not aesthetically unacceptable.	3.3. Moderate marginal staining, also present on other teeth, not aesthetically unacceptable.	4.3. Form differs but is not aesthetically displeasing.
4. Clinically unsatisfactory (but repairable)	1.4. Rough surface, cannot be masked by saliva film, simple polishing is not sufficient. Further intervention necessary.	2.4. Surface staining present on the restoration and is unacceptable; major intervention necessary for improvement	3.4. Marginal staining present on the restoration and is unacceptable; major intervention necessary for improvement	4.4. Form is affected and unacceptable aesthetically. Intervention (correction) necessary.
5. Clinically poor (replacement necessary)	1.5. Quite rough, unacceptable plaque retentive surface.	2.5. Severe staining and/or subsurface staining (generalized or localized); not accessible for intervention).	3.5. Severe staining and/or subsurface staining (generalized or localized); not accessible for intervention).	4.5. Form is completely unsatisfactory and/or lost. Repair not feasible/reasonable, replacement needed.

Table 3. World Dental Federation (FDI) Criteria Used for Clinical Evaluation: Functional and Biological properties.

Functional properties	5. Fractures and retention	6. Marginal adaptation	**Biological properties**	7. Recurrence of caries
1. Clinically excellent /very good	5.1. Restoration retained, no fractures/ cracks.	6.1. Harmonious outline, no gaps, no discoloration.	1. Clinically excellent / very good.	8.1. No secondary or primary caries.
2. Clinically good	5.2. Small hairline crack.	6.2. Small marginal fracture removable by polishing.	2. Clinically good.	8.2. Very small and localized demineralization.
3. Clinically sufficient / satisfactory	5.3. Two or more or larger hairline cracks and/or chipping (not affecting the marginal integrity or proximal contact).	6.3. Gap < 150 µm not removable 6.3.2. Several small enamel or dentin Fractures.	3. Clinically sufficient / satisfactory.	8.3. Larger areas of demineralisation but only preventive measures necessary (dentine not exposed).
4. Clinically unsatisfactory (but repairable)	5.4. Chipping fractures which damage marginal quality or proximal contacts; bulk fractures with or without partial loss (less than half of the restoration).	6.4. Gap > 250 µm or dentine/base exposed. chip fracture damaging margins. Notable enamel or dentine wall fracture.	4. Clinically unsatisfactory (but repairable).	8.4. Caries with cavitation. Localized and accessible and can be repaired.
5. Clinically poor (replacement necessary)	5.5. (Partial or complete) loss of restoration.	6.5. Filling is loose but in situ.	5. Clinically poor (replacement necessary).	8.5. Deep secondary caries or exposed dentine that is not accessible for repair of restoration.

Table 4. Status of the restorations according to clinical and demographic characteristics. (n=140 restorations).

Variables	**n (%) of restorations**	**Success (%)**	**Failure (%)**
Sex			
Boys	89 (64)	86 (96.6)	3 (3.4)
Girls	51 (36)	47 (92.1)	4 (7.9)
Teeth			
First molar	75 (54)	71 (94.6)	4 (5.4)
Second molar	65 (46)	62 (95.4)	3 (4.6)
Arch			
Upper	66 (47.1)	62 (93.9)	4 (6.1)
Lower	74 (52.9)	71 (95.9)	3 (4.1)
IPV			
>20%	105 (75)	101 (96.1)	4 (3.9)
<20%	35 (25)	32 (91.4)	3 (8.6)
ISG			
>20%	124 (88.6)	119 (96)	5 (4)
<20%	16 (11.4)	14 (87.5)	2 (2.5)

Table 5. Survival and repair analysis of conventional and *bulk-fill* composite resin restorations after 6-month follow-up.

	Survival analysis[#]		**Repair analysis[&]**	
Resin composite	Success (%)	Failure (%)	Success (%)	Failure (%)
Conventional	67 (95.7)	3 (4.3)	68 (97.1)	2 (2.9)
Bulk-fill	66 (94.3)	4 (5.7)	68 (97.1)	2 (2.9)

[*]No statistical difference between groups ($p>0.05$).
[#]Survival analysis - FDI scores 4 and 5 considered as failure.
[&]Repair analysis - only FDI score 5 considered as failure.

