UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL

FACULDADE DE ODONTOLOGIA

PROGRAMA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA

DOUTORADO EM ODONTOLOGIA

ÁREA DE CONCENTRAÇÃO EM CLÍNICA ODONTOLÓGICA

ÊNFASE EM DENTÍSTICA/CARIOLOGIA

Juliana Jobim Jardim

REMOÇÃO PARCIAL DE TECIDO CARIADO EM LESÕES DE CÁRIE PROFUNDAS DE DENTES PERMANENTES

Porto Alegre (RS), abril de 2010.

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Tese apresentada como parte dos requisitos obrigatórios para a obtenção do Título de Doutor em Odontologia com Ênfase em Dentística/Cariologia

Orientadora: Profª. Drª. Marisa Maltz

Linha de Pesquisa: Biomateriais e Técnicas Terapêuticas em Odontologia

Porto Alegre, abril de 2010.

AGRADECIMENTOS

- Aos meus pais, Eni e Wolmer, e às minhas irmãs, Jerusa e Jeovana, por toda a dedicação que tiveram aos meus estudos e ao meu bem estar. Por serem meus exemplos, por estarem prontos a me ajudar em qualquer momento, por me incentivarem a perseguir meus objetivos e por seguirem comigo na busca da minha felicidade. Amo vocês.

- À Profª. Drª. Marisa Maltz, minha "chefa", por ser meu exemplo de professora e pesquisadora, pela concepção e realização desta tese, por ser uma orientadora dedicada e questionadora, buscando sempre extrair o melhor de seus orientandos. Muito obrigada por todo o trabalho que dedicaste a mim desde o mestrado. Agradeço também pelas inúmeras vezes em que conversamos não como orientanda e orientadora, mas sim como amigas.

- Às queridas Profªs. Drªas. Heliana Dantas Mestrinho e Lilian Marly de Paula, parceiras nesse estudo, sempre prontas a ajudar, discutir, modificar, sugerir, e contribuir para que a nossa pesquisa seguisse adiante. Obrigada por tudo!

- À minha terceira irmã, Profª. Drª. Clarissa Cavalcanti Fatturi Parolo, colega de doutorado, docência e atividades de pesquisa, amiga pra todas as horas. Faz parte da minha vida de forma permanente e insubstituível.

- À Profª. Drª. Berenice Barbachan e Silva, minha "segunda mãe", pela amizade, pelo amor, pelos inúmeros conselhos (sempre tão sábios e oportunos!), por iluminar minha vida sempre, mesmo de longe.

- À Karina Podestá, minha amiga e parceira de pesquisa, por toda a ajuda fornecida no desenvolvimento deste trabalho, pela parceria nos momentos de crise, de comemoração e nas situações mais inusitadas das saídas de campo.

- À amiga Adriela Mariath, pela amizade que partilhamos desde a graduação, passando pelo mestrado, pela docência e pelo doutorado. Pelas inúmeras conversas, científicas ou sobre a vida, por dividir comigo anseios e felicidades. Meu exemplo de dedicação e inteligência.

- Ao doutorando Maurício dos Santos Moura, meu querido amigo, pela parceria na realização desse estudo, por estar sempre pronto a ajudar e pela amizade.

- À Luana Severo Alves, amiga querida e colega do doutorado, pela convivência, pela parceria e pela amizade.

- À mestranda Fernanda Mendes Giongo, pela ajuda, pela convivência e pela amizade.

- À Profª. Drª. Sandra Liana Henz, pela amizade e pelo incentivo constante.

- As amigos Richard Marcolini e Tiago Louzada, por fazerem com que este período não fosse só de estudos.

- A todos os alunos de iniciação científica que contribuíram para este trabalho e que se tornaram meus amigos queridos: Aline Macarevich, Telma Carneiro Mathias, Juliana Rosa, Alessandra Damo e Caroline Weber. Adoro vocês.

- À cirurgiã-dentista Cláudia Farias Osório, pelo auxílio na etapa inicial deste trabalho.

- A todos os cirurgiões-dentistas do Grupo Hospitalar Conceição e do Posto de Saúde Municipal Bom Jesus pelo auxílio na realização deste trabalho.

- Ao Prof. Dr. Cristiano Susin, por todos os ensinamentos, pela contribuição a esta tese desde a realização de seu projeto. Por me fazer adorar a Epidemiologia.

- A toda a equipe do Laboratório de Bioquímica e Microbiologia Bucal, o LABIM.

- Aos Profs. Drs. Fábio Sampaio e Maria Augusta Rebelo, pela participação na fase inicial deste trabalho.

