

**Universidade Federal de Uberlândia
Faculdade de Odontologia
Programa de Pós-Graduação em Odontologia**

Renata Afonso da Silva Pereira

Desempenho de restaurações diretas em dentes posteriores – Efeito da técnica restauradora, do tipo de material e do perfil do profissional.

Tese apresentada à Faculdade de Odontologia da
Universidade Federal de Uberlândia, como
requisito parcial para obtenção do Título de
Doutor em Odontologia na Área de Concentração
de Clínica Odontológica Integrada.

Uberlândia, 08 de agosto de 2019

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Reuniu-se no Anfiteatro/sala 23 Bloco 4L - Anexo A, Campus Umuarama, da Universidade Federal de Uberlândia, a Banca Examinadora, designada pelo Colegiado do Programa de Pós-graduação em Odontologia, assim composta: Professores Doutores: Aline Aredes Bicalho (ESTES -UFU); Luiz Renato Paranhos (UFU); Rafael Ratto Moraes (UFPEL); Sérgio Lima Santiago (UFC) e Carlos José Soares (UFU) orientador(a) do(a) candidato(a). O Prof. Dr. Rafael Ratto Moraes participou da defesa de Tese por meio de vídeo-conferência desde a cidade de Pelotas; O Prof. Dr. Sérgio Lima Santiago participou da defesa de Tese por meio de vídeo-conferência desde a cidade de Fortaleza; e os demais membros da Banca participaram *in loco*.

Iniciando os trabalhos o(a) presidente da mesa, Dr(a). Carlos José Soares, apresentou a Comissão Examinadora e o candidato(a), agradeceu a presença do público, e concedeu ao Discente a palavra para a exposição do seu trabalho. A duração da apresentação do Discente e o tempo de arguição e resposta foram conforme as normas do Programa.

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Nada mais havendo a tratar foram encerrados os trabalhos. Foi lavrada a presente ata que após lida e achada conforme foi assinada pela Banca Examinadora.



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DEDICATÓRIA

Dedico este estudo à minha **família**, e em especial: a
Deus.

Há momentos na vida que pensamos em olhar para trás, é
preciso pedir ajuda para poder continuar.

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“A melhor maneira que o homem dispõe para se
aperfeiçoar, é aproximar-se de Deus.”
(Pitágoras)

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Resumo

RESUMO

As resinas compostas têm sido consideradas materiais que proporcionam adequada resistência com ótima longevidade clínica quando usado em restaurações diretas de dentes posteriores vitalizados e com maior desafio nos dentes tratados endodonticamente. Este estudo tem como objetivo avaliar o desempenho das restaurações diretas em molares tratados endodonticamente e o efeito da técnica restauradora, e a longevidade das restaurações de dentes posteriores por meio de objetivos específicos que integram ensaio clínico randomizado, ensaio laboratorial, análise por elementos finitos e avaliação retrospectiva de prática do serviço público. Quatro objetivos integram esse estudo: **Objetivo 1:** investigar o efeito da contração total e pós-gel calculadas experimentalmente nas tensões de contração de resinas compostas em molares tratados endodonticamente empregando modelos bidimensionais por meio de método de elementos finitos. **Objetivo 2:** Investigar o comportamento biomecânico de restaurações molares em dentes tratados endodonticamente por meio de ensaio laboratorial de deformação de cúspide mensurada por extensometria e micro-CT, formação de bolhas e porosidades mensuradas por micro-CT, a resistência à fratura e padrão de falha pós fadiga. **Objetivo 3:** Avaliar por meio de ensaio clínico randomizado com acompanhamento de dois anos o comportamento das restaurações classe II em 56 molares tratados endodonticamente com resina bulk fill e técnica incremental. **Objetivo 4:** Avaliar de forma retrospectiva a longevidade das restaurações em dentes posteriores realizadas na rede municipal de saúde de Uberlândia. Pode-se concluir que a contração total resulta em maior tensão no esmalte e dentina radicular próxima à câmara pulpar quando comparado aos valores de contração pós-gel. Verificou-se ainda que diferentes resinas apresentam ranqueamentos diferentes em relação a contração total e pós-gel. A porosidade nas restaurações não teve influência na deformação da cúspide, resistência à fratura e modo de fratura. A utilização do ionômero de vidro modificado por resina para preenchimento da câmara pulpar associado a resinas compostas incrementais resultou em desempenho biomecânico similar às restaurações em resina bulk fill de viscosidade regular ou fluida. Na

avaliação clínica a técnica incremental com ionômero de vidro inserido na câmara pulpar e restaurações confeccionadas com resina bulk fill de viscosidade regular mostraram taxas de sucesso satisfatórias e similares em avaliação longitudinal de 2 anos. A técnica de restauração com resina bulk fill apresentou desempenho ligeiramente superior para os desfechos adaptação marginal e textura de superfície. Quando avaliadas restaurações realizadas no serviço público de saúde de Uberlândia em dentes posteriores, confeccionadas em amálgama ou resina composta, verificou-se alta taxa de sobrevida, sendo influenciadas pela área geográfica em que foram realizadas. Restaurações realizadas em pacientes com menores indicadores sociais tiveram menores taxas de sobrevida. O contexto geral desse estudo demonstra bom desempenho de restaurações diretas em dentes posteriores tanto nos aspectos mecânicos testados em estudos in vitro e simulações computacionais bem como em estudos clínicos randomizados e análise de prática clínica em serviço público.

Palavras – Chave: resina composta, incremento único, tensão de contração, análise por elementos finitos, sobrevida, resinas compostas

Abstract

ABSTRACT

Composite resins have been considered material that provide adequate mechanical resistance with optimal clinical longevity when used in direct restorations for vital or endodontically treated posterior teeth. This study aimed to evaluate the *in vitro* and clinical performance of direct restorations in endodontically treated and molar teeth and also the longevity of posterior restorations, amalgam or composite resin restorations, performed in public service. Four objectives integrated this study: **Objective 1:** to investigate the effect of total and post-gel shrinkage calculated experimentally on the shrinkage stress of composite resins in endodontically treated molars using two-dimensional finite element analysis. **Objective 2:** To investigate the biomechanical behavior of direct composite resin restorations in endodontically treated molar teeth by means of a laboratory test, cusp deformation measured by strain-gauge test, fracture resistance and failure modes calculated by axial compressive load test after fatigue and the presence of bubble formation and porosities measured by micro-CT. **Objective 3:** To evaluate, by using randomized clinical trial the behavior of class II restorations in 56 molars treated endodontically with bulk fill resin compared with incremental technique after two-year follow-up. **Objective 4:** To evaluate retrospectively the longevity of posterior amalgam or composite resin restorations, performed in the oral health public service of Uberlândia, MG. It can be concluded that the total shrinkage resulted in greater stress concentration in the enamel and root dentin near the pulp chamber when compared to the values of calculated using post-gel shrinkage. It was also found that tested resins have different rankings regarding the total and post-gel shrinkages. The porosity in the restorations had no influence on cusp deformation, fracture resistance and fracture modes. The use of resin-modified glass ionomer to fill the pulp chamber associated with incremental composite resin restoration resulted in similar biomechanical performance that regular viscosity or flowable bulk fill resin restorations. The incremental technique associated with glass ionomer inserted in the pulp

chamber performed similarly to the bulk fill regular viscosity composite resin resin after 2 years. The bulk fill resin presented slightly superior performance for the marginal adaptation and surface texture outcomes. The amalgam and composite resin posterior restorations performed in the public health service of Uberlândia, has high survival rate, being influenced by the geographical area in which they were performed. Restorations performed in patients with lower social indicators had lower survival rates. The general context of this study demonstrated good performance of direct restorations in posterior teeth in both scenarios when the mechanical aspects was tested usinh *in vitro* studies, as well as in clinical trials and practice-based analysis in public service.

Keywords: composite resin, bulk-fill, shrinkage stress, finite element analysis, survival resin; practice-based

Introdução

E Referencial Teórico

1. INTRODUÇÃO E REFERENCIAL TEÓRICO

A cárie dentária é uma das doenças bucais mais prevalentes e continua sendo importante problema de saúde pública, principalmente em crianças e adolescentes (Wyk *et al.*, 2010; Silveira *et al.*, 2015; Machado *et al.*, 2018). Por décadas o amálgama foi o primeiro material de escolha para restauração de dentes posteriores (Lynch *et al.*, 2013). No entanto, as resinas compostas, vêm ganhando popularidade devido às suas propriedades estéticas e adesivas, fazendo com que hoje seu uso ultrapasse o do amálgama na prática clínica (Zabrovsky *et al.*, 2018). No entanto, além das exigências estéticas, é de fundamental importância que as propriedades mecânicas, principalmente a restauração da integralidade funcional deva ser o critério mais importante na escolha do material restaurador (Moraschini *et al.*, 2015).

Embora as restaurações de amálgama apresentem alta longevidade funcional (Sjögren *et al.*, 2002), a necessidade de maior extensão no preparo cavitário necessário para prover retenção à restauração faz com que o uso do amálgama seja questionado frente a visão de uma odontologia conservadora (Moraschini *et al.*, 2015). Por essa razão, o uso de resinas compostas para restaurações em dentes posteriores tem aumentado em todo o mundo (Lynch *et al.*, 2014). Restaurações diretas de resina composta em dentes posteriores tornou-se procedimento de rotina na prática diária de clínicas privadas e de serviços públicos (Demarco *et al.*, 2012; Laegreid *et al.*, 2014). A capacidade das resinas compostas de reproduzirem cor e translucidez da estrutura dentária (Villarroel *et al.*, 2005), bem como a possibilidade de integração adesiva com as estruturas dentais são atributos que permitem ampla utilização em dentes posteriores (Ferracane *et al.*, 2011; Velo *et al.*, 2016).

Molares de pacientes jovens quando severamente afetados pela cárie, com conseqüente envolvimento pulpar, faz-se necessário o tratamento endodôntico e restauração direta em resina composta para preservar esses dentes (Salehrabi & Rotstein, 2004; Suksaphar *et al.*, 2017). Neste cenário, o emprego de procedimento restaurador adesivo direto pode ser indicado para reforçar a estrutura coronária enfraquecida, sendo mais conservador quando comparado com a restauração indireta (Sagsen & Aslan, 2006; Kwon *et al.*, 2012; Suksaphar *et al.*, 2017).

Resinas compostas apresentam bom desempenho em dentes posteriores vitais e tratados endodonticamente (Rosatto *et al.*, 2015; Pereira *et al.*, 2016). Contudo, apesar da sua grande popularidade e boa longevidade clínica (Da Rosa *et al.*, 2011), alguns problemas associados a característica intrínseca do material estão relacionados à contração durante o processo de polimerização (Tantbirojn *et al.*, 2015; Soares *et al.*, 2017). Fatores como propriedades mecânicas, composição química e a qualidade e quantidade de estrutura dentária remanescente determinam a geração e a magnitude das tensões de contração (Bicalho *et al.*, 2014; Al-Ahdal *et al.*, 2015; Soares *et al.*, 2018). As tensões resultantes têm sido associadas a deficiências marginais, fraturas de esmalte, trincas em base de cúspides (Rosatto *et al.*, 2015; Veloso *et al.*, 2018). Essas tensões são geradas quando o material perde a capacidade de se deformar, para aliviar as tensões no interior da restauração, o que se dá com a vitrificação do material durante o processo de polimerização (Versluis *et al.*, 2009). Porém, nem toda contração de polimerização resulta em tensão de contração (Versluis *et al.*, 2009; Enochs *et al.*, 2018) sendo importante distinguir a contração total e a contração que realmente provoca tensões, chamado de "contração pós-gel" (Sakaguchi *et al.*, 1997; Soares *et al.*, 2017; Enochs *et al.*, 2018).

As propriedades mecânicas das resinas compostas usadas em dentes posteriores devem atender aos princípios de resistência e adesão suficiente para suportar cargas mastigatórias (Soares *et al.*, 2013; Oliveira Schliebe *et al.*, 2016). Para caracterizar resinas compostas a obtenção do módulo de elasticidade, resistência à tração, resistência à compressão, são parâmetros que norteiam desempenho de diferentes produtos comerciais (Oliveira Schliebe *et al.*, 2016).

Vários protocolos restauradores, como a técnica incremental convencional (Versluis *et al.*, 1996; Zhu *et al.*, 2011), técnica incremental empregando incrementos de maior volume (Bicalho *et al.*, 2014; Bicalho *et al.*, 2014) têm sido preconizados como protocolos de eleição para dentes posteriores. Porém, essa técnica prolonga o tempo do tratamento, além de envolver certos riscos como a incorporação de bolhas de ar e contaminantes entre os incrementos individuais nas restaurações de resinas compostas (Rosatto *et al.*, 2015). Molares tratados endodonticamente normalmente

apresentam cavidades amplas e profundas, e por esta razão durante o procedimento restaurador, vazios e bolhas podem ser geradas. Estas intercorrências supostamente contribuem para acelerar a deterioração do material, resultando em infiltração marginal, descoloração, aumento do desgaste e menor resistência à flexão (Salehrabi *et al.*, 2004; Kim *et al.*, 2015). Além disso, diferentes materiais restauradores geram quantidades variadas de bolhas e porosidades após a inserção nas cavidades. Resinas compostas de baixa viscosidade, têm demonstrado melhor desempenho no preenchendo de cavidades, resultando em menor volume de bolhas e porosidades, no entanto, esses resultados foram encontrados em restaurações envolvendo pequenas cavidades (Lagouvardos *et al.*, 2015).

Para atuar de forma sinérgica na redução dos efeitos colaterais indesejados da contração de polimerização e ainda minimizar os efeitos em dentes posteriores tratados endodonticamente, materiais ionoméricos convencional ou modificado por resina tem sido recomendado como material intermediário (Kwon *et al.*, 2010; Taha *et al.*, 2011). O cimento de ionômero de vidro substitue parte do volume de resina composta, reduzindo conseqüentemente os efeitos colaterais da contração de polimerização (Pereira *et al.*, 2016). A associação do ionômero de vidro preenchendo a câmara pulpar, seguida da restauração da resina composta, demonstrou reduzir em deformação da cúspide e aumento na resistência à fratura, quando comparado ao uso exclusivo de resina composta inserida incrementalmente (Pereira *et al.*, 2016). Com o intuito de superar estas dificuldades, na última década foi desenvolvido nova geração de resinas compostas, conhecidas como “resinas bulk fill” utilizadas em porções únicas de até 5 mm de espessura, o que tornaria o procedimento restaurador, principalmente em cavidades extensas de dentes posteriores, muito mais rápido e simples (Rosatto *et al.*, 2015). As resinas bulk-fill apresentam formulações com novos monômeros à base de dimetacrilato, diferentes tamanhos e proporções de partículas de carga. O desenvolvimento de novos sistemas de iniciação e a adição de moduladores da reação de polimerização têm sido estratégias adotadas, permitindo a utilização de incrementos maiores, sem, entretanto, aumentar a tensão gerada na interface adesiva e sem comprometer as propriedades mecânicas (Czasch *et al.*, 2013; Oliveira Schliebe *et al.*, 2016). Os fabricantes afirmam que o preenchimento

das cavidades com resinas bulk-fill minimizam a incorporação de bolhas. Estudos relataram o mesmo padrão, declarando menor presença de vazios dentro das restaurações realizadas com resinas bulk-fill em comparação com a técnica incremental devido à diminuição do manuseio durante o procedimento restaurado (Jarisch *et al.*, 2016; Soares *et al.*, 2017)

A evidência científica gerada nos últimos 5 anos envolvendo resinas compostas bulk fill se dá na sua maioria em estudos laboratoriais e simulação computacional (Rosatto *et al.*, 2015). No entanto, há limitadas informações sobre a avaliação dos desfechos clínicos de procedimentos restauradores em dentes molares tratados endodonticamente, afetados por cárie. Fatores como propriedades do material, qualidade dos procedimentos adesivos, características do paciente, fatores ambientais bucais, localização e extensão da restauração, o risco de cárie e hábitos como o bruxismo, bem como fatores socioeconômicos, influenciam a longevidade das restaurações (Demarco *et al.*, 2012; van Dijken *et al.*, 2014). Informações adequadas e confiáveis são importantes para validar as vantagens das resinas bulk-fill, assim estudo de protocolos restauradores de dentes posteriores tratados endodonticamente podem influenciar na escolha de materiais e na conduta clínica a ser realizada.

Analisar de forma integrada a interferência de fatores no processo restaurador de dentes tratados endodonticamente não deve se limitar apenas aos ensaios laboratoriais, mas devem estar associados a outras metodologias, por exemplo, o método de elementos finitos (Magne & Belser, 2003; Soares *et al.*, 2006), uso de softwares de comparação de imagens, estudos retrospectivos e avaliações clínicas destes novos compósitos bulk fill, que nos permita responder se estes materiais podem ser mesmo tratados como boa alternativa para preenchimento da câmara pulpar dentes posteriores.

A associação de metodologias torna-se importante ferramenta na validação das respostas e na obtenção de importantes informações por meio da correlação de resultados de diferentes ensaios que podem melhor esclarecer o caminho da falha das resinas compostas e como elas podem ser minimizadas ou eliminadas.

Objetivos

2. OBJETIVOS

2.1 Objetivo Geral

Avaliar o desempenho das restaurações diretas em molares tratados endodonticamente e o efeito da técnica restauradora, e a longevidade das restaurações de dentes posteriores.

2.2 Objetivos Específicos

Objetivo específico 1

Capítulo 1 - *Can the post-gel and total shrinkage of conventional and bulk-fill resin composites result in similar shrinkage stress in endodontic treated molars?*

Analisar o efeito do uso dos valores de contração pós-gel e de contração total calculados experimentalmente na geração de tensões de contração de polimerização em molares tratados endodonticamente por meio do método de elementos finitos.

Objetivo específico 2

Capítulo 2 - *Can the porosity of Incremental and bulk fill resin composite filling techniques affect the biomechanical performance of endodontic treated molars?*

Analisar o efeito da porosidade gerada no interior de restaurações diretas de resinas compostas construída com a técnica incremental associada a base de ionômero de vidro e com resinas bulk fill no desempenho biomecânico de molares tratados endodonticamente.

Objetivo específico 3

Capítulo 3 - *Clinical performance of composite resin restorations in endodontically treated molars of adolescents: a 2-year randomized clinical trial comparing bulk fill and incremental filling technique*

Comparar o desempenho clínico em 2 anos de restaurações diretas de resina composta em molares tratados endodonticamente, utilizando duas técnicas restauradoras: técnica incremental e bulk fill.

Objetivo específico 4

Capítulo 4 - *Practice-based analysis of direct posterior restorations performed on health public service at Uberlandia-MG, Brazil: retrospective Long-term survival.*

Análise baseada em práticas de restaurações diretas posteriores realizadas no serviço público de saúde em Uberlândia-MG, Brasil: retrospectiva Sobrevida a longo prazo

Capítulos

Capítulos

3.1 CAPÍTULO 1

Can the post-gel and total shrinkage of conventional and bulk-fill resin composites result in similar shrinkage stress in endodontic treated molars?

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Can the post-gel and total shrinkage of conventional and bulk-fill resin composites result in similar shrinkage stress in endodontic treated molars?

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Can the post-gel and total shrinkage of conventional and bulk-fill resin composites result in similar shrinkage stress in endodontic treated molars?

Abstract

Objectives: Analyze the use of the total shrinkage or post-gel shrinkage calculated values on the generation of shrinkage stress in endodontically treated teeth by using finite element analysis.

Methods: Four composite resins were tested for post-gel shrinkage (P-Shr) by the strain-gauge test and total shrinkage (T-Shr) by using optical method (n=10). Two conventional composite resins: Z350, Filtek Z350 XT (3M-ESPE); TPH3, TPH3 Spectrum (Dentsply); and two bulk fill composite resins: POST, Filtek Bulk-Fill Posterior (3M-ESPE); SDR, SureFil SDR flow (Dentsply). Elastic modulus (E), diametral tensile strength (DTS) and compressive strength (CS) were also determined (n=10). The residual shrinkage stress was evaluated by finite element analysis with 4 restorative techniques: incremental for Z350 and TPH3; SDR/TPH3 (2 bulk increments + 2 occlusal increments); and 2 bulk increments of 5 mm for POST. Data of P-Shr, T-Shr, E, DTS and CS were analyzed by ANOVA and Tukey's test ($\alpha = 0.05$), and residual shrinkage was analyzed quantitatively and qualitatively by modified the von Mises criteria.

Results: SDR had CS values similar to those of TEC and lower than those of all other composites. CHA had DTS values similar to those of Z350 and higher than those of all other composites. SDR had higher T-Shr than did FBF, Z350 and TPH3. POST and Z350 had higher Shr than did TPH3 and SDR. T-Shr resulted in higher shrinkage stress than P-Shr values. SDR/TPH3 resulted in higher shrinkage stress when using T-Shr and lower values when using the P-Shr value.

Conclusion: T-Shr resulted in higher stress in the enamel and in root dentin close to the pulp chamber than P-Shr values. The selection of the T-Shr or P-Shr changed the ranking of the shrinkage stress of the tested composite resin.

