UNIVERSIDADE FEDERAL DO RIO DE JANEIRO
Centro de Ciências da Saúde
Faculdade de Odontologia

ESTUDO CLÍNICO PROSPECTIVO DE RESTAURAÇÕES ADESIVAS DIRETAS EM MOLARES DECÍDUOS: 48 MESES DE ACOMPANHAMENTO

MÁRCIA PEREIRA ALVES DOS SANTOS
CD, MO

Rio de Janeiro
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Tese de Doutorado submetida ao Programa de Pós-graduação em Odontologia (Área de Concentração: Odontopediatria) da Faculdade de Odontologia da Universidade Federal do Rio de Janeiro como parte dos requisitos para obtenção do título de Doutor em Odontologia (Área de Concentração: Odontopediatria).

Orientador:
Prof.ª Dr.ª Lucianne Cople Maia, CD, MO, DO

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FOLHA DE APROVAÇÃO

MÁRCIA PEREIRA ALVES DOS SANTOS

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"É propriamente não valer nada não ser útil a ninguém".
René Descartes

RESUMO

SANTOS, Márcia Pereira Alves dos. **Estudo clínico prospectivo de restaurações adesivas diretas em molares decíduos: 48 meses de acompanhamento.** Orientador: Prof.ª Dr.ª Lucianne Cople Maia. Rio de Janeiro, 2009. Tese (Doutorado em Odontologia, área de concentração em Odontopediatria) Faculdade de Odontologia, Universidade Federal do Rio de Janeiro, Rio de Janeiro, 2009.113. f

O presente estudo avaliou a sobrevida de restaurações adesivas diretas Classe I e Classe II em preparos cavitários biselados de molares decíduos após 48 meses de acompanhamento e determinou, por meio da revisão sistemática da literatura, o benefício ou não do bisel no ângulo cavo-superficial em preparos Classe I e Classe II para restaurações adesivas em molares decíduos. Para tal, quarenta e oito crianças com média de idade de 5,9 anos receberam 141 restaurações aleatorizadas pelo método da loteria, das quais, 46 restaurações feitas com Cimento de Ionômero de Vidro modificado por componentes resinosos, Vitremer®, 3M ESPE, 33 restaurações eram Classe I e 13 restaurações eram Classe II; das 51 restaurações realizadas com Compômero, Freedom®, SDI, 36 eram restaurações Classe I e 15 restaurações eram Classe II; das 44 restaurações com Compósito, TPH Spectrum®, Dentsply, 30 restaurações eram Classe I e 14 restaurações eram Classe II. As restaurações foram avaliadas por dois examinadores treinados (Kappa ponderado ≥ 0,85) por meio do método U.S. Public Health Service modificado e presença de biofilme dental visível no período inicial e após 12, 24, 36 e 48 meses de acompanhamento. Os dados foram tratados estatisticamente pelo Teste Qui-Quadrado e pela análise de sobrevida por meio da regressão de Cox e teste Kaplan-Meier com Log Rank a um nível de 95% de confiança. Após 48 meses, 11 dentes esfoliaram, 16 restaurações não foram avaliadas por falta às consultas, 83 restaurações foram consideradas sucessos clínicos, destas 26 restaurações eram de Vitremer® (20 eram Classe I e 06 eram Classe II); 32 eram de Freedom® (27 eram Classe I e 05 eram Classe II) e 25 eram de TPH Spectrum® (18 eram Classe I e 07 eram Classe II); 31 restaurações fracassaram por cárie secundária, fratura e perda total das restaurações. Portanto, a sobrevida das restaurações foi de 73.9% para o Vitremer®, 83.4% para Freedom® e 79.6% para TPH Spectrum®, sem diferença entre os materiais. Paralelamente, para a revisão sistemática foi realizada uma busca eletrônica com os descritores: preparo cavitário dental, dente/molar decíduo; materiais restauradores a base de compósitos limitados a estudos clinicos aleatórios controlados. Três estudos foram considerados como nível A de evidência científica. Após metanálise, a efetividade do bisel no ângulo cavo-superficial em molares decíduos não foi comprovada e por isso, tal procedimento atualmente não deve ser recomendado na prática clínica.

Palavras Chave: Ensaio clínico, materiais dentários, molar, dente decíduo, Análise de sobrevida, revisão sistemática.

SUMMARY

SANTOS, Márcia Pereira Alves dos. **Estudo clínico prospectivo de restaurações adesivas diretas em molares decíduos: 48 meses de acompanhamento**. Orientadora: Prof.ª Dr.ª Lucianne Cople Maia. Rio de Janeiro, 2009. Tese (Doutorado em Odontologia, área de concentração em Odontopediatria) Faculdade de Odontologia, Universidade Federal do Rio de Janeiro, Rio de Janeiro, 2009. 113. f

This study aimed to evaluate the survival of direct adhesive restorations in beveled Class I and Class II preparations in primary molars after 48 months, and to determine, through systematic review of the literature, the benefit of this cavity design for adhesive restorations in primary molars. Forty-eight children (mean age, 5 years and 9 months) received 141 restorations in beveled Class I and Class II preparations in primary molars randomly assigned by lottery method: 46 received treatment with Vitremer™ Tri-Cure Glass Ionomer System , 3M ESPE Dental Products, St. Paul, Minn., 33 Class I and13 Class II restoration; 51 received treatment with Freedom™, SDI, Bayswater, Victoria, Australia, 36 Class I and 15 Class II restorations; 44 received treatment with TPH Spectrum™ , Dentsply, Petropolis, Rio de Janeiro, Brazil; 30 Class I and 14 Class II restorations. Two calibrated examiners (weight *Kappa* ≥ 0.85) evaluated the restorations using modified USPHS criteria and Visible Plaque Index score at baseline and after 12, 24, 36 and 48 months. Qui-Square tests and survival analysis technique with Kaplan-Meier/ Log-Rank test and Cox regression evaluated the clinical performance of restorations at 95 confidence intervals. After 48-months, 11 teeth had exfoliated, 16 were drop-outs, 83 restorations were successful of which 26 were done with Vitremer™ (20 Class I / 06 Class II), 32 were done with Freedom™ (27 Class I/ 05 Class II) and 25 were done with TPH Spectrum™ (18 Class I / 07 Class II). Thirty-one restorations failed because of secondary caries, fractures and loss of retention. The cumulative survival was 73.9%, 83.4% and 79.6%, respectively for Vitremer™, Freedom™ and THP Spectrum™ with no differences among materials (Log Rank Mantel-Cox, $p>0.05$). However, the Class II cavity preparation reduced the survival of the restorations (OR = 5.1) for all materials evaluated ($p> 0.05$). In addition, for the systematic review, an electronic search with Mesh terms such as: dental cavity preparation, tooth / molar deciduous; resin based materials limited to randomized controlled trials was conducted. Three studies were considered as scientific evidence. After meta-analysis, the effectiveness of the bevel at cavosurface angle in Class I and Class II preparations for adhesive restorations in primary molars was not proven and therefore this procedure should not currently be recommended in clinical practice.

Keywords: Clinical Trial, Dental Materials, Molar, Tooth/Deciduous, Survival analyses.

RESUMEN

SANTOS, Márcia Pereira Alves dos. **Estudo clínico prospectivo de restaurações adesivas diretas em molares decíduos: 48 meses de acompanhamento**. Orientadora: Prof.ª Dr.ª Lucianne Cople Maia. Rio de Janeiro, 2009. Tese (Doutorado em Odontologia, área de concentração em Odontopediatria) Faculdade de Odontologia, Universidade Federal do Rio de Janeiro, Rio de Janeiro, 2009. 113. f

Les objectifs de cette étude était d'évalue le survie des restaurations adhésifs directes effectuées dans prepare occlusaux et occluso-proximales biseauté dans molaires primaire après 48 mois et de déterminer, grâce à un examen systématique de la littérature, le bénéfice de cette cavité design pour les restaurations adhésifs dans les molaires primaire. Cent quarante et un des restaurations par la méthode aléatoire de la loterie ont été réalisées dans 48 enfants avec la moyenne d'âge de 5,9 ans. Sur les quarante et six restaurations réalisés avec Vitremer®, 3M ESPE, 33 restaurations ont été de Classe I et 13 restaurations ont été de Classe II, des cinquante et un restaurations effectuées avec Fredom, ® SDI, 36 ont été restaurations Classes I et 15 restaurations ont été Classe II, de quarante et quatre restaurations réalisée avec TPH Spectrum®, Dentsply, 30 restaurations ont été Classe I et 14 restaurations ont été Classe II. Les restaurations ont été évalués par deux examinateurs (kappa pondérée ≥ 0,85) en utilisant la méthode modifiée U. S. Service de Santé Publique et de la présence de biofilm dentaire visible dans la période initiale et après 12, 24, 36 et 48 mois de suivi. Les données ont été analysées statistiquement par le Chi-Square test, technique d'analyse de survie avec de la régression de Cox, et le Kaplan-Meier test avec Log-Rank, le tout au niveau de 95% de confiance. Après 48 mois de suivi, 11 dents a exfoliée, 16 restaurations ont été abandons, 83 des restaurations ont été considérées cliniquement acceptables, dont 26 des restaurations ont été avec Vitremer® (20 ont été Classe I et 06 Classe II), 32 ont été avec Freedom® (27 ont été Classe I et 05 Classe II) et 25 ont été avec TPH Spectrum® (18 ont été Classe I et 07 Classe II). Trente et un des restaurations échoué en raison de caries secondaires, les fractures et la perte de la rétention. Le cumulative de survie était de 73,9%, 83,4% et 79,6%, respectivement pour Vitremer®, Freedom® et THP Spectrum® (p>0.05). Classe II preparation réduit le survie des restaurations pour tous les matériaux évalués (OR= 5.1; p> 0,05). Vitremer®, Freedom® et TPH Spectrum® utilisées dans les préparations de Classe I et II en molaires primaires biseauté, Pour l'examen systématique a été effectué une recherche électronique avec les mots-clés: préparation de la cavité dentaire, dent / molaire primaire; matériaux de restauration basée sur les composites limitée à des essais contrôlés randomisés. Trois études ont été considérés comme le niveau de preuve scientifique. Après méta-analyse, l'efficacité de le biseau sur les molaires primaires n'a pas été étayée et donc cette procédure ne doit pas actuellement être recommandées en pratique clinique.

Mots-clés: Étude clinique, Matériaux dentaires, Molaires primaires, le survie analyses, l'adhésion dentaire, Esthétique.

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LISTA DE SIGLAS

AF	Anatomical form
AC	Axial contour
C	Compósito
CI	Confidence Interval
CIVMR	Cimento de Ionômero de Vidro Modificado por componentes resinosos
CMP	Compósito modificado por poliácidos
CSr	Cumulative Survival rate
Df	Degree of freedman
DP	Desvio Padrão
I^2	Inconsistency test
Log	Logaritmo
MAFr	Mean Annual Failure rate
MA	Marginal Adaptation
M-H	Mantzel Hansal
MS	Marginal Staining
OR	Odds Ratio
P ou p	Statistical Significance ou nível de confiança
PE	Parameter Estimate
PMRBC	Polyacid Modified Resin Based Composite
PC	Proximal contact
r	Correlation ou correlação
RBC	Resin Based Composite
RC	Razão de Chances
RCT	Randomized clinical Trial or Randomized controlled trial
RJ	Rio de Janeiro
RMGIC	Resin Modified Glass Ionomer Cement
Rr	Risk ratio
RR	Relative Risk ou Risco Relativo
Rs	Restaurações
SC	Secondary Caries
SE	Standart Error
TP	Test Probability
TS	Sobrevida
UFRJ	Universidade Federal do Rio de Janeiro
USPHS or U. S. PHS	United States Public Health Service

LISTA DE SÍMBOLOS

º	Degree
®	Marca registrada
™	Trade Mark
$א^2$	Chi- Square test ou Teste Qui-quadrado

ÍNDICE

1. INTRODUÇÃO

A capacidade dos materiais restauradores adesivos em aderir ao substrato dental (Hickel, Dasch *et al.*, 1998) corrobora os preceitos mais modernos da Odontologia Minimamente Invasiva (AAPD, 2008), já que permite preservar estrutura dental sadia no momento da realização de preparos cavitários. Acrescenta-se que a melhoria das propriedades físicas e mecânicas destes materiais (Sakaguchi, 2005), bem como da sua habilidade em mimetizar a cor dos dentes (Peretz e Ram, 2002), do potencial por parte de alguns materiais de lixiviar íons fluoretos, além das favoráveis evidências científicas de estudos clínicos (Oliveira, Dias *et al.*, 2008; Prabhakar, Raju *et al.*, 2008; Dos Santos, Passos *et al.*, 2009) reforçam para que os mesmos configurem como alternativa ao uso do amálgama dental (AAPD, 2008), principalmente em Odontopediatria, à medida que os procedimentos restauradores adesivos utilizados em dentes decíduos podem diferenciar significativamente dos dentes permanentes (Brunthaler, Konig *et al.*, 2003; Hickel, Kaaden *et al.*, 2005) devido principalmente à variação na morfologia dental (McComb, 2001).

Por definição, materiais restauradores adesivos podem ser denominados compósitos por se constituírem de uma mistura física de dois ou mais materiais combinados para formar um novo material com propriedades distintas dos componentes originais. Esta mistura tem por objetivo a melhoria de suas propriedades (Sakaguchi, 2005). Geralmente são compostos por uma matriz (fase orgânica) que tem como função distribuir e transferir tensões para os outros componentes: as cargas (fase inorgânica) (Anusavice, 1998). Além disso, a matriz

protege a superfície da carga contra corrosão e liga uma carga a outra. Já a partícula de carga, também denominada de fase dispersa, tem por função o reforço estrutural do material, além de promover enchimento, o que modifica e melhora as propriedades do material. Ainda em relação a esta fase, ela está ligada a matriz por um agente de ligação ou silano (Anusavice, 1998). Dentre a classe dos materiais restauradores adesivos diretos, aqueles cuja reação de polimerização envolve a ativação por luz halógena são os mais utilizados (Hse, Leung *et al.*, 1999; Forss e Widstrom, 2003; Tyas, 2005; Fukuyama, Oda *et al.*, 2008); devido a sua superioridade em relação às propriedades mecânicas e ao controle do tempo de trabalho (Sakaguchi, 2005).

Contudo, a eficiência destes materiais não é determinada somente pelas propriedades físico-químicas (Anusavice, 2003), mas, por uma interação de fatores relacionados ao material propriamente dito, à técnica restauradora, à capacidade técnica do operador e às condições inerentes aos pacientes (Qvist, Manscher *et al.*, 2004). O resultado desta interação pode ser quantificado por meio do desempenho clínico segundo a longevidade das restaurações (Qvist, Manscher *et al.*, 2004). Caracteriza-se por insucesso ou falha, a presença de um grau irreversível de degradação funcional e/ou estético da restauração frente ao seu desempenho após determinado período de vida clínica (Bernardo, Luis *et al.*, 2007).

Existem algumas metodologias que caracterizam o desempenho clínico das restaurações ao longo do tempo de vida clínica (Ryge, 1980; Anusavice, 2003; Cvar e Ryge, 2005; Sarrett, 2005; Hickel, Roulet *et al.*, 2007). Dentre elas, pode-se mencionar a avaliação clínica direta segundo o método estabelecido pelo

serviço de saúde pública norte americano (United States Public Health Service - USPHS), originalmente descrito por Ryge, 1980 (Ryge, 1980; Cvar e Ryge, 2005). De acordo com este método, são realizadas avaliações por meio de inspeção visual e tátil, de acordo com os critérios para adaptação marginal, forma anatômica, descoloração cavo superficial marginal, presença de cárie secundária, presença de contato proximal e presença de contorno axial, a fim de lhes atribuir escores como Alfa, Bravo, Charlie ou Delta. Tal conduta visa qualificar as restaurações, em aceitáveis (Alfa e Bravo), ou seja, sucessos clínicos ou inaceitáveis (Charlie e Delta), isto é, insucessos ou falhas clínicas.

Constata-se uma grande variação dos percentuais de sucesso clínico quando os materiais restauradores adesivos são utilizados em Odontopediatria (Hickel, Kaaden *et al.*, 2005; Yengopal, Harneker *et al.*, 2009), o que pode justificar, a falta de evidências científicas no tocante à eleição do material restaurador em crianças (Yengopal, Harneker *et al.*, 2009). Se por um lado, tal fato é decorrente da escassez de estudos clínicos aleatórios e controlados (Yengopal, Harneker *et al.*, 2009) com período de acompanhamento clínico adequado (Mccomb, 2001), por outro lado, a diversidade de resultados pode ser devido à falta de comparabilidade metodológica entre os estudos. Além disso, o aprimoramento contínuo destes materiais quer seja por avanço tecnológico ou por apelo mercadológico, impõe grande rotatividade aos mesmos, o que dificulta a comparação do mesmo material nos diversos estudos realizados em diferentes períodos de tempo.

