

UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL
FACULDADE DE ODONTOLOGIA
PROGRAMA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA
MESTRADO EM CLÍNICA ODONTOLÓGICA - ODONTOPEDIATRIA

**LONGEVIDADE DE RESTAURAÇÕES ADESIVAS APÓS REMOÇÃO
TOTAL OU PARCIAL DE TECIDO CARIADO- ESTUDO
RETROSPECTIVO EM MOLARES PERMANENTES JOVENS DA
CLINICA DA GRADUAÇÃO E DO CURSO DE ESPECIALIZAÇÃO EM
ODONTOPEDIATRIA DA FO-UFRGS**

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PORTE ALEGRE

2015

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LONGEVIDADE DE RESTAURAÇÕES ADESIVAS APÓS A REMOÇÃO
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DA GRADUAÇÃO E DO CURSO DE ESPECIALIZAÇÃO EM
ODONTOPIEDIATRIA DA FO-UFRGS

Linha de pesquisa: Biomateriais e Técnicas Terapêuticas em Odontologia.

Dissertação apresentada ao Programa de Pós-Graduação em Odontologia da Universidade Federal do Rio Grande do Sul, como requisito parcial para a obtenção do título de Mestre em Clínica Odontológica – Odontopediatria.

Orientador: Prof. Dr. Fernando Borba de Araujo

PORTE ALEGRE

2015

CIP - Catalogação na Publicação

Tejeda Seminario, Alejandra
REMOÇÃO PARCIAL DE TECIDO CARIADO EM DENTES
PERMANENTES - ESTUDO RETROSPECTIVO EM PACIENTES DA
CLÍNICA DA GRADUAÇÃO E DO CURSO DA ESPECIALIZAÇÃO EM
ODONTOPEDIATRIA DA FO-UFRGS / Alejandra Tejeda
Seminario. -- 2015.
43 f.

Orientador: Fernando Borba de Araújo.

Dissertação (Mestrado) -- Universidade Federal do
Rio Grande do Sul, Faculdade de Odontologia,
Programa de Pós-Graduação em Odontologia, Porto
Alegre, BR-RS, 2015.

1. Longevidade. 2. Remoção Parcial de Tecido
Cariado. 3. Resina Composta. 4. Dente Permanente. I.
Borba de Araújo, Fernando, orient. II. Título.

Esta grande conquista é dedicada à minha família. Minha mãe, que é o meu melhor exemplo de mulher, amorosa, dedicada e lutadora. E meu irmão por me dar força e coragem nos momentos que eu precisava. Obrigada por estar sempre comigo e me deixar saber que o mais importante de uma família não é viver juntos, mas sim estarmos unidos.

Ao César, pelo amor e apoio incondicional. Quem foi que disse que para estar junto precisa estar perto? A distância separa dois corpos; mas nunca separa dois corações. Essa conquista é da gente!

AGRADECIMENTOS

E assim passaram dois anos, de momentos bons e ruins, de risos e choros, de trabalho e diversão, mas, sobretudo passaram dois anos de muito aprendizado e amadurecimento.

Agradeço à Universidade Federal do Rio Grande do Sul e ao Programa de Pós-Graduação em Odontologia pela excelência de ensino.

Agradeço a Deus,

Principalmente por me colocar na família que me colocou e por sempre guiar meus passos, por nunca me deixar sozinha e por sempre colocar anjos na minha vida, anjos que fizeram momentos únicos.

Porque dizem que os amigos são a família que a gente escolhe, nesse caso eu fui muito sortuda porque não me bastou ter a melhor família no Perú, também ganhei a melhor família no Brasil e de todas as coisas que eu vivi, nunca vou esquecer...

Nunca vou esquecer a decisão de fazer um mestrado fora do meu país e decidir vir morar no Brasil graças à oportunidade que a **Dra. Rosana Melgar** me deu.

Nunca vou esquecer a festa surpresa de despedida que minha família e amigos fizeram quando vim fazer a prova, tendo certeza que passaria no concurso e ficaria aqui.

Nunca vou esquecer a felicidade que senti quando abri o portal do aluno e vi que realmente tinha passado na prova tendo que me mudar dois anos para o Brasil.

Nunca vou esquecer a felicidade da minha família quando dei a notícia. E do incentivo que minha mãe **Maria Teresa** me deu sempre, abrindo mão de muitas coisas para realizar meus sonhos.

Nunca vou esquecer o quão compreensivo e amoroso foi meu namorado **César** com a minha decisão de continuar a carreira no Brasil, assim como nas minhas crises de estresse, conseguindo me acalmar. Obrigada pela paciência e tomara algum dia eu possa ser igual a ti.

Nunca vou esquecer a minha professora de Odontopediatria e orientadora do TCC **Ursula Albites** que me ensinou a amar a profissão e sempre ir em busca dos meus sonhos. Obrigada

por se preocupar comigo até hoje e sempre estar disposta a compartilhar seus conhecimentos e conselhos.

Nunca vou esquecer o presente que a faculdade de estomatologia da UCSUR me deu, as minhas amigas e colegas da graduação. Elas tornaram as clínicas e aulas mais divertidas. **Gina, Luciana e Shirley**, obrigada pela parceria até hoje, pela torcida incondicional; vocês não sabem o tamanho da minha felicidade em ter vocês por perto. Bom, perto do coração.

Nunca vou esquecer os momentos que a minha grande amiga e colega **Gina Iglesias** e eu passamos, assistindo o jogo do campeonato do nosso time pelo skype e ganhando! Divagando sobre o nosso futuro e quão bem sucedido seria. Algum dia tudo o que planejamos se tornará realidade e todo esforço e sacrifício terá valido a pena.

Nunca vou esquecer as tardes que passei revisando as fichas clínicas achando nelas desde escovas de dente até aparelhos ortodônticos.

Nunca vou esquecer as ligações para marcar consulta dos pacientes e de como meu nome podia sofrer diversas transformações assim como quando eles chegavam e perguntavam por mim dizendo “uma doutora que fala diferente marcou consulta comigo”.

Nunca vou esquecer as inúmeras tardes nas quais a Bruna, a Carol e eu passamos ligando para os pacientes, de preferência sexta à tarde “porque é o horário que as pessoas ficam em casa”, e da facilidade que eles têm para trocar de telefone ou simplesmente sumir do mundo.

Nunca vou esquecer a grande oportunidade e confiança que meu orientador, o **Professor Dr. Fernando Borba de Araújo** me deu ao aceitar-me na pós-graduação da UFRGS e de como ele sempre me fez sentir em casa. Obrigada por compartilhar os seus conhecimentos e conselhos.

Nunca vou esquecer os meus professores **Adriela Mariath e Jonas Almeida Rodrigues**, do capricho das suas aulas e de como eles conseguem captar a atenção dos alunos assim como a disposição de sempre ajudar e transmitir os seus conhecimentos. Aprendi muito com vocês!

Nunca vou esquecer o profissionalismo, dedicação e disponibilidade que o **Professor Dr. Luciano Casagrande** mostrou com o trabalho, nem dos momentos que ele sentou comigo para me explicar a estatística e dizer o quão importante era o meu trabalho; isso me motivou a continuar.

Nunca vou esquecer a gentileza e profissionalismo dos professores ***Marcos Britto Correa e Flavio Fernando Demarco*** da UFPEL, que permitiram a realização deste trabalho com os seus conhecimentos em estatística.

Nunca vou esquecer as aulas de estatística e biologia molecular e celular AVANÇADA com as minhas colegas do mestrado ***Juliane Brustolin, Claudia Azevedo, Carol Sarti, Bruna Lima e Ximena Concha***; gurias, conseguimos sair vitoriosas disso. Valeu a parceria e as boas risadas que a gente deu.