- À Profª. Drª. Denise Cortes, pela contribuição na elaboração do projeto deste estudo.

- Ao Dr. Roberto Decourt, pela ajuda na realização da análise de custo efetividade.

- Ao Prof. Paulo Yamaguti e à mestranda Cyntia Marques, pela colaboração inestimável a esse trabalho.

- À CAPES (bolsa de estudos), ao CNPq/MS (processo nº 403420/2004-0) e à FAPERG/MS/CNPq (processo nº 0415318) pelo apoio financeiro para a realização desta tese.

- Às indústrias Ivoclar/Vivadent, DFL e SDI, pelo apoio para realização da pesquisa.

PARTIAL REMOVAL OF CARIOUS DENTINE IN DEEP CARIES LESION IN THE PERMANENT DENTITION

Juliana Jobim Jardim

CONTENTS

ABSTRACT

Partial removal of carious dentine in deep caries lesions in the permanent dentition

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The partial removal of carious dentine was studied by means of a literature review and a multicenter randomized controlled clinical trial. The clinical trial compared the effectiveness of an alternative treatment for deep caries lesions and the stepwise excavation in Public Health Services in Brazil. The treatment consists of partial removal of carious dentine followed by restoration in one session. A cost-effectiveness analysis the two treatments was performed. The clinical performance of amalgam and resin restorations placed in deep caries lesions with or without decayed tissue beneath them was also evaluated. Inclusion criteria: patients with ≥ nine years old, permanent molars with deep caries lesions and absence of periapical alterations, pulp sensitivity; absence of spontaneous pain; negative percussion test. The subjects were assigned to: test-group - partial removal of carious dentine (PDR) and restoration, and control-group - stepwise excavation (SW). SW consists of partial removal of carious tissue, indirect pulp capping with calcium hydroxide cement; temporary filling; cavity re-opening after 60 days, removal of the remaining soft carious tissue and filling. Clinical and radiological exams were performed annually. The outcomes were: (1) pulp sensitivity to cold test and absence of periapical alterations, assuming those parameters as indicators of pulp vitality; and (2)

success of the restoration. To determine the cost-effectiveness of the treatments, the discounted cash flow method was adopted. The data were submitted to Kaplan-Meier, Log-rank test and logistic regression analysis, $P<0.05$. There were performed 299 treatments, 146 SW and 153 tests. There were no differences between the groups regarding baseline characteristics - age, gender and family income. The number of teeth evaluated after one and two years were 180 and 122. After one year of treatment performance, the therapy success rates were 97.9% and 74.1% of success in test and control groups respectively ($P<0.000$). After 2 years of follow-up, therapy survival rates of PDR and SW were 93.7% and 73.3% respectively ($P=0.000$). A total of 29 therapeutic failures were observed: PDR group - pulpitis (n=3), osteitis (n=1), hyperemia (n=2); SW group - pulpitis (n=15), necrosis (n=6), extraction (n=1) and restoration fracture (n=1). None of the variables studied showed a significant causal influence on the success rate, besides the type of treatment. After two year of follow-up, 181 restorations had been evaluated, 86 from the SW group and 95 from the PDR group; 65.8% were from the resin composite group and 34.2% were amalgam restorations. The survival analysis of the treatment associated with the filling material showed no difference in the rate of success ($P=0.564$). Regarding the treatment, both groups presented a similar rate of success: SW=95.3% and PDR=94.7% ($P=0.928$). Resin composite restorations presented 96.8% of success and amalgam restorations presented 94.1% of success ($P=0.446$). The reason for failure was fracture of filling material. The PDR provides an economy of R$ 143.37 (67.78%) per treatment compare to SW and 2.39% in the overall economy in the annual cost of the public health center. Partial caries removal could be performed as definitive

treatment and the procedure of re-opening the cavity to remove the residual infected dentine is not necessary. The maintenance of carious dentine does not interfere in the maintenance of pulp vitality. The presence of decayed tissue in deep caries lesions does not seem to interfere with the survival of the restorations. Performing the partial removal of carious dentine in one session generates benefits for the public finances (direct economy), for the public health services (increase in number of treatments performed) and for the patients (comfort and time).

Key-words: dental caries; dentine; dental restoration; silver amalgam; resin composite; survival analysis; cost-effectiveness analysis.

PREFACE

This thesis is based on the following papers, which will be referred to in the text by their Roman numerals. All papers are attached at the end of this document.

I – Jardim, J. J.; Maltz, M. State of art of dentine caries removal.