Clinical Relevance: *The clinician should be careful in the selection of the composite resin for posterior restorations considering the reduction of the polymerization shrinkage stress. However, the use of post-gel shrinkage values should guide the clinician in this selection.*

INTRODUCTION

Composite resin materials are widely used in restorative dentistry for restoring posterior vital and endodontic treated teeth.^{1,2} During the polymerization reaction, resin undergoes a transition from a predominantly viscous state to a basically solid-state due to a conversion of monomer molecules in polymer chains.^{3,4} Volumetric shrinkage is an inherent characteristic of resin-based materials.^{5,6} Several factors, such as mechanical properties, chemical composition, and the remaining tooth structure, determine the shrinkage stress,^{4,7-9} restorative technique and the curing method.¹⁰ This residual stress may result in propagation of enamel cracks, cuspal deflection,^{1,11,12} marginal loss, secondary caries and postoperative sensitivity.⁷

Various restorative protocols, such as the incremental technique,¹³ gradual polymerization,¹⁴ and larger increments,^{4,8} have been advocated to reduce the shrinkage stress. Recent trends are focused on modifications of the resin matrix, mainly for developing materials with reduced polymerization shrinkage and consecutively the shrinkage stress.¹⁵ Bulk fill composite resins allow application of increments from 4 mm up to 5 mm thickness^{1,16,17} with a high degree of uniform conversion by all increment, reduced shrinkage and shrinkage stress, and commercially available in low or high viscosity.^{12,18} The viscosity and composition of the bulk fill composite resin may interfere with the performance of the material during shrinkage measurement.^{1,19}

When the material is light-activated, the polymerization process develops, and the volumetric reduction causes shrinkage of the material.⁶ However, the relationship between shrinkage and stress is not that simple because not all shrinkage causes stress.^{6, 19, 20} Residual stresses will only be generated when the composite material can no longer relax in a timely manner; not all polymerization shrinkage causes shrinkage stresses.²⁰ It is important to distinguish between total shrinkage and the shrinkage that truly causes stresses, called the "post-gel shrinkage".^{6,21} However, the manufactures continue to inform the clinicians and propagate information regarding different materials using total shrinkage values. This information could be used for creating artificial benefit regarding specific composite resins that can present different rankings regarding total and post-gel shrinkage and total shrinkage reported values.

Shrinkage stresses cannot be measured directly; the use of finite element analysis (FEA) is a computational numerical analysis considered as the most comprehensive method to calculate the complex condition of the stress inside materials and structures.²² Therefore, the aim of this study was to evaluate the effect of the method used for calculation of polymerization shrinkage on the shrinkage stress of conventional and bulk fill composite resins for restoring endodontically treated tooth. The null hypothesis was that there would be no difference at residual shrinkage stress when using the total shrinkage (T-Shr) or post-gel shrinkage (P-Shr) values.

METHODS AND MATERIALS

Study design

Four commercial materials were used in this study including two conventional composites, namely, TPH3 (Dentsply, Konstanz, Germany) and Filtek Z350XT (3M ESPE, St Paul, MN, USA) and two bulk fill composite resins, namely, a flowable resin composite, Bulk Fill Surefil SDR Flow (Dentsply) and a regular paste resin composite, Filtek Bulk Fill Posterior (3M ESPE). The composition was described according to manufacturer's instructions (Table 1). All resin composites were tested for post-gel shrinkage (P-Shr), total polymerization shrinkage (T-Shr). Shrinkage stresses were analyzed using by finite element analysis (FEA).

Post-Gel Shrinkage (P-Shr)

P-Shr was determined for all tested composite resins (n=10) using the strain gauge method.²¹ The materials were shaped as a semi-sphere on top of a biaxial strain gauge (CEA-06-032WT-120, Measurements Group, Raleigh, NC, USA) that measured shrinkage strains in two perpendicular directions (X and Y-axes). A strain conditioner (ADS2000, Lynx, Tecnologia Eletrônica, São Paulo, SP, Brazil) converted electrical resistance changes in the strain gauge to voltage changes through a quarter-bridge circuit with an internal reference resistance. The strain values measured along the two axes were averaged because the material properties were homogeneous and isotropic on a macro scale. All materials were light-cured using a light-emitting diode (LED) unit Bluephase G2 (Ivoclar Vivadent, Schaan, Liechtenstein) with the light tip held at

a 1-mm distance from the surface of the composite and monitored for 10 minutes. The mean shrinkage strain was used as linear post-gel shrinkage input for the finite element analysis and could be converted to the volumetric percentage by multiplying by 3 and 100%.

Total shrinkage (T-shr)

T-Shr was calculated using the optical method.⁵ Each resin sample (n=10) was placed on a platform made of addition silicone (Express XT – Light body, 3M ESPE) in blue color, for a better contrast between resin and surface. Each sample was slightly rounded and placed on the silicon platform. The platform was placed under a microscope coupled to a camera (SZX16 & UC30, Olympus) so that the images could be captured in a standardized way. Once positioned, a photo was taken before photo activation. The light from the microscope was attached only to capture the images, to avoid premature polymerization of the compound through the optical microscope. Immediately after the first photo and before polymerization of the material, the sample was light-cured for 40 seconds using the Bluephase G2 (Ivoclar Vivadent), with an intensity of 1600 mW/cm² checked by a using resin calibrator (BlueLight, Halifax, Canada). After polymerization, the samples were monitored and photos were taken after 10 and 60 minutes of the initial light activation. All procedures were performed at room temperature, 22°C. ImageJ software (Public Domain, National Institute of Health, Bethesda, MD, USA), available free of charge on the internet, was used to evaluate pre, and post polymerization photos. The brightness of the image was adjusted to determine the maximum contrast between the resin sample and the silicon plate. Using the tool "wand tool", the contour of the sample was defined to obtain the total area. Through the photo of the total area of the samples before and after the polymerization, it was possible to calculate the volume change before and after the polymerization.

Compressive strength (CS) and diametral tensile strength (DTS) calculation

Compressive and diametral tensile strengths (n = 10) of composite resin were calculated. The composite resin was inserted into a cylindrical Teflon mold for the compressive strength test (6 mm height, 3 mm diameter) or the diametral

tensile strength test (2 mm height, 4 mm diameter). The specimens for the compressive test made with bulk-fill composites were polymerized with 4.0 mm for the first increment and 2.0 mm for second increment. For conventional composite the specimens were polymerized in three 2.0 mm increments by using LED light curing unit (Valo, Ultradent, USA) with 1400 mW/cm² light intensity using recommended curing times. The specimens were stored in distilled water for 24 h at 37°C, afterwards were submitted to compressive strength and diametral tensile testing in a universal testing machine (DL2000, EMIC) at a crosshead speed of 0.5 mm/min until failure occurred. Compressive strength values were calculated by dividing the fracture load (F) by the cross-sectional area and converting it into MPa. Diametral tensile strength values were calculated using the equation: $DTS = 2F/\pi dt$, where d is the specimen diameter, and t is the height of the specimen. DTS and CS values were converted into MPa.

Elastic modulus of composite resin calculation

The similar samples prepared for DTS test were prepared for analysis of the elastic modulus (E). The sample preparation was performed similarly as described in study before.¹ Using a Vickers indenter (CSM Micro-Hardness Tester; CSM Instruments, Peseux, Switzerland), indentations were made at the surface of the finished and polished composite resin surface. The indentations were carried out with controlled force, whereby the test load was increased or decreased at a constant speed ranging between 0 and 500 mN in 20 s intervals. The maximum force of 500 mN was held for five seconds. The load and the penetration depth of the indenter were continuously measured during the load-unload-cycle. The universal hardness was defined as the applied force divided by the apparent area of the indentation at the maximum force. The measurements were expressed in VH units by applying the conversion factor supplied by the manufacturer. The indentation modulus, comparable to the material's elastic modulus (E), was calculated from the slope of the tangent of the indentation depth curve at the maximum force.

Residual Stress Calculation: Finite Element Analysis

To calculate total and post-gel residual shrinkage stresses, a two-dimensional (2D) finite element simulation was carried out simulating a mesial-occlusal-distal restoration of an endodontic treated molar as described in study before.² The geometric model (Fig. 3A) was based on a digitized buccolingual cross-section of an endodontic treated molar embedded in an acrylic resin cylinder with a simulated periodontal ligament (PDL). The coordinates of points were obtained using public domain ImageJ software (ImageJ 1.48, National Institutes of Health, Bethesda, MD, USA). The mechanical properties of used materials were: enamel elastic modulus (E- GPa) 84 and Poisson's ratio (η) 0.30 (Craig & Powers, 2002); dentin E-18 and η -0.23;²³ polystyrene resin E-13.5 and η -0.31; and polyether E- 0.05 and η -0.45.²⁴ For the restorative composite resins the E was experimentally determined and are shown in Table 2. The Poisson's ratio was chosen to be the same for all composites at 0.24.²³ It was assumed a plane stress condition for the composites and a plane strain condition for the tooth cross-sections, PDL and acrylic resin cylinder.

The finite element analysis was performed using MSC.Mentat[®] (preprocessor and postprocessor) and MSC.Marc[®] (solver) software. One FEA model was generated for each of the four restorative protocols of the experimental study (Fig. 1A). The Filtek Z350XT and TPH3 restorations were built and cured in 6 increments (Fig. 1B and 1C, respectively). The bulk fill flowable, SDR, was placed in two increments up to 4 mm and covered with TPH3 built with 2 increments of 2 mm thickness on the occlusal surface (Fig. 1D). The bulk fill paste, Filtek Bulk Posterior (POST) was used in 2 increments of up to 5.0 mm (Fig. 1D). Polymerization shrinkage was simulated by thermal analogy. The temperature was reduced by 1°C, while the linear shrinkage value P-Shr or T-Shr was entered as the coefficient of linear thermal expansion. Nodal displacements were the constraint in the X and Y directions at the bottom and lateral surfaces of the support cylinder. Modified von Mises equivalent stress (mvm) was used to express the stress conditions, using the ratio of the compressive and tensile strengths. The compressive and tensile strength used for calculating the ratios for the restorative materials are shown in Table 2 and were calculated using the experimentally determined compressive and diametral tensile strength values. The compressive and tensile strengths of

enamel were 384.0 and 10.3 MPa and dentin 297.0 and 98.7 MPa, respectively.²³ The mean values of the 10% highest mvm stresses were determined for the enamel and dentin structures when simulating the T-Shr and P-Shr. Fortran custom-made subroutines were generated for obtain mvm stresses values from enamel-composite and dentin-composite interfaces.

Statistical Analysis

The P-Shr, T-Shr, E, DTS and CS data were tested for normal distribution (Shapiro–Wilk) and equality of variances (Levene’s test), followed by parametric statistical tests. One-way analysis of variance (ANOVA) was performed for each mechanical property. Multiple comparisons were made using Tukey’s test. All tests employed $\alpha = 0.05$ significance level and all analyses were carried out with the statistical package Sigma Plot version 13.1. The modified von Mises stresses values were analyzed qualitatively.

RESULTS

P-Shr and T-Shr (%) of resin composites

The P-Shr and T-Shr mean values and standard deviations of four composites are shown in Table 2. ANOVA showed a significant difference between the resin composites ($P < 0.05$). Tukey’s test showed that POST and Z350 had the highest Shr values, and SDR and TPH3 had lower Shr values (Table 2). SDR showed higher T-Shr values than did other resin composites (Table 2). Z350 and TPH3 had the highest, and POST had the lowest T-Shr values.

DTS (MPa), CS (MPa) and E (GPa) of resin composites

The DTS, CS and E mean values and standard deviations of four composites are shown in Table 3. ANOVA showed a significant difference between the resin composites ($P < 0.05$). Tukey’s test showed that Z350 had the highest CS values, and SDR had lower Shr values (Table 3). TPH3 had the highest DTS values, and SDR had the lowest values. Regarding E results, SDR had significantly lower values than Z350 and TPH3; Z350 had higher value than all other resin composites.

Shrinkage Stress (MPa) FEA results

Shrinkage stresses, expressed by modified von Mises values, generated by all tested restorative techniques are shown in Fig. 2, 3 and 4. The SDR/TPH3 bulk-filling technique and Z350 resulted in the highest stresses values at enamel and dentin structures at T-Shr and P-Shr, respectively (Fig. 2). The models generated with T-Shr values (Fig. 3) resulted in a substantial increasing on shrinkage stress compared to models with P-Shr values, irrespective of the restorative technique. SDR/TPH3 showed the highest values of shrinkage stress when simulating the T-Shr (Fig. 3B) and the lowest values when simulating the P-Shr.

Total and post-gel shrinkage interfaces stress values for the different resin techniques are presented in Fig. 4. SDR/TPH3 had the highest T-shr values on enamel-composite and dentin-composite interfaces, while the P-Shr stress for the SDR/TPH3 technique and TPH3 presented lowest values (Fig. 4 B and C).

DISCUSSION

The selection of direct restorative material with high performance and durability has led to the development of new materials. The change from the use of the incremental technique to the bulk-filling method may be a result of a simplified restorative technique that reduces the possibility of errors, has fewer operative steps and requires less clinical time.¹ The results of this study confirmed that P-Shr and T-Shr were dependent of material composition and that those values influenced the residual shrinkage stress; therefore, the null hypothesis was rejected.

Volumetric shrinkage is a consequence of the polymerization of resin-based materials during formation of a polymer network, causing dimensional changes.⁵ It is known that not all polymerization shrinkage causes shrinkage stresses.^{19, 20} The total shrinkage measures the entire amount of dimensional change of the composite during polymerization including the pre-gel stage, capable of flowing by releasing part of its tension, and post-gel stage.^{20,25,26} This fact may explain why the percentage of volumetric total shrinkage of all four

tested composites in this study presented values significantly higher than percentage results for post-gel shrinkage. Residual stresses will only be generated when the composite material cannot timely relax anymore, which happens when a more rigid polymer network structure has developed, which only occurs in the post-gel phase.

The percentage of polymerization shrinkage is influenced by the amount of organic content of the composite,²⁷ and by the percentage of inorganic content.²⁸ The post-gel volumetric shrinkage of the Z350 and POST composite resins were higher than the others due to the high content of filler in the resin matrix. It can be explained by the higher amount of filler that increases the modulus of elasticity and rigidity of the material,⁸ which tends to increase the shrinkage stress. The change of a resin composite to a solid material, characterized by the development of the elastic modulus, during the polymerization results in rigid restorations and consequently residual shrinkage stresses by the effect of polymerization contraction.¹ The lower post-gel shrinkage value of SDR could be explained by the lower amount of inorganic filler content, an attribute of flowable composites.²⁹ Additionally, the SDR resin has a polymerization modulator that acts at propagation of the linear and branched chains of the polymers of the resin, reducing the formation velocity of the polymer network, keeping its viscosity longer, providing lower stress compared to traditional composites.³⁰ Inversely, SDR presented the highest total shrinkage value, probably due to the smaller amount of filler content. The total volumetric contraction depends on factors such as the size of the charge particles and probably also the type of the organic matrix and concentration of monomers.³¹

Bulk-filling techniques reduce the increments number by using a larger volume of composite, which resulted in lower residual shrinkage stress when compared with the incremental filling techniques. The residual stress concentrates on the tooth structure located at cervical enamel.^{1,4,32} The lower shrinkage stress observed when flowable composite resin filling dentin and conventional composite resin were used may be explained by the lower P-Shr and E values that determine higher stress reliefs during the polymerization reaction.^{1,3} The stress presented at root dentin close to the pulp chamber was already expected once the model simulated an endodontically treated tooth with

the pulp chamber totally filled with resin composite. Therefore, the bulk fill resin composites show up as an alternative to restore endodontically treated teeth with lower shrinkage stress than incremental technique, due the lower stress generated at severely compromised dental structure.³² The highest values of residual shrinkage stress were verified when the total shrinkage values were simulated comparing with the post-gel values. The total shrinkage considers the total volumetric shrinkage of the increment, as presented to the majority of the manufacturers, but in reality, the shrinkage is not correlated with the volume change involved in stress.¹⁹ The post-gel shrinkage concept has turned out to be a useful factor to develop an understanding of the development and calculation of shrinkage stresses. From a clinical perspective, this study highlighted that the use of a bulk fill technique may contribute to less shrinkage stress generation on the endodontic treated molars, which are normally more suitable for fracture and crack propagation.^{33,34} It is important that the clinician be capable of differentiating the type of shrinkage for the company when choosing a dental composite once total shrinkage does not reflect shrinkage stress behavior, which is much better characterized by post-gel shrinkage.

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Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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Tables

Table 1. Composition of resin composites (manufacturer's information).

Material	CODE	Shade	Composite Resin Type	Increment size and light activation time	Organic matrix	Filler	Filler % wt/vol	Manufacturer
TPH3 Spectrum	TPH3	A2	Nanohybrid	2.0 mm – 20 s	BisGMA and BisEMA Dimethacrylate	Boro-silicate/aluminum/barium glass and silica	75.5/57.1	Dentsply, (Konstanz, Germany)
Filtek Z350 XT	Z350XT	A2	Nanofilled	2.0 mm – 20 s	Bis-GMA, Bis-EMA, UDMA, TEGDMA	Silica and zirconia nanofillers, agglomerated zirconia-silica nanoclusters	82/60	3M-ESPE (St. Paul, MN, USA)
Surefil SDR flow	SDR	A2	Bulk fill flowable	4.0 mm – 40 s	UDMA, BISGMA, EBPADMA, Procrylat resin	Silane treated ceramic and YbF3	68/44	Dentsply, (Konstanz, Germany)
Filtek Bulk-fill posterior	POST	A1	Bulk fill regular paste	5.0 mm – 10 s occlusal, 10 s buccal and 10 s palatal	UDMA, DDDMA, EDMAB	Silica, zirconia and YbF3	76.5/58.4	3M-ESPE (St. Paul, MN, USA)

Table 2. Experimentally determined mean (and standard deviation) Volumetric post-gel shrinkage and volumetric total shrinkage

Composite Resin	Post-gel shrinkage (%)	Total shrinkage (%)
Filtek Z350 XT (Z350)	0.7 ± 0.1 ^A	2.6 ± 0.2 ^B
TPH3 Spectrum (TPH3)	0.5 ± 0.0 ^B	2.5 ± 1.3 ^{BC}
Surefil SDR flow (SDR)	0.4 ± 0.1 ^C	3.9 ± 0.8 ^A
Filtek Bulk Fill Posterior (POST)	0.7 ± 0.1 ^A	2.1 ± 0.3 ^C

Different uppercase letters indicate significant difference between the composites provided by Tukey test ($P < 0.05$).

Table 3. Compressive strength, Diametral tensile strength and the corresponding Elastic Modulus.

Composite Resin	Compressive strength (MPa)	Diametral tensile strength (MPa)	Elastic Modulus (GPa)
Filtek Z350 XT (Z350)	255.5 ± 30.4 ^A	47.5 ± 6.5 ^A	18.5 ± 2.0 ^A
TPH3 Spectrum (TPH3)	164.4 ± 25.3 ^B	49.9 ± 7.2 ^A	15.6 ± 1.4 ^B
Filtek Bulk Fill Posterior (POST)	169.3 ± 15.8 ^B	42.4 ± 6.3 ^{AB}	12.8 ± 1.7 ^{BC}
Surefil SDR flow (SDR)	121.6 ± 13.4 ^C	39.4 ± 5.7 ^B	10.1 ± 0.9 ^C

Different letters mean significant difference between composite resins for each mechanical property provided by Tukey test ($P < 0.05$).

Figures

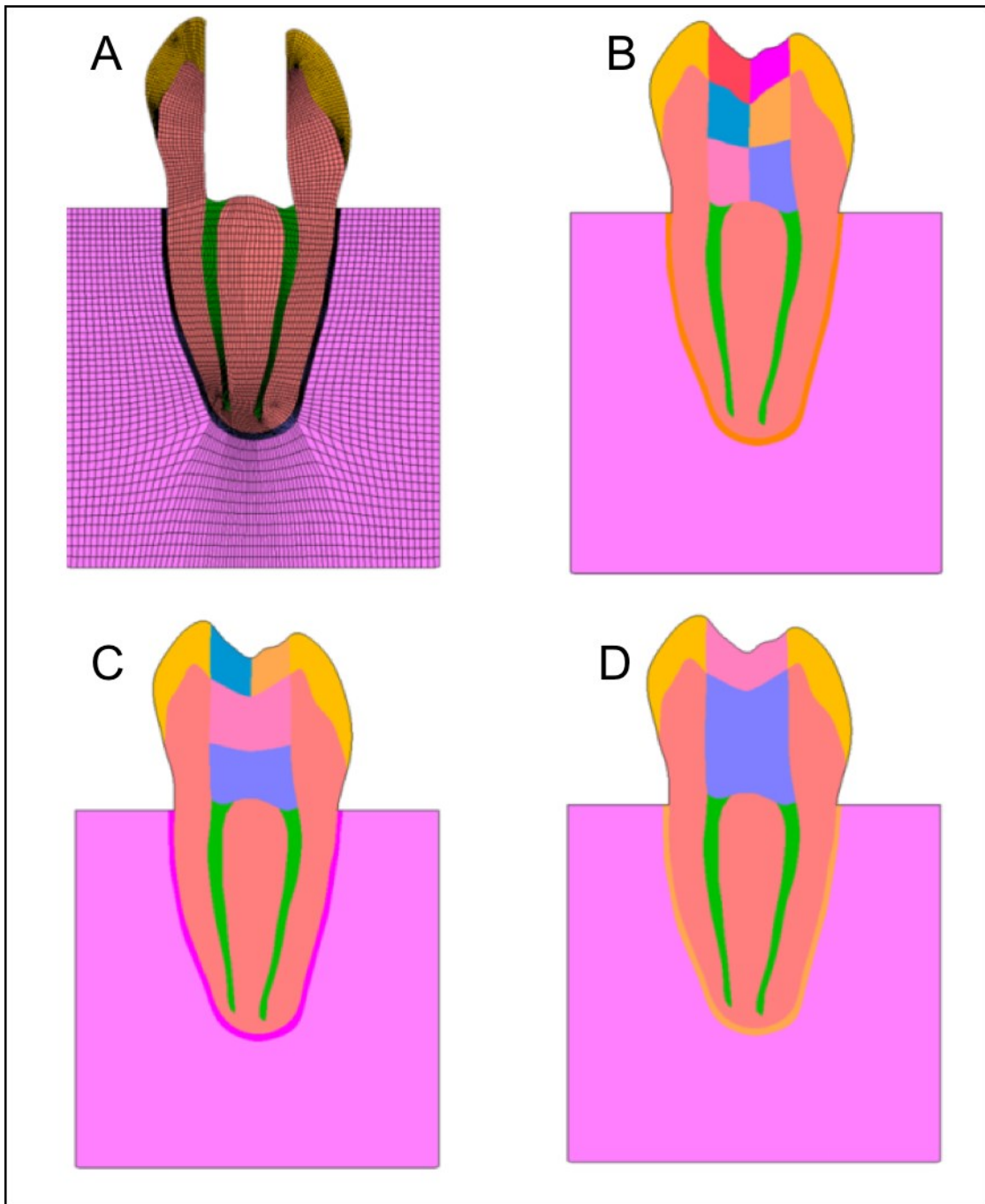


Figure 1. Two-dimensional FEA model generation. A. Principal model – mesh of endodontically treated tooth with a MOD preparation; B. Model simulating incremental filling technique using Z350XT or TPH3. C. Model simulating SDR flowable bulk fill used for restoring the dentin and two occlusal increments of TPH3 replacing the enamel; D. Model simulating Filtek Bulk Fill Posterior replacing the dentin and enamel.