Para caracterizar o desempenho clínico dos materiais restauradores adesivos em dentes permanentes, há um consenso em relação ao tempo de

acompanhamento, (Kramer, Garcia-Godoy *et al.*, 2005) entretanto, o mesmo não ocorre em relação aos dentes decíduos (Mccomb, 2001; AAPD, 2008). Ao se considerar que o ciclo biológico dos dentes decíduos equivale a um período que compreende de 08 a 10 anos (Qvist, Manscher *et al.*, 2004), pesquisas que avaliassem o desempenho clínico das restaurações adesivas em dentes decíduos por um período de tempo igual ou superior a 04 anos, forneceriam contribuições científicas relevantes, já que tal período corresponderia a meia vida dos dentes decíduos. Além disso, vale a pena ressaltar que somente o estudo de Dos Santos; Passos et al., 2009 (Dos Santos; Passos et al., 2009), avaliou o desempenho clínico de três tipos de restaurações adesivas por um período de 24 meses de acompanhamento, o que é considerado um tempo médio de acompanhamento (Hickel, Roulet *et al.*, 2007)

Por outro lado, existe uma controvérsia na literatura no tocante à realização do bisel quando da realização de preparos cavitários nos molares decíduos. O biselamento do ângulo cavo-superficial tem sido sugerido nos molares decíduos (Oldenburg, Vann *et al.*, 1985; Lee e White, 1998; Nozaka, Suruga *et al.*, 1999; Swanson, Feigal *et al.*, 2008), à medida que promove a remoção mecânica da camada aprismática, faz a exposição dos prismas de esmalte no sentido de seu longo eixo, aumenta a quantidade e melhora a qualidade da superfície de esmalte para adesão (Myers e Butts, 1985), o que reduz a microinfiltração (Nozaka, Suruga *et al.*, 1999; Swanson, Feigal *et al.*, 2008). Cabe ressaltar que poucos estudos (Oldenburg, Vann *et al.*, 1987; Oliveira, Dias *et al.*, 2008; Prabhakar, Raju *et al.*, 2008; Dos Santos, Passos *et al.*, 2009) avaliaram o benefício do bisel no ângulo cavo-superficial em preparos Classe I e Classe II em molares decíduos. Para elucidar tal questionamento, realizou-se uma revisão sistemática da

literatura, na qual se verificou o benefício ou não da realização do bisel no ângulo cavo-superficial de molares decíduos restaurados com materiais adesivos em relação à longevidade destas restaurações.

Dada a relevância dos estudos clínicos utilizando materiais restauradores em Odontopediatria no sentido de nortear as práticas terapêuticas vigentes, subsidiar filosofias para o processo ensino-aprendizado e ainda contribuir para o aperfeiçoamento dos próprios materiais restauradores (Sarrett, 2005), este trabalho teve como objetivos: descrever um estudo clínico prospectivo, aleatório e controlado que avaliou a sobrevida de restaurações adesivas Classe I e Classe II em molares decíduos, após 48 meses de acompanhamento, utilizando três tipos de materiais restauradores adesivos fotopolimerizáveis, além de estabelecer, por meio da evidência científica, a efetividade do bisel no ângulo cavo-superficial marginal dos preparos Classe I e Classe II em molares decíduos no que concerne à longevidade das restaurações adesivas fotopolimerizadas.

2. PROPOSIÇÃO

2.1 Avaliar o desempenho clínico de restaurações adesivas diretas Classe I e Classe II realizadas com três diferentes tipos de materiais restauradores adesivos: um compósito, um compômero e um cimento de ionômero de vidro modificado por componentes resinosos em molares decíduos após 48 meses de acompanhamento

2.1.1 Avaliar a sobrevida das restaurações de acordo com o material restaurador (um cimento de ionômero de vidro modificado por componentes resinosos, um compômero e um compósito) e o tipo de preparo cavitário (Classe I e Classe II) após 24 meses de acompanhamento.

2.1.2 Avaliar o percentual de falhas das restaurações após 48 meses de acompanhamento, considerando as variáveis: gênero e idade da criança, tipo de material restaurador, número de superfícies envolvidas na restauração, tipo de dente, posição e lado do dente na arcada e período da falha.

2.2 Realizar uma revisão sistemática da literatura no tocante à efetividade do bisel no ângulo cavo-superficial em preparos Classe I e Classe II em molares decíduos em relação à longevidade das restaurações adesivas para restaurações adesivas fotopolimerizáveis.

3. DELINEAMENTO DA PESQUISA

3.1. MATERIAIS E MÉTODO

3.1.1. Para o estudo clínico controlado aleatório prospectivo de duplo mascaramento

A relevância da presente pesquisa está na força de evidência científica face à conduta terapêutica proposta.

3.1.1.a - Área de estudo e aspectos éticos

O estudo foi aprovado pelo comitê de ética e pesquisa do Hospital Universitário Clementino Fraga Filho, da Universidade Federal do Rio de Janeiro (UFRJ) (Anexo 1) e foi protocolado sob o número de inscrição 0971.0.197.000-05 no Sistema Nacional de Informação sobre Ética em Pesquisa (SISNEP) (Anexo 2). Realizou-se nas dependências da clínica de Odontopediatria, no departamento de Odontopediatria e Ortodontia da referida instituição de ensino superior.

3.1.1.b - População de estudo e período de referência

A população estudada foi composta por crianças saudáveis, na faixa etária entre 03 a 09 anos de idade que procuraram atendimento odontológico na clínica de Odontopediatria da FOUFRJ entre os anos de 2003 e 2004.

3.1.1.c - Tamanho amostral

A seleção dos pacientes se realizou por conveniência. Todavia, supondo os parâmetros[*]: população infantil, intervalo de confiança de 95%, poder do estudo de 80%, a razão de 1:1 entre expostos e não expostos, e 11% de chances da restauração fracassar (Hickel, Kaaden *et al.*, 2005), constatou-se que 436 restaurações, divididas em dois grupos, grupo controle (n=218) e experimental (n=218) deveriam compor o universo amostral. No entanto, após o período de rastreamento compreendido entre os anos de 2003 e 2004, 141 restaurações foram realizadas. Destas, 46 restaurações foram realizadas com Vitremer®, um cimento de ionômero de vidro modificado por componentes resinosos; 51 restaurações foram realizadas com Freedom®, um compósito modificado por poliácidos, e 44 restaurações foram realizadas com o TPH Spectrum®, um compósito micro-híbrido. Desta forma, o número total de restaurações obtidas foi equivalente a 32% do tamanho amostral.

3.1.1.d - Desenho do estudo

Este estudo pode ser classificado como clínico prospectivo controlado e aleatório, no qual o dente foi a unidade de randomização e o material restaurador compósito (TPH Spectrum®) foi considerado como o material restaurador do grupo controle. Seu desenho paralelo permite que o indivíduo seja ao mesmo tempo, grupo controle e grupo experimental. Além disto, apresentou duplo mascaramento, pois tanto o paciente quanto pelo menos um dos avaliadores desconhecia o tipo de material restaurador utilizado nas restaurações. Por ter como objetivo inicial da pesquisa, avaliar a sobrevida dos materiais restauradores adesivos como Vitremer®,

[*] Dados obtidos a partir do programa Open Source Epidemiologic Statistics for Public Health – OpenEpi. Sample Size for Cross-Sectional, Cohort and Randomized Clinical Trial Studies. Acesso em Julho de 2009

do Freedom® e do TPH Spectrum® em preparos Classe I e Classe II realizados em molares decíduos, por um período de 24 meses, e posteriormente, após 48 meses de acompanhamento, o estudo é do tipo prospectivo. Dois artigos científicos (artigo 1 e artigo 2) foram originados a partir da pesquisa cuja metodologia está detalhadamente descrita no primeiro artigo.

Ao término de 48 meses de avaliação (artigo 2), as variáveis: gênero (feminino x masculino); idade das crianças (entre 5 a 7 anos x entre 8 a 10 anos); o tipo de dente restaurado (primeiro molar x segundo molar); a posição do dente na arcada (superior x inferior); o lado do dente na arcada (direito x esquerdo); o número de superfícies envolvidas com as restaurações (Classe I x Classe II); o tipo de material restaurador (Vitremer®, do Freedom® e do TPH Spectrum®) e finalmente o período das falhas clínicas (antes de 24 meses x depois de 24 meses) foram associadas ao fracasso clínico.

3.1.2. Para a revisão sistemática

Para determinar um possível benefício do bisel no ângulo cavo-superficial marginal em relação ao aumento da sobrevida das restaurações, realizou-se uma revisão sistemática com meta-análise a respeito da efetividade do bisel em preparos Classe I e Classe II quando da utilização de materiais restauradores adesivos. A submissão da revisão sistemática ao Grupo Cochrane foi realizada conforme metodologia definida pelo referido grupo que consiste em apresentar a proposta da revisão sistemática na forma de um protocolo conforme é mostrado a seguir, e originou o artigo 3.

Cochrane Oral Health Group

Proposal for a new Cochrane Review

Please complete and email/fax this form to:

Luisa Fernandez, Review Group Co-ordinator, Cochrane Oral Health Group, MANDEC, School of Dentistry, The University of Manchester, Higher Cambridge Street, Manchester, M15 6FH (UK) Phone: +44 161 275 7819

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Proposed Title

Class I and Class II unbeveled versus beveled preparations for direct resin-based restorations in primary molars. A systematic review

Motivation for the review

This systematic review is part of my PhD thesis

Description of proposal

Objective – The performance of dental restorations is influenced by several factors, including materials properties, operator experience, patient conditions and cavity preparations. Failure of dental restorations is of major concern in dental

practice and the primary reasons for composite failure were secondary caries, restoration fracture and marginal defects. Taking all these reasons into account, it is clearly understood the clinical longevity of these restorations depends on the maintenance of marginal integrity. Resin based restorations have been shown to be suitable materials for filling primary molars because of their advantages and physical properties. Among these is their ability to bond to dental substrate. Thus, dental substrate plays an important role on the quality of bonding. In any event, bonding to poorly prepared enamel can result in microleakage and loss of marginal integrity. Current restorative techniques rely on bonding to mineralized structures of primary and permanent teeth. It is known both dentitions have similar composition; however, some differences regarding morphology and mineral content have been well documented in the literature. The primary teeth are less mineralized than permanent teeth. The primary enamel and dentin are also thinner in comparison with the permanent teeth. The morphological structure of the intact primary enamel surface is different from that of the underlying middle enamel layer. Whereas, the appropriate preparation of the dental substrate for bonding procedures has been extensively studied in permanent teeth, researches have merely been extrapolated the results of these studies to primary teeth. Thus, this systematic review aims to determine using scientific based evidence the effect of Class I and Class II unbeveled versus beveled cavosurface margins in primary molars on the longevity of direct adhesive restorations in Class I and Class II cavity preparations in primary molars. This issue will help to make practical decision in relation to restorative dentistry management in children.

Rationale for review – There is insufficient evidence[1] to make any recommendations about which filling material is the choice for using in Pediatric

Dentistry.[1] For this reason, the choice for either cavity design or material selection is based upon clinical preference.[2] Due to the characteristics of primary teeth such as dental wear and limited lifespan[3], the range of restorative procedures performed in primary molars differs slightly from those for permanent teeth.

For direct restorative dentistry management, resin based restorative materials trend to increase their use for filling primary dentition[2-8] because of their physical properties and advantages among these are bonding to dental substrate, aesthetics, and the fluoride release potential of some of these materials.[9] In addition, there is scientific and non-scientific controversy about the use of silver amalgam.[6] The acid etching is the most useful choice for bonding of resin based restorative materials due to its simplicity and efficiency.[10] However, there is an uncertain knowledge regarding its effectiveness in primary teeth enamel because of prismless layer presence. [11]. On the other hand, bevel in load bearing area increases the possibility of the adverse effects on the occurrence of fractures at cavosurface margins because of the thickness of the restorative materials.

The bond stability of tooth/resin-based restoration interface is considered a major factor influencing the longevity of adhesive dental restorations.[12] The bond instability may lead to staining and breakdown in the marginal areas leading to the possibility of marginal leakage[13], recurrent caries, hypersensitivity of restored teeth and the development of pulpal pathology.[14] Whereas, the appropriate preparation of the dental substrate for bonding procedures has been extensively studied in permanent teeth[15], researches have merely been extrapolated the results of these studies to primary teeth. In permanent teeth, clinicians do not use bevels along occlusal enamel because bevels make the restorations more prone to marginal fractures. In primary teeth, differently from permanent teeth, children's bite force is

less than that of adults[16], and the primary teeth suffer physiological wear at the same rates as those of the resin-based composites, therefore minimizing the possibility of marginal fractures.

Moreover, histological studies showed the prismless layer in outer enamel negatively affects the quality of etching and bonding in primary teeth[17-19] because of its organization in the parallel direction of enamel prisms when viewed in relation to long axis of the primary molars. It is known that enamel surfaces etched by phosphoric acid appear to be affected at three levels: etched zone (a narrow zone of enamel totally removed by etching), a qualitative porous zone and a quantitative porous zone. The molecular bonding mechanism occurs through the latter two zones.[20] In the prismless layer there is no a pattern of acid conditioning due to its irregular porosity and limited imperviousness, which negatively affects adhesion.[19] Thus, if the prismless layer is modified by mechanical treatment before acid etching, the quality of bonding would be improved[19, 21, 22] since a constant and regularly distributed loss of interprismatic and intraprismatic substances would be achieved.[19, 23] Under these conditions, clinicians can improve marginal sealing and reduce microleakage.[22] Therefore, the actual cavity preparations for resin-based restorations would be improved if enamel anatomy is considered.[24] On the other hand, it is worth pointing out that the amount of tooth ground away for the bevel-treated cavity was greater than the amount in unbeveled ones.[22]

The ultimate test method to assess the clinical practice continues to be practice-based clinical trials.[14, 25] Indeed, the outcome of a clinical study is dependent not only on the material properties and patients; in many studies, patient-related factors[26] such as age, oral hygiene, occlusal loading are more influential than any material property. Furthermore, 'external' factors such as the

operator's skills[27] and/or technical approaches[28] could significantly influence the outcome.[25] In recognition of the impact of a particular trial on the existing state of knowledge, the relation between existing and new evidence should be illustrated by direct reference to an existing systematic review and/or meta-analysis. Once there is no systematic review or meta-analysis, authors are encouraged to conduct their own.[5, 29, 30]

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Types of study - Randomized and/or quasi-randomized controlled trials of resin based restorations in Class I and Class II preparations in primary molars of healthy children with a minimum period of twelve months follow-up.

Participants - The eligible trials will consist of young children (children between the ages of 3 and 12 years) with tooth decay involving at least two primary molar sin a parallel design at the start of the study. The primary caries lesion must be on occlusal or occluso-proximal surfaces (mesio- occlusal or disto-occlusal or mesio-disto-occlusal). Direct resin based restorations have to be performed in teeth with no clinical or radiographic signs of pulpal or periradicular pathology and pathological wear; All primary molars in the mouth have to be with occlusal and proximal contacts.

Interventions and specific comparisons to be made - We are interested in assessing the influence of technical intervention on the clinical longevity of resin-based restorations by comparing Class I and Class II beveled preparations with unbeveled ones. The main outcome will be the survival rate of theses restorations based on the cavosurface margin of Class I and Class II preparations in primary molars

Outcomes - The clinical relevance of this subject is the possibility of pointing out the importance of Class I and Class II cavosurface margins for resin based materials in primary molars to increase the survival rate of theses restorations. As a result, the reintervention on teeth restored is reduced what increases the life span of restorations as well the low cost-effective treatment.

What subgroup analysis do you intend to undertake? We intend to undertake these variables: sample size (number of patient and restorations), patients' age, technical procedures and materials used for restorative treatment, cavity design (Class I versus or Class II preparations; beveled or unbeveled cavosurface margins; number of surfaces), type of teeth (first or second primary molar), arch position (upper or lower); evaluation criteria, researchers experience, reliability of researchers involved in the studies, number of operators and number of evaluators (there is a training or a calibration for the study?), period of follow-up (at least twelve months), number of dropouts and withdrawals (maximum 30%), statistical results, success/failure rate of restorative treatment and authors' conclusions.

Other information relevant to this proposal - The possibility of decreasing the failure rate of restorative dentistry treatment in children improves their oral health.

Proposed authors (Please follow a Westernised style, that is, first name followed by the family name (i.e. First name/personal name (**名字** míngzi) and family name/surname (**姓** xìng)

Contact author name: (This is the person taking primary responsibility for the development of the proposal and ensuring the continuity of the review once published)

Márcia Pereira Alves dos Santos

Co-author(s) name(s): (There should be at least one co-author)

Roberta Barcelos
Ronir Raggio Luiz
Lucianne Cople Maia

Content expert name:

Márcia Pereira Alves dos Santos
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Methodologist name:

Márcia Pereira Alves dos Santos
Roberta Barcelos
Lucianne Cople Maia

Statistician name:

Ronir Raggio Luiz

Do you or your co-authors have any interests in this topic that could be perceived as conflicts of interest? If 'yes', what are they?