Nunca vou esquecer o capricho da mesa clínica da minha dupla querida ***Carol Sarti*** e de como ela se irritava ao ver tudo bagunçado, obrigada Obrigada pela paciência e grande amizade que a gente construiu nesses dois anos.

Nunca vou esquecer a ***Bruna Lima***, irmã que o mestrado me deu, a gente sempre vai ficar perto “hein Bru” obrigada pela paciência, amizade, e tempo que tu me dedicaste, obrigada pelo apoio nos momentos difíceis, obrigada por me ensinar falar português e não deixar que as pessoas me façam de “gato e sapato”, obrigada pelas maravilhosas manhãs, tardes e noites no LABIM onde a gente aprendeu a ficar unida na saúde e na doença. Essa amizade vai continuar o resto da vida!

Nunca vou me esquecer a minha querida ***Julcelaine***, pelas nossas divertidas conversas e por sempre ser uma pessoa extremamente atenciosa e sempre estar pronta para solucionar os problemas, valeu mesmo por sempre ser tão positiva.

Nunca vou esquecer as funcionárias da clínica Infanto Juvenil, ***Adri e Lucia***, sempre alegres e prontas para me receber com um “*Bom dia, meu amor*”.

Nunca vou me esquecer de toda a equipe da Pediatria: as colegas do Doutorado ***Joanna Pereira, Stefanie Werle, Fabiane Piva e Marcinha Gomes***, as novas mestrandas ***Fê, Nica e Dai***, e o sempre querido aluno de internato ***Ivam Freire***. Obrigada pela torcida e parceria.

Nunca vou me esquecer da ajuda e disponibilidade da ***Stefanie Werle***, não vou me esquecer da tua ajuda sem limites para tudo e mais um pouco, por sempre responder minhas dúvidas e me ensinar a fazer pizza de tapioca para uma dieta de proteínas. Sempre vou lembrar que a gente “não é obrigada” e que não tenho como saber algo que ninguém me ensinou. Obrigada mesmo por me transmitir confiança e segurança.

Nunca vou me esquecer dos momentos vividos na faculdade

- Brigas na hora almoço com a Carol e a Bru, gurias o RU não é nem bom nem ruim, é 1,30.
- Mesa pronta com todo o material estéril, claro só faltava o paciente aparecer.
- Aniversários onde o aniversariante tinha que levar o bolo
- Os cafés de meia manhã na sala da pediatria

Nunca vou esquecer o jeito tão carinhoso com o qual fui recebida na casa e família da **Maria Helena**, uma mulher simplesmente maravilhosa que me ajudou quando eu mais precisava e que me brindou seu carinho, apoio e amizade. Obrigada por me fazer sentir como uma filha e cuidar de mim todos esses meses. Nunca terei palavras suficientes para te agradecer.

Nunca vou me esquecer das corridas, saídas, festas, chimarrões, shows das melodys nas quintas feiras, açaí aos sábados a tarde até não parar de tossir, com minha parceira **Sarah Beltrame**, obrigada por esses dois anos de amizade, pela torcida e pela força para que tudo desse certo, amiga que eu vou levar para a vida toda.

Muito obrigada a todos que viveram comigo esses dois anos

Levo todos vocês no meu coração e para sempre

“Así como el día sigue a la noche. Todo final anuncia siempre un nuevo comienzo.

Que nos volvamos a ver!!!”

*Sem sonhos, a vida não tem brilho. Sem metas, os sonhos
não têm alicerces. Sem prioridades, os sonhos não se
tornam reais. Sonhe, trace metas, estabeleça prioridades e
corra riscos para executar seus sonhos. Melhor é errar
por tentar do que errar por se omitir!*

Augusto Cury

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LISTA DE ABREVIATURAS E SIGLAS

AFR - Annual failure rate / Taxa de falha anual

DMFT - Decayed missing filled teeth / Número de dentes cariados perdidos e obturados.

CCR - Complete caries removal / Remoção total de tecido cariado

CR - Composite resin / Resina Composta

FO-UFRGS - Faculdade de Odontologia da Universidade Federal do Rio Grande do Sul

GBI - Gengival blood index / Índice de sangramento gengival

GIC - Glass ionomer cement / Cimento de ionômero de vidro

PCR - Parcial caries removal / Remoção parcial de tecido cariado

RCT - Randomized clinical trial / Ensaio Clinico Randomizado

RMGIC - Resin-modified glass ionomer cement / Cimento de ionômero de vidro modificado por resina

VPI - Visible plaque index / Índice de placa visível

RESUMO

Objetivo: Avaliar a longevidade e os possíveis fatores associados com as falhas de procedimentos restauradores adesivos diretos realizados em molares permanentes jovens portadores de lesões cariosas ativas profundas em dentina submetidos a remoção parcial (RPTC) ou total (RTTC) de tecido cariado.

Métodos: A amostra de tipo censo foi composta por restaurações adesivas realizadas em molares permanentes jovens portadores de lesões cariosas ativas profundas em dentina submetidos à RPTC ou RTTC por alunos dos Cursos de Graduação e de Especialização em Odontopediatria da FO-UFRGS, Porto Alegre - RS. Foram avaliados possíveis fatores associados à sobrevida destas restaurações, tais como experiência de cárie (CPOD), índices de placa visível (IPV) e sangramento gengival (ISG), número de superfícies restauradas, nível de formação académica dos operadores e materiais capeadores e restauradores. Foi utilizada uma Curva de Sobrevida de Kaplan-Meier com teste de log-rank para analisar a longevidade das restaurações, e a Análise de regressão multivariada de Cox com fragilidade compartilhada para avaliar os fatores associados a falhas ($p < 0,05$).

Resultados: De 372 fichas clínicas, foram incluídos para análise 477 procedimentos restauradores adesivos realizados em 297 pacientes (9.14 ± 1.75 anos). A sobrevida das restaurações alcançou um índice de 57,9% em até 36 meses de acompanhamento, com uma taxa de falha anual (TFA) de 16,7%. Não houve diferença estatisticamente significativa quando a RTTC ou a RPTC foi realizada ($p = 0,163$). O modelo ajustado mostrou que os pacientes com gengivite (ISG > 20%) apresentaram 2,88 vezes mais risco de falha em suas restaurações ($p = 0,007$). Restaurações com mais de duas superfícies envolvidas apresentaram 3 vezes mais risco de falha do que aquelas com uma única superfície, enquanto que as restaurações realizadas com cimento ionómero de vidro modificado por resina (CIVRM) apresentaram 4,11 vezes mais chance de falha do que as realizadas com resina composta (RC).

Conclusão: O tipo de material restaurador, o número de superfícies restauradas e índice de sangramento gengival influenciaram na taxa de sobrevida das restaurações realizadas em lesões de cárie profunda em dentes permanentes jovens, independentemente da técnica de remoção de cárie utilizada. A falha restauradora, a qual foi determinada por uma subsequente anotação na ficha clínica de perda ou fratura da restauração, foi a principal causa de insucesso nos procedimentos restauradores adesivos, independentemente de ser removido ou não totalmente o tecido cariado.

Palavras chave: Longevidade, Remoção Parcial de Tecido Cariado, Resina Composta, Dente Permanente.

ABSTRACT

Objective: To evaluate the longevity and factors associated with failures of restorations performed in permanent molars after complete (CCR) and partial caries removal (PCR).

Methods: The sample was composed by adhesive restorations performed in deep caries lesion of permanent teeth that had been treated with CCR or PCR by undergraduate and graduate students in a public pediatric dental clinic. Factors such as caries experience (DMFT), visible plaque (VPI) and gingival bleeding (GBI) indexes, number of restored surfaces, type of capping and restorative materials were investigated. Kaplan–Meier survival curve with log-rank test was used to analyze the longevity of restorations. Multivariate Cox regression analysis with shared frailty was used to assess the factors associated with failures ($p<0.05$).