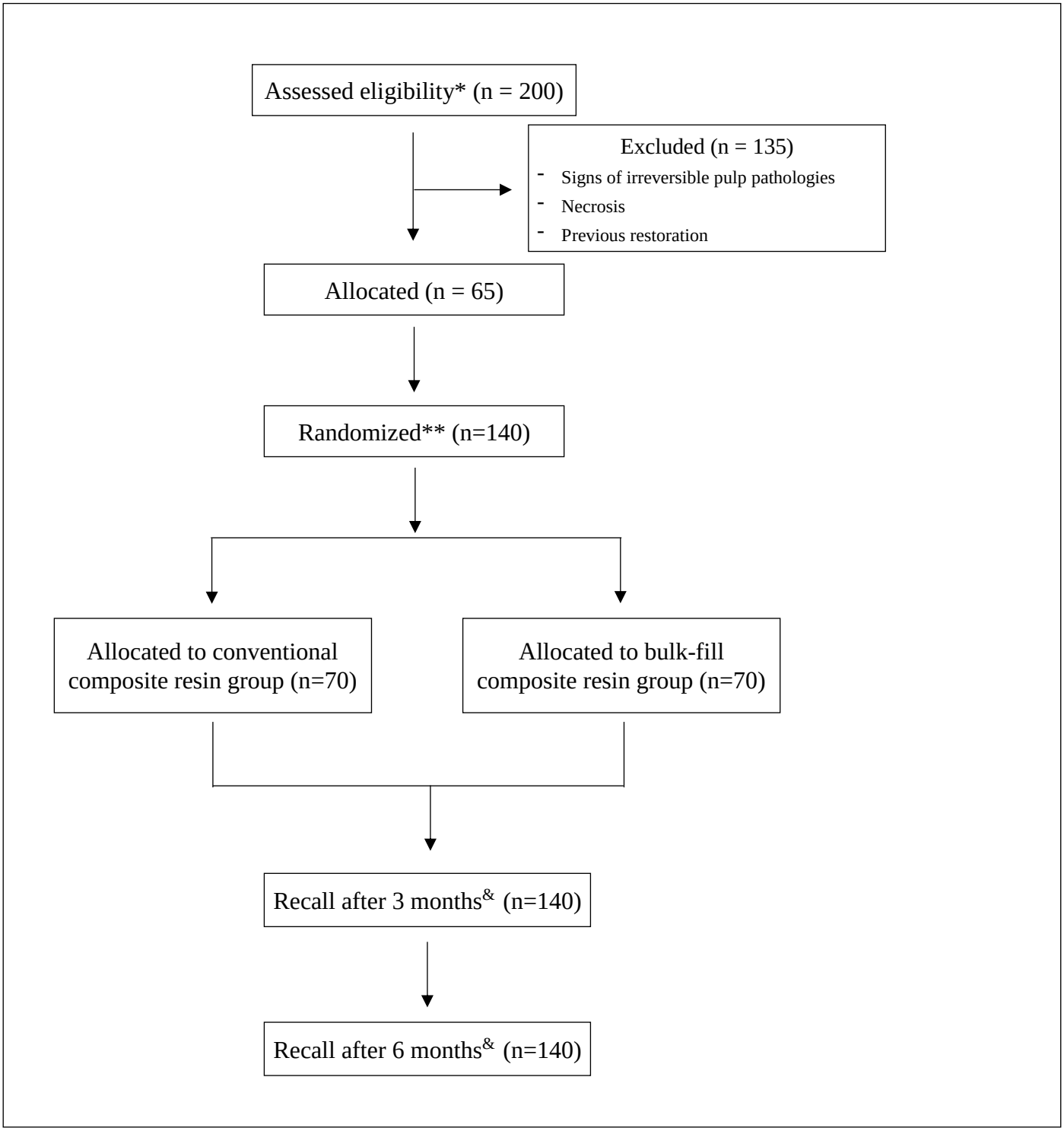
Table 6. Distribution of restorations according composite resin and scores of aesthetic parameter of the FDI criteria.

