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CINTHIA MARIA BAGGIO DE LUCA DA CUNHA

AVALIAÇÃO CLÍNICA DE DIFERENTES MATERIAIS PARA RESTAURAÇÃO DE MOLARES DECÍDUOS PELA TÉCNICA DE MÍNIMA INTERVENÇÃO

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Tese apresentada como pré-requisito para obtenção do título de Doutor na Universidade Estadual de Ponta Grossa, no curso de Doutorado em Odontologia – Área de Concentração Clínica Integrada. Linha de Pesquisa: Epidemiologia, Diagnóstico e Intervenção em Saúde Bucal.

Orientadora: Profª. Drª. Denise Stadler Wambier

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CINTHIA MARIA BAGGIO DE LUCA DA CUNHA

"Avaliação clínica de diferentes materiais para restauração de molares decíduos pela técnica de mínima intervenção."

Tese apresentada ao Programa de Pós-graduação Stricto sensu em Odontologia da Universidade Estadual de Ponta Grossa, como requisito parcial à obtenção do título de Doutor em Odontologia, área de concentração em Clínica Integrada, linha de pesquisa de Epidemiologia, Diagnóstico e Intervenção em Saúde Bucal.

Ponta Grossa, 29 de outubro de 2019

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DADOS CURRICULARES

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RESUMO

Da Cunha, C.M.B.L. **Avaliação clínica de diferentes materiais para restauração de molares decíduos pela técnica de mínima intervenção.** [Tese] Doutorado em Clínica Integrada. Ponta Grossa: Universidade Estadual de Ponta Grossa; 2019.

O objetivo destes estudos clínicos foi avaliar o desempenho clínico de diferentes materiais em restaurações realizadas pela técnica de Mínima Intervenção (remoção seletiva de tecido cariado), em molares decíduos de crianças entre 4 a 9 anos. O estudo 1 avaliou o desempenho clínico de um material restaurador à base de resina de dupla polimerização (Cention N - Ivoclar Vivadent, Schaan, Liechtenstein) com e sem aplicação prévia de adesivo universal, comparado ao cimento de ionômero de vidro resinoso (Vitremer, 3M Oral Care, St. Paul, MN, EUA), ao longo de 12 meses de acompanhamento. O estudo 2 avaliou o adesivo universal Tetric N-Bond (Ivoclar Vivadent, Schaan, Liechtenstein) nas técnicas de *self-etch* ou *etch and rinse* associado a restaurações em resina bulk-fill em um período de 12 meses de acompanhamento. O estudo 3 verificou no período de 24 meses, a taxa de sobrevivência de restaurações ART, realizadas com dois cimentos de ionômero de alta viscosidade- Íon Z (FGM Prod. Odont., Ltda, Joinville, SC, Brasil) e Ketac Molar Easymix (3M ESPE, St Paul, MN, EUA). Os resultados do estudo 1 demonstraram que o Cention N apresentou níveis de longevidade similares ao cimento de ionômero de vidro resinoso, todavia, o uso de sistema adesivo é indicado para restaurações oclusoproximais. No estudo 2, verificou-se que ambas as estratégias de adesão testadas (*self-etch* e *etch and rinse*) têm desempenho similar ao longo do tempo. Os dados do estudo 3 mostraram baixo grau de sobrevida das restaurações ART (oclusais e oclusoproximais) de ambos os materiais, sem diferença significativa entre classes. Estudos clínicos adicionais em pacientes infantis devem ser conduzidos para comprovar a eficácia, especialmente dos novos materiais, pois a escolha correta do melhor material restaurador para dentes decíduos ainda gera impasse no profissional odontopediátrico. Conclui-se que materiais restauradores resinosos podem ser utilizados após remoção seletiva de tecido cariado. Os cimentos de ionômero de vidro, mesmo os de alta viscosidade, ainda apresentam limitações, particularmente para restauração de cavidades ocluso-proximais.

Palavras-chave: Dente Decíduo; Estudo Clínico; Materiais Dentários; Criança.

ABSTRACT

Da Cunha, C.M.B.L. **Clinical evaluation of different materials for primary molar restoration by the minimal intervention technique.** [Tese] Doutorado em Clínica Integrada. Ponta Grossa: Universidade Estadual de Ponta Grossa; 2019.

The aim of these studies was to evaluate the clinical performance of different materials in restorations performed by Minimum Intervention (selective caries removal) in primary molars of children aged 4 to 9 years. Study 1 evaluated the clinical performance of a dual polymerization resin-based restorative material (Cention N - Ivoclar Vivadent, Schaan, Liechtenstein) with and without prior application of universal adhesive compared to a resin glass ionomer cement (Vitremer, 3M Oral Care, St. Paul, MN, EUA) over 12 months follow up. Study 2 evaluated the Tetric N-Bond universal adhesive (Ivoclar Vivadent, Schaan, Liechtenstein) on self-etch or etch and rinse techniques associated with bulk-fill restorations over a 12-month follow-up. Study 3 verified the survival rate of ART restorations performed with two high viscosity cements: Íon Z (FGM Prod. Odont., Ltda, Joinville, SC, Brasil) and Ketac Molar Easymix (3M ESPE, St Paul, MN, EUA) in 24 months follow-up. The results of study 1 demonstrated that Cention N showed leves of longevity similar to the resin glass ionomer cement, however, the use of adhesive system is indicated for occlusal-proximal restorations. In study 2, it was found that both adherence strategies tested (self-etch and etch and rinse) have similar performance over time. The data from study 3 showed a low degree of survival (occlusal and occlusal-proximal) in both materials used in the ART technique, with no difference significant btween classes. Further clinical studies in pediatric patients should be conducted to prove the efficacy, especially of new materials, as the correct choice of the best restorative material for primary teeth still impairs the dental professional. It is concluded that resin restorative materials can be used after selective removal. of decayed fabric. Glass ionomer cements, even those of high viscosity, still have limitations, particularly for composite cavities.

Keywords: Tooth, Deciduos; Clinical Study; Dental Materials; Child.

LISTA DE TABELAS

LISTA DE ABREVIATURAS E SIGLAS

ART	Tratamento Restaurador Atraumático
BER	*Bulk fill etch and rinse*
BSE	*Bulk fill self etch*
CAPES	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior
CIV	Cimento de Ionômero de Vidro
CONSORT	Consolidated Standards of Reporting Trials
CPI	Índice Periodontal Comunitário
ECR	Ensaio Clínico Randomizado
HR	Razão de risco
ICDAS II	International Caries Detection and Assessment System
LED	Diodo Emissor de Luz
OMS	Organização Mundial da Saúde

SUMÁRIO

1 Introdução

Na Odontopediatria, é constante a busca por procedimentos restauradores menos invasivos que ofereçam boa longevidade e que sejam bem aceitos pelas crianças (1). A situação ideal seria que os materiais restauradores fossem menos sensíveis às técnicas, resistentes aos desafios cariogênicos e mecânicos do meio bucal, com baixo custo, fáceis de aplicar, com menos etapas em seus protocolos clínicos e que atendessem às necessidades individuais de cada paciente. Tais características são fundamentais e direcionariam a escolha do material restaurador, visando a melhor situação para gerenciamento do comportamento de crianças e obtenção do reequilíbrio na condição bucal do paciente (2).

O amálgama foi utilizado durante muitos anos, tanto na saúde pública quanto em consultórios particulares, com excelentes propriedades mecânicas, as quais contribuíram para o sucesso das restaurações realizadas com esse material (3). Porém, seu uso tornou-se limitado pela falta de estética, excessivo desgaste da estrutura dentária e, seu conteúdo de mercúrio, que acabou sendo tema de discussão com relação aos impactos ambientais (4) e possíveis problemas à saúde humana (5).

Para suprir a lacuna deixada pelo amálgama nas restaurações de dentes posteriores, materiais à base de resina composta passaram a ser melhorados e testados constantemente. Mesmo apresentando menor longevidade quando comparados às restaurações de amálgama (6), esses materiais apresentam boa estética e desempenho clínico satisfatório ao longo dos anos. No entanto, essa categoria de material é mais sensível à técnica de trabalho (7), o operador deve ser habilidoso em manter a cavidade bucal livre de qualquer umidade (8), e as restaurações devem ser realizadas, em clínica odontológica.

Uma alternativa são os materiais à base de cimentos de ionômero de vidro (CIVs), que vem ganhando espaço nas pesquisas e nos consultórios de Odontopediatria, com ênfase para os CIVs de alta viscosidade. Eles apresentam propriedades positivas como adesão química à dentina e ao esmalte, coeficiente de expansão térmica semelhante à estrutura dentária (9), e em algumas formulações foram adicionados elementos que conferem ação antibacteriana ao material (10). Comparando-os com os CIV convencionais, apresentam melhores propriedades

mecânicas, como resistência à fratura e ao desgaste, porém, mesmo assim, o resultado estético (11) e a longevidade de restaurações – particularmente em cavidades compostas - ainda apresenta-se inferior comparado ao obtido com a resina composta.

A seleção de um material ideal para restaurações de dentes decíduos ainda gera impasse em clínicos, principalmente em abordagens minimamente invasiva, onde é preconizada a manutenção de dentina desmineralizada no assoalho cavitário. Com isso, não haverá progressão da lesão desde que haja vedamento marginal efetivo da restauração (12).

A máxima preservação de tecidos saudáveis (13) vem do conceito de Massler (14) e Fusayama (15), que há mais de 50 anos, descreveram o conteúdo da dentina cariada. A camada mais superficial (infectada) apresenta extenso aglomerado bacteriano e colágeno degradado e deve ser removida (13), enquanto a dentina mais profunda (afetada) deve ser mantida, pois apresenta uma trama colágena e potencial de remineralização (16).

As abordagens minimamente invasivas, principalmente nas lesões profundas de cárie, pretendem substituir as técnicas convencionais de remoção total de tecido cariado (17), reduzindo a incidência de exposição pulpar durante o preparo cavitário (18) e os potenciais efeitos negativos de tratamentos mais invasivos e onerosos (19).

Tratar dentes decíduos utilizando-se a técnica de remoção seletiva de tecido cariado ainda é um grande desafio encontrado na Odontopediatria. Mesmo com todos os benefícios dessa técnica, as evidências sobre a longevidade das restaurações são limitadas (20), e têm relação direta com o material restaurador escolhido (21).

A escolha do material deve ser baseada na extensão da lesão cariosa e nas condições específicas de cada paciente (22). Dentre os materiais restauradores usados nessa abordagem, os CIVs são os materiais que apresentam maior número de estudos, usados preferencialmente em restaurações atraumáticas. A revisão sistemática de Amorim et al., 2018 (23) mostrou taxas de retenção para um período de 24 meses das restaurações oclusais e oclusoproximais de 94,3 e 65,4%, respectivamente.

Outro material que poderia ser associado à remoção seletiva de tecido cariado é a resina *bulk fill*. Esta resina é particularmente interessante por permitir a inserção de camadas de até 4 mm de espessura, reduzindo o tempo de cadeira do paciente. Nesta mesma linha de raciocínio, pode-se associar às resinas *bulk fill* os adesivos universais, que dispensam o condicionamento prévio com ácido fosfórico (24).

Entre os materiais recentemente lançados no mercado, pode-se citar o Cention N (Ivoclar Vivadent, Schaan, Liechtenstein), que é considerado, segundo o fabricante, “a melhor alternativa ao amálgama”. Esse é um material resinoso de dupla polimerização, lançado em novembro de 2018. Outro material também bastante novo no mercado é o cimento de ionômero de vidro ÍON Z (FGM Produtos. Odontológicos, Ltda, Joinville, SC, Brasil), que é um CIV enriquecido com zinco. No conhecimento desta autora, tais materiais ainda não apresentam estudos clínicos de longevidade em dentes decíduos com remoção seletiva de tecido cariado.

Ensaios clínicos podem auxiliar na obtenção de evidências sobre os efeitos das intervenções em saúde (25) e são fundamentais para se conhecer o desempenho clínico a longo prazo de materiais restauradores e sua possibilidade de uso no cotidiano clínico do Odontopediatra. Assim, essa tese incluiu três estudos clínicos randomizados duplo-cegos testando diferentes técnicas e materiais em restaurações de molares decíduos após remoção seletiva de tecido cariado no tratamento de crianças na faixa etária de 4 e 9 anos.

2 Objetivos

2.1 Objetivo Geral

- Avaliar o desempenho clínico de diferentes técnicas e materiais nas restaurações de molares decíduos em crianças das escolas municipais da cidade de Ponta Grossa-PR., ao longo do tempo, pela abordagem minimamente invasiva.

2.2 Objetivos Específicos

- Comparar a taxa de sobrevivência de restaurações minimamente invasivas em dentes decíduos, com um novo material à base de resina e um cimento de ionômero de vidro modificado por resina, após 12 meses de acompanhamento, em cavidades oclusais e oclusoproximais.
- Comparar a taxa de sobrevivência das restaurações em molares decíduos, com remoção seletiva de tecido cariado, utilizando adesivo universal nos protocolos *self-etch* e *etch and rins*e associado a resina composta *bulk fill* após 12 meses de acompanhamento, em cavidades oclusais e oclusoproximais.
- Comparar a taxa de sobrevivência das restaurações ART em molares decíduos, restaurados com dois CIVs de alta viscosidade (um deles com zinco em sua composição) após 24 meses de acompanhamento, em cavidades oclusais e oclusoproximais.

3 Material e Métodos

Esta tese é composta por três estudos clínicos randomizados e duplo-cegos (participantes e avaliadores), aprovados pelo Comitê de Ética em Pesquisa da Universidade Estadual de Ponta Grossa (Paraná, Brasil), conforme anexos (A e C) e registrados no Registro Brasileiro de Ensaios Clínicos (REBEC), anexos (B e D). Os artigos desta tese seguiram o protocolo estabelecido pela declaração Consolidated Standards of Reporting Trials – CONSORT (25).

Critérios de inclusão para todos os estudos: crianças entre 4 e 9 anos devidamente matriculados em escolas municipais da cidade de Ponta Grossa (PR, Brasil) e que apresentaram o Termo de Consentimento Livre e Esclarecido (TCLE) devidamente assinados pelos pais ou responsáveis. A crianças selecionadas deveriam apresentar dentes que se enquadrassem nos escores 5 ou 6 do ICDAS II (26).

Critérios de exclusão para todos os estudos: crianças que se recusassem a participar do exame clínico e dos procedimentos restauradores, àquelas que relatassem dor presente ou antiga nos possíveis dentes a serem restaurados, ou, caso os dentes indicados à realização do procedimento restaurador apresentassem mobilidade ou fístula, eram automaticamente excluídos da amostra. Porém, quando houve possibilidade, esses dentes não incluídos foram restaurados com cimento provisório de óxido de zinco e eugenol IRM (Dentsply Brasil, Petrópolis, RJ, Brasil) para reduzir o desconforto da criança. Essas crianças foram encaminhadas para realização de procedimentos mais invasivos em Clínica Especializada da Universidade Estadual de Ponta Grossa (UEPG).

O exame inicial dos participantes foi realizado na própria escola, após assentimento de cada criança. Após escovação supervisionada, elas foram posicionadas em decúbito dorsal, sobre colchonetes, em espaços adaptados para esse fim, sob luz natural. O exame clínico foi iniciado após secagem dos dentes com gaze e roletes de algodão. Abaixadores de língua foram utilizados para auxiliar a observação da cavidade bucal de cada criança.

Os estudos foram iniciados com o recrutamento das crianças em março de 2016 e concluídos com a última avaliação das restaurações em janeiro de 2019.

3.1 Estudo 1 – Ensaio Clínico Randomizado pela Técnica de Remoção Seletiva de Tecido Cariado em Dentes Decíduos com Material à Base de Resina de Dupla Polimerização: Acompanhamento de 12 Meses.

A metodologia detalhada deste estudo está descrita no ARTIGO 1 (pág. 30).

3.1.1 Desenho do estudo, participantes e materiais

Este estudo consistiu em um ensaio clínico randomizado, paralelo, controlado, duplo-cego, que objetivou comparar dois materiais em restaurações de molares decíduos durante 12 meses. Os participantes que compuseram a amostra deste estudo foram 27 escolares devidamente matriculados em escolas municipais com idades entre 4 a 9 anos, aqueles cujos pais/responsáveis tivessem assinado o TCLE e que apresentassem no mínimo 3 lesões de cárie cavitadas escore 5 ou 6 do ICDAS II (International Caries Detection and Assessment System) (26) em molares decíduos vitais. O escore 5 representa cavitação em esmalte com exposição de dentina: até ½ da superfície da face analisada e escore 6 representa cavitação em esmalte com exposição de dentina: maior que ½ da superfície da face analisada.

Participantes não colaboradores (que se recusaram a participar dos exames clínicos) e portadores de necessidades especiais, foram excluídos; assim como pacientes que apresentaram molares decíduos com sinais e/ou sintomas relacionados a patologia pulpar (abscessos, fístulas, mobilidade patológica).

Os materiais testados foram: cimento de ionômero de vidro modificado por resina (Vitremer, 3M Oral Care, St. Paul, MN, EUA) e material a base de resina de dupla polimerização (Cention N, Ivoclar Vivadent, Schaan, Liechenstein).

3.1.2 Cálculo amostral

O cálculo amostral foi realizado considerando-se a taxa de sucesso de 2 anos do CIV modificado por resina (Vitremer) de aproximadamente 55% (27). Considerando-se uma triagem clínica de superioridade, o tamanho mínimo da amostra foi calculado em 33 restaurações por grupo, com um poder do teste de 80% de detectar uma diferença significativa ao nível de 5%. O número total de restaurações foi 107, pois foi adicionado 8% do cálculo amostral inicial para compensar possíveis perdas.

3.1.3 Randomização e sigilo de alocação

Este procedimento foi realizado por uma terceira pessoa, que não estava envolvida no protocolo do estudo, sendo utilizada uma randomização por blocos de 3. Envelopes opacos, selados e consecutivamente numerados contendo a identificação dos grupos foram preparados usando um *software* estatístico disponível on-line (www.sealedenvelope.com). A abertura do envelope somente ocorreu no dia do procedimento restaurador, após o preparo cavitário de cada dente, o que garantiu o sigilo de alocação. Em todos os casos, o dente mais posterior a ser restaurado recebeu a primeira restauração, sempre seguindo a sequência descrita dos quadrantes (5,6,7 e 8). O dente cavitado em sequência recebeu o tratamento aberto no segundo envelope e assim sucessivamente, até o terceiro dente.

3.1.4 Intervenção

De 433 crianças avaliadas, 27 foram selecionadas, sendo as 107 restaurações (oclusais e oclusoproximais) realizadas pelo mesmo operador (especialista em odontopediatria), no próprio ambiente escolar, com instrumentação manual, sem anestesia local e sob isolamento relativo.

Todas as restaurações seguiram o protocolo proposto de remoção seletiva de tecido cariado (22,28). O tecido infectado foi totalmente removido da junção esmalte-dentina e bordo cavo superficial, usando escavadores de dentina afiados (Kit ART 10 Instruments Set, GC Europe, Leuven, Bélgica) de tamanho compatível com a lesão, antes de prosseguir para as paredes pulpar (oclusais) e axial (oclusoproximais), onde o tecido afetado foi deixado na cavidade. Concluída a remoção de tecido cariado, a cavidade foi limpa com uma bolinha de algodão embebida em água e seca com uma nova bolinha de algodão (Cremer, Blumenau, Brasil). Nenhum material de forramento ou base foi utilizado para proteção da parede pulpar.

Nas restaurações oclusoproximais, uma matriz metálica (TDV, Pomerode, SC, Brasil) foi cortada, posicionada e estabilizada por uma cunha de madeira (TDV) para definir o contorno proximal da restauração.

Para todas as 35 restaurações com o cimento de ionômero de vidro modificado por resina (Vitremer, 3M Oral Care, St. Paul, MN, EUA), o primer (3M Oral Care), que acompanha o material, foi aplicado e fotopolimerizado por 20s com um dispositivo LED

(Bluephase N, Ivoclar Vivadent, Schaan, Liechtenstein) com uma intensidade de 1.200 mW / cm2. Uma medida de pó e uma gota do líquido do Vitremer foram colocadas em um bloco de mistura, o pó foi dividido ao meio e incorporado cada parte ao líquido, sendo misturado com uma espátula de plástico (conforme as instruções do fabricante). Após obtenção da consistência que permitiu a inserção na cavidade, com auxílio de um instrumento manual de condensação (Kit ART 10 Instruments Set, GC Europe, Leuven, Bélgica) o material foi inserido na cavidade e pressionado aplicando-se pressão digital com luva vaselinada. O excesso de vaselina e do material restaurador foram removidos com um Hollenback e depois a restauração foi fotoativada durante 40s com o mesmo dispositivo LED (1.200 mW / cm2; Bluephase N).

O Cention N foi testado usando dois protocolos diferentes: 36 restaurações sem adesivo (Cention N - Adh) e 36 restaurações com aplicação de adesivo (Cention N + Adh) antes da restauração.

Para as restaurações utilizando o Cention N - Adh, o pó e líquido do material foram misturados com espátula de plástico de acordo com as instruções do fabricante e inseridos e polimerizados na cavidade da mesma forma descrita anteriormente com o CIV Vitremer. No grupo Cention N + Adh, antes do material ser inserido em cada cavidade, foi aplicado ativamente o adesivo Tetric N-Bond Universal (Ivoclar Vivadent, Schaan, Liechtenstein) durante 20 s no esmalte e na dentina. Após esse período, foi fotopolimerizado por 10 s (1.200 mW / cm2; Bluephase N), seguido pela inserção do material conforme descrito anteriormente com o Vitremer. As características dos materiais utilizados neste estudo estão descritas na Tabela 1.