Results: 477 restorations placed in 297 children (9.14 ± 1.75 years) were included in the analysis. The survival of restorations reached 57.9% up to 36 months of follow-up, with overall annual failure rate of 16.7%. There was no difference when CCR or PCR were performed ($p=0.163$). The adjusted model showed that patients presenting gingivitis ($GBI>20\%$) have 2.88 times more risk of failure in their restorations ($p=0.007$). Multi-surface restorations showed a risk of failure more than 3 times higher than single-surface ($p=0.003$). Modified glass ionomer cement presented a risk of failure 4.11 times greater than composite resin ($p<0.001$). **Conclusion:** The type of restorative material, number of restored surfaces and gingivitis influenced the survival rate of restorations performed in deep carious lesion of young permanent teeth, independently of caries removal technique used.

Keywords: Longevity. Partial Caries Removal. Resin composite. Permanent teeth

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1 ANTECEDENTES E JUSTIFICATIVA

A diminuição da prevalência de cárie tem sido observada em todo o mundo (JÜRGENSEN, 2013). A mais recente Pesquisa Nacional de Saúde Bucal realizada no Brasil mostrou uma redução na prevalência de cárie, embora esta doença continue sendo o principal problema de saúde bucal em crianças e adolescentes (SB BRASIL, 2010).

A severidade da cárie também é grave nesta população jovem e a ocorrência precoce da lesão de cárie profunda em dentes permanentes jovens é bastante comum no decorrer da prática clínica (SB BRASIL, 2010). A abordagem restauradora destas lesões inclui a remoção total do tecido cariado (RTTC), que pode resultar na exposição do órgão pulpar, tornando o prognóstico do dente e o curso do seu tratamento menos previsível e com complicações imediatas ou em longo prazo (BARTHEL et al., 2010; SCHWENDICKE et al., 2013). No entanto, quando a técnica de remoção parcial de tecido cariado (RPTC) é realizada, ocorre a diminuição das exposições pulpares e sintomas pós-operatórios em comparação com a técnica de remoção total de tecido cariado (MALTZ et al., 2012; RICKETS et al., 2013; SCHWENDICKE et al., 2013;). Uma das vantagens da RPTC é manter o máximo possível da estrutura dentinária sadias, juntamente com a manutenção da vitalidade da polpa (RICKETS et al., 2013).

A técnica de RPTC é baseada na modificação do microambiente da dentina contaminada intencionalmente mantida no fundo da cavidade (VAN THOMPSON 2008). Já foi demonstrado que as bactérias remanescentes presentes nessa dentina perdem a viabilidade após o selamento da cavidade (PINTO et al., 2006; LULA et al., 2009) e a camada de dentina contaminada deixada na parede pulpar é remineralizada pela deposição de minerais pelo complexo dentino-pulpar, (MARCHI et al., 2008; CORRALO et al., 2013; FRANZON et al., 2014) independentemente do material forrador utilizado (DALPIAN et al., 2012). Nessa técnica chamada de “Remoção Parcial de Tecido Cariado”, é realizada a remoção total de tecido cariado das paredes laterais com instrumentos rotatórios, permitindo um substrato adequado para a adesão (PASHLEY et al., 1980) já que na parede pulpar, é realizada a remoção do tecido infectado (amolecido) com instrumentos manuais, deixando-se uma dentina desmineralizada e contaminada, considerada insatisfatória para a adesão (CASAGRANDE et al., 2009; MALTZ et al., 2012).

Evidências científicas consistentes reportam os bons resultados da técnica de RPTC (HAYASHI et al., 2011; MALTZ et al., 2012; RICKETTS et al., 2013; SCHWENDICKE et al., 2013). Recentemente, um estudo retrospectivo em dentes decíduos apresentou uma taxa de sucesso clínico e radiográfico da técnica de RPTC realizada por alunos do Curso de Graduação da FO. UFRGS de aproximadamente 80% após 4 anos (DALPIAN et al., 2014). Apesar das evidências científicas atuais ressaltarem o sucesso da RPTC, um considerável numero de profissionais ainda segue o protocolo clínico da remoção total de tecido cariado (WEBER et al., 2011; SCHWENDICKE et al., 2013), devido ao critério subjetivo do operador relacionado com a textura do tecido a ser eliminado ou mantido e ao desconhecimento sobre a viabilidade das bactérias remanescentes.

É importante ressaltar, que independentemente da técnica de remoção de tecido cariado, a seleção do caso clínico é fundamental para o sucesso do tratamento, sendo necessário um criterioso diagnóstico do estado de saúde pulpar. A lesão cariosa não deve envolver diretamente a polpa, que deve possuir vitalidade sem diagnóstico de pulpite irreversível ou necrose pulpar avaliada clínica ou radiograficamente. Além disso, as condições para a restauração da estrutura dental remanescente, devem ser consideradas para a indicação do procedimento restaurador adesivo (BJØRNNDAL, 2008; AAPD, 2009).

Atualmente, a literatura questiona o potencial efeito prejudicial da dentina contaminada na sobrevida ao longo prazo das restaurações de lesões cariosas onde foi realizada a RPTC. Há uma hipótese de que a dentina mantida na parede pulpar da cavidade pode atuar como uma camada frágil, que sob a fadiga da mastigação, pode levar à fratura da restauração (HEVINGA et al., 2010). No entanto, esta hipótese precisa ser avaliada clinicamente, uma vez que a resposta do complexo dentino-pulpar no processo de remineralização desse tecido não é considerada em estudos *in vitro* (MALTZ, et al., 2010).

A observação clínica longitudinal de molares permanentes jovens restaurados após RPTC pode auxiliar a elucidar estes questionamentos. O delineamento de um estudo observacional, com diferentes operadores e menor controle das variáveis envolvidas com a longevidade das restaurações poderia contribuir para a reprodução (validade externa) desta técnica na prática clínica.

2. OBJETIVOS

2.1 Objetivo Geral

Avaliar a longevidade de restaurações adesivas diretas em molares permanentes jovens portadores de lesões cariosas ativas profundas em dentina após procedimentos de remoção total (RTTC) ou parcial de tecido cariado (RPTC) realizados por alunos dos Cursos de Graduação e de Especialização em Odontopediatria da FO-UFRGS.

2.2 Objetivos Específicos

- Descrever os tipos de insucesso dos procedimentos restauradores adesivos com remoção parcial ou total de tecido cariado;
- Descrever os possíveis fatores associados (nível de formação académica dos operadores, idade do paciente, número de superfícies da restauração, técnica de remoção de tecido cariado, material capeador, material restaurador, IPV e ISG inicial e final) ao insucesso dos procedimentos restauradores adesivos com RPTC e RTTC em molares permanentes posteriores.

3 ARTIGO

Title: Longevity and associated risk factors in adhesive restorations of young permanent teeth after Complete and Partial Caries Removal.