		Baseline		6 months	
		Composite resin	*bulk-fill* resin	Composite resin	*bulk-fill* resin
SURFACE GLOSS	1	32	40	29	37
	2	38	30	38	29
	3	-	-	-	-
	4	-	-	-	-
	5	-	-	-	-
SURFACE STAINING	1	70	68	67	64
	2	-	2	-	2
	3	-	-	-	-
	4	-	-	-	-
	5	-	-	-	-
MARGINAL STAINING	1	69	69	63	63
	2	1	1	4	3
	3	-	-	-	-
	4	-	-	-	-
	5	-	-	-	-
ANATOMICAL FORM	1	39	51	34	44
	2	29	17	31	19
	3	2	2	2	3
	4	-	-	-	-
	5	-	-	-	-

Table 7. Distribution of restorations according composite resin and scores of functional and biological parameters of the FDI criteria.

		Baseline		6 months	
		Composite resin	*bulk-fill* resin	Composite resin	*bulk-fill* resin
FRACTURE/ RETENTION	1	70	69	64	64
	2	-	1	3	1
	3	-	-	-	1
	4	-	-	-	-
	5	-	-	1	1
MARGINAL ADAPTATION	1	66	67	65	61
	2	3	3	2	4
	3	1	-	-	1
	4	-	-	1	2
	5	-	-	1	1
RECURRENCE OF CARIES	1	70	68	67	66
	2	-	1	-	2
	3	-	1	-	1
	4	-	-	-	-
	5	-	-	-	-

Figure 1. Flow chart of the study design.



* Participants
** Teeth
& All teeth were evaluated at recall

3. DISCUSSÃO

A realização deste ensaio clínico randomizado resultou na redação de dois artigos que avaliaram aspectos clinicamente relevantes ao uso de uma resina composta *bulk-fill* na restauração de lesões de cárie em molares decíduos. No primeiro artigo, observou-se significativa redução do tempo clínico restaurador e do número de incrementos quando restaurações de lesões ocluso-proximais em molares decíduos foram realizadas com a resina *bulk-fill*. Esses achados são pioneiros em confirmar duas das principais vantagens atribuídas as resinas *bulk-fill* - simplificação técnica e menor tempo clínico, tendo em vista que dados prévios são resultantes de estudos laboratoriais (GULER et al., 2014; DE PINHO et al., 2017). Já no segundo artigo, mesmo que os resultados tenham sido obtidos após limitado tempo de acompanhamento, foi possível verificar desempenho clínico satisfatório e similar das restaurações de resina *bulk-fill* comparado ao da resina composta convencional. Evidentemente que tempos de acompanhamento mais longos são necessários para confirmar esses achados, dado que o período de 6 meses pode não ser suficiente para identificar diferenças entre as resinas. No entanto, foi possível observar que, mesmo após 6 meses de acompanhamento, falhas na adaptação marginal ocorreram nas restaurações pertencentes aos dois grupos experimentais.

Considerando os resultados deste estudo, somados aos já existentes na literatura, pode-se sugerir o uso das resinas *bulk-fill* como uma opção para a restauração de molares decíduos quando se deseja restaurações mais rápidas e redução do número de passos.

4. CONCLUSÃO

Com base nos resultados obtidos neste trabalho, considerando as limitações metodológicas, é válido concluir que:

O uso da resina composta *bulk-fill* na restauração de cavidades ocluso-proximais em molares decíduos é capaz de reduzir o tempo clínico e o número de incrementos de material necessários para a restauração, comparado ao emprego de resina composta convencional.

O comportamento clínico da resina composta *bulk-fill* é similar ao da convencional na restauração de cavidades ocluso-proximais em molares decíduos, após 6 meses de acompanhamento.