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Yes ( ) No (X)

Is this review the subject of specific funding and/or timing. If yes, please give details.

Yes ( ) No (X)

Has the review already been carried out or published? If yes, where has it been published?

Yes ( ) No (X)

Roles and responsibilities task who has agreed to undertake the task?

Draft the protocol: Márcia Pereira Alves dos Santos

Develop a search strategy: Márcia Pereira Alves dos Santos; Roberta Barcelos

Search for trials (usually 2 people): Márcia Pereira Alves dos Santos; Roberta Barcelos

Obtain copies of trials: Márcia Pereira Alves dos Santos; Roberta Barcelos

Select which trials to include (2 + 1 arbiter): Márcia Pereira Alves dos Santos; Roberta Barcelos; Lucianne Cople Maia

Extract data from trials (2 people): Márcia Pereira Alves dos Santos; Roberta Barcelos

Enter data into Review Manager: Márcia Pereira Alves dos Santos

Carry out the analysis: Márcia Pereira Alves dos Santos; Ronir Raggio Luiz

Interpret the analysis: Márcia Pereira Alves dos Santos; Roberta Barcelos; Luciane Cople Maia; Ronir Raggio Luiz

Draft the final review: Márcia Pereira Alves dos Santos; Roberta Barcelos; Luciane Cople Maia; Ronir Raggio Luiz

Update the review: Márcia Pereira Alves dos Santos

Other information, and assistance requested

Have you or a co-author written a systematic review before?

Yes

If yes, was it a Cochrane Review? If yes, please give details:

No

Do you have a copy of the Cochrane Handbook for Systematic Reviews of Interventions?

Yes

Have you attended a Cochrane review training workshop? If yes, which one?

No

If no, are you planning to? Which one?

Yes. Next year. On the 88th General Session & Exhibition of the IADR.

Do you have a copy of RevMan 4.2.10, the Cochrane Review Manager software?

No. I have a copy of RevMan 5.0

Have you seen the Cochrane Oral Health Group website?

Yes

Do you have ready access to email and the internet?

Yes

Do you have access to:

Medline - Yes

PubMed - Yes

Embase - Yes

***The Cochrane Library* -** Yes

Do you have access to a medical library: If yes, can you order journal articles not held in the Library?

Yes. Yes I can.

Do you have access to reference management software?:

Reference Manager (version 5) - Yes

EndNote (version 9) - Yes

ProCite (version) - Yes

Other (Epi Info version 2000) - Yes

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Using RevMan 4.2.10? No

Access to data on *The Cochrane Library*? No

Translation of articles? Yes

Training? Yes

Access to a statistician (strongly recommended)? No

Contact with consumer groups? No

Seeking funding/scholarship support? Yes

Provisional dates for submission of drafts to editorial base

(A) Draft PROTOCOL (6-8 months) October - December/2009

(B) **Draft REVIEW** (12-18 months) July-2010

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Supervisor's name: Lucianne Cople Maia

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4. DESENVOLVIMENTO DA PESQUISA

4.1. ARTIGO 1: Santos, M. P. A. ; Passos, M. ; Luiz, R. R.; Maia, L. C. A randomized trial of resin-based restorations in Class I and Class II preparations in primary molars. 24-month results. JADA. v.140, n. 2., Feb., p. 156-66.

4.2. ARTIGO 2: Santos, M. P. A. ; Luiz, R. R. ; Maia, L. C. A randomized controlled trial of resin-based restorations in Class I and Class II beveled preparations in primary molars: 48-month results.

4.3. ARTIGO 3: Santos, M. P. A. ; Barcelos, R., Luiz, R. R. ; Maia, L. C. Class I and Class II unbeveled versus beveled preparations for light-cured direct resin-based restorations in primary molars: A systematic review.

A randomized trial of resin-based restorations in Class I and Class II beveled preparations in primary molars

24-month results

Márcia Pereira Alves dos Santos, MSc; Mariana Passos, MSc; Ronir Raggio Luiz, PhD; Lucianne Cople Maia, PhD

ABSTRACT

Purpose. The authors conducted a randomized clinical trial to evaluate the survival rate of esthetic restorations in Class I and Class II beveled preparations in primary molars 24 months after placement. The null hypothesis was that there is no difference among survival rates of the restorative materials used.

Methods. Forty-eight children (mean age, 5 years 9 months) received 141 restorations in beveled cavosurface margins in primary molars randomly assigned by lottery method: 46 received treatment with Vitremer Tri-Cure Glass Ionomer System (3M ESPE Dental Products, St. Paul, Minn.) (33 Class I and 13 Class II restorations), 51 received treatment with Freedom (SDI, Bayswater, Victoria, Australia) (36 Class I and 15 Class II restorations); 44 received treatment with TPH Spectrum (Dentsply, Petropolis, Rio de Janeiro, Brazil) (30 Class I and 14 Class II restorations). Two examiners whose technique had been calibrated (weight $\kappa > 0.85$) evaluated the restorations using modified U.S. Public Health Service criteria and Visible Plaque Index score at baseline and at 12, 18 and 24 months.

Results. After two years, the authors censored data for 17 restorations, considered 101 restorations to be clinically successful and deemed 23 restorations failed because of loss of marginal integrity, anatomical form discrepancies and secondary caries. For Class I and Class II restorations, the cumulative survival rates were higher than 80 percent and 55 percent, respectively, for all materials (life table, Gehan-Wilcoxon Test, $P > .05$; $P > .05$).

Conclusions. At the 24-month clinical recall, the authors found no differences among materials in Class I ($P > .05$) or Class II beveled preparations ($P > .05$) in primary molars, but all materials showed higher survival rates in Class I than in Class II restorations.

Key Words. Randomized controlled trial; dental materials; survival rate; molar; primary teeth; dental cavity preparation.

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JADA CE CONTINUING EDUCATION ARTICLE 1

In pediatric dentistry, the range of restorative procedures performed in primary molars differs slightly from that of those performed in permanent teeth, owing to the characteristics of primary teeth, such as dental wear and limited life span.[1] Thus, resin-modified glass ionomer cements (RMGICs), polyacid-modified resin-based composites (PMRBCs) and resin-based composites (RBCs) have been shown to be suitable materials for filling primary molars[2-6] because of their advantages and physical properties. Among these are their ability to bond to dental substrate, their pleasing esthetic qualities and, in some of these materials, the fluoride release potential.[7] In addition, there is controversy in both scientific and lay communities about the use of amalgam.[4] Moreover, to date, no consistent guidelines have been published in the pediatric dental literature for either cavity design or material selection, and choices in these areas appear to be based on clinical preference.[6]

Whereas the appropriate preparation of the dental substrate for

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bonding procedures has been studied extensively in permanent teeth,[8] researchers have merely extrapolated the results of these studies to primary teeth. In permanent teeth, clinicians do not use bevels along occlusal enamel because bevels make the restorations more prone to marginal fracture at points of occlusal contact or functional slides. In primary teeth, differently from permanent teeth, clinicians could improve the bond quality by carrying out a mechanical treatment, such as removal of the prismless enamel by grinding, before performing acid etching. Under these conditions, a clinician could achieve a constant and regularly distributed loss of interprismatic and intraprismatic substances.[9] Moreover, in primary dentition, researchers have reported that beveled cavity margins should be the preferred configuration for adhesive restorative treatment because they reduce marginal microleakage.[10,11] Furthermore, children's bite force is less than that of adults,[12] and the primary teeth experience physiological wear at the same rates as those of the RBCs, therefore minimizing the possibility of marginal fractures.[11] However, in clinical trials,[13-19] investigators rarely adopted this beveled cavity configuration for Class I and Class II preparations in primary molars.

Restorative material assessment should be based on findings from practice-based clinical trials, because this is the most appropriate evidence to use in qualifying and understanding the behavior of restorative materials.[20] Indeed, the ability to evaluate the interaction of factors such as operator, design, material properties, site and patient conditions,[21] all modulated by time, can occur only in in vivo studies.[22] In contrast, laboratory studies provide only partial information, generally regarding the physical properties of restorative materials.[23,24]

Nevertheless, in the dental literature we consulted, we found no report that simultaneously compared the clinical performance of restorations made with RMGIC, PMRBC and RBC, mainly in Class I and Class II cavity preparations in children. Thus, we conducted a randomized clinical trial (RCT) to evaluate the survival rate of esthetic restorations done with three types of adhesive restorative materials, in Class I and Class II beveled preparations in primary molars, after 24 months. The null hypothesis was that there is no difference among survival rates of the restorative materials.

METHODS

This RCT was approved by the local human research ethics committee of Clementino Fraga Filho University Hospital of the Federal University of Rio de Janeiro, Brazil. We performed it at the Federal University of Rio de Janeiro School of Dentistry after obtaining the children's and guardians' agreement and signed terms of informed consent.

Subjects. During a period of 12 months, one instructor (L.C.M.) screened all children scheduled to start the dental treatment at the pediatric dental clinic according to these criteria:

- good mental and physical health;
- presence of at least two primary carious lesions—occlusal, occlusoproximal (mesio-occlusal or disto-occlusal) or both—on primary molars in a split-mouth design, with no clinical or radiographic signs of pulpal or periradicular disease and pathological wear;
- presence of all primary molars with occlusal and proximal contacts.

After performing clinical and bitewing radiographic examinations, we selected 48 healthy children between the ages of 3 and 9 years (mean, 5 years 9 months). Two trained pediatric dentists (M.P. and another dentist) who had participated in a pilot study that preceded this study treated the subjects, using local anesthetic and rubber dam isolation. Each child was treated by the same operator at each visit to avoid behavior problems on the part of the child. Each patient received at least two types of restorative materials, which the dentists chose randomly via the lottery method after completing the cavity preparations.

The study consisted of 141 restorations in total: 46 with RMGIC (Vitremer Tri-Cure Glass Ionomer System, 3M ESPE Dental Products, St. Paul, Minn.); 51 with PMRBC (Freedom, SDI, Bayswater, Victoria, Australia); and 44 with RBC (TPH Spectrum, Dentsply, Petropolis, Rio de

ABBREVIATION KEY. AC: Axial contour. **AF:** Anatomical form. **DO:** Disto-occlusal. **MA:** Marginal adaptation. **MO:** Mesio-occlusal. **MS:** Marginal staining. **NA:** Not available. **NS:** Not significant. **O:** Occlusal. **PC:** Proximal contact. **PMRBC:** Polyacid-modified resin-based composite. **RBC:** Resin-based composite. **RCT:** Randomized clinical trial. **RMGIC:** Resin-modified glass ionomer cement. SC: Secondary caries. **USPHS:** U.S. Public Health Service.

TABLE 1

Esthetic restorative materials investigated and technique used.

MATERIAL	BRAND NAME	BATCH NO.	BASIC COMPOSITION	ADHESIVE SYSTEM	TECHNIQUE
Resin-Modified Glass Ionomer Cement	Vitremer Tri-Cure Glass Ionomer System*	3303MPA3	Fluoroaluminosilicate glass; potassium persulfate, ascorbic acid, aqueous solution of polycarboxylic acid, water, hydroxyethyl methacrylate, photoinitiators, ethanol	Vitremer Primer*	Applied for 15 seconds, then light-cured for 20 seconds
Polyacid-Modified Resin-Based Composite	Freedom†	033808	Nonbisphenol A, strontium glass	Total-etch 37 percent phosphoric acid and Stae dentin/ enamel adhesive†	Acid etched for 30 seconds (conditioning enamel for 15 seconds and dentin for 15 seconds), washed with water, then dried with air spray; Stae adhesive system applied, dried gently with air spray and light-cured for 20 seconds
Resin-Based Composite	TPH Spectrum†	555055	Barium aluminoborosilicate glass filler, colloidal silica, bisphenol A glycidyl dimethacrylate (bis-GMA) adduct, ethoxylated bis-GMA and triethylene glycol dimethacrylate	Total etch 37 percent phosphoric acid and Prime & Bond NT‡	Acid etched for 30 seconds (conditioning enamel for 15 seconds and dentin for 15 seconds), washed with water, then dried with air

* Manufactured by 3M ESPE Dental Products, St. Paul, Minn.
† Manufactured by SDI, Bayswater, Victoria, Australia.
‡ Manufactured by Dentsply, Petropolis, Rio de Janeiro, Brazil.

TABLE 2

Initial sample distribution according to restorative materials used, primary molar type and cavity preparation type.*

RESTORATIVE MATERIAL USED (NO. OF RESTORATIONS)	CAVITY PREPARATION TYPE, ACCORDING TO TYPE OF PRIMARY MOLAR			
	First Primary Molar		Second Primary Molar	
	Class I (n = 45)	Class II (n = 25)	Class I (n = 54)	Class II (n = 17)
Vitremer Tri-Cure Glass Ionomer System† (46)	13	06	20	07
Freedom‡ (51)	17	10	19	05
TPH Spectrum§ (44)	15	09	15	05
TOTAL (141)	70		71	

* χ^2 test (Fisher exact test) $P = .77$.
† Manufactured by 3M ESPE Dental Products, St. Paul, Minn.
‡ Manufactured by SDI, Bayswater, Victoria, Australia.
§ Manufactured by Dentsply, Petropolis, Rio de Janeiro, Brazil.

Janeiro, Brazil) (Table 1). Seventy restorations were in first primary molars and 71 in second primary molars; 99 of them were Class I and 42 were Class II cavity preparations (Table 2). We noted a homogeneous distribution between first and second primary molars and Class I and Class II dental cavity preparations (χ^2 test, Fisher exact test; $P = .77$) (Table 2).

Cavity design and restorations. During the restorative procedure, the dentists removed only carious lesions and performed no retention such as undercutting or dovetailing. Thus, they made all Class I and Class II cavity preparations in primary molars as small as possible. The isthmus of occlusal dental cavity preparations was one-fourth to one-third of the buccal-lingual cuspal distances of primary molars. For proximal box preparations, the dentists restricted the cavity size to the contact point area. The dentists prepared the teeth with a 330 bur (KG Sorensen, São Paulo, Brazil) in a high-speed handpiece with a water coolant; they then used a round carbide bur at slow speed in dentin, as appropriate for the cavity size.

In addition, the dentists made bevels on the occlusal or occlusal-proximal cavosurface margins.

They made the bevels, which were approximately 0.5 millimeter wide, with a 2,200 FF diamond finishing bur (KG Sorensen, São Paulo, Brazil) by using 45° and 20° angulations for occlusal and occlusoproximal preparations, respectively. They made no bevels at the gingival margin. All cavity walls had supragingival margins. When they considered the cavity deep enough, the dentists applied a calcium hydroxide liner.

During the dental cavity preparation, if the dentists noted that pulp tissue was exposed or the required cavity size was larger than that in the study design, they performed the appropriate therapy but excluded the teeth from the sample.

The dentists randomly assigned the restorative materials (Table 1) via lottery method after completing the Class I and Class II preparations. They handled and applied the materials in accordance with the manufacturers' instructions (Table 1). They placed Vitremer in the cavity in a single increment with an appropriate syringe and light polymerized it for 40 seconds by using a halogen lamp with light power of 500 milliwatts per square centimeter, which they measured frequently with a radiometer. They placed TPH Spectrum and Freedom in increments no larger than 2.0 mm, by using an incremental technique until the cavity preparation was filled. They light polymerized each increment in the same way as they did for Vitremer. For Class II restorations, they used a metal matrix band and wooden wedge and filled the proximal box first, by using the same technique previously described.

The dentists checked occlusion by using carbon paper and adjusted it as necessary by using fine-granulation burs. They completed the final finishing and polishing procedures by using fine- and ultrafine-granulation diamond burs and finishing points with diamond polishing paste after one week. Some restorations were in contact with restored occlusal surfaces of teeth, and the dentists recorded all points of occlusal contact on enamel. After one month, the dentists evaluated all restorations. We considered the result of this evaluation the baseline.

Evaluation of the restorations. Two examiners whose technique had been calibrated (M.P. and M.P.A.S.), one of them different from the original operators who had placed the restorations, re-evaluated the restorations (weighted κ greater than 0.85 for inter- and intraexaminer agreement) 12, 18 and 24 months later, without knowledge of the restorative material under examination. When disagreement occurred between the two assessors, they reached a consensus at chairside with a third researcher (L.C.M.). The two examiners recalibrated their technique regarding the evaluation criteria every six months.

The examiners assessed each restoration according to modified U.S. Public Health Service (USPHS) criteria[25,26] for anatomical form, marginal adaptation, marginal staining, axial contour, proximal contact and secondary caries. The examiners considered Alfa and Bravo scores to indicate clinically acceptable and successful restorative treatment. Restorations receiving Charlie and Delta scores, which indicated clinically unacceptable and unsuccessful restorative treatment, had to be replaced, and we excluded them from the study. Furthermore, the examiners used the Visible Plaque Index[27] score to note the presence or absence of dental biofilm on the surface of or around restorations (Table 3[25,26]). They carried out all evaluations with a dental operating light, a mouth mirror, a dental explorer, dental floss and a spacer dental accessory.