Running title: Restoration longevity after complete and partial caries removal

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ABSTRACT

Objective: To evaluate the longevity and factors associated with failures of restorations performed in permanent molars after complete (CCR) and partial caries removal (PCR). **Materials and Methods:** The sample was composed by adhesive restorations performed in deep caries lesion of permanent molars. Factors such as gender, caries experience, visible plaque and gingival bleeding indexes, operator's experience, number of restored surfaces, type of capping and restorative materials were investigated. Kaplan-Meier survival with log-rank test was used to analyze the longevity of restorations. Multivariate Cox regression analysis with shared frailty was used to assess the factors associated with failures ($p<0.05$). **Results:** 477 restorations placed in 297 children (9.14 \pm 1.75 years) were included in the analysis. The survival of restorations reached 57.9% up to 36 months of follow-up with overall annual failure rate of 16.7%. There was no difference in longevity when CCR or PCR were performed ($p=0.163$). The CCR presented more pulp exposure than PCR ($p<0.001$). Patients presenting gingivitis have 2.88 times more risk of failure in their restorations ($p=0.007$). Multi-surface restorations showed a risk of failure more than 3 times higher than single-surface ($p=0.003$). Resin Modified Glass Ionomer Cement presented a risk of failure 4.11 times greater than Composite Resin ($p<0.001$). **Conclusion:** The type of restorative material, number of restored surfaces and presence of gingivitis influenced the survival of restorations, independently of caries removal technique used. **Clinical relevance:** This university-based study provides valuable information regarding the treatment-related variables that are risk factors for failure in posterior restorations performed in children.

Keywords: Longevity, Partial Caries Removal, Resin composite, Permanent teeth.

INTRODUCTION

The decrease in caries prevalence has been observed worldwide [1]. The latest National Oral Health Survey in Brazil showed a reduction in caries prevalence, even though, it still remains the main oral health problem for children and adolescents [2].

The severity of caries is also high in this young population and the occurrence of deep carious lesion in permanent teeth is a common feature in daily clinical practice [2]. The treatment based on the complete caries removal (CCR) in proximity to the pulp is often associated with immediate or long-term complications [3]. Recent researches have demonstrated that complete caries removal in acute deep carious lesions results in an increased pulp exposure and post-operative symptoms in comparison with the risk after partial caries removal (PCR) [4,5,6].

Therefore, minimal invasive techniques have great impact in the contemporary practice for treating dental caries, reducing the potential adverse effects of more invasive treatments in patients [7]. The goal of PCR is based on modification of the microenvironment of the contaminated dentin intentionally left under the restoration, thereby arresting the cariogenic process while preserving the tooth structure and pulp vitality [8].

In fact, there is sound scientific evidence that demonstrate the good results of such technique [4,5,9]. However, a high proportion of dentists still prefer to remove all the carious dentin under the imminent risk of a pulp exposure [10]. One of the reasons for clinicians to avoid use the PCR is the subjective criterion of the operator related to the texture of the tissue to be maintained. Also, there is some questioning in relation to the potential detrimental effect of affected dentin on the long-term survival of restorations. It has been hypothesized that the affected dentin left in the bottom of the cavity may act as a “soft” layer, which under constant masticatory efforts, could lead to the restoration fracture [11]. However, this assumption remains to be clinically evaluated.

The data available on the longevity of restorations performed in young permanent teeth after PCR is still limited [6,12], since the main outcome that had been frequently evaluated is “pulp vitality”. Moreover, in this randomized clinical trial was not investigated the influence of individual and tooth-related factors associate with the failure of the restorations after partial caries removal.

Thus, the aim of this retrospective university-based study was to evaluate the survival and associate risk factors of adhesive restorations placed in young permanent molars after complete (CCR) and partial caries removal (PCR). The hypothesis tested here was that restoration survival is not affected by caries removal technique used.

MATERIALS AND METHODS:

Study characteristics, participants and study design

For this study, the research protocol had the approval from the Research Committee (n. 26760) and the local University Ethics Committee (n. 35380414.2.0000.5347). Also, to collect the data, written informed consent was signed by the parents or guardians.

This retrospective university practice-based study was conducted at the Children and Youth Dental Clinic, School of Dentistry, Federal University of Rio Grande do Sul (UFRGS), Porto Alegre - Brazil. This public pediatric dental clinic attends children and adolescent patients free of charge, mainly from low socioeconomic backgrounds. The target population were children and adolescents treated during the period between 2009 and 2013, where they were attended by undergraduate and graduate dental students, supervised by professors, who are specialists in Pediatric Dentistry. All the information employed in this study was gathered from clinical records. To be eligible for the study, children/adolescents should have received at least one restoration (1, 2 or 3 or more surfaces), performed with composite resin (CR) or resin-modified glass ionomer cement (RMGIC), and placed in vital posterior permanent teeth, after complete or partial caries removal of deep lesions. The restorations should have been clinically and radiographically followed-up for at least 6 months, and individuals should attend the dental clinic at least twice/year. Patients with medically compromised health were excluded from the study.

Caries removal and restorative procedures

The CCR or PCR restorations were performed in one-appointment in deep caries lesion of young permanent teeth. After administration of local anesthesia and rubber dam isolation, dentinal carious tissue was completely removed from the lateral walls of cavities using round burs operated at low speed. The same procedure from lateral walls was performed in the pulp wall for CCR. The absence of carious tissue was confirmed using a blunt-tipped probe. For PCR, at the site of “risk for pulp exposure”, excavation was performed with a dentin excavator, using visual and tactile clinical criteria. Caries removal was stopped when dentin with a leathery consistency (hardened and dried) was achieved. In some cases, a calcium hydroxide liner (Dycal, Dentsply, Brazil) was placed prior to CR or RMGIC restoration. For composite resin restoration, cavity was conditioned by 37% phosphoric acid gel for 15 seconds in dentin and 30 seconds in enamel. The acid was removed by rinsing with water for 30 seconds and the cavity was gently dried with air and cotton pellets. A simplified bonding agent (Adper Single Bond, 3M ESPE, St. Paul, MN, USA) was used prior to the insertion of the composite resin (Filtek Z350, 3M ESPE, St. Paul, MN, USA) using the incremental technique. The cavities filled with RMGIC (Vitremer, 3M ESPE, St. Paul, MN, USA) followed the manufacturer’s protocol by applying the primer for 30 seconds in the entire cavity and then light cured for 20 seconds. The material was mixed in 1:1 ratio and placed into the cavity using a syringe system and then light cured for 40 seconds. For the proximal cavities, a metal matrix was adapted to the cervical margin with an interproximal wedge. The rubber dam was then removed and the occlusion was checked. Finally, a finish gloss layer was applied on the restorations with RMGIC and light cured for 20 seconds.

After treatment of caries disease and all caries lesions, each patient was included in a prevention program. The recalls consisted on visible plaque (VPI) and gingival bleeding (GBI) exams and dental hygiene orientation.

Data Collection

One dentist retrieved all the information from dental records. The factors potentially associated with treatment failure were investigated, including individual and restoration characteristics: gender; patient age (years); visible plaque (VPI) and gingival bleeding (GBI) indexes in the first appointment and at the end of the follow-up period; decayed, missed and filled teeth (DMF-T, moderate and high); type of arch (superior and inferior); type of caries removal (complete or partial); number of restored surfaces (1, 2 or 3 or more); base material or liner used (calcium hydroxide, glass ionomer cement or adhesive system); restorative material (CR or RMGIC); and pulp outcome (irreversible pulpitis or necrosis).

The visible plaque index and gingival bleeding index (Aimano & Bay) were used to evaluate the routine of plaque control by the patients. For the calculation of these indexes, the number of dental surfaces was divided by the surfaces with visible plaque or gingival bleeding. For the analysis, the values of these two indexes were dichotomized. A satisfactory biofilm control was considered when the VP and GB were fewer than 20% [13]. Caries experience was categorized in moderate and high using the median of DMF-T index as cut-point.

The primary outcome of the study was the failure of restorations in posterior permanent teeth. Failures were assessed by checking the patient’s records and were considered in the presence of loss of restoration or fracture requiring a re-intervention (restoration repair or replacement). Also, teeth underwent to pulp intervention (endodontic treatment) or extraction was categorized as failure. The radiographic outcome was performed by assessing the interproximal and periapical radiograph according the following criteria: presence of radiolucency in the furcation or periapex and increase in the periodontal space. The examiner was trained for diagnostic reproducibility, and this was determined by assessing 10% of the radiographs on two different moments (2 weeks interval). The intra kappa coefficient in the radiographic reproducibility evaluation was 0.86.