Tabela 1 – Materiais utilizados e Modo de aplicação dos materiais

Material (Fabricante e lote)	Composição	Modo de aplicação
Vitremer (3M Oral Care, St. Paul, MN, EUA)/1705132)	1. Primer Vitremer: copolímero de Vitrebond, metacrilato de 2-hidroxietilo; etanol e fotoiniciadores. 2. Vitremer Pó: Fluoroaluminossilicato de vidro e sistema redox 3. Vitremer Líquido: solução aquosa de um ácido polialcenóico modificado, metacrilato de 2-hidroxietilo; e fotoiniciadores	1. Dispensar 1 colher de pó e 1 gota de líquido em bloco de mistura. 2. Misturar o pó e o líquido por 45 s. 3. Inserir e condensar na cavidade e esculpir 4. Fotopolimerizar por 10 s-(1200 mW / cm2)
Tetric N-bond Universal (S54248) e Cention N (Ivoclar Vivadent, Schaan, Liechtenstein)	1. Tetric N-bond Universal: metacrilato de 2-hidroxietilo, di-hidrogenofosfato de metacriloiloxidecilo, metacrilato de glicidilo bisfenol, polímero de ácido carboxílico metacrilado, dimetadirato de decandiol, etanol, água, dióxido de silício altamente disperso e canforoquinona 2. Líquido do Cention N: dimetacrilato de uretano 4, dimetacrilato de triciclodecano-dimetanol, dimetacrilato de tetrametil-xililenodiuretano e dimetacrilato de polietilenoglicol 400 e iniciadores. 3. Pó do Cention N: enchimento de vidro de silicato de bário alumínio, trifluoreto de itérbio, um Isofiller, um enchimento de vidro de fluorosilicato de cálcio e bário de alumínio e um enchimento de vidro de fluorossilicato de cálcio (alcalino) com partículas entre 0,1 µm e 35 µm, iniciadores e pigmentos	1. Dispensar 1 colher de pó e 1 gota de líquido em bloco de mistura. 2. Misturar o pó e o líquido com uma espátula de plástico até obter uma consistência cremosa e homogênea (45 - 60 s). 3. Inserir e condensar na cavidade, e esculpir a anatomia oclusal. 4. Fotopolimerizar por 10 s- (1200 mW / cm2)

3.1.5 Avaliação clínica

Dois examinadores calibrados e cegos quanto ao tipo de material utilizado e que não haviam participado do tratamento restaurador, avaliaram as restaurações aos 3, 6 e 12 meses. Para a calibração, foram utilizadas fotografias de dentes decíduos com restaurações atraumáticas em diferentes condições. O avaliador classificou as restaurações em dois momentos distintos para cálculo da concordância. Para cada avaliador, em cada período de avaliação, foram repassados apenas os dados referentes aos nomes dos participantes e os dentes a serem avaliados, sem a descrição do material restaurador utilizado. Se ocorressem discordâncias nas avaliações, eles precisariam chegar a um consenso antes que o participante fosse dispensado. Foram obtidos valores de Kappa de 0,87 e 0,84 (intra e inter-avaliadores, respectivamente)

Cada avaliação foi realizada após a criança escovar os dentes, porém, placa e restos alimentares excedentes foram retirados com roletes de algodão úmidos antes das avaliações.

A avaliação clínica foi realizada utilizando espelhos bucais, sondas periodontais da OMS e uma fonte de luz. A ponta arredondada da sonda da OMS (diâmetro 0,5 mm) foi deslizada nas restaurações para detectar possíveis defeitos marginais e desgaste. Os critérios utilizados para avaliar as restaurações são os mesmos descritos por Amorim *et al.,* (29), conforme Tabela 2.

As restaurações classificadas como códigos 0, 1 e 2 foram consideradas bem-sucedidas, aquelas assinaladas com códigos 3, 4, 5, 6, 7 e 8 foram consideradas falhas, e as restaurações com o código 9 foram substituídas pela última pontuação obtida na avaliação anterior.

Tabela 2 - Critérios de avaliação de restaurações atraumáticas (29).

Código	Critérios
0	Presente, satisfatória
1	Presente, deficiência na margem cavitária menor do que 0,5 mm ou mais
2	Presente, deficiência na margem cavitária de 0,5 mm ou mais
3	Presente, fratura na restauração
4	Presente, fratura no dente
5	Presente, extensão da margem proximal igual ou superior a 0,5 mm.
6	Ausente, a maior parte ou toda a restauração faltando
7	Ausente, outro tratamento restaurador realizado
8	Ausente, dente faltando
9	Impossível diagnosticar

3.1.6 Análise Estatística

As análises estatísticas seguiram o protocolo por intenção de tratar de acordo com a sugestão do CONSORT (25). A estatística descritiva incluiu o cálculo da taxa de sucesso dos materiais restauradores em 3, 6 e 12 meses.

A fim de avaliar a intensidade da associação entre as taxas de sucesso dos diferentes materiais restauradores utilizados, calculou-se a razão de risco (HR), considerando uma análise global e os diferentes tipos de restaurações (oclusais e oclusoproximais), onde um intervalo de confiança de 95% foi estipulado. O teste Log-Rank (Mantel-Cox) foi usado para analisar as diferenças entre as curvas de sobrevivência: (1) para os diferentes materiais, (2) para diferentes classes de restauração, (3) para diferentes materiais no mesmo tipo de restauração e (4) para diferentes classes de restauração usando o mesmo material. Uma diferença foi considerada estatisticamente significativa se $p<0,05$.As curvas de sobrevida de Kaplan-Meier foram obtidas considerando-se os diferentes materiais, tipos de restaurações e a curva global. Todas as análises foram realizadas usando o SPSS Statistics para Windows, Versão 20.0 (Armonk, NY: IBM Corp).

3.2 Estudo 2 – Ensaio Clínico Randomizado, Duplo-Cego, com Resina *Bulk-Fill* utilizando Dois Protocolos de Aplicação do Sistema Adesivo Universal em Molares Decíduos: Acompanhamento de Um Ano.

A metodologia detalhada deste estudo está descrita no ARTIGO 2 (pág. 61).

3.2.1 Desenho do estudo e seleção dos participantes

Este estudo foi um ensaio clínico randomizado, duplo-cego (participante e avaliador), controlado, com uma taxa de alocação igual. Participaram 27 crianças de 6 a 9 anos, devidamente matriculados em escolas municipais, aqueles cujos pais/responsáveis tivessem assinado o TCLE e que apresentassem no mínimo 2 lesões de cárie cavitadas escore 5 ou 6 do ICDAS II (International Caries Detection and Assessment System) (26) em molares decíduos vitais.

Participantes não colaboradores (que se recusaram a participar dos exames clínicos) e portadores de necessidades especiais, foram excluídos; assim como pacientes que apresentaram molares decíduos com sinais e/ou sintomas relacionados a patologia pulpar (abscessos, fístulas, mobilidade patológica).

Um único operador (Odontopediatra) realizou as 89 restaurações. As cavidades foram preparadas com instrumentos manuais pela técnica de remoção seletiva da dentina cariada (22, 28).

3.2.2 Cálculo amostral e alocação dos grupos

O tamanho da amostra foi calculado com base em estudo clínico de Pires *et al.,* (30), onde a média de sobrevida de restaurações com adesivos universais em dentes decíduos após remoção seletiva foi de 80%. O cálculo amostral para essa triagem clínica de equivalência, com um alfa de 5% e um poder de teste de 90% foi de, no mínimo, 39 restaurações por grupo. Um acréscimo de 15% foi adicionado para compensar qualquer desistência ou perda, totalizando 89 restaurações.

Foi utilizada randomização por blocos de 4, sendo que um membro da equipe não envolvido no protocolo de pesquisa realizou o processo de randomização com tabelas geradas por um *software* estatístico disponível *online* (www.sealedenvelope.com) e preparou a identificação do grupo para cada dente

dente. Essa identificação foi colocada em envelope opaco, selado e consecutivamente numerado. A abertura do envelope somente ocorreu no dia do procedimento restaurador, após o preparo cavitário de cada dente, o que garantiu o sigilo de alocação. Em todos os casos, o dente mais posterior a ser restaurado recebeu a primeira restauração, sempre seguindo a sequência descrita dos quadrantes (5,6,7 e 8), sendo que o dente cavitado em sequência recebeu o tratamento aberto no segundo envelope. Todos os participantes receberam pelo menos duas restaurações, cada uma usando uma técnica adesiva e, todas as restaurações do mesmo participante foram realizadas no mesmo dia.

3.2.3 Materiais empregados e intervenção clínica

Neste estudo, o adesivo Tetric N-bond Universal (Ivoclar-Vivadent, Schaan, Liechtenstein) foi testado por meio de dois protocolos adesivos: com aplicação de ácido fosfórico prévio (BER- *bulk etch-and-rinse*) e sem aplicação de ácido fosfórico previamente ao adesivo (BSE- *bulk self-etch*). Todas as restaurações foram realizadas com a resina Tetric N-Ceram Bulk fill (Ivoclar-Vivadent, Schaan, Liechtenstein). Especificações dos materiais estão descritas na Tabela 3.

Tabela 3 – Materiais utilizados no estudo 2.

Material/Nome Comercial	**Composição**	**Lote**
1. Tetric N-bond Universal (Ivoclar-Vivadent, Schaan Liechtenstein) 2. N-etch gel (Ivoclar-Vivadent, Schaan Liechtenstein)	1.Metacrilato de hidroxietilo, di-hidrogenofosfato de metacriloiloxidecilo, metacrilato de glicidilo de bisfenol, polímero de ácido carboxílico metacrilado, dimetadirato de decandiol, etanol, água, dióxido de silício altamente disperso e canforoquinona. 2. Ácido fosfórico a 37%.	U42905
3. Tetric N-Ceram Bulk fill (Ivoclar-Vivadent, Schaan Liechtenstein)	3. Dimetacrilatos, polímero, vidro de bário, trifluoreto de itérbio, óxido misto (78% em peso).	U42905 V04429

Todas as restaurações foram realizadas na clínica odontológica da UEPG (Universidade Estadual de Ponta Grossa) e, os dentes restaurados foram submetidos

a isolamento absoluto do campo operatório. Após esse passo, a superfície do dente foi limpa com escova de Robinson (Microdont, Socorro, SP, Brasil) e pedra pomes (SS White Prod. Odontol. LTDA, Petrópolis, RJ, Brasil) diluída em água para remoção de resíduos e biofilme do dente a ser restaurado.

O preparo da cavidade foi feito conforme descrito no estudo 1. O protocolo de adesão para o grupo BER foi o seguinte: condicionamento da cavidade com ácido fosfórico a 37% (Ivoclar Vivadent, Schaan, Liechtenstein) por 30 s na superfície de esmalte e por 15 s na superfície da dentina, seguido de lavagem e secagem da cavidade. Uma camada do adesivo Tetric N-Bond Universal (Ivoclar Vivadent, Schaan, Liechtenstein) foi aplicada por 20 s com fricção vigorosa no esmalte e na dentina, seguida de secagem suave ao ar por 5 s e imediatamente fotopolimerizado por 10 s (1200 mW / cm2, Bluephase N). A luz foi direcionada perpendicularmente à superfície oclusal.

Para o grupo BSE, não foi realizada a aplicação do ácido fosfórico. Em ambos os grupos, a cavidade foi restaurada com um único incremento da resina Bulk-fill e fotopolimerizado por 10 s (1.200 mW / cm 2; Bluephase N).

Após remoção do isolamento absoluto, foi feita a checagem da oclusão com papel carbono (Accufilm, Angelus Indústria de Produtos Odontológicos S/A), realizado ajuste oclusal (se necessário), acabamento e polimento (na mesma sessão) com Optrapol NG % (Ivoclar Vivadent, Schaan, Liechtenstein) em baixa rotação.

3.2.4 Calibração e cegamento

Para a etapa da calibração, um professor, especialista em Dentística, com mais de 15 anos de experiência clínica e de pesquisa, restaurou um dente de cada grupo (BER e BSE) para identificar todas as etapas restauradoras envolvidas em cada técnica. Em seguida, o operador realizou quatro restaurações de cada grupo (BER e BSE) sob a supervisão do professor. As discrepâncias dos protocolos restauradores foram identificadas e discutidas com o operador antes de iniciar o estudo. A partir desse momento, o operador foi considerado calibrado para executar os procedimentos restauradores. Um examinador realizou a avaliação em 3, 6 e 12 meses (Kappa = 0,84). Este examinador estava cego e não estava envolvido na realização de restaurações. Como o mesmo material restaurador foi empregado nos dois grupos, as

restaurações tinham aparência clínica semelhante e o examinador não conseguia diferenciar os grupos.

Os pacientes também estavam cegos para a atribuição do grupo, sendo um estudo randomizado, duplo-cego. Não foi possível cegar o operador devido às diferenças evidentes entre as técnicas. Todas as avaliações foram feitas no próprio ambiente escolar, onde as crianças estudavam, usando sondas, espelhos bucais e uma fonte de luz.

3.2.5 Avaliação clínica

Todos os parâmetros durante a avaliação foram registrados usando um formulário padronizado (ANEXO E) e, os critérios utilizados para avaliar as restaurações foram os da World Dental Federation (FDI) (31).

Apenas os itens da FDI que se enquadravam melhor neste estudo foram selecionados. Assim, as restaurações foram classificadas clinicamente como muito boas (VG), clinicamente boas (GO), clinicamente suficientes / satisfatórias (SS), clinicamente insatisfatórias (mas podendo ser reparadas-UN) e clinicamente ruins (necessidade de substituição-PO). Somente as restaurações classificadas como clinicamente ruins (PO) foram contabilizadas como insucesso clínico na análise. A sensibilidade pós-operatória foi avaliada antes do exame clínico, aplicando-se fluxo de ar com uma seringa, por 10 s com uma distância aproximada de 2 cm.

3.2.6 Análise Estatística

As análises estatísticas seguiram o protocolo por intenção de tratar de acordo com a sugestão do CONSORT (25). A concordância intraexaminador foi avaliada com o valor do coeficiente kappa.

A estatística descritiva incluiu o cálculo da taxa de sucesso dos materiais restauradores em 6 e 12 meses. As diferenças nas classificações dos dois grupos após os períodos avaliados foram testados com a análise de variância de medidas repetidas de Friedman por classificação ($\alpha = 0,05$) e as diferenças nas classificações de cada grupo na análise inicial e após 12 meses foram avaliadas usando o Teste de Wilcoxon ($\alpha = 0,05$).

3.3 Estudo 3 – Ensaio Clínico Randomizado para Avaliar a Longevidade de Restaurações ART Realizadas com Diferentes Cimentos de Ionômero de Vidro em Molares Decíduos: Acompanhamento de 2 Anos.

A metodologia detalhada deste estudo está descrita no ARTIGO 3 (pág. 86).

3.3.1 Desenho do estudo, seleção dos participantes e cegamento

Este estudo foi um ensaio clínico randomizado, duplo-cego (participante e avaliador), controlado, com uma taxa de alocação igual. Participaram 27 crianças de 6 a 9 anos, devidamente matriculadas em escolas municipais, aqueles cujos pais/responsáveis tivessem assinado o TCLE e que apresentassem no mínimo duas lesões de cárie cavitadas escore 5 ou 6 do ICDAS II (International Caries Detection and Assessment System) (26) em molares decíduos vitais.

Participantes não colaboradores (que se recusaram a participar dos exames clínicos) e portadores de necessidades especiais, foram excluídos; assim como pacientes que apresentaram molares decíduos com sinais e/ou sintomas relacionados a patologia pulpar (abscessos, fístulas, mobilidade patológica).

3.3.2 Cálculo amostral

Considerando que a taxa de sucesso do material Ketac Molar Easy Mix (3M ESPE, São Paulo, MN, EUA) foi relatada em aproximadamente 41% em restaurações oclusoproximais (32, 33) durante dois anos de acompanhamento, neste estudo, foi realizado um cálculo de superioridade para determinar uma taxa de sucesso de 78% do material Íon Z, sendo necessárias 64 restaurações (32 por grupo), com um nível de alfa de 5% e um poder estatístico de 90%. Um valor de 15% foi adicionado para contemplar possíveis perdas durante o acompanhamento, totalizando 74 restaurações. Todos os cálculos para determinar o tamanho da amostra foram realizados com um programa específico, disponível on-line (www.sealedenvelope.com).

3.3.3 Materiais empregados e intervenção clínica

Foram empregados dois cimentos de ionômero de vidro de alta viscosidade: Ketac Molar Easy Mix (3M ESPE, São Paulo, MN, EUA) e Íon Z (FGM Prod. Odont., Ltda, Joinville, SC, Brasil). As descrições dos materiais estão na Tabela 4.

Tabela 4 - Composição, lote e modo de aplicação dos materiais

MATERIAIS	FABRICANTE/ NÚMERO DE LOTE	COMPOSIÇÃO	MODO DE APLICAÇÃO
Cimento de ionômero de vidro Íon Z	FGM Prod. Odont., Ltda, Joinville, SC, Brasil/ 1633600528	Pó: - Ingredientes ativos: ionômero de vidro micronizado. - Ingredientes inativos: pigmento (dióxido de titânio e óxido de ferro), cargas (vidro de cálcio-alumínio-zinco-flúor-silicato). Líquido: - Ingredientes ativos: ácido policarboxílico e ácido tartárico. - Ingredientes inativos: água deionizada.	Aplicar ativamente ácido poliacrílico durante 10 s. Enxaguar e deixar a cavidade umedecida. Preparar a proporção em 1:1 e espatular durante 30 s. Inserir na cavidade comprimindo o material restaurador com o dedo enluvado e vaselinado contra as paredes do preparo.
Cimento de ionômero de vidro Ketac Molar Easymix	3M ESPE, St Paul, MN, EUA/ 1611211	Pó: Vidro de fluorsilicato de alumínio, eudragit, lantânio e cálcio. Líquido: Água, copolímero de ácido acrílico e ácido maleico, ácido tartárico e ácido benzóico	Aplicar ativamente ácido poliacrílico durante 10 s. Enxaguar e deixar a cavidade umedecida. Preparar a proporção em 1:1 e espatular durante 30 s. Inserir na cavidade comprimindo o material restaurador com o dedo enluvado e vaselinado contra as paredes do preparo.

* De acordo com instruções do fabricante

As restaurações foram realizadas seguindo o mesmo protocolo de avaliação de ART em estudo proposto por Amorim *et al.,* (29) no próprio ambiente escolar. Foi utilizada randomização por blocos de 4, sendo que um membro da equipe não envolvido no protocolo de pesquisa realizou o processo de randomização com tabelas geradas por um *software* estatístico disponível *online* (www.sealedenvelope.com) e preparou a identificação do grupo para cada dente dente (A=Ketac ou B= Íon Z). Essa identificação foi colocada em envelope opaco, selado e consecutivamente numerado.

A abertura do envelope somente ocorreu no dia do procedimento restaurador, após o preparo cavitário de cada dente, o que garantiu o sigilo de alocação. Em todos os casos, o dente mais posterior a ser restaurado recebeu a primeira restauração com o material discriminado no envelope, sempre seguindo a sequência descrita dos quadrantes (5,6,7 e 8), sendo que o dente cavitado em sequência recebeu o material descrito no segundo envelope. Todos os participantes receberam pelo menos duas restaurações, cada uma usando uma técnica adesiva e, todas as restaurações do

mesmo participante foram realizadas no mesmo dia e, as cavidades foram preparadas com instrumentos manuais e pela técnica de remoção seletiva da dentina cariada (22, 28).

Cada dente selecionado foi isolado com roletes de algodão e a superfície do dente foi limpa com uma bolinha de algodão umedecida. Logo após, o tecido infectado foi totalmente removido da junção esmalte-dentina e bordo cavo superficial, usando escavadores de dentina afiados (Kit ART 10 Instruments Set, GC Europe, Leuven, Bélgica) de tamanho compatível com a lesão, antes de prosseguir com a remoção seletiva de tecido cariado das paredes pulpar (oclusais) e axial (oclusoproximais), onde a dentina afetada foi deixada na cavidade. Concluída a remoção de tecido cariado, a cavidade foi lavada com uma bolinha de algodão embebida em água e seca com uma nova bolinha de algodão (Cremer, Blumenau, Brasil). Não foi utilizada anestesia local nem material de forramento ou base.

Para as restaurações oclusoproximais, uma matriz metálica (TDV, Pomerode, SC, Brasil) foi cortada, posicionada e estabilizada por uma cunha de madeira (TDV) para definir o contorno proximal da restauração.

Antes da inserção dos materiais, os dentes foram condicionados por 10 s com ácido poliacrílico, e em seguida lavados por 5 s e secos com bolinha de algodão. O cimento de ionômero de vidro foi manuseado de acordo com as instruções do fabricante e foi inserido na cavidade com auxílio de um instrumento manual de condensação (Kit ART 10 Instruments Set, GC Europe, Leuven, Bélgica). Pequenas vibrações foram feitas com uma espátula em um lado das margens da cavidade para melhor escoamento do CIV. Após completo preenchimento da cavidade, uma pressão com o dedo enluvado e vaselinado foi aplicada para impedir a formação de bolhas e melhorar a adaptação do cimento às paredes da cavidade. O excesso de material foi removido com um Hollenback. Não houve proteção adicional com nenhum material além da vaselina. A oclusão foi verificada com papel de articulação. Foi solicitado para que as crianças atendidas não mastigassem alimentos sólidos por 1 hora após a colocação da restauração.

3.3.4 Avaliação clínica e acompanhamento

Após a colocação da restauração, os materiais apresentaram aparência clínica semelhante. Portanto, um examinador calibrado, que não estava envolvido no tratamento restaurador e que estava cego em relação ao tipo de material, avaliou as restaurações em 3, 6, 12 e 24 meses.

A avaliação clínica foi realizada com sondas periodontais da OMS, espelhos bucais e uma fonte de luz, após escovação dentária e limpeza das superfícies com algodão embebido em água. A esfera da sonda OMS (diâmetro 0,5 mm) foi usada para medir o tamanho de qualquer defeito marginal e a quantidade de desgaste. Os critérios para avaliação estão descritos na Tabela 2 (29).

As restaurações classificadas como códigos 0, 1 e 2 foram consideradas bem-sucedidas, aquelas assinaladas com códigos 3, 4, 5, 6, 7 e 8 foram consideradas falhas, e as restaurações com o código 9 foram substituídas pela última pontuação obtida na avaliação anterior.

As crianças que apresentaram falha em alguma restauração, foram encaminhadas às clínicas especializadas da UEPG, tiveram os dentes novamente restaurados (porém essa segunda restauração não foi contabilizada nem avaliada novamente).

4 Artigo 1- Randomized Clinical Trial of Selective Caries Removal Restorations using a New Dual-Cure Resin-Based Material: Interim Results of 12-Month Follow-Up.

TITLE: RANDOMIZED CLINICAL TRIAL OF SELECTIVE CARIES REMOVAL RESTORATIONS USING A NEW DUAL-CURE RESIN-BASED MATERIAL: INTERIM RESULTS OF 12-MONTH FOLLOW-UP

STATUS: SUBMETIDO

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Randomized clinical trial of selective caries removal restorations using a new dual-cure resin-based material: interim results of 12-month follow-up

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ABSTRACT

Background: The clinical performance of new restorative materials must be evaluated before recommending its use in primary teeth.

Purpose: To evaluate the survival rates of in primary teeth restorations performed with a new dual-cure resin-based material in comparison with a resin modified glass ionomer cement after 12-month follow-up.

Methods: 107 restorations were placed in 27 children. Two materials were used: Vitremer and a dual-cure resin-based material used with (Cention N+Adh) and without (Cention N–Adh) adhesive. Two calibrated and blinded examiners evaluated the restorations at 3, 6, and 12-month. Restoration survival was analyzed using Kaplan-Meier survival curves and Log-rank test (α = 5%).

Results: The overall survival rates after 12-month were 86% for Vitremer, 76% for Cention N+Adh and 72% for Cention N–Adh. When considering the type of the cavities, the difference was significant only for occlusoproximal cavities when Cention N-Adh was used (HR=0.46; CI=0.26 - 0.81; p=0.008).

Conclusion: The new dual-cure resin-based material showed similar survival rates to a resin modified glass ionomer cement. However, the use of an adhesive system is indicated when Cention N is used for occlusoproximal restorations.

Keywords: Dental atraumatic restorative treatment, Deciduous tooth, Survival rate, resin-based material, Glass ionomer cements.