II – Jardim, J. J.; Podestá, K.; Moura, M. S.; Yamaguti, P. M.; de Paula, L. M.; Mestrinho, H. D.; Maltz, M. Partial removal of carious dentine: a multicenter randomized controlled trial: 6 – 18 months results.

III – Moura, M.S.; Jardim, J. J., Marques, C.; de Paula, L. M.; Mestrinho, H. D.; Maltz, M. Partial caries removal in deep caries lesions: 19-30 months follow-up study.

IV – Jardim, J. J.; Moura, M.S.; Yamaguti, P. M.; Marques, C.; de Paula, L. M.; Mestrinho, H. D.; Maltz, M. Amalgam and resin composite restorations placed over decayed tissue in deep carious lesions – 2-year follow up.

V – Jardim, J. J.; Decourt, R.; de Paula, L. M.; Mestrinho, H. D.; Maltz, M. Cost-effectiveness of partial removal of carious dentine in deep caries lesion in Brazil.

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ABBREVIATIONS LIST

CCR – Complete caries removal

DCF – Discounted cash flow

DPC – Direct pulp capping

IPC – Indirect pulp capping

NPV – Net present value

PDR – Partial dentine removal

SW – Stepwise excavation

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1. INTRODUCTION

The management of deep caries lesions has been extensively discussed in the literature (1-11). These papers cover different subjects, including the appropriate instruments to remove the carious tissues, the amount of decayed tissue that needs to be remove (12) and yet the interaction between pulp and dentine (7, 13-14).

In order to preserve the dental structure as much as possible and also to avoid irreversible damages to the pulp, some conservative techniques have been proposed concerning the carious dentine removal (2-4, 8, 10). The stepwise excavation technique (SW) is one of them and consists of partial removal of the decayed tissue at the bottom of the cavity, temporary sealing for 1-6 months and then re-open the cavity, fully removal of carious tissue and restoration (2-4). During the time of temporary sealing, it is expect that the carious dentine left become harder and dry, both characteristics of inactive lesions, presenting a low level of bacterial infection. The aim of this procedure is to tallow the occurrence of physiological reactions in the pulp-dentine complex represented by dentine sclerosis and tertiary dentine formation (1, 15), ensuring protection to pulp tissue on the re-entry, avoiding pulp exposure. Many studies had demonstrated that this treatment can achieve a high level of success (2, 4-5). The disadvantages of SW are mainly the risk of pulp exposure during re-entering the cavity (2, 4-5), the failure of the temporary filling and the cost (need of two sessions to complete the treatment). Also, some patients may never return to the second appointment, once their pain problem is solved.

Furthermore, if all the decayed tissue is removed in a deep carious lesion and the pulp is exposed, a very common treatment applied is the direct pulp capping. A retrospective study evaluated the treatment outcome of pulp capped teeth after 5 and 10 years and showed that 79.7% of the teeth presented necrosis and suffered a postoperative root canal treatment or an extraction after 10 years (16).

In order to solve these problems, it has been proposed that a definitive restoration should be placed at the same session in which the partial caries removal is performed (8, 17-21). This series of publications have showed that the partial removal of caries dentine in deep lesions is a viable alternative to preserve dental vitality. In a single-arm clinical trial, patients with deep caries lesions in permanent posterior teeth had been submitted to partial dentine removal and resin restoration in one session (8). After 10 years of follow-up, the overall success rate was 62% (22). Radiographically, there was an increase in radiopacity of the carious dentine left at the bottom of the cavity, indicating a possible mineral gain during time (21). The number of microorganisms also reduced after sealing the cavity, reaching the levels usually encountered in cavities where all the carious tissue was removed according to hardness criteria (8, 23-25). In deciduous teeth, after indirect pulp capping, the increase in dentine hardness observed clinically could be also confirmed in vitro through microhardness test (26-27).

Ricketts et al (2006) (11), on a systematic review of the literature regarding conservative management of carious lesion, found that the SW presented clinical success. However, there is no controlled clinical trial

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performed in permanent teeth analyzing sealing of carious tissue in deep carious lesions.

The amount of carious tissue to be removed is only one aspect of the direct restoration procedure in deep carious lesions. The type of filling material to be used is also discussed, most of the studies varying between amalgam and resin composite (28). A greater need for aesthetics, the possibility to preserve more dental tissue and being metal free are some of the facts that had lead to choose e to improve resin composites for use in posterior teeth (29-31). Despite the improvement in the clinical performance and longevity of resin composite restorations placed in molars or premolars, when this filling material is compared to dental amalgam, the last one still presents higher rates of survival in a long-term basis (32-33). Mertz et al (1998) (34) showed that amalgam and resin restorations placed over decayed tissue in lesions confined to dentine outer half presented no differences in survival rates (10 year follow-up) compared to amalgam restorations placed after complete caries removal. The studies already published comparing amalgam versus resin composite in posterior teeth with deep caries lesions were performed using complete caries removal.

