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Programa de Pós-Graduação em Odontologia

Tese

Restaurações diretas em dentes posteriores: longevidade, causas de falhas e fatores relacionados

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RESTAURAÇÕES DIRETAS EM DENTES POSTERIORES: LONGEVIDADE, CAUSAS DE FALHAS E FATORES RELACIONADOS

Tese apresentada ao Programa de Pós-Graduação em Odontologia da Universidade Federal de Pelotas, como requisito parcial à obtenção do título de Doutor em Odontologia (área de concentração: Dentística).

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Dedicatória

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*Every experience is a paradox in that it means to be absolute, and yet is relative; in that it somehow always **goes beyond** itself and yet **never escapes** itself.*

Thomas Stearns Eliot

*Science is wonderfully equipped to answer the question "**How**?" but it gets terribly confused when you ask the question "**Why**?"*

Erwin Chargaff

*No **amount** of experimentation can ever prove me **right**; a **single** experiment can prove me **wrong**.*

Albert Einstein

*The most **exciting phrase** to hear in science, the one that heralds new discoveries, is not 'Eureka!' but '**That's funny**...'*

Isaac Asimov

*Whenever anyone says, '**theoretically**,' they really mean, '**not really**.'*

Dave Parnas

E por "cacoete" de pesquisa, eis a fonte:
http://www.brainyquote.com/quotes/topics/topic_science

NOTAS PRELIMINARES

A presente tese foi formatada conforme o manual de normas da Universidade Federal de Pelotas para elaboração de Teses Dissertações e Trabalhos Acadêmicos (2006). Foi utilizado o Nível de Descrição 4 – Estrutura em Artigos, que consta no Apêndice D do referido manual. Disponível no endereço eletrônico: (http://www.ufpel.tche.br/prg/sisbi/documentos/Manual_normas_UFPel_2006).

O projeto de pesquisa contido nesta tese é apresentado em sua forma final após qualificação realizada em outubro de 2012 e aprovado pela Banca Examinadora composta pelos Professores Doutores Marcos Britto Correa, Maximiliano Sérgio Cenci, Rafael Ratto de Moraes e Rudimar Antonio Baldissera.

Resumo

LEITE, Françoise Hélène van de Sande. **Restaurações diretas em dentes posteriores: longevidade, causas de falhas e fatores relacionados.** 2012. 96f. Tese de Doutorado – Programa de Pós-Graduação em Odontologia da Universidade Federal de Pelotas, Pelotas, RS, Brasil.

Os materiais mais amplamente utilizados para restaurações diretas em dentes permanentes posteriores são a resina composta (RC) e o amálgama. As RC têm sido cada vez mais utilizadas para estes procedimentos, no entanto esta mudança não é unânime, e difere entre os países. Neste sentido, tem-se procurado estabelecer a longevidade destas restaurações, investigar as causas mais frequentemente atribuídas às falhas, e determinar os fatores relacionados. Em busca de alto nível de evidência, revisões sistemáticas com critérios de inclusão estritos, que incluem apenas estudos clínicos controlados e randomizados, são necessárias para responder estas questões. No entanto, estudos clínicos deste tipo, e com longo período de acompanhamento são escassos, e insuficientes para gerar conclusões. Na presente tese, a longevidade de restaurações diretas em dentes posteriores, as falhas observadas e os fatores potencialmente relacionados foram abordados com uma revisão da literatura e também com um estudo clínico retrospectivo. A revisão sistemática foi realizada com estudos clínicos longitudinais com acompanhamento mínimo de 5 anos, e que investigaram a longevidade de restaurações diretas de amálgama e RC em restaurações em cavidades do tipo classe II. O objetivo foi investigar algumas observações de estudos prévios da literatura, incluindo a investigação do risco de cárie dos pacientes e também acerca da utilização de um material restaurador intermediário para restaurações de RC. Dentre as razões atribuídas às falhas restauradoras, as mais frequentemente relatadas foram cárie secundária e fratura da restauração. Os períodos de observação variaram de 5 até 12 anos. As taxas anuais de falha (TAF) variaram de 0-3,60% para RC, de 2,33-6,45% para RC com técnica de sanduíche, e de 1,5-3,85% para restaurações de amálgama. A análise quantitativa foi realizada com teste-T-independente. O risco de cárie afetou significativamente a TAF para restaurações de RC ($p=0,002$), enquanto que para amálgama as diferenças não foram estatisticamente significativas. A presença de um material intermediário com técnica de sanduíche em restaurações de resina também afetou significativamente a TAF ($p=0,001$). Complementando o tema desta tese, foi realizado um estudo retrospectivo em uma clinica odontológica privada. O objetivo foi investigar a sobrevivência, TAF, as razões de falha, e também os fatores que podem afetar a longevidade de restaurações diretas de RC. Trezentas e seis restaurações de RC em dentes posteriores, realizadas de janeiro de 1994 até dezembro de 2002 foram incluídas. A TAF foi de 3,2%, após 10 anos, e de 2,6% após 14 anos de acompanhamento. Nove fatores potencialmente relacionados à longevidade das restaurações foram investigados. A análise estatística foi realizada através de Regressão de Cox, e quatro fatores afetaram significativamente a TAF. Entre as variáveis do paciente, o risco estimado em relação à cárie e ao estresse oclusal mostraram um forte efeito sobre a longevidade das restaurações. Dentre as demais variáveis investigadas, o elemento dentário, a posição no arco, e a vitalidade pulpar foram os fatores que afetam a longevidade das restaurações. A conclusão geral a

partir desses estudos é que a avaliação do risco dos indivíduos deve fazer parte dos fatores investigados em avaliações acerca da longevidade de restaurações diretas.

Palavras-chave: Amálgama Dentário. Estudos longitudinais. Falha restauradora. Fatores de risco. Resinas Compostas. Revisão sistemática.

Abstract

LEITE, Françoise Hélène van de Sande. **Restaurações diretas em dentes posteriores: longevidade, causas de falhas e fatores relacionados.** 2012. 96f. Tese de Doutorado – Programa de Pós-Graduação em Odontologia da Universidade Federal de Pelotas, Pelotas, RS, Brasil.

The materials most widely used for direct restorations in posterior teeth are composite and amalgam. Although composites have been increasingly used on posterior teeth, the choice for this material is not unanimous for these restorations, and differs between countries. In this sense, the longevity of direct posterior restorations, the reasons most often attributed to failures, and the determination of the factors related to failures have been investigated. Seeking for the highest level of evidence, systematic reviews with strict inclusion criteria are needed, in which only randomized controlled clinical studies can be used to answer these questions. However, well controlled and randomized clinical studies with long follow-up periods are scarce and insufficient to draw any conclusions. Thus, the inclusion of clinical trials of different designs, with long-term monitoring periods, is needed to perform these investigations. In the present thesis, the longevity of direct posterior restorations, observed failures and potentially related factors were addressed with a literature review and with a retrospective clinical study. The systematic review was conducted with longitudinal studies with follow-up periods of at least 5 years, reporting the longevity of amalgam and composite class II direct restorations. The aim was to investigate some observations from previous studies in the literature. Focus was driven towards the investigation of the caries risk of the patients and also the presence of an intermediate restorative material for composite restorations. From the reasons attributed to failure, the most frequent were secondary caries along with tooth/restoration fracture. Observation periods ranged from 5 up to 12 years. The annual failure rates (AFR) ranged from 0-3.60% for composites, 2.33-6.45% to composites with sandwich-technique, and from 1.5-3.85% for amalgams. A quantitative analysis was performed with Independent-samples-T-test, in which a reduced number of studies could be included. Caries risk significantly affected the AFR for composite restorations ($p=0.002$), whereas for amalgam the differences were not statistically significant. The sandwich-technique in composite restorations affected significantly the AFR ($p=0.001$). The way of reporting clinical data hampers the ability to analyze variables with a large number of included studies. Complementing the theme of this thesis, a practice-base retrospective study was conducted. The aim was investigate the survival, AFR, reasons for failure and also look into factors that could affect the longevity of direct composite restorations. Three hundred and six composites restorations placed on posterior teeth from January 1994 up to December 2002 were included. The annual failure rate was 3.2% after 10 years, and 2.6% after 14 years of follow-up. After the analysis of nine factors that could affect survival, four were statistically significant in the Cox-regression analysis. Among patient variables, the estimated patient risk regarding caries and occlusal stress showed a strong effect on survival, whereas among tooth variables, tooth type, arch and pulp vitality were the significant factors affecting the longevity in this retrospective evaluation. The overall conclusion from those studies is that the risk assessment of the individuals should be taken into account when evaluating the longevity of direct restorations.

Key-words: Amalgam. Composite resins. Dental restoration failure. Longitudinal studies. Risk factors. Systematic review.

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1 Projeto de pesquisa

1.1 Introdução

Uma gradual mudança na utilização de materiais dentários restauradores diretos iniciou-se quando as resinas compostas tornaram-se uma alternativa viável para substituição do amálgama em dentes posteriores. Diversos fatores contribuíram para este fato, como a preocupação acerca da segurança em utilizar o amálgama (RATHORE et al., 2012; ROBERTS; CHARLTON, 2009), os avanços tanto nas resinas compostas como nos sistemas adesivos (BRESCHI et al., 2008; FERRACANE, 2011), e a possibilidade de realizar procedimentos conservadores e minimamente invasivos (BAGHDADI, 2002; ESPELID et al., 2001) aliados a estética (BRAGA et al., 2007; FERRACANE, 2011; ROULET, 1997). Esta mudança tem sido observada em diversos países e relatada em diversos levantamentos transversais (BRENNAN; SPENCER, 2003; ESPELID et al., 2001; FORSS; WIDSTROM, 2001; GILMOUR et al., 2007; MJOR et al., 1999; VIDNES-KOPPERUD et al., 2009). O declínio do emprego do amálgama ao longo dos anos tem sido acompanhado pela crescente utilização da resina composta em dentes posteriores, inclusive no Brasil (CORREA et al., 2012). Contudo, a aceitação de resinas compostas como material de escolha para restaurar dentes posteriores não é consensual em toda comunidade odontológica (SHENOY, 2008). Restaurações de amálgama em dentes posteriores ainda são amplamente realizadas (BRUNTON et al., 2012; CORREA et al., 2012; MAKHIJA et al., 2011; SHENOY, 2008).

Paralelamente, tem-se tentado responder questões acerca da longevidade de restaurações diretas em dentes posteriores, as causas de falhas, e os fatores relacionados. Até o presente, não há evidência suficiente para responder todas

estas questões, haja vista que estudos clínicos altamente controlados, randomizados e com longo período de acompanhamento são escassos.

Quando o foco é a comparação entre os principais materiais de uso direto, apenas dois estudos se mostraram elegíveis para comparação direta entre amálgama e resina composta em uma revisão realizada por Kovarik (2009). Ambos foram realizados em crianças/adolescentes, e, portanto, dificilmente sejam adequados para gerar conclusões generalizadas para a população adulta (KOVARIK, 2009).

No entanto, diversos estudos longitudinais avaliaram restaurações em dentes posteriores, apresentando resultados para taxas anuais de falha, falhas observadas e, em alguns estudos, alguns fatores possivelmente associados foram abordados. Dentre estes fatores, destacam-se: o elemento dentário (DA ROSA RODOLPHO et al., 2011; PALLESEN; QVIST, 2003; VAN DIJKEN, 2000; VAN NIEUWENHUYSEN et al., 2003); a extensão, o tipo da cavidade ou número de faces envolvidas (DA ROSA RODOLPHO et al., 2011; OPDAM et al., 2007b; SONCINI et al., 2007; VAN NIEUWENHUYSEN et al., 2003); os materiais restauradores (KOHLER et al., 2000; LETZEL et al., 1997; MAIR, 1998; MANNOCCI et al., 2005; OPDAM et al., 2007b; VAN NIEUWENHUYSEN et al., 2003), os operadores (COPPOLA et al., 2003; OPDAM et al., 2007a; OPDAM et al., 2004), o risco de cárie do paciente (ANDERSSON-WENCKERT et al., 2004; JOKSTAD; MJOR, 1991; KOHLER et al., 2000; OPDAM et al., 2010; OPDAM et al., 2007a), e a presença de uma camada restauradora intermediária em restaurações de resina composta (ANDERSSON-WENCKERT et al., 2004; OPDAM et al., 2007a; VAN NIEUWENHUYSEN et al., 2003).

O agrupamento de estudos longitudinais para avaliação conjunta de dados e/ou comparação de resultados se torna difícil em razão de diferenças na forma como os dados são coletados e reportados (BRUNTHALER et al., 2003; CHADWICK et al., 2001). Apesar disto, uma concordância acerca das razões mais frequentemente atribuídas às falhas pode ser observada em revisões de literatura, onde cárie secundária e fratura (material/ dentária) se destacam para restaurações diretas em dentes posteriores (BRUNTHALER et al., 2003; DEMARCO et al., 2012; MANHART et al., 2004). Neste sentido, a investigação dos fatores possivelmente relacionados a estas falhas é relevante.

Em uma revisão recente, restrita a resinas compostas (DEMARCO et al., 2012), foi relatado que as propriedades do material teriam pouco efeito sobre a longevidade. Por outro lado, o risco de cárie do indivíduo estaria relacionado com falha por cárie secundária, enquanto que falha por fratura teria uma característica multifatorial, como a presença de material restaurador intermediário, a resistência do material utilizado, bem como fatores do paciente, tais como o bruxismo (DEMARCO et al., 2012).

A partir do exposto, e contemplando o tema geral deste projeto de tese, dois estudos serão conduzidos. Uma revisão sistemática da literatura buscando estudos clínicos longitudinais, com longo período de acompanhamento de restaurações diretas em dentes posteriores na dentição permanente. Nesta, serão reportadas as taxas anuais de falhas e principais causas atribuídas, com enfoque no risco de cárie do indivíduo e a presença de material restaurador intermediário. De forma complementar, o outro estudo a ser conduzido será clínico retrospectivo, onde serão investigadas as taxas anuais e causas atribuídas à falha, comparativamente entre restaurações diretas em resina composta com e sem material restaurador intermediário. A hipótese a ser testada neste estudo é que restaurações realizadas com a utilização de um material restaurador intermediário apresentarão taxa anual de falha superior comparadas a restaurações totalmente adesivas.

Em posse dos resultados, espera-se contribuir com a determinação de alguns fatores relacionados às principais causas de falhas de restaurações diretas em dentes posteriores.

1.2 Objetivos

1.2.1 Objetivo Geral

Esta Tese de Doutoramento terá como objetivo geral avaliar a longevidade, as causas de falhas e fatores relacionados a restaurações diretas em dentes posteriores.

