

UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL  
FACULDADE DE ODONTOLOGIA

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REMOÇÃO PARCIAL DE TECIDO CARIADO EM DENTES PERMANENTES:  
ACOMPANHAMENTO DE CINCO ANOS

Porto Alegre

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Trabalho de Conclusão de Curso apresentado ao Curso de Graduação em Odontologia da Faculdade de Odontologia da Universidade Federal do Rio Grande do Sul, como requisito parcial para obtenção do grau de Cirurgiã-Dentista.

Orientadora: Prof<sup>ª</sup>. Dr<sup>ª</sup>. Marisa Maltz

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## RESUMO

KOPPE, B.T.F. **Remoção parcial de tecido cariado em dentes permanentes: acompanhamento de cinco anos.** 2012. 27f. Trabalho de Conclusão de Curso (Odontologia) – Faculdade de Odontologia, Universidade Federal do Rio Grande do Sul, Porto Alegre.

Este é um estudo de acompanhamento de cinco anos de um ensaio clínico randomizado controlado multicêntrico, que teve como objetivo avaliar a efetividade de uma abordagem alternativa no tratamento de lesões de cárie profundas em comparação ao tratamento expectante (TE). O tratamento alternativo consistiu na remoção parcial de tecido cariado (RPTC) e restauração em sessão única. A amostra incluiu molares com lesões chegando até metade interna de dentina e sem lesão periapical ao exame radiográfico, resposta positiva ao teste frio, negativa ao teste de percussão e ausência de dor espontânea. Estes foram randomicamente atribuídos ao grupo teste (RPTC) ou controle (TE). Os pacientes do grupo teste receberam remoção incompleta de tecido cariado e restauração em amálgama ou resina composta em uma sessão. Os pacientes do grupo controle, após remoção incompleta do tecido cariado, receberam capeamento pulpar indireto com cimento de hidróxido de cálcio e restauração temporária com cimento de óxido de zinco e eugenol modificado na primeira sessão. Após mediana de tempo de 90 dias, a cavidade era reaberta para remoção da dentina cariada remanescente e restauração em resina composta ou amálgama. O desfecho avaliado no estudo foi a vitalidade pulpar, determinada pela sensibilidade positiva ao teste térmico, negativa ao teste de percussão e ausência de alteração periapical ao exame radiográfico. Os dados de sobrevivência foram analisados através do modelo de regressão de Weibull com termo de fragilidade. As demais associações foram realizadas pelo teste do qui-quadrado. Foram executados 299 tratamentos, sendo 152 RPTC e 147 TE, em pacientes com idade entre 6 e 53 anos. Durante 5 anos de acompanhamento, 229 dentes foram avaliados. Foram observadas taxas de sucesso de 79% para o grupo teste e 56% para o grupo controle ( $p < 0,001$ ). Foram encontradas associações significativas entre sucesso e tratamento, número de faces restauradas e região. O desfecho foi favorável quando o tratamento foi RPTC comparado com TE; quando 1 face foi restaurada, em comparação com 2 ou mais; e quando a região Centro-Oeste foi comparada à região Sul. Foi encontrada associação significativa entre o número de faltas dos pacientes nas consultas de acompanhamento e sucesso, tendo maior número de insucessos entre aqueles que faltaram 3-4 consultas em comparação com os que faltaram de 0-2 ( $p = 0,015$ ). Os pacientes da região Sul caracterizaram-se como mais faltosos que os da região Centro-Oeste ( $p = 0,00$ ). Os resultados sugerem que a RPTC pode ser alternativa viável no tratamento de lesões profundas de cárie. Não parece haver a necessidade de uma segunda consulta para reabertura e nova remoção de tecido cariado como demanda o tratamento expectante para que a vitalidade pulpar seja mantida.

Palavras-chave: Cárie dentária. Ensaio clínico. Dentes permanentes. Tratamento expectante. Análise de sobrevivência. Remoção parcial de tecido cariado.

## ABSTRACT

KOPPE, B.T.F. **Partial caries removal in permanent teeth: 5-year follow-up.** 2012. 27p. Final paper (Graduation in Dentistry) – Faculty of Dentistry, Federal University of Rio Grande do Sul, Porto Alegre.