The examiners censored data for restorations in two conditions: if the restorations, although successful, were in teeth exfoliated during follow-up or if they were not evaluated because the child was absent at recall (absent at dental appointment).

For ethical reasons, the two examiners treated all the children's other dental care needs, and all patients and their guardians received oral instructions about proper brushing and flossing techniques. In addition, each patient received professional cleaning of the teeth and application of neutral topical fluoride during the dental appointments.

Data analysis. We performed a statistical analysis by using multivariate analyses with the Dunnett test. We took into account the modified USPHS criteria, as well as the presence or absence of dental biofilm, type of teeth (first or second molars, maxillary or mandibular primary molars), type of dental cavity preparation (Class I or Class II) and the restorative materials at a 2.5 percent level of significance.

To establish the relationship between presence or absence of dental biofilm and secondary caries among the restorative materials during the study, we performed the χ^2 test at a 5 percent level of significance.

For paired comparison analyses, we conducted the Friedman test for longitudinal assessment at

TABLE 3

Modified U.S. Public Health Service* criteria for rating restorations.

CRITERION	SCORE	RATING	MODIFIED CRITERION
Marginal Adaptation	Alfa	0	No visible evidence of a crevice along the margin
	Bravo	1	Visible evidence of a crevice along the margin into which the explorer will penetrate
	Charlie	2	Dentin or the base is exposed
	Delta	3	Restoration is fractured, mobile or missing
Anatomical Form	Alfa	0	Restoration is continuous with existing anatomical form
	Bravo	1	Restoration is discontinuous with existing anatomical form, but material is not sufficient to expose the dentin or base
	Charlie	2	Restoration is discontinuous and the dentin or the base is exposed
Cavosurface Margin Discoloration	Alfa	0	No discoloration anywhere along the margin between the restoration and adjacent tooth
	Bravo	1	Slight discoloration along the margin between the restoration and the adjacent tooth
	Charlie	2	Discoloration penetrates along the margin of the restorative material in a pulpal direction
Axial Contour	Alfa	0	Axial contour continuous with existing tooth form proximal embrasures
	Bravo	1	Slightly undercontoured or slightly overcontoured, not continuous with enamel
	Charlie	2	Moderately undercontoured or moderately overcontoured
	Delta	3	Decidedly undercontoured (tissue trauma evident)
Proximal Contact	Alfa	0	Proximal contact present
	Bravo	1	Proximal contact light, but present
	Charlie	2	No proximal contact
Secondary Caries	Alfa	0	No caries present
	Bravo	1	Caries present along the margin of the restoration
Visible Plaque Index	Alfa	0	Dental biofilm absent
	Bravo	1	Dental biofilm present, related to restorations

* Source: Cvar and Ryge[25] and Oldenburg and colleagues.[26]

a 5 percent level of significance. In addition, we used the Wilcoxon rank sum test to analyze differences among materials for each criterion at baseline and at the 12-, 18- and 24-month follow-ups at a 5 percent level of significance. For these analyses, we divided the data file into two groups of dental cavity preparations: Class I and Class II restorations.

We applied the life table analysis to assess the survival rate of the restorative materials. We used the Gehan-Wilcoxon test to compare the percentage of cumulative success of the three restorative materials, considering Class I and Class II restorations at a 5 percent level of significance.

RESULTS

After follow-up of 24 months, we re-evaluated 42 children (25 boys and 17 girls; mean age, 7 years 5 months). Table 4 shows the absolute frequency of clinical success (Alfa and Bravo scores), censored data and failures (Charlie and Delta scores) during the study for restorative materials and dental cavity preparations. In relation with the cumulative absolute frequency of restorations at the end of the study, we considered 101 restorations (75 Class I and 26 Class II) to be clinically successful; we censored data for 17 restorations for exfoliation or recall reasons (nine restorations and eight restorations, respectively), and we considered 23 restorations (one at 12 months, 18 at 18 months and four at 24 months) failed because of loss of marginal integrity as a result of poor marginal adaptation, marginal staining or both; anatomical form discrepancies; and secondary caries in different follow-up periods (Tables 5 and 6, pages 162 and 163, respectively).

We attempted to find a correlation between secondary caries and biofilm presence, taking into account the marginal adaptation changes (gaps), cavosurface discoloration and dental biofilm. Considering all the previously mentioned criteria, we could not correlate secondary caries with the

TABLE 4

Distribution of restorations during the study.

MATERIAL*/ CAVITY PREPARATION TYPE	NUMBER (%†) OF RESTORATIONS AT STUDY INTERVAL											
	Baseline			12 Months			18 Months			24 Months		
	Success	Censored Data	Failure	Success	Censored Data	Failure	Success	Censored Data	Failure	Success	Censored Data	Failure
Vitremer Tri-Cure Glass Ionomer System												
Class I	33/33 (100)	00/33 (0)	00/33 (0)	31/33 (93.9)	02/33 (6.1)	00/33 (0)	24/31 (77.4)	03/31 (9.7)	04/31 (12.9)	22/24 (91.7)	01/24 (4.2)	01/24 (4.2)
Class II	13/13 (100)	00/13 (0)	00/13 (0)	13/13 (100)	00/13 (0)	00/13 (0)	08/13 (61.5)	01/13 (7.7)	04/13 (30.8)	08/08 (100)	00/08 (0)	00/08 (0)
Freedom												
Class I	36/36 (100)	00/36 (0)	00/36 (0)	35/36 (97.2)	01/36 (2.8)	00/36 (0)	32/35 (91.4)	02/35 (5.7)	01/35 (2.9)	30/32 (93.8)	01/32 (3.1)	01/32 (3.1)
Class II	15/15 (100)	00/15 (0)	00/15 (0)	15/15 (100)	00/15 (0)	00/15 (0)	07/15 (46.7)	02/15 (13.3)	06/15 (40)	07/07 (100)	00/07 (0)	00/07 (0)
TPH Spectrum												
Class I	30/30 (100)	00/30 (0)	00/30 (0)	28/30 (93.3)	01/30 (3.3)	01/30 (3.3)	24/28 (85.7)	03/28 (10.7)	01/28 (3.6)	23/24 (95.8)	00/24 (0)	01/24 (4.2)
Class II	14/14 (100)	00/14 (0)	00/14 (0)	14/14 (100)	00/14 (0)	00/14 (0)	12/14 (85.7)	00/14 (0)	02/14 (14.3)	11/12 (91.7)	00/12 (0)	01/12 (8.3)
TOTAL												
Class I	**99/99 (100)**	**00/99 (0)**	**00/99 (0)**	**94/99 (94.9)**	**04/99 (4.1)**	**01/99 (1.0)**	**80/94 (85.1)**	**08/94 (8.5)**	**06/94 (6.4)**	**75/80 (93.8)**	**02/80 (2.5)**	**03/80 (3.8)**
Class II	**42/42 (100)**	**00/42 (0)**	**00/42 (0)**	**42/42 (100)**	**00/42 (0)**	**00/42 (0)**	**27/42 (64.3)**	**03/42 (7.1)**	**12/42 (28.6)**	**26/27 (96.3)**	**00/27 (0)**	**01/27 (3.7)**

* Vitremer Tri-Cure Glass Ionomer System is manufactured by 3M ESPE Dental Products, St. Paul, Minn. Freedom is manufactured by SDI, Bayswater, Victoria, Australia. TPH Spectrum is manufactured by Dentsply, Petropolis, Rio de Janeiro, Brazil.
† Percentage of restorations involved in each recall period.

presence of dental biofilm (Pearson product moment correlation, $P > .05$). However, a small group of children accumulated the majority of secondary carious lesions.

The influential variable in the performance of restorations was Class II preparations ($r = -0.216$; $P = .001$; χ^2 McNemar, $P = .001$). Table 7 (page 164) shows the cumulative survival rates for Class I and Class II restorations.

DISCUSSION

To estimate the effect of cavity design on the survival rate of adhesive restorations with different restorative materials, a clinical trial such as ours ideally should include nonbeveled cavities as a variable. Studies using a split-mouth design that evaluate different cavity configurations and materials in the same patients seem to be more appropriate than do studies dealing with different materials in different patients. The reason is that in studies conducted according to a split-mouth design, test and control groups are subjected to the same individual conditions. On the other hand, it is hard to fulfill this requirement when two cavity configurations and three types of restorative materials should be considered in the clinical trial. For this reason, beveled cavity preparations are preferred for adhesive restorative treatment,[10,11,28] so we adopted that configuration for our study.

Regarding anatomical form, TPH Spectrum showed better clinical performance in Class I restorations than did Vitremer at 12 months and 18 months of follow-up; in Class II restorations, TPH Spectrum performed better than did Freedom at the 18-month recall. These results are in agreement with those of an in vitro study that evaluated the wear and the surface hardness of RMGIC, compomers and RBC and found a negative correlation between hardness and wear, which means that RBC showed the highest values for surface hardness and the lowest scores for wear in comparison with compomer and RMGIC, respectively.[29] This finding could be explained by

TABLE 5

Reasons for restoration failure and number of failed restorations, according to criteria adopted in the study.

PERIOD OF FOLLOW-UP	CAVITY DESIGN	RESTORATIVE MATERIAL*	FAILURE REASONS ACCORDING TO MODIFIED USPHS CRITERIA† (CHARLIE AND DELTA SCORES‡)						DENTAL BIOFILM PRESENCE	NO. OF FAILURES
			MA§	AF§	MS§	AC§	PC§	SC§		
12 Months	Class I	Vitremer Tri-Cure Glass Ionomer System (Vitremer)	—¶	—	—	NA#	NA	—	—	—
		Freedom	—	—	—	NA	NA	—	—	—
		TPH Spectrum	01	01	—	NA	NA	—	—	01
	Class II	Vitremer	—	—	—	—	—	—	—	—
		Freedom	—	—	—	—	—	—	—	—
		TPH Spectrum	—	—	—	—	—	—	—	—
18 Months	Class I	Vitremer	04	03	—	NA	NA	02	01	04
		Freedom	01	01	—	NA	NA	01	—	01
		TPH Spectrum	01	01	—	NA	NA	—	01	01
	Class II	Vitremer	04	03	—	03	02	03	02	04
		Freedom	06	04	04	04	04	06	05	06
		TPH Spectrum	02	02	—	02	02	02	02	02
24 Months	Class I	Vitremer	01	—	—	NA	NA	—	—	01
		Freedom	01	01	01	NA	NA	01	01	01
		TPH Spectrum	01	—	—	NA	NA	01	—	01
	Class II	Vitremer	—	—	—	—	—	—	—	—
		Freedom	—	—	—	—	—	—	—	—
		TPH Spectrum	01	01	—	—	—	01	01	01

* Vitremer Tri-Cure Glass Ionomer System is manufactured by 3M ESPE Dental Products, St. Paul, Minn. Freedom is manufactured by SDI, Bayswater, Victoria, Australia. TPH Spectrum is manufactured by Dentsply, Petropolis, Rio de Janeiro, Brazil.
† USPHS: U.S. Public Health Service. Source: Cvar and Ryge[25] and Oldenburg and colleagues.[26]
‡ See Table 3 for score definitions.
§ MA: Marginal adaptation. AF: Anatomical form. MS: Marginal staining. AC: Axial contour. PC: Proximal contact. SC: Secondary caries.
¶ No failed restorations according to the criteria.
# Not applicable.

RBC's chemical composition, such as the inorganic filler particle size, because it is one of the most important factors in wear resistance and maintenance of its anatomical form.[30] However, at the end of the study, we found no difference among the tested materials as regards clinical performance: all restorative materials had a similar cumulative survival rate. Assuming that a restoration has a 24-month life span, the anatomical form criterion does not have the relevant clinical significance to influence the performance of restorations. Moreover, physiological wear of primary teeth minimizes the damage caused by form alterations.

It is important to point out that most unsuccessful restorations (six Class I and 12 Class II) appeared at the 18-month follow-up (Tables 4 and 5[25,26]). Although one could consider this a short-term failure,[31] most failures occurred as consequence of secondary caries, followed by loss of marginal integrity as a result of poor marginal adaptation and marginal staining (Table 5[25,26]). This finding corresponds with those of Hickel and colleagues,[32] which could be explained by the fact that as marginal quality decreased, secondary caries prevalence increased.[33] This finding, in turn, could be a consequence of problems with the bonding system, influenced by cavity design and the operator's technical ability,[32] rather than with the composite itself, because bond strength values decreased significantly after secondary caries formed (as noted by Peris and colleagues[34]). According to an in vitro model study, the size of the gap between tooth structure and restorative material affects secondary caries development along the cavity wall, and bigger lesions tended to

TABLE 6

Significance of differences in clinical performance of restorations in relation to the criteria in the study.

FOLLOW-UP PERIOD*	BEVELED CAVITY DESIGN	TWO-BY-TWO COMPARISONS BETWEEN RESTORATIVE MATERIALS†‡	MODIFIED USPHS CRITERIA§						DENTAL BIOFILM PRESENCE
			MA¶	AF¶	MS¶	AC¶#	PC¶#	SC¶	
12 Months	Class I	Vitremer Tri-Cure Glass Ionomer System (Vitremer) × Freedom	NS**	NS	NS	NA††	NA	NS	NS
		Freedom × TPH Spectrum	NS	NS	NS	NS	NS	NS	NS
		TPH Spectrum × Vitremer	$P < .05$	$P < .05$	NS	NS	NS	NS	NS
	Class II	Vitremer × Freedom	NS	NS	NS	NS	NS	NS	NS
		Freedom × TPH Spectrum	NS	NS	NS	NS	NS	NS	NS
		TPH Spectrum × Vitremer	NS	NS	NS	NS	NS	NS	NS
18 Months	Class I	Vitremer × Freedom	NS	NS	NS	NA	NA	NS	NS
		Freedom × TPH Spectrum	NS	NS	NS	NA	NA	NS	NS
		TPH Spectrum × Vitremer	$P < .05$	$P < .05$	NS	NA	NA	NS	NS
	Class II	Vitremer × Freedom	NS	NS	NS	NS	NS	NS	NS
		Freedom × TPH Spectrum	$P < .05$	$P < .05$	$P < .05$	NS	NS	NS	NS
		TPH Spectrum × Vitremer	$P < .05$	$P < .05$	NS	NS	NS	NS	NS
24 Months	Class I	Vitremer × Freedom	NS	NS	NS	NA	NA	NS	NS
		Freedom × TPH Spectrum	NS	NS	NS	NA	NA	NS	NS
		TPH Spectrum × Vitremer	NS	NS	NS	NA	NA	NS	NS
	Class II	Vitremer × Freedom	NS	NS	NS	NS	NS	NS	NS
		Freedom × TPH Spectrum	NS	NS	$P < .05$	$P < .05$	NS	NS	NS
		TPH Spectrum × Vitremer	NS	NS	$P < .05$	NS	NS	NS	NS

* Statistical differences calculated according to the Friedman test, $P < .05$.
† Wilcoxon rank sum test.
‡ Vitremer Tri-Cure Glass Ionomer System is manufactured by 3M ESPE Dental Products, St. Paul, Minn. Freedom is manufactured by SDI, Bayswater, Victoria, Australia. TPH Spectrum is manufactured by Dentsply, Petropolis, Rio de Janeiro, Brazil.
§ USPHS: U.S. Public Health Service. Source: Cvar and Ryge[25] and Oldenburg and colleagues.[26]
¶ MA: Marginal adaptation. AF: Anatomical form. MS: Marginal staining. AC: Axial contour. PC: Proximal contact. SC: Secondary caries.
# Available only for Class II restorations.
** NS: Not significant.
†† NA: Not applicable.

be associated with bigger gap sizes.[35] The earlier presence of failed restorations occurred as a result of the effect of the bevel on the margins of cavity preparations, mainly in Class II restorations. Thus, the thin layer of restorative material seemed to influence the occurrence of microcracks in cavity margins of all restorations,[36] which was associated with bonding system failures due to thermal stresses, mechanical stresses or both[37] and which resulted in a loss of marginal integrity between the restoration and the cavity walls. This condition caused gaps that could be colonized by oral microorganisms and thus could lead to secondary caries formation.[38] Dentists should understand that caries and marginal problems are linked, and both of these could be at work in marginal changes.

Curiously enough, investigators have reported that restorations with both marginal discoloration and marginal deterioration at 36 months failed 8.7 times more frequently at 60 months than did restorations with sound margins.[39] Nothwithstanding the fact that our study provided 24-month follow-up results, it tended to confirm that marginal deterioration can be an important predictor of restoration failures that lead to an increase in the incidence of secondary caries.