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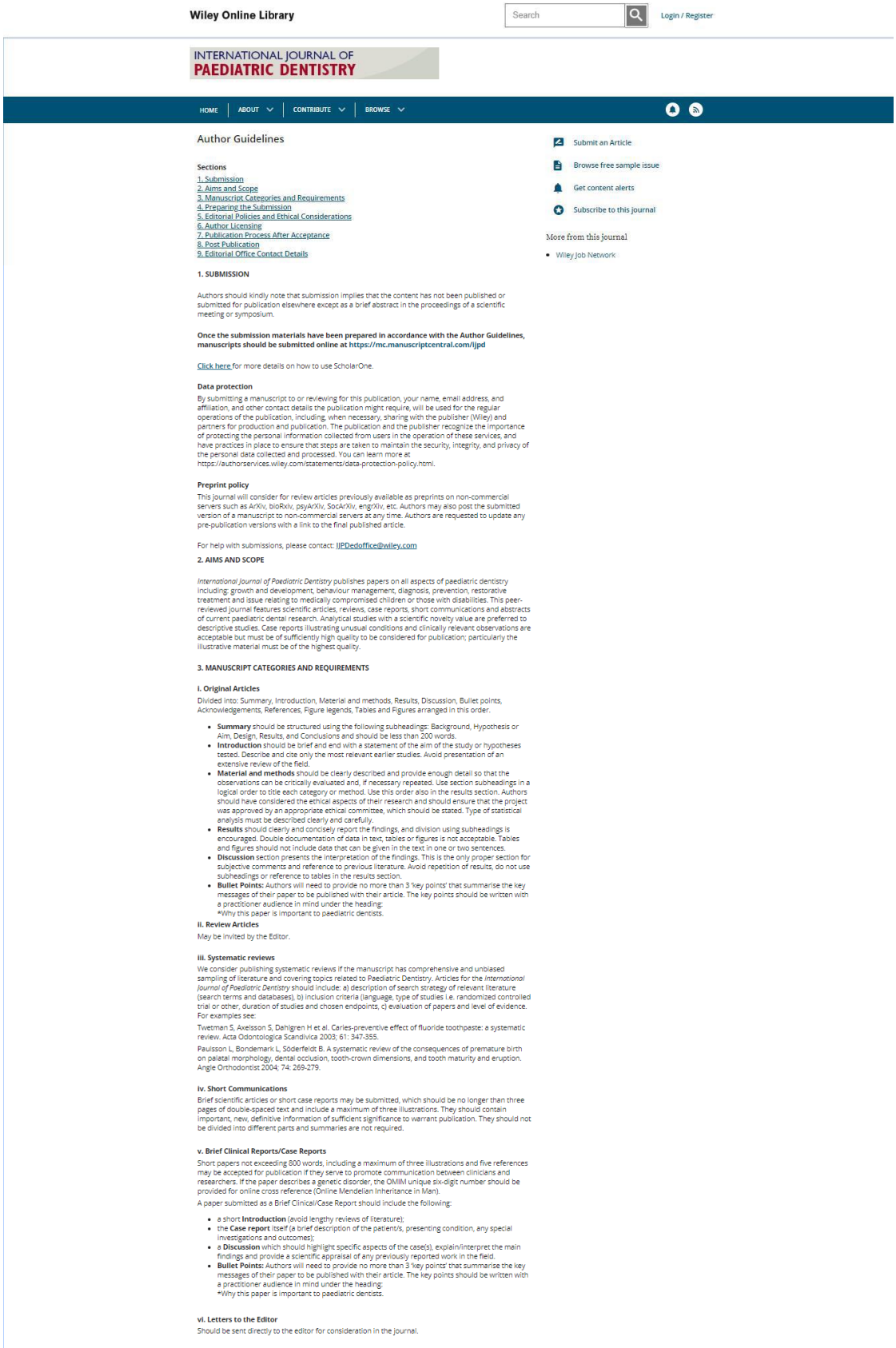
ANEXOS



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

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1. King VM, Armstrong DM, Apps R, Trott JR. Numerical aspects of pontine, lateral reticular, and inferior olivary projections to two paravermal cortical zones of the cat cerebellum. J Comp Neurol 1998;390:537-551.