This study is a 5-year follow-up to a multicenter randomized clinical trial which aimed to evaluate the effectiveness of an alternative treatment to stepwise excavation (SW) in the management of deep caries lesions. This treatment consisted of partial caries removal (PCR) and tooth restoration in a single session. The sample included molars with caries lesions reaching the inner half of dentin and no periapical lesion in radiographic exam, positive response to cold test, negative to percussion test and absence of spontaneous pain. These teeth were randomly assigned to test (PCR) or control (SW) groups. Patients from the test group received partial caries removal and tooth restoration in amalgam or resin composite in one session. Patients from the control group received incomplete caries removal, indirect pulp capping with calcium hydroxide cement and temporary filling with a modified zinc oxide-eugenol cement. After a median time of 90 days, the tooth was reopened for removal of the remnant decayed tissue and then restored with amalgam or resin composite. The outcome stipulated was pulp vitality, which was determined by positive response to cold test, negative response to percussion test and absence of periapical lesion in radiographic exam. Survival data was analyzed using the Weibull regression model with frailty term. Other analyses were done using the chi-square test. In total, 299 treatments were conducted (152 PCR; 147 SW), in patients with ages varying from 6 to 53 years. Through 5 years of follow-up, 229 teeth were evaluated. Survival rates were 79% for the PCR group and 56% for the SW group ( $p < 0.001$ ). Statistically significant associations were found between outcome and treatment, number of restored surfaces and region. The outcome was favorable when treatment was PCR, compared to SW; when one surface was restored, compared to 2 or more; and when the Midwest region was compared to the South. Association was found between outcome failure and number of absences to follow-up appointments. Patients who failed to show to 3-4 follow-up appointments had significantly more treatment failures than those who missed 0-2 appointments ( $p = 0.015$ ). Patients from the South region were also significantly more absent than those in the Midwest ( $p = 0.00$ ). The present results suggest that PCR can be considered as a viable option in treating deep caries lesions. There is no apparent need to reopen the cavity for further caries removal to preserve pulp vitality.

**Keywords:** Dental caries. Clinical trial. Permanent teeth. Stepwise excavation. Survival analysis. Partial caries removal.

## LISTA DE ABREVIATURAS

TE – Tratamento expectante

RPTC – Remoção parcial de tecido cariado

CPO-D – Número de dentes cariados, perdidos e obturados

SW – Stepwise excavation

PCR – Partial caries removal



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## 1 INTRODUÇÃO

A evolução da saúde bucal brasileira nas últimas décadas tem sido evidenciada principalmente através do consistente declínio dos valores do índice CPO-D registrados nos levantamentos epidemiológicos nacionais. De fato, o valor, que já chegou aos 6,7 dentes com experiência de cárie em crianças de 12 anos (BRASIL,1986), hoje é igual a 2,07 (BRASIL, 2011). Tal redução vem sendo atribuída à adição de flúor nas águas de abastecimento e nos dentifrícios (NARVAI et al., 1999).

Em contrapartida a tais resultados favoráveis, encontra-se a iniquidade na distribuição da doença cárie, em que uma minoria da população concentra a maior parte dos casos e com maior gravidade. Devido em grande parte às desigualdades sociais, culturais e econômicas a que é submetida a população brasileira, o componente “C” (dentes cariados) ainda é extremamente elevado na população mais jovem (NARVAI et al., 2006). O mesmo observa-se na população adulta, com os agravantes do aumento da experiência de cárie com a idade (CPO-D igual a 16,75 na faixa etária de 35 a 44 anos e 27,53 na de 65 a 74 anos) e da predominância do componente “perdido”, que chega a 91,9% nos indivíduos de 65 a 74 anos (BRASIL, 2011). Tais dados refletem as disparidades nas condições de vida da população e a desigualdade no acesso aos serviços odontológicos prestados a ela (PINTO et al., 2012; BARROS; BERTOLDI, 2002).

Em 2006, as exodontias correspondiam a 14% dos procedimentos clínicos prestados em âmbito nacional (NARVAI et al., 2006). Quatro anos depois, chegavam ainda a 10,4% dos atendimentos na região Sul (FISCHER et al., 2010). A Política Nacional de Saúde Bucal insere a saúde bucal na Atenção Básica de forma a buscar modificações neste quadro.

A caracterização da Atenção Básica como “porta de entrada” do sistema de saúde implica em sua necessidade de assumir a responsabilidade sobre o manejo dos problemas de saúde mais prevalentes na população, principalmente através de ações de prevenção de agravos (STARFIELD, 2004). Associados à prevenção, também fazem parte do conjunto de ações da Atenção Básica o diagnóstico, o tratamento, a reabilitação e a manutenção da saúde em nível primário (BRASIL, 2008b).

Por conseguinte, visando atender às necessidades da população e seguindo as diretrizes propostas pela Política Nacional de Saúde Bucal, os tratamentos odontológicos ofertados pela Atenção Básica devem priorizar procedimentos conservadores. Estes procedimentos são definidos como aqueles que sejam executados com objetivo de manutenção do elemento dentário, de modo a inverter a lógica mutiladora predominante nos serviços públicos (BRASIL, 2004).

Assim, dentro da visão da saúde coletiva, é necessária a busca por técnicas que possibilitem a preservação de elementos dentários, sem demandar maiores recursos tecnológicos e financeiros e adaptando-se a diferentes cenários e contextos da realidade dos serviços de saúde pública no Brasil. De forma geral, objetiva-se o alcance de métodos de tratamento que tenham boa relação custo-efetividade e beneficiem um grande número de pessoas (JARDIM, 2010).