We should note, however, that a small number of children in our study had most of the caries. Furthermore, we did not notice any apparent

TABLE 7

Comparison of survival experiences of Class I and Class II restorations.*

PERIOD (i)†	MATERIAL‡	CAVITY DESIGN	n(i)*	d(i)*	w(i)*	s(i)*
Baseline	Vitremer Tri-Cure Glass Ionomer System (Vitremer)	Class I	33	00	00	1
		Class II	13	00	00	1
	Freedom	Class I	36	00	00	1
		Class II	15	00	00	1
	TPH Spectrum	Class I	30	00	00	1
		Class II	14	00	00	1
12 Months	Vitremer	Class I	33	00	02	1
		Class II	13	00	00	1
	Freedom	Class I	36	00	01	1
		Class II	15	00	00	1
	TPH Spectrum	Class I	30	01	01	0.97
		Class II	14	00	00	1
18 Months	Vitremer	Class I	32	04	03	0.87
		Class II	13	04	01	0.68
	Freedom	Class I	35	01	02	0.97
		Class II	15	06	02	0.57
	TPH Spectrum	Class I	29	01	03	0.93
		Class II	14	02	00	0.86
24 Months	Vitremer	Class I	30	01	01	0.84
		Class II	12	00	00	0.68
	Freedom	Class I	34	01	01	0.94
		Class II	14	00	00	0.57
	TPH Spectrum	Class I	27	01	00	0.89
		Class II	14	01	00	0.80

* Survival life table and pairwise comparisons via the Gehan-Wilcoxon statistic: S(i) = 1.00 for 100 percent survival rate and is calculated from

$$S(i) = 1 \times 1 - \left(\frac{d\,(i)}{n\,(i) - (w\,(i)/2)} \right)$$

in which n (i) = number of nonfailed restorations at the initial period (i); d (i) = number of failed restorations in the period (i); w (i) = number of censored data (restorations not evaluated at recall because of child's absence at dental appointment + successful restorations in the exfoliated teeth). Comparisons of survival rates for Class I restorations: Vitremer Tri-Cure Glass Ionomer System × Freedom (P = .139); Freedom × TPH Spectrum (P = .460); TPH Spectrum × Vitremer (P = .502). Comparisons of survival rates for Class II restorations: Vitremer × Freedom (P = .522); Freedom × TPH Spectrum (P = .133); TPH Spectrum × Vitremer (P = .425).

† Vitremer Tri-Cure Glass Ionomer System is manufactured by 3M ESPE Dental Products, St. Paul, Minn. Freedom is manufactured by SDI, Bayswater, Victoria, Australia. TPH Spectrum is manufactured by Dentsply, Petropolis, Rio de Janeiro, Brazil.

effect of fluoride release from Vitremer and Freedom restorations in this study. This finding is in agreement with those of a review[40] showing that in prospective clinical studies, researchers had not observed whether the incidence of secondary caries could be reduced by the fluoride release from RMGIC and PMRBC. In contrast, studies conducted under simulated cariogenic conditions in vitro demonstrated that fluoride-releasing materials did show cariostatic effects and may affect bacterial metabolism.[41-44]

It is important to highlight our finding that only a small number of children accounted for most of the caries in our study. This finding suggests that saliva and salivary pellicle may play important roles in the fluoride release from RMGIC and PMRBC restorative materials and in the occurrence of secondary caries. Furthermore, in our study, the presence of dental biofilm was more evident with both RMGIC and PMRBC than

with RBC. Our results, therefore, are supported by those in the dental literature.[45-47] Dentists should take these findings into account when selecting restorative materials, especially for children who have caries.

Otherwise, we found no correlation between dental biofilm and secondary caries for any restorative materials in any of the evaluation periods for any type of dental cavity preparation. The lack of correlation could be explained by the small number of occurrences in relation to presence of dental biofilm and secondary caries. Thus, we could not achieve statistical significance in our study because great differences are necessary to achieve significance in statistical analyses with a small sample size.

Our results showed that all materials exhibited a survival rate percentage without any statistically significant difference among them for beveled dental cavities of both Class I and Class II restorations (Table 7). Thus, our results confirm our study's null hypothesis. Moreover, more Class II restorations than Class I restorations failed, across all restorative materials (Tables 5 through 7[25,26]). The reasons for the greater failure rate of Class II restorations could be, as suggested by Angker and colleagues,[48] the cavity size and depth, which reduce the bond strength to dentin.[49] Furthermore, especially in children, it is technically more difficult to perform Class II restorations than Class I restorations—and, therefore, the restorations may not be of as high a quality and so may be susceptible to failure. This finding could justify the short-term failure results, mainly in Class II restorations.

Although the dental literature showed a different percentage of clinical success for adhesive restorative materials,[13-19,26,50] the annual survival rates of all materials tested in our study are in agreement with those in a systematic review,[32] in spite of those studies' having shown results for unbeveled Class I and Class II cavity preparations. The variability of the results reported in the dental literature could be as a result of the diversity of methodologies and a misunderstanding of the results,[51] which limit the comparability of different clinical studies.[31]

CONCLUSIONS

For beveled Class I preparations, we found that Vitremer, Freedom and TPH Spectrum restorative materials demonstrated survival rate percentages of 84 percent, 94 percent and 89 percent, respectively, during a period of 24 months (Gehan-Wilcoxon test, $P > .05$). For beveled Class II preparations, we found that Vitremer, Freedom and TPH Spectrum restorative materials showed lower survival rate percentages than they did in Class I preparations during a period of 24 months—68 percent, 57 percent and 80 percent, respectively—with no statistical significance among the restorative materials (Gehan-Wilcoxon test, $P > .05$).

TPH Spectrum showed better marginal integrity and maintenance of anatomical form during a period of 24 months than did the other materials we tested (Wilcoxon rank sum tests, $P < .05$; $P < .05$). This, according to our findings, makes it the material of choice for restoring Class I and Class II beveled primary molars. ■

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Article 2 – RANDOMIZED CONTROLLED TRIAL OF RESIN-BASED RESTORATIONS IN CLASS I AND CLASS II BEVELED PREPARATIONS IN PRIMARY MOLARS: 48-MONTH RESULTS

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Short (running) title: Adhesive restorations in primary molars: 48-Month RCT

Keywords: Randomized Clinical Trial; Dental - Failure rate; Molar, Tooth, Deciduous; Dental Cavity Preparation.

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Abstract

Purpose: This randomized clinical trial evaluated the survival rate of resin-based restorations, in Class I and Class II beveled preparations in primary molars, after 48 months follow-up.

Methods: Forty-eight children (mean age, 5 years and 9 months) received 141 restorations in beveled cavosurface margin preparations in primary molars randomly assigned by lottery method: 46 received treatment with Vitremer™ Tri-Cure Glass Ionomer System (3M ESPE Dental Products, St. Paul, Minn.) (33 Class I and13 Class II restorations); 51 received treatment with Freedom™ (SDI, Bayswater, Victoria, Australia) (36 Class I and 15 Class II restorations); 44 received treatment with TPH Spectrum™ (Dentsply, Petropolis, Rio de Janeiro, Brazil); (30 Class I and 14 Class II restorations). Two calibrated examiners (weight $\kappa \geq 0.85$) evaluated the restorations using modified USPHS criteria and Visible Plaque Index score at baseline and after 12, 24, 36 and 48 months. Cox regression with survival analysis and logistic regression evaluated the clinical performance of restorations at 95 confidence intervals.

Results: After 48-months, 11 teeth had exfoliated, 16 restorations were drop-outs, 83 restorations were clinically successful of which 26 were done with Vitremer™ (20 Class I / 06 Class II), 32 were done with Freedom (27 Class I/ 05 Class II) and 25 were done with TPH (18 Class I / 07 Class II). Thirty-one restorations failed because of secondary caries, fractures and loss of retention. The cumulative survival was 73.9%, 83.4% and 79.6%, respectively for Vitremer™, Freedom™ and THP Spectrum™ with no differences among materials (Log Rank Mantel-Cox, $p>0.05$). However, the Class II cavity preparation reduced the survival of the restorations (OR = 5.1) for all materials evaluated ($p> 0.05$).

Conclusions: Taking into account the survival rate, the life expectancy of Vitremer™, Freedom™ and THP Spectrum™ in Class I and Class II restorations could be comparable after 48 months of following-up.

Introduction

If clinical longevity is the primary criterion in material selection, dental amalgam would be preferable than composite restorations.[1-3] However, due to unaesthetic color but also environmental concerns, there are controversial discussions about the use of amalgam as a contemporary restorative material. [4]

In parallel, tooth-colored restorative materials have been widely used for restoring primary teeth[5-7] not only to reflect the concept of Minimal Intervention in Dentistry which implies conservative cavity preparations, but also due to differences in morphology, wear behavior and dimensions of preparations of the primary teeth in comparison with permanent teeth. [8] Moreover, the limited life span of deciduous teeth allows a greater diversity in the choice of adhesive restorative material. Taking this particularly into account, resin-modified glass ionomer cements, polyacid modified composite resins (compomers) and composite resins have been shown to be more suitable because of light-induced cure and the improvements of their mechanical properties.[9] Otherwise, the order of survival restorations in Paediatric Dentistry is doubtfulness.[5,10-12]

Many clinical trials have been published [5, 10, 11] in which secondary caries, bulk and or marginal fractures are of major concerns. [13] However, it is difficult to analyze and compare the results because of the differences in the clinical protocol. [14] A previous clinical trial showed that there was no difference among the survival rates of light-cured resin based restorations in Class I and Class II beveled

preparations in primary molars. However, the results of this clinical trial reported a medium-term period follow-up.[15]

Under the auspices of evidence-based dentistry[14], it is highly recommended randomized controlled trials with long-term period to follow the clinical outcomes of the materials, once this study design have long been recognized as the 'gold standard' for evidence research related to clinical practice.[16] Thus, the present study aimed to evaluate the survival rates of restorations done with a resin-modified glass ionomer cement, a compomer and a composite restoration in Class I and Class II beveled preparations in primary molars after 48 months. The null hypothesis was there is no difference among restorative materials.

Materials and methods

Study design and Participants

This randomized clinical trial (RCT) was approved by the Local Human Research Ethics Committee of Clementino Fraga Filho University Hospital of the Federal University of Rio de Janeiro, Brazil and was carried out at the School of Dentistry of the Federal University of Rio de Janeiro, after obtaining the children's and guardian's agreement and signed terms of informed consent.

Subjects

During a period between 2003 and 2004, all children scheduled to start the dental treatment in Pediatric Dental clinic were screened by one instructor according to these criteria: be mentally and physically healthy with at least two occlusal (O) and/or occluso-proximal (MO or DO) primary caries lesions on primary molars in a split-mouth design, with no clinical or radiographic signs of pulpal or periradicular pathology and pathological wear; have all primary molars with occlusal and proximal contacts.

After clinical and bitewing radiographic examination, 48 healthy children between 3 and 9 years of age (mean 5 years and 9 months) were selected. The subjects were treated with local anesthesia and rubber dam isolation by two trained pediatric dentists. Each child was treated by the same operator to avoid behavior problems. Each patient received at least two types of restorative materials, which were randomly chosen by the lottery method.

The study consisted of 141 restorations in total: 46 with resin modified glass ionomer cement, RMGIC, Vitremer™ Tri Cure Glass ionomer cement, 3M/ESPE, St Paul, Minn. USA; 51 with polyacid modified resin composite; Compomer, PMRBC, Freedom™, SDI, Bayswater, Victoria, Australia and 44 with resin composite, RCB, TPH Spectrum™, Dentsply, Petropolis, Rio de Janeiro, Brazil (Table 1). The distribution of all variables in the study is showed in Table 2.

Cavity design and restorations

During the restorative procedure, the operators removed only carious lesions and performed no retention such as undercutting or dovetailing. Thus, they made all Class I and Class II cavity preparations in primary molars as small as possible. The isthmus of occlusal dental cavity preparations was one-fourth to one-third of the buccal-lingual cuspal distances of primary molars. For proximal box preparations, the dentists restricted the cavity to the contact point area. The dentists prepared the teeth with a 330 bur (KG Sorensen, São Paulo, Brazil) in a high speed hand-piece with water coolant. They then used a round carbide bur at slow speed in dentin as appropriate for the cavity size.

In addition, the dentists made bevels on the occlusal or occlusal-proximal cavosurface angle. They made the bevels, which were approximately 0.5mm wide, with a 2,200 FF diamond finishing bur (KG Sorensen, São Paulo, SP, Brazil)

using 45^0 and 20^0 angulations' for occlusal and occluso-proximal preparations, respectively. They made no bevels at the gingival margins. All cavity walls had supragingival margins. The dentists applied a calcium hydroxide liner when more than half the floor of the cavity had been compromised.

During the dental cavity preparation, if the dentists noted that pulp tissue was exposed, or the required cavity size was larger than that in the study design, they performed the appropriate therapy but excluded the teeth from the sample.

The dentists randomly assigned the restorative materials (Table 1) via lottery method after completing the Class I and Class II preparations. They handled and applied in accordance with the manufacturers' instructions (Table 1). They placed Vitremer™ in the cavity in a single increment with appropriate syringe and light polymerized it for 40 seconds by using a halogen lamp with irradiance of 500 miliwatts per square centimeter measured with radiometer (Optilux Demetron, USA). They place TPH Spectrum™ and Freedom™ in increments no larger than 2.0 mm maximum, by using an oblique incremental technique until the cavity preparation was filled. Each increment was light-cured in the same way as they did for Vitremer™.

For Class II restorations, metal matrix band and wooden wedge were used and the box of proximal cavity preparation was filled first, with the same technique previously described. Occlusion was checked with carbon paper (Accufilm II, Parkell, USA) and adjusted with fine granulation burs. Final finishing and polishing procedures were done with fine, and ultrafine granulation diamond burs (KG Sorensen, São Paulo, Brazil) and finishing points with diamond polishing paste (Dentsply, Rio de Janeiro, RJ, Brazil) after one week. Some restorations were in contact with restored occlusal surfaces of teeth, and all points of occlusal contact

on enamel were obtained. After a period of one month, all restorations were evaluated. This was considered the baseline in order to standardize the study.

Evaluation of the restorations

The restorations were re-evaluated by two different blinded examiners, one of them different from the original operators (total weighted Kappa from 0.85 to 0.92 for intraexaminer and interexaminer agreements). Each restoration was assessed at baseline placement and at 12, 24, 36 and 48 months later, with modified USPHS criteria[17, 18] for anatomic form, marginal adaptation (MA), cavosurface discoloration (CS), axial contour (AC), proximal contact (PC) and secondary caries (SC). The Alfa and Bravo scores were considered clinically acceptable/success of restorative treatment, otherwise, Charlie and Delta scores (Figure 1) were clinically unacceptable/ unsuccessful restorative treatment had to be replaced and excluded from the study. Furthermore, the visible plaque Index[19] was used to observe the presence or absence of dental biofilm on the surface or around restorations (Figure 1). All evaluations were carried out with a dental operating light, mouth mirror, dental explorer and dental floss.

For ethical reasons, all the children's other needs were treated and all patients and their guardians received one to one verbal oral hygiene instructions about proper brushing and flossing techniques. In addition, each patient received professional cleaning of the teeth and neutral topical fluoride application during the dental appointments. All procedures were done by the operators involved in the study.

Data analysis

To obtain the failure rates of restorations, the authors calculated the relative risk (RR) of restorations that consisted of the ratio of the number of events

(frequency of failures for each restorative material) to the number of restoration-years. The mean annual failure rate of restorations was calculated according to the formula:$(1-y)^4=(1-x)$ in which '*y*' expresses the mean annual failure rate and '*x*' the total failure rate at 48 months.[20] Furthermore, to obtain the Odds ratio (OR) of restorations, the authors considered the ratio of the number of events to the number of restorations for each restorative material.

Variables such as the type of tooth (first or second primary molar), the arch (maxillary or mandibular), the side of tooth (right or left), the number of restored surfaces (one or two surfaces), the type of restorative material (Vitremer™, Freedom™ or TPH Spectrum™) the period of failure (from baseline to 24 months or from 24 months to 48 months) were considered in the multivariate analysis. The intention to treat analysis scored the restorations as failed if they were replaced or repaired; otherwise they were scored as censored in cases of exfoliation of the tooth with restoration in situ, patient drop-out or successful restoration. In addition, the presence of dental biofilm was correlated with failures of restorations.

To assess the multivariate influence on the failure of restorations, Data were statistically treated using multiple logistic regression analysis at 5 percent of significance level and odds ratio (OR) together with the 95 percent of confidence interval. For that, Chi-square tests investigated the association between each variable with failure at 5 percent level of significance. All variables with a significant relation to failure were employed as an independent variable in the model. Regression parameter estimates with corresponding standard errors and odds (risk) ratios were estimated for significant variables. The variables and interactions between significant variables and failure were added and removed

from the models by backward stepwise elimination (Wald test) to fit the final model.

The time to failure for Vitremer™, Freedom™ and TPH Spectrum™ restorations was displayed through Kaplan-Meier survival curves using Cox regression model in a backward stepwise elimination (Wald test) at 5 percent level of significance. All data were analyzed using an SPSS statistical package.