Considering all that, there are still at least two questions that need to be answered:

(1) Is there a real need to re-open the cavity after partial excavation?

(2) The remained carious tissue affects the performance of amalgam and resin composite restorations?

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2. OBJECTIVES

The main objectives of this study were:

2.1 To review the literature regarding the removal of carious dentine (Paper I).

2.2 To evaluate the effectiveness of an alternative treatment for deep caries lesions in Health Services in Brazil. The treatment consists of partial removal of carious dentine followed by restoration in one session (Papers II and III).

2.3 To compare the clinical performance of amalgam and resin restorations placed in deep caries lesions with or without decayed tissue beneath them. The risk factors that could be associated to restoration failure were also evaluated. (Paper IV).

2.4 To evaluate the cost-effectiveness of two treatments – stepwise excavation and partial caries removal – for deep caries lesions (Paper V).

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3. MATERIALS AND METHODS

3.1 Review of the literature (Article I)

In order to review the literature regarding dentine caries removal, a search of the PUBMED, LILACS and Cochrane Library was conducted through February 2010, using as keywords “deep caries lesions”, “stepwise excavation”, “indirect pulp capping”, “direct pulp capping”, “partial caries removal” and “caries removal”. The outcome effects target on this review were: pulp sensibility, bacterial levels and restoration survival rates. English, Portuguese and Spanish language literatures were reviewed. The gray literature, that is, information not reported in the periodic scientific literature, was not examined.

3.2 Clinical experiments (Articles II, III and IV)

Study design:

This is a multicenter randomized controlled clinical trial (Registration number at www.clinicaltrials.gov NCT00887952). The follow-up period was set in, at least, five years.

The clinical treatment was carried out by 22 dentists and supervised by the main researches (MM, LMP, HM and JJJ) during two years. The centers evolved were located at the cities of Brasília (Federal District - FD), at the Center-East of Brazil, and Porto Alegre (Rio Grande do Sul - RS), at the South region. The RS center was the main responsible by the research. In the FD center, both sample selection and treatments were performed by 10 dentists of the Brasilia University Hospital. In the RS center, the sample selection and treatments were performed by five dentists of the Federal Health Service, four

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dentists of the Municipal Health Service and three dentists (two post-graduate students and a clinician) of the Federal University of Rio Grande do Sul. All dentists were updated and trained before the beginning of the clinical procedures by two main researchers (MM and LMP).

The materials used to perform the treatments, as well as the clinical files, were supplied by the RS center to all the execution centers, ensuring that they were all standardized.

Sample

The sample size calculation was based on a difference in percentage of success of stepwise excavation and partial removal of caries after a 5-year follow-up period, of 60.9% (35) versus 82% (19) respectively, at an $\alpha = 5\%$ with a power of 90%. Those studies defined pulp sensitivity as the main outcome. This resulted in the need for 76 restorations per treatment group. Taking into account a dropout rate of 56% after two years (36), from a study using a similar population, the number of restorations required was at least 119 restorations per group.

The sample selection was performed by two ways: the exam of the usual subjects attending to the services and the active search by individuals that may fulfill the inclusion criteria. The active search was carried out by the researchers in community programs, local schools and through newspaper and radio advertisement.

Inclusion-criteria

- At the time of the treatment, the patients should have at least nine years old.
- Permanent molars presenting primary deep caries lesion were included, as long as the complete caries removal could lead to pulp exposure;
- Caries lesion reaching dentine inner half detected by radiographic exam;
- Positive response to the cold test (-20ºC refrigerated gas - Aerojet, Rio de Janeiro, RJ, Brazil);
- Absence of spontaneous pain;
- Negative sensitivity to percussion;
- Absence of periapical lesion accessed by radiographic exam;

Exclusion criteria

- Subjects with general diseases affecting salivary glands or the production of saliva, therefore their caries experience, were not included in the project.
- Cuspal loss.

Study groups

The subjects were randomly assigned to test or control groups:

Test - partial removal of carious dentine plus restoration in one session (PDR)

Control – stepwise excavation (SW)

Each of these groups was divided according to the filling material: amalgam or resin composite.