No tratamento da cárie dentária, a técnica convencionalmente indicada consiste na remoção completa do tecido cariado seguida de restauração do remanescente dentário. Na abordagem de lesões profundas, porém, a prática odontológica se depara com um dilema, visto que tal tratamento pode levar frequentemente à exposição pulpar (LESKELL et al., 1996). Na ocorrência desse evento, mesmo com a realização do tratamento proposto com capeamento pulpar direto ou pulpotomia, o prognóstico do dente passa a ser mais desfavorável, muitas vezes levando à necessidade de endodontia (BARTHEL et al., 2000; BJØRNDAL et al., 2010). O tratamento endodôntico, por sua vez, implica numa maior demanda por tecnologias leves e duras, bem como aporte financeiro, determinando a referência do paciente a maiores níveis de complexidade de atenção dentro do sistema de saúde (BRASIL, 2008a). Além disso, a fragilização de dentes endodonticamente tratados pode resultar em restaurações complexas e possíveis fraturas.

Com tais fatores em vista, foram propostos ao longo dos anos tratamentos que buscassem redução do risco de exposição do órgão pulpar. Valendo-se de métodos com custos acessíveis e que permitem a preservação do tecido dentário e da vitalidade pulpar, estes tratamentos podem colaborar para a evolução do atendimento odontológico na Atenção Básica. Entretanto, deve-se ressaltar que tais técnicas, por trabalharem com remoção incompleta do tecido cariado, foram desenvolvidas para a recuperação de dentes com inflamações pulpares reversíveis. Isto significa que estes devem ter presença de vitalidade pulpar verificada através de teste frio, ausência de história de dor espontânea prévia ao tratamento e ausência de patologias periapicais ao exame radiográfico (BJØRNDAL, 2008).

Uma das alternativas apresentadas é o tratamento expectante (TE) (MAGNUSSON; SUNDELL, 1977). Esta técnica, indicada para dentes cuja extensão da lesão de cárie envolva mais que dois terços da dentina, compreende a escavação completa do tecido cariado das paredes circundantes da cavidade, seguida da remoção do tecido mais necrótico e infectado da parede pulpar. A cavidade é, então, selada com material provisório por 6 a 8 meses. Após este período, é realizada reabertura da cavidade para remoção completa do restante de tecido cariado e, por fim, restauração definitiva (BJØRNDAL, 2008).

O objetivo deste tratamento não é a remoção completa do tecido cariado, mas sim uma modificação no meio ambiente da lesão, proporcionando uma alteração na velocidade de desenvolvimento da doença de rápida para lenta, ou mesmo paralisação de sua progressão (BJØRNDAL, 2002). Na primeira consulta, visa-se ao isolamento dos microrganismos da cavidade oral, enquanto na segunda observa-se a reação dentinária após o período de selamento. Neste momento, sabe-se que a presença de características clínicas de paralisação da lesão – tecido endurecido e seco – está associada a um menor crescimento de microbiota cariogênica e que esta já não apresenta a mesma composição de uma lesão ativa profunda (BJØRNDAL et al., 1997; BJØRNDAL; LARSEN, 2000).

Mesmo com os resultados favoráveis apresentados pelo TE, apresentando tanto diminuição do risco de exposição pulpar quanto manutenção da vitalidade pulpar em acompanhamentos longitudinais (LESKELL et al., 1996; BJØRNDAL; THYLSTRUP, 1998; BJØRNDAL et al., 2010), alguns pontos podem interferir no seu sucesso. Dentre eles, estão o risco de expor a polpa durante a reabertura (BJØRNDAL et al., 2010; BJØRNDAL; THYLSTRUP, 1998; LEKSELL et al., 1996; MAGNUSSON; SUNDELL, 1977), falha da restauração temporária e custo elevado pela necessidade de duas consultas para completar o tratamento. Além disso, alguns pacientes podem não retornar para a consulta final, momento em que já não possuem mais sintomatologia dolorosa (JARDIM, 2010).

Evidências sugerem que, associada a um bom selamento da cavidade, a permanência de parte do tecido cariado após escavação não interfere com o processo de inativação da lesão. Estes resultados contribuíram para a dúvida sobre a necessidade da reabertura da cavidade em um segundo momento para nova escavação (KIDD, 2004; BJØRNDAL, 2008). Em recente revisão de literatura, Ricketts et al. (2008) relataram que não há evidências que suportem tal necessidade de reintervenção.

Desta forma, com vistas a solucionar os problemas relativos ao TE, foi proposto um tratamento alternativo em que a escavação parcial do tecido cariado e a restauração definitiva são realizadas em uma única consulta. Poucos estudos, entretanto, relatam o tratamento de remoção parcial de tecido cariado (RPTC) como definitivo. Em sua maioria, estes avaliam os resultados em dentição decídua, o que significa menor período de monitoramento pela menor permanência do dente em boca (FALSTER et al., 2002; FRANZON et al., 2007; MARCHI 2006; MARCHI, 2008). O selamento de lesões cariosas em dentes permanentes foi estudado em lesões na metade externa de dentina (BAKHSHANDEH et al., 2012; MERTZ-FAIRHURST et al., 1998) e em lesões profundas (MALTZ et al., 2011). Em ambos os casos,

os resultados se mostram favoráveis à manutenção da vitalidade dentária, viabilizando este tratamento como alternativa ao TE