Data analysis:

The descriptive analysis provides the distribution summary according to the independent variables. Data collected from patient records were included in a database and analyzed using Stata 11.2 software (College Station, Texas, USA). The annual failure rate (AFR) of the restorations was calculated according to the formula:

$(1-y)^z = (1-x)$, in which "y" expresses the mean AFR and "x" the total failure rate at "z" years. Restorations placed in teeth with pulp exposure during the dentin excavation (trans-operative) were excluded from the longevity analysis.

Survival analysis was performed to assess factors associated with the longevity of restorations. For analysis, data were censored at 36 months of follow-up. Survival curves of restorations were assessed through Kaplan-Meier method. Differences between curves were tested by log-rank test. Curves were adjusted by all variables included in final Cox Regression Model.

Multivariate Cox regression models with shared frailty were performed to identify factors associated with failure of restorations. These models consider that observations within the same group (the patient) are correlated, sharing the same frailty, being analogous to multilevel regression models with random effects. Hazard ratios and their respective 95% confidence intervals (HR; 95%CI) were obtained. A backward stepwise procedure was used to select covariates in the fitting of the model. Only those variables presenting P-values <0.20 were selected to be included in the final model. A significance level of 5% was considered.

RESULTS

In this retrospective study, the information were retrieved from 372 dental records. Four hundred seventy-seven restorations placed in 297 subjects were included in the analysis (Figure 1. Flow diagram). Boys comprised 46.7% of the sample. The mean age of children was 9.1 years (± 1.7), presenting DMF-T mean of 6.3 (± 3.2). The mean of initial visible plaque index at the first visit was 35.3% (± 27.7), and gingival bleeding index was 27.0% (± 26.2). The mean of VPI and GBI at the last appointment was 26.0% (± 22.6) and 16.7% (± 18.0), respectively. The follow-up period ranged from 6 to 36 months.

The distribution of restorations placed in posterior permanent teeth according to individual and tooth-level variables is shown in Table 1.

Overall, the survival rate of restorations up to 36 months reached 57.9%. The clinical and radiographic success was 82.8% (395/477). Considering all outcomes (failures=82), pulp complications (22/82 - 26.8%) were less prevalent than restorative failures (60/82 - 73.2%). According to the caries removal technique, CCR presented more pulp exposition than PCR during dentin caries excavation ($p<0.001$). Pulp necrosis after restoration was observed in 4.9% and 4.5% for CCR or PCR, respectively.

The overall annual failure rate (AFR) after 3 years follow-up was 16.7%. Considering the restorative material placed in deep caries cavities of posterior permanent teeth, the AFRs were 14.6% and 26.7% for composite resin and resin modified resin glass ionomer restorations, respectively. Regarding caries removal, AFR in restorations where PCR was performed was 17.3%, while for CCR was 13.1%. No tooth was extracted due to restorative failures.

No difference was found in terms of the longevity of the restorative procedures executed by students with different level of education ($p=0.688$).

Figure 2 shows the Kaplan-Meier curves of the restorations up to 36 months follow-up. Patients with GB index greater than 20% experienced more failures in restorations ($p=0.008$). The number of restored surfaces had detrimental effect over the longevity of the fillings. Teeth presenting three restored surfaces presented more failures when compared to one and two restored surfaces ($p<0.001$). Teeth restored with CR presented more longevity than those teeth restored with RMGIC ($p<0.001$). There was no difference in terms of longevity of restorations when partial or complete caries removal was performed ($p=0.780$).

Table 2 shows the results for Cox regression analysis, with crude and adjusted Hazard Ratios. The adjusted model showed that multi-surface restorations (3 or more surfaces) placed in posterior permanent teeth had a risk of failure of 3.22 times more than those placed in single-surface ($p=0.003$). Regarding the restorative material, RMGIC, in comparison with composite resin, had a risk of failure 4.11 times greater after up to 3 years of follow-up ($p<0.001$). Patients presenting gingivitis (GB>20%) have 2.88 times more risk of failure in their restorations ($p=0.007$). The association has lost significance in the adjusted analyses for capping material used under the restorations.

DISCUSSION

This retrospective university-based study provides valuable information regarding the longevity of restorations performed in deep carious lesion of young permanent molars and the associated risk factors for failure in a pediatric population. The survival rate of the restorations reached 57.9% after 3 years of follow-up. The presence of gingivitis and the treatment-related variables, such as the number of restored surfaces and the type of restorative material, were associated with failure of posterior adhesive restorations in young patients. The type of caries removal technique did not produce detrimental effect on restoration survival, accepting the null hypothesis of this study.

For survival analyses, the Kaplan-Meier estimator was used in this study. Although the survival rate at 36 months appears to be low, it is important to note that the estimator takes into account the censored data, i.e., those restorations that have not yet reached the 36-month evaluation in this retrospective analysis. This explains the low estimated survival rate (57.9%) of restorations when compared exclusively to clinical and radiographic success (82.8%), where just the failures were counted (82/477), independently of the time in function.

The PCR constitutes the first option to treat deep carious lesion of deciduous and permanent teeth at the Children and Youth Dental Clinic (UFRGS), and undergraduate and graduate students have practiced it since the mid-90s. In the present research, majority of the restorative procedures involved partial caries removal in deep caries lesion (78.82%), which was performed in one-appointment. Two alternatives of incomplete caries removal are currently available: two-step (stepwise), which carious tissue is incompletely removed in the proximity of pulp wall and a temporary filling is placed. After the period necessary to development of tertiary dentin, a second visit is required to re-entry and provides the complete removal of the remained caries dentin [14]. In one-step partial caries removal, infected demineralized dentin is partially removed nearest to the pulp, and a definitive restoration is placed in only one visit [15]. Data from a randomized clinical trial already showed the advantage of one-step compared with two-step partial caries removal when pulp vitality was defined as the outcome [6].

Recently, a systematic review with meta-analysis demonstrated that partial caries removal had a significant overall risk reduction of pulp exposure (OR [95% CI] 0.31 [0.19-0.49]) compared with complete caries excavation [3]. Corroborating with the current literature, results from this retrospective study revealed that CCR was more harmful for the pulp, since induced pulp exposures more frequently than PCR ($p<0.001$). Pulp exposure occurring during caries removal and treated with conservative pulp therapies produces very low clinical success rate after long periods of time [16]. The pulp necrosis (4.6%) that was observed along follow-up period, for both CCR and PCR, could be associated with the limitation of establishing a correct diagnosis of pulp inflammation at the time of restorative procedure. This difficulty is especially present in teeth with incomplete root formation, wherein the responses of vitality tests are not accurate.

While the researches have strongly support that PCR prevents pulp exposure and pulp sensitivity compared to CCR, the effectiveness in terms of longevity of the restorations is still lack of evidences [5]. The PCR showed higher frequency of restorative failures (15.4%) compared to CCR (2.0%). Hevinga and colleagues (2010) already showed a reduction of the *in vitro* fracture resistance of occlusal composite restorations performed on caries dentin compared with total caries removal restorations [11]. Evidences from laboratory studies suggest that the softer and demineralized dentin may not sufficiently support the load from masticatory function and could reduce the bond resistance between the adhesive restoration and the tooth substrate. However, a recent *in vitro* study performed in pre-molars by Schwendicke and colleagues demonstrated that the marginal characteristics of restorations were affected by the depth of lesions but not by the performed caries excavation [17]. In the adjusted Cox regression analysis from the present study, the type of carious removal (partial or complete) was not found to be a significant factor affecting the restoration survival. This is an important finding from the present study, since that the potential detrimental effect on the restoration longevity has been considered a shortcoming for PCR technique and this is one of the first clinical studies investigating this hypothesis.