Randomization and blinding procedures

The choice between test and control was done by raffle: the treatment group was written on a paper, numerated and kept on a dark flask. A person other than the dentist executing the treatment selected a paper from the dark flask at the appropriate moment (see Clinical procedures). The filling material was determined at weekly basis, alternating in each execution center between amalgam and resin.

Blinding of the participants was not possible due to the fact that the treatments needed a different number of appointments. Blinding of the operators was done for the caries removal procedure (see Clinical procedures).

Clinical procedures

The patients were submitted to the following procedures: anesthesia and rubber dam isolation of the area to be treated; access to the affected area using rotator instruments, if necessary; complete removal of carious dentine from the surrounding cavity walls according to hardness criteria (low-speed metal burs and/or hand excavator); removal of the necrotic disorganized dentine from the cavity floor (hand excavator); washing of the cavity with distilled water; drying with sterile filter paper; group randomization. The tooth of the PDR received: partial filling of the cavity with glass ionomer cement (Vitro Fil, DFL, Rio de Janeiro, RJ, Brazil); restoration using amalgam (GS-80, SDI, Bayswater WA, Australia) or resin composite (Tetric EvoCeram + Excite + Total Etch, Ivoclar/Vivadent, Liechtenstein) according to the manufacturer's instructions. In the resin composite restorations, the incremental technique was used. The tooth of the SW received: indirect pulp capping with calcium hydroxide cement

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(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); cavity reopening after 60 days, followed by removal of the remaining decayed dentine and filling according to the same procedures described to PDR.

Clinical and radiographic evaluations

Outcomes were defined as: (1) pulp sensitivity to cold test and absence of periapical alterations, assuming those parameters as indicators of pulp vitality (combined effect); and (2) success of the restoration. Cold test is considered the gold standard to indicate pulp vitality (Gopikrishna et al, 2008). The treatment evaluation was performed in annual basis.

Clinical evaluation of the restorations was carried by trained dentists right after the treatment and then annually. The restorations were recorded as (1) in function, (2) censored, if the patient dropped out of the study or (3) failed, if they were repaired or replaced or the tooth was indicated for extraction (37).

The radiological registrations were performed at the very beginning of the study (periapical and bite-wing radiography), during screening, right after the treatment (bite-wing radiography) and annually (control visits, periapical radiography).

As baseline characteristics, the following items were recorded: subjects' age, gender, family income. Regarding the treatment, the variables analyzed were surfaces evolved in the filling, size of the cavity and time spent to complete the restoration.

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All data were recorded at the clinical files and also via-web, using a digital system specially developed for the study (http://odonto.cityzoom.net).

3.3. Cost-effectiveness analysis (Article V)

To determine the cost-effectiveness of the treatments, the discounted cash flow method (DCF) was adopted. This is a method of valuing a project, company, or asset using the concepts of the time value of money. All future cash flows are estimated and discounted to give their present values – the sum of all future cash flows, both incoming and outgoing, is the net present value (NPV), which is taken as the value or price of the cash flows in question. Using DCF analysis to compute the NPV takes as input cash flows and a discount rate and gives as output a price. By far the most widely used method of discounting is exponential discounting, which values future cash flows as "how much money would have to be invested currently, at a given rate of return, to yield the cash flow in future". The value of an asset is the value of the future benefits it brings. The value of an investment is that cash flows that it will generate for the investor: interest payments, dividends, repayments, returns of capital, etc. (38). In the present study, a 12% annual discount rate was used.

The costs of the treatments were defined according to the charges published by the Federal Council of Odontology. The costs were expressed in the local currency (R$ 1 = US$ 1.76). The total cost of each treatment was calculated using the following parameters:

- Filling material: silver amalgam. This is the most used filling material in the public health services which took part of the study.

- X-ray exam: one periapical radiography (R$ 11.23) for the PDR group and two for the SW group (before and after temporary sealing).
- Number of faces involved in the restoration: a mean cost of the treatments was calculated using the prevalence of the number of faces registered in the clinical study (1 surface 85.6%; 2 surfaces 13.3%; 3 surfaces 1.1%) to compose the final cost. Thus, the mean cost of an amalgam restoration was set as follow: one surface restoration costs R$ 47.91 multiplied by 0.86 + two surfaces R$ 59.32 multiplied by 0.13 + three surfaces R$ 68.48 multiplied by 0.01.
- The cost of the failures for each group was added to the cost calculation according to the rates from the one year follow-up (2% of the cost for the PDR group and 26% for the SW group). The failure of the therapy was considered the lack of pulp vitality, so the cost of an endodontic treatment for molar teeth was used (R$ 366.52).
- In the SW group, the cost of the temporary filling (R$ 36.85) was added to the final cost of the treatment reached for the PDR group.