1.2.2 Objetivos específicos

a. Revisar sistematicamente a literatura acerca de estudos longitudinais de restaurações diretas em dentes posteriores em cavidades do tipo classe II, reportando as taxas anuais de falha e principais causas de falha. Dois fatores serão investigados em relação às taxas de falha: o risco de cárie do paciente e a presença de um material restaurador intermediário em restaurações de resinas compostas.

b. Avaliar clinicamente restaurações de resina composta em dentes posteriores com no mínimo dez anos de acompanhamento, através de um estudo longitudinal retrospectivo, avaliando comparativamente as taxas anuais e causas de falha com o uso de técnica totalmente adesiva ou utilização de material restaurador intermediário.

1.3 Material e métodos

1.3.1 Revisão sistemática da literatura

1.3.1.1 Delineamento

Os estudos a serem revisados compreenderão estudos clínicos prospectivos e retrospectivos de acompanhamento de restaurações de amálgama e/ou resina composta. A estratégia de busca dos estudos a serem revisados envolverá uma pesquisa nas seguintes bases de dados: *Cochrane Library, PubMed, the Web of Science (ISI)* e *Scopus*, utilizando combinações e variações das seguintes palavras-chave: *‘’restoration’’, ‘’composite’’, ‘’amalgam’’, ‘’clinical’’, ‘’in vivo’’, ‘’longevity’’, ‘’longitudinal’’, ‘’follow-up’’, ‘’prospective’’, ‘’retrospective’’, ‘’posterior’’, ‘’class II’’*. A busca será limitada a textos disponibilizados em língua inglesa, publicados de Janeiro de 1990 a Novembro de 2012. Transcrição da busca, conforme realizada na base de dados PubMed: ‘(((((("composite") OR "amalgam") AND "restoration")) AND ((("posterior teeth") OR "molar") OR "premolar")) AND ((((((((((("clinical") AND "longitudinal") OR "follow up") OR "prospective") OR "retrospective") AND "evaluation") OR "survival") OR "longevity") OR "long term") OR "annual failure rate") OR "restoration failure"). Filters: From 1990/01/01 to 2012/12/31, English.

Os critérios utilizados para inclusão serão: estudos clínicos prospectivos ou retrospectivos com no mínimo cinco anos de acompanhamento, a utilização de amálgama ou resina composta com técnica restauradora direta para restauração de cavidades do tipo classe II, em dentição permanente. Para inclusão, os estudos devem conter dados que permitam calcular a taxa anual de falha, discriminar as causas atribuídas às falhas, apresentar dados da população incluída ou critérios usados na inclusão/ exclusão dos indivíduos e relatar os materiais restauradores

utilizados. Relatos de caso clínico ou publicações de séries de casos clínicos não serão considerados para esta revisão.

A revisão será realizada conforme as diretrizes para reportagem de revisões sistemáticas e meta-análises - PRISMA *statement - Transparent Reporting of Systematic Reviews and Meta-Analyses* (MOHER et al., 2009). A seleção dos artigos será realizada independentemente por dois pesquisadores em acordo aos critérios determinados. A seleção inicial será realizada avaliando o título dos artigos, e os selecionados serão reavaliados pelo resumo. Diferenças de inclusão/ exclusão de artigos serão discutidas para obtenção de consenso. Adicionalmente será realizada uma busca manual nas referências dos artigos selecionados e revisões sistemáticas acerca do mesmo tema.

A análise qualitativa dos estudos será realizada através da extração de dados referentes ao tempo de acompanhamento, o número de restaurações incluídas originalmente e avaliadas no último acompanhamento, o risco de cárie dos pacientes, os materiais restauradores utilizados (incluindo a utilização de material restaurador intermediário), os critérios utilizados para avaliação das restaurações e as falhas observadas. Para cada estudo, a taxa anual de falha será calculada. Se possível, uma avaliação quantitativa, através de meta-análise será realizada, com o agrupamento das taxas anuais de falha conforme o risco de cárie do indivíduo, e conforme a utilização de material restaurador intermediário. Os dados coletados serão dispostos em forma de tabelas e figuras, com o objetivo de facilitar o entendimento e possibilitar a comparação dos estudos e respectivas taxas anuais de falhas.

1.3.2 Estudo clínico

1.3.2.1 Delineamento

Este estudo será do tipo longitudinal retrospectivo com dados obtidos em uma clínica odontológica privada. Serão selecionados os pacientes que receberam restaurações diretas de resina composta em dentes permanentes posteriores, as quais tenham sido realizadas com técnica totalmente adesiva (TA). Os dados referentes à técnica de sanduíche com material restaurador intermediário (TS)

utilizado foram coletados anteriormente (DA ROSA RODOLPHO et al. 2011). As restaurações serão avaliadas com critérios definidos (HICKEL et al., 2010) (Anexos), e os grupos experimentais serão independentes, representados pelas referidas técnicas. Os fatores em estudo serão as técnicas utilizadas (TA, TS) enquanto os desfechos avaliados serão as falhas observadas (reparo ou substituição das restaurações), e a taxa de anual de falha.

1.3.2.2 Seleção de pacientes e critérios de inclusão

Inicialmente este projeto será submetido ao Comitê de Ética em Pesquisa da Faculdade de Medicina da Universidade Federal de Pelotas. Uma vez aprovado, os pacientes serão selecionados a partir de um arquivo de prontuários de uma clínica privada de acordo com os seguintes critérios de inclusão: os pacientes devem ter sido submetidos a procedimentos restauradores entre os meses de Janeiro de 1994 e Dezembro de 2002; possuir ao menos uma restauração direta de resina composta em dentes permanentes posteriores; apresentar dentes antagonistas e adjacentes aos dentes avaliados; e ter realizado visitas ao o mesmo dentista com periodicidade anual, nos últimos 10 a 18 anos. Este levantamento será realizado nas fichas clínicas individuais, verificando registros clínicos e radiográficos. Dois dos pesquisadores envolvidos no estudo e sem contato prévio com os pacientes ficarão responsáveis pelo exame dos prontuários e seleção dos pacientes de acordo com os critérios de inclusão descritos. Os pacientes que forem selecionados serão convidados a participar do estudo, através de contato por telefone ou carta.

1.3.2.3 Descrição do procedimento restaurador

Os detalhes sobre os materiais e procedimentos realizados já foram descritos previamente (DA ROSA RODOLPHO et al., 2006). Resumidamente, um único operador executou todas as restaurações em uma clínica privada localizada na cidade de Caxias do Sul, RS, Brasil. As restaurações foram realizadas com isolamento absoluto, as cavidades preparadas com brocas de baixa rotação (número 2 e 3, KG Sorensen, Barueri, SP, Brasil) para remover tecido cariado e brocas carbide em alta rotação (número 245 e 330 KG Sorensen) para remoção de restaurações antigas. Os preparos realizados foram conservadores, restritos à remoção de tecido cariado ou de restaurações insatisfatórias, sem desgastes adicionais ou bisel no ângulo cavo superficial. As cavidades com técnica de

sanduíche foram restauradas com uma camada de cimento de ionômero de vidro convencional (Ketac-Fil, 3M ESPE, St. Paul, MN, USA), a qual recobria toda a porção de dentina da cavidade. Em cavidades bastante profundas uma cobertura com cimento de hidróxido de cálcio (Dycal, Dentsply, Petrópolis, RJ, Brasil) era realizada previamente a colocação do cimento de ionômero de vidro.

A partir desta etapa, os demais procedimentos foram realizados igualmente nas duas técnicas. Todas as etapas de condicionamento ácido, aplicação do primer, do adesivo, e foto-ativação foram realizadas de acordo com as instruções dos fabricantes. A resina composta foi inserida através de técnica incremental e a ativação foi realizada com fotopolimerizador Visilux light curing unit (3M ESPE, St.Paul, MN, USA). Os procedimentos de acabamento e polimento foram realizados após uma semana, usando pontas diamantadas de granulação fina (N. 1190FF, 3168FF, 2135FF; KG Sorensen) e pontas de borracha (N. 8001, 8010, 8040 e 8045; KG Sorensen) com uma pasta para polimento de óxido de alumínio (Micro I e Luster past, Kerr; Orange, CA, USA). Discos de óxido de alumínio e tiras de lixas foram usados para o polimento em faces proximais. O mesmo profissional que confeccionou as restaurações realizou a avaliação inicial (baseline), onde todas as restaurações foram consideradas clinicamente ideais.

1.3.2.4 Avaliação das restaurações e análise estatística

As avaliações das restaurações serão realizadas por dois avaliadores não relacionados com a inserção das restaurações, de forma independente, utilizando os critérios preconizados por Hickel et al. (2010) (Anexos). Os avaliadores serão previamente calibrados, e deverão apresentar índice de concordância inter-examinador de no mínimo 80% através na estatística Kappa. Para treinamento e calibração, os critérios a serem empregados na avaliação serão estudados em aula teórica e através de fotos de casos clínicos no website www.e-calib.info, preparados por Prof. Dr. R. Hickel, Prof. Dr. J.F. Roulet, Dr. S. Heintze e Dr. A. Peschke, que ilustram os diferentes níveis para cada critério. Seguindo esta etapa, os avaliadores examinarão 10 pacientes com restaurações em dentes posteriores, para que sejam discutidos os critérios de avaliação, servindo esta etapa como exercício. A seguir os examinadores realizarão a etapa de calibração, avaliando restaurações em 20 pacientes, sem contato entre os examinadores. A concordância inter-examinador será testada pela estatística Kappa. Um pesquisador com experiência em avaliações

clínicas será o padrão-ouro. O exercício será repetido duas vezes na tentativa de se alcançar níveis aceitáveis. Em caso de não ser alcançada concordância em níveis aceitáveis, a avaliação se dará por consenso entre os examinadores. Após esta etapa, o exame dos pacientes e avaliação das restaurações serão realizados na mesma clínica odontológica onde as restaurações foram confeccionadas, utilizando sonda exploradora e espelho clínico.

Os dados serão tabulados e submetidos à análise estatística. Estatística descritiva será usada para reportar a frequência de distribuição para os critérios avaliados e causas de falha. As diferenças entre a primeira avaliação (*baseline*) e esta avaliação serão analisadas através de testes não paramétricos para avaliação de frequências (McNemar e qui-quadrado). A longevidade das restaurações, em anos, será avaliada por análise de sobrevivência de acordo com a estratégia sugerida por Hickel et al. (2007) (HICKEL et al., 2007), que consiste primariamente na aplicação do método de Kaplan-Meier para a confecção de curvas de sobrevivência, seguido de Log-Rank test e Regressão de Cox em modelo de fragilidade compartilhada, a qual permite estudar o efeito de diferentes fatores no desfecho longevidade de restaurações e considerar múltiplas restaurações por paciente.

1.4 Aspéctos éticos

O projeto será submetido ao Comitê de Ética em Pesquisa (Faculdade de Medicina/ UFPel). Após aprovação do projeto, os voluntários que forem selecionados receberão uma carta informativa sobre o estudo (apêndice 1) e os que desejarem participar do estudo assinarão um termo de consentimento livre e esclarecido (apêndice 2).

1.5 Artigos previstos

1.5.1 Longevity of direct posterior restorations on the long term: a systematic review

1.5.2 Long term clinical evaluation and failures related to total etch and sandwich posterior composite restorations

Cronograma

Atividade	2011	2012	2013
Pesquisa Bibliográfica	X*	X	
Elaboração do Projeto		Ago-Set	
Submissão ao CEP		Out	
Qualificação		Out	
Treinamento e calibração		Out	
Seleção de pacientes		Nov	
Exame clínico dos pacientes selecionados		Nov-Dez	
Tabulação dos dados		Nov-Dez	
Descrição dos resultados e análise estatística			Jan
Redação dos artigos			Jan
Redação da Tese			Fev
Defesa			Mar

* X Todos os meses do referido ano.

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Orçamento

Orçamento previsto para viabilização do projeto

Descrição	Quantidade	Custo (unidade)	Custo (total)
Contato com pacientes	400	2,00	800,00
Luvas de procedimentos, caixa com 100 unidades	6	15,00	90,00
Máscara, caixa com 50 unidades	6	16,00	96,00
Viagens a Caxias do Sul	5	200,00	1.000,00
Hospedagem em Caxias do Sul	20	100,00	2.000,00
Apresentação em congressos	1	700,00	700,00
		Total	R$ 4.686,00

Fontes de financiamento

Recursos dos pesquisadores e recursos do Projeto Pesquisador Visitante Especial CNPq do PPGO (Processo: 400614/2012-0).

3 Relatório do trabalho de campo

Esta seção não se refere propriamente à descrição do trabalho de campo, pois a execução do projeto foi realizada conforme previsto. No entanto, foram realizadas alterações em relação à elaboração dos artigos.

Durante a fase de campo, na coleta de dados e exames clínicos, decidiu-se ampliar a investigação dos fatores relacionados aos pacientes, analisando toda a história clínica contida nos prontuários. Desta forma, o risco de cárie e estresse oclusal de cada paciente foi estimado utilizando critérios simplificados reportados anteriormente na literatura, descritos no artigo 2. O artigo que seria realizado para comparar a técnica de sanduíche e a técnica adesiva foi substituído por um artigo avaliando a longevidade, causas de falhas e fatores relacionados às falhas em restaurações de resinas compostas.

4 Artigo 1

Title: Long-term longevity of direct class II posterior restorations: a systematic review.[J]

Short title: Longevity of class II restorations

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As tabelas e figuras estão inseridas no texto para facilitar a leitura do artigo.

Long-term longevity of direct class II posterior restorations: a systematic review

ABSTRACT

Objectives: Systematically review longitudinal studies with at least 5 years of observation to investigate the longevity of amalgam and composite in class II restorations, focusing in the effect of caries risk of the patient and the use of base/liner underneath composite restorations.
Sources: Cochrane Library, PubMed, the Web of Science (ISI) and Scopus.
Study selection: Longitudinal studies with primary data of direct class II restorations in permanent dentition with a minimum follow-up period of 5 years. A minimum of 20 restorations should be evaluated at the last recall. The studies should present the reason for failure, description of patients' selection, clinical set and/or caries-risk status and information regarding the use of liner or base for composite restorations.
Conclusion: Mean annual failure rates were 1.83- 2.64- 4.10% for total-etch composite, amalgam and composite with a base/liner, respectively. The patient caries risk was a factor that affected the survival of direct class II restorations. Composite restorations were more affected by the patient caries risk status than amalgam restorations. The use of a glass ionomer base/liner for covering all dentin walls (sandwich technique) was related to an increased risk for failure in composite restorations.

Clinical significance: The caries risk of the patients should become part of the variables under evaluation when a restoration is placed. The sandwich technique with glass ionomer cements recovering all dentin walls should not be recommended. There was not sufficient evidence to recommend or discard the use of modified sandwich techniques.