Maltz et al. (2002), em ensaio clínico de braço único, realizaram remoção parcial de tecido cariado e restauração definitiva em resina composta em 32 dentes permanentes com lesões profundas de cárie. As taxas de sobrevivência dos tratamentos foram de 97%, 90%, 82% e 63% aos 1,5, 3, 5 e 10 anos de acompanhamento, respectivamente (MALTZ et al., 2011). As avaliações radiográficas dos casos também apresentaram resultados positivos, com aumento da radiopacidade da dentina deixada sob a lesão, sugerindo ganho mineral (ALVES et al., 2010). Reduções no número de microrganismos presentes na cavidade após selamento (MALTZ et al., 2002; MALTZ et al., 2004; ORHAN et al., 2008; LULA et al., 2009) e aumento da microdureza dentinária em decíduos também foram reportadas (FRANZON et al., 2007; MARCHI et al., 2008).

A literatura atual aponta para o fato de não existirem publicações de ensaios clínicos, randomizados e controlados que avaliem a remoção parcial de tecido cariado como tratamento definitivo em dentes permanentes (RICKETTS et al., 2008; BJØRNDAL et al., 2008). Além disso, após a realização do tratamento, é necessário o acompanhamento longitudinal destes pacientes. Como a taxa de sobrevivência tende a diminuir com o tempo, resultados obtidos em curto prazo podem superestimar a real efetividade do tratamento (BARTHEL et al., 2000; MALTZ et al., 2011).

Frente ao exposto, iniciou-se em 2005 o trabalho “Tratamento alternativo de lesões de cárie profundas – um estudo multicêntrico”, cujo objetivo foi avaliar a efetividade da remoção parcial do tecido cariado como alternativa no tratamento da cárie dentária em serviços de saúde pública de Porto Alegre e Brasília. Neste ensaio clínico, foram tratados 299 dentes, randomicamente alocados nos grupos controle (TE) ou teste (RPTC), sendo posteriormente realizados acompanhamentos de dezoito meses (JARDIM, 2010), dois (MOURA, 2010) e três anos (GARCIA, 2011).

Dessa forma, faz-se necessária a continuidade do acompanhamento longitudinal deste estudo, o qual propõe respostas para possibilitar a indicação da remoção parcial de tecido cariado no tratamento da cárie dentária, em alternativa ao tratamento expectante e, em extensão, à remoção completa de tecido cariado. Este tratamento pode vir a servir como ferramenta útil na Atenção Básica em Odontologia, onde a remoção total de tecido cariado ainda corresponde a 71% da escolha técnica dos cirurgiões-dentistas do serviço público de saúde de Porto Alegre (WEBER et al., 2011), aumentando o risco de exposições pulpares e consequentes tratamentos de maior complexidade.

## 2 ARTIGO

### Background

The conventional treatment for caries lesions consists of complete removal of decayed tissue followed by restoration of the tooth remnant. When managing deep lesions, this technique generates an elevated risk of having the pulp exposed during the procedure<sup>1</sup>. In the occurrence of such an event, the indicated conservative treatment of direct pulp capping shows poor long term prognosis and often leads to endodontic treatment need<sup>2</sup>. In order to avoid pulp exposure and its consequent complications, conservative techniques of carious dentin removal have been proposed. These approaches involve partial removal of infected carious tissue. As such, they have been developed for treatment in asymptomatic teeth with reversible pulp inflammation only<sup>3</sup>.

One of these alternative treatments is the stepwise excavation (SW)<sup>4</sup>. It consists of complete excavation of decayed tissue from the surrounding cavity walls followed by removal of the more necrotic and infected dentin at the pulpal wall and temporary sealing from 6-8 months. In a second appointment, the cavity is reopened, the remaining carious tissue is removed and the tooth is restored<sup>3</sup>. The aim of the SW technique is to slow or halt the progression of the caries process by isolating the micro-organisms from the oral environment and stimulating reactions from the pulp-dentin complex, such as dentine sclerosis and tertiary dentin formation. After the sealing period, dentin is expected to become harder and dryer, with a lower level of bacterial infection, thus characterizing an arrested lesion. As a result, pulp protection is increased for the final excavation<sup>5,6,7</sup>. Many studies have demonstrated high levels of success for the SW treatment, both in reducing levels of pulp exposure and in maintaining pulp vitality<sup>1,8,9</sup>. However, SW still presents some disadvantages which consist mainly of a remaining risk of pulp exposure during the re-entering of the cavity in the final excavation<sup>1,4,8,9</sup>, failure of the temporary filling and elevated cost due to the need of two sessions for completing the treatment. Furthermore, some patients may not return for the final appointment considering their pain symptomatology has already been treated in the first intervention<sup>10</sup>.

Previous studies have suggested that, when combined with effective sealing, leaving some carious tissue in the cavity does not interfere with the process of arresting the lesion<sup>11,12,13</sup>. These results contributed to the questioning regarding the necessity of reopening the cavity for a second excavation<sup>3,14</sup>. In a recent review, Ricketts et al.<sup>15</sup> reported that there was no evidence that supported such need.