To calculate the economic value of the alternative treatment (PDR), a public health service unit composed by three dentists in four hour work shifts was used. The number of treatments performed per day was supposed to be eight per dentist, being a total of 528/month. The prevalence of deep caries lesions in permanent molars that fulfill the inclusion criteria of the study was set

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in 5%, using data from the study sample selection (528 patients/month, 22 days in a month, 1.2/day). The economy of the PDR was determined in daily, monthly and annual basis.

3.4 Statistical data processing

Survival analyses were performed to estimate therapy and restoration success rate (Kaplan-Meier survival curves plus Log Rank test). The possible correlation between the variables recorded and the outcomes was analyzed by logistic regression.

Qui-square test or Mann-Whitney test was used to compare patients followed-up after two years and patients lost to recall.

The significance level was set in 5% and the unit of analysis was the restoration.

All the analyses were made using Statistical Package for Social Science (SPSS) software, version 13.0.

3.5 Ethics

The study was approved by the Federal University of Rio Grande do Sul Ethics Committee, the Porto Alegre Municipal Ethics Committee, the Conceição Hospital Ethics Committee and the Brasilia University Hospital Ethics Committee. All participants signed an informed consent. All the dental needs presented by the subjects enrolled in this research were provided, except prosthetic rehabilitation and orthodontic treatment.

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4. RESULTS

4.1 Literature review (Article I)

After the search in the databases, a few randomized controlled clinical trials were found, so studies presenting the same outcomes, however using different designs (clinical studies without control group, series of cases, in vitro studies) were included. This result did not allow a meta-analysis of the study's results. The results of the review were used in the discussion of articles II, III and IV.

4.2 Clinical Procedures (Articles II, III and IV)

There were performed 299 treatments, 146 SW and 153 tests. The participants were mainly adolescents studying in public schools. Regarding the socioeconomic status, most participants presented low family income. There were no differences between the groups regarding baseline characteristics - age, gender and family income (Table 1).

Table 1. Subjects baseline characteristics according to treatments.

Group/ Variable	N	Age (years) mean±SD	Male	Female	Family income (R$) R$ 1 = US$ 1.75 Median (quartiles 75 and 25)
SW	146	16.6±7.5	56	90	600.00 (800.00-380.00)
PDR	153	16.3±7.2	54	99	600.00 (960.00-380.00)

There were no differences between the groups at baseline (P>0.05)

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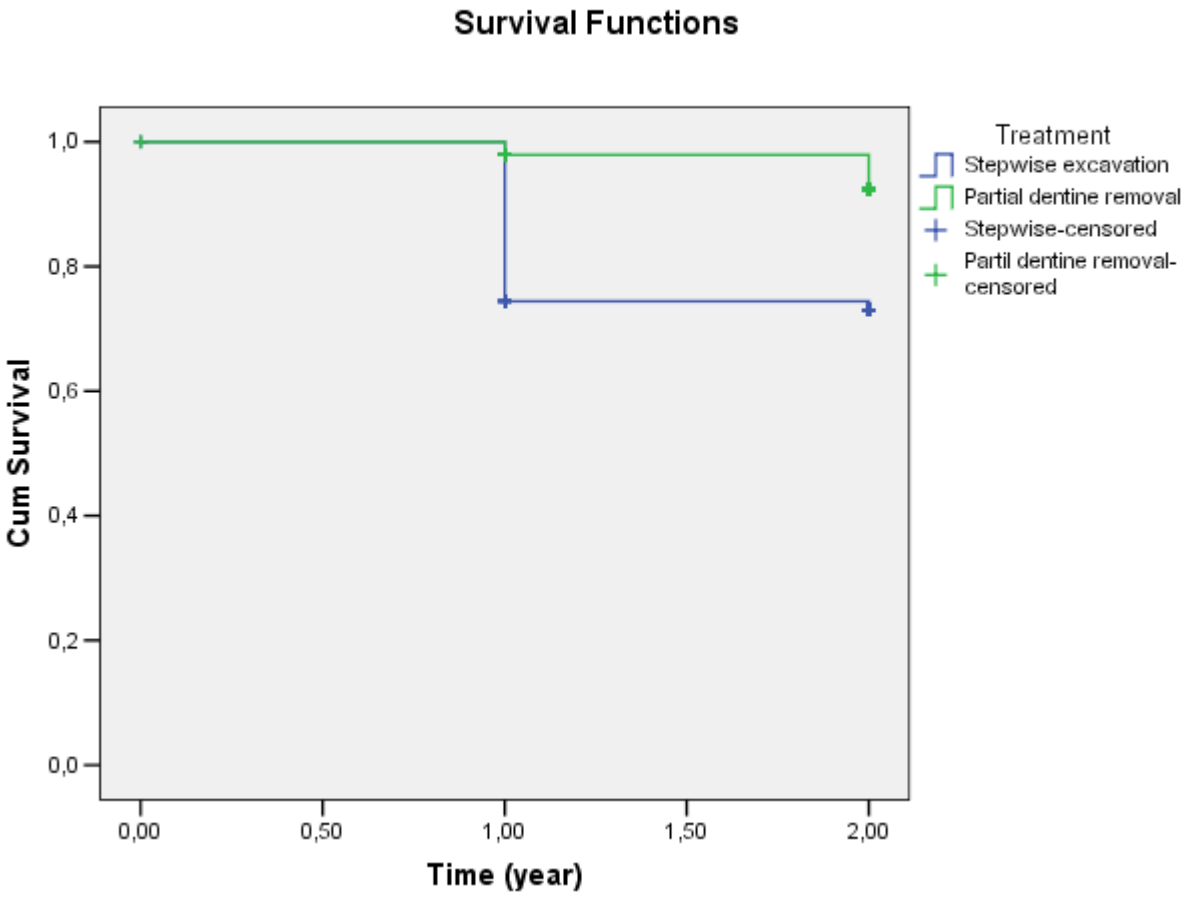
The number of teeth evaluated after one and two years were 180 and 122, been the cumulative drop-out rate was 40%. There were no differences between the evaluated patients and those lost to recall regarding family income, gender, restorative material and number of restored surface. However, differences were found regarding age and treatment (Table 2).