Keywords: Longitudinal studies; Systematic review; Composite resins; Amalgam; Risk factors; Dental Restoration Failure.

1. Introduction

In the past decades, a worldwide shift from amalgam as the predominant posterior direct restorative material towards composite resin has taken place[1-3]. Nonetheless, acceptance of composite resin as the material of choice on posterior teeth differs among countries in the world[4,5]. Review papers that have been published in this aspect vary in outcome considerably, and still there is no conclusion in which way amalgam and composite compare to each other. Whereas reviews by Hickel and coworkers conclude that annual failure rates of both types of posterior materials are similar[6,7], others still conclude that amalgam has a superior performance compared to composite[1,8]. More conclusive evidence is necessary considering that the longevity of dental restorations is a major factor influencing dental health care, and that most of the work performed by dentists in general practices is based on replacements of failed restorations[9,10].

Systematic reviews and meta-analysis of randomized controlled trials are considered as the highest level of evidence to solve research questions regarding the comparison of therapies in medicine and dentistry[11]. When searching for the longevity of restorations, a chain of factors contributes to hinder the attainment of this level of evidence, *i.e.*: *i.* differences in outcome between different restorative therapies usually become visible after longer periods of follow-up , *ii.* materials are no longer on the market and outcomes are less attractive to be funded by *e.g.* manufacturers, *iii.* an increased number of volunteers are lost during follow-up compromising the outcome. Therefore, randomized controlled trials with extensive observation periods are seldom available.

Alternatively, other clinical studies are available*, i.e.* cross-sectional, and non-randomized longitudinal clinical studies with prospective or retrospective design. Cross-sectional studies were conducted in the past to investigate longevity of dental restorations, being mainly based on data from failed restorations. From these studies it was concluded that dental restorations had a shorter lifetime in general practice than in longitudinal clinical studies[7]. However, cross-sectional studies were found to be deceptive for longevity assessment[12]. On the other hand, prospective and retrospective studies are longitudinal follow-ups that lack randomization or control, but they may provide valuable information of the clinical longevity of restorations, especially if outcomes are presented with objective measurements and longer observation times are reported.

Several longitudinal studies evaluated restorations in posterior teeth, presenting results for annual failure rates and for the types of failures observed. Additionally, factors possibly associated with failure were investigated in some, like the tooth[13-15]; cavity type, extension or number of faces involved[13,16,17], the material used[14,15,18-20], the operator[15,21,22], the caries risk of the patient[23,24], and the presence of an intermediate layer in composite resin restorations[14,23,25].

The clustering of longitudinal studies for joint evaluation and/ or comparison of results is difficult, since the way data are collected and reported differs[26,27]. Nevertheless, there is an agreement that fracture and secondary caries are the reasons most often attributed to failure of direct restorations in posterior teeth[7,26,28]. In this sense, the investigation of factors possibly related to these failures is relevant. Recently, it has been suggested that the properties of the material have little effect on longevity[28], at least for composite restorations. Moreover, failure for secondary caries would be related to the caries risk of the individual, whereas fracture would have a multifactorial cause, like the presence of an intermediate restorative material, the properties of the material used as well as patient factors such as bruxism[28].

This review paper was carried out to assess the long term longevity of amalgam and composite class II posterior restorations, collecting data from longitudinal clinical studies published from 1991 up to 2012, with a minimum observation period of 5 years. The focus was to investigate the effect of caries risk of the patient and lining materials on restoration longevity.

2. Methods

2.1. Literature search

This systematic review was conducted following the guidelines of the PRISMA statement - Transparent Reporting of Systematic Reviews and Meta-Analyses[29,30]. The search was conducted in the Cochrane Library, PubMed, the Web of Science (ISI) and Scopus for full articles published in English from January 1990 up to Nov 2012. Hand-searching included the reference list of selected papers and review articles on the subject.

2.2. Inclusion and exclusion criteria

The eligibility criteria for inclusion were:

- longitudinal studies of direct class II restorations in permanent dentition;
- follow-up periods for at least 5 years;
- primary data evaluation;
- a minimum of 20 restorations evaluated at the last recall;
- availability of data for reason for failure;
- description of patients' selection, clinical set and/or caries-risk status;
- information regarding the use of liner or base for composite restorations.

The exclusion criteria were applied as follows:

- studies that were not related to the questions addressed, *i.e.* presenting different outcome, primary teeth, anterior teeth, indirect restorations, orthodontic and endodontic reports;
- restorations with different cavities designs - classes I, III, IV and V;
- pooled results for different cavity designs;
- in vitro or in situ studies;
- cross-sectional and case-reports studies;
- earlier follow-ups from the same study.

2.3. Search

The following terms were used to search for articles: ''composite'', ''amalgam'', ''restoration'', ''clinical'', ''longevity'', ''longitudinal'', ''follow-up'', ''prospective'', ''retrospective'', ''evaluation'', ''posterior teeth'', ''molar'' and ''premolar''. PubMed search was performed as follows: '(((((("composite") OR "amalgam") AND "restoration")) AND ((("posterior teeth") OR "molar") OR "premolar")) AND ((((((((((("clinical") AND "longitudinal") OR "follow up") OR "prospective") OR "retrospective") AND "evaluation") OR "survival") OR "longevity") OR "long term") OR "annual failure rate") OR "restoration failure"). Filters: From 1990/01/01 to 2012/12/31, English.

2.4. Study selection

The articles identified in all databases were screened for duplicates that were automatically excluded (Figure 1). Then titles were screened by two reviewers (N.O.,

M.C.) independently. Those that were considered of interest for this review were printed as abstracts, or if the abstract was missing, as full-article. After abstract screening, the remaining articles were ordered in full-text. During the evaluation process, disagreements were identified by a third reviewer (F.S.) and the three (N.O., M.C., F.S.) reached consensus. After selection, the reference lists of included studies were hand searched, and 7 studies with potential for inclusion were screened in the same way.

2.5. Evaluation of included articles

The articles that met the inclusion criteria were subjected to critical appraisal, which was carried out by two reviewers (F.S., N.O.). Data was extracted using a pilot-tested table, in duplicate, and included the observation period, study design, patient caries-risk status, materials used, number of restorations included originally and observed at last recall, and failed restorations (total failure, secondary caries, tooth or restoration fracture, endodontic treatment or pain, and others). The patient caries-risk status was either stated by the authors in the article or classified (high/ low/ undetermined risk) according to information given on patient selection and patient related factors.

2.6. Data analysis

Data was organized into tables to describe the included studies. Qualitative analysis included the reasons for failure, survival and annual failure rate according to caries-risk status and use of base/liner for resin composite restorations. The quantitative analysis was performed with Independent samples T test with IBM SPSS Statistics 20 (α=0.05). Within composite restorations, 6 datasets were included to assess the caries risk status (low/ high) and annual failure rate, and the use of base/liner (yes/ no) was assessed with 22 datasets. Within amalgam restorations 5 datasets were included to assess the caries-risk status (low/ high) and the outcome.

3. Results

A total of 1551 papers were originally identified. After removing duplicates, 1194 remained for title screening. Then, 858 were excluded, 336 abstracts were selected for reading, resulting in 54 full-text articles assessed for eligibility. From these

articles, seven additional records were identified and assessed for eligibility. After applying the criteria 21 studies were included for data extraction (Fig. 1).

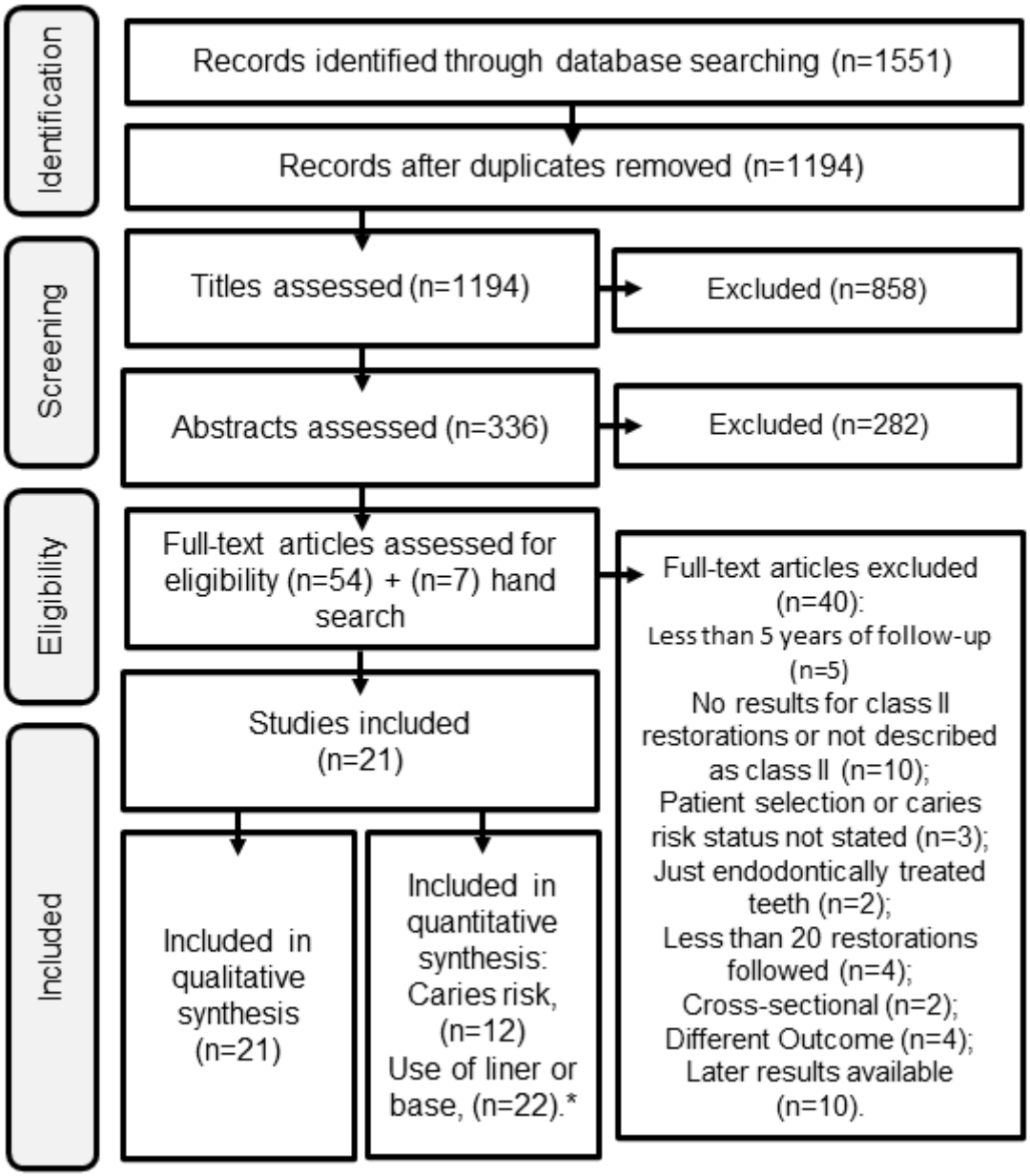

Fig. 1 Flow diagram of study identification[31].

***Note:** the number of datasets included is bigger than number of studies since 2 studies presented 2 separate datasets according to patient risk**.**

The included studies presented variations in design, described in detail in Table 1. Two were retrospective[24,25] and 19 were prospective follow-ups, in which randomization was performed in 9 studies[32-40]. In 8 studies a split mouth design was used[32-35,37-39,41], and 2 had separate groups for an independent analysis[36,42]. From the studies in which the design was not stated or planned in methods section, 5 have

used statistical methods to take in account multiple restorations in the same patient[24,25,40,43,44], whereas in 4 studies there was no statement regarding this aspect[23,45-47]. The clinical set where the studies took place also varied. Eight were in general private dental practices, 4 in public health dental clinics, 4 in dental school clinics, and 3 had a combination of clinical sets involved. Patient inclusion was mentioned with limited detail in 5 studies[34,36,45-47].

Table 1 – Characteristics of selected studies regarding design and patient inclusion.

Reference	P/R	Controlled for	Randomization	Design for analysis	Clinical set	Patient inclusion
van Dijken and Pallesen in press [32]	P	Materials, 2 composites. Comparable cavity sizes.	Material allocation	Split mouth	PDHSC	No patient was excluded because of caries activity, periodontal condition or parafunctional habits; patients were classified according to caries risk status but results were not given separately
Kramer et al. 2011 [33]	P	Materials, 2 composites. Large class II without cusp replacements.	Material allocation	Split mouth	GP	Patients with no further restorations planned in other posterior teeth, high level of oral hygiene, and absence of any active periodontal or pulpal disease.
van Dijken and Pallesen 2011 [41]	P	Technique, with and without flowable resin layer. Comparable cavities size.	No	Split mouth	GP	No patient was excluded because of caries activity, periodontal condition or parafunctional habits; patients were classified according to caries risk status but results were not given separately.
Opdam et al. 2010 [24]	R	Material, amalgam and composite.	Not applicable	Patients contributed with multiple restorations, what was taken into consideration in the statistical analysis.	GP	Patients were classified regarding caries risk based on file history; results were given separately according to caries risk status.
Fagundes et al. 2009 [34]	P	Material, 2 composites.	Material allocation	Split mouth	DSC+MDC	Patients were recruited from dental school clinic and from military police dental clinic.
Kiremitci et al. 2009 [45]	P	No, just one composite was used.	No	1 to 3 restorations per patient, but it's not mentioned if that was taken into account during analysis.	DSC	Patients regularly attending the University Dental Clinic.
van Dijken and Lindberg 2009 [35]	P	Material, 2 composites. Class II cavities with comparable size.	Material allocation	Split mouth	PDH + DSC	Patients were classified according to caries risk status but results were not given separately.
Bernardo et al. 2007 [36]	P	Material, amalgam and composite. Arch, tooth type, number of surfaces and size.	Material allocation	Independent groups	-	Caries active patients between 8 and 12 y/o.
Lindberg et al. 2007 [37]	P	Techniques, total etch and open sandwich. Cavities with	Treatment allocation	Split mouth	PDH	No patient was excluded because of caries activity, periodontal condition or parafunctional habits;

		comparable size in matching teeth.				patients were classified according to caries risk status but results were not given separately.
Opdam et al. 2007 [25]	R	Techniques, total etch and closed sandwich.	Not applicable	Patients contributed with multiple restorations, what was taken into consideration in the statistical analysis.	GP	Patients were classified regarding caries risk based on file history; results were given separately according to caries risk status.
van Dijken and Sunnegardh-Gronberg 2006 [42]	P	Material, 2 composites. Class II cavities, medium to large sized.	No	Independent groups	GP	No patient was excluded because of caries activity, periodontal condition or parafunctional habits, patients were classified according to caries risk status but results were not given separately.
Andersson-Wenckert et al. 2004 [23]	P	Techniques, different thickness of the sandwich layer	No	1 or 2 restoration per patient, but it's not mentioned if that was taken into account during analysis.	GP	Patients were classified according to caries risk status but results were not given separately.
Pallesen and Qvist 2003 [38]	P	Materials and technique (direct filling and inlay). Class II cavities, medium to large sized. Vital teeth.	Technique allocation and material	Split mouth	? DSC	No patient was excluded because of caries activity, periodontal condition or parafunctional habits; it is stated that the study population showed low to moderate caries activity but results were not given according to caries risk status.
Kohler et al. 2000 [43]	P	Material, 2 composites.	No	When the patient had more than one filling, the choice of filling for statistical analysis was decided by ballot.	PDH	Baseline microbiological counts (mutans streptococci) were determined, and after analysis, the cut off was set at 500 000 cfu ms/ml saliva, therefore patient caries risk status was estimated as 37.8%. Although the authors presented failures and mutans counts for each patient, it is not presented per restoration and data couldn't be assessed separately for risk.
van Dijken 2000 [48]	P	Technique, direct filling with open or closed sandwich and inlay.	No	Descriptive statistics with frequency distribution since sample size was small, and patient could have more than one restoration.	GP	Patients' caries-risk was estimated by the sum of risk factors. 45% presented more than 3 factors, and were classified as high risk. Results were not given according to caries risk status.
Wassell et al. 2000 [39]	P	Techniques, direct filling and inlay.	Patient/operator allocation, treatments and order of restoration placement	Split mouth	DSC	Patients with poor oral hygiene, poor gingival health or unresponsive to instruction were excluded.
Nordbo et al. 1998 [49]	P	Cavity design without control, material (2 composites).	No	-	PDH	Patients were adolescents (13 to 17 y/o) with active caries lesions, attending to a suburban public dental service.
Rasmusson and Lundin 1995	P	Materials, 6 composites. Small class II	No	Patients received 1 to 3 restorations, but	PHD	Patients were not particularly selected, and mean DFT was 14.5.