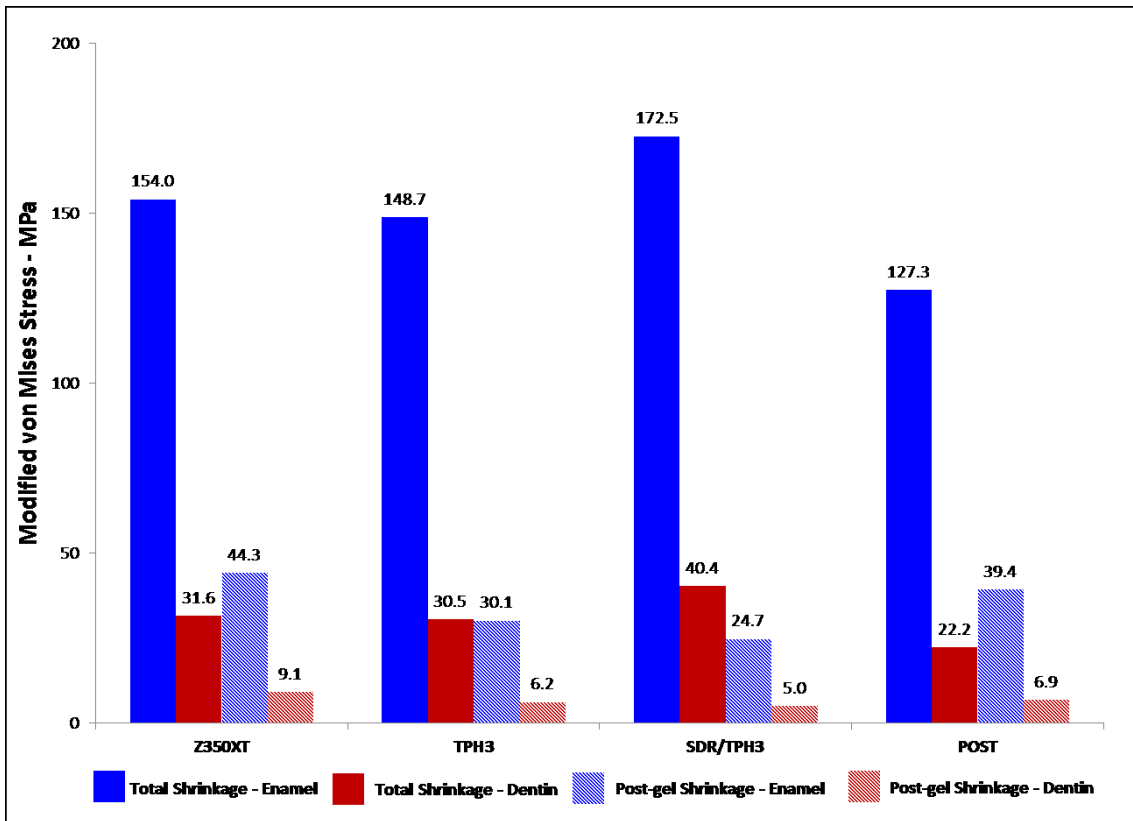


Figure 2. The 10% highest values of modified von Mises stress (MPa) extracted from enamel and dentin structures calculated using total and post-gel shrinkage of conventional and bulk fill composite resins.

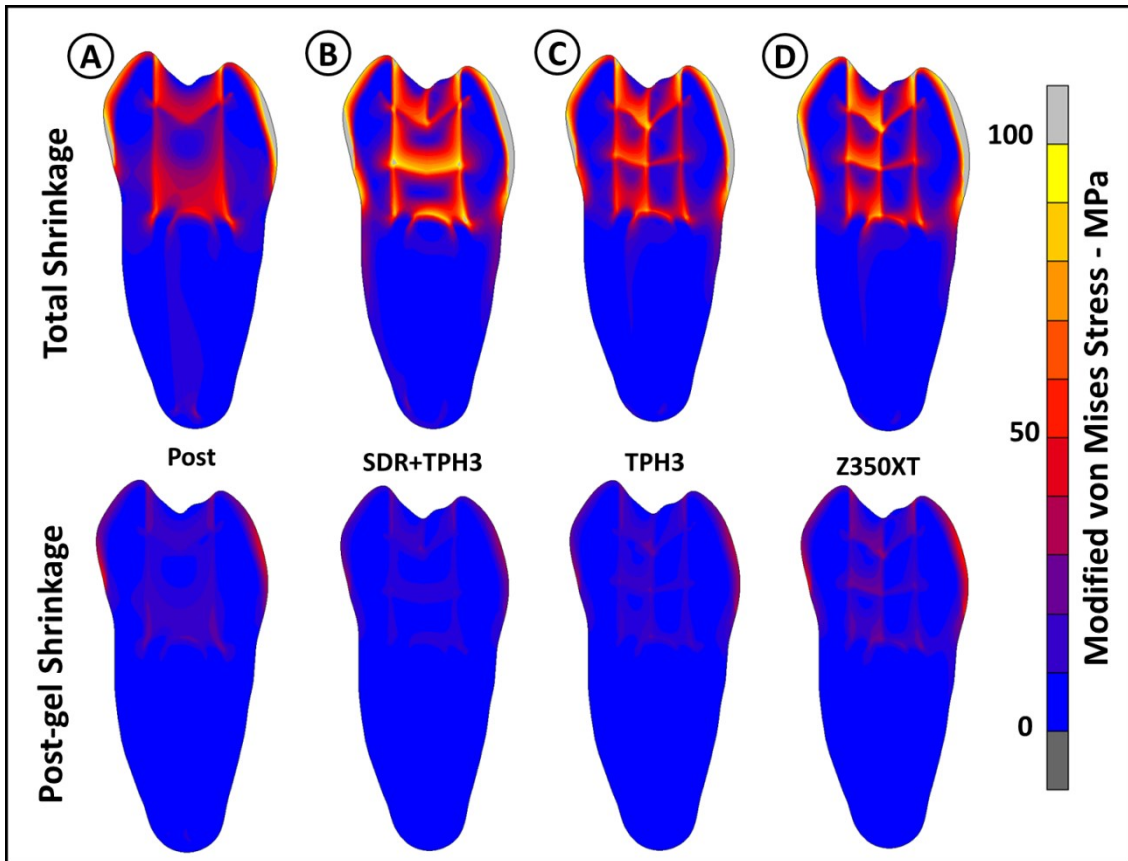


Figure 3. Modified von Mises shrinkage stress (MPa) distribution for the different restorative materials and techniques after polymerization using total shrinkage values and post-gel shrinkage values.

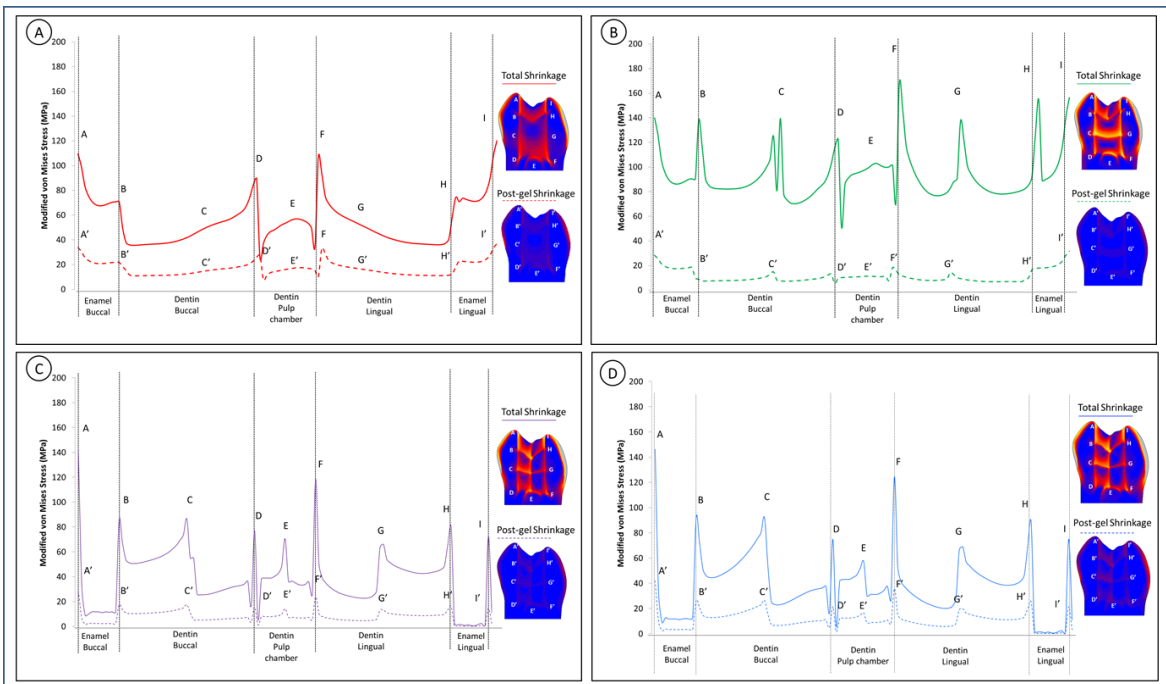


Figure 4. Total and post-gel shrinkage Modified von Mises stresses from composite-enamel and dentin-composite interfaces values for the different resin techniques.

Capítulos

3.2 CAPÍTULO 2

Can the porosity of Incremental and bulk fill resin composite filling techniques affect the biomechanical performance of endodontic treated molars?

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Can the porosity of Incremental and bulk fill resin composite filling techniques affect the biomechanical performance of endodontic treated molars?

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Running title: Biomechanics analysis on restored endodontic treated molars

Keywords: resin composite, bulk-fill, glass ionomer, mechanical properties, micro-CT, porosity, endodontic treated molar.

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Can the porosity of Incremental and bulk fill resin composite filling techniques affect the biomechanical performance of endodontic treated molars?

Abstract

Objectives: To analyze the effect of the porosity caused by incremental and low and high viscosity bulk fill filling techniques on biomechanical performance of endodontically treated molars.

Methods: Forty intact molars received standardized MOD cavity preparation, were endodontically treated and randomly divided into 4 filling techniques (n=10): two conventional incremental conventional composite resins (Filtek Z350XT, 3M ESPE; TPH Spectrum, Dentsply) associated with resin modified glass ionomer cement, RMGIC (Vitremer, 3M ESPE) for filling pulp chamber; and two bulk fill composite resins: low viscosity resin composite (Surefill SDR flow, Dentsply) associated with TPH3 Spectrum; and a high viscosity bulk fill resin composite (Filtek Bulk Fill Posterior, 3M ESPE). The volume of the porosity inside of the restoration was calculated by micro-CT. Cusp deformation caused by polymerization shrinkage was calculated using the strain-gauge and micro-CT methods. Cusp deformation was also calculated during 100N occlusal loading and at fracture. The fracture resistance and fracture mode were calculated. Data were analyzed using one-way ANOVA and Tukey test. Fracture mode was analyzed by Qui-square test. The volume of porosity was correlated with cusp deformation, fracture resistance and fracture mode ($\alpha=0.05$).

Results: Incremental resin composites associate with RMGIC resulted in significantly higher porosity than both bulk fill techniques. However, no significant difference was found among groups for cusp deformation (irrespective of the moment measured and method used), fracture resistance and fracture mode. No correlation was observed on volume of porosity and all tested parameters.

Conclusions: The porosity on the restorations had no influence on the cuspal deformation, fracture resistance and fracture mode. The use of the RMGIC for filling the pulp chamber associated with incremental composite resins resulted

in similar biomechanical performance of flowable and regular paste bulk fill composite resin restorations of endodontic treated molars.

Clinical relevance: *The presence of the porosity confined inside the restoration had no effect on the biomechanical performance of endodontically treated molars. The clinicians should select the restorative materials thinking more on the mechanical properties and lower polymerization shrinkage.*

INTRODUCTION

Dental decay is still considered a global endemic disease, mainly in children and adolescents. It is a chronic and multifactorial disease, which can cause morbidity such as pain and suffering.¹ In the oral cavity if a cariogenic environment continues the first molar can be more frequently affected by caries. It is the first permanent posterior teeth in the mouth with broad dentin tubules, wide pulp chamber which may facilitate the infection of the dental pulp requiring frequently the endodontic treatment.^{2,3}

Young molar severely damaged by caries being necessary endodontic treatment and direct composite resin restoration to preserve these teeth.⁴ The adhesive restorative procedure, have been indicate to reinforce weakened tooth structure, being more conservative when compared with indirect restoration.⁵⁻⁸ Restorative protocols with oblique filling technique and light cured in 2 mm increments have been shown to achieve good mechanical properties while minimize the shrinkage stress caused by several light activations.⁹⁻¹¹ The use of glass ionomer to fill the pulp chamber followed by composite resin restoration resulted in the most favorable conditions by reducing cuspal strain and increasing fracture resistance, compared to the use of only composite resin inserted incrementally.¹² Regular bulk fill composite or flowable bulk fill composite resin covered with a low post-gel shrinkage composite can minimize the negative effects of residual shrinkage stress, being a viable alternative for a restorative protocol of endodontic treated molars.¹³

Endodontically treated teeth have large and deep cavity, and for this reason during de restorative procedure the presence of voids and bubbles is supposed to accelerate the deterioration of the material, resulting in marginal infiltration, discoloration, increased wear and lower flexural strength.¹⁴ The voids between the increments can be resulted during the insertion of the

material.^{15,16} In addition, differences between restorative materials in the amount of voids and gaps remaining after condensation of the materials in the cavities have showed low viscous composite resins, as the best in filling cavities without voids or gaps, however, these results were correlated to small cavities.¹⁷ Nevertheless, the correlation between voids and the polymerization shrinkage and the mechanical resistance of posterior composite resins are inconclusive.¹⁸ Therefore, the aim of this study *in vitro* was to evaluate the effect of the porosity of incremental composite resins associated with RMGIC, bulk fill flowable with conventional composite resin and regular paste bulk fill composite resins on the biomechanical performance of endodontically treated molar teeth with class II cavity. The null hypothesis was that porosity of the restoration would not influence the biomechanical performance of restored endodontically treated molar teeth.

METHODS AND MATERIALS

Study design

Forty human molars received standardized class II mesio-occlusal- distal (MOD) cavity preparations and were endodontic treated. Teeth were restored with four different protocols according to manufacturer's instructions. The number of samples for each methodology was based on the coefficient of variability and the sample calculation. The power of test was 80% with a minimum detectable difference of 20%, there was a residual standard deviation of 15% and a significance level of 0.05, resulting in 10 samples per group. The composition of the resin composites as provided by the manufacturers are listed in Table 1. Teeth were tested for cuspal deformation using strain-gauges during restorative procedure (CSt- Re), using micro-CT images and during 100N occlusal loading (CSt- 100N) and at fracture resistance (CSt-Fr). Fracture resistance of axial occlusal compressive loading and fracture mode (Fm) was evaluated after test.

Tooth Selection and Cavity Preparation

Forty extracted, intact, caries-free human third molars were used (Ethics Committee in Human Research approval no. 06257012.1.0000.5152). Teeth were selected with an intercuspal width within a maximum deviation of 10%

from the determined mean.¹¹ The intercuspal width of selected molar teeth varied between 5.2 to 6.2 mm. To have the periodontal ligament simulated, teeth had their roots covered with 0.3-mm layer of a polyether impression material (Impregum, 3M ESPE, St Paul, MN, USA), and embedded with polystyrene resin (Cristal, Piracicaba, Brazil) up to 2 mm below the cementum-enamel junction to simulate the alveolar bone.¹⁹ Then, the teeth were cleaned using a rubber cup and fine pumice water slurry. Class II mesio-occlusal-distal (MOD) cavities with approximately 4/5 of the intercuspal width and 5mm depth were prepared in all samples with a diamond bur (#3099 diamond bur, KG Sorensen, Barueri, Brazil) with abundant air-water spray, using a cavity preparation machine.²⁰ The machine consisted of a high-speed handpiece (Extra torque 605 C, Kavo do Brasil, Joinvile, Brazil) coupled to a mobile base that can move vertically and horizontally with three precision micrometric heads (152-389, Mitutoyo, Suzano, Brazil), attaining a 0.002 mm level of accuracy. Endodontic access was manually performed with a diamond bur (#1016 HL KG Sorensen), and endodontic treatment done by an operator calibrated to use the rotary nickel-titanium (Ni-Ti) System (Dentsply Maillefer). Teeth were then instrumented at the previously determined working length using rotary files (ProTaper Universal; Dentsply Maillefer), following the manufacturer's instructions. Each instrument was passively introduced into the root canals at a 250-rpm rotation rate (X Smart; Dentsply Maillefer). Irrigation was performed using 1% NaOCl after each instrument. The roots were filled with gutta-percha (Dentsply Maillefer) and calcium hydroxide based endodontic sealer (Sealer 26, Dentsply Maillefer).

Teeth were randomly divided into four groups (n = 10) following the materials and restorative procedures techniques:

Group 1-RMGIC/Z350XT: RMGIC (Vitremer, A2 Shade, 3M ESPE) was used to fill the pulp chamber. The RMGI was manipulated and inserted using commercial syringe (Centrix, Shelton, CT, USA) following manufactures' instructions, and light cured for 20 s using the LCU Bluephase G2 (Ivoclar Vivadent AG, Austria), with 1,200 mW/cm² checked by using MARC Resin Calibrator (BlueLight, Halifax, Canada). Selective etching of enamel was done for 10 seconds, and a two-step self-etching adhesive system (Single Bond Universal, 3M ESPE) were used for hybridization procedures in all groups. The

conventional nanofilled composite resin (Filtek Z350, 3M ESPE) was incrementally inserted in 8 increments of 2,0mm starting by proximal surfaces (2 increments to reconstruct the medial proximal surface; 2 increments to reconstruct the distal proximal surface; and 4 increments reconstructing occlusal box.

Group 2-RMGIC/TPH: RMGIC (Vitremer, 3M ESPE) to fill the pulp chamber followed by incremental filling technique with microhybrid composite resin (TPH3 Spectrum, Dentsply), following the same restorative protocol described for group 1.

Group 3-SDR/THP: low viscosity bulk fill composite resin, Surefill SDR (Dentsply) was inserted in 2 increments of approximately 4.0mm to replace dentin and covered with two increments of 2.0 mm of conventional resin composite, TPH3 (Dentsply) for reconstruct the enamel, following the same restorative protocol described for group 1.

Group 4-POST: high viscosity bulk fill resin composite Filtek Bulk Posterior (3M ESPE) was inserted in 2 increment of approximately 5mm from the pulp chamber to replace dentin and enamel, following the same restorative protocol described for group 1.

After restoration, all specimens were stored in relative humidity at 37°C for 24h and then finished using diamond burs (KG Sorensen, Barueri, SP, Brazil). The sequence followed was a fine grain (gold 2135F) followed by an extra fine grain bur (silver 2135FF), all diamond burs were used with intermittent water spray.²¹

Cuspal Deformation – strain gauge and micro-CT

Cuspal deformation was measured with strain gauges (PA-06-060CC-350L, Excel Sensores, Embú, Brazil), with an internal electrical resistance of 350 Ω , a gauge factor of 2.07, and a grid size of 21.02 mm². It is important to mention that a gauge factor is a proportional constant between electrical resistance variation and strain. One strain gauge was placed on the external surface of the lingual cusp and the other next to the buccal cusp in the height of the pulp chamber. The region where a finite element model had indicated the presence of the highest polymerization strains.²²

In addition, two strain gauges were fixed to another intact tooth to compensate for dimensional deviations due to temperature effects. The strain gauges were bonded with cyanoacrylate-based adhesive (Super Bonder, Loctite, Itapeví, Brazil), and the wires were connected to a data acquisition device (ADS0500IP, Lynx, São Paulo, Brazil).^{11,23,24.}

Cuspal Deformation and voids volume of restorations on micro-CT

To evaluate the cuspal deformation and voids volume produced by the resin restorations protocols, the teeth were scanned after cavity preparation and after restoration using a micro-CT device (SkyScan 1272, Bruker, Belgium) as previously described by Oliveira *et al.*, 2018. To standardize and allow superimposition of the images, the teeth were placed in the micro-CT in the same position with the buccal face facing the door. The image acquisition consuming approximately 38 minutes to scan each tooth using the following parameters: exposure time of 1100 milliseconds, energy 100 KV-100 μ A, 180° rotation at the 0.500 step, Cu filter of 0.11 mm thickness, and a 12 μ m voxel size. The scan images acquired by micro-CT was imported to a workstation and rebuilt using Nrecom software (version 1.6.10.1, Skyscan, Bruker, Belgium) in approximately 1.050 slices, respecting the anatomical limits of the samples. The reconstructed images were overlaid using DataViewer software (version 1.5.1.2, SkyScan, Bruker, Belgium). To align the different images of the prepared and restored teeth, a reference point was selected that was distant from the area affected by shrinkage. The volume of root portion of the tooth below cemento-enamel junction which included both the pulp chamber and canals were used as a reference. The prepared tooth image and the restored tooth image (target) were superimposed, this generated a volume of difference image (Diff). This Diff image represented the volume of the cusp deformation caused by the polymerization shrinkage of the resin composite restoration. The micro-CT analyzer software (CTAn, version 1.13, SkyScan, Bruker, Belgium) was used to threshold the regions of interest (ROI), and to calculate the difference between the overlapping all 2D images presents in volume of interest (VOI), using 3D analysis tool. The number of layers was the same for all analyzed Diff images, at total of 800 layers, each with a resolution of 0.4 μ m. The regions of interest were positioned in the same area of the cusp where the strain gauge

was positioned in the sample. The cusp deformation volume values were obtained in mm³ and the percentage of this deformation was calculated as a function of the total volume of each cusp.