Table 2. Subject's baseline characteristics according to the proportion of the evaluated patients and those lost to recall.

Variable	**P**
Gender	0.638
Age	0.029
Family income	0.146
Treatment	0.015
Restorative material	0.245
Number of restored surfaces	0.068

After one year of treatment performance, the therapy success rates were 97.9% and 74.1% of success in test and control groups respectively. A significant difference was observed between the groups when the survival analysis was performed (P<0.000) (Figure 1). After 2 years of follow-up, therapy survival rates of PDR and SW were 93.7% and 73.3%, respectively (P=0.000) (Figure 1).

Figure 1. Survival analysis of treatments according to time (in year).



During the performance of the SW four cases of pulp exposure were observed. Three cases were treated with direct pulp capping and one case

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received endodontic treatment right after the pulp exposure. After two years, two patients presented irreversible pulpitis and one patient maintained pulp sensitivity.

A total of 29 therapeutic failures were observed, 6 in the PDR and 23 in the control group. Reasons for failure in the PDR were pulpitis (n=3), osteitis (n=1), hyperemia (n=2). In SW, failures occurred due to pulpitis (n=15), necrosis (n=6), extraction (n=1) and tooth fracture (n=1). The number of failures in the SW group was 22 in the first year, increasing to 23 at the second year. In the PDR, 2 failures were observed in the first year, increasing to 6 at the second year. The reason for the tooth extraction is not clear, once it was performed by a dentist not enrolled in the research group.

At the final model of logistic regression analysis, considering pulp sensitivity as outcome, none of the variables included showed a significant causal influence on the success rate, besides the type of treatment (Table 3).

Table 3. Logistic regression analysis final model considering pulp sensitivity as the dependent variable. Age and family income were treated as continuous variables. All the other variables were categorical.

Variable	**P**	**95% CI**	
		Lower	**Upper**
Treatment	0.001	0.056	0.506
Filling	0.355	0.573	4.731

material			
Age	0.630	0.952	1.086
Gender	0.617	0.273	2.163
Number of surfaces	0.210	0.673	6.059
Size of the cavity	0.201	0.179	1.437
Family income	0.706	1.000	1

The time used to perform the treatments was different for all the groups. The PRC was the faster treatment performed, presenting 38.9% less time than the SW group (Table 4).

Table 4. Time (minutes) used to perform the treatments according to groups and filling material.

Treatments	Time	
	Mean	SD
SW	78.3[a]	21.3
PDR	47.85[b]	15.4

Means followed by different letters are different (P = 0,000)

4.3 Restorations evaluation (Article IV)

After two year of follow-up, 181 restorations had been evaluated, 86 from the SW group and 95 from the PDR group. Regarding the filling material, 65.8% were from the resin composite group and 34.2% were amalgam restorations (Table 5). The majority of the restorations analyzed were placed in one tooth surface (Table 6).