INTRODUCTION

When restoring a cavitated carious lesion, the dentist should aim the inactivation/control of the disease process, the preservation of dental hard tissues, the avoidance of initiating the cycle of restoration and the preservation of the tooth as long as possible (1).

These principles were defined at the International Caries Consensus Collaboration meeting in 2015, and they are based in a biological and minimally invasive approach for dental restorations. Therefore, when a restoration is needed, the preparation of the tooth should focus on selective removal of the carious dentin; and the restoration on the protection of pulp-dentine complex and good cavity seal (1, 2).

In agreement with these up-to-date concepts, one of the best choice of restorative treatment for deciduous teeth is the selective removal of carious dentin followed by an adhesive restoration of the cavity, as preconized by the Atraumatic Restorative Treatment protocol (ART), that comprises the removal of soft, completely demineralized carious tooth tissue, using hand instruments, followed by the restoration of the cavity with a high viscosity glass ionomer cement (HVGIC) (3). This approach also represents a patient friendly restorative procedure (4) and it was shown similar longevity rates when compared to “conventional” restoration procedures in deciduous teeth (5-8).

Notwithstanding, the longevity rates for multiple surfaces restorations is still lower than single surface ones (9, 10). This finding may be related to the fact that high viscosity glass ionomer cements shows some features that still need improvement. Glass ionomer cement (GIC) suffers from longer setting times, so the maximal mechanical properties of this material are not achieved immediately after the placement of the restoration. In addition, GICs can be difficult to handle, leading to cervical gaps due to inadequate adaptation to the cavity walls (11).

Alternative materials have been launched in the market trying to overcome the problems of GIC. An interesting option to HVGIC is Cention N, which is a new category of filling material classified as a subgroup of the composite material class (alkasite composites). It was developed as an alternative to glass ionomer cements and amalgam (12). It is a power-liquid dual-cure resin-based material that, after

manipulation exhibits a paste-like consistency, which facilitates the insertion into the cavities and allows its use as a bulk material (13). According to the manufacturer's descriptions, Cention N contains alkaline fillers that release hydroxide, fluoride and calcium ions to regulate the pH value during acid attacks (13). Due to the higher amount of filler, this product showed higher mechanical properties than GIC (14, 15).

This new material was recently evaluated in permanent teeth as conventional restorative material (16). However, to the best of our knowledge, the clinical performance of Cention N restorations with selective caries removal in primary teeth has not been reported in the literature yet. Thus, the aim of this clinical study was to compare the survival rate of occlusal and occlusoproximal restorations after selective caries removal in in primary teeth, performed with Cention N associated or not to adhesive system and a resin modified glass ionomer cement after 12 months of clinical service. The null hypothesis tested was that no difference would be detected in the survival rates of restorations performed with the different materials tested in the 12 month follow-up period.

MATERIAL AND METHODS

This article has been prepared according to the protocol established by the Consolidated Standards of Reporting Trials statement – CONSORT (17).

Ethical approval

The local Ethics Committee on Investigations Involving Human Subjects reviewed and approved the protocol and issued a consent form for this study (protocol 2.064.952). Written consents were obtained from parents/guardians of the participating patients

Protocol registration

This clinical trial was registered in REBEC (www.ensaiosclinicos.gov.br) clinical registry under protocol number U1111-1198-3193. All participants were informed about the nature and objectives of the study.

Trial design, settings and allocations of data collection

This was a double-blind, superiority, split-mouth randomized clinical trial with an

equal allocation ratio.

Recruitment

The children included in the clinical trial were evaluated in municipal schools in the local city and, therefore, the child was chosen by convenience sampling (according to eligibility criteria). No type of advertisement was done in any type of midia.

Eligibility criteria

In order to be included in the trial, participants should be between 4 to 9 years old, without systemic diseases. They should present at least three primary posterior teeth with a Class I and/or II carious lesions in vital teeth. Cavities should be scored 5 or 6 in the ICDAS system (18), since an open access to carious dentin should be present. All cavity preparations were done by hand instruments, according to the ART guidelines (19).

Participants were excluded if their teeth were fistulated or with spontaneous pain. Children who do not accept the oral examination, do not attend the scheduled restoration day, and those whose parents / guardians do not sign the Informed Consent Form were also excluded. In such circumstances, parents were advised to seek dental care in the National Health System.

Sample size calculation

The sample size calculation was performed considering the 2-year success rate of resin-modified glass ionomer cement (Vitremer) of approximately 55% (20). Thus, a minimum sample size of 33 restorations per group was required with a test power of 80% to detect a significant difference at 5% level. The total number of restorations was 107, as 8% of the initial sample calculation was added to compensate for possible losses.

Random sequence generation and allocation concealment

The randomization was done on an intra-individual basis so that each subject ended up with three restorations, each one resulting from one of all possible restorative procedures. We used blocked randomization (block size of 3) with an equal allocation

ratio to form the allocation list for the three comparison groups. These randomization schemes were performed using a software available at http://www.sealedenvelope.com.

A staff member not involved in the research protocol performed the randomization process with computer-generated tables. Details of the allocated groups were recorded on cards contained in sequentially numbered, opaque, sealed envelopes. Opening the envelope only on the day of the restorative procedure guaranteed the concealment of the random sequence. In all cases, the tooth followed the quadrant sequence (5,6,7,8) received the treatment described first, while the tooth with the next number in sequence received the treatment mentioned second, with placement continuing in a similar manner until the third tooth.

Study intervention

Two different materials were used: Vitremer (3M Oral Care, St. Paul, MN, USA) and Cention N (Ivoclar Vivadent, Schaan, Liechtenstein). The materials specifications are summarized in Table 1. Cention N was tested using two different protocols: without adhesive (Cention N - Adh) and with adhesive application (Cention N + Adh) before restoration with Cention N.

All restorations were carried out at school environment, in a classroom adapted for this purpose. Children were positioned in mattresses on the tables and the restorations were done following ART guidelines (19). All procedures were performed by one experienced pediatric dentist assisted by a dental student. The envelopes containing the computerized generated random sequence were opened immediately before the beginning of the restorative procedure for each tooth.

All restorations were done without local anesthesia and the field was isolated with cotton rolls. The cavity preparation followed the sequence described below: (1) tooth surface was cleaned with a wet cotton pellet to remove debris and plaque to improve the visibility of the dental cavity; (2) the infected dentin was removed from the surrounding walls and the enamel-dentin junction using sharp spoon excavators (Kit ART 10 Instruments Set, GC Europe, Leuven, Belgium) of appropriate size before proceeding to the cavity floor. To avoid pulpal exposure in deep cavities, the remaining dentin was left untouched. The cavity was then cleaned with a small cotton pellet

soaked in water and dried with a dry cotton pellet (Cremer, Blumenau, SC, Brazil). No liner or base were used. For all Class II cavities, after the cavity preparation, a metallic matrix (TDV, Pomerode, SC, Brazil) was cut, burnished, positioned and stabilized by a wooden wedge (TDV) to define the proximal contour of the restoration.

For the Vitremer (3M Oral Care) restorations, a Vitremer Primer was applied following the manufacturer's instructions and light-cured for 20 s with a LED device (Bluephase N, Ivoclar Vivadent, Schaan, Liechtenstein) with a intensity 1.200 mW/cm2. One trained operator handled mixed Vitremer powder and liquid on a glass plate with a plastic spatula according to the manufacturer's instructions, and inserted into the cavity pressing with resin spatula, overfilled and pressed down using a petroleum jelly-coated finger (21). Excess material was removed with a Hollenback carver and light-cured for 40 s with the same LED device (1.200 mW/cm2; Bluephase N, Ivoclar Vivadent). No finishing gloss was applied in the surface of the material.

For the Cention N restorations with adhesive (Cention N + Adh), one coat of the adhesive Tetric N-Bond Universal in the self-etch mode (Ivoclar Vivadent, Schaan, Liechtenstein) was applied scrubbing during 20 s in the enamel and dentin. After this time, a gently air-dry was applied for 5 s and immediately light-cured for 10 s (1.200 mW/cm2; Bluephase N, Ivoclar Vivadent). After this, Cention N powder and liquid were handled mixed according to the manufacturer's instructions and inserted into the cavity in the same way as previously described. After excess remotion, the restorations were light-cured for 40 s (1.200 mW/cm2; Bluephase N, Ivoclar Vivadent).

For the Cention N restorations without adhesive (Cention N - Adh), after caries removal, the Cention N was mixed and inserted according to the manufacturer's instructions. After excess remotion, the restorations were light-cured for 40 s (1.200 mW/cm2; Bluephase N, Ivoclar Vivadent). For all Groups, the occlusion was checked with articulating paper and the restorations were polished with OptraPol Next Generation (Ivoclar Vivadent, Schaan, Liechtenstein).

Blinding

The examiners were not involved with the restoration procedures and therefore blinded to the group assignment, performed the clinical evaluation. Patient were also blinded to group assignment in a double-blind randomized clinical trial design.

Clinical evaluation

After restoration placement, the materials presented similar clinical appearance. Therefore, two calibrated examiners, who were not involved in the placement of restorations and who were also blinded to the type of material, evaluated the restorations at three, six and 12 months. Debris and plaque from the tooth surface was removed before evaluation using a wet cotton pellet.

Clinical evaluation was performed using OMS periodontal probes, plane front-surface mirrors and a light source. The ball point of the OMS probe (diameter 0.5mm) was used to measure the size of any marginal defect and the amount of wear. The criteria used to evaluate the ART restorations were those of a previous study (22). Restorations scored as codes 0, 1 and 2 were considered successful, those scored as codes 3, 4, 5, 6, 7 and 8 were considered failures, and the restorations scored code 9 (unable diagnostic) were replaced with the last score obtained in the previous evaluation. Both examiners evaluated all the restorations once and independently. An intra and inter-examiner kappa test was performed during the clinical evaluations. However, if any disagreements occur during the evaluations, they had to reach a consensus before the participant was dismissed.

The 12-month evaluation period is an interim analysis; the clinical trial protocol intends a 3-year follow-up.

Statistical analysis

The statistical analyses followed the intention-to-treat protocol according to the CONSORT suggestion (17). Inter-examiner agreement was assessed with kappa coefficient values. Descriptive statistics included the computation of the success rate of the restorative materials at both 3, 6 and 12 months.

In order to evaluate the intensity of the association between the success rates of the different restorative materials used, the hazard ratio (HR) was calculated, considering an overall analysis and the different types of restorations (occlusal and occlusalproximal); a 95% confidence interval was stipulated.

The Kaplan-Meier survival curves were obtained considering the different materials, types of restorations and the overall curve. Log-Rank (Mantel-Cox) test was

used to analyze the differences between the survival curves: (1) for the different materials, (2) for different types of restoration, (3) for different materials in the same type of restoration and (4) for different types of restoration using the same material. It was applied in uncensored and censored data (restorations scored as code 9). A difference was considered statistically significant if $P<0.05$. All the analysis were performed using IBM SPSS Statistics for Windows, Version 20.0 (Armonk, NY: IBM Corp).

Results

The experimental protocols were implemented exactly as planned, and no modifications were performed. A total of 433 children were examined and 27 children with a mean age of six plus or minus two years old (range 4 to 9) constituted the study sample (Table 2). Reasons for exclusion can be seen in Figure 1. One-hundred and seven restorations were inserted, 35 for Vitremer, 36 for Cention N + Adh and 36 for Cention N – Adh (Table 2). Three children received only two restorations, 20 children received four restorations and 4 children received six restorations. Kappa values ranged from 0.82 to 0.87, respectively (data not shown).

The number of failure restorations according to each score are depicted on the Table 3. A higher number of the failures occurred in the occlusalproximal cavities when compared with occlusal cavities in all periods of evaluation. For the occlusal restorations, It can see that neither Vitremer nor Cention N + Adh had failure at 3 months and 6 months (Table 3).

The survival curves, with censored and uncensored data, are presented in Figures 2, 3 and 4. Log-rank Mantel-Cox test did not indicate difference between the materials in the overall analysis ($p=0.052$) (Figure 2) or when occlusal restorations were considered (Figure 3) ($p=0.315$). Notwithstanding, significant differences were detected between restorative materials in occlusoproximal restorations ($p=0.005$) (Figure 4). There was no difference between censored and uncensored data.

The Hazard ratio (HR) was calculated using Vitremer as the reference material as we investigated the intensity of the association between the restorative material and the success of the restorations (Table 4). In an overall analysis, Cention N - Adh had a poorer performance among all the tested materials (HR=0.54; CI= 0.31 - 0.95; $p=0.031$). When considering the type of the cavities, the difference was significant only

for occlusoproximal cavities when Cention N - Adh was used (HR=0.46; CI=0.26 - 0.81; p=0.008).

No differences were detected for the risk of success when Vitremer was used as restorative material for occlusal or occlusoproximal restorations (HR=3.72; CI=0.49 - 27.89; p=0.201). Comparing the type of restoration, the chance of success increased 3.05 times in occlusal restorations with Cention N – Adh comparing with occlusoproximal restorations (CI 95%=1.17 - 7.93; p=0.022) and 13.46 times in occlusal restorations with Cention N + Adh comparing with occlusoproximal restorations (CI95%=1.84 - 98.26; p=0.010).

Discussion

This clinical trial showed that restorations in deciduous teeth using a new resin based restorative material showed similar longevity rates as the restorations made with the commonly used resin modified glass ionomer cement. However, the use of an adhesive system is indicated when Cention N is used for restoring occlusoproximal cavities.

Our study protocol intended an overall analysis of the restorations, irrespective of the number of dental surfaces involved. This is the scenario of the paediatric dentist's clinical practice, where the need of restoration of different cavities sizes, sometimes in the same patient, is a common finding on a daily basis. This analysis is presented in Figure 2 and Table 4. Notwithstanding, the literature shows that there is a remarkable difference in the longevity rates of occlusal and oclusoproximal cavities (23, 24), which instigate the authors to perform additional statistical analysis based on this criterion. Indeed, this allowed the observation that the survival rates of occlusal restorations were not influenced by the restorative material, whereas occlusoproximal restorations exhibit poorer performances, particularly when Cention N was used without adhesive system.

Considering that it is expected that materials with a resin component (like compomers and resin-modified glass-ionomers) to have similar survival rates in deciduous teeth (25), in the present study, it was selected the most used resin modified glass ionomer cement (26, 27) in randomized clinical trials that evaluated deciduous teeth restorations (Vitremer - 3M Oral Care, St Paul, MN, USA) 29 as a control group to compare with Cention N.

The strategy behind this clinical trial was to associate the atraumatic aspects of the Atraumatic Restorative Treatment (no need of local anesthesia, absolute isolation or rotatory instruments, the possibility of placing restorations outside of the dental office) with the use of light-cured/bulk restorative materials (that allows a better time management for the dentist during the restorative procedure). The restorations were also performed in a minimally invasive approach with selective removal of carious dentin. Therefore, this is probably one of the best situations for treating pediatric patients nowadays, that takes into account the biological management of carious lesions 1 and contributes to the behavior management of the children reducing the treatment-induced anxiety (28).

The literature had already shown the lack of superiority between the most commonly used restorative materials in Pediatric Dentistry when complete caries removal protocol was used (compomer, resin-modified glass-ionomer, amalgam and composite resin) (29). This is also true for restorations with partial caries removal, as in the ART protocol, that showed similar longevity rates when comparing HVGIC ART restorations to conventional restorations with different restorative materials (22, 5). Consequently, the development of a new restorative material demands the implementation of randomized clinical trials to establish the real place of Cention N in this scenario.

Unfortunately, there is no published papers until now that addressed the interaction between Cention N and deciduous affected dentin. Nevertheless, the manufacturer states that Cention N can be used with or without adhesive system, so we decided to investigate both protocols. When Cention N is used without adhesive system, it is explicitly described in the Cention N recommendations that “retentive preparation should be ensured” (12). However, we followed the concepts of minimal intervention and no extra retention was performed, which probably contribute to the higher failures rate of Cention N restorations without adhesive systems, that occurred even in occlusal cavities (3 restorations were lost after 12 months follow-up).

It is recognized that, when the resultant preparation is shallow with divergent walls, retention in composite resin restorations is largely determined by the ability of adhesives to bond to the cavity walls (30). This is the main reason to lower success rate of Cention N – Adh during the follow-up period of the present study.

This is the main reason to apply Cention N associated with an universal adhesive, that are essentially one-step self-etch adhesives that may be associated with phosphoric acid etching (31, 32). This versatile bonding philosophy allows the clinician to apply the simplest option of each strategy, mainly because there is not difference between them (33, 34). As simplification of the bonding procedure is a clinical goal, mainly in the primary teeth, the universal adhesive was applied in the self-etch mode.

This was confirmed in a recently published randomized clinical trial which showed that universal adhesives perform equally as etch-and-rinse strategy in deciduous teeth after partial caries removal, with good survival rates of composite resin restorations after 12 months of follow-up (35). In the case of Vitremer, the manufacturer recommend the application of a primer previously to the final restoration. The Vitremer primer application form a submicrohibrid layer that is similar to the one produced with self-etch adhesives (36) and may contribute to the longevity of the adhesive interface (37) and consequently, the survival rate of the restorations.

However, there are a significant number of the failure restorations when Vitremer and Cention N + Adh were evaluated in the present study and several factors could be responsible for this issue. Bonding to caries-affected dentin is a clinical challenge, mainly because several chemical, biological and physical modifications can occur as result of the caries process, leading to a clinical distinct situation, known by caries-affected dentin (38, 39). Usually, lower bond strength is found to caries-affected dentin when compared with bonding procedures to sound dentin (40-42), due to a poorly hybridized hybrid layer (40). The same phenomenon occurs when Vitremer was applied in caries-affected dentin (37, 43).

Of course, in a selective caries removal concept, this pattern of bonding to dentin may be even worse. A recent review regarding management of caries indicated that carious dentine can be left in the cavity to preserve pulpal health, but it should be limited to areas over the dental pulp; it is especially important that the periphery of the cavity should support the restoration sufficiently and allow a tight seal (1). In this study, although all the treatments were done in a school environment and with cotton wool rolls isolation, this important step in the cavity preparation was carefully accomplished in order to achieved the best restoration seal possible in a field condition.

Another problem is the possibility of saliva contamination. It is known that the saliva contamination jeopardize the resin-dentin bonding strength to self-etch adhesive

(44-46). A closer view regarding the influence on saliva contamination in the survival rate of the restorations shows conflicting results. Regarding survival rates of occlusal-proximal ART restorations after two years, there are results showing no difference between cotton wool rolls or rubber dam isolation (47) and better rates with rubber dam use (48). A recent systematic review about survival rates of conventional restorations in primary teeth pointed out that restorations placed using rubber dam presented better survival rates (49). The saliva control with cotton wool rolls can be very challenging when the dentist is dealing with very young patients with difficult behavior. Therefore, it is clear that future clinical trials must be done to investigate the performance of Cention N when the restorations are placed under rubber dam isolation.

However, the most important factor is that, the majority of the failures were concentrated in occlusal-proximal cavities and the main cause of failure, regardless the study group, was the loss of the restoration. Multi-surface fillings have been identified as risk factors for failures in young permanent molars after partial caries removal (50) and also in deciduous teeth restored with total 49 or partial caries removal in the ART approach (9, 10, 51).

It would be expected that Cention N could overcome this flaw, since the manufacturer states that it presents higher mechanical properties compared to conventional (Fuji II) and several HVGICs (12). Also, we opted to use Cention N in dual-cure mode, as light-curing the material resulted in higher Vickers hardness (12).

However, these expectations were not fulfilled and, to a certain point, patient related reasons may be responsible for this. Although the patients enrolled in this study received oral hygiene instructions at the beginning of the trial and again at each follow-up appointment, we selected patients with at least three carious cavities in posterior teeth (ICDAS 5 and 6), which is an indicative of an active caries profile. The literature shows that high level of caries prevalence may influence the posterior restoration survival in deciduous (52, 53) and permanent teeth (50) of children. Therefore, this could had influenced this clinical trial results, as the presence of a cariogenic biofilm, that acts both on tooth and restorative material surfaces, may impair restorations survival (53).

Regarding this issue, Vitremer has the property of fluoride release comparable with conventional GIC. Also, this material could be re-charged when a topical fluoride application is performed (54). Abudawood, Donly (2017) 55 showed that Cention N

has the same fluoride release pattern than Vitremer, as well as Cention N also could be re-charged when in contact with fluoride.

However, regarding the fluoride release, there are some controversial results in the literature (55, 56). Cention N has an advantage over Vitremer. As pointed in the introduction section, Cention N contains alkaline fillers that release hydroxide, fluoride and calcium ions to regulate the pH value during acid attacks (13) and according to manufacturer's descriptions, these ions will be able to prevent tooth demineralization (12). Unfortunately, this was not measured in the present clinical trials and future in situ studies need to be done to evaluate the capacity of Cention N to prevent the appearance of new caries lesions around restorations.

It worth to mention that, during this 12 month follow-up period, we did not detect any pulp pathology related to pain, facial swelling or sinus tract, which confirms the success of selective caries removal in deciduous teeth as stated by the dental literature (57, 58) and the absence of negative pulp reactions to all restorative materials evaluated.

Conclusion

All evaluated materials are suitable for restoring occlusal cavities after selective caries removal. However, Cention N need to be used with adhesive in occlusoproximal cavities, due to a poorer performance of the Cention N without adhesive group after 12 months of follow-up.

Figure and Tables legends

Figure 1 - Flow chart of the study.

Figure 2 - Kaplan-Meier survival estimates among the materials for restorations in primary teeth (log-rank p = 0.052).

Figure 3 - Kaplan-Meier survival estimates among the materials for occlusal restorations in primary teeth (log-rank p = 0.315).

Figure 4 - Kaplan-Meier survival estimates among the materials for occlusalproximal restorations in primary teeth (log-rank p = 0.005).

Table 1 - Restorative materials: composition and application mode.

Table 2 - Characteristics of the children and features of the restored cavities for both study groups.