Results

After 48-months, 31 restorations failed (14 Class I and 17 Class II) of which 12 were done with Vitremer™ (07 Class I and 05 Class II); 08 were done with Freedom™ (02 Class I and 06 Class II); 11 were done with TPH Spectrum™ (05 Class I and 06 Class II) and 110 restorations were 'clinically acceptable' (censored) of which 34 were done with Vitremer™ (26 Class I and 08 Class II), 43 were done with Freedom™ (34 Class I and 09 Class II) and 33 were done with TPH Spectrum™ (25 Class I and 08 Class II). The reasons and number of failures could be seen in Chart 1. The relative risk (RR), mean annual failure rates, odds ratio (OR) and survival rates of Vitremer™, Freedom™ and TPH Spectrum™ restorations could be seen in Table 3. The multivariate logistic regression analysis revealed that higher number of restored surface (Class II) increased the risk of failures otherwise, more failures occurred in the beginning of study (Tables 4 and 5). The presence of dental biofilm was not correlated with failed restorations.

Among censored restorations, eleven teeth had exfoliated, 16 restorations were drop-outs and 83 restorations were successful of which 26 were done with Vitremer™ (20 Class I / 06 Class II), 32 were done with Freedom™ (27 Class I/ 05 Class II) and 25 were done with TPH Spectrum™ (18 Class I / 07 Class II). The survival curves of restorative materials are shown in Figure 2. There was no

statistical difference among the cumulative survival of the materials (Log Rank - Mantel-Cox, p=0.734).

Discussion

Long-term randomized controlled clinical trials taking into account adhesive restorative materials are urgently needed in Pediatric Dentistry in order to establish the scientific based evidence about this topic .[10, 11, 16] The present clinical trial fulfilled this item since it evaluated the survival rates of three different types of adhesive restorative materials in children by the direct comparison among restorations after 48 months of following-up in a randomized controlled trial design (RCT).

Differently from as proposed by some authors [14, 16, 21] the present RCT adopted the modified U.S. Public Health Service (USPHS)[17, 18] as evaluation criteria for restorations. The controversy of this method exists, once the detected alterations relies on the examiner's visual acuity, manual sensitivity, technique and experience of operator which remains to be standardized for the purpose of randomized controlled trial methodologies. However, in the present study, the examiners had been trained with high level of agreement (weight Kappa > 0.85). In addition, the main outcome was failure rate of restorations. In these circumstances, there was a minor possibility to introduce an evaluation bias. Moreover, the statistical method in the current study was based on the multivariate analysis[22] which warranted its statistical power even though with small sample size. It supports its validity.[22]

Many studies[14, 23, 24, 25] associated unsuccessful restorations with some variables such as tooth position in the arch[23] or with patients' age.[24] In the present clinical trial, the higher number of restored surfaces increased the risk of failed

restorations (Tables 4 and 5). It probably occurs because of the cavity size and the depth[26, 27] of preparations which decrease the bonding quality[28] specially when base material is used as protection of the pulp tissue.[23] Based on this, the null hypothesis was denied once Class II restorations showed higher failures rates than Class I for all materials (Tables 4 and 5) what it had already been showed.[3, 5]

Most failures occurred at the beginning of study (Tables 4 and 5) and most of them were due to secondary caries which corroborates previous studies.[1-3, 10, 11, 28, 29] Spite of this, the mean annual failure of Vitremer™, Freedom™ and TPH Spectrum™ was respectively, 1.86; 1.68 and 1.82 (Table 2). These outcomes were in accordance with the findings of longitudinal randomized controlled trials of direct posterior restorations in primary teeth with the same method design as the present study.[5, 30, 31, 32, 33, 34] In addition, this result was comparable with survival rate of Amalgam restorations [30, 31], and showed that spite of resin-based restorations suffering from degradation in the resin-tooth interfaces[13] after aging in the oral cavity[35], in children it did not compromise their clinical longevity. It demonstrates that the durability of restorations in primary molars depends on many factors [36,37,38] like handling of the material, the bonding capacity of the restorative system, application and curing technique used, as well as thermal, mechanical and chemical degradation. It is also worthwhile mention that all restorations are done in university clinic by calibrated and experienced operators with controlled patients which seemed to explain the lower failure rate of restorations.

In respect with high prevalence of failures at the beginning of study, although there was no a statistical significance between secondary caries and dental biofilm accumulation, most of failures were caused by secondary caries in

the same rate for all restorative materials, especially in Class II restorations, even for Vitremer™ or Freedom™ which are known to be fluoride releasing materials. These findings are supported by a previous report.[39] In opposite, TPH Spectrum™ restorations seemed to show better clinical results in relation with dental biofilm accumulation, probably due to its smoother surface. [40] On the other hand, Freedom™ accumulated the greatest amount of dental biofilm. In part, it could be explained by its surface roughness and by the fact that compomer had higher adsorption potential for acquiring dental biofilm. [41] It is worthwhile point out that a restrict number of children had the most of secondary caries in the initial period of study.

Another important clinical outcome in the present clinical trial was marginal defects as consequence as fractures or gaps. In relation to Class I restorations with Vitremer™, seven restorations failed due to marginal fractures at cavo surface margins. In fact, it shows that Vitremer™ has no mechanical properties to support a load stressed-bearing area in a thin layer.[42] Additionally, in Class I restorations the basically difference between Freedom™ and TPH Spectrum™ was related to marginal adaptation, in that the first showed better clinical results, although with no statistical difference (Figure 2). It suggests that Freedom™ had superior ability to maintain the marginal sealing. It could be explained by its chemical composition which allowed this material suffered more hygroscopic expansion than composite resin. [43]

In summary, in determining the restorative material of choice, the dentist should consider the important factor of longevity. From these results, the present clinical trial states that Vitremer™, Freedom™ and TPH Spectrum™ showed survival rates with no difference among them, 73.9%, 83.4% and 79.6%,

respectively. All materials showed higher survival rates in Class I than in Class II with no difference among materials. Consequently, they can be equally recommended for restoring Class I and Class II of primary molars if a life span of four years is estimated. As part of an evidence-based practice, clinicians need to be aware of the levels of evidence in the literature and need to properly inform patients and their family of the true clinical outcomes that are associated with the use of restorations in primary molars, so that patients and their families are themselves making informed decisions about their dental care.

Table 1. Esthetic restorative materials investigated and technique used.

Material	Brand name	Batch Number	Basic composition	Adhesive protocol	Technique
RMGIC	VitremerTM Tri-Cure Glass ionomer System™	3303MPA3	Fluoroaluminosilicate glass; potassium persulfate, ascorbic acid, aqueous solution of polycarboxylic acid, water, hydroxyethyl methacrylate, photoinitiators, ethanol	VitremerTM Primer*	Applied for 15 seconds, then light-cured for 20 seconds.
PMCBR	Freedom™	033808	Strontium glass, non BISGMA	Total etch 37% phosphoric acid Stae™ dentin/enamel adhesive†	Total acid etch for 30 seconds (condition enamel for 15 seconds and dentin for 15 seconds). Washed with water then dried with air spray. Applied Stae adhesive system; gently dried with air spray and light-cured for 20 seconds.
RBC	TPH Spectrum™	555055	Borosilicate glass/pyrogenic silica potassiumpersulfate and ascorbic acid; BISGMA, UDMA e TEDMA	Total etch 37% phosphoric acid/ Prime & Bond NT™‡	Total etched for 30 seconds (condition enamel for 15 seconds and dentin for 15 seconds). Washed with water then dried with air spray. Applied Prime & Bond NT adhesive system; gently dry with air spray, reapplied and light-cured for 20 seconds.

*Manufactured by 3M ESPE Dental Products, St. Paul, Minn.
†Manufactured by SD, Bayswater, Victoria, Australia.
‡Manufactured bt Dentsply, Petropolis, Rio de Janeiro, Brazil.

Table 2: Number of restorations placed by categorical and continuous predicted variables in the study.

Primary molar	Gender	Male (n=100)												Female (n=41)										Total
	Age	5-7 years (n=41)						8-10 years (n=59)						5-7 years (n=32)						8-10 years (n=9)				
	Material	Vitremer (n=13)		Freedom (n=12)		TPH (n=16)		Vitremer (n=21)		Freedom (n=22)		TPH (n=16)		Vitremer (n=09)		Freedom (n=13)		TPH (n=10)		Vitremer (n=03)		Freedom (n=04)		TPH (n=02)	
	Dental cavity preparation	Cl I	Cl II	Cl I	Cl II	Cl I	Cl II	Cl I	Cl II	Cl I	Cl II	Cl I	Cl II	Cl I	Cl II	Cl I	Cl II	Cl I	Cl II	Cl I	Cl II	Cl I	Cl II	Cl I	Cl II	
55		02	01	00	01	01	00	05	00	00	00	02	01	01	00	01	00	02	01	02	00	00	00	00	00	**20**
54		01	00	02	01	01	03	02	01	00	01	03	02	01	00	03	01	00	00	00	00	00	00	00	01	**23**
64		00	01	02	01	02	00	00	00	05	01	01	00	00	02	01	00	00	00	00	00	00	01	00	00	**17**
65		00	02	00	00	01	01	01	02	01	00	01	00	00	00	04	00	01	00	00	00	01	00	01	00	**16**
75		03	00	01	01	00	00	02	01	07	00	00	01	00	00	01	00	02	00	00	01	01	00	00	00	**21**
74		01	01	00	01	03	00	02	01	01	00	01	00	01	00	01	00	00	00	00	00	00	00	00	00	**13**
84		00	00	01	01	02	01	01	00	02	02	01	00	03	00	00	01	02	00	00	00	00	00	00	00	**17**
85		01	00	00	00	01	00	03	00	01	01	01	02	01	00	00	00	01	01	00	00	00	01	00	00	**14**
Total		**08**	**05**	**06**	**06**	**11**	**05**	**16**	**05**	**17**	**05**	**10**	**06**	**07**	**02**	**11**	**02**	**08**	**02**	**02**	**01**	**02**	**02**	**01**	**01**	**141**

Table 3 – Relative risks, mean annual failures, odds ratio, at 95 percent of Confidence Intervals and cumulative survival rates of restorations.

Material	RR (%)	CI 95% (%)	MAFr (%)	OR (%)	CI 95% (%)	CSr (%)
Vitremer™	8.5	[5.2-14.9]	1.86	26.1	[15.1-40.1]	73.9
Freedom™	5.6	[3.6-12.3]	1.68	15.7	[7.6-27.6]	83.4
TPH™	6.3	[4.7-14.0]	1.82	20.4	[10.5-34.2]	79.6
Test	Qui-Square		--------	Qui-Square		Pooled Log Rank Mantel-Cox
Statistical significance (p value)	= 0.394		--------	= 0.449		= 0.734

RR – Relative Risk of restorative material
MAFr – Mean Annual failure rate of each restorative material
OR – Odds ratio
CI – Confidence interval
CSr – Cumulative survival rate

Table 4: Variables and its association with failures

Variables	Frequency		Failure rate (RR)	*Odds ratio*	
	Absolute	**Relative**		**OR**	**IC95%**
Gender					
Female	07	17.1%	22.6%	0.73	(0.36 – 1.48)
Male	24	24%	77.4%	1.12	(0.89 – 1.40)
Age in years old					
05 a 07	19	26%	61.3%	1.25	(0,89 – 1.75)
08 a 10	12	17.6%	38.7%	0.76	(0.47 – 1.23)
Tooth type					
First primary molar	14	20%	45.2%	0.89	(0.58 – 1.36)
Second primary molar	17	23.9%	54.8%	1.12	(0.77 – 1.62)
Arch					
Maxillary	16	21.3%	51.6%	0.96	(0.66 – 1.41)
Mandibular	15	22.7%	48.4%	1.04	(0.69 – 1. 58)
Tooth Side					
Right	14	19.2%	45.2%	0.84	(0.55 – 1.29)
Left	17	25%	54.8%	1.18	(0.81 – 1.72)
Number of restored surfaces*					
1 - Class I	14	14.1%	45.2%	0.58	(0.39 – 0.87)
2 - Class II	17	40.5%	54.8%	2.41	(1.50 – 3.86)
Period of failure*					
until 24 months	23	57.5%	74.2%	4.80	(2.96 – 7.79)
Before 24 months	08	7.9%	25.8%	0.30	(0.17 – 0.56)
Restorative Material					
Vitremer™	12	29.4%	38.7%	26.1	[15.1-40.1]
Freedom™	08	35.3%	25.8%	15.7	[7.6-27.6]
TPH Spectrum™	11	35.3%	35.5%	20.4	[10.5-34.2]

***Chi- Square tests; p<0.05**

Table 5: Variables of significance for survival of restorations with their corresponding degrees of freedom (DF), test probability (TP), parameter estimate (PE), standard error (SE), and risk ratio (Rr) at 95% confidence intervals after 48 months.

Variables	DF	Test probability	Parameter estimate	Standard error	Risk ratio	95% IC Lower	Upper
Number of restored surfaces							
1 – Class I	**1**	**-**	**-**	**-**	**1**	**-**	**-**
2 – Class II	**1**	**0.003**	**8.935**	**0.546**	**5.116**	**1.754**	**14.919**
Period of failure*							
until 24 months	**1**	**0.000**	**28.390**	**0.563**	**2.050**	**0.017**	**0.150**
Before 24 months	**1**	**-**	**-**	**-**	**1**	**-**	**-**

Chart 1 – Failure reasons of restorations at the end of study.

Restored surface	Restorative Material	Reasons for failure*	Number of failures*
Class I	Vitremer Tri-Cure Glass Ionomer System®	Marginal fracture	07
	Freedom®	Marginal adaptation Marginal discoloration Secondary caries	02
	TPH Spectrum®	Marginal adaptation	05
Class II	Vitremer Tri-Cure Glass Ionomer System®	Secondary caries Loss of retention	05
	Freedom®	Secondary caries	06
	TPH Spectrum®	Marginal adaptation Secondary caries	06

***** The restorations could have more than one reason for failure.

Figure 1 – Modified U.S. Public Health Service criteria for rating restorations [17,18]

Criteria	Score	Score Number	Modified USPHS Criteria
Marginal Adaptation	Alpha	**0**	No visible evidence of a crevice along the margin
	Bravo	**1**	Visible evidence of a crevice along the margin into which the explorer will penetrate
	Charlie	**2**	Dentin or the base is exposed
	Delta	**3**	The restoration is fractured, mobile or missing
Anatomic Form	Alpha	**0**	The restoration is continuous with existing anatomical form
	Bravo	**1**	The restoration is discontinuous with existing anatomical form, but the material is not sufficient to expose the dentin or base
	Charlie	**2**	The restoration is discontinuous and the dentin or the base is exposed
Cavosurface margin Discoloration	Alpha	**0**	No discoloration anywhere along the margin between the restoration and adjacent tooth
	Bravo	**1**	Slight discoloration along the margin between the restoration and the adjacent tooth
	Charlie	**2**	The discoloration penetrated along the margin of the restorative material in a pulpal direction
Axial contour	Alpha	**0**	Axial contour continuous with existing tooth form proximal embrasures
	Bravo	**1**	Slightly under contoured or slightly over contoured, not continuous with enamel
	Charlie	**2**	Moderately under contoured or moderately over contoured
	Delta	**3**	Decidedly under contoured (tissue trauma evident)
Proximal Contact	Alpha	**0**	Proximal contact is present
	Bravo	**1**	Proximal contact is light, but present
	Charlie	**2**	No proximal contact
Secondary Caries	Alpha	**0**	No caries present
	Bravo	**1**	Caries present along the margin of the restoration
Visible Plaque index	Alpha	**0**	Dental biofilm absent
	Bravo	**1**	Dental biofilm presence related to restorations

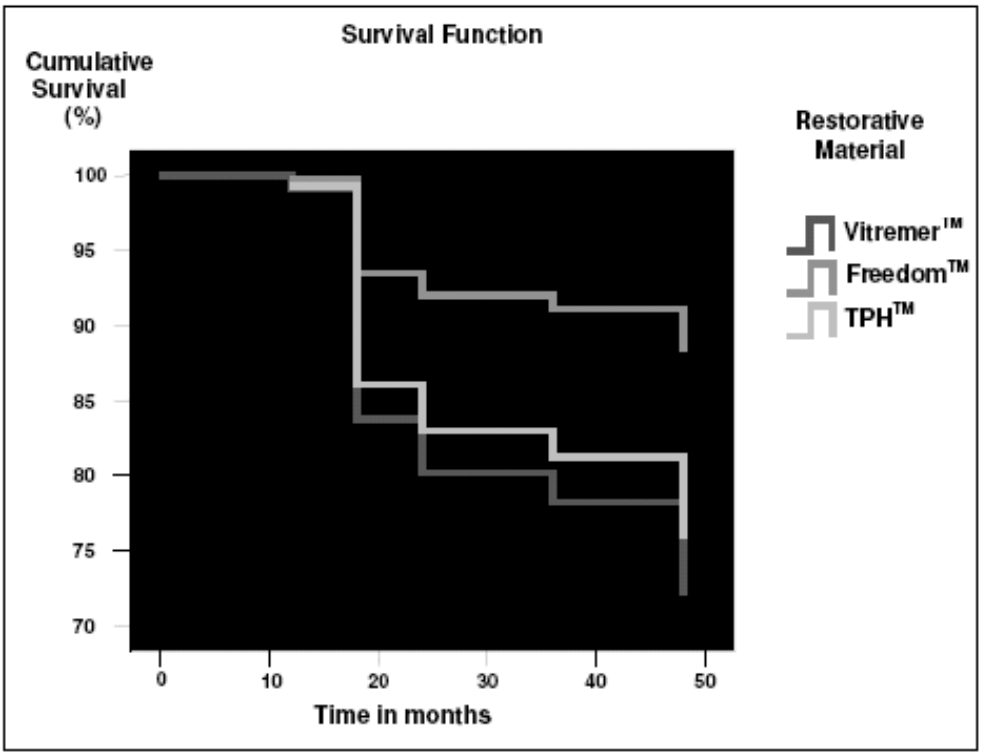

Figure 2 – Cumulative survival distributions of the restorations after 48-month results with no statistical difference (p=0.734) although the curves show a higher cumulative survival rate for Freedom™.