Still in analyzer software CTAn, the tooth scanned images after restorative procedure were evaluated for voids volume. Initially, a new region of interest (ROI) was defined, located this time in the region of the restorative material. Then, the threshold was done based on the density difference between the voids and the restorative material. Using 3D analysis tool, it was possible to extract the data referring of voids volume in mm³ and to calculate how much these voids volumes represented in proportion to the total volume of the restorative material and was expressed as percentage.

Using the CT-VOL software (version 2.0, SkyScan, Bruker, Belgium), tridimensional images were generated from the differences in cusp shape volumes caused by dental composite shrinkage and images of porosity in restorations.

Mechanical cycling test

After cuspal deformation measurements and micro-Ct scanning, to simulate 5 years aging, chewing cycles were simulated to induce mechanical fatigue (Biocycle, Biopdi, São Paulo, SP, Brazil). The samples were submerged in water at about 37°C and cycled 1,200,000 times from 0 to 50 N axial compressive loading with a 8-mm diameter stainless steel sphere on the occlusal cusps with a 2 Hz frequency.^{25,26.}

Cuspal strain during fracture procedure (CSt-Fr), fracture resistance and fracture mode

Strains were recorded under 100 N loading (CSt-100N) with strain gauges. The load required (N) to cause fracture of the samples was recorded on a computer with control and data acquisition software (TESC; EMIC). Strains were also recorded at failure load (CSt-Fr). Axial compressive loading with a stainless-steel sphere 8 mm in diameter at a crosshead speed of 0.5 mm/min in a universal testing machine (DL2000; EMIC, São José dos Pinhais, PR, Brazil) with a 500 N load cell was used.

The fracture modes of each sample were evaluated by three operators and then assigned to one of four categories proposed by Burke²⁷: (I) fractures involving a small portion of the coronal tooth structure; (II) fractures involving a small portion of the coronal tooth structure and cohesive failure of the restoration; (III) fractures involving the tooth structure, cohesive and/or adhesive failure of the restoration, with root involvement that can be restored in association with periodontal surgery; and (IV) severe root and crown fracture, which determine extraction of the tooth.

Statistical analysis

The cuspal deformation, fracture resistance, and void volume data were tested for normal distribution (Shapiro Wilk's test) and equality of variances (Levene's test), followed by parametric statistical tests. One-way ANOVA was performed in a split-plot arrangement for cusp strain values, with the plot represented by restorative protocol and the subplot represented by cusp type. One-way analysis of variance (ANOVA) was performed for fracture resistance and void volume values. Multiple comparisons were made using Tukey's test. Pearson correlation test was used to correlate the measured cusp deformation caused by polymerization shrinkage obtained from the strain gauge and micro-CT methods. The failure mode data were subjected to Chi-square test. All tests employed $\alpha = 0.05$ significance level and all analyses were carried out with the statistical package Sigma Plot version 13.1 (Systat Software Inc, San Jose, CA, USA).

RESULTS

Porosity of the restorations - micro-CT

The porosity generated during restorative procedures evaluated by micro-CT are shown in Fig. 1. One-way ANOVA showed significant effect of restorative technique on the percentage of porosity ($P < 0.001$). The POST had lower porosity than RMGIC/TPH3 and RGMIC/Z350XT. The SDR/TPH3 had similar porosity than all other groups.

Cuspal deformation – strain gauge and micro-CT

The cuspal deformation means and standard deviations caused by polymerization shrinkage, occlusal loading and at fracture resistance measured by strain gauges (n = 10) are shown in Table 2. One-way ANOVA showed that all restorative protocols had similar cuspal deformation at polymerization shrinkage (P = 0.992), occlusal loading (P = 0.342) and at fracture resistance (P = 0.941). However, the cusp type had a significant effect for all the measured moments polymerization shrinkage (P < 0.001), occlusal loading (P < 0.001) and at fracture resistance (P < 0.001). The lingual cusp had a significantly higher deformation than the buccal cusp at all measured moments. The Pearson correlation showed lower correlation between cuspal deformation measured with strain gauge caused by polymerization shrinkage with porosity inside the restoration (P = 0.576), during occlusal loading (P = 0.345) and at fracture resistance (P = 0.125).

The cuspal deformation means and standard deviations measured after restorative protocols by using micro-CT method are shown in Table 2 and Fig. 3. One-way ANOVA showed that all restorative protocols showed similar cusp deformation (P = 0.325), however the cusp type (P < 0.001) had a significant effect. The micro-CT showed that the lingual cusp had a greater deformation than the buccal cusp. The Pearson correlation showed lower no correlation between cuspal deformation measured with micro-ct caused by restorative procedure (P = 0.352).

Fracture Resistance and fracture mode

The means and standard deviations of fracture resistance for all restorative techniques are shown in Table 4. One-way ANOVA showed no significant difference among groups (P = 0.786). Chi-square test showed no difference on the fracture mode for all tested restorative protocols (P = 0.911). The ratio between the maximum resistance and cusp deformation at fracture moment is shown in Table 4. No difference was found among tested restorative protocols (P = 0.741).

DISCUSSION

In the present study the null hypothesis was accepted, the porosity inside the different materials used to fill in the pulp chamber did not interfere on the cusp

deformation, fracture resistance and fracture mode of the endodontically treated molars.

The use of the glass ionomer to fill the pulp chamber has demonstrated lower cusp deformation and higher fracture resistance when compared with incremental filling technique. The groups RMGIC/Z350XT and RMGIC/TPH, which has the presence of RMGIC inserted into the pulp chamber combined to incrementally inserted conventional composite resin, resulted in a higher number of voids, probably due to the fact that RMGIC requires mixing and insertion method can incorporate voids within the material.^{28,29} The higher amount of porosity presented in these two groups were located inside the pulp chamber. The insertion of the RMGIC into the pulp chamber can also lead to air entrapment between the same and the tooth structure. Laboratory studies have shown that insertion using different methods as the Centrix syringe, or simple low-cost syringe, are effective in decreasing porosity in the material.²⁹ It is important to evaluate if voids are also affected by the size of the cavity, during clinicians effort to insert the material to the bottom of the cavity.³⁰ Additionally, the restoration of deep cavities using the incremental technique with increments of 2 mm may cause entrapment spaces and consequently air voids between the increments.^{15,16,31} Thus, as least as possible the material manipulation by the operator during its insertion is recommended.^{16,18}

When restoring the cavity using bulk fill composite resin, the risk of voids generation between increments decreased significantly, as observed for the POST group, since the material can be inserted in a single increment (4-5 mm). Although if the viscosity of the material is high, which could be a void aggregating factor.¹⁶ The manipulation of the material during insertion is minimal and have the possibility to be condensed during their insertion to better accommodate the material, which is influential factor on the porosity.³² A possible explanation for the SDR/TPH protocol having less quantity of voids when compared with the others protocols which used glass ionomer in pulp chamber could be because SDR flow was inserted with its own active tip.¹⁶ This material do not need mixing process, and the voids found may be originated from the encapsulation process of the material, and its intrinsic porosity, which can not be controlled by the operator.³²

Teoretically, the presence of voids may represent points of crack propagation, which may result in reduced material resistance and restoration longevity.^{29,33} However in this the present study, the porosity inside the restorations was not sufficient to influence the mechanical performance of restorations, since no difference among the restorative protocols was observed for all biomechanics parameters evaluated. This can be attributed to the fact that despite the presence of porosities in the materials, the total volume of voids was smaller when compared to the total volume of the restoration. In addition, the higher volume of voids was located inside the pulp chamber of the restorations and not at in critical points, such as in the interface region and close to occlusal surface.

The cuspal deformation, fracture resistance and failure mode of the different protocols of restored teeth are the results of the interaction among multiple factors, such as restorative preparation design, magnitude and type of load, mechanical properties of restoration, and the use of low-modulus intermediate layers.³⁴ The use of RMGIC to fill pulp chamber can reduce the composite resin volume needed to fill the cavity, reducing the side effects of polymerization shrinkage caused by incremental filling technique.³⁵ On the other hand the use of bulk fill composite resin irrespective of the viscosity, reduce the polymerization shrinkage stress and contribute with better similar biomechanical performance.

Cuspal deformation during restorative procedures, occlusal loading of 100N deformation and the maximum load to fracture were not influenced by the different restorative's protocols. It has been shown that, the lingual surface of the reminiscent tooth, showed higher deformation than buccal surface during occlusal loading at 100N and at the fracture moment, irrespective of the restorative protocol. The lower volume of dentin on the lingual surface could explain the higher deformation.³⁶ The different tested protocols has similarity regarding the lower elastic modulus used to restore the pulp chamber. All the materials used, RMGI, SDR and also the POST has lower elastic modulus than conventional composite resin, leading to a higher capacity of elastic deformation.^{12,13,21} The presence of porosity located inside the restoration was not a significant factor to compromise the biomechanical performance of the endodontically treated molars restored with direct composite resin restorations.

CONCLUSION

Within the limitations of this in vitro study, the porosity generated during restorative protocols had no influence on the cuspal deformation, fracture resistance and fracture mode. The use of the RMGIC for filling the pulp chamber associated with incremental filling technique resulted in similar biomechanical performance of low and high viscosity bulk fill composite to restore endodontically treated molar teeth.

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Conflict of Interest

The authors certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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Tables

Table 1. Resin composite information based on manufacturer's reported data.

Material	Code	Shade	Composite type	Increment size and light activation time	Organic matrix	Filler	Filler % w/vol
Vitremer (3M-ESPE, St Paul, MN, USA)	RMGIC	A2	Resin modified glass ionomer cement	2.0 mm - 40 seconds	Poly (acrylic-itaconic acid with pendent methacrylate, H ₂ O	Fluoroaluminosilicate glass, microencapsulated.	-
Filtek Z350 (3M-ESPE, St Paul, MN, USA)	Z350	A2	Nanohybrid composite	2.0 mm - 20 seconds	Bis-GMA, UDMA, TEG-DMA	Silica and zirconia nanofillers, agglomerated zirconiasilica nanoclusters.	78.5/59.5
TPH3 Conventional (Dentsply - Konstanz, BW, Germany)	TPH3	A2	Nanohybrid composite	2.0 mm – 20 seconds	Bis-GMA, Bis-EMA.	Barium, Boron, Alumino-silicate glass.	75/57
Surefil Flow (Dentsply - Konstanz, BW, Germany)	SDR	A2	Low viscosity Bulk fill	4.0 mm – 20 seconds	Modified UDMA, dimethacrylate and difunctional diluents.	Barium and strontium aluminofluoro-silicate glass.	68/44
Filtek Posterior Bulk fill Regular (3M-ESPE, St Paul, MN, USA)	POST	A2	High Viscosity Bulk fill	5.0 mm – 20 seconds	AUDMA, UDDMA, UDMA.	Silica, zirconia, and YbF ₃ .	76.5/59.5

Table 2. Means and standard deviation of cusp deformation caused by polymerization shrinkage of filling techniques measured using micro-CT (%).

Groups	Cusp strain filling technique %		
	Buccal cusp	Lingual cusp	Mean cusps
SDR/THP	2.0 (0.3) ^{Aa}	2.8 (0.4) ^{Ab}	2.3 (0.3) ^A
POST	2.2 (0.3) ^{Aa}	2.7 (0.2) ^{Ab}	2.5 (0.2) ^A
RMGIC/Z350XT	2.4 (0.3) ^{Ab}	3.2 (0.9) ^{Ab}	2.8 (0.4) ^A
RMGIC/TPH	2.5 (0.5) ^{Ab}	3.0 (0.4) ^{Ab}	2.7 (0.2) ^A

Different letters indicate a significant difference – upper caser used for comparing the resin composites and lower caser letters used for comparing the cusp location ($p < 0.05$).

Table 3. Means and standard deviation of cusp deformation (μS) caused by polymerization shrinkage, occlusal loading and at fracture resistance measured by strain gauges (n = 10).

Groups	Cusp strain filling technique(μS)			Cusp strain at 100 N loading (μS)			Cusp strain at fracture load(μS)		
	Buccal cusp	Lingual cusp	Mean cusps	Buccal cusp	Lingual cusp	Mean cusps	Buccal cusp	Lingual cusp	Mean cusps
SDR/THP	173.7 (45.4) ^a	226.5 (65.9) ^b	180.1 (41.3) ^A	21.0 (6.6) ^a	49.9 (8.6) ^b	35.5 (7.5) ^A	368.7 (63.9) ^a	640.2 (244.8) ^b	486.8 (81.7) ^A
POST	161.5 (54.8) ^a	338.3 (78.6) ^b	249.9 (44.0) ^A	22.3 (8.5) ^a	47.2 (13.1) ^b	35.8 (9.5) ^A	348.0 (75.3) ^a	556.8 (194.2) ^b	457.7 (76.9) ^A
RMGIC/Z350XT	164.1 (56.6) ^a	341.2 (75.2) ^b	256.9 (46.0) ^A	22.5 (9.5) ^a	35.2 (10.3) ^b	28.8 (8.4) ^A	285.6 (62.9) ^a	502.8 (179.9) ^b	394.2 (73.4) ^A
RMGIC/TPH	178.9 (66.2) ^a	341.7 (88.0) ^b	260.6 (50.7) ^A	22.2 (6.9) ^a	36.0 (9.4) ^b	29.1 (8.6) ^A	287.3 (84.2) ^a	564.1 (190.7) ^b	427.5 (85.3) ^A

Different letters indicate a significant difference – upper caser used for comparing the resin composites and lower caser letters used for comparing the cusp location (p < 0.05).

Table 4. Means (Confidence Interval–95% Confidence Interval) of Fracture Resistance (N), Mode of Fracture, and the Ratio Between Maximum Cusp Deformation/Fracture Resistance Measured by the Axial Compression Test (n=10).

Group	Fracture resistance (N)	Fracture mode				Ratio between strain/fracture resistance
		I	II	III	IV	
SDR/THP	1390.9 (1080.2 – 1701.5) ^A	0	1	9	0	0.36 ^A
POST	1375.5 (1047.0 – 1704.4) ^A	0	0	10	0	0.31 ^A
RMGIC/Z350XT	1294.7 (944.7 – 1644.7) ^A	0	2	8	0	0.32 ^A
RMGIC/TPH	1261.3 (886.5 – 1636.1) ^A	0	2	8	0	0.33 ^A

Figures

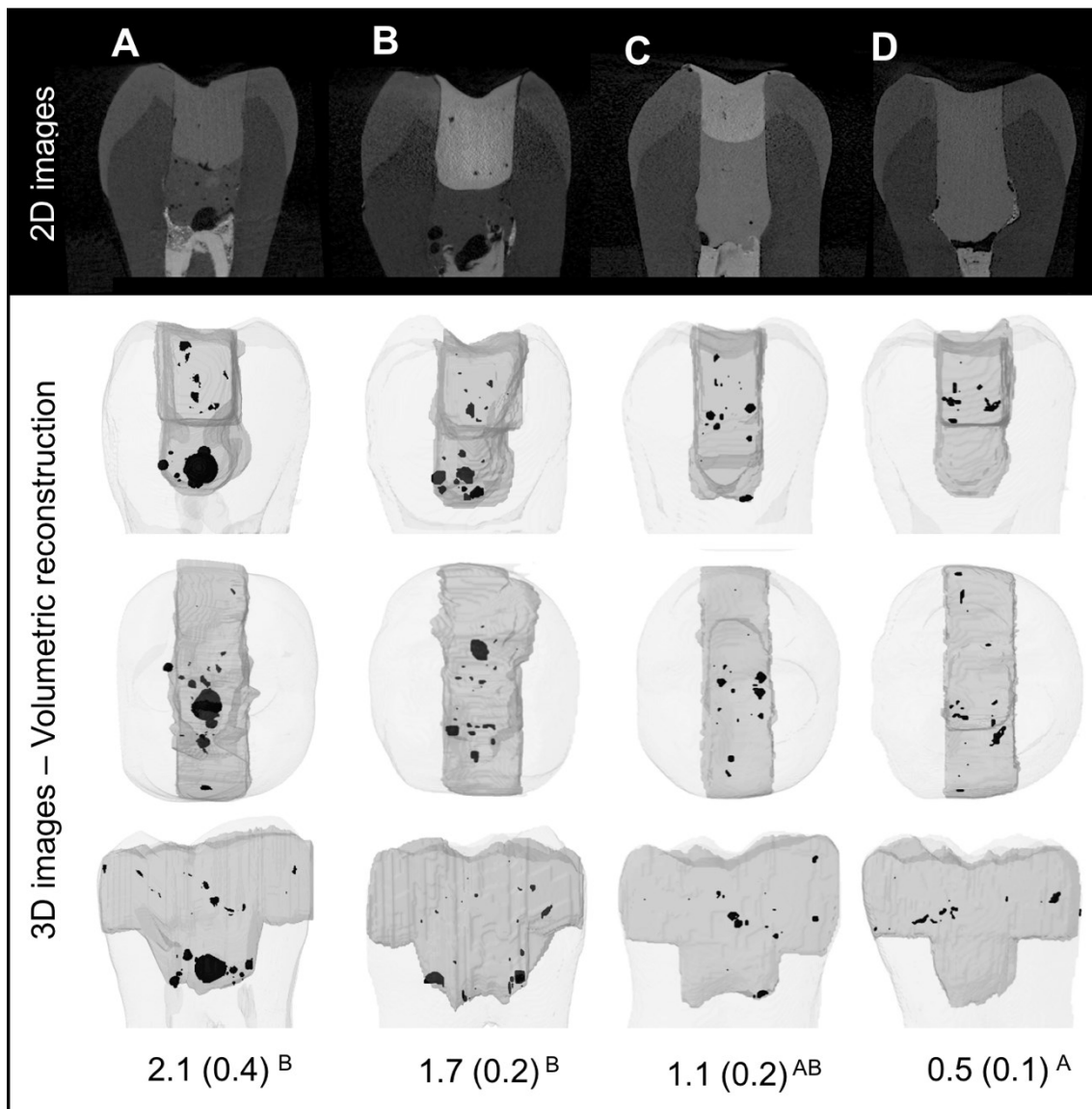


Figure 1. 2D and 3D porosity images into the restorations: A. RMGIC/Z350XT, B. RMGIC/TPH, C. SDR/TPH, D. POST. Means and standard deviation of the percentage of bubbles volumes into the restoration measured by microCT (n = 10). Different letters indicate a significant difference for comparing the resin composites (P < 0.05).

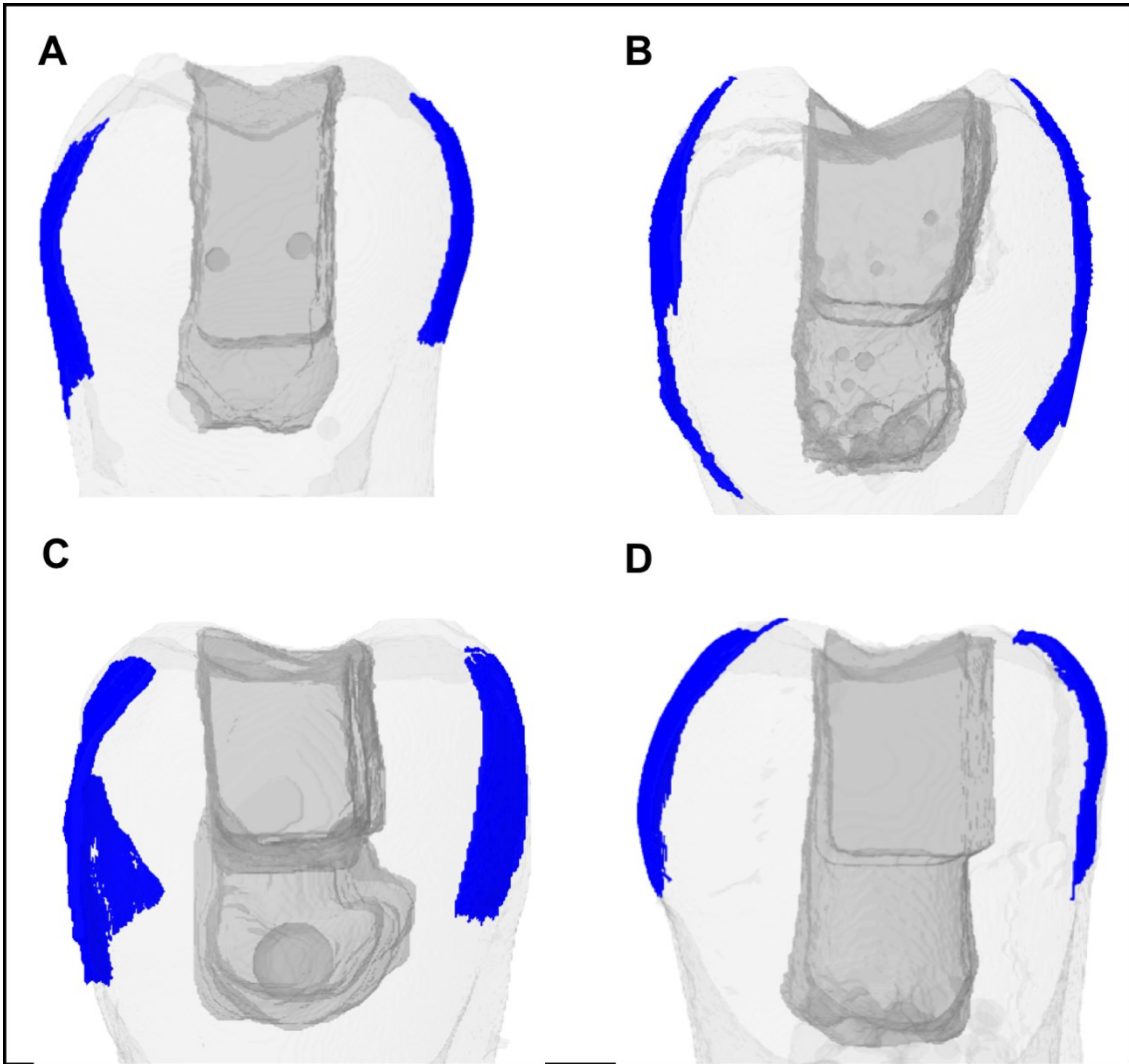


Figure 2. Fig. 5. Volume of cusp deformation calculated with Micro CT – in 3D. Difference of overlap of prepared images in proximal view. A. SDR/TPH, B. RMGIC/TPH, C. RMGIC/Z350XT, D. POST.