Table 3 - Scores of failure plus score 9 (unable to diagnose) according to the restorations size and evaluation period for each treatment at 3, 6 and 12 months of clinical evaluation

Table 4 - Cox regression analysis of success in occlusal and occlusoproximal restorations associated with restorative materials tested

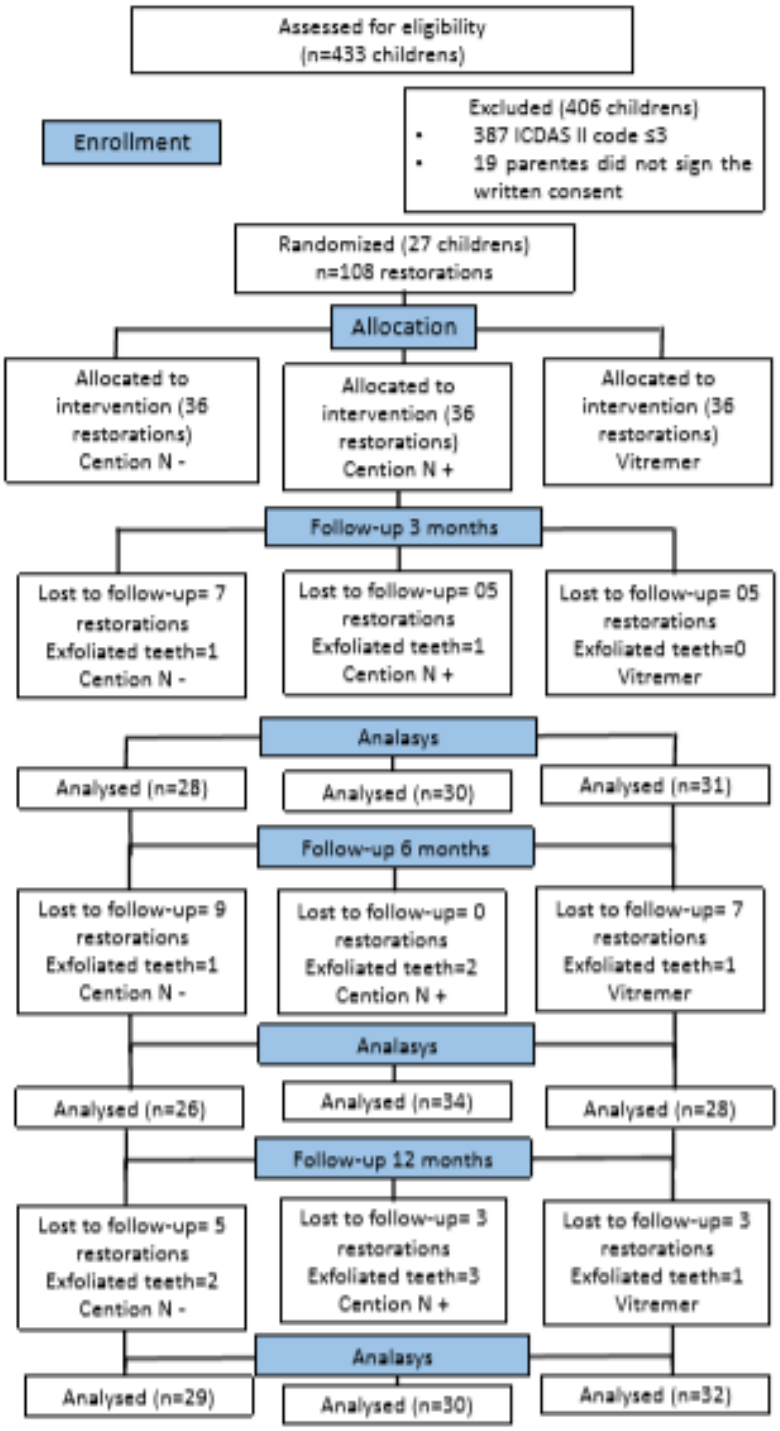

Figure 1 – Flow chart of the study.

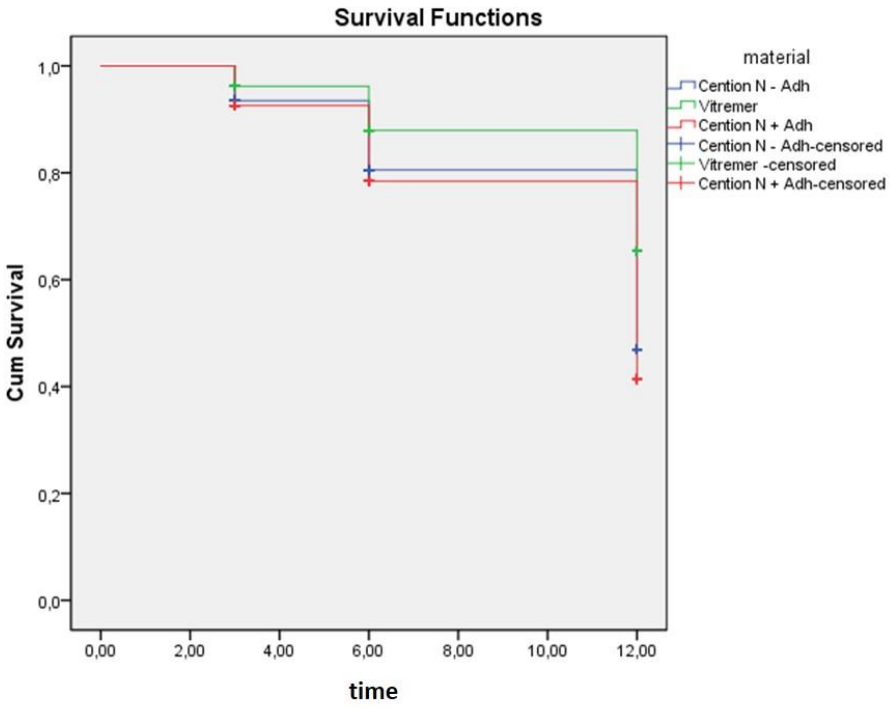

Figure 2 - Kaplan-Meier survival estimates among the materials for restorations in primary teeth (log-rank p = 0.052).

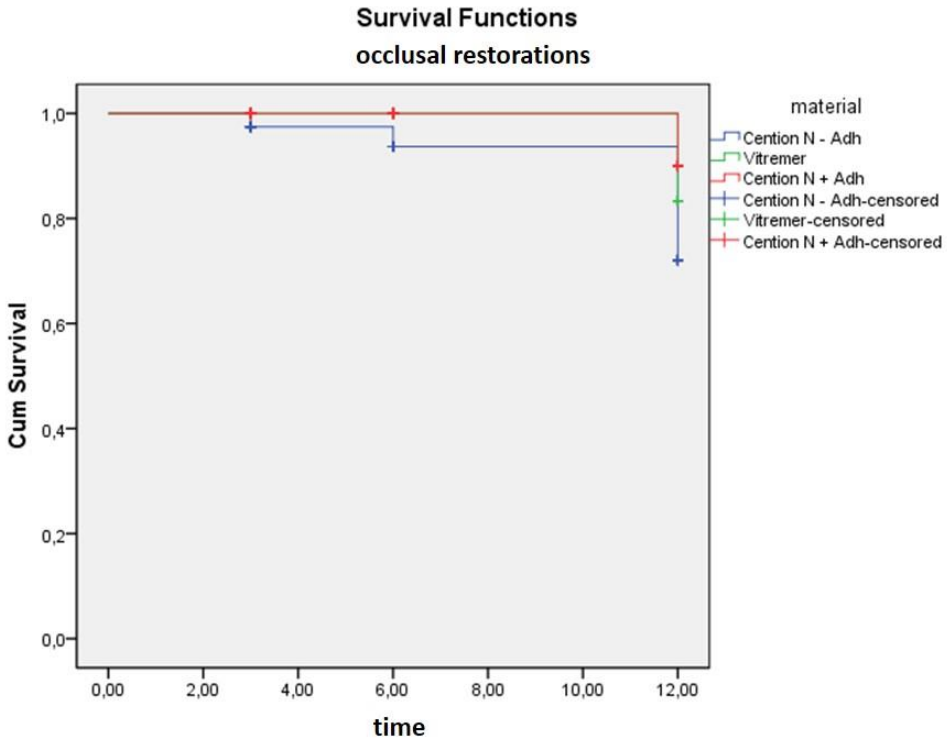

Figure 3 - Kaplan-Meier survival estimates among the materials for occlusal restorations in primary teeth (log-rank p = 0.315).

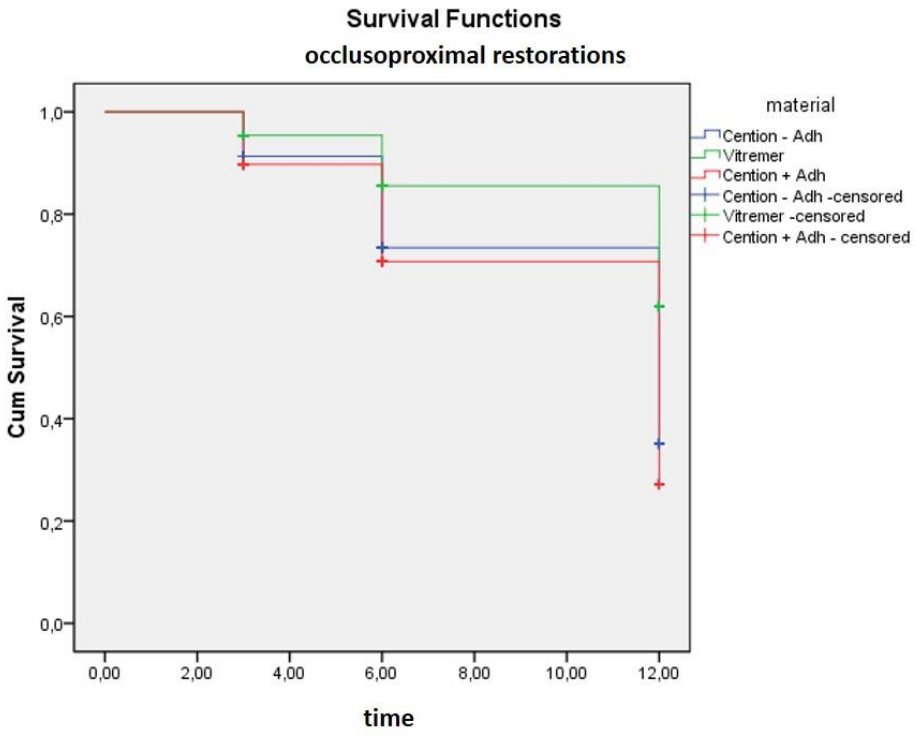

Figure 4 - Kaplan-Meier survival estimates among the materials for occlusalproximal restorations in primary teeth (log-rank p = 0.005).

Table 1 – Restorative materials: composition and application mode

Restorative materials (batch number)	**Composition (*)**	**Application Mode (*)**		
		Adhesive/Primer Application mode		Restorative Material
Vitremer ***(3M Oral Care/***	1. Vitremer primer: Vitrebond copolymer, 2-hydroxyethyl methacrylate;, ethanol and photoinitiators. 2. Vitremer Powder: fluoroaluminosilicate glass and redox system 3. Vitremer Liquid: aqueous solution of a modified polyalkenoic acid, 2-hydroxyethyl methacrylate; and photoinitiators	Yes (**Vitremer)**	1. Apply primer to enamel and dentin and scrub for 30 s 2. Gently air dry for 10 s 3. Light-cure for 20 s at 1200 mW/cm^2	1. Dispense 1 scoop of powder and 1 drop of liquid next to each other on a mixing pad plate. 2. Mix the powder and the liquid for 45 s). 3. Apply the material to the cavity, condense it thoroughly and then sculpt the occlusal anatomy. 4. Light-cure for 10 s at 1200 mW/cm^2
Tetric N-bond Universal* (S54248) *and Cention N (Ivoclar Vivadent, Schaan, Liechnstein)	1. Tetric N-bond Universal: 2-hydroxyethyl methacrylate, methacryloyloxydecyl dihydrogen phosphate, bisphenol glycidyl methacrylate, methacrylated carboxylic acid polymer, decandiol dimethadrylate, ethanol, water, highly dispersed silicon dioxide and camphorquinone 2. Cention N Liquid: 4 Urethane dimethacrylate, Tricyclodecan-dimethanol dimethacrylate, Tetramethyl-xylylen-diurethane dimethacrylate and Polyethylene glycol 400 dimethacrylate and initiators. 3. Cention N Powder: barium aluminium silicate glass filler, ytterbium trifluoride, an Isofiller, a calcium barium aluminium fluorosilicate glass filler and a calcium fluorosilicate (alkaline) glass filler, with a particle size of between 0.1 µm	No (**Cention N - Adh)**	--	1. Dispense 1 scoop of powder and 1 drop of liquid next to each other on a mixing pad plate. 2. Mix the powder and the liquid on the mixing pad using a plastic spatula until a homogeneous, creamy consistency is achieved (45 – 60 s). 3. Apply the material to the cavity, condense it thoroughly and then sculpt the occlusal anatomy. 4. Light-cure for 10 s at 1200 mW/cm^2
		Yes (**Cention N - Adh)**	1. Scrub one coat of adhesive for 20 s 2. Gently air thin for 5 s 3. Light-cure for 10 s at 1200 mW/cm^2	

	and 35 µm, initiators and pigments			

Table 2 - Characteristics of the children and features of the restored cavities for both study groups.

Characteristics of research subjects	**Number of children**		
Gender distribution			
Male	17		
Female	10		
Age distribution (years)			
4 to 6	13		
7 to 9	14		
Characteristics of lesions	**Number of lesions (n=107)**		
	Vitremer	**Cention N - Adh**	**Cention N + Adh**
Type of cavity			
Occlusal	06	13	10
Occlusalproximal	29	23	26
Tooth distribution			
First Primary molar	13	13	18
Second Primary molar	22	23	18
Arch distribution			
Maxillary	16	20	13
Mandibular	19	16	23

Table 3 - Scores of failure plus score 9 (unable to diagnose) according to the restorations size and evaluation period for each treatment at 3, 6 and 12 months of clinical evaluation

		Scores according to the restorations size*									
		Occlusal					**Occlusoproximal**				
Period	**Treatment**	**3**	**6**	**7**	**8**	**9**	**3**	**6**	**7**	**8**	**9**
3-month	Cention N-Adh	--	01	--	--	01	--	05	--	01	06
	Cention N+Adh	--	--	--	--	01	01	04	02	01	02
	Vitremer	--	--	--	--	01	--	02	--	--	05
6-month	Cention N-Adh	--	01	--	--	02	01	05	--	01	07
	Cention N+Adh	--	--	--	--	01	--	06	03	02	05
	Vitremer	--	--	--	--	03	01	04	--	01	03
12-month	Cention N-Adh	--	03	--	--	01	01	09	--	--	04
	Cention N+Adh	--	--	--		01 03	--	11	03	02	02
	Vitremer	--	01	--	--	02	01	05	--	01	01

(*) Only scores 3, 6 7 8 and 9 were observed along of this clinical evaluation

Table 4 - Cox regression analysis of success in occlusal and occlusoproximal restorations associated with restorative materials tested

Variable	Comparisions	Sucess		HR (IC 95%)	p-value
		N	%		
Occlusal	Vitremer	17	94,4%	Reference	
	Cention N -adh	34	87,2%	1,67 (0,10 – 26,65)	0,718
	Cention N +adh	29	96,7%	3,85 (0,45 – 32,92)	0,219
Occlusoproximal	Vitremer	69	79,3%	Reference	
	Cention N –adh	42	60,9%	0,46 (0,26 – 0,81)	0,008
	Cention N +adh	43	55,1%	0,87 (0,53 – 1,44)	0,593
Vitremer	Occlusal	17	94,4%	3,72 (0,49 – 27,89)	0,201
	Occlusoproximal	69	79,3%		
Cention N -adh	Occlusal	34	87,2%	3,05 (1,17 – 7,93)	0,022
	Occlusoproximal	42	60,9%		
Cention N +adh	Occlusal	29	96,7%	13,46 (1,84 – 98,26)	0,010
	Occlusoproximal	43	55,1%		

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5 Artigo 2- A Double-Blind Randomized Clinical Trial of Bulk-Fill Restorations Performance with an Universal Adhesive System in he Etch-And-Rinse and Self-Etch Strategy:One-Year Follow-Up.

TÍTULO: A DOUBLE-BLIND RANDOMIZED CLINICAL TRIAL OF BULK-FILL RESTORATIONS PERFORMED WITH AN UNIVERSAL ADHESIVE SYSTEM IN THE ETCH-AND-RINSE AND SELF-ETCH STRATEGY: ONE-YEAR FOLLOW-UP

STATUS: FINALIZADO

A double-blind randomized clinical trial of bulk-fill restorations performed with an universal adhesive system in the etch-and-rinse and self-etch strategy: one-year follow-up

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ABSTRACT

Objective: To evaluate the survival of bulk fill restorations in primary molars treated by Minimal Intervention with an universal adhesive system in the etch-and-rinse technique and, in the self-etch strategy after 12-month of follow-up.

Design: This was a randomized, double-blind, superiority, parallel clinical trial with a different allocation ratio. 27 children received 89 restorations made with Tetric N-Ceram Bulk fill in the etch-and-rinse and self-etch strategy with Tetric N-Bond Universal adhesive (Ivoclar Vivadent, Schaan, Liechtenstein). All treatments were performed by one pediatric dentist and the manufacturer's instructions of the materials were followed. One calibrated and blinded examinor evaluated the restorations at 6 and 12-months. Restoration survival was analyzed using Friedman and Wilcoxon test (α = 5%).

Results: The overall survival rates after 12-month for occlusoproximal restorations were 41.8% (self-etch=42.6%; etch-and-rinse=41%) and 86.75% (self-etch=84.6%; etch-and-rinse=88.9%) for occlusal restorations. There was no statistical difference between the groups tested at 6-month and 12-month recall ($p > 0,05$). When class I vs class II were compared, there was significant difference ($p < 0,05$), regardless the period of evaluation in the both groups.

Conclusion: After 12-month follow-up period, the self-etch strategy showed similar survival in the restorations comparing to the etch-and-rinse technique with bulk fill composite.

Keywords: Deciduous tooth, clinical trial, survival analysis, bulk-fill resin, selective caries removal, dental caries.

Introduction

In pediatric dental practice, the resolution of a dental problem in the shortest possible time is much wanted by the pediatric dentists, in order to minimize the child's discomfort, stress and anxiety frequently related to dental treatment.

In face of that, the professional that treat children are often in search for quicker restorative procedures and less technique-sensitive protocols. This can be achieved with the use of materials that require less application steps, with reduced risk of contamination. This is one reason for the selective caries removal is replacing the invasive complete caries removal protocol (1). This modification reduced the incidence of pulpal exposure during removal of carious tissue (2), and the potential side effects of more invasive treatments (3). In addition, minimally invasive therapies present a high survival rate, they are less prone to pulp involvement over the years (4), and reduce the costs of treatment compared to conventional invasive treatment (5).

When the procedure is a dental restoration, a reduction in the clinical time can be achieved by using bulk fill composite resins and universal adhesives quick clinical these should have adequate longevity during the life cycle of the deciduous tooth. It is essencial checking the technique and material that best suit the patient's condition (1).

With the purpose of optimize time and easy of placement, "bulk-fill" composites have been introduced into the dental market for posterior restorations. The manufacturers of this class of material has introduced changes to allow it to cure at a depth up to 4 mm (6-10) (11, 12). This higher depth of cure was achieved by changes in the size, type and content of filler particles, by changes in the resin translucency (8, 13) and in the type of initiatior-activactor system. This material has shrinkage and microleakage values lower than or closer to the composite resins for incremental placement (7, 14, 15).

As important as the choosing the less invasive caries removal technique and the best restorative material is the type of adhesive strategy to be used with composite resins. Modern adhesive systems can employ the etch-and-rinse and self-etch protocols (16). The first approach use phosphoric acid for substrate conditioning before adhesive application. On the other hand, the self-etch adhesives (17) do not require multiple steps for bonding. The application of an acidic adhesive in a single step allows

for simultaneous conditioning and monomer infiltration, reducing the lack of discrepancy between etching and resin infiltration into the dentin (18).

Nowadays there are multimode, universal adhesive in the dental market which are the latest generation of adhesives on the market. These adhesives can be used either in the self-etch or etch-and-rinse modes. In pediatric dentistry, where the time spent by procedures is very important, the use of self-etch approach is an interesting protocol (19).

Considering the lack of studies with the bulk fill composites and universal adhesives in primary teeth (15, 20), mainly with different bonding protocols we conduced the present randomized clinical trial. The aims of this study were to evaluate the effectiveness of single and multiple-surfaces restorations (Black class I or II) using bulk fill composite restorations in primary teeth with or without etching of the cavity before application of a universal adhesive system using selective caries removal.

Material and methods

Protocol registration

The experimental design followed the CONSORT (Consolidated Standards of Reporting Trials statement) (21). This clinical trial was registered in REBEC (www.ensaiosclinicos.gov.br) clinical registry under protocol number RBR-98r97j.

Ethical approval

The local Ethics Committee on Investigations Involving Human Subjects reviewed and approved the protocol and consent form for this study (protocol 1.795.655).

Trial design, settings and locations of data collection

This study was designed as a double-blind randomized controlled trial, with a different allocation ratio. The recruitment started at May 2, 2017 and all procedures in the selected volunteers were performed from August 5, 2017, to August 23, 2017.

Recruitment

The children included in the clinical trial were those recruited from one public school (choiced by convenience) in the city of Ponta Grossa, PR, Brazil.

Eligibility criteria

To be eligible, participants had to be between 6 to 9 years old, without systemic diseases and present at least two active carious lesion (class I or II of Black) in vital molars.

Exclusion criteria

Children who refused to participate in the screening examination and those whose parents/guardians did not sign the Informed Consent Form was not included in the trial. Children with very deep and large cavities (cusp loss) and high risk of pulpal exposure during excavation were not included. Additionally, it was excluded participants with complaint of spontaneous pain, edema and/or fistula. Children with these conditions were referred to specialized services.

Sample size calculation

The sample size was calculated based on the previous sample size calculations performed in similarly designed studies of posterior restorations (22). Based on previous investigations, a power analysis determined that for an alpha value 5% and a power of 80%, 40 restorations per group would be required. Accordingly, assignment continued until some more restorations were enrolled in the two groups of this study to compensate for any unexpected dropouts. Thus, 89 restorations were performed in a total of 27 patients.

Random sequence generation and allocation concealment

The selected teeth from each patient were submitted to different protocols determined by simple randomization with block sizes of two and four. The random sequence was generated by a software freely available online site www.sealedenvelope.com.

A staff member not involved in the research protocol performed the randomization process with computer-generated tables. Details of the allocated group were recorded on cards contained in sequentially numbered, opaque, and sealed envelopes, by the same staff member. The envelope containing the allocation assignment was opened on the treatment day before the beginning of the restorative procedure to prevent selection bias. In all cases, the tooth designated by the highest

number (eg. 55, 54, 65, 64, 75, 74, 85 and 84) received the treatment registered in the first open envelope, while the tooth with the next number in sequence received the treatment mentioned in the second envelope and so on. All patients received at least two restorations, each using an adhesive technique.

Study intervention

Oral hygiene guidelines and professional prophylaxis were provided for all children prior to treatment. The 89 restorations were performed by the same operator in the dentistry clinic of the Ponta Grossa State University.

Two adhesive techniques were compared. For that, Tetric N-Bond Universal (Ivoclar Vivadent, Schaan, Liechtenstein) was applied in the etch-and-rinse (BER) technique (44 restorations) and, in the self-etch (BSE) strategy (45 restorations). All restorations were performed with a regular bulk fill compound (Tetric N-Ceram Bulk fill [TBF]).