It is also important to highlight that clinically the presence of affected dentin under the restorations may not be a problem, since such lesions are normally surrounded by sound dentin or enamel [18]. Moreover, all these information must be seen under the light of biological balance perspective. Life expectation is increasing worldwide, thereby if more invasive procedures are avoided, especially at the younger ages, the occurrence of

pulp intervention and its detrimental consequences can be prevented or, at least, postponed. In the same way, a cost-effectiveness study of one- and two-step incomplete and complete excavations showed that complete excavation of deep caries lesions raises the risk of pulp damage and often initiates a cascade of re-intervention, which ultimately leads to untimely tooth extraction. The study used a model that simulates the treatment of a molar tooth with a deep caries lesion in a 15-year-old patient. Results revealed that one-step PCR is less sensitive and time-consuming technique, besides reduces costs and keeps teeth vital for longer [3].

The presence of a lining material under the restorations could represent a significant effect on longevity of the restorations [19]. A practice-based study showed that the use of a calcium hydroxide liner under the composites placed in permanent teeth of children and adolescents presents a lower survival [20]. Also, the failures observed over time in restorations with a base or liner of a GIC, have been credited to the fatigue, related to the weaker cement layer [21]. In crude analysis of our research, the use of a capping or base material (calcium hydroxide or glass ionomer cement) resulted in restorations with lower survival rate ($p<0.001$), but it lost significance after the adjustments (0.193). A possible explanation for this occurrence is based on the size of the cavities receiving the capping material. Commonly, larger cavities received the capping or base materials, thus, the size of the restored cavity had a greater influence on the failures of the restorations than the capping material, after the adjustment of the data. Corroborating our results, a recent long term (up to 18 years of follow-up) clinical study showed no difference in posterior composite restoration survival, when using a “soft” intermediate material (resin-modified glass ionomer cement) compared to those performed only using the adhesive system, without intermediate material [22].

In Brazil, there is a preference by tooth-colored direct materials, such glass ionomer cement and composite resin, to restore primary and permanent teeth of children and adolescents [23]. The GIC-base materials have several advantageous characteristics that qualify it for use in children's clinic. They are used as restorers and base materials because they reduce the marginal leakage and compensate for the polymerization shrinkage of composite restorations [24]. Moreover, presents chemical adhesion to dentin and release fluoride ions which can prevent the formation of adjacent lesions [25]. However, the major reason for their widespread use in pediatric dentistry is related to the easiness of the technique, which is extremely important in the management of difficult behavior patients [26]. Considering the restorative material placed in deep caries lesions of posterior permanent teeth, the survival rates after 3 years were 62.2% for composite fillings and 39.3% for light-cured modified glass ionomer restorations ($p<0.001$). It is well documented in the literature the superior behavior of composite restorations compared to GIC, which is credited to its mechanical properties. Composite resin presents higher resistance to wear, higher microhardness, and a smoother surface when compared with GIC [27], and these characteristics over time should play a significant influence on the longevity of restorations. A recent study, evaluating posterior restorations placed in primary teeth from patients of low-socioeconomic income in a Pediatric Clinic [28], showed a significantly higher risk of failure for glass ionomer than for composite restorations after up to 4 years of follow-up.

The number of restored surfaces also had detrimental effect over the longevity of the fillings. Teeth presenting three restored surfaces presented more failures when compared to one and two restored surfaces ($p<0.001$). One study demonstrated that restorations with 3 or more involved surfaces have a relative risk of failure of 3.3 compared to Class I restorations [29]. A systematic review and a prospective practice based study on permanent teeth already demonstrated a higher failure rate of multi-surface restorations [20-30]. Several studies have shown that cavity size, cavity type, and the number of restores surfaces are associated to the failure risk [29-31].

It is well documented in literature that dental biofilm is a marker for oral health patterns. While evaluating the trajectory of dental plaque from childhood until adult life in a birth cohort, investigators observed that a lifetime exposure to dental biofilms may be a key risk factor in cumulative dental diseases, such as caries experience, failure in restorative procedures and tooth loss [32]. The children and adolescents under care at the Children and Youth Dental Clinic (UFRGS) receive treatment free of charge, and after oral rehabilitation, they are included in a therapeutic program that is based in oral health instruction and programmed recall intervals, as determined by the caries risk assessment. This approach had a positive impact in terms of oral health promotion, since it was observed at the end of the follow-up period a general reduction in visible plaque index and the gingival sites with bleeding. The results, in the adjusted model, showed that patients presenting more sites with gingival bleeding ($GBI>20\%$) have 2.88 times more risk of failure in their restorations ($p=0.007$). It is important

to call attention to this clinical parameter (GB), which is a more "faithful" reference from oral hygiene routine performed by patients, because they usually brush their teeth before the dentist appointment. Thus, gingival bleeding reveals that dental cleaning is not performed continuously. The population evaluated in the present study comprises moderate to high-risk patients, which represents a challenging situation for restorations survival. Individuals with higher caries risk were more likely to exhibit failed composite restorations compared to those with lower caries risk [33]. However, in our study, in the adjusted Cox regression the level of caries experience was not associated with restoration failure.

All 477 restorative procedures were performed by undergraduate (fourth clinical year) and graduate students (specialization program) under the supervision of senior professors. No difference was found in terms of longevity of the restorations executed by students with different level of education. Usually, it is believed that the operator could be an influent factor in restorations' longevity [19]. Nevertheless, clinical studies do not support this supposition [34]. A recent study showed that undergraduate students at the 4th year from public Brazilian dental schools are able to produce high-quality anterior and posterior composite restorations [35].

It is important to highlight that the design of the present study is an excellent alternative for assessing the quality of the restorative procedures performed in a general practice, allowing the collection of reliable data, which is not feasible in Randomized Clinical Trial (RCT) where designs are followed [36]. Therefore, retrospective practice based studies provide greater external validity, while the results of RCTs often cannot be extended to clinical practice because of the controlled conditions that are imposed [19].

Usually, investigations on clinical performance of dental materials utilize single-level analysis to associate individual factors with failures in restorations, assuming that the observations are independent. The inclusion of more than one tooth per child can be considered a bias of evaluation, since systemic and behavioral factors can interfere with the individual's response to treatment, leading to incorrect and potentially misleading results. The statistical analysis performed here accounted for the correlation of observations within each child using Cox regression models with shared gamma frailty, which considers that observations within the patient are correlated. This take into account the effect of clustering than, if ignored, can lead to misinterpretation of the results.

In relation to the limitations of this study, we could consider the relatively short-term clinical evaluation of these restorations. It has been considered that most of the failures could occur after 5 or 10 years with modern restorative materials [18]. Nevertheless, the young age of the patients and the challenging environment could accelerate the aging and therefore provide important information for clinicians and researches dealing with younger individuals.

In conclusion, our data suggest that partial caries removal may not affect the longevity of adhesive posterior restorations performed in permanent molars in young patients, treated at the Children and Youth Dental Clinic, School of Dentistry, Federal University of Rio Grande do Sul (UFRGS). The restorative material, number of surface and the oral hygiene (gingival bleeding) influenced the survival rate of the evaluated restorations.

Figure 1 – Flow diagram of the study.