Capítulos

3.3 CAPÍTULO 3

Clinical performance of composite resin restorations in endodontically treated molars of adolescents: a 2-year randomized clinical trial comparing bulk fill and incremental filling technique

Artigo a ser submetido para publicação no periódico **Clinical Oral Investigation**

Clinical performance of composite resin restorations in endodontically treated molars of adolescents: a 2-year randomized clinical trial comparing bulk fill and incremental filling technique

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Running title: Bulk fill restorations for endodontically treated molars.

Keywords: composite resin, bulk fill, incremental filling technique, glass ionomer, clinical trial, endodontically treated molar.

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Clinical performance of composite resin restorations in endodontically treated molars of adolescents: a 2-year randomized clinical trial comparing bulk fill and incremental filling technique

ABSTRACT

Objectives: To compare the 2-year clinical performance of direct composite resin restorations of endodontically treated molars, using two filling techniques: bulk fill and incremental filling technique.

Methods: Sixty-eight endodontically treated molars were restored in 54 adolescents (10-18 years old, mean= 14.0 ± 2.4). Teeth were randomly assigned to the incremental filling technique (Filtek Z230/Vitremer, 3M-ESPE, n = 31) or high viscosity bulk fill technique (Filtek Bulk Fill Posterior, 3M-ESPE, n = 37). The restorations were clinically evaluated at baseline, 12 and 24 months by two independent raters using the modified United States Public Health Service criteria. Data analysis included descriptive statistics, bivariate non-parametric tests, and Generalized Estimating Equation (GEE) analysis.

Results: No significant differences were found for all group-characteristics on the type of restorative technique ($P > 0.05$). Friedman test showed significant differences concerning the 2-year assessment ($P < 0.001$) for all clinical outcomes compared to baseline. For the longitudinal assessments, bulk fill composite resin filling technique performed better only for marginal adaptation ($P = 0.040$) and surface texture ($P = 0.014$). The number of residual walls, teeth location, age and gender had non-significant effects.

Conclusions: Both direct restorative techniques showed satisfactory success rates during the 2-year longitudinal assessment. The bulk fill technique performed slightly better for marginal adaptation and surface texture.

Clinical Relevance: Bulk fill composite resin filling technique is a good alternative for restoring endodontically treated molar teeth in adolescents. The detrimental effects of time on the assessed clinical parameters occurred irrespective to the filling technique.

1. Introduction

Dental caries is one of the most prevalent oral health diseases and still remains an important public health problem [1]. Higher risk behaviours for dental caries is observed in adolescents, due to the precarious plaque control and reduction of care with oral hygiene, aggravated by the higher consumption of a sugary foods [2], as well as adverse socioeconomic and individual psychosocial characteristics [3]. The negative effects of dental caries in adolescents include difficulty chewing, decreased appetite, weight loss, difficulty sleeping, irritability, low self-esteem, and decreased school performance [4].

The first permanent molars are more likely to develop caries lesions due to the lower density of calcium, the large fissure numbers inaccessible for cleaning, and are more affected by poor oral hygiene in earlier ages [5]. Caries in young molars frequently requires restorative intervention, since most of these lesions are extensive. In addition, restoration of extensively damaged young molar teeth may be more complicated due to anatomic and eruption features, and they are often associated with pain and pulp involvement, leading to endodontic treatment need before restoration.

The use of composite resin for restoration of posterior teeth has become a routine procedure in daily practice [6,7], due to better aesthetics and conservative preparations [7,8]. However, there is limited data concerning the assessment of clinical outcomes of restorative procedures in endodontically treated young molar teeth severally affected by caries. Factors such as the material properties, quality of adhesive procedures, patient features, oral environmental factors, the location and extension of the restoration, the risk of caries and habits such as bruxism, as well as socioeconomic factors were reported to influence the longevity of these restorations [6,9]. Poor hygiene control was also considered a relevant risk factor for the long-term performance of composite resin restorations in molar teeth in young patients [10]

Although direct composite resin is less costly, it is also less effective than indirect restoration for endodontically treated teeth, and over long-term follow-up periods the initial treatment costs may be outweighed by costs of further interventions [11]. However, in some clinical settings the restoration of endodontically treated molars in children and adolescents with direct composite

resin tends to be the most suitable alternative to prevent early tooth extraction, mainly in circumstances of social and economic vulnerability.

For composite resin restorations, the incremental technique is the most common procedure in clinical practice, aiming to avoid depth-of-cure limitations and to overcome polymerization shrinkage stress [12,13]. The use of the incremental technique associated with the filling of the pulp chamber with glass ionomer cement reduces cuspal strain and increases the fracture resistance of the tooth [14]. However, this technique requires longer clinical time, due to the insertion of several oblique increments, which must be at most 2 mm thick to allow complete polymerization of the composite resin increment [9].

More recently, the bulk fill composite resin was introduced to simplify this clinical procedure by reducing the clinical time for insertion and polymerization, and making the clinical procedure easier to perform [15-17]. Bulk fill composite resins can be inserted in volumes up to 5-mm in thickness with proper polymerization and low polymerization shrinkage [17,18]. A recent systematic review reported that bulk fill composite resins present similar clinical performances when compared to conventional resin composites over a follow-up period from 12 to 72 months, and suggested that they could be a viable alternative for direct restorations in posterior teeth [19]. However, there is scarce information on clinical performance of bulk fill resin composites compared with conventional resin composites used for direct restorations of endodontically treated young molars. Therefore, this study aimed to compare the 2-year success rates of direct restorations of endodontic treated molars by using two different techniques: (1) the incremental filling technique with conventional composite resin associated with Resin Modified Glass Ionomer Cement (RMGIC) to fill the pulp chamber, and (2) the bulk fill high viscosity filling technique. The null hypothesis is that there will be no difference in clinical performance between these two protocols.

2. Materials and methods

2.1 Study design and sample size calculation

This study was designed as a randomized clinical trial, comprising adolescent patients with need to restore endodontically treated molar teeth, and

comparing two different composite resin techniques: incremental or bulk fill. Longitudinal assessment was performed immediately after restoration and after 12 and 24 months. The study protocol was previously approved by the local Research Ethics Committee (#5152/ 2015) and parents signed the consent for the adolescents to participate after being informed of the aims of the study. Enrolment of participants occurred between February 2016 to September 2018. All procedures were performed at the School of Dentistry of the Federal University of Uberlândia, Brazil.

Eligible participants were adolescents aged 10 – 18 years old, diagnosed with molar teeth with deep and large carious lesions with pulp involvement, and referred to endodontic/restorative treatment. Exclusion criteria comprised patients with chronic disease with oral manifestations or other oral pathologies considered serious, patients with severe periodontal disease that may compromise direct restoration in posterior tooth, patients with allergies to any of the material used in this study, patients with signs or symptoms of bruxism and teeth grinding, and patients with ceramic restorations opposing to the tooth to be restores.

The primary outcome of this study was the success rates of direct restorations of endodontic treated molars. Sample size calculation considered a restoration survival rate of 84% [20], $\alpha=0.05$ (type I error rate), $1-\beta=0.80$ (study power) and the equivalence limit of 30%. A 20% increase in each group was adopted to compensate possible participant dropout. In cases when the patient had more than one tooth to be restored, the restored tooth level was considered as the primary sample unit for sample size calculation.

2.2 Randomization

An independent researcher not involved directly in the study performed the allocation of the teeth for the two filling techniques using a simple randomization method based on a computer-generated system (<https://www.sealedenvelope.com/>). Group assignment was kept inside numbered, opaque, sealed envelopes, and was opened immediately before the restorative procedures in order to guarantee the randomization concealment and minimize bias due to the knowledge of which intervention was being received by study participants.

2.3 Restorative procedures

All the restorative procedures were performed in the university clinical setting by last-year undergraduate students, under supervision of a senior researcher.

Caries removal was completed using a round steel bur (KG Sorensen, Barueri, SP, Brazil) in a slow-speed hand piece. Tissue removal was terminated when dentin surface was hard on probing and teeth were isolated using a rubber dam. Root canals were instrumented with nickel-titanium rotary files (Protaper Next, Dentsply, Maillefer; Ballaigues, Switzerland) driven by the XSmart Plus® motor (Dentsply, Maillefer; Ballaigues, Switzerland). A 2.5 % solution of sodium hypochlorite (Asfer Quimica, São Bernardo do Campo, SP, Brazil) was used as an irrigant between each instrument during root canal preparation. The smear layer was removed by irrigating with 17 % EDTA (Asfer Quimica), followed by irrigation with normal saline solution. Calcium hydroxide paste (Ultracal XS, Ultradent, St Louis, MO, USA) was used as interappointment dressing in all treated teeth for at least 15 days. After checking the absence of pain, edema and fistula, the root canals were then dried and filled with gutta-percha (Dentsply) and AH Plus (Dentsply) root canal sealer using lateral condensation technique. At the end of the root canal therapy, all teeth were sealed with restorative glass ionomer cement and occlusal contacts were checked.

After endodontic treatment the teeth were cleaned with pumice and water. The amount of tooth structure remaining was recorded considering the number of the residual walls: 4 walls, which define class I cavity preparation; 3 walls, which define class II cavity preparation with at least one marginal bridge remaining; 2 walls, which define class II cavity preparation with no proximal wall. All restorations were performed under isolation with rubber dam.

Two restorative resins were selected to be used in each of the two filling techniques tested in this study: (1) an incremental nanohybrid composite resin (Filtek Z350XT, 3M ESPE) associated with RMGIC (Vitremer, 3M ESPE) used for filling of the pulp chamber or, and (2) a high viscosity bulk fill composite resin (Filtek Bulk Fill Posterior, 3M ESPE).

Incremental filling technique (control group): the RMGIC was manipulated as recommended by the manufacturer and used to fill up the pulp chamber, thereby creating a flat surface of the pulpal floor level with the gingival wall of the proximal boxes. The RMGIC was light cured for 40 seconds using a LED light-curing unit with 1200 mW/cm² output (Radii Cal, SDI, Bayswater, Australia). The output of the curing unit was checked after with a MARC Resin Calibrator (BlueLight, Halifax, Canada). Selective enamel etching was performed for 15 seconds using 37% phosphoric acid (Condac 37%, FGM, Joinville, SC, Brazil), and a universal adhesive system (Single Bond Universal, 3M ESPE) was used for hybridization procedure. A matrix band (Unimatrix, TDV, Pomerode, SC, Brazil) with wooden wedges (TDV) was used in cases of class II restorations. The resin composite was applied using an incremental filling technique beginning at the gingival wall, not exceeding 2-mm in thickness. Each increment was polymerized for 20 seconds. Occlusal adjustments were made using articulating paper (Accufilm, Parkell, Edgewood, NY, USA). Finishing was completed with finishing diamond burs (KG Sorensen), and polishing was accomplished with abrasive silicone rubber points (Viking Kg Sorensen, Barueri, SP, Brazil).

Bulk fill technique (experimental group): Hybridization of tooth structure, matrix band and wooden wedges was performed similar to the incremental filling technique. The depth of the cavity from the pulp floor to occlusal was measured by using periodontal probe. The Filtek Bulk Fill Posterior resin composite (3M ESPE) was applied using 5-mm in thickness to fill the pulp chamber and proximal boxes. The first layer was polymerized for 20 seconds. The second layer was inserted and condensed creating the occlusal anatomy. The rubber dam was removed and the occlusal adjustments, surface finishing and polishing were performed using similar procedures used in the incremental filling technique.

2.4 Outcome assessment

Two experienced dentists not involved with the restorative stage performed the evaluation of the restorations. They were blinded to the identification of the restorative techniques and the study group assignment, and

were previously trained and calibrated regarding the methods and criteria for assessment. The modified US Public Health Service / Ryge criteria (Table 1) was used for direct clinical evaluation of the restorations, according to seven clinical characteristics (retention, colour, marginal discoloration, marginal adaptation, surface texture, anatomic form, and secondary caries). For each of these features, restorations were rated as “Alpha”, which corresponds to excellent, “Bravo” to clinically acceptable, and “Charlie” to clinically unacceptable results. Time points for assessment were immediately after restoration (baseline) and after 12, and 24 months.

2.5 Statistical Analysis

Data analysis included descriptive statistics of the main features of patients and restored teeth, as well as the ratings of restoration outcomes. Data from raters' assessments were cross-tabulated with the 3-point ordinal scale of the Ryge criteria and the weighted Kappa statistic was calculated to assess the reliability of measurements, by testing the inter-rater agreement between the two independent examiners. Overall agreement was almost perfect (Kappa=0.98) considering all measurements (n = 1344), ranging from 0.96 to 1.0 for the different clinical outcomes. Due to the excellent reliability of the measurements, the ratings of the first examiner were considered for data analysis.

For an initial exploratory analysis, Mann-Whitney and Friedman non-parametric tests were used to compare the scores obtained for the two restorative materials and the paired comparisons of the overall scores obtained in the three time points for each of the evaluated outcomes. Subsequently, the Generalized Estimating Equation (GEE) analysis was used to fit a regression model for the temporal trends of the repeatedly measured outcomes from baseline to the 1- and 2-year follow-ups. GEE models also accounted for the clustered effect of data and the influence of correlated factors that affects restoration outcomes. For construction of the GEE models, the restoration level was set as the primary unit of analysis, whilst the patient level was set as a within-subject variable, since some patients had more than one restored tooth. The different time points for repeated outcome assessment was also set as a

within-subject variable that account for the multiple observations recorded for each subject.

The parameters for construction of the regression models included both between and within-subject factors. The clinical independent variables were tested as predictors of the restoration outcomes (filling technique, number of the residual wall, location of the restored teeth), as well as age and gender which were tested as base variables. Time point variable was used as a within-subject factor in the model, to assess the longitudinal trends in the repeated measures of the restoration outcomes. In addition to the main effects of the independent factors, clinically relevant interactions between factors were also tested to obtain the best fit for the final models for each of the outcomes.

Considering that the outcomes were measured in an ordinal response scale, we used ordinal logistic (multinomial) distribution and cumulative logit as the link function to specify the type of the model. GEE regression parameters estimates were expressed as regression coefficients and their standard errors (SE), and significance of the model effects were tested using the Wald chi-square statistics. Models with the multinomial ordinal distribution do not have a single intercept term, therefore threshold parameters that define transition points between adjacent categories are specified and included in the model. For all hypothesis tests the statistical significance was set at $\alpha=0.05$ and the IBM-SPSS 24.0 software was used for data analysis.

3. Results

From 81 adolescents assessed for eligibility, 56 were enrolled in the study, out of those two patients withdrawn of the treatment. Participants were 26 females and 28 males, mean age 14.2 ± 2.4 years, corresponding to 68 restored molars. The number of restored teeth per patient ranged from a single tooth for 42 patients, two teeth for 10 patients and three teeth for 2 patients. Randomization resulted in 27 patients assigned to the bulk filling technique (BFT group: $n=37$) and 27 patients to the incremental filling technique (IFT: $n=31$) for 12 months of follow-up. For the 24-month follow-up we had 24 patients for the BFT group with 32 restored teeth with reasons for withdrawals: Inability to come to return ($n = 3$), for the IFT group we had 20 patients with 24 teeth restored with reasons for withdrawals: Inability to come to return ($n = 7$).

Most participants (n = 44) provided data at the 24-mo follow-up. The overall adherence to the study protocol was 69%. The complete patient flowchart in the different phases of the study is detailed in Figure 1.

Table 2 details the baseline characteristics of patients, restored teeth and restorations according to the filling technique. No significant differences were found between groups of restorative technique at baseline ($P > 0.05$).

Table 3 shows the frequency distribution of the ratings of the clinical parameters for evaluation of restorations, according to the different time points of patient assessment and the two filling technique groups – bulk filling and incremental filling. Bivariate non-parametric comparisons of the different time points (Friedman test) showed significant differences, specifically concerning the 2-year assessment ($P < 0.001$) for all clinical outcomes. The results of the comparison between the two restorative techniques revealed no differences at baseline ($P > 0.05$). For the longitudinal assessments, differences between filling techniques were found only for marginal adaptation ($P = 0.040$) and surface texture ($P = 0.014$).

The construction of the GEE models for each of the clinical outcomes was performed using the following strategy: (1) the filling techniques, time point variable, number of residual wall (dichotomized as 4 and 2-3 walls), teeth location (upper/lower, 1st/2nd molar), age and gender were entered as predictors, considered as main factors in the regression models using the forced entry method to test the main effects of each variable; (2) the two-way interactions explored as predictors were the filling technique versus time points and number of residual walls; (3) selection of the final regression model was based on the significance (p-values) of model effects. As a result, the number of residual walls, teeth location, age and gender were excluded due to non-significant effects. Similarly, no interactions between factors were found to be significant. Therefore, the best model fits for the data of each outcome included only the filling technique and time point variable as main factors.

In Table 4, GEE results showed that for all clinical outcomes at least one of the independent variables (filling technique and/or time points) had a significant effect on the model, as expressed by the threshold estimates ($P < 0.001$). All outcomes presented a significant detrimental effect (greater score on the ordinal scale score) for the 2nd follow-up period contrasted to baseline

status of the restorations ($P < 0.001$; $P < 0.01$ for surface texture). Similar significant effects were observed for the 1st year follow-up, except for surface texture ($P = 0.661$).

The effects of the restorative filling technique were significant for marginal adaptation ($P = 0.022$) and surface texture ($P = 0.020$). The positive signal (>0) of the regression coefficients means that the incremental filling technique showed greater likelihood of poorer scores concerning these outcomes, independent of the time point effect. No significant effect of the interaction between filling technique and time of assessment was found, which suggest that the detrimental effect time occurred irrespective to the filling technique for large restorations in endodontic treated molar teeth.

4. Discussion

This 2-year randomized clinical trial compared the longitudinal performance of large restorations in endodontically treated young molar teeth using a bulk fill composite resin (Filtek Posterior) and a widely used incremental nanohybrid composite resin (Filtek Z350XT) associated with RMGIC to fill the pulp chamber. Overall findings showed that the two filling techniques performed similarly concerning longitudinal clinical parameters. However, the bulk fill composite resin showed better performance regarding the marginal adaptation and surface texture after 2 years. Additionally, the detrimental effect of time, when comparing baseline with 1- and 2-years outcomes, affected similarly the two groups.

The longitudinal performance of large direct composite resin restorations in endodontically treated young molars may be affected by multiple biological, functional, behavioural and socioeconomic factors. The inequalities in caries incidence and distribution may not be only due to inevitable biological variations, but also from differences in the social and economic status in which patients are inserted [21,22]. Patients enrolled in this study were adolescents from lower socioeconomic status, most of them had poor oral hygiene and limited access to private dental service. Most of them were referred to teeth extraction at the university dental emergency service.

In our sample of adolescents, the parents' educational level was low and it is considered a risk factor for higher incidence of dental caries [23].

Unfavourable socioeconomic conditions and lower level of education of the parents, the greater the number of teeth affected by caries, as well as their severity [24,25]. In addition, parents with a higher educational level are probably more interested and responsible for health issues, such as maintaining a healthy diet and good oral hygiene, and this may have an impact on their children's oral health.

From a biological perspective, the performance of direct composite resin restorations may be affected by oral hygiene level, since *S. mutans* herewith is not only a cariogenic, but also a composite-degradative component of the oral microbiome [26]. Additionally, larger composite resins restorations in molar teeth are submitted to higher masticatory loading, and when associated with the acid environment caused by poor hygiene, may accelerated the restorative material deterioration [26,27].

Significantly higher failure rate for multi-surface and complex restorations compared with occlusal single-surface restorations has been reported previously [28,29]. However, there is scarce data regarding endodontically treated molar teeth. In our study, no significant differences regarding the number of the tooth remaining walls were found, irrespective of the filling technique. This aspect may be due to the fact that most of the restored molar teeth included in this study had large cavities after endodontic treatment. Several studies have demonstrated that resin composite in molar teeth reported poorer clinical performance compared to premolars [19,30]. In addition, no significant effect was observed concerning tooth type, if first or second molar teeth, and position in the maxilla or mandible. This may be due to the lower number of second molar teeth included in this study and also due to the extension of the restoration, which transfers to the restorative material or to the tooth-material most part of the occlusal loading.

Comparing the filling techniques, until recently, increment filling with 2 mm increments and separate light curing have been considered as the standard procedure for direct composite restorations in posterior teeth [31]. However, previous studies reported that the bulk fill restorative resin demonstrated similar clinical performance when compared to the incremental filling technique [19,32-34]. In our study both techniques performed similarly for secondary caries, retention, colour stability and marginal discoloration. Secondary caries is a type

of failure more related to the patient characteristics [6,29], whilst retention is greatly dependent on the adhesive procedures, which was the same for the two techniques. Additionally, the restorations dimensions and the location in the arch were similar for both groups.