All restorations were made using a rubber dam (SS White Prod. Odontol. LTDA. Petrópolis, RJ, Brazil). Before that, topical anesthesia was applied around the gum for clamp placement due to the discomfort produced by the clamp pressure. After isolation, all restorations were performed following the protocol of the minimal intervention (23, 24). The cavity preparation followed this sequence: (1) tooth surface was cleaned with a rotating brush (Microdont, Socorro, SP, Brazil) and pumice stone (SS White) and water to remove debris and plaque to improve the visibility of the dental cavity; (2) the infected dentin was removed from the surrounding walls and the enamel-dentin junction using sharp spoon excavators (Kit ART 10 Instruments Set, GC Europe, Leuven, Belgium) of appropriate size.

Demineralized dentin was left on the cavity floor; (3) the tooth was washed and dried (5 s) for the insertion of the adhesive system and restorative material according to the techniques proposed in this research, as described below. For Class II restoration, after the cavity had been prepared, a metallic matrix (TDV, Pomerode, SC, Brazil) was cut, burnished, positioned and stabilized by a wooden wedge (TDV) to define the proximal contour of the restoration. No liner or base was used before restoration.

Adhesive techniques

Tetric N-Ceram Bulk Fill (Ivoclar Vivadent) was inserted by two techniques: Bulk etch-and-rinse (BER) and Bulk self-etching (BSE) approach. For the BER group, prior to the application of the adhesive, a 37% phosphoric acid (Ivoclar Vivadent) was applied in enamel and for 15 s on the surface of the dentin, rinsed and dried for the same time. One coat of Tetric N-Bond Universal adhesive (Ivoclar Vivadent) was vigoroulsly rubbed for 20 s on the enamel and dentin, followed by gentle air-dry for 5 s and light-curing for 10 s (1200 mW/cm2, Bluephase N, Ivoclar Vivadent). The light was directed perpendicular to the occlusal surface.

Then the cavity was filled with a single volumetric increment of composite resin Tetric N-Ceram Bulk fill (Ivoclar Vivadent) and photopolymerized for 10 s (1,200 mW/cm2; Bluephase N, Ivoclar Vivadent). For the BSE group, one coat of the same adhesive (Tetric N-Bond Universal) was was applied as described for the earlier group except that no acid etching was performed.

Occlusal checking was performed after restoration placement with carbon paper (Accufilm, Angelus Dental Products Industry S/A) and the final finishing and polishing performed with Optrapol NG (Ivoclar Vivadent).

Blinding and Clinical evaluation

Before evaluation, each child had their teeth brushed with toothpaste and toothbrush, and the restoration was also cleaned with cotton pellet by the evaluator. One trained examiner who performed calibration online at the website www. e-calib.info tool performed the evaluation at baseline, six and 12 months (intra-examiner agreement was assessed This examiner was blinded to group assignment and was not involved in the placement of restorations. As the same restorative material was employed for both groups, the restorations had similar clinical appearance and the examiner could not guess the group assignment.

Patients were also blinded to group assignment in a double-blind randomized clinical trial design. It was not possible to blind the operator because of the evident differences between the techniques.

All evaluations were done in the schools where children were studying using probes, plane front-surface mirrors and a light source. The criteria used to evaluate the restorations was World Dental Federation (FDI) criteria (25). The primary clinical

outcome analyzed was the retention and fracture of the material. However, several secondary outcomes were also evaluated: marginal adaption, anatomic form, surface luster, color stability, match and translucency, marginal discoloration and pos-operative sensitivity. All parameters during evaluation were recorded using a standardized paper case report form.

According to the criteria, restorations were clinically classified as very good (VG), clinically good (after very good correction) (GO), clinically sufficient/satisfactory (small failures without adverse effects but not adjustable without damage to the tooth) (SS), clinically unsatisfactory (prophylactic repair) (UN) and clinically poor (need for replacement) (PO) (Table 3). Pos-operative sensitivity was evaluated prior to examination, by applying air stream for 10 s from a syringe placed 2 cm from the tooth surface (air dry). Only restorations classified as clinically poor (PO) were counted as unsuccessful.

Statistical analysis

The statistical analyses followed the intention-to-treat protocol according to the CONSORT suggestion (21). Intra-examiner agreement was assessed with kappa coefficient value. Descriptive statistics included the computation of the success rate of the restorative materials at both 6 and 12 months. The differences in the ratings of the two groups after 6 and 12 months were tested with the Friedman repeated measures analysis of variance by rank ($\alpha = 0.05$) and the differences in the ratings of each group at baseline and after 12 months were evaluated using the Wilcoxon test ($\alpha = 0.05$).

Results

This is an interim analysis of a 3 years clinical evaluation study. The distribution of the restorations according to the method used in the study (including compositions, application steps and number of batches) are presented in Table 1 and the overview of the distribution of the restorations according to the type of tooth and arch are presented in Table 2.

The flow chart shows the absents in the 3, 6 and 12-months recall (Figure 1). The BER (Bulk etch-and-rinse) and BSE (Bulk self-etch) groups were implemented exactly as planned and no modification was done. Intra-examiner agreement was assessed with kappa coefficient values (0.84). A total of 234 children were examined

and 27 children with a mean age of six to nine constituted the study sample. The number of successful and failed restorations according to each criterion are depicted in Table 3.

Fractures and retention

The overall survival rates after 12-month for occlusoproximal restorations were 41.8% (Bulk self-etch=42.6%; Bulk etch-and-rinse=41%) and 86.8% (Bulk self-etch=84.6%; Bulk etch-and-rinse=88.9%) for occlusal restorations. There was no statistical difference between the groups tested at 6-month and 12-month recall ($p > 0.05$). When occlusal vs occlusoproximal were compared, there was significant difference for every periods of evaluation in the both groups ($p < 0.05$) (Table 3).

For occlusal restorations, no significant difference was detected when baseline vs. 12-month time was compared for the BSE group ($p > 0.05$). However, for the BER group, in the same periods of evaluation, there was significant difference ($p < 0.05$). For the occlusoproximal restorations, the both groups (BER and BSE) showed significant difference ($p < 0.05$) when baseline vs. 12-month time was compared (Table 3).

When analyzing the total of the restorations of BER vs BSE, there was no significant difference detected in the different periods of evaluation ($p > 0.05$) (Table 3).

Marginal adaption, anatomic form, surface luster, color stability, translucency and surface staining

In regard to the criteria above, no significant difference was detected between the two groups at different recall times neither when baseline was compared with 6 and 12-months recall times (Table 4, $p > 0.05$).

Marginal staining

The two groups (BER and BSE) presented a statistically significant difference ($p < 0.05$) between the baseline vs. 12-month when class I was evaluated (that is, it discolored more with time). For class II, only the BSE group presented significant difference (baseline vs. 12-month) ($p < 0.05$) (Table 4).

Only the BER group presented a significative difference ($p < 0.05$) between the different periods of evaluation (base vs. 6, base vs. 12 and 6 vs. 12). For BSE material, there was no significative difference between the times ($p > 0.05$). Within the same time, there was significative difference between class I and class II for both materials ($p < 0.05$). (Table 4).

Postoperative sensitivity

No restorations had post-operative sensitivity at 6 and 12-month recall using FDI criteria ($p > 0.05$) (Table 4).

Discussion

The uniqueness of this investigation lies in the fact that it is the first in vivo study to evaluate two adhesive systems with Bulk fill for restoration in primary molars, where the selective removal of the carious tissue was performed. The longevity of restorative treatments is related, among other factors, to the type of material and work technique employed (26).

Research in dental materials relentlessly seeks a material biocompatible and resistant to ensure the longevity of the restorations and the dental element. For primary teeth, this last requirement (longevity) is less critical in view of the short time in the oral cavity. However, the ease and speed of the work technique is fundamental to ensure adequate restoration and well accepted by the child patient (27, 28). In fact, there is still no scientific basis to state which is the best restorative material for primary teeth, especially for occlusal-proximal cavities (29).

When attending children, the professional needs to use a restorative material that presents a good clinical performance and at the same time allows a fast work (27). Beside of this, reduced chair time results in decreased cost and discomfort for patients and increased productivity for dentists.

Faced with these facts, other alternatives of restorative treatment need to be tested, especially in primary teeth with the Bulk-fill system. The fluid composite resin filling technique could be an advantageous material faced the facility of the use. There are not so many studies available as conventional composites (30), but some in vitro and in vivo studies were performed to analyze different aspects of Bulk-fill composites.

Study showed that this system promotes durability of the class II restorations in permanent teeth similar to conventional incremental techniques during the five year evaluation (21).

In our study, when class I vs class II were compared, there was significant difference ($p < 0.05$) for every periods of evaluation in the both groups. In terms of microleakage, Bulk-fill composites did not show significantly different from conventional composites (15). It provides a bond to dentin (31) and microtensile bond strength similar than the conventional incremental technique (32), and great performance in terms of polymerization stress and bond strength (33).

According to the conclusion of Kim's study, the bulk-fill composites are not perfect substitutes for conventional composites (33). Of course, this statement should be well analyzed, because it is important to make the appropriate indication according to each clinical situation, selecting a good quality bulk-fill composite with a suitable adhesive system, or if necessary, other material. The patient's oral condition also needs to be examined before indicating treatment. For example, adhesive restorations placed in high-caries experience patients have limited survival rates (34).

Aware of this fact, we selected children who needed restorations but showed good oral condition, free of residual roots, abscesses or fistulas. Children who needed more complex treatment were referred for specialized service.

Few clinical studies are reported in the literature using bulk-fill composite in primary teeth (35). In our research we compared only one kind of Bulk-fill resin and two adhesive techniques (etching-and-rinse and self-etch system) and found no statistical difference between them. There are mention in the literature about a similar performance to another regular nanohybrid resin, and that the adhesive used (two self-etching adhesives) was the most relevant factor of influence (36).

A study carried out using a Bulk Fill and conventional composite concluded that Restorations (Class I) in primary molars can be performed successfully using a self-etch adhesive (35).

In our study, the step of adding acid conditioning (etch-and-rinse) did not result in increased retention of the restorations. A similar result was found in the literature, when the adhesion system did not influence the restorations' longevity and tendency

for better outcome, without statistical difference between etch-and-rinse and self-etch approach (37).

These results are very interesting because if there is no difference between the adhesive systems (etching-and-rinse and self-etch system), the pediatric dentist can choose from the one that consumes fewer clinical steps thus reducing working time. However, there are controversy in the literature, and a recent study with the bulk-fill composite concluded that 3-step adhesive approach was better than 1-step adhesive (38).

Other results associated with the aesthetics of the restorations were recorded, such as surface gloss, color and translucency (even the bulk materials being more translucent (28), however these criteria are of less interest for this research that included posterior deciduous teeth. Marginal staining was also evaluated, and the results showed that both groups showed discoloration over time, regardless of the technique used.

About the fracture and retention rates, the results obtained by Öter et al., 2018 (35) were better than ours, since all bulk filled restorations in deciduous teeth were still in operation after 1 year. In this study, the retention rates were 70,5% (57-82%) for the BER group, and 71,1% (57-82%) por the BSE group.

Especially in deciduous teeth due to the large pulp volume, sensitivity is an important item to be checked. One of the main factors that causes dentin sensitivity is the hydrodynamic movement of the dentin fluid, and probably the sensitivity is higher in young teeth (39). Therefore, postoperative sensitivity may be a problem with restorations in deciduous teeth. Unlike this, Altan H et al., showed that the intrapulpal temperature in primary teeth did not increased during the curing/setting with a bulk-fill resin composite (28). Once incremental placement techniques are generally accepted as reducing contraction stresses (39), but this material showed similar postoperative sensitivity comparing to a conventional composite restoration in occlusal cavities of primary teeth (35).

In our study, we had no complaint of sensitivity when using the two adhesive systems approach at 6 and 12 months and there was no case of pulp necrosis. This factor is justified, because the postoperative sensitivity may mainly depend on the

restorative technique, and not on a type of dentin adhesive (40). For five years, no postoperative symptoms were reported in permanent teeth treated with a fluid composite resin filling technique (21).

There are certain limitations to selecting patients for clinical studies such as finding carious lesions in the same mouth to perform and compare different techniques under similar conditions. It is also difficult to find restorations that are not as wide and deep, that can receive rubber dam isolation. Even with the difficulty of selecting the sample, it was possible to include 89 restorations and all the children were examined for 12 months, with no missing on the exam day.

To conclude, it is important to point out that the Bulk fill system relates to the ease of work, the material is carried with the applicator tip directly into the cavity and requires no mixing as occurs with glass ionomer (CIVS) cements. Although they are available in the encapsulated version, the cost is high for use in public services. In our research we use absolute isolation but we suggest that self-etch system and Bulk fill be tested under relative insulation.

The findings of this research may help the clinician to select the proper material with regard to its applicability in various clinical situations.

Conclusion

This study did not showed statistical difference between the bulk fill restorations in primary molars with an universal adhesive system in the etch-and-rinse and self-etch technique.

Figure and Tables legends

Table 1 - Adhesive system and restorative materials: composition, application mode and batches.

Table 2 - Characteristics of the children and features of the restored cavities for both study groups.

Table 3 - World Dental Federation (FDI) criteria used for clinical evaluation (34).

Table 4 - Fracture and retention rate values for the both groups evaluated in the FDI criteria (34) in the different periods of evaluation (Baseline, 6-month, 12-month).

Table 5 - Number of Evaluated Restorations for Each Experimental Group Classified According to the World Dental Federation Criteria (FDI) (34).

Figure 1- Flow chart of the study.

Table 1. Adhesive system and restorative materials: composition, application mode and batches.

Tetric N-bond Universal N-etch gel	Ivoclar-Vivadent/U42586 Ivoclar-Vivadent/U42905	2-hydroxyethyl methacrylate, methacryloyloxydecyl dihydrogen phosphate, bisphenol glycidyl methacrylate, methacrylated carboxylic acid polymer, decandiol dimethadrylate, ethanol, water, highly dispersed silicon dioxide and camphorquinone/ Phosphoric acid 37%	Etch-and-rinse (BER group)	Apply Etchant for 15 s. Rinse for 10 s. Air dry to remove excess of water.	*According to the manufacturer's instructions
			Self-etch (BSE group)	DO NOT USE ETCHANT	
Tetric N-Ceram Bulk fill	Ivoclar-Vivadent/V04429	Tetric N-Ceram Bulk fill (V04429): Dimethacrylates, polymer filler, barium glass, ytterbium trifluoride, mixed oxide (78 wt%/–).	Filling of the cavity with one increment of the material. Light-cure for 10 s at 1200 mW/cm2.		

Table 2 - Characteristics of the children and features of the restored cavities for both study groups.

Characteristics of research subjects	**Number of children**	
Gender distribution		
Male	13	
Female	14	
Age distribution (years)		
6 to 7	21	
8 to 9	06	
Characteristics of lesions	**Number of lesions (n=89)**	
	BER	**BSE**
Type of cavity		
Class I	27	26
Class II	17	19
Tooth distribution		
First Primary molar	16	15
Second Primary molar	28	30
Arch distribution		
Maxillary	23	21
Mandibular	21	24

Table 3. World Dental Federation (FDI) criteria used for clinical evaluation

	1. Fractures and retention	2. Marginal adaptation	3. Anatomic form	4. Surface lustre	5. Color match and translucency/ Surface staining	6. Marginal staining	7. Postoperative (hyper-)sensitivity
1. Clinically very good (VG)	1.1 Restoration retained, no fractures/cracks.	2.1 Harmonious outline, no gaps, no discoloration.	3.1 Form is ideal.	4.1 Lustre comparable to enamel.	5.1 Good color match, no difference in shade and/or translucency/ No surface staining.	6.1 No marginal staining.	7.1 No hypersensitivity, normal vitality.
2. Clinically good (after correction very good) (GO)	1.2 Small hairline crack.	2.2.1 Marginal gap (50µm). 2.2.2 Small marginal fracture removable by polishing.	3.2 Form is only slightly deviated from the normal	4.2.1 Slightly dull, not noticeable from speaking distance. 4.2.2 Some isolated pores.	5.2 Minor deviations in shade or translucency/ Minor surface staining, easily removable by polishing.	6.2 Minor marginal staining, easily removable by polishing.	7.2 Minor hypersensitivity for a limited period of time, normal vitality.
3. Clinically sufficient/ satisfactory (minor shortcomings with no	1.3 Two or more larger hairline cracks and/or chipping (not affecting the marginal integrity).	2.3.1 Gap < 150 µm not removable. 2.3.2 Several small enamel or dentin fractures	3.3 Form deviates from the normal but is esthetically acceptable.	4.3.1 Dull surface but acceptable if covered with film of saliva. 4.3.2 Multiple pores on more than one third of the surface	5.3.1 Distinct deviation but acceptable. Does not affect esthetics: 5.3.1 more opaque 5.3.2 more translucent 5.3.3 darker 5.3.4 brighter/ Moderate surface staining that may also present on other teeth, not esthetically unacceptable.	6.3. Moderate marginal staining, not esthetically unacceptable.	7.3.1 Moderate hypersensitivity 7.3.2 Delayed/mild sensitivity; no subjective complaints, no treatment needed.
4. Clinically unsatisfactory (repair for prophylactic reasons) (UN)	1.4 Chipping fractures which damage marginal quality; bulk fractures with or without partial loss (less than half of the restoration).	2.4.1 Gap > 250 µm or dentin/base exposed. 2.4.2 Chip fracture damaging margins. 2.4.3 Notable enamel or dentin wall fracture.	3.4 . Form is affected and unacceptable esthetically. Intervention/correction is necessary.	4.4.1 Rough surface, cannot be masked by saliva film, simple polishing is not sufficient. Further intervention necessary. 4.4.2 Voids.	5.4 Localized clinically deviation that can be corrected by repair: 5.4.1 too opaque. 5.4.2 too translucent. 5.4.3 too dark. 5.4.4 too bright. /Unacceptable surface staining on the restoration and major intervention necessary for improvement.	6.4. Pronounced marginal staining; major intervention necessary for improvement.	7.4.1 Intense hypersensitivity. 7.4.2 Delayed with minor subjective symptoms. 7.4.3 No clinical detectable sensitivity. Intervention necessary but not replacement.
5. Clinically poor (replacement	1.5 (Partial or complete) loss of restoration.	2.5 Filling is loose but *in situ* .	3.5 Form is unsatisfactory and/or lost. Repair not feasible / reasonable, replacement needed	4.5 Very rough, unacceptable plaque retentive surface.	5.5 Unacceptable. Replacement necessary/ Severe surface staining and/or subsurface staining, generalized or localized, not accessible for intervention.	6.5 Deep marginal staining, not accessible for intervention.	7.5 Intense, acute pulpitis or non vital tooth. Endodontic treatment is necessary and restoration has to be replaced.
Overall esthetic score	Acceptable function (n and %):		Not acceptable (n, % and reasons):	Acceptable esthetically (n and %):	Not acceptable (n, % and reasons/ Acceptable esthetically (n and %):	Acceptable esthetically (n and %):	Acceptable biologically (n and %):

Table 4. Fracture and retention rate values for both groups evaluated in the FDI criteria (34) in the different periods of evaluation (Baseline, 6-month, 12-month)

Periods of evaluation	BER occlusal cavities (n/%)	BER occlusoproximal cavities (n/%)	**BER total (n/%)**	Retention rate % (interval of confiance-95%)	BSE occlusal cavities (n/%)	BSE occlusoproximal cavities (n/%)	**BSE total (n/%)**	Retention rate % (interval of confiance-95%)
Baseline				100				100
6-month	2 (7.4)	6 (35.3)	8 (18.18)	81.82 (68-90)	2 (7.7)	6 (31.6)	13 (29.54)	82.22 (69-91)
12-month	3 (11.1)	10 (59.6)	13 (29.54)	70.45 (56-82)	4 (15.4)	9 (47.4)	13 (28.88)	71.1 (57-82)

Table 5 - Number of Evaluated Restorations for Each Experimental Group Classified According to the World Dental Federation (FDI) Criteria

FDI Criteria	(*)	Baseline				6-month				12-month			
		Occlusal		Occlusoproximal		Occlusal		Occlusoproximal		Occlusal		Occlusoproximal	
		BER	**BSE**	**BER**	**BSE**	**BER**	**BSE**	**BER**	**BSE**	**BER**	**BSE**	**BER**	**BSE**
Fractures and retention	VG	27	26	17	19	24	24	11	12	23	20	6	8
	GO	-	-	-	-	1	-	-	1	1	1	1	1
	SS	-	-	-	-	-	-	-	-	-	1	-	1
	UN	-	-	-	-	-	-	-	-	-	-	-	-
	PO	-	-	-	-	2	2	6	6	3	4	10	9
Marginal adaptation	VG	27	26	17	19	24	23	11	11	24	20	5	6
	GO	-	-	-	-	1	1	-	1	-	-	2	3
	SS	-	-	-	-	-	-	-	1	-	1	-	1
	UN	-	-	-	-	-	-	-	-	-	1	-	-
	PO	-	-	-	-	-	-	-	-	-	-	-	-
Anatomic form	VG	27	26	17	19	23	20	8	8	22	17	4	4
	GO	-	-	-	-	2	2	3	1	2	2	3	1
	SS	-	-	-	-	-	1	-	4	-	2	-	5
	UN	-	-	-	-	-	1	-	-	-	1	-	-
	PO	-	-	-	-	-	-	-	-	-	-	-	-
Surface luster	VG	27	26	17	19	20	18	11	9	17	15	7	3
	GO	-	-	-	-	5	5	-	4	6	5	-	7
	SS	-	-	-	-	-	1	-	-	1	2	-	-
	UN	-	-	-	-	-	-	-	-	-	-	-	-
	PO	-	-	-	-	-	-	-	-	-	-	-	-
Color stability, translucency and surface staining	VG	22	24	16	17	20	22	10	11	19	19	4	8
	GO	5	2	1	2	5	2	1	2	5	3	3	2
	SS	-	-	-	-	-	-	-	-	-	-	-	-
	UN	-	-	-	-	-	-	-	-	-	-	-	-
	PO	-	-	-	-	-	-	-	-	-	-	-	-
Marginal Staining	VG	27	26	17	19	12	14	9	6	10	12	2	1
	GO	-	-	-	-	5	2	1	2	5	3	3	2
	SS	-	-	-	-	8	8	1	3	8	7	2	5
	UN	-	-	-	-	-	-	-	2	1	-	-	2
	PO	-	-	-	-	-	-	-	-	-	-	-	-
Postoperative sensivity	VG	27	26	17	19	25	24	11	13	24	22	7	10
	GO	-	-	-	-	-	-	-	-	-	-	-	-
	SS	-	-	-	-	-	-	-	-	-	-	-	-
	UN	-	-	-	-	-	-	-	-	-	-	-	-
	PO	-	-	-	-	-	2	6	6	3	4	10	9

* VG: Clinically very good, GO: Clinically good (after correction very good), SS: Clinically sufficient/satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth), UN: Clinically unsatisfactory (repair for prophylactic reasons), PO: Clinically poor (replacement necessary).