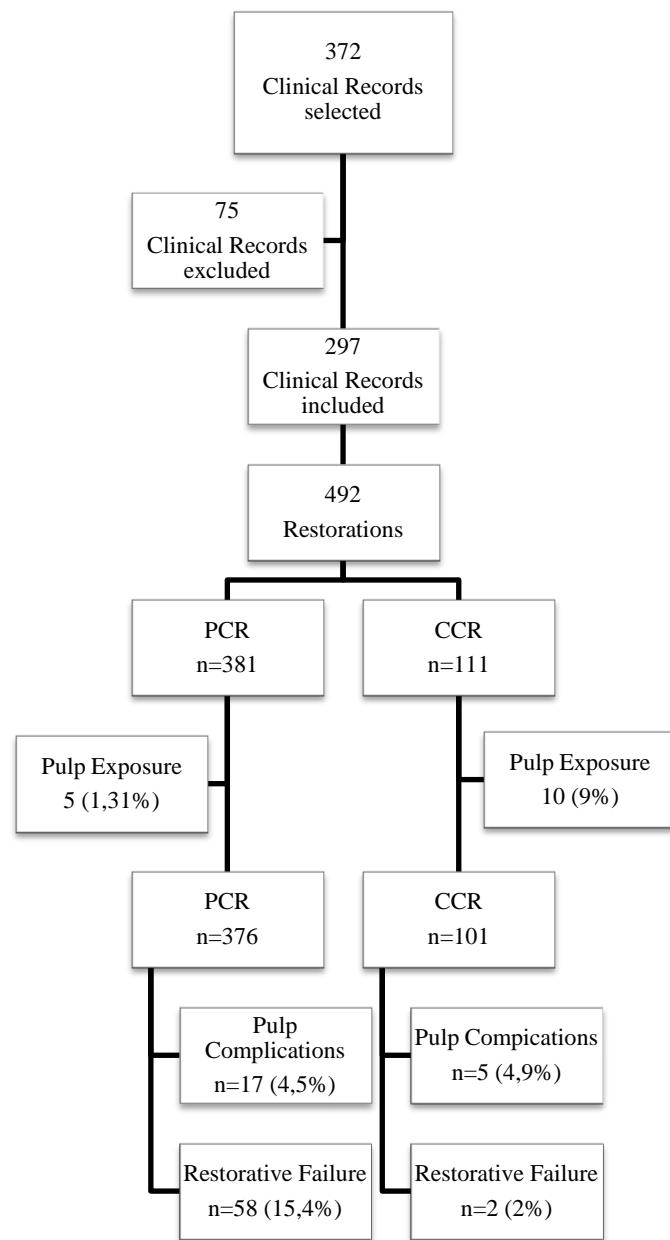


Figure 2 – Adjusted Kaplan–Meier survival curves. (A) Partial (PCR) and Complete (CCR) caries removal technique presented similar survival ($p=0.780$). (B) Teeth presenting multi-restored surfaces showed more failures ($p<0.001$); (C) Modified Resin Glass Ionomer Cement (MRGIC) presented more failures than Composite Resin (CR) ($p<0.001$). (D) Patients with gingivitis (GBI>20%) experienced more restorative failures ($p=0.008$). Curves were adjusted by all variables included in final Cox Regression Model.

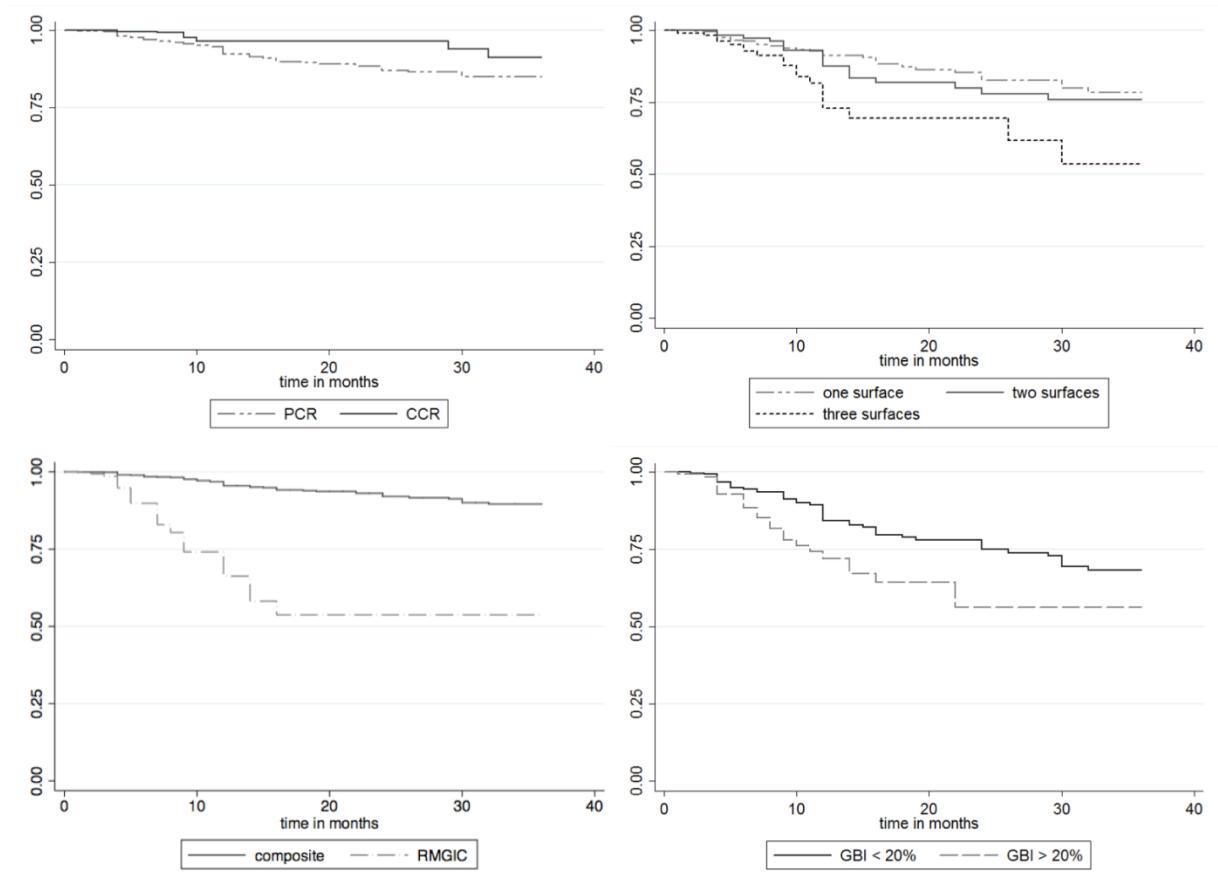


Table 1. Distribution of restorations in permanent teeth according individual and tooth-level variables.

Variables	PCR n (%) of restorations	CCR n (%) of restorations
<i>Gender</i>		
Male	190(39.83)	33(6.92)
Female	186(38.99)	68(14.25)
<i>Plaque index (follow-up)</i>		
Up 20%	164(42.82)	47(12.27)
More than 20%	139(36.29)	33(8.62)
<i>Gingival Bleeding Index (follow up)</i>		
Up 20%	215(56.13)	64(16.71)
More than 20%	88(22.98)	16(4.18)
<i>Caries experience</i>		
Moderate caries group	196(41.10)	51(10.69)
High caries group	180(37.73)	50(10.48)
<i>Type of arch</i>		
Maxillary	163(34.17)	40(8.38)
Mandible	213(44.65)	61(12.79)
<i>Caries removal</i>	376(78.82)	101(21.18)
<i>Number of Surfaces</i>		
1	229(48)	66(13.83)
2	89(18.66)	27(5.66)
3 or more	58(12.16)	8(1.68)
<i>Capping Material</i>		
Adhesive System	218(45.70)	64(13.42)
GIC/Calcium Hydroxide	158(33.12)	37(7.76)
<i>Restorative Material</i>		
Composite Resin	294(61.64)	83(17.40)
RMGIC	82(17.19)	18(3.77)

Table 2. Unadjusted (u) and adjusted (a) Hazard Ratios (HR:95%CI) for failure of the restorations according to clinical variables. Cox Regression Analysis.