Significant effects on marginal adaptation and surface texture were found, in which the bulk fill technique performed better after 2 years for marginal adaptation, as reported in other study [35], and after 1 year for surface texture. In vitro studies have demonstrated that incremental filling technique resulted in higher stress concentration at enamel margins caused by higher shrinkage stress [13,14,36]. The contact loading at this area, that occurs frequently in larger cavities, such as the cavities in our study, is associated with higher stress concentration at the interface, and may explain the poorer quality of the marginal adaptation in the incremental technique [37]. However, this outcome may take longer follow-up times to be evidence in clinical assessment, which may be related to fatigue failure. Late failures are often caused by tooth or restoration fractures or deterioration of the restorative material [38]. Regarding the surface texture, which is checked visually, may be explained by the bulk fill filling technique ability to reduce the risk of entrapping air voids between subsequent increments with negative effects on mechanical strength [39].

This study has some strength regarding its design and data analysis. We considered the hierarchical structure of repeated longitudinal data, and the control of the clustering effect of the multiple restorations for the same patient in part of the sample. Nevertheless, the low incidence of unsatisfactory outcomes suggest that longer follow-up periods are needed to assess the long-term performance of the restorations, as influenced by the filling technique. In addition, there were some limitations regarding the clinical setting and patient profile. Therefore, a stricter monitoring of the patients is recommended to minimize loss of follow-up and missing data.

Nevertheless, the success rates of the restorations performed in the university clinic can be considered as satisfactory. The use of resin composite restorations in this clinical setting have been increasingly used for posterior teeth since 1995 and it became the preferred restorative material in the dental school in cases of primary caries, and the bulk fill technique has been taught and used routinely only within the last three years. In addition, all students

involved in this study received a special training in the pre-clinical lab using extracted molar teeth before treating patients.

The patient profile and the teeth condition selected for this study make this clinical approach a challenging application of direct composite resins. However, the clinical performance of the restorations could be considered satisfactory after 2 years of evaluation. The association of endodontic treatment and direct restoration may be a suitable alternative to preserve young molar teeth severally affected by caries. In addition, the use of bulk fill technique may be considered a good alternative for restoring endodontic treated molar teeth in children and adolescents, saving clinical time and resulting in similar clinical outcomes when compared to the traditional incremental filling technique.

5. Conclusions

The direct composite resin restoration of endodontically treated molar teeth in adolescents using the bulk fill and incremental filling techniques, showed satisfactory success rates during the 2-year period. Comparative performance of the two techniques was similar for the two techniques, however the bulk filling technique performed slightly better considering the scores of marginal adaptation and surface texture.

Conflict of interest

The authors have no conflict of interest.

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Table 1. United States Public Health Service (USPHS) Ryge Criteria for Direct Clinical Evaluation of Restoration.

Parameters	Score	Scores USPHS criteria	Outcomes
Retention	Alfa (A)	There is no loss of restorative material	Success
	Bravo (B)	Partial loss of the restorative material but does not determine the substitution of the restoration	
	Charlie (C)	Significant loss of the restorative material determining the substitution of the restoration.	Unsuccess
Color	Alfa (A)	There is no mismatch in color, shade, and/or translucency between restoration and the adjacent teeth structure	Success
	Bravo (B)	There is a mismatch between restoration and adjacent tooth structure, but not outside the normal range of tooth color, shade and/or translucency	
	Charlie (C)	There is a mismatch between restoration and adjacent tooth structure outside the normal range of tooth color, shade and/or translucency	Unsuccess
Marginal Discoloration	Alfa (A)	No discoloration anywhere on the margin between the restoration and the tooth structure	Success
	Bravo (B)	Presence of discoloration that does not penetrate along the margin of the restorative material in a pulp direction	
	Charlie (C)	Presence of discoloration that penetrates along the margin of the restorative material in a pulp direction	Unsuccess
Marginal adaptation	Alfa (A)	Absence of visible cracks in the restoration margins where the explorer can penetrate	Success
	Bravo (B)	Presence of visible cracks in the restoration margins where the explorer penetrates, but the dentin / base is not exposed	
	Charlie (C)	Presence of visible cracks in the restoration margins where the explorer can penetrate, fractured or missed in part or in total	Unsuccess
Surface Texture	Alfa (A)	As smooth as the surrounding enamel, no surface porosity or cracks	Success
	Bravo (B)	Rougher than surrounding enamel, slight surface porosity or cracks	
	Charlie (C)	Very rough, obvious surface porosity or cracks	Unsuccess
Anatomic form	Alfa (A)	The restoration is not under-contoured (i.e. The restorative material is not discontinuous with existing anatomic form)	Success
	Bravo (B)	Restoration in discontinuity with the original anatomical shape (missed material), but the dentin or base material are not exposed	
	Charlie (C)	Restoration in discontinuity with the original anatomical shape (missed material), with exposure of dentin or base material	Unsuccess
Secondary Caries	Alfa (A)	Absence of caries in the margins of restorations (The restoration is a continuation of existing anatomic form adjacent to the restoration)	Success
	Charlie (C)	Presence of caries in the margins of restorations (There is evidence of dark keep discoloration adjacent to the restoration - but not directly associated with cavosurface margins)	Unsuccess

Table 2

Main features of patients (n=54), restored teeth and restorations (n=68).

Variable		Filling technique		p-value
		BFT	IFT	
Gender	Female	10	16	0.102 [£]
	Male	17	11	
Age	Mean (SD)	14.04 (2.85)	13.92 (1.89)	0.856 [€]
Teeth location	Upper 1 st molar	10	8	0.244 [£]
	Upper 2 nd molar	1	0	
	Lower 1 st molar	24	14	
	Lower 2 nd molar	2	9	
Number of walls*	4	13	10	0.702 [£]
	3	10	11	
	2	14	10	
Time to restore	Median (IQR)	15 (56)	14 (49)	0.829 [¥]

BFT – Bulk filling technique; IFT – Incremental filling technique

* 4 walls – class I cavity preparation; 3 walls – class II cavity preparation with at least one marginal bridge remaining; 2 walls – class II cavity preparation with no proximal wall.

[£] Chi-square test

[€] T-test

[¥] Mann-Whitney test

Table 3

Clinical ratings of restorations using bulk filling technique (BFT) and incremental filling technique (IFT) at baseline and after 12 and 24-months follow-up.

Outcomes	Score	Baseline		1 year		2 years	
		BFT (n=37)	IFT (n=31)	BFT (n=37)	IFT (n=31)	BFT (n=32)	IFT (n=24)
Retention	Alfa (A)	37	31	32	27	22	13
	Bravo (B)	0	0	4	4	1	0
	Charlie (C)	0	0	1	0	9	11
Color	Alfa (A)	36	28	31	23	21	11
	Bravo (B)	1	3	6	8	8	9
	Charlie (C)	0	0	0	0	3	4
Marginal discoloration	Alfa (A)	35	29	30	24	22	11
	Bravo (B)	2	2	7	7	10	11
	Charlie (C)	0	0	0	0	0	2
Marginal adaptation	Alfa (A)	35	27	29	17	18	7
	Bravo (B)	2	4	8	14	7	10
	Charlie (C)	0	0	0	0	7	7
Surface texture	Alfa (A)	35	26	35	25	29	15
	Bravo (B)	2	5	2	6	2	7
	Charlie (C)	0	0	0	0	1	2
Anatomic form	Alfa (A)	30	24	25	18	13	8
	Bravo (B)	7	7	12	13	7	6
	Charlie (C)	0	0	0	0	12	10
Secondary caries	Alfa (A)	37	31	37	30	26	21
	Bravo (B)	0	0	0	0	0	0
	Charlie (C)	0	0	0	1	6	3

Table 4

GEE regression models for the assessed clinical outcomes (dependent variables) and their corresponding factor effects. Model estimates are expressed as regression coefficient (standard error) and statistical significance [B (SE) / p-value]. Statistically significant effects of the model factors are highlighted in bold.

Parameter	Categories	Outcomes						
		Retention	Color	Marginal discoloration	Marginal adaptation	Surface texture	Anatomic form	Secondary caries
Model Threshold**	(1)	26.2 (0.48) / <0.001	3.22 (0.58) / <0.001	3.10 (0.63) / <0.001	2.91 (0.46) / <0.001	3.09 (0.62) / <0.001	1.54 (0.37) / <0.001	25.4 (0.93) / <0.001
	(2)	26.7 (0.42) / <0.001	5.43 (0.58) / <0.001	6.54 (0.73) / <0.001	4.98 (0.51) / <0.001	5.53 (0.65) / <0.001	3.43 (0.30) / <0.001	--
Technique	Incremental filling	0.44 (0.53) / 0.410	0.80 (0.49) / 0.101	0.62 (0.53) / 0.240	1.00 (0.51) / 0.022	1.52 (0.65) / 0.020	0.31 (0.42) / 0.466	-0.15 (---) / 0.829
	Bulk filling	REF	REF	REF	REF	REF	REF	REF
Time points	2-year follow-up	25.7 (0.33) / <0.001	2.66 (0.55) / <0.001	2.50 (0.51) / <0.001	2.92 (0.51) / <0.001	1.03 (0.40) / 0.009	2.40 (0.34) / <0.001	23.8 (1.1) / <0.001
	1-year follow-up	24.0 *	1.42 (0.45) / 0.002	1.43 (0.45) / 0.002	1.57 (0.45) / <0.001	0.15 (0.35) / 0.661	0.74 (0.22) / 0.001	21.3 *
	Baseline	REF	REF	REF	REF	REF	REF	REF

* Only the parameter estimate at the last interaction is displayed due to Hessian matrix singularity.

**Threshold parameters that define transition points between adjacent categories.

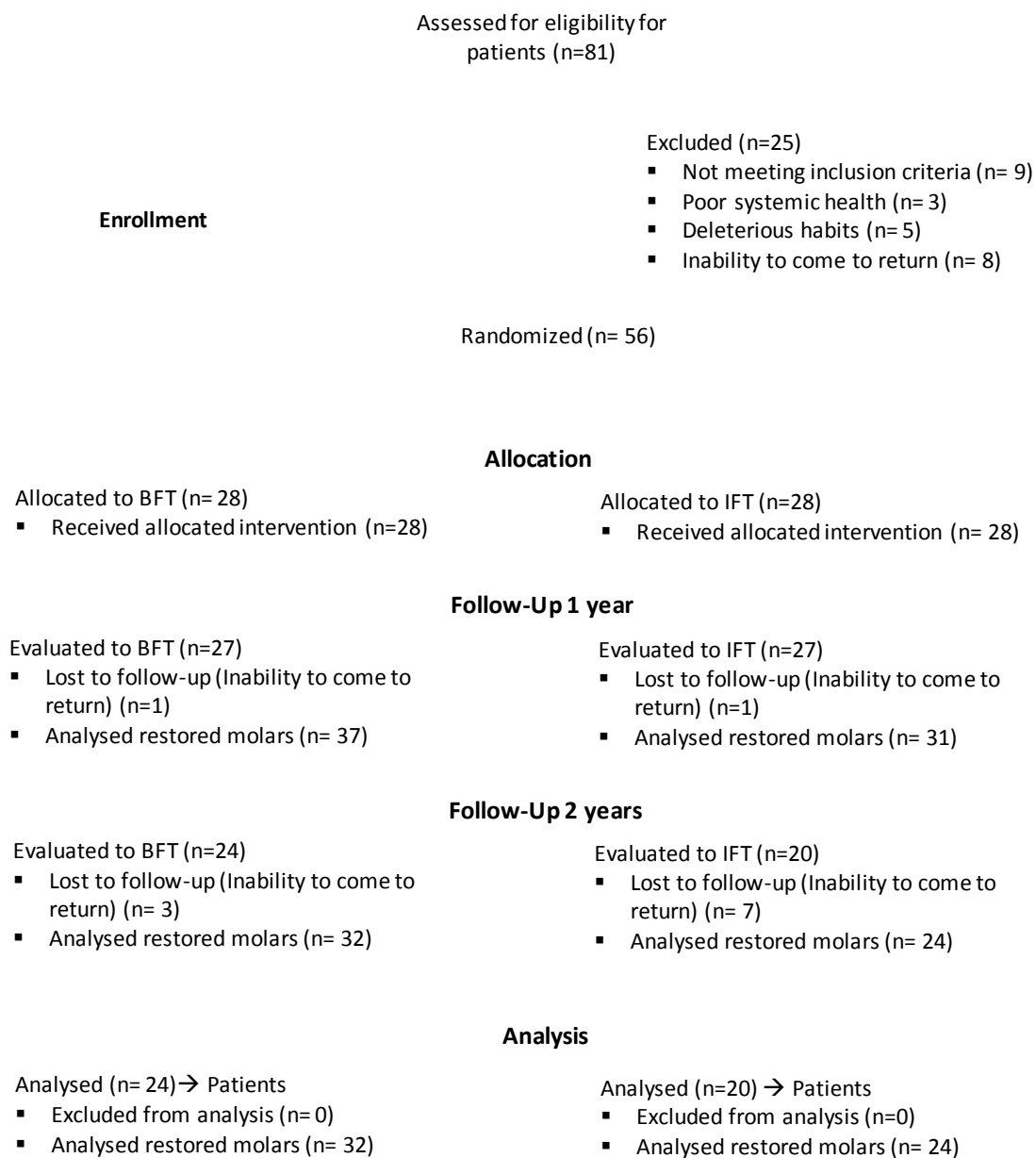


Fig. 1 Flow diagram of participants in the months trial up to 24 post-treatment.

Capítulos

3.4 CAPÍTULO 4

Practice-based analysis of direct posterior restorations performed on health public service: retrospective Long-term survival in Brazil.

Artigo a ser enviado para publicação no periódico **Community Dentistry And Oral Epidemiology**

Practice-based analysis of direct posterior restorations performed on health public service: retrospective Long-term survival in Brazil.

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Running title: Long-term survival of posterior restorations in public service.

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Practice-based analysis of direct posterior restorations performed on health public service: retrospective Long-term survival in Brazil.

ABSTRACT

OBJECTIVE: The aim of this patient document-based retrospective study was to evaluate longevity of posterior restorations according to type of tooth, size of restoration, restorative material used, characteristic of the dentists, and tested the hypothesis that the public health unit geographic location influenced the longevity of the long-term survival of these restorations.

MATERIALS AND METHODS: Data were extracted from electronic patient files of the Uberlândia City Public Dental Service (SUS), MG, Brazil. Were analyzed 2,405 class I and II restorations performed 5 to 29 years ago (mean of 8.9 years) in 351 patients (6.8 teeth / patient) of 11 public health units. It was considered success: restorations did not repair or replaced until the date of evaluation; and failure: replacement of restorations, fractures of teeth or restorations or dental extraction. Data were analyzed using the Kaplan-Meier test for survival of the restorations and Cox regression for the effects of variables on survival rates.

RESULTS: A total of 2,405 restorations placed in 351 patients comprised the final sample. The restorations were preferably of amalgam (85%), involving a single face (70%); with the majority without lining (85%). The overall success rate was 95% and the mean observation time was 8.4 years. The survival of the restoration reached 86% (95%CI: 81.9-89.6) up to 29 years and the mean survival time was 26.5 years (95%CI: 26-27 years). Significant difference was only observed for geographic location where the restorations were performed.

CONCLUSION: The restorations performed on the evaluated public health service presented high survival rate for restorations in posterior teeth being influenced by the geographical area where it was performed.

CLINICAL RELEVANCE:

The current epidemiological dental patient-centered study showed high survival rate of posterior restorations performed at public oral health service.

1. Introduction

Direct restoration is the prevalent dental health services performed in both private and public clinics in the majority of developed and developing countries.¹ These treatments represent important financial issue for patients and healthcare systems, especially if they fail require the replacement.² Despite the decrease in caries prevalence in many countries, there is still a high need for posterior restorative treatment.³

In general, amalgam had been the first choice material used for posterior teeth restoration for decades.⁴ Minamata Convention have encouraged alternatives to amalgam restorations, instigating a change the routine in restorative dentistry.^{5,6} However, is common to observe that clinicians prefer to use amalgam restoration in public services due the conditions that the restorations are performed and also because the stigma that amalgam has better longevity than resin composite.⁶ Composite resins materials, have been gaining popularity due to its aesthetics and adhesive properties, which are overtaking amalgam nowadays.⁷ Composites resins have had significant improvements in their physical properties making nowadays the choice material for different clinical applications.⁸ However, there is low-quality evidence to support that resin composites lead to higher failure rates and risk of secondary caries than amalgam restorations.^{9,10}

The option for selecting composite resin or amalgam in several countries has been determined by covering of the treatment for health insurance or public service rules.³ The Unified Public Health System ("Sistema Único de Saúde" - SUS) is one of the largest free charged access to health actions and services in the world.¹¹ Considered one of the best public health systems in the world, it benefits about 75% of Brazilian people with health care including procedures from simple to highly complexity.^{11,12} One of the improvements that plays an important role in the SUS was the insertion of oral health care called "Smiling Brazil".¹¹ The decision for choosing amalgam or composite resin in SUS public service is not determined by cost or for previous determination of

SUS benefits. Today, large databases of insurances and public health services facilitate retrospective analyses of outcome data close to clinical reality,¹ serve as an evaluation instrument to investigate and improve service establishment to the population. The practice-based research performed is nowadays highly recommended and can present a great contribution for decision making of restorative material selection.¹³ The providing of accurate information on restoration survival is of relevance, as it is the factors which may influence a better assistance.^{1,3} The failure of posterior restoration is not only related to material properties, but mainly dependent of the patients and operators behavior.³

The correlations between profile of the clinicians and the education level of the patients and access of oral health service with the material selected to restore posterior teeth in public service may affect the clinical performance.¹³ Therefore, the aim of this document-based retrospective study was to evaluate longevity of posterior restorations according to type of tooth, size of restoration, restorative material used, characteristic of the dentists performed in the Brazilian public health service. The null hypothesis of the study was that the public oral health geographic location and the education level of the patients would not influence the longevity of the long-term survival of these restorations.

2. Materials and Methods

2.1 Study design

This retrospective practice-based study was performed on the records of the Oral Health Care of the city of Uberlândia, MG, Brazil to evaluate the longevity of the direct posterior restorations. Data were extracted from patient files of the Uberlândia City Public Dental Service (SUS), MG, Brazil. All the restorations were performed by clinicians of the Primary Health Care of the Brazilian SUS. The medical records were evaluated from January 1986 to December 2015. Currently, Uberlândia presents coverage of the Family Health Strategy of 41%, considering 74 family health teams implanted. Oral Health coverage is equivalent to 16%.

Inclusion Criteria: Patients attended the Oral Health Care unit of the SUS in service (Uberlândia, MG, Brazil) during the study period had in the treatment

record at least one procedure on posterior teeth. Based on these criteria, 351 patients with of total of 2405 posterior restoration attended on 12 public health units distributed in 5 regions of the urban area: downtown: Uberlândia is a municipality that offers services of low, medium and high complexity in oral health, the municipal territory is divided into 5 health regions; Center, North, South, East and West; the municipality has 82 health care units, of which 68 are in the Urban Zone and 6 in the Rural Zone, and oral health has dental care in 30 of these units, the unit choices list was based on the medical files of the medical records the units, because at the time of data collection the municipality was making the transition to the electronic medical record were included in the present study.

Exclusion Criteria: Restorations performed with compomers, zinc oxide and modified eugenol.

2.2. Ethics considerations

Our data are based on patient documents from the database of the Uberlândia City Oral Health Center (OHC) of SUS system. The original recordings having been made at each appointment. Before providing us with the data, an OHC-SUS system removed the identification numbers, replacing them with consecutive numbers to ensure confidentiality. The ethical commit of Federal University of Uberlândia approved the study protocol. The Department of Social Services and Healthcare of the City of Uberlandia approved the study protocol CAAE: 57908016.8.0000.5152.

2.3 Restorations evaluated

A total of 2,405 class I and II restorations made 5 to 29 years ago (mean of 8.9 years) in 351 patients (6.8 teeth/patient) comprised our final sample. A total of 836 medical records were evaluated, 485 medical records were excluded using the exclusion criteria, and the medical records were defined using a systematic sample.

Two experienced clinicians were previously trained and calibrated regarding the methods and assessment the oral health records that involved all aspects of the restoraterion: Gender of patients (male or female); restorative

material used for each restoration (amalgam or composite resin); the tooth type (premolars and molars); the tooth arc (mandibular and maxilla); the number of the restoration faces (1 or 2 and more); the use of pulp/dentin base protection (yes or no); the Public Health Unit (the location in city region (Center, East, North, West, South)); the gender of professionals that performed the restoration (male or female); clinicians with specialization (yes or no); the graduation time (less than 29 years and more than 29 years); the condition of the restoration (failure or success). Restorations of the posterior teeth were considered clinically functional and aesthetic success since they were not repaired or replaced with the minimal survival period of 4 years. It was considered as clinical failure when the restoration failure and the teeth were submitted to indirect rehabilitative treatments, replacement of the restorations, fractures of the teeth or restorations leading to dental extraction.¹⁴

2.4 Statistical Analysis

The extracted data were compiled into statistical software package STATA 14.0 (Stata 14.0 for Windows; Stata Corporation, College Station, TX, USA) to be analyzed. Data analysis included descriptive statistics of the main features of patients and restored teeth, as well as the ratings of restoration outcomes. The differences between the variables and the failure rate of the restorations were analyzed using the chi-square test. The longevity of the restorations was evaluated through the survival analysis using the Kaplan-Meier method. Differences in survival rates according to the studied variables were evaluated through the Cox regression analysis. For all hypothesis tests the statistical significance was set at $\alpha=0.05$.