Because of this lack of support for the second intervention in the SW treatment, combined with the need to overcome its disadvantages, an alternative treatment has been proposed. In this technique, partial removal of decayed dentin and restoration are completed in a single session. However, there have been few studies which have analyzed partial caries removal (PCR) as a definitive treatment for permanent teeth. Most of these have been carried out in primary teeth, thus reducing the follow-up period<sup>16,17,18,19</sup>. Still, the ones which were conducted in permanent dentition and studied sealing of carious tissue have mostly pointed towards favorable results regarding pulp vitality<sup>11,12,13</sup>. Only one of these<sup>13</sup> included deeper lesions reaching the inner part of the dentin, whereas two<sup>11,12</sup> studied lesions restricted to the outer dentin only. In their single-arm study, Maltz et al.<sup>13</sup> reported a success rate of 63% at the 10 year follow-up. Moreover, the radiographic analysis of these teeth presented unchanged or decreased lesion depth and tertiary dentin formation<sup>20</sup>. Other results also showed decreased count of bacteria after sealing<sup>21,22,23</sup> and increased microhardness of the remnant dentin in primary teeth<sup>17,18</sup>.

There were no controlled, randomized clinical trials with long-term follow-up that evaluated PCR followed by restoration in one session as a definitive treatment for deep caries lesions in permanent teeth. Long-term follow-up is decisive when evaluating different treatment outcomes. Considering that survival rates tend to drop over time, short-term results might overestimate the treatment's effectiveness<sup>13,24</sup>. Our previous follow-ups presented success rates of 98% in 18 months and 91% in 3 years<sup>25</sup> for the proposed PCR alternative treatment.

The aim of this study was to compare the outcomes of SW and PCR treatments performed on deep caries lesions regarding conservation of pulp vitality in a 5 year follow-up period.

## **Methods**

### **Study design**

This study is a 5 year follow-up of a multicenter randomized controlled clinical trial (registration number at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) NCT00887952). From 2005 to 2007, 299 clinical treatments were performed by 22 dentists specifically trained for the study and supervised by five main researchers. These treatments were conducted in two centers located in the cities of Porto Alegre and Brasília, at either Public Health Service units or Federal Universities.

## **Sample**

Sample size was estimated based on the difference between the success rates for each treatment after a 5 year follow-up period (SW – 60,9% and PCR – 82%), at  $\alpha = 5\%$ , with a power of 90%. This resulted in the need of 76 restorations per treatment group<sup>26,27</sup>. The number of restorations was increased to 119 per group when a drop-out rate of 56% after 2 years was taken into consideration<sup>28</sup>.

Participants were selected from the usual subjects attending the Public Health Services or via an active search for individuals that could fulfill the inclusion criteria which included search in community programs, local schools and newspaper and radio advertisement. The sample consisted of patients with deep caries lesions in permanent molars. Selection criteria included: molars with deep caries lesions (reaching dentin inner half or further at radiographic exam); positive response to cold test ( $-20^{\circ}\text{C}$  refrigerated gas - Aerojet, Rio de Janeiro, RJ, Brazil); negative response to percussion; absence of spontaneous pain; absence of periapical lesion (radiographic exam). Patients were excluded if they presented cuspal loss or caries beneath the gingival margin.

All subjects were informed of the research risks and purposes and signed an informed consent; they received dental care by the researchers throughout their participation in the study. Patients did not receive financial incentive seeing as that Public Health Services in Brazil are free. The study was approved by the Federal University of Rio Grande do Sul Ethics Committee (protocol 18/05), the Porto Alegre Municipal Ethics Committee (protocol 27/06), the Conceição Hospital Group Ethics Committee (Protocolo 070/05) and the Brasilia University Hospital Ethics Committee (protocol 045/2005).

## **Study groups**

Patients were randomly assigned for test or control groups. The control group received the stepwise excavation treatment, while the test group received partial caries removal followed by restoration in one session. Both groups were then again divided according to filling material: amalgam or resin composite.

## **Randomization and blinding process**

The randomization unit was the tooth and its inclusion in either test or control groups was done as follows: treatment group was written on a numerated piece of paper and kept in a dark flask; a person other than the dentist would select a piece of paper from the flask and the



treatment carried out as indicated. Filling material was determined by alternating between amalgam and resin composite every other week. Blinding of patients was not possible due to the different number of appointments needed for each treatment. The operator was blinded throughout the procedure until randomization, in order to avoid possible influence in the process of removing decayed dentin in both groups. The treatment outcome assessment at the 5 year follow-up was also done blindly. The collected data were recorded in clinical files and then transferred to a digital online system (<http://odonto.cityzoom.net>).