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ARTIGO 3 - CLASS I AND CLASS II UNBEVELED VERSUS BEVELED DENTAL PREPARATIONS FOR LIGHT-CURED DIRECT RESIN-BASED RESTORATIONS IN PRIMARY MOLARS: A SYSTEMATIC REVIEW

Short Title: DIRECT ADHESIVE RESTORATIONS IN PRIMARY MOLARS: A SYSTEMATIC REVIEW

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Key-Words: Dental cavity preparation, Molar, Teeth; Deciduous, Glass Ionomer Cements, Compomers, Composite Resins.

ABSTRACT

Objective: To evaluate the effectiveness of Class I and Class II unbeveled versus beveled dental preparations for light-cured direct resin-based restorations in primary molars. Methods: MEDLINE (1970 to May 2009), BIREME (up to May 2009), The Cochrane Oral Health Group´s Trials Register (up to May 2009), CENTRAL (The Cochrane Library 2009, Issue 2), EMBASE (1996 to May 2009) and SIGLE (1976 to 2005) with a combination of the Medical Subject Headings (MeSH) such as: dental cavity preparation; teeth/deciduous; molar; randomized clinical trial were electronically searched. Only studies published in English language and with a minimal observation period of 12 months were considered. Additionally, the reference lists of the selected articles and the electronic databases from relevant scientific journals were also handsearched. The eligible trials consisted of prospective randomized or quasi-randomized controlled clinical trials of Class I and Class II dental preparations using high-speed hand piece, with the effect of cavosurface angle on the cavity configurations, involving children (3-12 old years), with at least two primary caries lesions in primary molars, with success rate or survival time of resin-based restorations as the main measured outcome parameter. The literature search produced 44 articles, 05 of which fulfilled the selection criteria. Results: Meta-analyses found no statistically significant difference between Class I unbeveled or

beveled dental preparations (OR = 0.84, CI, 0.30 to 2.34, p =0.73). Conclusions: A systematic review of randomized controlled clinical trials evidenced a lack of effectiveness of Class I bevel dental preparations for prevention failed restorations. There was no evidence for the Class II dental preparations.

INTRODUCTION

The performance of dental restorations is influenced by several factors, including materials properties and restorative technique, operator experience, patient conditions and dental cavity preparations. [1, 2] Previous systematic reviews showed that there is insufficient evidence about which material is the choice for using in Pediatric dentistry. [3, 4] It is important to highlight that in both reviews mentioned, the type of cavity preparation was not considered as a variable in relation with success rates of restorations. Thus, the choice for either cavity design or material selection still appears to be based upon clinical preference. [5]

For direct restorative dentistry management in children, resin-based restorative materials trend to increase their use [6-12] not only due to the characteristics of primary teeth such as dental wear and limited lifespan[13] but also their mechanical and chemical property improvements. [14] However, the bond stability of tooth/resin-based restoration interface is considered a major factor influencing the longevity of adhesive dental restorations. [2, 15-17] The acid etching is the most useful choice for bonding of resin-based restorative materials due to its simplicity and efficiency. [18] It is known that enamel surfaces etched by phosphoric acid appear to be affected at three levels: etched zone (a narrow zone of enamel totally removed by etching), a qualitative porous zone and a quantitative porous zone. The molecular bonding mechanism occurs through the latter two zones. [19]

Studies demonstrated ungrounded primary enamel bears a prismless superficial layer which is known to be acid resistant and negatively affects the quality of bonding. [20-22] It occurs because of prismless organization in the parallel direction of enamel prisms when viewed in relation to long axis of the primary molars. [23] Therefore, the cavity preparations for resin-based restorations would be improved if the prismless layer is modified by mechanical treatment before acid etching. [24-26] On the other hand, the amount of tooth ground away for the bevel-treated cavity was greater than the amount in unbeveled ones [14] and beveled dental preparations often obscures a well-delineated cavosurface finish line, commonly resulting in a thin layer of material at the margin, which is prone to fracture under occlusal loading. [27]

The ultimate test method to assess the clinical problems continues to be practice-based clinical trials. [14, 28] In recognition of the impact of randomized controlled trials on the existing state of knowledge, the relation between existing and new evidence should be illustrated by direct reference to an existing systematic review and/or meta-analysis. When there is no systematic review or meta-analysis, authors are encouraged to conduct their own. [14, 28] Thus, the purpose of this study was, using evidence-based dentistry, to compare the success rates of resin-modifed glass ionomer cements (RMGICs), composite resins (CRs) and polyacid-modified composite resins (PMCRs) in Class I and Class II unbeveled versus beveled dental preparations of primary molars.

MATERIALS AND METHODS

Search strategy

Electronic searches in the MEDLINE (1970 to May 2009), in the BIREME (up to May 2009), in The Cochrane Oral Health Group´s Trials Register (up to May 2009), CENTRAL (The Cochrane Library 2009, Issue 2), EMBASE (1996 to May 2009) and in the System for Information on Grey Literature in Europe (SIGLE -1976

to 2005) databases were undertaken with a combination of the Medical Subject Headings (MeSH) such as: dental cavity preparation; teeth/deciduous; molar; randomized clinical trial. To screening more studies, detailed search strategies were developed for each database searched. This was based on the search strategy developed for MEDLINE but revised appropriately for each database (Table 1). The journal articles were selected by examining: (1) titles; (2) abstracts and (3) full texts (Table 1).

The eligible trials consisted of prospective randomized or quasi-randomized controlled clinical trials of Class I and Class II dental preparations using high-speed hand piece, with effect of cavosurface angle on the cavity configurations, involving younger children (between 3 and 12 years old) with at least two primary caries lesions in primary molars in the beginning of study, with success rates or survival time of RMGIC, CR and PMCR restorations as the main measured outcome parameter.

The exclusion criteria applied during the search strategy were: articles of the same study with shorter follow-up; trials with systemically compromised children; trials using metallic restorations or conventional glass ionomer cement restorations or sandwich restorations or indirect restorations; trials with pulp therapy interventions and clinical trials which the only outcomes were based on clinical criteria. [34,36]

Data were independently extracted, in duplicate, by two review authors and the evidence level of the studies was analyzed according to Hickel et al., (2005) [14] (Table 2). Disagreements were resolved by a consultation with a third review author. The literature search produced 44 articles, 03[6, 7, 36] of which fulfilled the selection criteria with A score, 01[35] received B1score and 01[29] received B2 score. Both clinical trials with B[29,35] scores were lately excluded because although they had made Class I

or Class II beveled dental preparations in such studies there were no control groups. Then, the review authors extracted data from A studies[6, 7, 36] and entered them into Meta review, Review Manager 5.0[37] (Cochrane Collaboration, Oxford, UK), Windows, based software product. Meta-analyses were conducted using direct and indirect techniques. The direct technique compared two by two cavity preparations in the same study. For this reason, the data extracted from RCT[36] were dichotomized in unbeveled and beveled dental preparations. Odds ratios and at 95 percent confidence interval (CI) were calculated from a model (Mantzel-Haenzel fixed model effects) that included main effects for cavity dental preparations and failed restorations. Proportional data from each study were combined by pooling the events in the control (unbeveled) and the experimental (beveled) groups. The indirect technique used the same statistical method for comparison among the three studies at 10 percent level of significance. Finally, the sensitivity analysis examined the heterogeneity of studies and the authors assessed the publication bias visually using a funnel plot.

RESULTS

Qualitative analyze results

Three randomized controlled clinical trials[6, 7, 36] were included in this review. Table 4 showed data synthesis of studies. The review authors evaluated 315 Class I dental cavity preparations of which 184 received intervention and 146 received no intervention. RMGIC (Vitremer, 3M, ESPE, USA) restored 84 Class I dental preparations whilst 231 were treated with CRs (TPH Spectrum, Dentsply, Germany and two experimental composite resins). Due to lack of data for comparison of Class II preparations, the effect of the intervention in both conditions could not be assessed. No comparison was performed among resin-based materials.

Statistical analyze results

Figure 1 showed failure rates and at 95 percent confidence intervals of each and all studies.

The odds ratio of Prabhakar et al., 2008[6], Oliveira et al., 2008[7] and Oldenburg, Vann & Dilley, 1987[36] studies were respectively, 0.10 (CI, 0.01 to 1.93), 1.0 (CI, 0.19 to 5.23) and 5.17, (CI, 0.28 to 95.58) (Figure 1). Meta-analyses of these three comparisons showed the beveled group had no significantly lower failures than the unbeveled group (0.84; CI, 0.30 to 2.34, p =0.73) with no inconsistency across studies (Chi^2 = 3.51, df = 2; p = 0.17; I^2 = 43%) (Figure1). Sensitivity analyses detected an unclear methodology for allocation concealment in the RCT conducted by Oldenburg, Vann & Dilley, 1987.[36] However, there was no publication bias which was visualized by funnel plot symmetry (Figure 2).

DISCUSSION

In this systematic review, the authors classified three studies [6, 7, 36] as level A of evidence and therefore within the appropriate methodology such as adequate reporting of randomization and allocation concealment, to recommend the intervention or not. It is important because enables an evaluation of intervention effects with no interference on the summary measures. In addition, it assures the high-quality in meta-analyses. [38] It could be proven once the results showed that the exposures the risk was comparable in the three studies (Table 1). It is important to emphasize, however, that Prabhakar et al., 2008 study [6] suggests an increased risk of exposure when the intervention is associated with no intervention (p=0.055).

Only one RCT[19] evaluated Class II dental cavity preparations. Therefore, there is no evidence of the effectiveness of intervention considering this type of cavity

design. Moreover, comparison among restorative materials could not be performed, corroborating previous systematic reviews. [3, 4, 14, 39] Thus, it is strongly recommended RCTs involving Class II unbeveled versus beveled preparations using direct light-cured resin based restorations to collect outcomes that are important to patients and users.

In the RCTs[6, 7, 36], the tooth was the unit of randomization, and the individual served as both control and experimental groups. This study design can increase statistical efficiency, and on average, fewer patients are needed.[40] However, it may lead to recruitment problems and difficulties in the statistical analyses[28]. These limitations are both presented in the primary studies of this systematic review. There was a small sample size and statistical methods were based on non parametric tests which may be related to the weak statistical power of studies. Although study power can be improved by increasing the sample size, it takes longer costs more to recruit patients and it is more expensive.[41] Indeed, this is not always achievable, especially in split-mouth studies in which individuals might have a minimum of comparable and repeated occurrences to be treated with different types of intervention. Therefore, it is imperative to have appropriate strategies in order to design a better methodology for obtaining internal and external validity of clinical studies. Concerning these, it has been proposed that more important than sample size required to RCTs is the statistical method of analyzing changes in outcome variables, so analysis of covariance should be used.[41]

Clinical studies are prone to individuals failing to attend recall appointments or withdrawals. [42] In Pediatric Dentistry this subject gains particularly relevance since primary teeth exfoliate. This inevitably calls into question the validity of the results, because it is not known whether these drop-outs indeed were failures. The RCTs

used in this review have validity once they analyzed the outcomes by intent to treat avoiding the misleading effects that can arise in the intervention research.

It is important to highlight that in clinical trials the patients, operators and assessors should all be blind as regards any treatment/intervention conditions[42] because open outcome assessment has also been shown to overestimate treatment effects. [43] But, it is recognized that it is not always possible to blind operators, particularly in restorative procedures, such as dental cavity preparations, due to the differences among dental cavity configurations. In all RCTs, the patients and at least one assessor were blind. For these reasons, the selected studies were categorized as double-blind, in spite of this not being clearly mentioned.

A comparison among the RCTs[6, 7, 36] tested the inconsistency across the studies. Heterogeneity was not detected although an inconsistency analysis result (I^2=43%) was closer to 50 percent than 0 percent, the ideal value. [44] This can be explained by the fact that in this RCT[36] the results were in favor unbeveled dental preparations while in the RCT[6] the results were in favor of experimental groups, i.e., beveled preparations. In the RCT[7] there was no difference between intervention and control (Figure 1). Thus, the weight effect of each RCT[6, 7, 36] ensured the homogeneity of this systematic review. However, it points out the necessity to include others trials into the Meta-analyze. Such conduct bears significance with a larger sample size.

The authors of this systematic review at this time to include the data for the meta-analysis intentionally turned a variable which had three sub-levels into a dichotomous variable, so data were differently pooled into two groups, thereby it was understood as allocation concealment bias. On the other hand, the funnel plot showed a symmetrical distribution (Figure 2). Publication bias has long been

associated with funnel plot asymmetry, and true heterogeneity in treatment effects may also lead to funnel plot asymmetry. [45] In the absence of bias, the plot should resemble a symmetrical inverted funnel (Figure 2) as showed in the present systematic review. It occurs in the meta-analyzed results and suggests no introduction of publication bias. However, these results should be interpreted with considerable caution because are based on a limited number of results of small trials. [45]

Taking into account the results there is evidence of no effectiveness of intervention in the experimental or control group (Figure 1) although the diamond in the forest plot was slight shifted to beveled dental preparations. These findings corroborated the results of primary studies from the data were extracted and could be justified by the small sample size and the low failure rates of restorations (Figure 1).

CONCLUSIONS

Implications for practice

The evidence is insufficient to support the intervention bevel on Class I dental preparations. It is recommended that Class I dental preparations remain with no bevel at cavosurface angle. Otherwise, there is no evidence about Class II dental preparations.

Implications for research

Randomized controlled trials are needed with sufficient sample size to be determined definitively the effectiveness of intervention. Accordingly, multicenter studies using the same methodology designed in these RCTs, would contribute to solve this controversy. In this opportunity, the random model effects should be considered for analyzing the data.

There is an urgent need for well designed, randomized controlled clinical trials to compare the effects of the intervention bevel on the Class II preparations.

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Table 1 - Sensitivity of electronic databases searched.

Databases	MeSH (Keys Words)	Results		
		Title	Abstracts	Full text
EMBASE (1996 - May 2009)	Dental cavity preparation; deciduous molar; Combine of: restorations.m_titl. *dentition, primary/ or *tooth/ or *molar/ molar/ and *tooth, deciduous/ (limit to randomized controlled trial)	14	00	00
MEDLINE (1966 - May 2009)	Dental cavity preparation, deciduous molar, randomized clinical trial (MeSH terms)	31	11 [6-12,24,29-33]	02 [6,7]
BIREME (1996 – May 2009)	Dental cavity preparation; deciduous molar; Combine of: [MH]"Deciduous Tooth " and "Molar" and "Dental Restoration Failure" [words]	04	02[7, 35]	01[35]
COCHRANE LIBRARY (2009, issue 2)	"tooth, deciduous and dental cavity preparation and clinical study in Publication Type in The Cochrane Central Register of Controlled Trials"	176	0	00
SIGLE (up 2005)	Dental cavity preparation; deciduous molar; randomized clinical trial	0	0	00
HAND-SEARCHING (May 2009)	Reference lists	02	02[29, 36]	02[29, 36]
	Electronic Dental journals	04	00	00
Total		230	14	05

Table 2 - Evidence level for clinical studies according to Hickel et al., 2005[14]

Level	Levels of evidence for rating clinical studies
A	Evidence from meta-analyses of randomized controlled trials Evidence from at least one randomized controlled trial
B1	Evidence from at least one controlled study without randomization Evidence from at least one other type of quasi-experimental study
B2	Evidence from descriptive studies, such as comparative studies, correlation studies, and case controlled studies
C	Evidence from expert committee reports or opinions, consensus, conferences and or clinical experience of respected authorities, or both.

Table 3 – Distribution of studies after evaluation data.

Clinical trials, years	Level of Evidence[14]
Prabhakar et al., 2008[6]	A
Oliveira et al., 2008[7]	A
Cunha, 2000[29]	B2
Dos Santos, et al., 2009[35]	B1
Oldenburg, Vann & Dilley, 1987[36]	A

Table 4 - Data synthesis of RCT studies.