3. Results

The patients attended in eleven public health units, 68% were women, 97% without systemic alterations. The restorations were preferably of amalgam (85%), involving a single face (70%); with the majority without lining (85%). About 70% of clinicians are specialists, the vast majority of women (96%) with about 25 years of training. The success rate was 95% and the mean observation time was 8.4 years. The survival of the restoration reached 86%

(95%CI: 81.9-89.6) up to 29 years and the mean survival time was 26.5 years (95%CI: 26-27 years).

No significant difference on survival was found between amalgam or composite resin ($P = 0.671$). No significant difference on what was found for gender of patients on the survive rates of the restorations ($P = 0.555$). Specialists had similar failure rates than generalists ($P = 0.206$). The use of pulp-dentin protection base material had no influence on the survival rate of posterior restorations ($P = 0.147$). The number of the faces of the restorations had no influence on the survival rate of posterior restorations ($P = 0.139$). No significant difference was found for gender of professionals that performed the restorations ($P = 0.071$).

Professionals graduated until 29 years had significant lower failure rate (3.8%) than professionals graduate with more than 29 years (6.8%, $P = 0.006$). Significant difference was observed for geographic location where the restorations were performed ($P < 0.001$). Restorations performed on the OHC unit powerts regions, north (8.5%) and west (7.0%) areas, had significantly higher than of the south (0.6%), east and center (2.3%). The regions north and west, are also regions with lower coverage of dental care in proportion to the resident population.

4. Discussion

The null hypothesis of this restrospective practice-based study was rejected, as the geographic location of OHC-SUS unit of Uberlândia city and also the graduation time profile of the clinicians influenced the long-term survival of both direct posterior restorations, amalgam and composite resin.

The longevity of direct posterior composite restorations is well established for permanent teeth.¹⁵ there are aspectos that can significantly influence the survival rates of composite restoration, such as the extension of decays leading to the size of the cavity and occlusal problems.^{16,17} Restoration replacement is one of the most common dental procedures in public and private dental offices, representing a high financial cost for the individual and for the he public health system.^{5,6}

In the mid- 1980s 90% of dental school curriculum did not include any consistent teaching on posterior composite resins, and the percentage dropped to 4% in the late 1990s and to 0% by the early 2000s.^{5,6} Nowadays some universities teach only composite resin restoration, including sometimes, teaching maintenance procedures of amalgam restoration.¹⁸

The 'National Programme for Improving Access to and Quality of Primary Care' in Brazil evaluated the southeast region with 5,027 dental teams between 2013 and 2014 showed that 98.4 % of dental teams performed composite resin and 93.5% performed amalgam posterior restorations.^{19,20} On the past 25 years, has been a steady growth in the use of composite resin materials for posterior teeth restoration. The new generation of professors who have joining to the teaching process with more experience on performing posterior composite restoration may have also have contributed to the changes of composites use for restoration in posterior teeth, especially because of the preference for aesthetic materials.¹⁸ Certainly, it is sensible to assume that the change assimilated within the university will be further reflected in the choices the young graduates will make.⁷ Professionals with low period of graduation preferred composite resin for posterior restorations in the majority of cases, differently of experienced university's members who encouraged amalgam.⁷ The prevalence for amalgam restoration performed in the evaluated public service can be related to the graduation time of the clinicians that work on this health system. The job stability in the public service evaluated reflected on continue activity at the same location and make possible to correlate the restoration performance with the clinician's profiles. The teaching process received for the most clinicians were, only or prevalently, performing amalgam restorations. Probably the combination of these factors with the paradigm that amalgam performed better than composite resin, which were expontly, responded by all the oldest clinicians, may contribute for material choice during posterior composite restoration.

Accordingly, to our study, the clinician ages and their graduation time had significant effect on the restorations surviving. Probably the possible causes that justifies such as the younger dentists will be recent graduated who might be still following the teaching practices from dental school. However, the use of the

most up-to-date technique usually is taken as the younger dentist may have been trained to adopt a more cautious, 'wait and see' approach.⁷ An important aspect observed in this study was that, the city region of Public Health Unit that had a lower percentage of restoration failures was concentrated in OHC-SUS units which professionals have the shortest training time. Additionally, the most of the older clinicians had the principle that marginal staining can be diagnosed as a secondary caries, determining early replacement of the restoration. The main reason is most likely to the increased awareness of the advantage of a minimally invasive approach in treating decays.⁸

The present study showed no statistical influence for the positions of the tooth in the arch.^{21,22} Other studies report that restorations in the mandibular arch perform less favourably than those in the maxillary arch.¹³ Restorations placed by male dentists perform slightly worse than those placed by females.¹³ In the present study no difference was found for gender of the operators, probably because of the small number of the male clinicians that work on the evaluated public service.

No significant effect was observed for number of the faces of the restorations. Several studies have demonstrated that multiple surfaces restorations performed worst than single surface restoration.¹⁴ However, in this study, was not possible to predict the real dimension of the performed restoration since the analyses were made only based on the reported description presentd on the patient records. The single surface restorations may also be volumetrically larger than minimal class II restorations due the black principals learned by clinicians during the graduation training. Additionnaly, the most multiple surface restorations performed in this study were two-surface restorations. In accordance of a recent study two-surface restoration survival more closely to that single surface restoration, rather than midway between a single-surface and a three-surface restoration.¹³ Our results agree with other study that found no significant difference for the restorative material in relation to cavity size.²³ A systematic review found 1.55% of failures per year for posterior composite resin restorations.²⁴ This result corresponded to a four-year survival rate of about 94%, and that shows that survival rates in different risk groups were inferior but still over 90% at 4 years.²⁵

Many patient and dentist-related factors influence success and survival of dental restorations.²⁶ A prospective study conducted including 63 molars in a Swedish public health service practice revealed a success rate of 72% at 5 years, which was inferior compared to other general practice data.²⁷ Another prospective trial from the Danish public health service including 4355 restorations with an observation period of over 8 years showed favourable 84% eight-year survival rate.²⁸

The longevity of both materials, especially they can be more equivalent in many ways.^{14,29} Other factor that had a significant impact on the result of the present study was the geographic location OHC SUS unit where the restorations were performed. This effect is clearly related to the profile of the population, expressed by education level, access for primary oral health care, family income. This study confirms the great diversity of the population that use the public health system in different location of the same city. Some determinants of these inequalities can be identified and includes geographic, social inequalities in the supply of health care services, as well as individual lifestyle factors, social and community networks and socioeconomic, cultural and environmental conditions.³⁰ Furthermore, the use of dental services is influenced by the availability of those services, counting even with the geographic distribution of dentists, as well as with the resources of the health service to fit the needs of communities.³¹ In the north and west regions of the Uberlândia city there is lower assistance to the oral health care, with a reduced access of the population to the primary oral health care. Unfortunately, the disadvantaged population can be also considered higher in these referred regions, which may explain the lower survival of the posterior restorations. This informations are important from the public health policy and can contribute with the govern strategies to prioritize the investment in the regions with the population with more vulnerability.

The public oral health system of the city Uberlândia showed high survival rate for both composite resin and amalgam posterior restoracion, expressing the quality of service offered. The findings of this study are important to help the public systems not only in Brasil or in developing countries to better design strategies for improve oral health police. We can speculate that the improving

the longevity of posterior restoration can be obtained through the better qualification of the clinicians including continuing education programs and also increasing the primary health attention mediated by education for social economic vulnerable population.

5. Conclusions

In this study it is possible to conclude that restorations performed on the public health service presented high survival rates for both amalgam and composite resin restorations in posterior teeth. The longevity of the restoration was influenced by the geographical area where it was performed and also for the profile of the clinicians regarding the graduation time. Patients with lower social indicators had lower survival rates, and clinicians with lower graduation time presented higher survival rates.

Conflict of interest

The authors have no conflict of interest.

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Table 1. Main features of patients, restored teeth, restorative material, use of pulp/dentin base protection professional, location where the restorations were performed.

Variable		N.	%
Gender of patients	Female	1.637	68.1
	Male	768	31.9
Restorative Material	Amalgam	2.045	85.0
	Resin Composite	362	15.0
Tooth type	Premolars	886	36.8
	Molars	1.519	63.2
Tooth arc	Maxilla	1200	49.9
	Mandibula	1205	50.1
Number of faces of the restorations	1 face	1.663	69.2
	2 or more faces	742	30.8
Use of pulp/dentin base protection	Yes	363	15.1
	No	2.042	84.9
City region of Public Health Unit	Center	179	7.4
	East	278	11.6
	North	388	16.1
	West	1.092	45.4
	South	468	19.5
Gender of Professionals	Female	2.311	96.1
	Male	94	3.9
Professionals with specialization	Yes	1.718	71.4
	No	687	8.6
Graduation time	Less than 29 years	1,240	51.6
	More than 29 years	1,165	48.4
Condition of the restoration	Success	2.283	94.9
	Failure	122	5.1

N – Number of occurrences; % – percentage;

Table 2. Survival rate of the restorations regarding features of gender of the patients, restored tooth type, tooth arch, restorative material, number of restorative surface, use of pulp/dentin base protection, location where the patients received treatment, professional characteristics – level of the graduation, gender and professional experience time.

Variable		Success		Failure		P value
		N.	%	N.	%	
Gender of patients	Female	1.551	94.8	86	5.2	0.055
	Male	732	95.3	36	4.7	
Tooth type	Premolars	886	95.6	39	4.4	0.252
	Molars	1.519	94.5	83	5.5	
Tooth arc	Maxilla	1.146	94.4	54	4.6	0.201
	Mandibula	1.137	95.5	68	5.5	
Restorative Material	Amalgam	1.941	95.0	102	5.0	0.671
	Resin Composite	342	94.5	20	5.5	
Number of faces of the restorations	1 face	1.586	93.4	77	6.6	0.139
	2 or more faces	697	95.2	45	4.8	
Use of pulp/dentin base protection	Yes	1.944	93.4	98	6.6	0.147
	No	339	95.2	24	4.8	
City region of Public Health Unit	Center	175	97.8	4	2.2	<0.001*
	East	272	97.8	6	2.2	
	North	355	91.5	33	8.5	
	West	1.016	93.0	76	7.0	
	South	465	99.4	3	0.6	
Professionals with specialization	Yes	1.637	95.3	81	4.7	0.206
	No	646	94.0	41	6.0	
Gender of Professionals	Female	2.190	98.9	121	1.1	0.071
	Male	93	94.8	1	5.2	
Graduation time	Less than 29 years	1,192	96.1	48	3.9	0.006*
	More than 29 years	1,091	93.7	74	6.3	

N – Number of occurrences; % – percentage; * significant difference

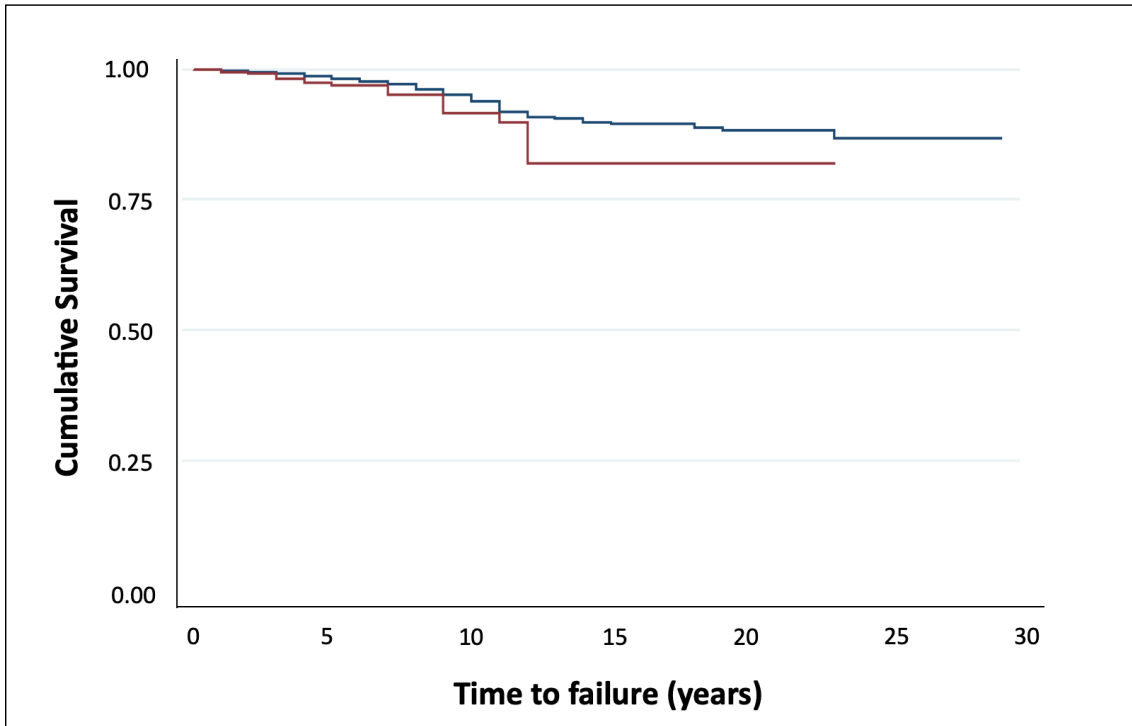


Fig. 1 Kaplan-Meier plots comparing subgroups amalgam and composite resin. P values indicate no significant differences between subgroups. Survival times are censored if the event (ie, failure of the restoration) has not occurred during the follow-up period (blue line for amalgam restorations; red line for composite resin restoration).

Considerações finais

4. CONSIDERAÇÕES FINAIS

Restaurações diretas cumprem função importante de restabelecer função em dentes posteriores com baixo custo e boa longevidade clínica. Esta tese teve como objetivo, por meio de sequência de estudos que envolvem ensaios *in vitro*, simulações computacionais, estudo clínico randomizado e análise de desempenho de prática clínica no serviço público, contribuir com evidências científicas para a tomada de decisão no protocolo restaurador de dentes posteriores.

Inicialmente há de se destacar a importância de associações de diferentes estratégias de estudo para construir evidências mais sólidas e relevantes. Estudos *in vitro*, são necessários e continuarão a ser desenvolvidos nas pesquisas em odontologia, especialmente na área de materiais dentários e odontologia restauradora. Porém, eles apresentam nicho de abrangência limitada à análise de processos e protocolos que visam nortear e criar parâmetros básicos de interferência dos materiais e de procedimentos clínicos. As vantagens dos ensaios laboratoriais se baseiam no fato que estes são de rápida execução e de custo muitas vezes mais reduzido, facilitando a obtenção de resultados em menor prazo. Eles podem expor grandes fragilidades de novos materiais, que são colocados no mercado com propostas inovadoras e ganhos em relação aos anteriormente disponíveis, porém sem embasamento para essas informações mercadológicas. Os resultados do objetivo 1 demonstraram que o clínico deve ter cuidado na seleção de resinas compostas para dentes posteriores considerando apenas a redução de tensão de contração de tensões de contração de polimerização, divulgadas por fabricantes de resinas compostas. Muitos fabricantes adequam os processos de divulgação de marketing centrados em informações privilegiadas que os convém. Este primeiro estudo mostrou que diferentes resinas se comportam de forma variada quando analisadas sob a ótica dos valores de contração total ou pós-gel. Assim, recomenda-se que os clínicos guiem suas tomadas de decisões baseadas na propriedade que realmente resulta em tensões de contração que é a contração pós-gel. Esse estudo pode também contribuir com

a indústria de resinas compostas, pela implementação de padronização de informações nas bulas dos materiais com indicação desse parâmetro.

No segundo estudo foi mostrado que a porosidade e presença de bolhas, amplamente propagada como sendo um grande potencial de falha em restaurações posteriores, não teve influência na deformação da cúspide, resistência à fratura e modo de fratura. Essa informação deve ser analisada com estrito olhar no limite do delineamento desenvolvido. As bolhas presentes se confinaram no interior da câmara pulpar, e nessa condição não influenciaram nos parâmetros testados. Cuidado deve ser tomado na extrapolação desses resultados para restaurações classe II em dentes vitalizados. Esse estudo mostrou ainda que a utilização do ionômero de vidro modificado por resina utilizado no preenchimento da câmara pulpar associada a resinas compostas inserido de forma incremental resultou em desempenho biomecânico similar as restaurações confeccionadas com técnicas de resina bulk fill pasta ou fluidas. Isso mostra que o uso de material com menor módulo de elasticidade no interior da câmara pulpar pode contribuir com esse benefício. Ressalta-se porém, o benefício secundário que o cimento de ionômero de vidro pode resultar nesse cenário, que é a facilidade de acesso em caso de necessidade de retratamento endodôntico.

Na avaliação clínica presente nesse estudo, há de se destacar a condição de desafio extremo que foram sujeitas as resinas compostas. O cenário de cavidades extremamente amplas, realizadas por alunos de graduação, em dentes tratados endodonticamente e na cavidade oral de crianças e adolescentes com vulnerabilidade social é desafiador. As técnicas de restaurações incremental com ionômero de vidro na câmara pulpar e restaurações com resina bulk fill pasta mostraram taxas de sucesso satisfatórias durante a avaliação longitudinal de 2 anos. A técnica de restauração com resina bulk fill apresentou desempenho ligeiramente melhor apenas para adaptação marginal e textura da superfície. Embora o tempo de avaliação de 2 anos seja curto, esse cenário mostra que essa nova classe de material resinoso apresenta desempenho promissor e similar às técnicas consagradas na prática clínica. Portanto, ao se fazer balanço em condições

específicas de que o ganho de tempo e de simplificação seja necessário, o uso de resina bulk fill pode ser utilizado com segurança pelo clínico.

Por fim, o estudo de avaliação retrospectiva de restaurações em dentes posteriores realizadas em unidades básicas de serviço de saúde pública da cidade de Uberlândia trouxe importantes informações para reflexões na prática do ensino e na tomada de decisões administrativas. Os profissionais que atuam no serviço público em sua maioria realizam ainda com maior prevalência restaurações de amálgama. Porém, o desempenho das restaurações de amálgama ou resina composta apresentaram similares e alta taxas de sobrevida. A longevidade dessas restaurações foi influenciada por dois fatores: tempo de atuação do profissional e pela região onde elas foram realizadas. Restaurações realizadas em pacientes com menores indicadores sociais tiveram menores taxas de sobrevida. E ainda profissionais com maior tempo de atuação profissional resultam em taxas de sobrevida menores que profissionais formados a menos tempo. Essas informações geram importantes contribuições na necessidade de se buscar equilibrar a oferta de educação para saúde e ampliar a rede de serviço em regiões de maior fragilidade social do município. E ainda contribui com o despertar da necessidade de se estabelecer programas de educação continuada para que os profissionais se atualizem frente aos novos protocolos e visões de prática clínica conservadora e centrada na promoção de saúde. Expõe ainda a necessidade de se buscar ampliar ações de cuidados básicos para a saúde bucal de forma mais abrangente e homogênea nas cidades brasileiras, buscando reduzir desigualdades ainda evidentes.

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Апекс

6.1 Pareceres do Comitê de ética



PARECER CONSUBSTANCIADO DO CEP

DADOS DA EMENDA

Título da Pesquisa: Análise clínica em protocolos restauradores em dentes posteriores

Pesquisador: Carlos José Soares

Área Temática:

Versão: 5

CAAE: 49372815.5.0000.5152

Instituição Proponente: Universidade Federal de Uberlândia/ UFU/ MG

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.685.725

Apresentação do Projeto:

Foi apresentada uma emenda ao projeto original com as seguintes propostas de mudanças e suas justificativas:

- Mudar a resina Bulk Fill SDR do GRUPO 2, que é uma resina fluida, pela resina Filtek Bulk Fill (3M ESPE), que é uma resina tipo pasta. Pelo trabalho ser feito com adolescentes, esta resina possibilitará trabalhar em um menor tempo clínico;
- Mudar a resina TPH3 do GRUPO 1 pela resina Z350.
- Realizar tomografia computadorizada que é um exame de imagem para os casos que forem complexos, por oferecer uma imagem radiográfica tridimensional como diagnóstico diferencial para necessidade de avaliação de suspeita de reabsorção interna ou externa, estruturas de corpo estranho, compreensão da anatomia do dente, avaliação do número e localização dos canais radiculares entre outras necessidades, buscando oferecer ao paciente um correto diagnóstico e tratamento odontológico.

Objetivo da Pesquisa:

Segundo o projeto:

Objetivo Primário: avaliar o desempenho das restaurações diretas em molares tratados endodonticamente.

Objetivo Secundário: Avaliar o comportamento e padrão quantitativo das restaurações classe II em

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Continuação do Parecer: 1.685.725

molares tratados endodonticamente com resina bulk fill e técnica incremental, por meio de ensaio clínico randomizado com acompanhamento de três anos.

Avaliação dos Riscos e Benefícios:

Segundo os pesquisadores:

RISCOS: de acordo com o relatado no projeto, não há riscos evidentes que estejam relacionados com este projeto, que comprometa a saúde dos pacientes participantes das avaliações clínicas, moldagens. Nos exames radiográficos, os riscos à exposição radiográfica serão pequenos, dentro das doses e proteções estabelecidas seguras. O paciente será orientado sobre isso no TCLE. Todas as medidas de biossegurança serão tomadas como protocolo de rotina durante as avaliações clínicas. A análise clínica das restaurações e moldagens dos dentes molares será feita após a autorização do paciente. O único risco é a identificação do sujeito de pesquisa o que contraria a Resolução CNS 466/12. Porém, a equipe executora se compromete a tratar os sujeitos participantes de forma sigilosa, não fazendo a identificação dos mesmos. Além disso, após a avaliação, os participantes receberão orientações acerca da higienização bucal assim como hábitos alimentares saudáveis. Os pacientes não sofrerão nenhum prejuízo ou dano, uma vez que serão assistidos pelo Hospital Odontológico, que dispõem de toda assistência e atenção necessárias ao seu bem estar. Os pacientes convidados, mas que não demonstrarem interesse em participar ou que desistirem da pesquisa, terão seu plano de tratamento realizado normalmente, sem nenhuma intervenção ou prejuízo e novos convites serão realizados a outros pacientes. A tomografia computadorizada cone beam que será utilizada se for necessário mostra-se muito útil no diagnóstico diferencial de patologias de origem endodôntica e não-endodôntica. ... uma das maiores vantagens da técnica cone beam está na redução da dose de radiação ao paciente. A dose efetiva varia, mas pode ser quase tão baixa quanto a de uma radiografia panorâmica convencional e consideravelmente inferior que uma tomografia computadorizada médica, os riscos à exposição da tomografia computadorizada de cone beam serão pequenos, dentro das doses e proteções estabelecidas seguras.