Book
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Internet document
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Tables

Tables should be self-contained and complement, not duplicate, information contained in the text. They should be supplied as editable files, not pasted as images. Legends should be concise but comprehensive – the table, legend, and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

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- Case reports : CARE
- In vitro studies: CRIS
- Qualitative research : COREQ
- Diagnostic / prognostic studies : STARD
- Quality improvement studies : SQUIRE
- Economic evaluations : CHEERS
- Animal pre-clinical studies : ARRIVE
- Study protocols : SPIRIT
- Clinical practice guidelines : AGREE

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APÊNDICES

APÊNDICE A – TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO.

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Este termo tem como objetivo, informar, esclarecer e pedir autorização para a participação de seu/sua filho (a) na pesquisa intitulada "**Desempenho de uma resina *Bulk-fill* em restaurações classe II em molares decíduos – Ensaio Clínico Randomizado**" a ser desenvolvida pela aluna de pós-graduação Larissa D'Olanda Gindri e pela professora Dra. Rachel de Oliveira Rocha.

A cárie é uma doença causada por uma associação de fatores como o acúmulo de placa, consumo exagerado de açúcar, má higiene bucal e a ausência do uso do flúor. Quando não detectada precocemente e não tratada de forma correta, pode levar a grande destruição dos dentes. Nestas situações, o uso de restaurações é recomendado a fim de proporcionar ao paciente, condições adequadas de higienizar os seus dentes e evitar que a lesão de cárie progrida, evitando dor e até a perda dos mesmos. Assim, esta pesquisa tem como objetivo avaliar o desempenho, em longo prazo, de restaurações em dentes decíduos, sob diferentes materiais.

Para isso, o paciente receberá como tratamento para as suas lesões (cavidades) uma restauração de resina composta (massinha) da mesma cor do dente. Este estudo será realizado na Clínica Odontológica da Universidade Federal de Santa Maria e após o tratamento, o paciente deverá retornar ao mesmo local aos 3, 6, 12, 18 e 24 meses após a restauração para o dentista fazer uma nova avaliação do (s) dente (s) restaurado (s). Caso o (s) dente (s) de leite do fundo esfoliem (caiam), os responsáveis pela criança deverão trazer o (s) dente (s) guardado (s) (armazenado (s)) em água.

Os procedimentos clínicos poderão consistir em: exame da boca e dos dentes, preenchimento de fichas clínicas, radiografias dos dentes e tratamento da doença cárie (restaurações), sob anestesia local. Como esta pesquisa se trata de um procedimento odontológico, o risco previsto para seu/sua filho (a) é que ele (a) possa ficar cansado ou haver desconforto durante o exame da boca e/ou durante a realização da restauração. Não há efeitos colaterais dos materiais utilizados no estudo aos pacientes envolvidos.

Como benefícios, os pacientes receberão instrução de higiene bucal e as ferramentas necessárias para isso (escova, fio e creme dental) e o tratamento dos dentes envolvidos na pesquisa. O (a) sr (a) será **informado (a) a procurar** assistência odontológica caso seja observado algum outro problema durante o exame do seu/sua filho (a) e em caso de dor, será oferecido tratamento de urgência pela pesquisadora.

A participação no estudo é **voluntária** e isenta de qualquer de ônus ou bônus para os participantes. Todos os dados de seu/sua filho (a) serão mantidos em sigilo. Seu/sua filho (a) poderá retirar-se do estudo a qualquer momento sem que ocorra penalização ou prejuízo de qualquer natureza. Para esclarecer qualquer dúvida, o (a) senhor (a) poderá falar com o pesquisador pelo telefone escrito no final deste documento.