[46]		restorations, 98% in premolars.		it's not mentioned if that was taken into account during analysis.		
Mjor and Jokstad 1993 [47]	P	Materials, composite, amalgam and metal-reinforced glass ionomer. Small class II restorations.	No	Number of restorations and material per patient varied, but restorations were used as independent units.	DSC	Caries active adolescents (13 y/o) were selected, low incidence of caries in general.
Jokstad and Mjor 1991 [40]	P	Materials (5 amalgams), operator, patient age and gender, tooth, cavity type, number of restored teeth.	Material allocation	Patients with more than one restoration were taken into account in the statistical analysis, and restorations were used as \independent units.	GP + PDH + DSC	Patients were classified according to caries activity, estimated by the incidence of primary and secondary caries during the first 8 y of the trial. Results are not given separately.
van Dijken 1991 [44]	P	Materials, 3 amalgam. Each patient needed at least three class II restorations of about equal sizes.	No	Each patient was treated as a statistical unit.	GP	Patients selected presented less than 3 caries risk factor, being considered a low caries-risk group.

P-prospective;R-retrospective; Clinical Set: GP-general private dental practice; PDH-public dental health clinic; DSC-dental school clinic; MDC-military dental clinic; PDHSC-public dental health school clinic

Observation periods ranged from 5 up to 12 years and patient mean age was 32 (7-85) y/o (Table 2). In 8 studies the number of the patients originally included or the number of patients present at the last recall was not provided[34,36,37,39,42,45,47,49]. From the studies in which this information was provided the patient mean recall rate was 87% (51-100%). The lowest recall rate was seen in a 10 year follow-up of amalgam restorations[40], whereas a 100% recall was reported for a 6 year evaluation of large class II composite restorations[33]. A total of 3,241 restorations were followed. Considering restorations, 10 studies reported a recall rate higher than 90%[32,33,35,37,38,41,44,45,48,49]. In 4 it ranged from 71-84%[23,42,43,46], whereas the lowest recall rate were seen in two studies, 39[40] and 55%[47]. The rough data are presented for each study in Table 2. Caries-risk was expressed and/or included in the analysis in 11 studies; however, only 2 studies presented separate results per risk group[24,25]. The others[23,32,35,37,41-43,48] presented pooled results and were treated as undetermined risk (Table 2). Three studies were classified as low risk[33,39,44], and 2 as high risk[36,49] (Table 2). Regarding the restorative material 16 studies have evaluated only composites, 2 only amalgams, while 3 included both materials. The use of a liner or base material was present in 10 studies[23,25,34,37,39,41,43,46-48] (Table 2). In one

study[43] the result was not given according to base/liner, and it was not included in the analysis.

Table 2 – Description of selected studies regarding material, observation period in years, number of restorations, patient related factors and given classification of caries risk status.

Reference	Material	Observation Period	Number of Patients (Originally Included)	Patients Mean Age (Range)	Restoration evaluated (originally included)	Caries-Risk Status (CR)	Classification for CR	Liner/ Base
32	C	6	50 (52)	53 (29-52)	118 (122)	31% H	Un	No
33	C	6	30 (30)	33 (24- 59)	68 (68)	Sp	L	No
41	C/Fb	7	46 (48)	57 (21- 85)	114 (118)	39% H	Un	57
24	C/A	12	273 (n.a.)	48 (23-77)	1949 (n.a.)	17.9% H	L&H	No
34	C/Fb	5	33	33,5 (8-52)	36	All in	Un	15
45	C	6	33	34	44 (47)	All in	Un	No
35	C	5	46 (50)	43 (17- 64)	97 (106)	26% H	Un	No
36	C/A	7	472	10 (8-12)	869*	Ca	H	No
37	C/Cb	9	(57)	35 (17- 68)	135 (150)	All in	Un	66
25	C/S	9	248 (n.a.)	(18- 80)	458 (n.a.)	51.7% H	L&H	82
42	C	6	63	54 (23- 78)	73 (87)	26% H	Un	No
23	S	6-7	119 (151)	44 (14- 80)	220 (268)	47% H	Un	Yes
38	C	11	27 (28)	35 (19- 64)	53 (54)*	All in	Un	No
43	C/S	5	35 (45)	26 (11- 63)	51 (63)	37.8% H	Un	Not all
48	S	11	37 (40)	48 (27- 70)	33 (34)*	45% H	Un	Yes
39	S	5	(73)	30 (20-40)	45*	Sp	L	Yes
49	C	7.2	37	(13-17)	51 (51)	Ca	H	No
46	S	5	153 (213)	33	176 (247)	All in	Un	Yes
47	S/A	5	(142)	13	69 (179)	All in	Un	Yes
40	A	10	108 (210)	(8- 71)	256 (468)	All in	Un	-
44	A	6	42 (44)	37 (25-65)	126 (132)	<3RF	L	-

*n.a.-not applicable (retrospective). Material: C-resin composite; Fb-flow composite base and composite; A-amalgam; S-sandwich technique and resin composite; Cb-compomer base and resin composite. Restoration evaluated (originally included): Restoration evaluated at last recall (originally included in the study), *the number presented is for the class II direct restorations when the original study included other techniques or cavity type. Caries-Risk Status (CR): %H-percentage of high CR identified; Sp-selected patients with high oral hygiene required and/or related clinical parameters; Ca-caries active children/adolescents included; All in-all patients were included without particular selection regarding CR; <3RF-patients included presented less than 3 caries-risk factors. Classification for CR (as applied): Un-undetermined; L-low caries-risk; H-high caries-risk; L&H- low and high caries-risk with separated results for each.*

The evaluation criteria was mostly (n=17) based on United States Public Health Service guidelines (UPSHS), modified or not, with the support of radiographic, photographic and impression evaluations in some reports. The remaining studies (n=4) used a simplified criteria by evaluating the restoration as clinically acceptable and in function, or as clinically poor and failed (SCE) (Table 3). Main reasons for

failure in each study are presented in Table 3, and mean values of each reason for failure in relation to total failures are presented in Table 4. Within amalgam, 35% of total failures were attributed to secondary caries, while 54% were attributed to fracture (restoration/tooth) (Table 4). Within composite, the failure for secondary caries and fracture of total-ecth restorations were 40% and 26% respectively, whereas for restorations with liner/base, 42% and 48% respectively (Table 4).

Table 3. Evaluation criteria and failures distribution among studies.

Reference	Evaluation Criteria	M	Total Failure (%of failure)	Secondary Caries	Fracture Restoration	Fracture Tooth	Endodontic treatment/ pain	Others
32	USPHSm	C	14 (11.8)	6*	3*	3	1	1
33	USPHSm + rx + ph + im	C	0	-	-	-	-	-
41	USPHSm	C/Fb	17 (14.9)	5	9	3		
24	SCE	C	114 (15.3)	61	7	11	26	9
		A	446 (24.4)	82	11	125	30	45
34	USPHSm	C/Fb	2 (5.9)	1*****	1*****			1
45	USPHS	C	0	-	-	-	-	2
35	USPHSm	C	12 (12.4)	8	2	2		
36	SCE + rx	C	100 (22.6)	87	13			
		A	43 (10.1)	30	13			
37	USPHSm + rx	C	8 (11.6)	4	3		1	
		Cb	6 (9.1)	4			2	
25	SCE	C	43 (11.4)	26	4	2	5	6
		S	34 (41.5)	11	7	11	2	3
42	USPHSm + rx	C	14 (18.7)	5	5	4		
23	USPHSm + rx	S	42 (19.1)	10	11	9	2	10
38	USPHSm + rx + im	C	9 (17.0)	2	4			3
43	USPHSm + rx + ph + im	C/S	18 **12 (35.5 or ******23.5)	7	1	1		3+ ******2 marginal discoloration + ******4 marginal defects
48	USPHSm	S	9 (27.3)	3	2	2		2
39	USPHSm + rx + SCE	S	5 (11.1)		1	1	3	
49	SCE	C	16 (31.4)	10				6
46	USPHS + im	S	27 (15.3)	11	5		1	10
47	USPHS + SCE	S	9 (25)	5	4			
		A	4 (12.1)	1	3			
40	USPHS + ph + im	A	68 (26.6)	30	24	8		6
44	USPHS + ph + im	A	13 (10.3)	2	8	3		

**1 Restoration has failed for both reasons. **Failure if marginal defects and marginal discoloration are not considered true failures.*
Evaluation criteria: USPHS-United States Public Health Service guidelines for measuring the clinical research performance of restorative materials; USPHSm-Modified USPHS; rx-radiographic evaluation; ph-photographic evaluation; im-impression evaluation; SCE-simplified clinical evaluation. M-Material: C-resin composite; Fb-flow composite base and

composite; A-amalgam; S-sandwich technique and resin composite; Cb-compomer base and resin composite.

Table 4. Mean values of each reason for failure in relation to total failures according to material/technique

	Range%	Mean(SD)%		95% CI (mean) lower	Upper
Amalgam					
Secondary Caries	15.4-69.8	34.5	(22.6)	6.4	62.7
Fracture Restoration	2.5-75.0	40.9	(28.3)	5.7	76.1
Fracture Tooth	0.0-28.0	12.6	(12.9)	-3.4	28.6
Endo	0.0-6.7	1.3	(3.0)	-2.4	5.1
Others	0.0-10.1	3.8	(5.2)	-2.7	10.2
Composite					
Secondary Caries	0.0-87.0	39.9	(26.0)	25.5	54.4
Fracture Restoration	0.0-52.9	17.5	(17.6)	7.8	27.2
Fracture Tooth	0.0-28.6	8.3	(9.9)	2.8	13.8
Endo	0.0-60.0	7.6	(16.0)	-1.3	16.5
Others	0.0-100	17.8	(27.9)	2.3	33.2
Sandwich-technique					
Secondary Caries	23.8-66.7	42.1	(16.1)	25.2	59.0
Fracture Restoration	0.0-44.4	35.4	(21.6)	7.0	37.0
Fracture Tooth	0.0-32.4	12.7	(14.4)	-2.4	27.8
Endo	0.0-33.3	7.9	(12.7)	-5.4	21.2
Others	0.0-37.0	15.3	(14.9)	-0.3	30.9

SD-standard deviation; CI-confidence interval of the mean

Survival and annual failure rate (AFR) are presented in Table 5. The survival of amalgam restorations ranged from 63-90%. The lowest and highest survival were found in studies with high caries risk individuals, in a 12[24] and 7[36] -year evaluation respectively. The AFR for high risk individuals of composite restorations ranged from 2.66-3.85%[24,25,36,49], and from 0-2.33%[24,25,33,39] for low risk individuals. Among sandwich restorations, AFR ranged from 2.33-6.45%, one study presented data for low and high risk individuals[25], one was classified as low[39], while all the others were classified as undetermined risk[23,46-48].

Table 5. Survival and annual failure rate percentages according to caries-risk.

Reference	M	Survival%	AFR%	CR
32	C	88.1	2.08	Un
33	C	100.0	0	L
41	C/Fb	85.1	2.28	Un
24	C	66.8	3.30	H
	C	91.5	0.74	L
	A	62.8	3.80	H
	A	79.0	1.95	L
34	C/Fb	94.1	1.21	Un
45	C	95.5	0.77	Un
35	C	87.6	2.61	Un
36	C	77.4	3.60	H
	A	89.9	1.50	H
37	C	88.4	1.36	Un
	Cb	90.9	1.05	Un
25	C	78.5	2.66	H
	C	93.9	0.70	L
	S	64.5	4.75	H
	S	54.9	6.45	L
42	C	81.3	3.38	Un
23	S	80.9	3.47	Un
38	C	83.0	1.68	Un
43	C/S	64.7	8.34	Un
48	S	72.7	2.85	Un
39	S	88.9	2.33	L
49	C	68.6	3.85	H
46	S	84.7	3.28	Un
47	S	75.0	5.59	Un
	A	87.9	2.55	Un
40	A	73.4	3.04	Un
44	A	89.7	1.80	L

M-Material: C-resin composite; Fb-flow composite base and composite; A-amalgam; S-sandwich technique and resin composite; Cb-compomer base and resin composite. CR-Caries Risk: Un-undetermined; L-low caries risk; H-high caries risk.

The mean AFR among studies was 2.64% for amalgam, 1.83% for composite and 4.10% for composite with sandwich-technique (Table 6). From the analysis according to caries risk, statistically significant differences were seen between low and high risk for annual failure rates within composite studies (p=0.002), whereas

differences within amalgam studies were not significantly different (p=0.326; Table 7). The differences in AFR regarding total-etch technique or the use of a base/liner underneath composite restorations (sandwich-technique) were statistically significant (p=0.001; Table 7).