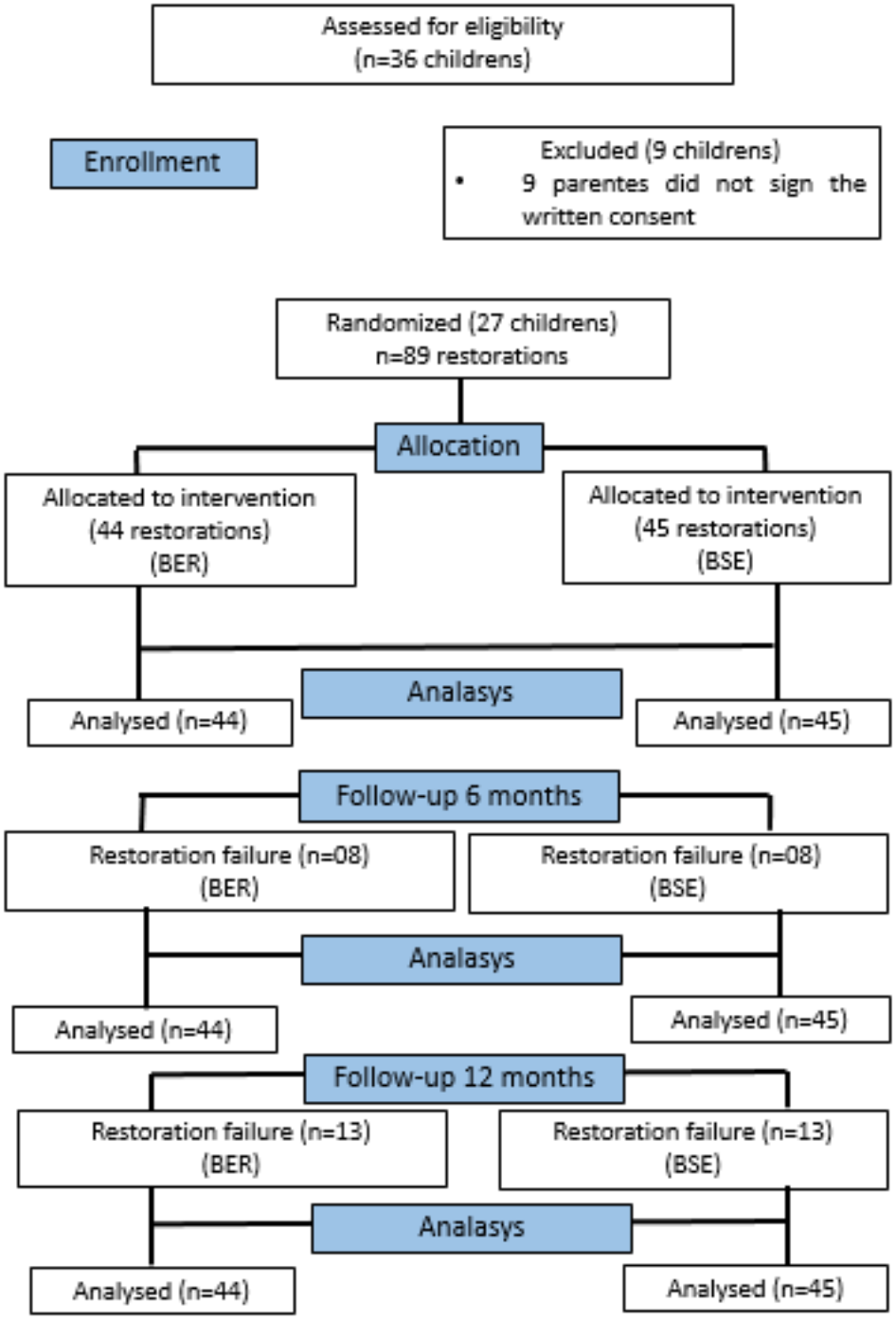

Fig. 1- Flow chart of the study

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5 Artigo 3- Randomized Clinical Trial of Atraumatic Restorative Treatment-Art using Glass- Ionomer Cements in Deciduous Teeth: 24-Month Follow-Up

TÍTULO: RANDOMIZED CLINICAL TRIAL OF ATRAUMATIC RESTORATIVE TREATMENT-ART USING GLASS- IONOMER CEMENTS IN DECIDUOUS TEETH: 24-MONTH FOLLOW-UP

STATUS: FINALIZADO

Randomized clinical trial of atraumatic restorative treatment-art using glass- ionomer cements in deciduous teeth: 24-month follow-up

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ABSTRACT

Objective: To evaluate the survival of restorations with selective caries removal in primary teeth performed with two glass ionomer cement for occlusal and occlusoproximal cavities after 3,6,12 and 24-month of follow-up.

Design: This was a double-blind, superiority, randomized clinical trial with an equal allocation ratio. 23 children received 74 restorations made with Íon Z (FGM Prod. Odont., Ltda, Joinville, SC, Brasil) and Ketac Molar (3M ESPE, St Paul, MN, EUA). All treatments were performed by one pediatric dentist and the manufacturer's instructions of each material were followed. A calibrated and blinded examiner evaluated the restorations at 3, 6, 12 and 24-month. Restoration survival was analyzed using Kaplan-Meier survival analysis and Log-rank test (α = 5%).

Results: The overall survival rates after 24-month for the restorations were 21.6% (Íon Z=16,2%; Ketac Molar=27%) with no difference statistically significant between the GIC's ($p > 0.05$). When considering the type of the cavities, there was no statistically significant difference between classes in the different materials evaluated ($p > 0.05$).

Conclusion: ÍON Z and Ketac Molar restorations presented similar survival rates over a 2-year period for all, single-surface, and multiple-surface restorations.

Keywords: Dental atraumatic restorative treatment, Deciduous tooth, Survival rate, Glass ionomer cements

Introduction

Atraumatic Restorative ART is a pain free technique (1), being part of the essential educational prevent strategies of the public health care policies (2). This minimally invasive approach, which involves removal of decayed tissue using hand instruments alone, usually without use of anaesthesia and electrically-driven equipment (3), can be used safely in primary and permanent tooth cavities (4). Initially selected for underdeveloped countries and for people with disability (5), now it is suitable for all patients, regardless of the economic and social situation (6).

High viscosity ionomer cements are the most recommended materials for this type of restorations (7). A smaller glass particle size and an increase in the powder: liquid ratio of this type of material give it better mechanical properties (8, 9), surface hardness and compressive strength (10). Manually or encapsulated mixed, the variety of materials available diversify the options for the clinicians (11). Ketac Molar Easymix and Fuji IX are still used as reference materials in this technique (12-14), but the relatively high cost of these materials compromise their use, either in public health or private practice in low-income populations (15). Hight costs often prevent the treatment and care of the population, not enabling the care of public health patients (16). For this, manufacturers of dental materials are investing in this category of restorative material, developing some with lower costs, easier to handle and with greater antimicrobial properties (15).

The Ion Z (FGM Prod. Odont., Ltda, Joinville, SC, Brasil), one of the two material used in the research, is a lowcost material compared with the conventional high viscosity glass ionomer cements used in the technique. Besides that, the zinc and titanium dioxide in its composition may be the components responsible for the improvement in the antimicrobial activity of the material (17, 18).

Once there is lack in vivo studies using this material, the purpose of this study was to compare the survival rate of ART (occlusal and occlusoproximal) in primary teeth, performed with Íon Z and a high viscosity glass ionomer cement, after 24 months. Our hypothesis is that there is no difference in the clinical performance of the ART performed with the different GICs.

Material and Methods

Ethical approval

The local Ethics Committee on Investigations Involving Human Subjects reviewed and approved the protocol and issued a consent form for this study (064688/2015) and it was also registered on REBEC (Brazilian Registry of Clinical Trials). The UTN (Universal Trial Number) of this study is RBR-U1111-1198-3193. Experimental design followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Trial design, settings and allocations of data collection

This was a double-blind, randomized clinical trial with an equal allocation ratio. All procedures in the selected volunteers were performed in Jan 17, 2017 and the evaluation finished in Jan, 2019.

Eligibility criteria

In order to be included in the trial, participants should be between 4 to 9 years old from one municipal school (chosen by convenience sampling) in the city of Ponta Grossa-PR (Brazil). They should present at least two primary posterior teeth with a Class I and/or II carious lesions in vital teeth. Cavities should be scored 5 or 6 in the ICDAS system (19) and the parents / guardians should have signed the Informed Consent Form.

Participants were excluded if their teeth were fistulated or with spontaneous pain, children who do not accept the oral examination or do not attend the scheduled restoration day. In such circumstances, parents were advised to seek dental care in the National Health System. No type of advertisement was done in any type of media. All details are in the flowchart (Fig.1).

Sample size calculation

The success rate of the occlusoproximal restorations with Ketac™ Molar Easymix (3M ESPE, São Paulo, MN, EUA) was reported in approximately 41% (20, 21) for two years of follow-up. For a 78% success rate of the experimental group (Íon Z-FGM Prod. Odont., Ltda, Joinville, SC, Brasil), was required 64 restorations (32 per group), with the level of 5% significance and a power of 90%. An amount of 15% were added to contemplate possible losses during the follow-up, totalizing 74 restorations.

All calculations for determining the sample size were carried out with a specific program, freely available online, for this purpose (www.sealedenvelope.com).

Blinding, Random sequence generation and allocation concealment

A total of 74 restorations were placed in 23 children aged 4-9 years. The selected teeth from each patient were submitted to the different treatments determined by simple randomization. The random sequence was generated by a software freely available online (www.sealedenvelope.com) by an investigator who was not involved in the implementation of the study.

This was a double-blind clinical trial. Neither the patient nor the evaluator had knowledge of the technique that would be applied to the teeth. For this purpose, the random sequence generated was individually placed in opaque, consecutively numbered and sealed envelopes, which were only opened by the operator one minute before the intervention. The group determined in the envelope was indicated to the tooth by the randomization, following the sequence of the quadrants (5,6,7 and 8). It was always initiated by the most posterior tooth of the arch.

Study intervention

Two glass ionomer cements were used, Ketac Molar (3M ESPE, St Paul, MN, EUA) named as Group A (control group) and Íon Z (FGM Prod. Odont., Ltda, Joinville, SC, Brasil), named as Group B (experimental group). All restorations were carried out in the school, in a space adapted for this purpose. All children received oral health instruction, than they were positioned in mattresses on the tables and all the procedures were performed by the same dentist helped by a dental assistant. The envelope-containing group (A or B), generated by random sequence, was opened immediately before the begging of the procedure in the teeth.

All restorations were done without local anesthesia following ART guidelines (22). The envelopes containing the computerized generated random sequence were opened immediately before the beginning of the restorative procedure for each tooth.

The field was isolated with cotton rolls and the cavity preparation followed the sequence described below: (1) tooth surface was cleaned with a wet cotton pellet to remove debris and plaque to improve the visibility of the dental cavity; (2) the infected dentin was removed from the surrounding walls and the enamel-dentin junction using

sharp spoon excavators (Kit ART 10 Instruments Set, GC Europe, Leuven, Belgium) of appropriate size before proceeding to the cavity floor. To avoid pulpal exposure in deep cavities, the remaining dentin was left untouched. The cavity was then cleaned with a small cotton pellet soaked in water and dried with a dry cotton pellet (Cremer, Blumenau, SC, Brazil). No liner or base were used. For all occlusoproximal cavities, after the cavity had been prepared, a metallic matrix (TDV, Pomerode, SC, Brazil) was cut, burnished, positioned and stabilized by a wooden wedge (TDV) to define the proximal contour of the restoration.

For the both groups, the teeth were conditioned for 10 s with a wet cotton wool pellet saturated with the GIC liquid (polyacrylic acid), washed for 5 s with wet cotton pellets and dried with cotton pellets.

The drawn GIC (A or B) was handled according to the manufacturer's information, hand-mixed and inserted into the cavity. Slight vibrations were made with the spatula on one side of the cavity margins for better adaptability of the GIC into the cavity, until filling the whole cavity. A pressure with a vaseline gloved finger was used to prevent the formation of bubbles and to improve the adaptation of the cement to the cavity walls. Excess material was removed with a Hollenback carver. The occlusion was checked with articulating paper. The patient was advised not to chew solids for 1 h after the placing of the restoration.

Clinical evaluation

After restoration placement, the materials presented similar clinical appearance. Therefore, one calibrated examiner, who was not involved in the placement of restorations and who was also blinded to the type of material, evaluated the restorations at three, six ,12 and 24 months. Debris and plaque from the tooth surface were removed before evaluation using a wet cotton pellet.

Clinical evaluation was performed using WHO periodontal probes, plane front-surface mirrors and a light source. The ball of the CPI probe (diameter 0.5mm) was used to measure the size of any marginal defect and the amount of wear. The criteria used to evaluate the ART restorations were those of a previous study (23). Restorations scored as codes 0, 1 and 2 were considered successful, those scored as codes 3, 4, 5, 6, 7 and 8 were considered failures, and the restorations scored code 9

(unable diagnostic) were replaced with the last score obtained in the previous evaluation.

Follow-up

All evaluations were performed by a single trained and calibrated evaluator (Kappa> 0.85) blinded to the type of material used. The children who participated in the study were evaluated at the school they studied, In the same place they had their teeth restored and they were evaluated after 3, 6, 12 months and 24 months. The evaluation of restorations was performed according to Amorim et al., 2014 (24).

Results

A total of 48 children were examined and 23 children with a mean age of four to nine constituted the study sample, harmoniously shared between the sexes: female (52.2%) and male (47.8%) (Table 1).

Regarding the clinical performance of ART restorations, as shown in Table 2, there is a percentage of overall success of 71.6%, 55.4%, 32.4% and 21.6% in 3 months, 6 months, 1 year and 2 years of follow-up, respectively. Moreover, among the GICs studied, this difference was not statistically significant ($p > 0.05$).

The survival curves, with censored and uncensoderd data are presented in Figures 2 and 3. Log-rank Mantel-Cox test did not indicate difference between the two different GICs over the 2 years when comparing the losses of atraumatic restorations ($p = 0.356$) (Figure 2). Assessing the survival rate of the different materials in the different periods of evaluation in Figure 2, the average survival time for Ketac was 12.7 months and 12 months for Íon Z (with no statistical difference), regardless of class type (I or II).

The median of survival rate estimated for occlusal restorations with Ketac was 17.2 months and 10.5 months for occlusoproximal restorations. The median of survival rate of occlusal restorations with Íon Z was 15.5 months and 10.5 months for occlusoproximal. Even though the survival rates were lower for class II of both materials, there was no statistically significant difference between classes in the different materials evaluated by Log-rank Mantel-Cox (Figure 3).

Discussion

This randomized clinical trial investigated the 24 months survival rate of ART restorations on occlusal and occlusoproximal surfaces of the deciduous molars using two different glass ionomer cements: Ketac™ Molar Easymix (3M ESPE, São Paulo, MN, EUA) e Íon Z (FGM Prod. Odont., Ltda, Joinville, SC, Brasil). The success rates of Ketac and Íon Z were respectively 27% and 16% after 2 years.

This research followed the established protocol and no changes were made and 56% of the sample was between 4 to 6 years old. All sample was composed by children attending public schools in the city. Selection bias was controlled by having the allocation of patients conducted by the same dentist. Children and the evaluations were considered blinded to the procedure, as the treatments performed were done by the ART strategy. Different operators can interfere in restorations' longevity (21, 25, 26). For this, an experienced operator performed the restorations and received training in the ART approach prior to the start of this study.

However, there are limitations to this current research. The operator was not blinded to the material applied and to overcome this performance bias, the operator received the information about which material to use only after the teeth was prepared to receive the restoration.

Why this paper is important to paediatric dentists, ART is commonly used in the management of caries lesions by pediatric dentists; however, the longevity of approximal ART restorations still presents a concern between clinicians. Already widespread, high viscosity GIC is known as the material of choice when using this approach.

The ART technique is an alternative option for single-surfaces restorations in permanent and primary teeth. However, the application of the GIC-ART technique for load-bearing approximal restorations should be carefully considered before employing this option, especially in primary teeth (27).

The systematic review and meta-analysis from Tedesco et al., showed that the survival rates of occlusoproximal restorations drop in approximately 30% in 2 to 3 years of follow-up, suggesting that restorations in occlusoproximal cavities still remain a challenge for the clinician (28). The median of survival rate in our study was 10.5

months for occlusoproximal restorations with Ketac and 10.5 months for occlusoproximal using Íon Z, with no statistically significant difference between classes and groups ($p>0.05$).

The literature shows different brands and type of material for this technique. The GIC ÍON Z, choiced to be the experimental group for this study, did not showed any clinical trial for deciduous teeth in the literature.

This material has zinc and titanium dioxide in its composition. These two components could be responsible for improving the antimicrobial activity of the material and would promote a longer survival rate in restorations, but this situation did not occured. Zinc acts by altering or damaging the bacterial cell membrane (29, 30) and stimulates the metabolic effect on mineralization, increasing occlusion of dentinal tubules and improving adhesive properties of the GIC (31). Along with titanium dioxide free particles, which could also accelerate bacterial cell death. (32). The antimicrobial capacity of zinc and titanium dioxide depends on the concentration present in the material (29), however the manufacturer does not comment the concentration of these added products. Therefore, further laboratorial and clinical studies should be developed to evaluate the material.

Another important fact to be considered is the cost of the GIC's used in this study. It is important to note that materials costs vary depending on whether these items are imported or produced locally (33).

Even though this trial did not evaluate the cost-efficacy of those materials, their difference is evident. One package of Ketac Molar is US$ 106 and ÍON z is sold in Brazil for US$ 13 dollars (1 dollar = 4.11 brazilian reais). This can be an important outcome to be evaluated in further studies.

In the present study, ION Z is the cheapest GIC, in comparison with the Ketac Molar Easymix. Therefore, the results can serve as input for public health managers in the choice of the most cost-effective GIC for basic dental care. The main contribution was to present a comparative effectiveness of the two GICs, such that one is cheaper than the gold standard of the literature with no significant differences regarding effectiveness ($p>0.05$). This information thus aids in the selection of the lowest-cost

treatment, which enables the care of a larger number of children presenting an interesting choice of GIC for ART in public health (34).

This cost analyses are important in that they provide dental practitioners with crucial information, helping them make decisions about planning, management, and health promotion processes (35).

Clinical trials with long follow-up times following restorative procedures are difficult and expensive. Moreover, it is difficult to standardize cavity dimensions in these trials, therefore, large sample sizes are required. Another aspect is the difficult selective carious tissue removal of soft dentin. This situation may increase the risk of experiencing restoration failure in primary teeth, owing the limited evidence level (36).

Different operators can interfere too in restorations' longevity (21, 25, 26). For this, an experienced operator performed the restorations and received training in the ART approach prior to the start of this study.

Another issue that could be considered is the immediate protection of the restoration. In our study, the pressure with petroleum jelly gloved finger was used to improve the adaptation of the material to the cavity walls, to prevent the formation of bubbles and for protection against possible late material reactions. Besides that, the flexural strength of glass ionomer cements may be affected by the lack of protection after restoration. A petroleum jelly used as a protection to prevent water loss or gain would result in slightly stronger cements in this regard (37).

Hesse et al.,(38) showed superior results using a nanofilled particles coating as a protection material after the restorations.

The results of this study indicate that the glass ionomer cement Íon Z had similar survival rate when compared to Ketac Molar, gold standard widely used in ART research. However, further clinical studies should be performed to prove the in vivo effectiveness of the Íon z, especially in molars deciduous.

Conclusion

There was no significant difference between the two glass ionomer evaluated, regardeless the type of cavity in 24-month follow up. Further clinical studies in

deciduous teeth should be conducted to prove efficacy, especially of the new material: Íon Z

Figure and Tables legends

Table 1 - Characteristics of the children and features of the restored cavities for both study groups.

Table 2 - Clinical performance of ART restorations with different GICs measured in 3 months, 6 months, 1 year and 2 years according to ART criteria.

Figure 1- Flow chart of the study.

Figure 2- Kaplan–Meyer survival curve of ARTs over the 2-year follow-up study

Figure 3- Kaplan–Meyer survival curve of ARTs over the 2-year follow-up study according to the different classes evaluated.

Table 1. Characteristics of the children and features of the restored cavities for both study groups.