### **Clinical procedures**

All treatments were performed under the same protocol, as follows: local anesthesia and rubber dam installation; access to the lesion using diamond burs, if necessary; complete removal of carious tissue from the surrounding cavity walls with hand excavators and/or low-speed metal burs, according to the hardness-tactile criteria (harness probe); careful partial caries removal from the pulpal wall (only disorganized soft tissue was removed); cavity cleansing with distilled water and drying with sterile filter paper; group randomization. Teeth assigned to control group (SW) received indirect pulp capping with calcium hydroxide cement (Dycal, Caulk/Dentsply, Rio de Janeiro, RJ, Brazil) and temporary filling with a modified zinc oxide-eugenol cement (IRM, Caulk/Dentsply, Rio de Janeiro, RJ, Brazil); the cavity was then reopened after a median time of 90 days (25<sup>th</sup> percentile = 60 days; 75<sup>th</sup> percentile = 150 days; mean, 120 ± 120 days), remaining soft carious tissue was removed and the tooth restored with glass ionomer cement (Vitro Fil, DFL, Rio de Janeiro, RJ, Brazil) plus amalgam (SDI, Bayswater WA, Australia) or resin composite (Tetric EvoCeram, Ivoclar/Vivadent, Liechtenstein). Teeth allocated to the test group (PCR) immediately received restoration with glass ionomer cement and amalgam or resin composite after caries removal.

### **Outcome follow-up**

Outcome success was evaluated by assessment of pulp vitality, which was considered as teeth with positive response to cold test, negative response to percussion, absence of spontaneous pain and absence of periapical lesion (radiographic examination). Patients with loss of pulp vitality in prior follow-ups were not evaluated. Baseline data such as age, gender and filling material, as well as data regarding number of surfaces restored during treatment were collected for posterior analysis of correlation with outcome.

### **Statistical methods**

Parametric survival models with individual level frailty were utilized for outcome with treatment as the exploratory factor. An adjustment was done for potential predictors such as age, gender, region, filling material and number of restored surfaces. Carious response is clustered within the patient and therefore statistical methods must take into consideration the correlation which may occur between teeth in the same individual. Survival analyses were performed using the goodness-of-fit test with likelihood statistic to estimate treatment success rates. The Weibull regression model was used for comparing survival curves. Censored observation (missing data) was stipulated for all patients lost to follow-up. All patients evaluated at least once contributed to survival rate. The time to the event was counted and analyzed in days. Significance level was set as 5% and the unit of analysis was the tooth. Chi square tests were performed to evaluate relationships between absenteeism and outcome and absenteeism and region, within the population in attendance to the 5 year appointment. Comparison between evaluated and non-evaluated patients was also analyzed by chi-square test. All analyses were performed with STATA software, version 12.0.

### **Results**

This study was conducted as an intention-to-treat analysis. As such, protocol deviations were included in the study sample as well as their follow-up evaluations. Cases of filling failure, secondary caries or absence in the second SW appointment were all treated and included for follow-up survival analysis. Teeth presenting filling failure or secondary caries received restoration repair. If such failure involved the pulpal wall, the treatment performed was the same as the allocation process had determined for that patient at the beginning of the study. A total of 42 patients failed to show at the second appointment of SW treatment (median time of 90 days after the first). When successfully reached, they received the remaining proper procedures as specified by the SW protocol. Patients who failed to show at some follow-up appointments were also evaluated if contact was possible for the following ones.

At the end of the first phase of the study, 299 treatments [PCR=152; SW=147 (Fig. 1)] had been conducted in 233 patients. This sample was composed mainly of low-income individuals, with a mean age of  $17.17 \pm 10.91$  years (median=14 yrs; minimum=6 yrs; maximum=53 yrs). Mean DMFT was  $7.9 \pm 5.7$ . Sixty-two percent of the teeth included in the

study were first molars, 33% second molars and 5% third molars. Treatment groups did not show differences regarding age, monthly family income, filling material, number of surfaces restored and gender. At the 5 year mark (1825 days), a total of 229 teeth (115 from PCR group and 114 from SW group) were followed-up at least once (Fig. 1). Success rates were equivalent to 79% in the PCR group and 56% in SW group ( $p < 0.001$ ). Results from the survival analysis for the Weibull regression are presented in Fig. 2.

The Weibull regression model with individual level frailty was developed for outcome using treatment (SW, PCR) as the exploratory factor, after controlling for gender, region, age, filling material, and number of restored surfaces. Significant associations were found for treatment, number of restored surfaces and region. The outcome was more favorable in Midwest region; when the treatment was PCR compared with SW; and among single-surface restorations in comparison with multiple-surface ones (Table 1).

Out of the 229 teeth evaluated, 114 were from patients who showed up for the 5 year appointment. Forty-eight teeth had already showed treatment failure before the 5 year follow-up (36 SW; 13 PCR), 70 were never evaluated and 67 teeth evaluated at least once before were not examined at this time. No difference was found between the evaluated and non-evaluated patients regarding gender, age, treatment, filling material or number of restored faces, with the exception of region (Midwest region had significantly more patients lost to follow-up than the South [ $p = 0.00$ ]). Out of the 114 evaluated teeth at year 5 (46 SW; 68 PCR), 10 presented treatment failure (3 SW; 7 PCR). Two of the three failed SW treatments were from patients who did not show for the second appointment. These patients had different follow-up attendance throughout the 5 year period. Only 18 showed up every year, while others missed one (26), two (39), three (18) or four (13) appointments. After dividing these patients into two groups (0-2 absences; 3-4 absences), the ones who had more missing appointments (3-4) had significantly more failures in treatment outcome ( $p = 0.015$ ; Table 2). Furthermore, patients were also significantly less absent in the Midwest region when compared to the South region ( $p = 0.00$ ; Table 2).