Table 6. Annual failure rate among studies.

Material/technique	N	Range	Mean AFR%		95% CI (mean) Lower	Upper
Amalgam	7	1.50-3.85	2.64	(0.95)	1.76	3.52
Total-etch	15	0.00-3.60	1.83	(1.12)	1.21	2.45
Sandwich	7	2.33-6.45	4.10	(1.52)	2.69	5.51

N-number of included datasets; Mean AFR-mean annual failure rate (standard deviation)

Table 7. Annual failure rate according to caries risk and presence of base/liner underneath composite restorations.

Material	Risk	N	Mean AFR%	P*	95% CI of the Difference Lower Upper
Amalgam	Low	2	1.88 (0.11)	0.326	-4.36 2.01
	High	3	3.05 (1.34)		
Composite	Low	3	0.48 (0.42)	0.002	-3.73 -1.68
	High	3	3.19 (0.48)		
Technique					
Total-etch	-	15	1.83 (1.12)	0.001	-3.47 -1.08
Sandwich	-	7	4.10 (1.52)		

***Independent T-test (α=0.05).*

4. Discussion

The present review study was the first to focus on patient caries risk and presence of a base/liner underneath composite restorations as factors potentially affecting the longevity of restorations. The findings presented here are of utmost importance because usually the factors related to failure of restorations are not explored in the literature. Causes of failure are usually reported only descriptively in the trials. Moreover, this review is an update of the reasons for failure and longevity of posterior class II restorations, since the last reviews where amalgam and composite restoration were surveyed[7] and non-randomized trials were assessed[1].

The decision to select only class II restorations for longevity analysis was based in previous reports that showed different survival rates according to cavity type[9,10,13,15]. In these studies, a lower failure risk was observed for occlusal cavities,

demonstrating that failure were more prone to occur when proximal involvement (class II) was present. A major effort was made to select studies where the caries risk of the patient could be qualified. However, even though it was possible to find a number of reports where this risk was taken into account during analysis, it was not feasible to include all those studies into a quantitative analysis, since the failures were not given according to the estimated risk. The major drawback of the current review is that only two studies from the same author presented results according to risk[24,25], and a few others were classified into high[36,49] or low risk[33,39,44] according to patients inclusion criteria. Then, although a quantitative analysis was performed, results should be interpreted with caution because it represents the analysis from a reduced number of studies. Analyzing the studies where the caries risk was taken into account (but not included in the quantitative analysis), the authors reported that more failures due to secondary caries were seen in patients with high caries risk status[32,35,37,42,43]. Lindberg et al.[37] reported that 6.6% of the restorations failed because of recurrent caries, of which 4.4% were found in caries active individuals. Similarly, van Dijken et al.[42] reported that except for one case, all failures for secondary caries were observed in high caries risk patients, and Andersson-Wenckert et al.[23] found that approximately 70% of all failures occurred in high caries-risk individuals. Therefore, the inclusion of those studies would probably lead to the same result. The studies where the caries risk was estimated[23-25,32,35,37,42,43] were based on criteria from previous reports[50,51]. This simplified risk assessment appears to be successful since high caries risk patients were related to a lower survival of restorations.

Secondary caries and fracture (restoration/tooth) are the main reasons that have been attributed to failure of restorations in other reviews[7,26,28], which is in accordance with the present findings. Within amalgam, most frequent reasons were, from the most to the less frequent, fracture of the restoration, secondary caries and fracture of the tooth. Comparing the results from composites, fracture of the restoration was much more frequently seen in the presence of a base/liner (35%) than in total-etch restorations (18%). Also, failures for tooth fracture were similar for amalgam and composites with a base/liner (12%). The use of an intermediate layer of glass ionomer cement used in the past - the sandwich or laminate technique, was performed to achieve adhesion to dentin, protect the pulp and for stress-relieving of polymerization shrinkage[52]. All dentin portion of the cavity was covered with a glass

ionomer base while the enamel portion was etched and restored with composite. In such case, the reduced thickness of the composite may affect the fracture or compression strength, as suggested in previous studies[25,53]. The low cohesive strength of the glass ionomer cement itself was described as the cause of failure when used as a base under composites[54]. Also, the strengthening effect of glass ionomer cement bases on cuspal stiffness has been reported to be smaller than of composite resin bases[55]. In this sense a higher fracture rate of sandwich restorations could be expected, but this would probably depend on the thickness of the base/liner applied to the cavity. After the introduction of reliable dentin adhesion, polyacid-modified resin composite (compomer) and flow composites have been used as cavity base/liners to protect the pulp and/or for stress-relieving of polymerization shrinkage. Nonetheless, reports from in vitro and in vivo studies did not show any improvement justifying this technique[34,37,41,52,56]. In the present review two studies have included lining with flow composites[34,41], and one with a compomer base[37]. They were treated as total-etch restorations since no differences with the total-etch controls were seen in each study[34,37,41]. Regarding the use of base/liner effect on restoration survival, the old sandwich technique presented AFR of 4%, whereas for total-etch it was lower than 2%. The newer base/lining technique, where flow composites are used, may not add any beneficial or prejudicial effect on restoration longevity, since no differences in AFR were seen at least in 5 and 7 years of follow-up[34,41]. Longer periods of observation are needed to see if a low-elastic modulus layer could affect survival.

5. Conclusion

Based on the analysis from the included studies it can be concluded that:

- The lower annual failure rates were found for composite, followed by amalgam and composite with sandwich-technique.
- The patient caries risk was a factor that affected the survival of direct class II restorations. Composite restorations were more affected by the patient caries risk status than amalgam restorations.
- The use of a glass ionomer base/liner for covering all dentin walls (sandwich technique) was related to an increased risk for failure in composite class II restorations.

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5 Artigo 2

Title: The influence of patient risk factors on the longevity of posterior composite restorations: retrospective results from a10 to 15 years follow-up. [J]

Short title: Patient risk factors affect restoration longevity

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As tabelas e figuras estão inseridas no texto para facilitar a leitura do artigo.

The influence of patient risk factors on the longevity of posterior composite restorations: retrospective results from a 10 to 15 years follow-up.

ABSTRACT

Objectives: To evaluate the longevity of resin composite restorations in posterior teeth, focusing on the influence of potential patient risks factors.

Methods: The patient records of a dental practice were used to select patients who received composite restorations in posterior teeth from January 1994 to December 2002. In total 306 posterior composite restorations (44 patients) were investigated. The history of each restoration was extracted from the dental records and a clinical evaluation (FDI criteria) was performed with all that were still in situ. The patient risk status was assessed regarding caries and ‘’occlusal stress’’. Survival analysis was performed using the Kaplan–Meier method followed by Log-Rank test for equality of survival distribution ($\alpha = 0.05$). The evaluation of associated factors to failure was made by multivariate analysis of Cox’s regression with shared frailty.

Results: In total, 13% of the restorations have failed for secondary caries and 10% due to restoration/tooth fracture, representing 42 and 33% of the total failures (92) respectively. Seventeen% failed in the group classified as no risk, and 50% in the group with one risk factor, either caries or occusal stress. The patient variables, gender and age did not affect longevity ($p=0.347$ and 0.938 respectively) but risk did ($p<0.001$). Tooth type ($p<0.001$), arch ($p=0.013$) and pulpal vitality ($p=0.003$) significantly affected restoration survival.

Conclusions: Among patient variables, the estimated caries and occlusal stress risks showed a significant role on the longevity of restorations. Tooth type, arch and pulpal vitality were the significant tooth variables affecting survival.

Clinical Significance: The patient risk status should become part of the factors to be taken into consideration for evaluation of restoration longevity. Simplified criteria should be considered assess to caries and occlusal stress risks.

Keywords: Risk assessment; Caries; Composite resins; Restoration; Longitudinal study.

1. Introduction

Randomized controlled trials provide a high level of evidence for hypothesis testing[1], including the longevity of dental restorations on posterior teeth. However, long-term investigations are scarce, and they may not reflect the survival of restorations in general dental practices[2,3]. In controlled studies, a key methodological rule relays on the reduction of variability of all factors that are not under investigation, such as operator/patient-related factors[3]. Therefore, the basis of knowledge regarding restoration longevity takes into account the analysis of studies of different designs[2-7].

The main objective when placing a restoration is to recover functionally, biologically and esthetically, the lost tooth structure using a dental material. Factors related to patients[4,8-10] and operators[11,12] are probably key components in determining restoration longevity[4]. Also, a significant effect on survival has been related to the materials used[13-15], the restorative technique[10,15], the tooth characteristics and cavity variables[4,15-18].

The aim of this retrospective longitudinal study was to evaluate the longevity of resin composite restorations in posterior teeth, especially focusing on the influence of potential patient risks factors.

2. Materials and methods

2.1. Patients' selection

The study protocol was approved by the local Ethics Committee (N.139.840). Then, patient records of a private dental practice in Brazil (PARR) were used to collect data and select patients for this study. All dental records of patients who attended the dental practice from January 1994 to December 2002 and received at least one posterior restoration were searched for eligibility according to the following criteria:

a. Only composite resin restorations.
b. The restorations under investigation should be in occlusion and with at least one adjacent tooth as verified by the clinical and radiographic registers.
c. Patients should have been present for check-up or follow-up treatment in the last 10 to 18 years, with at least 1 annual recall.

The case reports of 56 adult patients were selected, who were invited by phone calls and letters to visit the practice for evaluation. Prior to the clinical evaluation, the

volunteers signed an informed consent term. From the 56 patients that fulfilled the inclusion criteria to be evaluated, 12 did not accept the invitation. As a result, 44 patients (61.4% female and 38.6% male) with mean age of 47.2 (24.6–71.2) agreed to participate in the study. In total 306 posterior composite restorations were investigated (range 2–14 restorations/patient, average 7/patient), as shown in Table 1, distributed according to patients' gender, tooth and number of restored surfaces.

Table 1 - Distribution of restorations according to patients' gender, tooth and number of surfaces.

		Premolar			Molar			
		Upper	**Lower**	*Sum*	**Upper**	**Lower**	*sum*	***Total***
Sex	**Number of surfaces**							
	1	0	3	*3*	9	11	*20*	*23*
Male	2	11	8	*19*	16	11	*27*	*46*
	≥3	10	4	*14*	3	16	*19*	*33*
sum		*21*	*15*	***36***	*28*	*38*	***66***	***102***
	1	5	4	*9*	5	12	*17*	*26*
Female	2	24	16	*40*	29	15	*44*	*84*
	≥3	24	10	*34*	27	33	*60*	*94*
sum		*53*	*30*	***83***	*61*	*60*	***121***	***204***
Grand Total								***306***

2.2. Restorative procedures

The restorations were placed under rubber dam isolation by one operator (PARR). Cavities were prepared using diamond burs and low-speed steel burs were used to remove carious tissue. No bevels were made, and preparations were restricted to carious tissue or failed restorations removal. In deep cavities, a thin layer of calcium hydroxide (Dycal; Dentsply, Petrópolis, RJ, Brazil) and conventional glass-ionomer cement (Ketac-Fil; 3M ESPE, St. Paul, MN, USA) was used to cover the deeper parts of the pulpal wall. Bonding procedure was performed according to the manufacturers' instructions. The cavities were etched using 35% phosphoric acid and one of the following adhesive systems were used, Scotchbond Multi-Purpose – a conventional 3 step system, or Single Bond (3M ESPE) – a two-step system with one bottle primer/ adhesive. The composites were placed with an incremental technique and each increment was light activated for 40 s using a quartz–tungsten–halogen curing unit (Visilux; 3M ESPE). The composites used and their characteristics are described in Table 2. Finishing and polishing of occlusal and free surfaces was achieved using fine-grit diamonds and soft silicone points/ discs with aluminum oxide paste. The proximal surfaces were finished with abrasive finishing strips.

Table 2 - Description and distribution of the universal microhybrid composites used.

Distribution (%)	Composite	Brand	Fillers[a]	w%[b]	MPS[a]	Filler Morphology[a]
17.0	**Z100**	3M ESPE	Silane treated zirconia, silica.	80	0.6	Round
20.3	**Tetric Ceram**	Ivoclar Vivadent	Ba glass, Ba-Al-fluorosilicate glass, mixed oxide, dispersed silica, ytterbium trifluoride.	76	0.7	Irregular
19.6	**Charisma**	Heraeus Kulzer	Al-F glass, Ba glass pyrogenic SiO2.	76	0.7	Irregular
4.2	**Others***	-	-	-	-	
38.9	**Combined****	-	Z100/Tetric Ceram/ Charisma	-	-	

[a] *Sabbagh et al.*[19]; [b] *Sabbagh et al.*[20]
**Others- in 13 (4.2%) cases others resin composite were used and they will not be presented separately.*
***Combined- is used to describe when two or three of the listed composites were used in the restoration.*
w%- percentage of fillers by weight
MPS- mean particle size (μm).

2.3. Evaluation and statistical procedures

Data collection was carried out through extracting the history of each restoration from the dental records and also a clinical evaluation of all that were still in function in the last dental appointment. Date of placement, materials used, restored surfaces, date and reasons for failure were recorded. All re-interventions were registered as failure, being either due to replacement or repair. Most patients in the practice had a partial or complete annual periapical radiographic exam, which was assessed by the examiners. Additionally, the whole patient file (all procedures and radiographs) was assessed, including anterior teeth and dates (before 1994 and after 2002) not included for the present evaluation. From the complete patient history, a classification into different risk status was performed regarding caries and ‘’occlusal stress risk’’ (bruxism related). Patients presenting carious lesions (radiograph) and treatment for caries (restoration) that did not show new lesions in subsequent years were recorded as “low risk”. Patients, that at each radiographic examination showed new carious lesions and two or more treatments for caries (even in other teeth) in consecutive years, were recorded as “high risk”. The period for this analysis included 3 years before and after the period of interest (1991-2005). Also from the patient files, it was noted that a number of patients were being or had been treated for bruxism/parafunctional habits. Then, patient ‘’occlusal stress’’ risk was estimated through self-report and clinical evaluation[22,23] (Table 3). The clinical evaluation was

performed in November 2012, in accordance to FDI criteria[21]. These criteria evaluate esthetic, functional and biological properties of restorations, which have been described in detail previously[21]. The examiners (FHS and MSC) were calibrated and blinded to type of material. During the clinical examination, the surfaces were dried with air stream and examined using an explorer and dental mirror. The evaluation was performed independently. In case of disagreement, a third combined evaluation was taken with both examiners so they reached a consensus. Additional radiographs were only made when necessary to complement the clinical evaluation, avoiding unnecessary radiation exposure for the patients.