Characteristics of research subjects	**Number of children**	
Gender distribution		
Male	11	
Female	12	
Age distribution (years)		
4 to 6	13	
7 to 8	10	
Characteristics of lesions	**Number of lesions (n=74)**	
	Ketac	**Íon Z**
Type of cavity		
Class I	12	11
Class II	25	26
Tooth distribution		
First Primary molar	19	20
Second Primary molar	18	17
Arch distribution		
Maxillary	20	20
Mandibular	17	17

Table 2. Clinical performance of ART restorations with different GICs measured in 3 months, 6 months, 1 year and 2 years according to ART criteria

	3 months(a)			6 months(a)			12 months(a)			24 months(a)			
	Ketac molar n (%)	Íon-z n (%)	Total n (%)	Ketac molar n (%)	Íon-z n (%)	Total n (%)	Ketac molar n (%)	Íon-z n (%)	Total n (%)	Ketac molar n (%)	Íon-z n (%)	Total n (%)	
Success	24 (65)	29 (78.4)	53 (71.6)	20 (54)	21 (57)	41 (55.4)	14 (38)	10 (27)	24 (32.4)	10 (27)	6 (16)	16 (21.6)	p > 0.05 (b)
Failure	13 (35)	8 (21.6)	21 (28.4)	17 (46)	16 (43)	33 (44.6)	23 (62)	27 (73)	50 (67.6)	27 (73)	31 (84)	58 (78.4)	p > 0.05 (b)

a. ART criterion: success (codes 0, 1, and 2), failure (codes 3, 4, 5, 6, 7 and 8)
b. Chi-square test, level of significance $p<0.05$

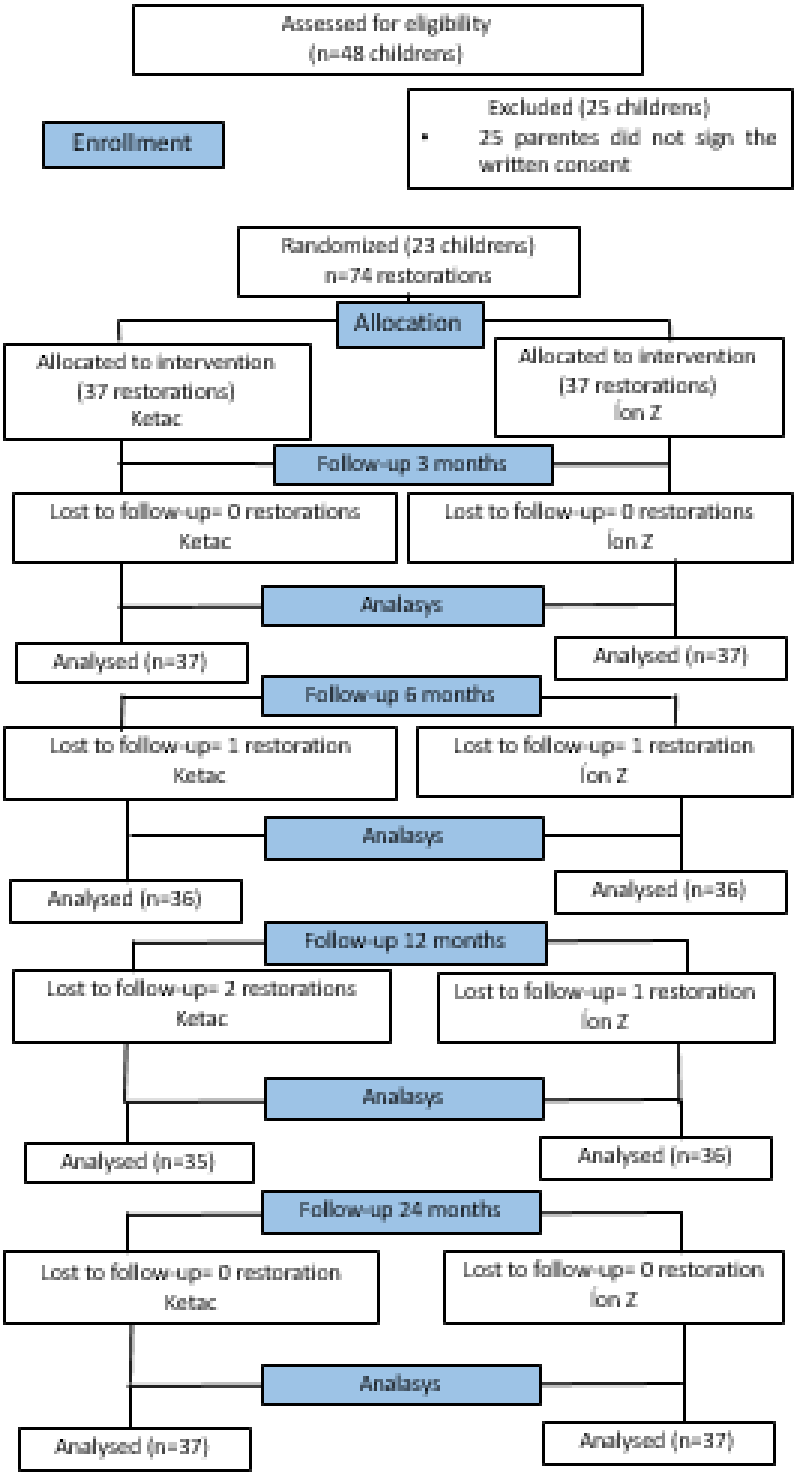

Fig. 1 Flow chart of the study

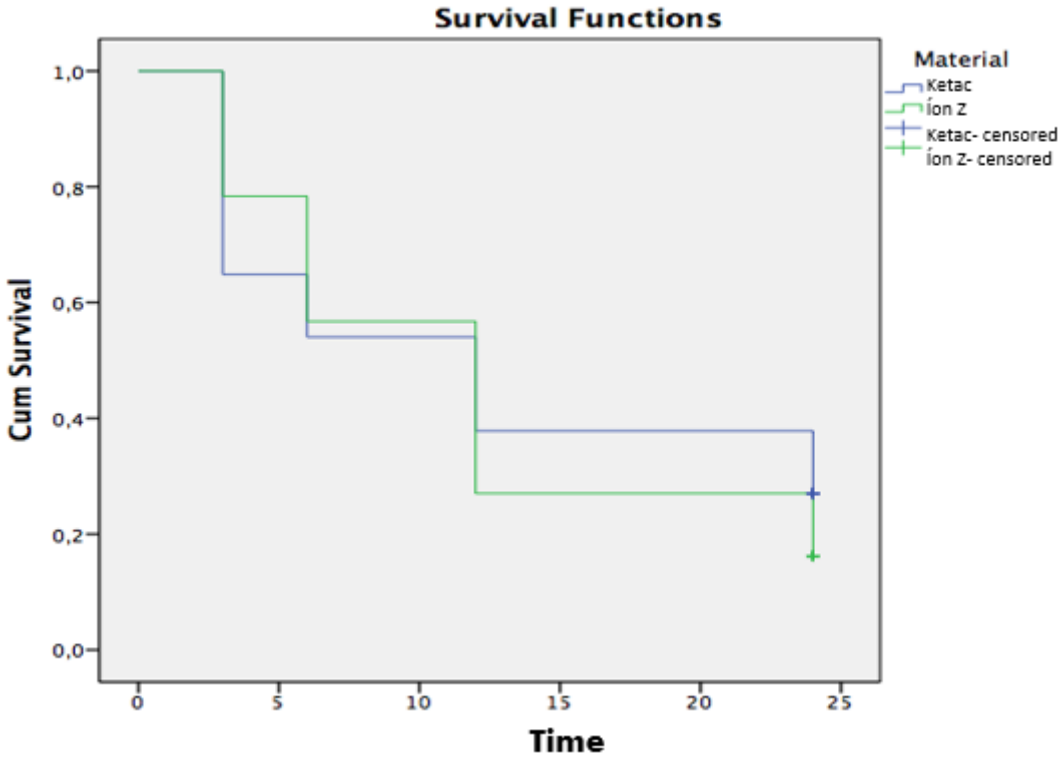

Fig. 2 Kaplan–Meyer survival curve of ARTs over the 2-year follow-up study

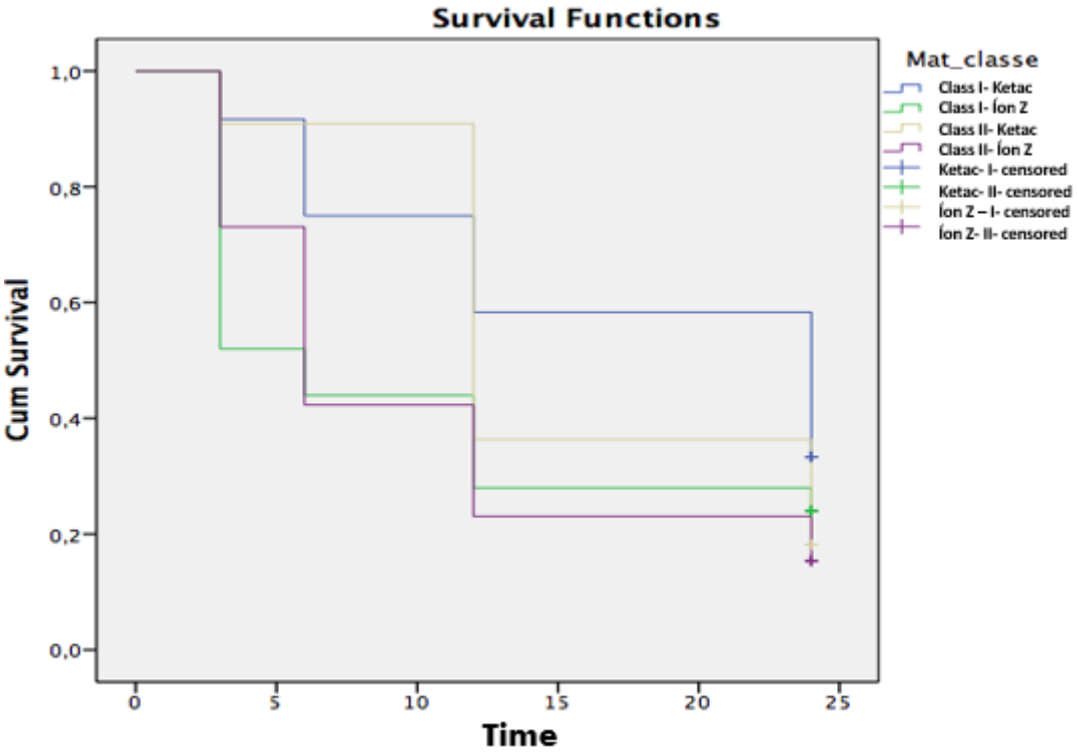

Fig. 3 Kaplan–Meyer survival curve of ARTs over the 2-year follow-up study according to the different classes evaluated

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7 Discussão

A pesquisa em materiais dentários procura incansavelmente um material biocompatível e resistente para garantir a longevidade das restaurações e do elemento dentário. Para dentes decíduos, o requisito “longevidade” é menos crítico, tendo em vista o pouco tempo na cavidade oral. No entanto, a facilidade e rapidez da técnica de trabalho são fundamentais para garantir uma restauração adequada e bem aceita pelo paciente infantil (34, 35). De fato, ainda não há base científica para afirmar qual é o melhor material restaurador para os dentes decíduos, por isso, diversos materiais e técnicas devem ser estudados.

Em relação ao protocolo restaurador, a remoção seletiva do tecido cariado é a técnica mais estudada atualmente e vem apresentando excelentes resultados, favorecendo a recuperação biológica do dente, minimizando as chances de exposição e reduzindo a necessidade de tratamentos mais complexos e onerosos (28). A remoção seletiva foi utilizada nos três estudos clínicos que compõe esta tese, associada a restaurações com materiais resinosos ou ionoméricos.

O CIV de alta viscosidade, em função da sua utilização no protocolo das ARTs, tem sido citado como o material de primeira escolha para restauração em dentes decíduos (23). No entanto, os CIVs de alta viscosidade, considerados como padrão ouro na literatura, como o Fuji 9 Gold Label (GC Europe-Leuven, Belgium) e Ketac Molar Easy Mix (3M ESPE, St Paul, MN, EUA), são considerados materiais muito caros, especialmente para a Saúde Pública no Brasil.

Por essa razão, um dos estudos desta tese teve como objetivo testar um novo material ionomérico, de fabricação nacional nominado Íon Z (FGM Prod. Odont., Ltda, Joinville, SC, Brasil), cujo custo é mais acessível, buscando desta forma ampliar o leque de opções de materiais restauradores em restaurações minimamente invasivas. É importante ressaltar que os custos dos materiais odontológicos afetam diretamente o valor de um procedimento restaurador (36). Portanto, resultados favoráveis a um CIV nacional poderiam direcionar a escolha dos gestores de saúde pública para o atendimento odontológico básico (37).

No artigo 3, ao se comparar o CIV Ketac Molar (padrão-ouro em estudos sobre ARTs) ao Íon Z (CIV de alta viscosidade com zinco e dióxido de titânio em sua formulação), não foram observadas diferenças significativas na longevidade das

restaurações atraumáticas realizadas com um ou outro CIV ($p > 0.05$). Por isso, o Íon Z poderia ser uma boa opção para tratamento dos dentes decíduos. No entanto, estudos clínicos adicionais devem ser realizados para se comprovar esta hipótese, uma vez que esta triagem clínica foi realizada em campo, com pacientes com grande quantidade de lesões cariosas e, ambos fatores poderiam ter influenciado a baixa taxa de sobrevida das restaurações obtidas com ambos os materiais.

Deve-se ter em mente que restaurações atraumáticas em cavidades oclusais apresentam excelentes taxas de sucesso clínico em dentes decíduos e permanentes (38). Já as restaurações oclusoproximais são um grande desafio para a Odontopediatria, independentemente do material restaurador utilizado (39). Todas as triagens clínicas que compõe esta tese corroboram com essa informação, sendo a perda total das restaurações oclusoproximais a principal falha observada, assim como em outros estudos encontrados na literatura (33-41).

Ao substituir o CIV de alta viscosidade por CIV modificado por resina e pelo novo material a base de resina de dupla polimerização (Cention N), como realizado no primeiro artigo, era esperado um melhor desempenho dos materiais em cavidades oclusoproximais. Realmente, isto foi obtido, mas a falha das restaurações em cavidades compostas permanece uma constante.

Por ser um material resinoso, o Cention N foi utilizado associado ou não ao sistema adesivo. Foi possível observar que, em restaurações minimamente invasivas com remoção seletiva de tecido cariado, a presença do adesivo favoreceu a longevidade das restaurações, particularmente nas cavidades oclusoproximais. Para materiais resinosos, a ligação à dentina afetada por cárie é um desafio clínico, pois várias modificações químicas, biológicas e físicas ocorrem como resultado do processo de cárie (42, 43). Independentemente dessa questão, a dentina cariada pode ser deixada na cavidade para preservar a saúde pulpar, mas deve ser limitada à parede pulpar ou axial; é especialmente importante que a periferia da cavidade ofereça suporte suficiente à restauração e permita uma boa vedação (22).

Nos estudos 1 e 3, embora todos os tratamentos tenham sido realizados em ambiente escolar e com isolamento relativo, esta etapa importante na preparação da cavidade foi cuidadosamente realizada para obter o melhor selamento da restauração em condições de campo. Porém, deve-se levar em conta que o controle de saliva com roletes de algodão em situações como essa, sem estrutura adequada, pode ser muito

desafiador quando o profissional está lidando com pacientes novos e de difícil comportamento, podendo comprometer o desempenho clínico das restaurações (40, 44).

O uso do dique de borracha e a utilização de equipo odontológico para execução das restaurações poderia explicar a taxa de sucesso das restaurações do estudo 2. Nele, as restaurações foram feitas com o material resinoso Bulk Fill, porém testando duas técnicas adesivas com um adesivo universal: *self-etch* e *etch-and-rinse*. Lenzi *et al*., comentam que os adesivos universais funcionam igualmente após a remoção parcial da cárie nas duas estratégias em dentes decíduos, com boas taxas de sobrevivência de restaurações de resina composta após 12 meses de acompanhamento (45). O estudo 2 confirma essa afirmação, mostrando não haver diferença estatística significativa entre as técnicas, sendo uma informação muito importante, pois o tempo de trabalho é um fator de grande importância no atendimento infantil.

Uma das vantagens das restaurações adesivas é que elas permitem reparos. Mesmo que as restaurações apresentem falhas ao longo do tempo, a maioria poderia ser reparada, permitindo abordagens mais conservadoras para dentes com lesões de cárie profunda (46).

A quantidade e a frequência com que os açúcares são ingeridos na dieta pelas crianças, a placa visível nos dentes, a exposição ao flúor apenas no suprimento da água e a dificuldade de acesso ao tratamento odontológico, aumentam a probabilidade de risco de cárie (47). Porém, como toda a amostra incluída foi de crianças dentro desse panorama, esse possível viés estaria controlado.

Outro fator que pode influenciar nas propriedades mecânicas dos materiais, principalmente dos cimentos de ionômero de vidro e, consequentemente aumentar o risco de falhas é a sua forma de manipulação, pois a mistura incorreta desse material pode interferir na longevidade das restaurações (48). Esse fato poderia alterar resultados do artigo 1 e 3 (o qual apresentou grande porcentagem de insucesso clínico com o passar do tempo). Diante disso, duas opções se tornariam viáveis para tratamento minimamente invasivo em crianças, onde o tempo de trabalho clínico é muito importante: cimentos encapsulados (porém eles necessitam de eletricidade e possuem alto custo) e outros materiais resinosos (porém também necessitariam de eletricidade), sendo excluídos da abordagem ART.

Outro aspecto a ser levado em conta é o tamanho da cavidade selecionada, principalmente oclusoproximais. Esse tipo de cavidade, de tamanho pequena e média pode ser uma razão para maior índice de sucesso clínico (49). Cavidades pequenas preparadas pela abordagem ART, minimizam o contato da superfície restaurada com as cúspides oclusais, reduzindo assim a probabilidade de desgaste excessivo ou fratura do material (50). Porém nos nossos estudos, não houve mensuração do tamanho das cavidades.

Lesões cariosas oclusoproximais amplas resultam em preparos com retenção limitada devido a anatomia dos dentes decíduos, sendo o risco de falha maior em restaurações com um número maior de faces acometidas, principalmente quando há dentina remanescente dentro da cavidade (19).

A padronização das dimensões das cavidades em ensaios clínicos é uma tarefa muito difícil, assim, grandes amostras seriam necessárias para demonstrar diferença ou não entre materiais e técnicas. Talvez, outros estudos adicionais, com um maior número amostral possa gerar dados complementares aos estudos realizados nessa tese.

Todas essas questões levantadas nos 3 estudos realizados justificam a dificuldade do profissional da área da Odontopediatria em escolher o melhor material associado ao correto protocolo de uso. Por isso, mais estudos clínicos randomizados devem ser realizados, principalmente com os materiais mais novos no mercado para comprovação clínica do sucesso clínico em dentes decíduos.

8 Conclusão

Com base nos resultados dos nossos estudos, pode se concluir que:

- Houve grande variação nas taxas de sobrevivência dos estudos realizados.
- Quando o material Cention N for utilizado em restaurações oclusoproximais em dentes decíduos, o uso do sistema adesivo universal deve ser indicado.
- Pode-se excluir a etapa de condicionamento ácido previamente ao sistema adesivo universal utilizando resina *Bulk fill* em dentes decíduos.
- Não houve diferença estatística significativa entre as taxas de sobrevivência dos cimentos de ionômero de vidro Ketac Molar Easymix e Íon Z, independente do tipo de cavidade avaliada, após 24 meses de acompanhamento clínico das restaurações minimamente invasivas.

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Anexo A - Aprovação do Estudo Clínico pela Comissão de Ética em Pesquisa da Universidade Estadual de Ponta Grossa

UNIVERSIDADE ESTADUAL DE PONTA GROSSA - UEPG

Plataforma Brasil

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Ensaio clínico randomizado duplo cego utilizando diferentes materiais em dentes decíduos pela técnica ART: três anos de acompanhamento.

Pesquisador: Ana Cláudia Rodrigues Chibinski

Área Temática:

Versão: 2

CAAE: 60614616.3.0000.0105

Instituição Proponente: Universidade Estadual de Ponta Grossa

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.064.952

Apresentação do Projeto:

Projeto de Pesquisa: Ensaio clínico randomizado duplo cego utilizando diferentes materiais em dentes decíduos pela técnica ART: três anos de acompanhamento.

Objetivo da Pesquisa:

Objetivo Primário:

Realizar restaurações classe I e II em crianças de 4 a 9 anos nas próprias instituições de ensino da cidade de Ponta Grossa-PR com diferentes materiais.

Objetivo Secundário:

- Verificar o desempenho das restaurações, em função dos diferentes materiais utilizados, nos períodos de 6, 12, 24, 36 meses após término de realização das mesmas; - Verificar o desempenho de restaurações, em função do tipo de cavidade restaurada (classe I ou II), nos períodos de 6, 12, 24, 36 meses após término de realização das mesmas; - Encaminhar as crianças com lesões de maior severidade (dor espontânea, indicação de exodontias, endodontias) para atendimento na UEPG. - Realizar escovação supervisionada e palestras sobre higienização para todas as crianças avaliadas nas escolas, não só para as selecionadas para o estudo.

Endereço: Av. Gen. Carlos Cavalcanti, nº 4748, UEPG, Campus Uvaranas, Bloco M, Sala 100.
Bairro: Uvaranas **CEP:** 84.030-900
UF: PR **Município:** PONTA GROSSA
Telefone: (42)3220-3108 **E-mail:** coep@uepg.br

UNIVERSIDADE ESTADUAL DE PONTA GROSSA - UEPG

Continuação do Parecer: 2.084.052

Avaliação dos Riscos e Benefícios:

Riscos:

Sensibilidade pós procedimento.

Benefícios:

Benefícios- Contribuição social e científica na área de Odontologia Preventiva e Restauradora

Comentários e Considerações sobre a Pesquisa:

A técnica de Restauração atraumática (ART) é uma técnica amplamente utilizada na Odontologia Preventiva e Minimamente invasiva, porém a baixa taxa de longevidade de restaurações classe II pela técnica sugere baixa resistência e alto grau de desgaste do material de primeira escolha utilizado (cimento de ionômero de vidro de alta viscosidade), permanecendo assim, esses tipos de restaurações e o uso dos diversos materiais, desafio e limitação para o clínico. Para isso, o objetivo do Trabalho será realizar restaurações classe I e II em crianças de 4 a 9 anos nas próprias instituições de ensino da cidade de Ponta Grossa-PR com diferentes materiais, verificando o desempenho das restaurações, em função dos diferentes materiais utilizados, e do tipo de cavidade restaurada (classe I ou II) nos períodos de 6, 12, 24, 36 meses após término de realização das mesmas.

Considerações sobre os Termos de apresentação obrigatória:

Em anexo e de acordo com as normativas

Recomendações:

Solicita-se que ao final do projeto de pesquisa seja enviado o relatório final por notificação via plataforma brasil para evitar pendências com a Propesp ou com o CEP-UEPG

Conclusões ou Pendências e Lista de Inadequações:

Aprovado

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_800687.pdf	25/04/2017 18:20:22		Aceito
Outros	autoriz_pesquisa.jpg	25/04/2017 18:18:44	Ana Cláudia Rodrigues Chibinski	Aceito

Endereço: Av. Gen. Carlos Cavalcanti, nº 4748, UEPG, Campus Uvaranas, Bloco M, Sala 100.
Bairro: Uvaranas **CEP:** 84.030-900
UF: PR **Município:** PONTA GROSSA
Telefone: (42)3220-3108 **E-mail:** cosp@uepg.br

UNIVERSIDADE ESTADUAL DE PONTA GROSSA - UEPG

Continuação do Parecer: 2.084.552

TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_para_plataforma_projeto_2.docx	23/11/2016 15:56:18	Ana Cláudia Rodrigues Chibinski	Aceito
Folha de Rosto	folhaderostopdfprojeto2.pdf	03/10/2016 15:20:34	Ana Cláudia Rodrigues Chibinski	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_final_Plataforma.docx	28/09/2016 11:16:12	Ana Cláudia Rodrigues Chibinski	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

PONTA GROSSA, 16 de Maio de 2017

Assinado por:
ULISSES COELHO
(Coordenador)

Endereço: Av. Gen. Carlos Cavalcanti, nº 4748. UEPG, Campus Uvaranas, Bloco M, Sala 100.
Bairro: Uvaranas **CEP:** 84.030-900
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ANEXO B- REBEC: “Ensaio Clínico Randomizado Duplo Cego utilizando diferentes Materiais em Dentes Decíduos pela Técnica ART: Três Anos de Acompanhamento”.