Eu, _____, abaixo assinado, concordo em participar do estudo "**Desempenho de uma resina *Bulk-fill* em restaurações classe II em molares decíduos – Ensaio Clínico Randomizado**" como sujeito. Fui suficientemente informado a respeito das informações que li ou que foram lidas para mim, descrevendo o estudo "**Desempenho de uma resina *Bulk-fill* em restaurações classe II em molares decíduos – Ensaio Clínico Randomizado**". Eu discuti com a cirurgiã-dentista Larissa D'Olanda Gindri

sobre a minha decisão em participar nesse estudo. Ficaram claros para mim quais são os propósitos do estudo, os procedimentos a serem realizados, seus desconfortos e riscos, as garantias de confidencialidade e de esclarecimentos permanentes. Ficou claro também que minha participação é isenta de despesas e que tenho garantia do acesso a tratamento hospitalar quando necessário. Concordo voluntariamente em participar deste estudo e poderei retirar o meu consentimento a qualquer momento, antes ou durante o mesmo, sem penalidades ou prejuízo ou perda de qualquer benefício que eu possa ter adquirido, ou no meu acompanhamento/assistência/tratamento neste Serviço.

Eu, _____, RG_____ declaro que fui devidamente esclarecido (a), e estou de acordo com os termos acima expostos, autorizando a participação de meu/minha filho (a)_____ nesta pesquisa.

Local e data _____
Nome e Assinatura do sujeito ou responsável: _____

Declaro que obtive de forma apropriada e voluntária o Consentimento Livre e Esclarecido deste sujeito de pesquisa ou representante legal para a participação neste estudo.

Santa Maria ____, de _____ de 20___

_____
Pesquisador responsável
Telefone para contato: (55) 99018273

APÊNDICE B – TERMO DE ASSENTIMENTO.

Assentimento informado para participar da pesquisa: **Desempenho de uma resina *Bulk-fill* em restaurações classe II em molares decíduos – Ensaio Clínico Randomizado**

Nome da criança/adolescente:

Eu, Larissa D'Olanda Gindri e a professora Rachel de Oliveira Rocha vamos realizar uma pesquisa para avaliar materiais restauradores – 'massinha para obturar dente'. Nós vamos escolher crianças com tua idade (de 5 a 9 anos) que tenham cárie nos dentes de trás. Depois nós vamos conversar com os pais e com as crianças para ver quem vai querer participar e se os pais vão concordar. Só depois nós vamos fazer as restaurações.

Se seus pais quiserem que você participe, mas você não quiser, não tem problema, não precisa participar. Se depois de fazer a restauração, você quiser desistir de participar da pesquisa, não tem problema, é só falar.

Você pode conversar com outras crianças para ver o que elas vão decidir.

Para fazer a restauração ('massinha'), nós vamos precisar fazer o seu dentinho dormir (anestesia local), colocar a barraquinha (isolamento absoluto) e limpar o dente (remoção de tecido cariado). Depois colocamos a massinha no seu dente e você já estará pronta para ir embora. Às vezes, as crianças ficam cansadas, sentem o lábio dormente e ficam com a gengiva um pouco dolorida. Se isso acontecer, você nos avisa e nós recomendamos um remédio.

Você vai voltar depois de um tempo para nós vermos se o dente continua bem.

Não falaremos que você está na pesquisa com mais ninguém e seu nome não irá aparecer em nenhum lugar.

No final da pesquisa, nós vamos escrever um trabalho para uma revista, mas antes vamos mostrar para você e seus pais os resultados.

Ninguém ficará bravo ou desapontado com você se você disser não. A escolha é sua. Você pode pensar nisto e falar depois se você quiser. Você pode dizer sim agora e mudar de ideia depois e tudo continuará bem.

Qualquer coisa é só falar comigo (Larissa) ou com a professora Rachel ou ainda, pedir para alguém falar conosco.

Assinatura da criança ou adolescente: _____

Assinatura dos pais/responsáveis: _____

Assinatura do pesquisador:

_____

Prof. Rachel de Oliveira Rocha
Departamento de Estomatologia