Table 3. Patient risk estimation concerning bruxism/ parafunctional habits was determined by self-report[a] and clinical examination[b].

Self-report
1. Has anyone heard you grinding your teeth at night?
2. Is your jaw ever fatigued or sore on awakening in the morning?
3. Are your teeth or gums ever sore on awakening in the morning?
4. Do you ever experience temporal headaches on awakening in the morning?
5. Are you ever aware of grinding your teeth during the day?
6. Are you ever aware of clenching your teeth during the day?
Clinical examination
Presence of:
- Facets parallel to the normal planes of contour
- Noticeable flattening of cusps or incisal edges
- Total loss of contour and dentinal exposure when identifiable

[a] *Pintado et al.*[22]
[b] *Adapted from Koyano et al.*[23]

Statistical analysis was carried out using the Stata 11.0 software package. Descriptive statistics based on the FDI criteria was independently performed for each of the 18 clinical characteristics evaluated and causes of failure. Differences between the materials were analyzed using Fisher's Exact test ($\alpha = 0.05$). Survival analysis was performed using the Kaplan–Meier method to obtain the survival curves for the variables of interest followed by Log-Rank test for equality of survival distribution between groups ($\alpha = 0.05$). The evaluation of associated factors to failure during the study period was made by multivariate analysis of Cox's regression with shared frailty, which considers that observations within the same patient (the 44 individual patients) are correlated. This model for survival analysis is analogous to the multilevel regression models with random effects, therefore considers the intragroup correlation. The Hazard Ratios with respective 95% confidence intervals were determined. Only variables presenting $p<0.200$ were selected for multivariate analysis.

3. Results

In the present study, 306 posterior composite restorations were evaluated. Date of placement and date of failure were recorded from the dental records. Distribution of the reasons for failure is shown in Table 4 for the entire follow-up period. In total, 39 (13%) of the restorations have failed for secondary caries and 30 (10%) due to restoration or tooth fracture, representing 42 and 33% of the total failures (92) respectively. When the reason for failure was not described in the patient file, it was recorded as unknown, which occurred in 17 (18%) of the cases.

Table 4 - Distribution of the 92* failed restorations during the monitoring period.

Cause of failure	Time of failure in years (percentage of failed restorations)									
	0-4	**(%)**	**5-9**	**(%)**	**10-14**	**(%)**	**15-18**	**(%)**	**Total**	**(%)**
Secondary Caries	19	(21)	17	(18)	3	(3)	0	-	39	(42)
Fracture of restoration/ tooth	17	(18)	10	(11)	2	(2)	1	(1)	30	(33)
Crown placement	0	-	2	(2)	0	-	0	-	2	(2)
Endodontic treatment	2	(2)	0	-	0	-	0	-	2	(2)
Tooth extraction	0	-	1	(1)	0	-	1	(1)	2	(2)
Unknown	8	(9)	7	(7)	2	(2)	0	-	17	(18)

**90 failures were retrieved from the dental records and 2 failures were detected at the clinical examination.*

The clinical evaluation was performed with 216 restorations that were still in situ (Table 5). Exact test revealed that all materials scored similarly on all criteria (Table 5), except for marginal staining (p=0.029) and marginal adaptation (p=0.035; Table 5; Table 6). Regarding the clinical parameter of marginal staining, Charisma restorations performed better, with 85% presenting no staining, whereas Z100 presented 60% without staining and 14% of the restorations with moderate staining (Table 6). For marginal adaptation 76% and 56% of the Charisma and Tetric Ceram restorations presented no marginal opening or gap respectively, whereas 9% of the Tetric Ceram presented gaps <250 μm (Table 6).

Table 5 - Clinical evaluation of the 216* in situ restorations and failure distribution among composites from all the 306 restorations.

	Evaluation criteria/ scores**	Z100 N=35 1/2/3/4/5	Tetric Ceram N=43 1/2/3/4/5	Charisma N=46 1/2/3/4/5	Combined♣ N=83 1/2/3/4/5	Others N=7 1/2/3/4/5	p-value♠
1	Surface luster	30/4/1/0/0	31/12/0/0/0	39/5/2/0/0	63/18/2/0/0	6/1/0/0/0	.393
	Staining a. surface	29/3/3/0/0	37/6/0/0/0	45/1/0/0/0	74/8/1/0/0	7/0/0/0/0	.118
	b.margin	21/9/5/0/0	31/12/0/0/0	39/5/2/0/0	51/25/7/0/0	4/3/0/0/0	.029
	Color stability /translucency	10/15/10/0/0	16/16/11/0/0	23/18/5/0/0	19/45/19/0/0	2/4/1/0/0	.083
	Anatomical form	16/18/1/0/0	21/18/4/0/0	30/15/1/0/0	50/25/8/0/0	3/4/0/0/0	.332
2	Fracture /retention	32/3/0/0/0	38/4/1/0/0	44/1/1/0/0	81/2/0/0/0	6/0/1/0/0	.070
	Marginal adaptation	22/13/0/0/0	24/15/4/0/0	35/9/2/0/0	50/32/1/0/0	2/5/0/0/0	.035
	Occlusal contour /wear a. qualitatively	16/16/3/0/0	22/18/3/0/0	29/16/1/0/0	40/37/6/0/0	2/5/0/0/0	.605
	b. quantitatively	16/16/3/0/0	22/18/3/0/0	29/16/1/0/0	40/37/6/0/0	2/5/0/0/0	.605
	Approximal anatomical form a. contact point	27/1/1/0/0	37/0/0/0/0	38/0/0/0/0	68/1/0/0/0	5/0/0/0/0	.753
	b. contour	27/1/1/0/0	37/0/0/0/0	38/0/0/0/0	68/1/0/0/0	5/0/0/0/0	.753
	Patient's view	35/0/0/0/0	43/0/0/0/0	46/0/0/0/0	83/0/0/0/0	7/0/0/0/0	-
3	Post-operative sensitivity/ vitality	35/0/0/0/0	43/0/0/0/0	46/0/0/0/0	83/0/0/0/0	7/0/0/0/0	-
	Recurrence of caries/ erosion/ abfraction	35/0/0/0/0	43/0/0/0/0	46/0/0/0/0	83/0/0/0/0	7/0/0/0/0	-
	Tooth integrity	35/0/0/0/0	42/1/0/0/0	46/0/0/0/0	81/0/0/2/0	7/0/0/0/0	.683
	Periodontal response	35/0/0/0/0	43/0/0/0/0	46/0/0/0/0	83/0/0/0/0	7/0/0/0/0	-
	Adjacent mucosa	35/0/0/0/0	43/0/0/0/0	46/0/0/0/0	83/0/0/0/0	7/0/0/0/0	-
	Oral/ general health	35/0/0/0/0	43/0/0/0/0	46/0/0/0/0	83/0/0/0/0	7/0/0/0/0	-
		Z100 N=52	**Tetric Ceram N=62**	**Charisma N=60**	**Combined N=119**	**Others N=13**	
	Failed restorations (%within material)	17 (32.7)	19 (30.6)	14 (23.3)	36 (30.3)	6 (42.2)	.794

**216 that were considered present after evaluating the patient records. Two were found to have failed, 1 due to tooth fracture and 1 tooth extraction for future implant placement.*
***For each evaluation criterion a score from 1 to 5 is given: 1-3 when the restoration is clinically acceptable, while scores 4 and 5 designate failure, with intervention or replacement need.*
1-Esthetical properties, 2-Functional properties and 3-Biological properties.
♣Combined-is used to describe the restorations that were confectioned using a combination of 2 or more composites (Z100/ Tetric Ceram/ Charisma and/or others).
♠Fisher's exact test.

Table 6 - Frequencies distribution of marginal staining and adaptation scores among composites.

	Z100	Tetric Ceram	Charisma	Combined	Others
Marginal Staining (scores) Description	%	%	%	%	%
(1) no staining	60.0	72.0	84.8	61.4	57.1
(2) minor staining	25.7	27.9	10.8	30.1	42.8
(3) moderate staining	14.2	0	4.3	8.4	0
Marginal Adaptation (scores) Description					
(1) no gaps or discolored lines	61.7	55.8	76.1	60.2	28.5
(2) gaps <150 µm, small lines or steps	38.2	34.8	19.5	38.5	71.4
(3) gaps <250 µm, several marginal fractures or steps	0	9.3	4.3	1.2	0

Distribution of restorations and the failures per patient risk group are shown in Table 7. Patients presenting one risk factor, either caries or ‘’occlusal stress’’, were classified as one (risk) factor, while patients presenting both were classified as two (risk) factors. Taking into account the number of restorations placed in each group, 58% failed in the group with two risk factors, whereas 13% failed in the group classified as no risk.

Table 7 – Restorations and failure distribution according to risk status.

		Restorations					Within
Risk	**Patients (n)**	**%**	**(n)**	**%**	**Failed (n)**	**From total %**	**group%**
no risk	24	54.5	124	40.5	16	17.0	12.9
one factor	15	34.1	130	42.5	46	50.0	35.4
two factors	5	11.4	52	17.0	30	33.0	57.7

The restorations included were followed for different periods, therefore the cumulative survival retrieved from life tables were used to calculate annual failure rate percentages (AFR%) for each 2 years of the monitoring period. AFR ranged from 2.6-3.4%, the highest AFR% was seen up to 4 years (Table 8). The lowest AFR was seen up to 14 years of evaluation, where 183 (60%) of restorations were included (Table 8).

Kaplan–Meier survival curves are shown in Fig. 1 for premolars and molars in both jaws. Regarding tooth vitality, 6% of the restorations were placed in endodontically treated teeth. Fig. 2 shows Kaplan-Meier survival curves for vital and non-vital endodontically treated teeth, and Fig. 3 shows Kaplan-Meyer curves according to the estimated risk of the patients.

Table 8 - Survival and annual failure rate (AFR) according to the follow-up time in years.

years	Survival%	AFR%
2	94	3.0
4	87	3.4
6	82	3.3
8	78	3.1
10	72	3.2
12	69	3.0
14	69	2.6

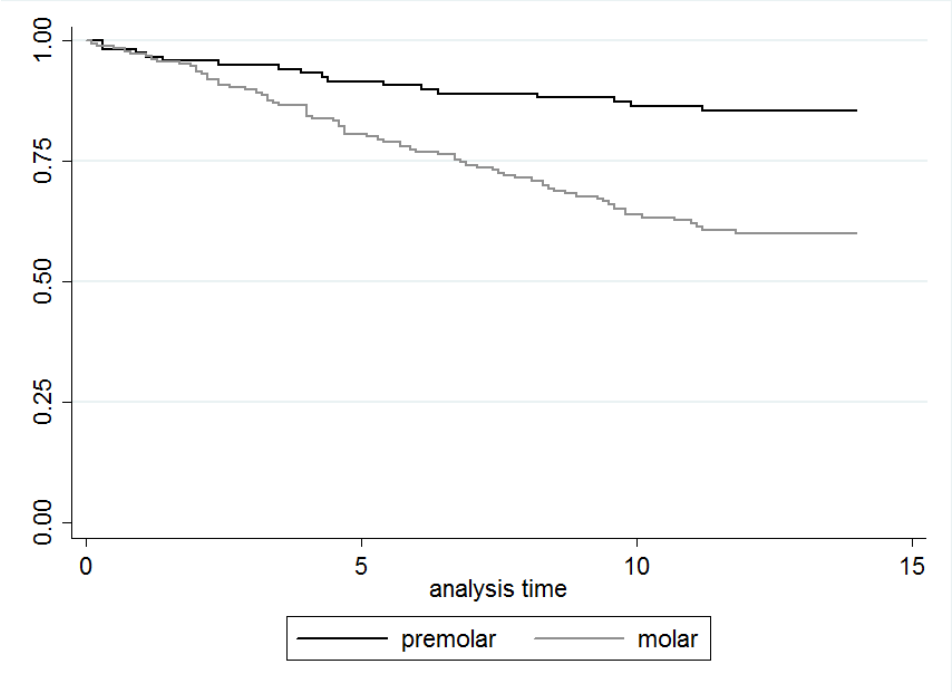

Fig. 2 - Kaplan-Meyer survival curves for premolar and molar teeth.

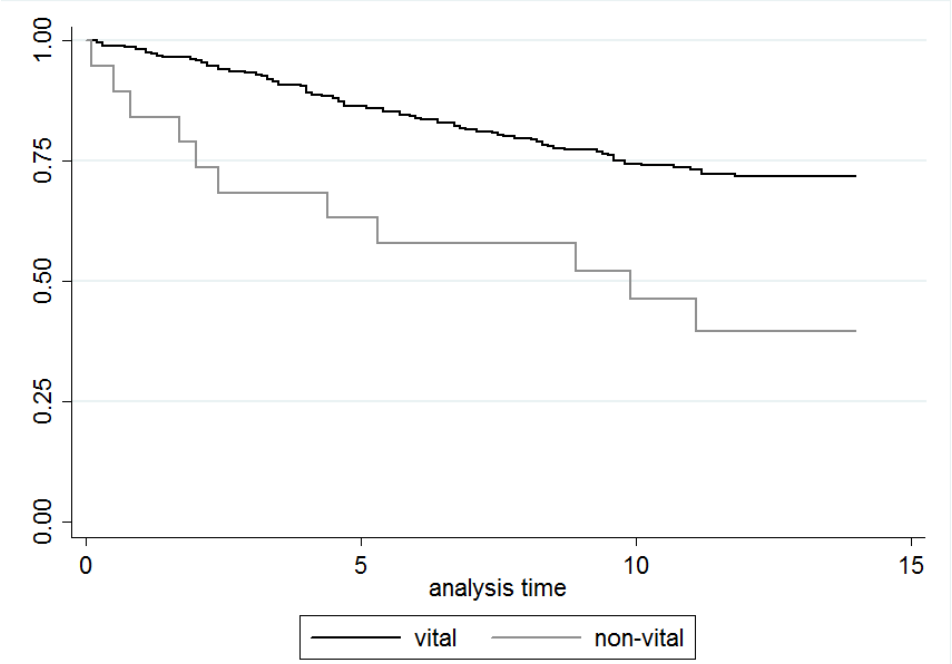

Fig. 3 - Kaplan-Meyer survival for vital and non-vital endodontically treated teeth.