RBR-9nqszr

Ensaio clínico randomizado duplo cego utilizando diferentes materiais em dentes decíduos pela técnica ART: três anos de acompanhamento

Data de registro: 22 de Junho de 2017 às 15:34

Last Update: 23 de Julho de 2019 às 09:17

Tipo do estudo:

Intervenções

Título científico:

PT-BR

Ensaio clínico randomizado duplo cego utilizando diferentes materiais em dentes decíduos pela técnica ART: três anos de acompanhamento

EN

Randomized double blind clinical trial using different materials on teeth By ART technique: three years of follow-up

Identificação do ensaio

Número do UTN: U1111-1198-3193

Título público:

PT-BR

Diferentes materiais para a técnica de Restauração Atraumática em dentes decíduos, uma investigação clínica

EN

Different materials for the Atraumatic Restorative Treatment technique in deciduous teeth, a clinical investigation

Acrônimo científico:

Acrônimo público:

Identificadores secundários:

Plataforma Brasil
Órgão emissor: 60614616.3.0000.0105

Comitê de Ética em Pesquisa da Universidade Estadual de Ponta Grossa.
Órgão emissor: CEP: 2.064.952

Patrocinadores

Patrocinador primário: Universidade Estadual de Ponta Grossa

Patrocinadores secundários:

Instituição: Universidade Estadual de Ponta Grossa

Fontes de apoio financeiro ou material:

Instituição: Universidade Estadual de Ponta Grossa

Condições de saúde

Condições de saúde ou problemas:

PT-BR	EN
Tratamento dentário restaurador sem trauma; Cárie dentária; Crianças; Dente decíduo	Dental Atraumatic Restorative Treatment; Dental caries; Child; Tooth Deciduous

Descritores gerais para as condições de saúde:

PT-BR	ES	EN
C07: Doenças estomatognáticas	**C07:** Enfermedades estomatognáticas	**C07:** Stomatognathic diseases

Descritores específicos para as condições de saúde:

PT-BR	ES	EN
C07.793.720.210: Cárie Dentária	**C07.793.720.210:** Caries Dental	**C07.793.720.210:** Dental Caries
A14.549.167.860.700: Dente Decíduo	**A14.549.167.860.700:** Diente Primario	**A14.549.167.860.700:** Tooth, Deciduous
E06.070: Tratamento Dentário Restaurador sem Trauma	**E06.070:** Tratamiento Restaurativo Atraumático Dental	**E06.070:** Dental Atraumatic Restorative Treatment
M01.060.406: Criança	**M01.060.406:** Niño	**M01.060.406:** Child

Intervenções

Categorias das intervenções

Other

Intervenções:

Intervenções:

PT-BR

Serão realizadas 108 restaurações (36 no grupo controle, 36 no grupo intervenção com adesivo e 36 no grupo intervenção sem adesivo previamente) em molares decíduos em escolas Municipais da cidade de Ponta Grossa. Controle: o biofilme dental excedente será removido com escovação dental supervisionada. O preparo cavitário consistirá na remoção da dentina infectada com colheres de dentina escolhidas de acordo com o tamanho da cavidade. Após este procedimento, a cavidade será limpa com algodão embebido em água e seca com rolos de algodão. O Primer (indicado pelo fabricante) será aplicado e fotopolimerizado 20s. Então, o cimento de ionômero de vitro será manipulado de acordo com as instruções do fabricante e inserido na cavidade com espátulas de resina e será fotopolimerizado. Será checada a oclusão do paciente com papel carbono, e, caso haja excesso, estes serão removidos.
Intervenção com adesivo previamente: os mesmos passos do procedimento do grupo controle serão realizados com material diferente.
Intervenção sem adesivo previamente: Seguirá a mesma sequência do preparo cavitário, mas não existirá a aplicação prévia do adesivo. Assim, o material será inserido diretamente na cavidade e será fotopolimerizado.

EN

There will be 108 restorations (36 in the control group, 36 in the intervention group with adhesive and 36 in the intervention group without adhesive previously) in primary molars in municipal schools in the city of Ponta Grossa. Control: The excess dental biofilm will be removed with supervised dental brushing. Cavity preparation will consist of the removal of infected dentin with dentine spoons chosen according to cavity size. After this procedure, the cavity will be cleaned with cotton soaked in water and dried with cotton rolls. Primer (indicated by the manufacturer) will be applied and photopolymerized 20s. Then, the tumer ionomer cement will be handled according to the manufacturer's instructions and inserted into the cavity with resin spatulas and will be photopolymerized. The patient will be occluded with carbon paper, and if there is excess, they will be removed.
Intervention with adhesive previously: the same steps of the procedure of the control group will be realized with different material.
Intervention without adhesive previously: It will follow the same sequence of the preparation cavity, but there will not be the previous application of the adhesive. Thus, the material will be inserted directly into the cavity and will be photopolymerized.

Descritores para as Intervenções:

PT-BR

E06.323.428: Restauração Dentária Permanente

ES

E06.323.428: Restauración Dental Permanente

PT-BR

E06.584: Reabilitação Bucal

ES

E06.584: Rehabilitación Bucal

muito profundas; dentes fistulados; dentes com referida dor espontânea.

Tipo do estudo

Desenho do estudo:

PT-BR

Ensaio clínico de tratamento, randomizado controlado, paralelo, duplo cego, dois braços.

EN

Clinical trial of treatment, randomized controlled, parallel, double blind, two arms.

Programa de acesso expandido	Enfoque do estudo	Desenho da intervenção	Número de braços	Tipo de mascaramento
Nenhum	Treatment	Parallel	2	Double-blind

Desfechos

Desfechos primários:

PT-BR

Retenção das restaurações nas cavidades a longo prazo. Este número será obtido através de escores atribuídos às restaurações em suas avaliações (escores 0 e 1 serão considerados sucesso, os escores 2 ao 6 insucesso e os escores 7,8 e 9 serão excluídos da amostra). os valores serão transformado em percentual representados em gráficos. As avaliações serão feitas a cada 6 meses, 1 ano, 2 e 3 anos.

EN

Retention of restorations in the long-term cavities. This number will be obtained through scores attributed to restorations in their evaluations (scores 0 and 1 will be considered success, scores 2 to 6 fail and scores 7, 8 and 9 will be excluded from the sample). The values will be transformed into percentages represented in graphs.Evaluations will be done every 6 months, 1 year, 2 and 3 years.

Desfechos secundários:

PT-BR

Não são esperados desfechos secundários.

EN

Secondary outcomes are not expected.

Contatos

Contatos para questões públicas

Nome completo: Alessandra Reis

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Filiação: Universidade Estadual de Ponta Grossa

Contatos para questões científicas

Nome completo: Alessandra Reis

Endereço: Av. General Carlos Cavalcanti, 4748.

Anexo C – Aprovação do Estudo Clínico pela Comissão de Ética em Pesquisa da Universidade Estadual de Ponta Grossa

UNIVERSIDADE ESTADUAL DE PONTA GROSSA - UEPG

Plataforma Brasil

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Ensaio clínico randomizado duplo cego utilizando resina Bulk Fill flow em dentes decíduos pela técnica ART: três anos de acompanhamento

Pesquisador: Ana Cláudia Rodrigues Chibinski

Área Temática:

Versão: 1

CAAE: 60614716.7.0000.0105

Instituição Proponente: Universidade Estadual de Ponta Grossa

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.795.655

Apresentação do Projeto:

Ensaio clínico randomizado duplo cego utilizando resina Bulk Fill flow em dentes decíduos pela técnica ART: três anos de acompanhamento

Objetivo da Pesquisa:

Realizar restaurações classe I e II em crianças de 4 a 9 anos com resina Bulk-fill flow.

Avaliação dos Riscos e Benefícios:

Riscos associados a sensibilidade pós procedimentos.

Benefícios:

Contribuição social e científica na área de Odontologia Preventiva e Restauradora.

Comentários e Considerações sobre a Pesquisa:

Pesquisa simples rotineira e de ampla execução.

Considerações sobre os Termos de apresentação obrigatória:

Corretos.

Recomendações:

Aprovação.

Endereço: Av. Gen. Carlos Cavalcanti, nº 4748, UEPG, Campus Uvaranenas, Bloco M, Sala 100.
Bairro: Uvaranas **CEP:** 84.030-900
UF: PR **Município:** PONTA GROSSA
Telefone: (42)3220-3108 **E-mail:** coep@uepg.br

UNIVERSIDADE ESTADUAL DE PONTA GROSSA - UEPG

Continuação do Parecer: 1.766.655

Conclusões ou Pendências e Lista de Inadequações:

Aprovado

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_799957.pdf	03/10/2016 15:15:55		Aceito
Folha de Rosto	BULKFOLHADEROSTOPDF.pdf	03/10/2016 15:14:23	Ana Claudia Rodrigues Chibinski	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_PlataformaBrasil_bulk.docx	03/10/2016 10:21:03	Ana Claudia Rodrigues Chibinski	Aceito
Projeto Detalhado / Brochura Investigador	Final_Projeto_Bulk_para_Plataforma.docx	28/09/2016 11:08:17	Ana Claudia Rodrigues Chibinski	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

PONTA GROSSA, 27 de Outubro de 2016

Assinado por:
ULISSES COELHO
(Coordenador)

Endereço: Av. Gen. Carlos Cavalcanti, nº 4748, UEPG, Campus Uvaranenas, Bloco M, Sala 100.
Bairro: Uvaranas **CEP:** 84.030-900
UF: PR **Município:** PONTA GROSSA
Telefone: (42)3220-3108 **E-mail:** coep@uepg.br

ANEXO D – REBEC: “Ensaio Clínico Randomizado Duplo Cego utilizando Resina Bulk Fill em Dentes Decíduos pela Técnica Minimamente Invasiva: Três Anos de Acompanhamento”.

Ensaios Clínicos

USUÁRIO SENHA

PT | ES | EN

NOTÍCIAS | SOBRE | AJUDA | CONTATO

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RBR-98r97j

Ensaio clínico randomizado duplo cego utilizando resina Bulk Fill flow em dentes decíduos pela técnica minimamente invasiva: três anos de acompanhamento.

Data de registro: 4 de Maio de 2017 às 14:13

Last Update: 18 de Junho de 2019 às 15:27

Tipo do estudo:

Intervenções

Título científico:

PT-BR

Ensaio clínico randomizado duplo cego utilizando resina Bulk Fill flow em dentes decíduos pela técnica minimamente invasiva: três anos de acompanhamento.

EN

Randomized double blind clinical trial using Bulk Fill flow resin in deciduous teeth by minimally invasive technique: three years of follow-up.

Identificação do ensaio

Número do UTN: U1111-1196-3132

Título público:

PT-BR

Investigação clínica em dentes decíduos utilizando resina Bulk Fill flow.

EN

Clinical investigation in deciduous teeth using Bulk Fill flow resin.

Acrônimo científico:

Acrônimo público:

Identificadores secundários:

1.795.655

Órgão emissor: Comitê de Ética em Pesquisa da Universidade Estadual de Ponta Grossa

60614716.7.0000.0105

Órgão emissor: Plataforma Brasil/ Sistema Nacional de Ética em Pesquisa

Patrocinadores

Patrocinador primário: Universidade Estadual de Ponta Grossa

Patrocinador primário: Universidade Estadual de Ponta Grossa

Patrocinadores secundários:

Instituição: Universidade Estadual de Ponta Grossa

Fontes de apoio financeiro ou material:

Instituição: Universidade Estadual de Ponta Grossa

Condições de saúde

Condições de saúde ou problemas:

PT-BR
Cárie dentária; Crianças; Dente decíduo

EN
Dental caries, Child; Tooth, Deciduous

Descritores gerais para as condições de saúde:

PT-BR
C07: Doenças estomatognáticas

ES
C07: Enfermedades estomatognáticas

EN
C07: Stomatognathic diseases

Descritores específicos para as condições de saúde:

PT-BR
C07.793.720.210: Cárie Dentária

ES
C07.793.720.210: Caries Dental

EN
C07.793.720.210: Dental Caries

PT-BR
M01.060.406: Criança

ES
M01.060.406: Niño

EN
M01.060.406: Child

PT-BR
A14.545.167.860.700: Dente Decíduo

ES
A14.545.167.860.700: Diente Primario

EN
A14.545.167.860.700: Tooth, Deciduous

Intervenções

Categorias das intervenções
Other

Intervenções:

Intervenções:

PT-BR
Serão realizadas 89 restaurações (44 no Grupo BCR e 45 para Grupo BSE)em molares decíduos em Clínicas Odontológicas da Universidade Estadual de Ponta Grossa. Grupo BCR: O Biofilme dental excedente será removido com profilaxia com pedra pomes, água e escova Robinson Reta. Previamente ao preparo cavitário, o dente que será restaurado, será submetido ao isolamento absoluto. O preparo cavitário consistirá na remoção da dentina infectada com colheres de dentina escolhidas de acordo com o tamanho da cavidade. Após este procedimento, a cavidade será limpa com jato de água e seca com ar comprimido e então condicionada com ácido fosfórico a 37% sobre o esmalte, e depois, dentina. O ácido deverá ser deixado para reagir sobre o esmalte por 15 a 30 segundos e na dentina por 10 a 15 segundos. Em seguida, será enxaguado com um fluxo vigoroso de água por pelo menos 5 segundos e seco com ar comprimido até que a superfície fique opaca. Será então aplicado adesivo

EN
There will be 89 restorations (44 in the BER Group and 45 in the BSE Group) in primary molars in Dental Clinics of the State University of Ponta Grossa. BER Group: The excess dental Biofilm will be removed with prophylaxis with pumice stone, water and Straight Robinson brush. Prior to cavity preparation, the tooth to be restored will be subjected to absolute insulation. Cavity preparation will consist of the removal of infected dentin with dentine spoons chosen according to cavity size. After this procedure, the cavity will be flushed and dried with compressed air and then conditioned with 37% phosphoric acid on the enamel, and then dentin. The acid should be allowed to react on the enamel for 15 to 30 seconds and in the dentin for 10 to 15 seconds. It will then be rinsed with a vigorous flow of water for at least 5 seconds and dried with compressed air until the surface is opaque. The adhesive will then be actively applied for 20 seconds, air-dried for 5 seconds and photoactivated for 20 seconds. Then, the insertion of the

ativamente durante 20 segundos, seco com jato de ar por 5 segundos e fotoativado por 20 segundos. Então, a inserção do material na cavidade será feita com o auxílio de espátulas de resina, sendo a Resina Bulk fill flow inserida em um único incremento. O material será fotoativado de acordo com o tempo pré-determinado pelo fabricante (30s). Após fotopolimerização, será checada a oclusão do paciente com papel carbono, caso haja excesso, estes serão removidos. Então, o material será polido com pontas polidoras de borracha devidamente adaptadas em Baixa Rotação. Grupo BSE: O Biofilme dental excedente será removido com profilaxia com pedra pomes, água e escova Robinson Reta. Após, o dente que será restaurado será submetido ao isolamento absoluto. O preparo cavitário consistirá na remoção da dentina infectada com colheres de dentina escolhidas de acordo com o tamanho da cavidade. Após este procedimento, será aplicado adesivo ativamente durante 20 segundos, seco com jato de ar por 5 segundos e fotoativado por 20 segundos (sem aplicação prévia de ácido fosfórico). Então, a inserção do material na cavidade será feita com o auxílio de espátulas de resina, sendo a Resina Bulk fill flow inserida em um único incremento. O material será fotoativado de acordo com o tempo pré-determinado pelo fabricante (30s). Após fotopolimerização, será checada a oclusão do paciente com papel carbono, caso haja excesso, estes serão removidos. Então, o material será polido com pontas polidoras de borracha devidamente adaptadas em Baixa Rotação.

material into the cavity will be done with the aid of resin spatulas, with the Bulk fill resin being inserted in a single increment. The material will be photoactivated according to the time predetermined by the manufacturer (30s). After photopolymerization, the patient will be occluded with carbon paper, if there is excess, they will be removed. Then the material will be polished with properly adjusted rubber polishing tips in Low Rotation.
BSE Group: The excess dental biofilm will be removed with prophylaxis with pumice stone, water and Straight Robinson brush. Afterwards, the tooth that will be restored will be subjected to absolute isolation. Cavity preparation will consist of the removal of infected dentin with dentine spoons chosen according to cavity size. After this procedure, the adhesive will be applied actively for 20 seconds, air-dried for 5 seconds and photoactivated for 20 seconds (without prior application of phosphoric acid). Then, the insertion of the material into the cavity will be done with the aid of resin spatulas, with the Bulk fill resin being inserted in a single increment. The material will be photoactivated according to the time predetermined by the manufacturer (30s). After photopolymerization, the patient will be occluded with carbon paper, if there is excess, they will be removed. Then the material will be polished with properly adjusted rubber polishing tips in Low Rotation.

Descritores para as intervenções:

PT-BR	ES
E06.323.428: Restauração Dentária Permanente	**E06.323.428:** Restauración Dental Permanente
A14.549.167.860.700: Dente Decíduo	**A14.549.167.860.700:** Diente Primario

Recrutamento

Situação de recrutamento: Recruitment completed

País de recrutamento
Brazil

Data prevista do primeiro recrutamento: 2017-05-02

Data prevista do último recrutamento: 2017-05-03

Tamanho da amostra alvo:	Gênero para inclusão:	Idade mínima para inclusão:	Idade máxima para inclusão:
30	-	6 Y	9 Y

Critérios de inclusão:

PT-BR	EN
Crianças Voluntárias sadias; ambos os gêneros; devidamente matriculadas em escolas municipais ou estaduais; com nível de higiene oral aceitável; com no mínimo 6 anos e no máximo 9 anos.	Healthy volunteer children; Both genders; Duly enrolled in municipal or state schools; With an acceptable oral hygiene level; With a minimum of 6 years and a maximum of 9 years.

Critérios de exclusão:

PT-BR	EN
Crianças que não aceitarem o exame bucal ou a realização das restaurações; as que faltarem no dia agendado das restaurações; aquelas cujos responsáveis não assinarem o Termo de Consentimento Livre e Esclarecido; dentes com lesões cariosas muito profundas; dentes fistulados; dentes com referida dor espontânea.	Children who do not accept oral examination or restoration; Those that are missing on the scheduled restoration day; Those whose managers do not sign the Free and Informed Consent Form; Teeth with very deep carious lesions; Fistulated teeth; With such spontaneous pain.

Tipo do estudo

Desenho do estudo:

PT-BR	EN
Ensaio clínico de tratamento, randomizado controlado, paralelo, duplo-cego, dois braços.	Clinical trial of treatment, randomized controlled, parallel, double-blind, two arms.

Programa de acesso expandido	Enfoque do estudo	Desenho da intervenção	Número de braços	Tipo de mascaramento	Tipo de alocação	Fase do estudo
Falso	Treatment	Parallel	2	Double-blind	Randomized-controlled	N/A

Desfechos

Desfechos primários:

PT-BR	EN
Desfecho Primário: Retenção e fratura das restaurações nas cavidades a longo prazo. Os critérios que serão utilizados para avaliar as restaurações são de Hickel et al, 2007. Os valores serão transformados em porcentagens representados em gráficos.	Primary outcome: Retention and fracture of long-term restorations in the cavities. The criteria that will be used to evaluate restorations are by Hickel et al, 2007. The values will be transformed into percentage represented in graphs.

Desfechos secundários:

PT-BR	EN
Desfechos secundários: Serão avaliados os seguintes aspectos: adaptação marginal, forma anatômica, brilho da superfície, estabilidade da cor, translucidez e coloração da superfície, coloração marginal e a sensibilidade pós-operatória das restaurações. Os critérios que serão utilizados para avaliar as restaurações são de Hickel et al, 2007. Os valores serão transformados em porcentagens representados em gráficos.	Secondary outcome: The following aspects will be evaluated: marginal adaptation, anatomical shape, surface brightness, color stability, translucency and surface color, marginal staining and postoperative sensitivity of restorations. riteria that will be used to evaluate restorations are of Hickel et al, 2007. The values will be transformed into percentage represented in graphs.

Contatos

Contatos para questões públicas

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Contatos para informação sobre os centros de pesquisa

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Revisão Anterior

Links adicionais:

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Anexo E – Ficha Clínica usada para Avaliação do Paciente

Classe I

Avaliação Número 1 FDI -Nome da escola

Nome	Surface lustre									
	A (VG)		B (G)		C (S)		D (US)		E (P)	
	A	B	A	B	A	B	A	B	A	B
N.dente	0	0	0	0	0	0	0	0	0	0
e classe										
	A (VG)		B (G)		C (S)		D (US)		E (P)	
N.dente	A	B	A	B	A	B	A	B	A	B
e classe	0	0	0	0	0	0	0	0	0	0

Nome	Color match and translucency									
	A (VG)		B (G)		C (S)		D (US)		E (P)	
	A	B	A	B	A	B	A	B	A	B
N.dente	0	0	0		0		0	0	0	0
e classe										
	A (VG)		B (G)		C (S)		D (US)		E (P)	
N.dente	A	B	A	B	A	B	A	B	A	B
e classe	0	0	0		0		0	0	0	0

Nome	Esthetic anatomic form									
	A (VG)		B (G)		C (S)		D (US)		E (P)	
	A	B	A	B	A	B	A	B	A	B
N.dente	0	0	0	0	0	0	0	0	0	0
e classe										
	A (VG)		B (G)		C (S)		D (US)		E (P)	
N.dente	A	B	A	B	A	B	A	B	A	B
e classe	0	0	0	0	0	0	0	0	0	0

Nome	Fracture of material and retention									
	A (VG)		B (G)		C (S)		D (US)		E (P)	
	A	B	A	B	A	B	A	B	A	B
N.dente	0	0	0	0	0	0	0	0	0	0
e classe										
	A (VG)		B (G)		C (S)		D (US)		E (P)	
N.dente	A	B	A	B	A	B	A	B	A	B
e classe	0	0	0	0	0	0	0	0	0	0

Nome	Marginal adaptation									
	A (VG)		B (G)		C (S)		D (US)		E (P)	
	A	B	A	B	A	B	A	B	A	B
N.dente	0	0	0	0	0	0	0	0	0	0
e classe										
	A (VG)		B (G)		C (S)		D (US)		E (P)	
N.dente	A	B	A	B	A	B	A	B	A	B
e classe	0	0	0	0	0	0	0	0	0	0

Classe II

Avaliação Número 1 FDI -Nome da escola

Nome	Surface lustre									
	A (VG)		B (G)		C (S)		D (US)		E (P)	
	A	B	A	B	A	B	A	B	A	B
N.dente	0	0	0	0	0	0	0	0	0	0
e classe										
	A (VG)		B (G)		C (S)		D (US)		E (P)	
N.dente	A	B	A	B	A	B	A	B	A	B
e classe	0	0	0	0	0	0	0	0	0	0

Nome	Color match and translucency									
	A (VG)		B (G)		C (S)		D (US)		E (P)	
	A	B	A	B	A	B	A	B	A	B
N.dente	0	0	0		0		0	0	0	0
e classe										
	A (VG)		B (G)		C (S)		D (US)		E (P)	
N.dente	A	B	A	B	A	B	A	B	A	B
e classe	0	0	0		0		0	0	0	0

Nome	Esthetic anatomic form									
	A (VG)		B (G)		C (S)		D (US)		E (P)	
	A	B	A	B	A	B	A	B	A	B
N.dente	0	0	0	0	0	0	0	0	0	0
e classe										
	A (VG)		B (G)		C (S)		D (US)		E (P)	
N.dente	A	B	A	B	A	B	A	B	A	B
e classe	0	0	0	0	0	0	0	0	0	0

Nome	Fracture of material and retention									
	A (VG)		B (G)		C (S)		D (US)		E (P)	
	A	B	A	B	A	B	A	B	A	B
N.dente	0	0	0	0	0	0	0	0	0	0
e classe										
	A (VG)		B (G)		C (S)		D (US)		E (P)	
N.dente	A	B	A	B	A	B	A	B	A	B
e classe	0	0	0	0	0	0	0	0	0	0

Nome	Marginal adaptation									
	A (VG)		B (G)		C (S)		D (US)		E (P)	
	A	B	A	B	A	B	A	B	A	B
N.dente	0	0	0	0	0	0	0	0	0	0
e classe										
	A (VG)		B (G)		C (S)		D (US)		E (P)	
N.dente	A	B	A	B	A	B	A	B	A	B
e classe	0	0	0	0	0	0	0	0	0	0