Variables	HR ^u (95% CI)	P-value	HR ^a (95% CI)	P-value
<i>Caries experience</i>		0.169		-
Moderate	1.00		-	
High	1.62 (0.81;3.25)			
<i>Number of surfaces</i>		0.000		0.003
1	1.00		1.00	
2	1.23 (0.62;2.42)		1.00 (0.49;2.05)	
3 or more	3.79 (1.84;7.82)		3.22 (1.49;6.97)	
<i>Caries Removal</i>		0.444		-
Partial	1.00		-	
Complete	0.70 (0.28; 1.74)			
<i>Capping material</i>		0.001		0.193
Adhesive System	1.00		1.00	
GIC/Calcium Hydroxide	2.70 (1.50;4.84)		1.54 (0.80;2.96)	
<i>Restorative material</i>		0.000		0.000
Composite Resin	1.00		1.00	
RMGIC	3.88 (1.89;7.96)		4.11 (1.91;8.81)	
<i>Gingival bleeding index (follow up)</i>		0.044		0.007
Up 20%	1.00		1	
More than 20%	2.22 (1.02;4.85)		2.88 (1.33;6.24)	

Stata 11.2, College Station, Texas, USA

COMPLIANCE WITH ETHICAL STANDARDS:

Conflict of Interest: Author Alejandra Tejeda Seminario declares that she has no conflict of interest; Author Marcos Britto Correa declares that he has no conflict of interest; Author Stefanie Bressan Werle declares that she has no conflict of interest; Author Marisa Maltz declares that she has no conflict of interest; Author Flávio Fernando Demarco declares that he has no conflict of interest; Author Fernando Borba de Araujo declares that he has no conflict of interest; and Author Luciano Casagrande declares that he has no conflict of interest.

Ethical approval: All procedures performed in the present research were in accordance with the ethical standards of the Resolution of the National Council on Ethics in Research (n. 466, /2012) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from the parents or guardians of all children included in the study. The protocol of this research was submitted and approved by the Research Committee (n. 26760) and the Ethic Committee (n. 35380414.2.0000.5347) of Federal University of Rio Grande do Sul, Porto Alegre, RS - Brazil.

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4 CONSIDERAÇÕES FINAIS

- Os dados do presente estudo sugerem que a técnica da remoção parcial de tecido cariado não afetou a longevidade das restaurações adesivas em molares permanentes de pacientes jovens tratados nas Clinicas dos Cursos de Graduação e de Especialização em Odontopediatria da Faculdade de Odontologia da UFRGS, Porto Alegre -RS.
- A taxa de sobrevivência das restaurações avaliadas foi influenciada pelo tipo de material restaurador, pelo número de superfícies envolvidas na restauração, e pela higiene oral do paciente (ISG).

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ANEXO



UNIVERSIDADE FEDERAL DO
RIO GRANDE DO SUL / PRÓ-
REITORIA DE PESQUISA -



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Titulo da Pesquisa: Remoção Parcial de Tecido Cariado em Dentes Permanentes - Estudo retrospectivo em pacientes da Clínica da Graduação e do Curso de Especialização em Odontopediatria da FO-UFRGS

Pesquisador: Fernando Borba de Araujo

Área Temática:

Versão: 4

CNAE: 35380414 2 0000 5347

Instituição Proponente: Universidade Federal do Rio Grande do Sul

Retocinador Principal: Financiamento Próximo

DADOS DO BARECER

Número do Parecer: 899.013

Data da Relatoria: 26/11/2014

Apresentação do Projeto:

Como informado no parecer anterior, a apresentação da versão atual do projeto de pesquisa está adequada, com introdução atualizada e objetivo e metodologia claros.

Objetivo da Pesquisa:

A pesquisa pretende avaliar o comportamento clínico e radiográfico de procedimentos restauradores adesivos envolvendo a remoção parcial de tecido cariado em dentes permanentes realizados por alunos da Graduação e do Curso de Especialização em Odontopediatria da Faculdade de Odontologia da UFRGS.

Avaliação dos Riscos e Benefícios:

Como mencionado no parecer anterior, os pesquisadores atenderam às solicitações e a versão atual do texto dos riscos e benefícios da pesquisa está adequada. Cabe ressaltar que na versão atual do projeto de pesquisa os pesquisadores assumem o compromisso de preservar a confidencialidade dos dados mediante a assinatura do termo de compromisso na utilização dos dados e identificação dos indivíduos por meio de código numérico no banco de dados. Como benefício, informam que a Remoção Parcial de Tecido Cariado é um processo conservador que apresenta bons resultados e reproduzibilidade clínica não.

Endereço: Av. Paulo Gama, 110 - Sala 317 do Prédio Anexo 1 da Reitoria - Campus Centro

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Página 01 de 01

Continuação do Parecer: 899.017

só quando realizadas por pessoas com treinamento específico, mas também realizadas por clínicos gerais, beneficiando o paciente na medida em que esta técnica é menos invasiva e reduz o risco de exposição pulpar.

Comentários e Considerações sobre a Pesquisa:

Em atendimento à solicitação "Informar claramente o número de questionários que serão avaliados na pesquisa, e esse número deverá ser o mesmo no projeto de pesquisa e Formulário da Plataforma Brasil", os pesquisadores informaram: "Uma amostra de conveniência será composta por prontuários clínicos de pacientes entre 7 e 12 anos de idade atendidos durante a Graduação e o Curso de Especialização em Odontopediatria, que realizaram procedimentos clínicos restauradores adesivos com remoção parcial de tecido cariado em dentes permanentes no período de 2007 até 2013. Considera-se que, em média, são atendidas 120 crianças por semestre, sendo avaliados mil seiscentos e oitenta prontuários". O número 1680 foi citado no formulário da Plataforma Brasil.

Considerações sobre os Termos de apresentação obrigatória:

Como mencionado no parecer anterior, foram anexados todos os documentos necessários para a pesquisa.

Recomendações:

Como as solicitações foram atendidas, recomenda-se aprovação do projeto de pesquisa quanto aos seus aspectos éticos.

Conclusões ou Pendências e Lista de Inadequações:

Os pesquisadores atenderam às solicitações. Assim, recomenda-se aprovação da versão atual do projeto de pesquisa.

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

Aprovado.

Continuação do Parecer: 899.017

PORTO ALEGRE, 04 de Dezembro de 2014

Assinado por:

MARIA DA GRAÇA CORSO DA MOTTA
(Coordenador)

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APÊNDICE

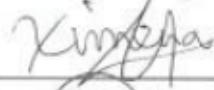
Termo de Compromisso para Utilização de Dados

Título do Projeto

Remoção Parcial de Tecido Cariado em Dentes Permanentes – Estudo Retrospectivo em pacientes da Clínica da Graduação e do Curso da Especialização em Odontopediatria da FO-UFRGS

Os pesquisadores do presente projeto se comprometem a preservar as informações que serão coletadas em bases de dados do Ambulatório da Clínica Infanto-Juvenil da Faculdade de Odontologia da UFRGS. Concordam, igualmente, que estas informações serão utilizadas única e exclusivamente para execução do presente projeto. As informações somente poderão ser divulgadas em atividades acadêmicas e científicas, no contexto do projeto de pesquisa aprovado.

Porto Alegre, 25 de setembro de 2014.

Nome dos Pesquisadores	Assinatura
Fernando Borba de Araújo	
Luciano Casagrande	
Ximena Concha Melgar	
Alejandra Tejeda Seminario	