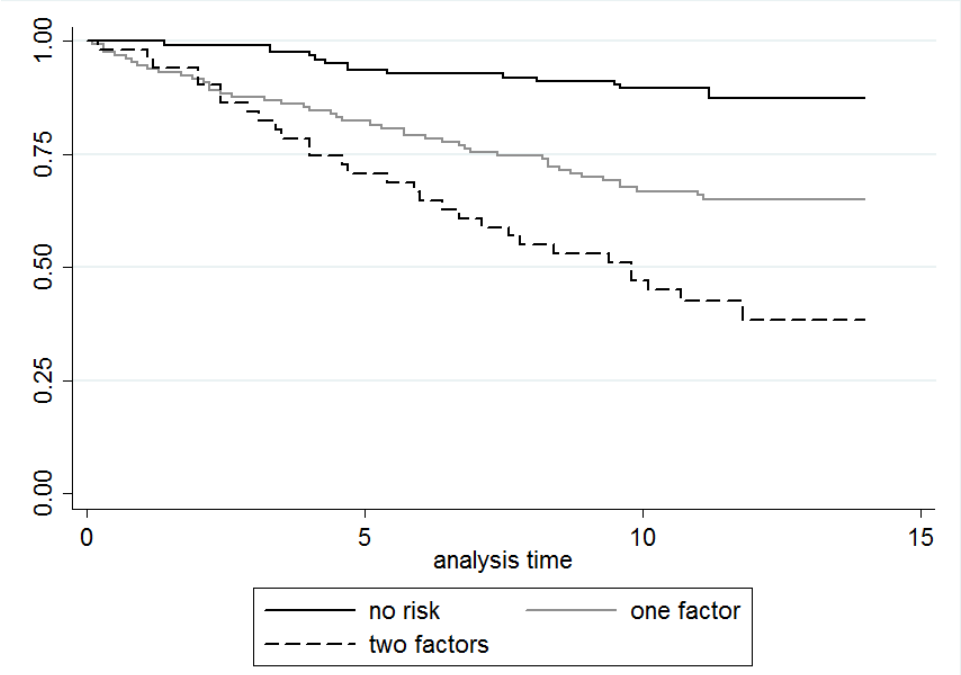

Fig. 4 - Kaplan-Meyer survival curves according to the estimated patient risk.

The results for the Cox regression analysis are shown in Table 9. The patient variables under study, gender and age at placement (categorized in over/under 30 y/o) did not affect longevity (p=0.347 and 0.938 respectively) but risk did (p<0.001). The Hazard Ratio of the presence of one and two risk factors was 36- 83% respectively, compared to no risk. Tooth type and arch significantly affected the

survival of the restorations. The Hazard Ratio of molar teeth was 33% higher than premolar, and was 17% higher for the lower jaw than upper jaw. Endodontically treated teeth also showed to affect survival (p=0.003), presenting a Hazard Ratio of 30% when compared to vital teeth. The number of restored surfaces did not influence the longevity of the restorations (p=0.515). The composite materials under evaluation, individually or combined did not significantly affect the longevity (p = 0.211).

Table 9 - Crude (c) and adjusted (a) Hazard Ratios (HR) for independent variables and failure of posterior restorations. Cox Regression Analysis (n=306 restorations).

Independent Variables	HR[c] (95% CI)	P	HR[a] (95% CI)	P
Gender		0.347		-
- Male	1.00		-	
- Female	1.35 (0.72 – 2.53)			
Age		0.938		-
- ≤30	1.00		-	
- ≥31	0.97 (0.54 – 1.75)			
Risk factor		0.170		<0.001
- No Risk	1.00		1.00	
- One factor	3.57 (0.66 – 19.28)		3.61 (1.99 – 6.52)	
- Two factors	6.85 (0.61 – 76.93)		8.32 (4.38 – 15.80)	
Arch		0.004		0.013
- Maxilar	1.00		1.00	
- Mandibular	1.88 (1.22 – 2.91)		1.73 (1.12 – 2.65)	
Tooth type		<0.001		<0.001
- Premolar	1.00		1.00	
- Molar	3.44 (2.01 – 5.90)		3.34 (1.95 – 5.74)	
Tooth vitality		0.023		0.003
- Vital	1.00		1.00	
- Non-vital (endodontic treated)	2.22 (1.11 – 4.42)		2.97 (1.40 – 5.09)	
Number of surfaces		0.515		-
- 1	1.00		-	
- 2	0.74 (0.39 – 1.39)			
- 3	0.77 (0.37 – 1.61)			
- 4	0.52 (0.18 – 1.49)			
- 5	1.26 (0.52 – 3.02)			
Material		0.211		-
- Z-100	1.00		-	
- Tetric Ceram	1.10 (0.52 – 2.36)			
- Charisma	0.64 (0.28 – 1.47)			
- Combined	1.22 (0.64 – 2.35)			
- Others	2.02 (0.75 – 5.47)			

4. Discussion

The longevity assessment in the present study represents the result of a retrospective evaluation on posterior composite restorations, all placed by a single experienced operator. In practice-based retrospective studies patients are not particularly selected, and materials are not randomly placed in matched size cavities, or evenly distributed according to tooth or arch. The clinical set was a private

practice; therefore it's assumed that the socioeconomic status of the individuals was medium to high. For inclusion all patients should have been present for regular dental appointments, what could have led to the inclusion of highly motivated individuals but also of high risk individuals. Taking all these information into account, the collection and reporting of these data with appropriate statistical methods provide valuable information, since few studies with observations periods up to 15 years are available. Moreover, very few studies focus on the influence of patients' risk factors on the longevity of restorations, as reported in the present study.

The materials used in all restorations were universal microhybrid composites with no substantial differences, resulting in similar failures for each composite either used alone or with a multilayer technique with the combination of those composites. Regarding the clinical evaluation of the in situ restorations, all composites showed acceptable clinical scores for all criteria. Therefore, even when statistically significant differences were seen, it was not considered as clinically relevant[2].

Among all variables under evaluation, tooth vitality, tooth type and arch showed to affect longevity. These findings are in accordance with other reports. Regarding tooth type, higher failure risk has been consistently found for molars [16-18,24-26] than premolars, in the lower jaw[17]. As for tooth vitality not many studies have investigated the influence of endodontic treatment and the longevity of posterior composites. van Nieuwenhuysen et al.[26] also found an increased risk for failure in endodontically treated teeth. Analyzing Nagasiri et al.[27] results, where just endodontically treated teeth were included for evaluation of restorations, an annual failure rate of 12.4% was revealed, much higher than in most clinical reports where vital teeth are included[9,17,28-30]. The removal of pulp roof in endodontically treated teeth produces a significant reduction in resistance to fracture[31]. In addition, the remaining tooth structure in endodontically treated teeth may be more reduced in a one or two surfaces restoration than in a number of vital restorations involving two/three or more surfaces. Within non-vital teeth, the remaining tooth structure has been reported as a factor affecting survival[27,32]. In the present study 16% of the restorations were one-surface, while 43 and 42% were two and three or more surfaces respectively. The number of restored surfaces did not influence the longevity, which is in accordance with some previous reports[24,33,34]. Kubo et al.[35] has reported significantly poorer survival for class I restorations than class II and other cavity types. However, a 22-year follow-up of posterior composites[18] showed a better

survival for class I compared to class II restorations. In addition, it was observed that restoration survival decreased significantly with the increase of restored surfaces[30,35], and the longevity increased significantly for restorations of smaller size[29,30]. The comparison of cavity size, class type and number of restored surfaces may not reflect correctly how compromised the tooth structure is. In this sense, an objective measurement of the cavity size in relation to the remaining tooth structure would lead to a more accurate conclusion.

Analyzing the annual failure rate, the last monitoring period where 100% of the restorations were included was up to 10 years, with 3.2% of AFR. Further analysis was performed up to 15 years, with 2.6% of AFR for 60% of the restorations. When looking just for survival, without taking into account the observation periods, the drop in survival was from 94 to 69% from the second year up to 12-14 years. However, the annual failure rates were kept almost constant through the first 12 years indicating that earlier and later failures were balanced. This might represent the normal routine in a general clinical practice, where all factors that contribute to a restoration failure, such as patient, operator and tooth related are present. Looking into the range of AFR reported in other studies, a variation from 0[36,37] up to 8.6%[38] have been found for posterior restorations. Therefore, studies with common characteristics are more useful for comparison such as retrospective or prospective studies that were carried out in general clinical sets and restorations were performed with total etch technique (regardless of the composite type). van Dijken and Pallesen[28], Opdam et al.[9,10] and van Dijken and Sunnegardh-Gronberg[14] studies reported AFR% of 3.38 after 6 years, 1.68 after 12 years, 1.4 and 2.6 after 9 years of follow-up, respectively. The AFR found in the present evaluation is within the aforementioned range, and it is probably related to the fact that 46% of the individuals presented one or two risk factors, in which 83% of the total failures have occurred.

The caries risk was estimated based on previous reports[9,14,24,39] that were able to qualitatively assess the risk using simplified criteria. Considering that bruxism and parafunctional habits seem to be risk factors that could also affect survival[4], an estimation of this risk was also performed. Here, it was simply called as ‘’occlusal stress risk’’ since it was not intended as a true measurement for bruxism, temporomandibular disorders or tooth surface loss. The clinical parameters to assess these disorders are still not clear[40-42], therefore, self-reported parafunctional habits along with the diagnostic of the treating clinician and clinical examination of the tooth

wear pattern were used to estimate the risk[23]. Although the estimation of both risks was taken without validated clinical parameters, the results appear to reflect that simplified measures could be used at least in retrospective evaluations. Symptoms and wear patterns have evolved for a long time, which facilitates the clinical exam and awareness of the treating clinician and the patient. Nonetheless, there is an urgent need to validate objective methods to determine the individual risk regarding ‘’occlusal stress’’ and caries. The patient risk status should become part of the factors to be taking into consideration for restoration longevity evaluation.

5. Conclusion

Among patient variables, the estimated caries and occlusal stress risks showed a significant role on the longevity of restorations. Tooth type, arch and pulpal vitality were the significant tooth variables affecting survival.

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6 Conclusões

Fazendo uma avaliação conjunta dos estudos realizados na presente tese é possível concluir que a determinação de fatores de risco do paciente é necessária para analisar a longevidade de restaurações diretas. A presença de um ou dois fatores de risco aumenta a chance de falha restauradora em 3 a 8 vezes respectivamente. Estas avaliações são fundamentais para poder testar e direcionar terapias a pacientes de diferentes riscos.

A avaliação do risco de cárie do paciente parece ser mais importante em restaurações de resina composta do que de amálgama. No entanto, as taxas anuais de falha se mostraram mais elevadas em pacientes com alto risco de cárie para restaurações realizadas com os dois materiais.

A utilização de materiais restauradores intermediários com técnica de sanduíche convencional apresentou um maior risco de falha do que com técnica adesiva. Nenhuma diferença foi observada para longevidade de restaurações adesivas em relação às técnicas mais modernas que utilizam materiais restauradores intermediários. Estudos adicionais ainda são necessários para avaliar o material intermediário empregado, a espessura da camada intermediária e a longevidade destas restaurações em comparação com a técnica adesiva.

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Apêndices

APÊNDICE A – Carta de informação ao paciente

UNIVERSIDADE FEDERAL DE PELOTAS
FACULDADE DE ODONTOLOGIA
PROGRAMA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA

CARTA DE INFORMAÇÃO AO PACIENTE

O objetivo do presente estudo será avaliar o desempenho clínico de restaurações de resina composta em relação à técnica utilizada, confeccionadas em dentes posteriores.

Dessa forma, o(a) Senhor(a) deve apresentar ao menos uma restauração em resina composta em dentes posteriores, realizada a mais de 10 anos. Além disso, todas as restaurações, reparos ou substituições deverão ter sido realizados por um único dentista (PARR).

Uma vez enquadrado de acordo com esses critérios, o(a) Senhor(a), foi incluído(a) no grupo de paciente com possibilidade de participar do estudo, sendo que este será conduzido por um grupo de pesquisadores: Paulo Antônio da Rosa Rodolpho, Françoise Hélène van de Sande Leite, Maximiliano Sérgio Cenci, Flávio Fernando Demarco e Niek Opdam.

Este estudo constará apenas de uma avaliação clínica das restaurações, os quais serão executados na mesma clínica odontológica onde foram realizadas, através de um espelho bucal e uma sonda exploradora. Além disso, fotografias serão realizadas somente das restaurações avaliadas, dessa forma, preservando a identidade dos pacientes.

Uma vez que fui esclarecido(a) de como o estudo será realizado, dou pleno consentimento aos pesquisadores para executarem esses procedimentos de avaliação clínica das restaurações. Além disso, concordo com a publicação dos resultados e eventuais fotografias relacionadas às restaurações.

Por estarem entendidos e conformados, assinam o presente termo.

Local e data.

_____

Assinatura do paciente

_____

Documento do paciente

_____

Responsável pelo estudo

APÊNDICE B – Termo de consentimento livre e esclarecido

UNIVERSIDADE FEDERAL DE PELOTAS

FACULDADE DE ODONTOLOGIA

PROGRAMA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Por este instrumento que atende às exigências legais, o(a) senhor(a)_____, portador(a) da cédula de identidade nº_____, após leitura minuciosa da CARTA DE INFORMAÇÃO AO PACIENTE, devidamente explicada pelos profissionais, ciente dos procedimentos aos quais será submetido, não restando dúvidas a respeito do lido e do explicado, firma este termo de CONSENTIMENTO LIVRE E ESCLARECIDO em concordância em participar da pesquisa proposta no que lhe é cabível, conforme a carta de informação ao paciente.

Fica claro que o paciente, a qualquer momento, pode retirar seu consentimento e deixar de participar do estudo alvo da pesquisa e ciente que todo trabalho realizado se torna informação confidencial guardada por força do sigilo profissional (Art. 9º do Código de Ética Odontológica).

Por estarem entendidos e conformados, assinam o presente termo.

Local e data.

_____

Assinatura do paciente

_____

Responsável pelo estudo

APÊNDICE C – Termo de ciência dos pesquisadores

TERMO DE CIÊNCIA DOS PESQUISADORES

Os pesquisadores envolvidos no Projeto '**Restaurações Diretas em Dentes Permanentes Posteriores: Longevidade, Causas de Falhas e Fatores Relacionados**'' estão cientes do conteúdo do referido projeto e se comprometem com sua execução, bem como da divulgação dos resultados provenientes do estudo.