## **Discussion**

Our study aimed to compare the performances of PCR and SW treatments in the management of deep caries lesion regarding maintenance of pulp vitality in 5 years of follow-up. There was a significant difference between success rates for the proposed treatments ( $p < 0.001$ ). The alternative treatment with PCR and restoration in a single session presented a 79% success rate in 5 years, compared to 56% in the SW group. In our previous follow-ups,

PCR had success rates of 98% and 91% at 1 and 3 years, and SW had 93% and 69% rates for the same respective evaluations.

The multivariate analysis showed significant association between pulp vitality and variables studied in three cases. A lower success rate was found in teeth with two or more surfaces restored. This can be attributed to the fact that the extension of restoration is an indicator of filling failure, with single-surface restorations showing greater longevity than multi-surface ones<sup>29</sup>. Restoration failure can lead to exposure of the remaining decayed tissue to the oral environment. Consequently, progression of the lesion may occur as well as an eventual pulp necrosis.

The success rate was also higher for the Midwest region than for the South. One explanation for this difference could be the higher number of incomplete SW treatments analyzed in the South region (18) compared to the Midwest (8). Our previous study, at the 3 year follow-up, showed that there is a statistically significant ( $p < 0.001$ ) difference in outcomes for complete (88%) and incomplete (13%) SW treatments<sup>25</sup>. Another possible explanation could be patient absenteeism. A significant association was found between number of absences in follow-up appointments and outcome. Patients less prone to attend follow-up examinations had an increased rate in outcome failure. Accordingly, patients in the Midwest region attended their appointments more regularly than the ones in the South region (Table 2). These findings concur with suggestions found in previous studies that patients with less frequent visits to the dentist tend to have poorer oral health condition<sup>30</sup>.

Stepwise excavation has been considered the treatment of choice in the management of deep caries lesions for many years. Despite the positive results achieved by SW (74% - 91% at 1 year follow-up)<sup>8,9</sup> in maintaining pulp vitality, this technique's underlying problems such as pulp exposure may still occur, even if the risk is decreased<sup>1,4</sup>. In the present study, failure of the subject to attend the second appointment was also prevalent. Forty-two patients did not return to complete the treatment. Leaving the treatment incomplete greatly decreases its chance of success<sup>25</sup>. Furthermore, the fact that the need for 2 sessions may increase cost<sup>10</sup> and discomfort for patients must be taken into consideration, as well as the fact that if they do not return, temporary filling is likely to fail<sup>31</sup>.

The partial caries removal treatment was proposed to overcome these adversities. However, studies regarding PCR were mainly focused on primary teeth<sup>16,17,18,19</sup> or permanent teeth with superficial lesions<sup>11,12</sup>. Only one single-arm study evaluated PCR treatment in deep caries lesions in permanent teeth for 5 years<sup>13</sup>. This study showed success rates of 97%, 90% and 82% at 1.5-, 3-, 5-year follow-ups, respectively. The results of the present randomized

trial showed similar rates (98%, 91% and 79% at 1, 3 and 5-year follow-ups). Additionally, the comparison between PCR and SW in this study showed statistically significant difference, with PCR treatment having a 60% lower risk of failure.

### **Conclusion**

The present results corroborate to the support of the PCR technique in the management of deep caries lesions. Success rates were significantly increased by the PCR treatment when compared to SW excavation in a 5 year follow-up. The findings suggest that re-entering the cavity for a second excavation is unnecessary in the maintenance of pulp vitality.