RCTs	Study design									Recall (%)	Statistical tests	Follow -up (Ms)
	R	A	B	P (Age in years)	Material	Dental preparations*						
						Unbeveled		Beveled				
						Class I	Class II	Class I	Class II			
Prabhakar et al., 2008[6]	Yes. No mention	No mention	Patient and examiner	N=42 (5-9)	RMGIC	**39/42**	------	**42/42**	------	100	McNemar Chi-Square	12
Oliveira et al., 2008[7]	Coin toss	After cavity preparation	Patient and examiner	N=32 (4-10)	CR	**44/47**	------	**44/47**	------	90	Wilcoxon Friedman	18
Oldenburg, Vann & Dilley,1987[36]	A table of random	After cavity restoration with a table of random	Patient and examiner	N=50 (4-8)	CR	**42/42**	**51/60**	**90/95**	**108/128**	83	McNemar Chi-Square	48

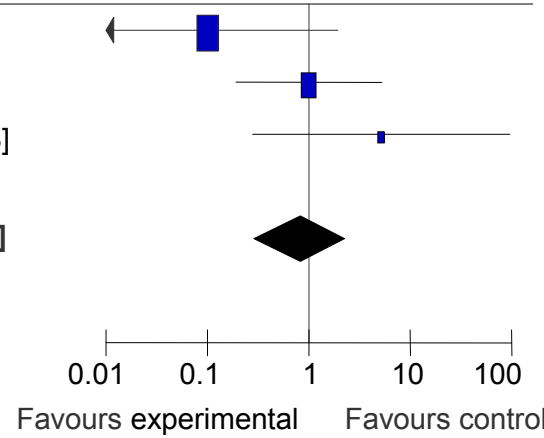
R – Randomization
A - Allocation concealment
B – Blinding
P – Number (absolute frequency) of patients
----- No data
*Ratio of successful restorations to the total restorations
(Ms) - Months

Figure 1 – Failure rates, at 95 percent Confidence Intervals and measure of association of Class I unbeveled versus beveled dental cavity preparations

	Beveled group		Unbeveled group		Odds Ratio	Odds Ratio
RCTs	**Events**	**Total**	**Events**	**Total**	**Weight M-H, Fixed, 95% CI**	**M-H, Fixed, 95% CI**
Prabhakar et al., 2008[6]	0	42	4	42	56.2% 0.10 [0.01, 1.93]	
Oliveira et al, 2008[7]	3	47	3	47	35.5% 1.00 [0.19, 5.23]	
Oldenburg et al., 1987[36]	5	95	0	42	8.2% 5.17 [0.28, 95.58]	
Total (95% CI)	**184**		**131**		**100.0% 0.84 [0.30, 2.34]**	
Total events	8		7			

Heterogeneity: Chi² = 3.51, df = 2 (P = 0.17); I² = 43%

Test for overall effect: Z = 0.34 (P = 0.73)



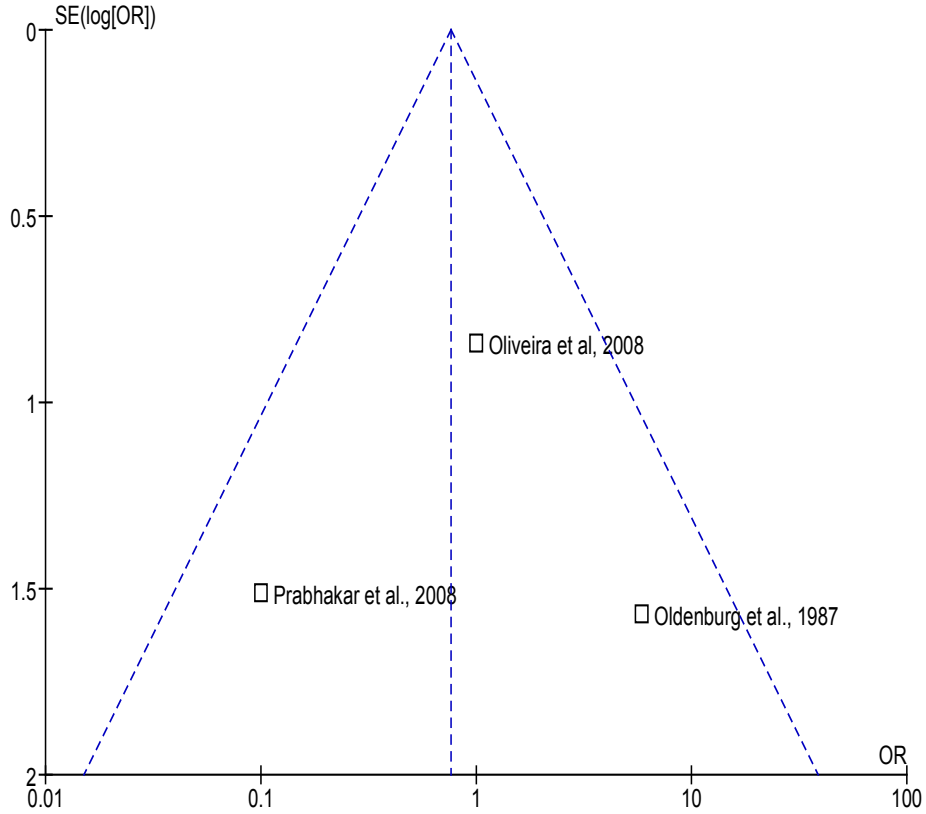


Figure 2 - The symmetry of Funnel plot evidence no effect of publication bias on the present

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5. DISCUSSÃO

Estudos clínicos prospectivos têm grande relevância cientifica, à medida que, a partir de seus resultados, são delineadas novas condutas terapêuticas ou tecnológicas para a prática clínica (Hickel, Roulet *et al.*, 2007b; Mjor, 2008). Sendo assim, a padronização de um protocolo clínico com parâmetros reprodutíveis de avaliação devem ser rigorosamente delineados (Hickel, Roulet *et al.*, 2007b; Mjor, 2008). Por isso, o desenho de estudo tipo controlado aleatório e duplo cego e paralelo, em que o indivíduo tem a possibilidade de ser do grupo controle e ao mesmo tempo do grupo experimental, é uma exigência para a constatação da evidência científica. Entretanto, deve-se ter cautela na interpretação de seus resultados, particularmente naqueles estudos com reduzido universo amostral em que nenhuma estratégia para análise dos resultados foi considerada (Tu, Blance *et al.*, 2005). No presente estudo, embora o universo amostral tenha sido composto por 141 restaurações, o que foi equivalente a 32 % do tamanho amostral calculado (n=436), não só o desenho do estudo, mas também a estratégia para a análise dos dados, que considerou variáveis dependentes e independentes por meio de uma regressão logística, foi determinante para a comparabilidade dos resultados com outros estudos de maior tamanho amostral. Isto assegura a validade do presente estudo.

De um modo em geral, o maior número de falhas ocorreu indistintamente para os três materiais, embora tenha sido com maior freqüência nos primeiros vinte e quatro meses. Vale ressaltar, que a maioria das falhas ocorreu em um grupo específico de crianças que acumularam um elevado percentual de

insucessos decorrentes principalmente de cárie secundária. Isto foi marcadamente percebido nas restaurações Classe II, particularmente com o material restaurador Freedom®, seguido pelo Vitremer® e pelo TPH Spectrum®. Em relação ao compômero, resultados similares foram observados por Soncini, Maserejian et al., 2007 (Soncini, Maserejian *et al.*, 2007) após cinco anos de acompanhamento. Dessa forma, tal comportamento clínico deve ser levado em consideração quando da seleção deste material como de eleição para restaurações Classe II em crianças sujeitas ao alto desafio cariogênico.

Por outro lado, ao considerar valores absolutos, o mesmo material demonstrou resultados superiores aos demais nas restaurações Classe I. Em parte isto pode ser justificado pela sua composição química que assegura maior ductilidade do compômero frente ao compósito e ao cimento de ionômero de vidro modificado por componentes resinosos particularmente na interface dente biselado/restauração, ou seja, em uma interface de pouca espessura quando submetidos aos esforços mastigatórios. Tal fato pode ser confirmado pelo grande número de fraturas marginais e de alterações na adaptação marginal decorrentes do compósito e do cimento de ionômero de vidro modificado por componentes resinosos nas restaurações Classe I. Isto quer dizer que estresse gerado na interface dente/ material restaurador decorrente da contração de polimerização quando estes materiais foram fotopolimerizados. Acrescenta-se que o compômero apresenta um grau de expansão higroscópica superior ao compósito, portanto possui maior capacidade para manter o selamento marginal quando comparado ao compósito (Huang, Tay *et al.*, 2002).

Ao considerar todos os aspectos relativos ao fracasso das restaurações, pode-se perceber que as restaurações fracassaram basicamente por dois

motivos: cárie secundária e defeitos marginais. Em ambas as condições, pode-se notadamente identificar um comprometimento da qualidade marginal embora com diferentes repercussões clínicas. No caso de fratura das restaurações, a intervenção clinica poder-se-ia resumir a um reparo da restauração ao invés da sua total substituição (Hickel, Roulet *et al.*, 2007a). Tal fato é importante, principalmente no que tange a preservação de substrato dental quando da necessidade do retratamento restaurador, mas também da possibilidade de consultas com menor tempo clinico, o que é almejado particularmente no atendimento de crianças. Cabe ressaltar, porém que a metodologia adotada no presente estudo, não contemplou este quesito. Além disso, o método USPHS é incapaz de detectar tais diferenças (Cvar e Ryge, 2005), e em função desta limitação Hickel et al., 2007 (Hickel, Roulet *et al.*, 2007a) já enfatizaram a necessidade de se contemporizar este critério (Cvar e Ryge, 2005), já que houve evolução tecnológica e da aplicabilidade destes materiais restauradores. Desta forma, é de fundamental importância que se aplique um método de avaliação com maior sensibilidade para detectar sutis alterações nas restaurações (Hickel, Roulet *et al.*, 2007).

A durabilidade das restaurações adesivas *in vivo* (De Munck, Van Landuyt *et al.*, 2005) está diretamente relacionada à sua degradação marginal (Hayashi e Wilson, 2003), assim alternativas que promovam a melhoria ou mesmo aumente a estabilidade da interface material restaurador adesivo/substrato dental, aumentariam a sobrevida destas restaurações (De Munck, Van Landuyt *et al.*, 2005). Nesse sentido, o preparo cavitário é uma etapa importante para o procedimento restaurador adesivo (Nozaka, Suruga *et al.*, 1999), sobretudo, nos dentes decíduos, onde o direcionamento e a espessura dos prismas de esmalte,

bem como a camada superficial aprismática podem influenciar no seu desempenho clínico (Oliveira, Dias *et al.*, 2008; Prabhakar, Raju *et al.*, 2008), comprometendo a qualidade da adesão. Sendo assim, o biselamento do ângulo cavo-superficial tem sido sugerido (Oldenburg, Vann *et al.*, 1985; Lee e White, 1998; Nozaka, Suruga *et al.*, 1999; Swanson, Feigal *et al.*, 2008), à medida que promove a remoção mecânica da camada aprismática, faz a exposição dos prismas de esmalte no sentido de seu longo eixo, aumenta a quantidade e melhora a qualidade da superfície de esmalte para adesão (Myers e Butts, 1985), o que reduziria a microinfiltração (Nozaka, Suruga *et al.*, 1999; Swanson, Feigal *et al.*, 2008). Cabe ressaltar que poucos estudos (Oldenburg, Vann *et al.*, 1987; Oliveira, Dias *et al.*, 2008; Prabhakar, Raju *et al.*, 2008) avaliaram o benefício do bisel no ângulo cavo - superficial em preparos Classe I e Classe II em molares decíduos. De acordo com a revisão sistemática da literatura realizada no presente estudo, há insuficientes evidências sobre sua efetividade. Por isso, até a presente data, a realização do bisel no ângulo cavo - superficial marginal durante a execução dos preparos Classe I e Classe II em molares decíduos, não deve ser recomendada.

Por fim, entende-se que a relevância deste estudo, em seus diferentes componentes, está na possibilidade de contribuir com bases científicas concretas para a tomada de decisão quando da seleção do material restaurador adesivo direto em molares decíduos. Tais resultados assegurarão o aumento da sobrevida das restaurações e do próprio elemento dental, dentro de uma perspectiva conservadora e minimamente invasiva.

6. CONCLUSÕES

6.1. Após 24 meses, Vitremer®, Freedom® e THP Spectrum® demonstraram as sobrevidas comparáveis tanto para as restaurações Classe I quanto para as restaurações Classe II. Embora, as restaurações Classe II tenham sobrevida menor que as restaurações Classe I. Clinicamente, o desempenho do TPH Spectrum® demonstrou melhores resultados em relação à manutenção da integridade marginal e da forma anatômica.

6.2. Após 48 meses de acompanhamento se verificou que o maior número de superfícies na restauração quintuplicou a chance de falhas para todos os materiais restauradores e o maior número de falhas ocorreu nos primeiros 24 meses. A sobrevida dos materiais restauradores foram aproximadamente 74%, 83% e 80% respectivamente para o Vitremer®, Freedom® e TPH Spectrum®, sem diferença entre os materiais.

6.3. O bisel no ângulo cavo-superficial marginal nos preparos Classe I e Classe II em molares decíduos para restaurações adesivas não deve ser recomendado na prática clínica.

7. RECOMENDAÇÕES

Estudos clínicos aleatórios e controlados com longo período de acompanhamento devem ser realizados em Odontologia, particularmente em Odontopediatria a fim de nortear a prática clínica baseada em evidência científica. Entretanto, a complexidade destes estudos é notória, e a composição do universo amostral uma limitação. A realização de estudos multicêntricos pode ser um caminho para equacionar tal condição.

No tocante aos materiais restauradores adesivos, os estudos clínicos deveriam considerar a qualidade da adaptação marginal como um desfecho importante para a longevidade das restaurações.

Ainda há necessidade de estudos clínicos controlados e randomizados com tamanho amostral apropriado para determinar a efetividade do bisel no ângulo cavo-superficial marginal quando da realização de restaurações Classe I e Classe II adesivas diretas.

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9. ANEXOS

Anexo 1.

UNIVERSIDADE FEDERAL DO RIO DE JANEIRO
Hospital Universitário Clementino Fraga Filho
Faculdade de Medicina
Comitê de Ética em Pesquisa - CEP

CEP - MEMO - nº 074/04 Rio de Janeiro, 11 de fevereiro de 2004.

Do : Coordenador do CEP

A (o) : Sr.(a) Pesquisador(a): Dra. Márcia Pereira Alves dos Santos

Assunto: Parecer sobre projeto de pesquisa

Sr.(a) Pesquisador(a),

Informo a V. Sa que o CEP constituído nos Termos da Resolução n.° 196/96 do Conselho Nacional de Saúde e, devidamente registrado na Comissão Nacional de Ética em Pesquisa, recebeu, analisou e emitiu parecer sobre a documentação referente ao protocolo de pesquisa e seu respectivo Termo de Consentimento Livre e Esclarecido, conforme abaixo discriminado:

Protocolo de Pesquisa: 197/03 - CEP

Título: "Avaliação longitudinal do comportamento clínico de restaurações adesivas diretas em dentes decíduos posteriores "

Pesquisador (a) responsável: Dra. Márcia Pereira Alves dos Santos

Data de apreciação do parecer: 04/03/04.

Parecer: **"APROVADO "**

Informo ainda, que V. Sa. deverá apresentar relatório semestral (previsto para 04/09/04), anual e/ou relatório final para este Comitê acompanhar o desenvolvimento do projeto. (item VII.13.d., da Resolução n.° 196/96 – CNS/MS).

Atenciosamente,

Prof. Luiz Carlos Duarte de Miranda
Coordenador do CEP

Anexo 2.

Andamento do projeto CAAE: 0971.0.197.000-05

Título do Projeto de Pesquisa
AVALIAÇÃO CLÍNICA DE RESTAURAÇÕES COMPÓSITAS EM PREPAROS OCLUSAIS BISELADOS EM MOLARES DECÍDUOS

Situação	**Data Inicial no CEP**	**Data Final no CEP**	**Data Inicial na CONEP**	**Data Final na CONEP**
Aprovado no CEP	16/09/2005 10:25:35	06/10/2005 15:31:47	31/08/2005 00:00:00	

Descrição	**Data**	**Documento**	**Nº do Doc**	**Origem**
1 - Envio da Folha de Rosto pela Internet	31/08/2005 14:29:44	Folha de Rosto	FR-67967	Pesquisador
3 - Protocolo Aprovado no CEP	06/10/2005 15:31:03	Folha de Rosto	634/05	CEP
4 - Protocolo Aprovado no CEP	06/10/2005 15:31:42	Folha de Rosto	634/05	CEP
5 - Protocolo Aprovado no CEP	06/10/2005 15:31:47	Folha de Rosto	634/05	CEP
2 - Recebimento de Protocolo pelo CEP (Check-List)	16/09/2005 10:25:35	Folha de Rosto	0971.0.197.000-05	CEP

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