_____

Prof. Dr. Maximiliano Sérgio Cenci
Orientador

_____

Prof. Dr. Flávio Fernando Demarco
Co-orientador

_____

Françoise Hélène van de Sande Leite
Aluna de Doutorado do Programa de Pós-Graduação em Odontologia, área Dentística

Anexos

ANEXO A – termo de aprovação do Comitê de Ética em Pesquisa

FACULDADE DE MEDICINA DA UNIVERSIDADE FEDERAL DE PELOTAS

Plataforma Brasil

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: RESTAURAÇÕES DIRETAS EM DENTES PERMANENTES POSTERIORES: LONGEVIDADE, CAUSAS DE FALHAS E FATORES RELACIONADOS

Pesquisador: Maximiliano Sérgio Cenci

Área Temática:

Versão: 2

CAAE: 09418712.5.0000.5317

Instituição Proponente: Faculdade de Medicina da Universidade Federal de Pelotas

DADOS DO PARECER

Número do Parecer: 139.840

Data da Relatoria: 06/11/2012

Apresentação do Projeto:

Estudo clínico longitudinal retrospectivo, onde pacientes que procuraram atendimento em clínica odontológica privada receberam restaurações em dentes posteriores, as quais foram realizadas com resinas compostas com técnica totalmente adesiva ou técnica de

sanduíche com material restaurador intermediário. Os pacientes deverão ter recebido ao menos uma restauração em dentes posteriores. Os grupos experimentais serão independentes, representados pelas referidas técnicas. Para avaliação das restaurações, serão aplicados os critérios de avaliação clínica preconizados por Hickel et al., 2010 (HICKEL et al., 2010). Os pacientes serão selecionados a partir de um arquivo de prontuários de uma clínica privada de acordo com critérios pré-determinados de inclusão, e convidados a participar do estudo, através de contato por telefone ou carta.

Objetivo da Pesquisa:

O objetivo geral é avaliar a longevidade clínica de restaurações diretas em dentes permanentes posteriores, as principais causas de falha atribuídas,e determinar alguns fatores potencialmente relacionados às falhas. No estudo clínico, os objetivos específicos serão avaliar comparativamente as taxas de sobrevivência e causas de falha com o uso de técnica totalmente adesiva ou utilização de material restaurador intermediário.

Avaliação dos Riscos e Benefícios:

Riscos:

Endereço: Rua Prof Araujo, 473 sala 201
Bairro: Fragata **CEP:** 96.030-000
UF: RS **Município:** PELOTAS
Telefone: (53)3284-4900 **Fax:** (53)3221-3554 **E-mail:** patricia@fau.com.br; cep.famed@gmail.com

FACULDADE DE MEDICINA DA UNIVERSIDADE FEDERAL DE PELOTAS

Não existem riscos previstos.

Benefícios:

Avaliação odontológica gratuita.

Comentários e Considerações sobre a Pesquisa:

Os pacientes serão selecionados a partir de um arquivo de prontuários de uma clínica privada de acordo com os seguintes critérios de inclusão: os pacientes devem ter sido submetidos a procedimentos restauradores entre os meses de janeiro de 1987 e dezembro de 2002; possuir ao menos uma restauração direta de resina composta em dentes posteriores; apresentar dentes antagonistas e adjacentes aos dentes avaliados; e ter continuamente realizado visitas ao mesmo dentista nos últimos 10 a 25 anos. Este levantamento será realizado nas fichas clínicas individuais, verificando registros clínicos e radiográficos. Dois dos pesquisadores envolvidos no estudo e sem contato prévio com os pacientes ficarão responsáveis pelo exame dos prontuários e seleção dos pacientes de acordo com os critérios de inclusão descritos. Os pacientes que forem selecionados serão convidados a participar do estudo, através de contato por telefone ou carta.

Considerações sobre os Termos de apresentação obrigatória:

OK

Recomendações:

OK

Conclusões ou Pendências e Lista de Inadequações:

OK

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

PELOTAS, 06 de Novembro de 2012

Assinador por:
Patricia Abrantes Duval
(Coordenador)

Endereço: Rua Prof Araujo, 473 sala 201
Bairro: Fragata **CEP:** 96.030-000
UF: RS **Município:** PELOTAS
Telefone: (53)3284-4900 **Fax:** (53)3221-3554 **E-mail:** patricia@fau.com.br; cep.famed@gmail.com

ANEXO B – Termo de autorização para coleta de dados na clínica privada

Odontologia Cosmética & Restauradora

Paullo Rodolfho, C.D.

CRO 7192

DECLARAÇÃO

Através desta declaramos conceder autorização à realização de pesquisa intitulada "Restaurações diretas em dentes permanentes posteriores: Longevidade, causa de falhas e fatores relacionados." sob responsabilidade do pesquisador Prof. Dr. Maximiliano Sérgio Cenci FO-UFPel a ser realizada nos prontuários e exames clínicos nos pacientes selecionados, no consultório odontológico do CD. Paullo Rodolpho.

Caxias do Sul, 1 de novembro de 2012.

Gleise Vanz

Paullo Rodolpho

Paulo Rodolfo, CD
CRO 7192
Av. Júlio de Castilhos, 1348 Sala 20
95010-000 - Caxias do sul - RS
Fone/Fax (54) 3223-8001

Av. Júlio de Castilhos, 1348, sala 203
CEP 95010-000 Caxias do Sul RS
Fone/Fax 3223.8001

ANEXO C- Quadros A, B e C - Critérios de avaliação extraídos de Hickel et al (2010).

Quadro A

A. Esthetic properties	1. Surface lustre	2. Staining a. surface b. margin	3. Color match and translucency	4. Esthetic anatomical form
1. Clinically excellent / very good	1.1 Lustre comparable to enamel.	2a.1 No surface staining. 2b.1 No marginal staining.	3.1 Good color match, no difference in shade and/or translucency.	4.1 Form is ideal.
2. Clinically good (after polishing probably very good)	1.2.1 Slightly dull, not noticeable from speaking distance. 1.2.2 Some isolated pores.	2a.2 Minor surface staining, easily removable by polishing. 2b.2 Minor marginal staining, easily removable by polishing.	3.2 Minor deviations in shade and/or translucency	4.2 Form is only slightly deviated from the normal.
3. Clinically sufficient / satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/o damage to the tooth)	1.3.1 Dull surface but acceptable if covered with film of saliva. 1.3.2 Multiple pores on more than one third of the surface.	2a.3 Moderate surface staining that may also present on other teeth, not esthetically unacceptable. 2b.3 Moderate marginal staining, not esthetically unacceptable.	3.3 Distinct deviation but acceptable. Does not affect esthetics: 3.3.1 more opaque 3.3.2 more translucent 3.3.3 darker 3.3.4 brighter	4.3 Form deviates from the normal but is esthetically acceptable.
4. Clinically unsatisfactory (but reparable)	1.4.1 Rough surface, cannot be masked by saliva film, simple polishing is not sufficient. Further intervention necessary. 1.4.2 Voids.	2a.4 Unacceptable surface staining on the restoration and major intervention necessary for improvement. 2b.4 Pronounced marginal staining; major intervention necessary for improvement.	3.4 Localized clinically deviation that can be corrected by repair: 3.4.1 too opaque. 3.4.2 too translucent. 3.4.3 too dark. 3.4.4 too bright.	4.4. Form is affected and unacceptable esthetically. Intervention/correction is necessary.
5. Clinically poor (replacement necessary)	1.5 Very rough, unacceptable plaque retentive surface.	2a.5 Severe surface staining and/or subsurface staining, generalized or localized, not accessible for intervention. 2b.5 Deep marginal staining, not accessible for intervention.	3.5 Unacceptable. Replacement necessary.	4.5 Form is unsatisfactory and/or lost. Repair not feasible / reasonable, Replacement needed.

Quadro B

B. Functional properties	5. Fracture of material and retention	6. Marginal adaptation	7. Occlusal contour and wear a) qualitatively b) quantitatively	8. Approximal anatomical form a. contact point b. contour	9. Radiographic examination (when applicable)	10. Patient's view
1. Clinically excellent / very good	5.1 No fractures / cracks.	6.1 Harmonious outline, no gaps, no white or discolored lines	7a.1 Physiological wear equivalent of enamel. 7b.1Wear corresponding to 80-120% of enamel.	8a.1 Normal contact point (floss or 25 µm metal blade can pass) 8b.1 Normal contour.	9.1 No pathology, harmonious transition between restoration and tooth.	10.1 Entirely satisfied with esthetics and function.
2. Clinically good	5.2 Small hairline crack.	6.2.1 Marginal gap (<150 µm), white lines. 6.2.2 Small marginal fracture removable by polishing. 6.2.3 Slight ditching, slight step/flashes, minor irregularities.	7a.2 Normal wear only slightly different from that to enamel. 7b.2 50-80% or 120-150 % wear compared to that of corresponding enamel.	8a.2. Contact slightly too strong but no disadvantage (floss or 25 µm metal blade can only pass with pressure). 8b.2 Slightly deficient contour.	9.2.1 Acceptable material excess present. 9.2.2 Positive/negative step present at margin <150 µm.	10.2 Satisfied. 10.2.1 Esthetics. 10.2.2 Function, e.g., minor roughness
3. Clinically sufficient / satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/o damage to the tooth)	5.3 Two or more or larger hairline cracks and/or material chip fracture not affecting the marginal integrity or approximal contact.	6.3.1 Gap < 250 µm not removable. 6.3.2. Several small marginal fractures. 6.3.3 Major irregularities, ditching or flash, steps.	7a.3 Different wear rate than enamel but within the biological variation. 7b.3 < 50 % or 150-300 % of corresponding enamel	8a.3. Somewhat weak contact, no indication of damage to tooth, gingiva or periodontal structures; 50 µm metal blade can pass 8b.3 Visible deficient contour	9. 3. 1 Marginal gap < 250 µm. 9. 3. 2 Negative steps visible < 250 µm. No adverse effects noticed. 9.3.3 Poor radiopacity of filling material.	10.3 Minor criticism but no adverse clinical effects. 10.3.1 Esthetic shortcomings. 10.3.2 Some lack of chewing comfort. 10.3.3 Unpleasant treatment procedure.
4. Clinically unsatisfactory / (but reparable)	5.4.1 Material chip fractures which damage marginal quality or approximal contacts. 5.4.2 Bulk fractures with partial loss (less than half of the restoration).	6.4.1 Gap > 250 µm or dentine/base exposed. 6.4.2. Severe ditching or marginal fractures. 6.4.3 Larger irregularities or steps (repair necessary)	7a.4 Wear considerably exceeds normal enamel wear; or occlusal contact points are lost. 7b.4 Restoration > 300 % of enamel wear or antagonist > 300 %.	8a.4 Too weak and possible damage due to food impaction; 100 µm metal blade can pass 8b.4 Inadequate contour Repair possible.	9.4.1 Marginal gap >250 µm. 9.4.2 Material excess accessible but not removable. 9.4.3 Negative steps >250µm and reparable.	10.4 Desire for improvement 10.4.1 Esthetics. 10.4.2 Function, e.g., tongue irritation Reshaping of anatomic form or refurbishing is possible.
5. Clinically poor (replacement necessary)	5.5 (Partial or complete) loss of restoration or multiple fractures.	6.5.1 Restoration (complete or partial) is loose but in situ. 6.5.2 Generalized major gaps or irregularities.	7a.5 Wear is excessive. 7b.5 Restoration or antagonist > 500 % of corresponding enamel.	8a.5 Too weak and/or clear damage due to food impaction and/or pain/gingivitis. 8b.4 Insufficient contour requires replacement	9.5.1 Secondary caries, large gaps, large overhangs 9.5.2 Apical pathology 9.5.3 Fracture/loss of restoration or tooth.	10.5 Completely dissatisfied and / or adverse effects, incl. pain.

Quadro C

C. Biological properties	11. Postoperative (hyper-)sensitivity and tooth vitality	12. Recurrence of caries (CAR), erosion, abfraction	13. Tooth integrity (enamel cracks, tooth fractures)	14. Periodontal response (always compared to a reference tooth)	15. Adjacent mucosa	16 Oral and general health
1. Clinically very good	11.1 No hypersensitivity, normal vitality.	12.1 No secondary or primary caries	13.1 Complete integrity.	14.1. No plaque, no inflammation, no pockets.	15.1 Healthy mucosa adjacent to restoration.	16.1 No oral or general symptoms.
2. Clinically good (after correction maybe very good) No treatment required.	11.2 Minor hypersensitivity for a limited period of time, normal vitality.	12.2 Small and localized 1. Demineralization 2. Erosion or 3. Abfraction.	13.2.1 Small marginal enamel fracture (<150 µm). 13.2.2 Hairline crack in enamel (<150 µm).	14.2. Little plaque, no inflammation (gingivitis), no pocket development 14.2.1 without 14.2.2 with overhangs, gaps or inadequate anatomic. form	15.2 Healthy after minor removal of mechanical irritations (plaque, calculus, sharp edges etc.)	16.2 Minor transient symptoms of short duration; local or generalized.
3.Clinically sufficient / satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth)	11.3.1 Moderate hypersensitivity 11.3.2 Delayed/mild sensitivity; no subjective complaints, no treatment needed.	12.3 Larger areas of 1. Demineralisation 2. Erosion or 3. Abrasion/abfracti on, dentine not exposed Only preventive measures necessary ().	13.3.1 Marginal enamel defect <250µm 13.3.2 Crack <250µm; 13.3.3 Enamel chipping. 13.3.4 Multiple cracks	14.3. Difference up to one grade in severity of PBI compared to baseline and compared to control tooth. 14.3.1 without 14.3.2 with overhangs, gaps or inadequate anatomic form.	15.3 Alteration of mucosa but no suspicion of causal relationship with restorative material.	16.3. Transient symptoms, local and/or general.
4. Clinically unsatisfactory (repair for prophylactic reasons)	11.4.1 Intense hypersensitivity. 11.4.2 Delayed with minor subjective symptoms. 11.4.3 No clinical detectable sensitivity. Intervention necessary but not replacement.	12. 4.1 Caries with cavitation and suspected undermining caries 12.4.2 Erosion in dentine 12.4.3 Abrasion/ abfraction in dentine. Localized and accessible can be repaired.	13.4.1 Major marginal enamel defects; gap > 250 µm or dentine or base exposed. 13.4.2 Large cracks >250 µm, probe penetrates. 13.4.3. Large enamel chipping or wall fracture	14.4. Difference of more than one grade of PBI in comparison to control tooth or increase in pocket depth > 1mm requiring intervention. 14.4.1 without 14.4.2 with overhangs, gaps or inadequate anatomic form	15.4 Suspected mild allergic, lichenoid or toxic reaction.	16.4 Persisting local or general symptoms of oral contact stomatitis or lichen planus or allergic reactions. Intervention necessary but no replacement.
5. Clinically poor (replacement necessary)	11.5 Intense, acute pulpitis or non vital tooth. Endodontic treatment is necessary and restoration has to be replaced.	12.5 Deep caries or exposed dentine that is not accessible for repair of restoration.	13.5. Cusp or tooth fracture.	14.5 Severe / acute gingivitis or periodontitis 14.5.1 without 14.5.2 with overhangs, gaps or inadequate anatomic form	15.5 Suspected severe allergic, lichenoid or toxic reaction.	16.5. Acute / severe local and/or general symptoms.