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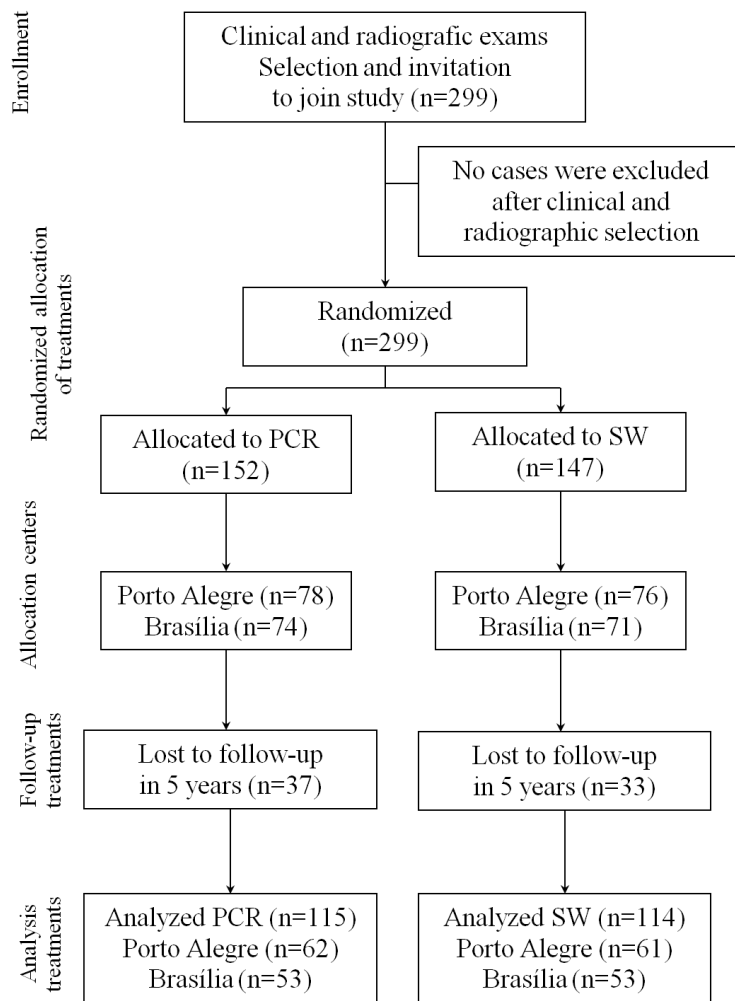
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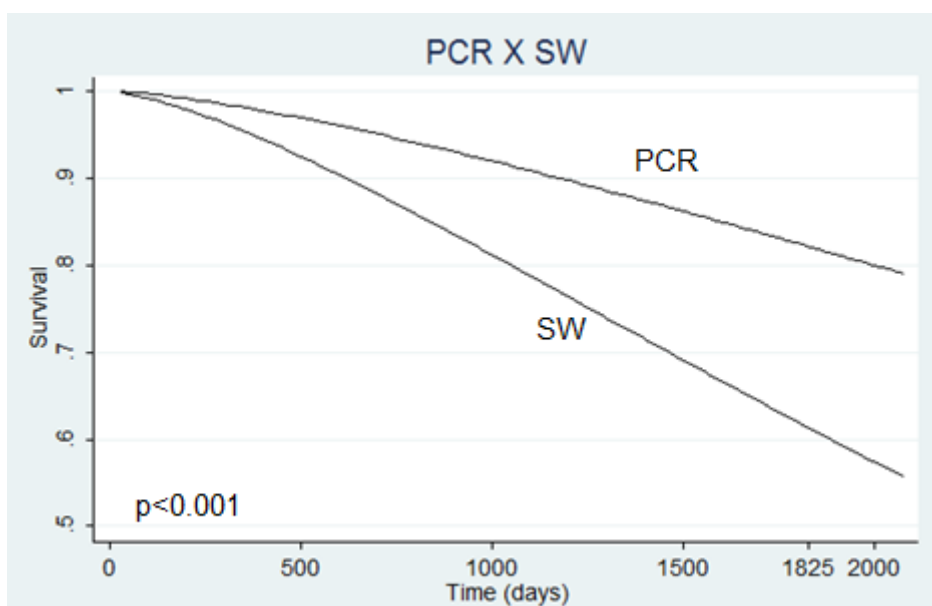
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**Figure 1.** Participant and follow-up flowchart



**Figure 2.** Survival rates for PCR x SW treatments (Weibull regression model)



**Table 1.** Association between pulp necrosis and explanatory variables (Weibull regression).

Variables	Multivariable Weibull Regression			
	N (%)	HR	95 % CI	p
<b>Gender</b>				
Male	85 (37%)	1.00		
Female	144 (63%)	1.34	0.77 – 2.35	0.30
<b>Region</b>				
Midwest	106 (46%)	1.00		
South	123 (54%)	2.06	1.13 – 3.77	0.02
<b>Age</b>				
≤ 17 years	149 (65%)	1.00		
> 17 years	80 (35%)	0.63	0.36 – 1.10	0.10
<b>Treatment</b>				
Stepwise excavation	114 (50%)	1.00		
Partial dentine removal	115 (50%)	0.40	0.23 – 0.69	0.001
<b>Filling material</b>				
Amalgam	82 (36%)	1.00		
Composite resin	147 (64%)	0.99	0.55 – 1.76	0.96
<b>Number of restored surfaces</b>				
One	200 (87%)	1.00		
Two or more	29 (13%)	2.09	1.07 – 4.07	0.03

HR = Hazard ratio; CI = confidence interval

**Table 2.** Comparison between absenteeism, outcome and region (Chi square test)

	Number of absences – N (%)		p
	0 - 2	3 - 4	
<b>Outcome</b>			
Pulp vitality	79 (95%)	25 (81%)	
Pulp necrosis	4 (5%)	6 (19%)	0.01
<b>Region</b>			
Midwest	38 (93%)	3 (7%)	
South	45 (62%)	28 (38%)	0.00

### **3 CONCLUSÃO**

A partir dos resultados apresentados neste estudo podemos concluir que a remoção parcial de tecido cariado seguida de restauração em sessão única pode ser uma alternativa viável no tratamento de lesões profundas de cárie. Além disso, em comparação ao tratamento expectante, demonstra parecer desnecessária a segunda intervenção para reabertura e nova remoção de tecido cariado para que a vitalidade pulpar seja mantida ao longo do tempo.

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