BENEFÍCIOS: Há benefícios diretos aos participantes, pois a pesquisa objetiva a avaliação da longevidade e eficácia das técnicas restauradoras com resina composta, isso beneficia não só o paciente participante como também toda a sociedade, uma vez que essas avaliações julgarão a qualidade das técnicas. Espera-se com este trabalho incentivar projetos favoráveis à inclusão social, contribuir com a integração UFU/comunidade, melhorar as condições essenciais de desenvolvimento da extensão na UFU e subsidiar pesquisas clínicas envolvendo tratamento endodôntico e restauradores de molares. Os voluntários receberão gratuitamente o tratamento

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Continuação do Parecer: 1.685.725

restaurador dentro dos conceitos clássicos da Odontologia. Durante o estudo, os responsáveis pela pesquisa darão toda a assistência necessária para o tratamento na área de Dentística e caso alguma restauração falhe, esta será trocada sem custo.

Comentários e Considerações sobre a Pesquisa:

- Foi apresentada a justificativa para alteração da resina do Grupo 1.
- Foi justificada a realização da tomografia computadorizada e foram apresentados os baixos riscos relacionados a esse exame de imagem.

Considerações sobre os Termos de apresentação obrigatória:

Todos foram apresentados.

Recomendações:

Não há.

Conclusões ou Pendências e Lista de Inadequações:

Foram apresentadas as respostas aos questionamentos feitos pelo CEP/UFU no Parecer anterior conforme a Lista de pendências seguinte:

1- Esclarecer o porquê da alteração da resina a ser utilizada no GRUPO 1.

RESPOSTA: "... troca da resina utilizada no grupo 1 de TPH3 para Z 350, pois em trabalhos a resina Z350 tem sido utilizada como padrão "ouro" quando há comparação de técnicas operatórias em odontologia, pensando sempre ofertar o melhor para o paciente, ..." ATENDIDA

2- Informar se a tomografia computadorizada será realizada no Hospital Odontológico da FOUFU.

RESPOSTA: Informamos que a tomografia computadorizada será realizada no Hospital Odontológico da FOUFU. ATENDIDA

3- Apresentar os riscos e os cuidados que serão tomados em relação à tomografia computadorizada. Essas informações devem ser acrescentadas nos dois projetos e nos Termos de Consentimento Livre e Esclarecido e de Assentimento.

RESPOSTA: "Para superar as limitações radiográficas convencionais e proporcionar imagens com maior resolução surgiram as tomografias computadorizadas, que são técnicas de aquisição de imagens em três dimensões (3D). Dentre elas, está a tomografia computadorizada cone beam (CBCT) que requer uma dose de radiação significativamente menor do que a tomografia computadorizada médica (TCM) e está sendo muito utilizada na área odontológica. A tomografia

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Continuação do Parecer: 1.685.725

computadorizada cone beam que iremos utilizar se for necessário mostra-se muito útil no diagnóstico diferencial de patologias de origem endodôntica e não-endodôntica. ... uma das maiores vantagens da técnica cone beam está na redução da dose de radiação ao paciente. A dose efetiva varia, mas pode ser quase tão baixa quanto a de uma radiografia panorâmica convencional e consideravelmente inferior que uma tomografia computadorizada médica, os riscos à exposição da tomografia computadorizada de cone beam serão pequenos, dentro das doses e proteções estabelecidas seguras. ATENDIDA.

4- Deixar claro nos Termos de Consentimento Livre e Esclarecido e de Assentimento que os participantes podem ser submetidos a radiografia ou a tomografia computadorizada e a justificativa para tal exame.

RESPOSTA: Foram apresentados os Termos com as alterações necessárias. ATENDIDA.

-----P E N D Ê N C I A-----

A lista de pendências anterior foi atendida. No entanto há correção a ser feita conforme descrito abaixo:

1- Corrigir o segundo parágrafo do TCLE (inserido na Plataforma Brasil como Modelo TCLE novo) e no segundo parágrafo do Termo de Assentimento pois em ambos é feita referência a filho: "Serão realizadas consultas de controle ... será preciso também que seu filho responda ..."

=====

Responder às pendências em um documento (WORD[.doc] ou .pdf) anexo e alterar no corpo do projeto os tópicos que forem diretamente impactados pelas respostas às pendências.

CASO O PESQUISADOR NÃO ANEXE ESTE DOCUMENTO COM O DETALHAMENTO DAS RESPOSTAS ÀS PENDÊNCIAS, O PROTOCOLO SERÁ DEVOLVIDO AO PESQUISADOR SEM TER SIDO ANALISADO PELO CEP E PERMANECERÁ COM PENDÊNCIAS.

O pesquisador tem prazo de 30 dias para responder à(s) pendência(s). Após este prazo o mesmo

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Continuação do Parecer: 1.685.725

deverá submeter Novo PROTOCOLO de pesquisa para avaliação pelo sistema CEP/CONEP.

Considerações Finais a critério do CEP:

OBS: o CEP/UFU informa que a recorrência de uma mesma pendência por três vezes acarretará na "NÃO APROVAÇÃO" do protocolo de pesquisa.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_687866 E1.pdf	28/06/2016 21:54:59		Aceito
Outros	JUSTIFICATIVAALTERACAORESINAGRUPO1.docx	28/06/2016 21:50:22	Renata Afonso da Silva Pereira	Aceito
Outros	JUSTIFICATIVARISCOCUIDADOSTOMOGRAFIA.docx	28/06/2016 21:47:59	Renata Afonso da Silva Pereira	Aceito
Outros	JUSTIFICATIVAOTOMOGRAFIACOMPUTADORIZADA.docx	28/06/2016 21:44:53	Renata Afonso da Silva Pereira	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Modelo_Termo_Assentimento_para_Menorarrumadonovo.doc	28/06/2016 21:42:05	Renata Afonso da Silva Pereira	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	MODELO_TCLE_para_o_responsavel_igual_pelo_menor_sujeito_de_pesquisarrumadonovo.doc	28/06/2016 21:41:42	Renata Afonso da Silva Pereira	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Modelo_TCLEnovo.doc	28/06/2016 21:41:24	Renata Afonso da Silva Pereira	Aceito
Projeto Detalhado / Brochura Investigador	projetodetalhadonovo.doc	28/06/2016 21:39:33	Renata Afonso da Silva Pereira	Aceito
Outros	EMENDA.docx	23/05/2016 22:23:25	Renata Afonso da Silva Pereira	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.doc	29/12/2015 20:44:56	Renata Afonso da Silva Pereira	Aceito
Outros	justificativaTCLE.docx	29/12/2015 20:42:51	Renata Afonso da Silva Pereira	Aceito
Outros	Justificativastermoassentimento.docx	29/12/2015 20:41:13	Renata Afonso da Silva Pereira	Aceito

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Continuação do Parecer: 1.685.725

Outros	JUSTIFICATIVAquestionarioOHIP.docx	15/11/2015 22:01:40	Renata Afonso da Silva Pereira	Aceito
Outros	Modelofichaclinica.docx	15/11/2015 21:56:06	Renata Afonso da Silva Pereira	Aceito
Folha de Rosto	folhaderosto.pdf	18/09/2015 23:10:30	Renata Afonso da Silva Pereira	Aceito
Outros	Modelodoinstrumentodecoleta.pdf	08/09/2015 22:37:16	Renata Afonso da Silva Pereira	Aceito
Outros	_Lynk.pdf	08/09/2015 22:34:02	Renata Afonso da Silva Pereira	Aceito
Outros	Solicitacao_do_pesquisador_para_a_ins tituicao_0.pdf	08/09/2015 22:33:18	Renata Afonso da Silva Pereira	Aceito
Outros	Modelo_Termo_de_Compromisso_Equi pe_Executora.pdf	08/09/2015 22:31:53	Renata Afonso da Silva Pereira	Aceito
Declaração de Instituição e Infraestrutura	Declaracao_Instituicao_Co_Participante. pdf	08/09/2015 22:30:12	Renata Afonso da Silva Pereira	Aceito

Situação do Parecer:

Pendente

Necessita Apreciação da CONEP:

Não

UBERLÂNDIA, 12 de Agosto de 2016

Assinado por:

Sandra Terezinha de Farias Furtado
(Coordenador)

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PARECER CONSUBSTANCIADO DO CEP

DADOS DA EMENDA

Título da Pesquisa: Análise clínica em protocolos restauradores em dentes posteriores

Pesquisador: Carlos José Soares

Área Temática:

Versão: 5

CAAE: 49372815.5.0000.5152

Instituição Proponente: Universidade Federal de Uberlândia/ UFU/ MG

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.685.725

Apresentação do Projeto:

Foi apresentada uma emenda ao projeto original com as seguintes propostas de mudanças e suas justificativas:

- Mudar a resina Bulk Fill SDR do GRUPO 2, que é uma resina fluida, pela resina Filtek Bulk Fill (3M ESPE), que é uma resina tipo pasta. Pelo trabalho ser feito com adolescentes, esta resina possibilitará trabalhar em um menor tempo clínico;
- Mudar a resina TPH3 do GRUPO 1 pela resina Z350.
- Realizar tomografia computadorizada que é um exame de imagem para os casos que forem complexos, por oferecer uma imagem radiográfica tridimensional como diagnóstico diferencial para necessidade de avaliação de suspeita de reabsorção interna ou externa, estruturas de corpo estranho, compreensão da anatomia do dente, avaliação do número e localização dos canais radiculares entre outras necessidades, buscando oferecer ao paciente um correto diagnóstico e tratamento odontológico.

Objetivo da Pesquisa:

Segundo o projeto:

Objetivo Primário: avaliar o desempenho das restaurações diretas em molares tratados endodonticamente.

Objetivo Secundário: Avaliar o comportamento e padrão quantitativo das restaurações classe II em

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Continuação do Parecer: 1.685.725

molares tratados endodonticamente com resina bulk fill e técnica incremental, por meio de ensaio clínico randomizado com acompanhamento de três anos.

Avaliação dos Riscos e Benefícios:

Segundo os pesquisadores:

RISCOS: de acordo com o relatado no projeto, não há riscos evidentes que estejam relacionados com este projeto, que comprometa a saúde dos pacientes participantes das avaliações clínicas, moldagens. Nos exames radiográficos, os riscos à exposição radiográfica serão pequenos, dentro das doses e proteções estabelecidas seguras. O paciente será orientado sobre isso no TCLE. Todas as medidas de biossegurança serão tomadas como protocolo de rotina durante as avaliações clínicas. A análise clínica das restaurações e moldagens dos dentes molares será feita após a autorização do paciente. O único risco é a identificação do sujeito de pesquisa o que contraria a Resolução CNS 466/12. Porém, a equipe executora se compromete a tratar os sujeitos participantes de forma sigilosa, não fazendo a identificação dos mesmos. Além disso, após a avaliação, os participantes receberão orientações acerca da higienização bucal assim como hábitos alimentares saudáveis. Os pacientes não sofrerão nenhum prejuízo ou dano, uma vez que serão assistidos pelo Hospital Odontológico, que dispõem de toda assistência e atenção necessárias ao seu bem estar. Os pacientes convidados, mas que não demonstrarem interesse em participar ou que desistirem da pesquisa, terão seu plano de tratamento realizado normalmente, sem nenhuma intervenção ou prejuízo e novos convites serão realizados a outros pacientes. A tomografia computadorizada cone beam que será utilizada se for necessário mostra-se muito útil no diagnóstico diferencial de patologias de origem endodôntica e não-endodôntica. ... uma das maiores vantagens da técnica cone beam está na redução da dose de radiação ao paciente. A dose efetiva varia, mas pode ser quase tão baixa quanto a de uma radiografia panorâmica convencional e consideravelmente inferior que uma tomografia computadorizada médica, os riscos à exposição da tomografia computadorizada de cone beam serão pequenos, dentro das doses e proteções estabelecidas seguras.

BENEFÍCIOS: Há benefícios diretos aos participantes, pois a pesquisa objetiva a avaliação da longevidade e eficácia das técnicas restauradoras com resina composta, isso beneficia não só o paciente participante como também toda a sociedade, uma vez que essas avaliações julgarão a qualidade das técnicas. Espera-se com este trabalho incentivar projetos favoráveis à inclusão social, contribuir com a integração UFU/comunidade, melhorar as condições essenciais de desenvolvimento da extensão na UFU e subsidiar pesquisas clínicas envolvendo tratamento endodôntico e restauradores de molares. Os voluntários receberão gratuitamente o tratamento

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Continuação do Parecer: 1.685.725

restaurador dentro dos conceitos clássicos da Odontologia. Durante o estudo, os responsáveis pela pesquisa darão toda a assistência necessária para o tratamento na área de Dentística e caso alguma restauração falhe, esta será trocada sem custo.

Comentários e Considerações sobre a Pesquisa:

- Foi apresentada a justificativa para alteração da resina do Grupo 1.
- Foi justificada a realização da tomografia computadorizada e foram apresentados os baixos riscos relacionados a esse exame de imagem.

Considerações sobre os Termos de apresentação obrigatória:

Todos foram apresentados.

Recomendações:

Não há.

Conclusões ou Pendências e Lista de Inadequações:

Foram apresentadas as respostas aos questionamentos feitos pelo CEP/UFU no Parecer anterior conforme a Lista de pendências seguinte:

1- Esclarecer o porquê da alteração da resina a ser utilizada no GRUPO 1.

RESPOSTA: "... troca da resina utilizada no grupo 1 de TPH3 para Z 350, pois em trabalhos a resina Z350 tem sido utilizada como padrão "ouro" quando há comparação de técnicas operatórias em odontologia, pensando sempre ofertar o melhor para o paciente, ..." ATENDIDA

2- Informar se a tomografia computadorizada será realizada no Hospital Odontológico da FOUFU.

RESPOSTA: Informamos que a tomografia computadorizada será realizada no Hospital Odontológico da FOUFU. ATENDIDA

3- Apresentar os riscos e os cuidados que serão tomados em relação à tomografia computadorizada. Essas informações devem ser acrescentadas nos dois projetos e nos Termos de Consentimento Livre e Esclarecido e de Assentimento.

RESPOSTA: "Para superar as limitações radiográficas convencionais e proporcionar imagens com maior resolução surgiram as tomografias computadorizadas, que são técnicas de aquisição de imagens em três dimensões (3D). Dentre elas, está a tomografia computadorizada cone beam (CBCT) que requer uma dose de radiação significativamente menor do que a tomografia computadorizada médica (TCM) e está sendo muito utilizada na área odontológica. A tomografia

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Continuação do Parecer: 1.685.725

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4- Deixar claro nos Termos de Consentimento Livre e Esclarecido e de Assentimento que os participantes podem ser submetidos a radiografia ou a tomografia computadorizada e a justificativa para tal exame.

RESPOSTA: Foram apresentados os Termos com as alterações necessárias. ATENDIDA.

-----P E N D Ê N C I A-----

A lista de pendências anterior foi atendida. No entanto há correção a ser feita conforme descrito abaixo:

1- Corrigir o segundo parágrafo do TCLE (inserido na Plataforma Brasil como Modelo TCLE novo) e no segundo parágrafo do Termo de Assentimento pois em ambos é feita referência a filho: "Serão realizadas consultas de controle ... será preciso também que seu filho responda ..."

=====

Responder às pendências em um documento (WORD[.doc] ou .pdf) anexo e alterar no corpo do projeto os tópicos que forem diretamente impactados pelas respostas às pendências.

CASO O PESQUISADOR NÃO ANEXE ESTE DOCUMENTO COM O DETALHAMENTO DAS RESPOSTAS ÀS PENDÊNCIAS, O PROTOCOLO SERÁ DEVOLVIDO AO PESQUISADOR SEM TER SIDO ANALISADO PELO CEP E PERMANECERÁ COM PENDÊNCIAS.

O pesquisador tem prazo de 30 dias para responder à(s) pendência(s). Após este prazo o mesmo

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Continuação do Parecer: 1.685.725

deverá submeter Novo PROTOCOLO de pesquisa para avaliação pelo sistema CEP/CONEP.

Considerações Finais a critério do CEP:

OBS: o CEP/UFU informa que a recorrência de uma mesma pendência por três vezes acarretará na "NÃO APROVAÇÃO" do protocolo de pesquisa.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_687866 E1.pdf	28/06/2016 21:54:59		Aceito
Outros	JUSTIFICATIVAALTERACAORESINAGRUPO1.docx	28/06/2016 21:50:22	Renata Afonso da Silva Pereira	Aceito
Outros	JUSTIFICATIVARISCOSCUIDADOSTOMOGRAFIA.docx	28/06/2016 21:47:59	Renata Afonso da Silva Pereira	Aceito
Outros	JUSTIFICATIVAOTOMOGRAFIACOMPUTADORIZADA.docx	28/06/2016 21:44:53	Renata Afonso da Silva Pereira	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Modelo_Termo_Assentimento_para_Menorarrumadonovo.doc	28/06/2016 21:42:05	Renata Afonso da Silva Pereira	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	MODELO_TCLE_para_o_responsavel_igual_pelo_menor_sujeito_de_pesquisarrumadonovo.doc	28/06/2016 21:41:42	Renata Afonso da Silva Pereira	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Modelo_TCLEnovo.doc	28/06/2016 21:41:24	Renata Afonso da Silva Pereira	Aceito
Projeto Detalhado / Brochura Investigador	projetodetalhadonovo.doc	28/06/2016 21:39:33	Renata Afonso da Silva Pereira	Aceito
Outros	EMENDA.docx	23/05/2016 22:23:25	Renata Afonso da Silva Pereira	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.doc	29/12/2015 20:44:56	Renata Afonso da Silva Pereira	Aceito
Outros	justificativaTCLE.docx	29/12/2015 20:42:51	Renata Afonso da Silva Pereira	Aceito
Outros	Justificativastermoassentimento.docx	29/12/2015 20:41:13	Renata Afonso da Silva Pereira	Aceito

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Continuação do Parecer: 1.685.725

Outros	JUSTIFICATIVAquestionarioOHIP.docx	15/11/2015 22:01:40	Renata Afonso da Silva Pereira	Aceito
Outros	Modelofichaclinica.docx	15/11/2015 21:56:06	Renata Afonso da Silva Pereira	Aceito
Folha de Rosto	folhaderosto.pdf	18/09/2015 23:10:30	Renata Afonso da Silva Pereira	Aceito
Outros	Modelodoinstrumentodecoleta.pdf	08/09/2015 22:37:16	Renata Afonso da Silva Pereira	Aceito
Outros	_Lynk.pdf	08/09/2015 22:34:02	Renata Afonso da Silva Pereira	Aceito
Outros	Solicitacao_do_pesquisador_para_a_ins tituicao_0.pdf	08/09/2015 22:33:18	Renata Afonso da Silva Pereira	Aceito
Outros	Modelo_Termo_de_Compromisso_Equi pe_Executora.pdf	08/09/2015 22:31:53	Renata Afonso da Silva Pereira	Aceito
Declaração de Instituição e Infraestrutura	Declaracao_Instituicao_Co_Participante. pdf	08/09/2015 22:30:12	Renata Afonso da Silva Pereira	Aceito

Situação do Parecer:

Pendente

Necessita Apreciação da CONEP:

Não

UBERLANDIA, 12 de Agosto de 2016

Assinado por:

Sandra Terezinha de Farias Furtado
(Coordenador)

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6.2 Normas dos periódicos

1. Operative Dentistry

<https://www.jopdent.com/authors/authors.php>

2. Operative Dentistry

<https://www.jopdent.com/authors/authors.php>

3. Clinical Oral Investigation

https://www.springer.com/medicine/dentistry/journal/784?detailsPage=pltc_i_1060698

4. Community Dentistry and Oral Epidemiology

<https://onlinelibrary.wiley.com/page/journal/16000528/homepage/forauthors.html>

6.3 Release para imprensa

O presente estudo avaliou o desempenho das restaurações diretas em molares tratados endodonticamente, o efeito da técnica restauradora, e a longevidade das restaurações de dentes posteriores. A principal função dos dentes é realizar a mastigação dos alimentos, a cárie acontece quando há desequilíbrio no meio bucal que favorece a desmineralização do esmalte dentário. Quando temos perda da estrutura dentária existe a necessidade de restauração no dente. Ainda há casos, em que a cárie atinge a polpa do dente, e há necessidade de fazer o tratamento de canal. As resinas compostas são os materiais mais utilizados para restaurações em dentes posteriores, a técnica incremental é o padrão ouro para esse tipo de procedimento. Resinas bulk fill, ganham a cada dia mais adeptos e vem sendo utilizadas em cavidades amplas, reduzindo tempo de trabalho. Concluímos que as tensões geradas pelas resinas compostas são melhor definidas quando se baseia na contração pós-gel das resinas. Restaurações realizadas com ionômero de vidro e técnica incremental apresentam comportamento biomecânico similar às técnicas de resinas bulk fill. Na avaliação clínica de 2 anos de restaurações com resinas bulk fill realizadas em pacientes adolescentes, mostrou que desempenho similares que restaurações realizadas com ionômero de vidro com técnica incremental. As restaurações executadas no serviço público de Uberlândia apresentaram taxa de sobrevida de 95%, mostrando efetividade nas ações realizadas. Porém, essa longevidade foi menor em regiões de maior vulnerabilidade social. Além disso profissionais com maior tempo de formação apresentaram pior desempenho de suas restaurações.