Table 5. Number of restorations according to treatment and filling material at baseline and at two year follow-up.

Treatment	Material			
	Amalgam		Resin Composite	
	Baseline	Follow up	Baseline	Follow up
SW	64	37	83	49
PDR	58	25	85	70
Total	122	62	168	119

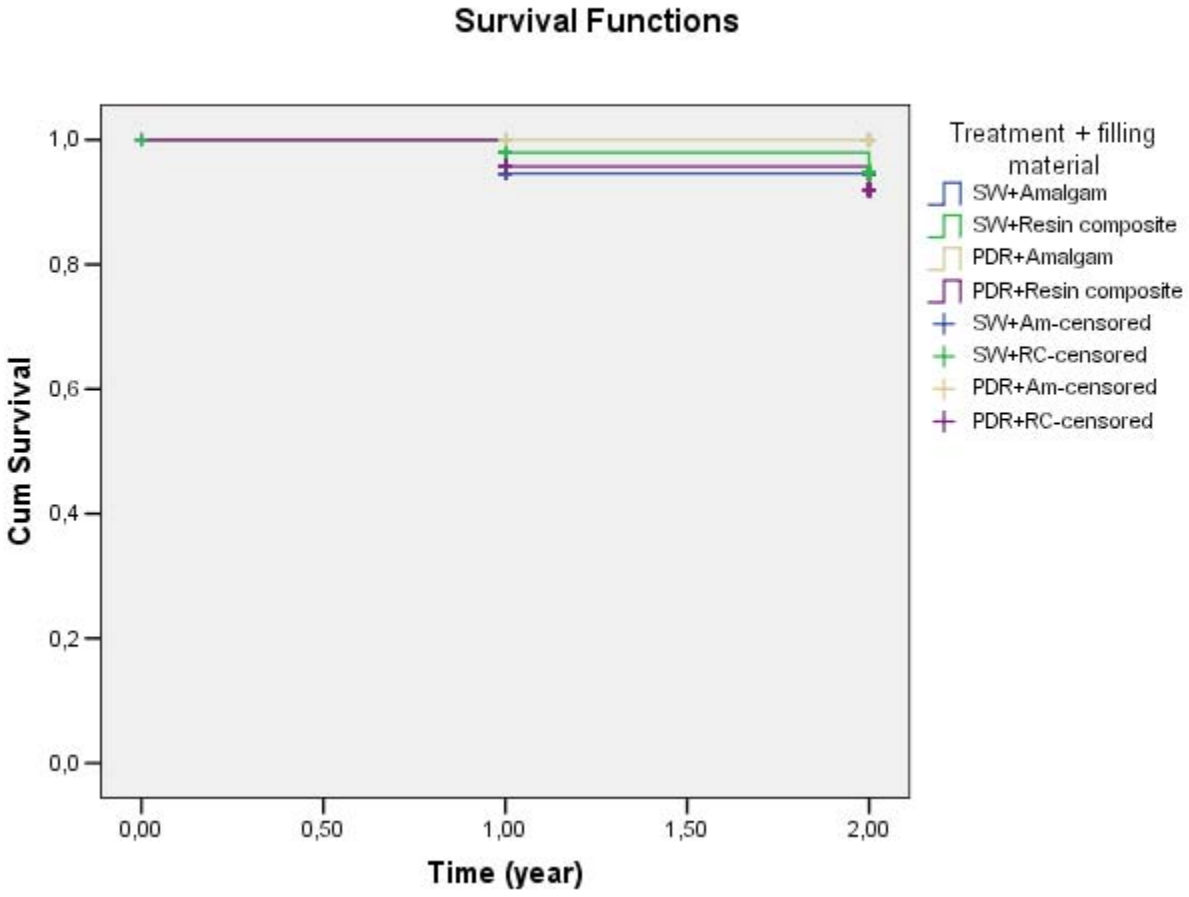
Table 6. Distribution of treatments and filling materials according to the number of surfaces included in the restoration (% within the treatment group and of total).

Treatment	Number of surfaces			Total
	1	2	3	
SW	76 (88.4%)	10 (11.6%)	0 (0.0%)	86 (47.5%)
PDR	79 (83.2%)	14 (14.7%)	2 (2.1%)	95 (52.5%)
Filling Material	**1**	**2**	**3**	**Total**
Amalgam	52 (83.9%)	9 (14.5%)	1 (1.6%)	62 (34.2%)
Resin	103 (86.6%)	15 (12.6%)	1 (0.8%)	119 (65.8%)

composite				
Total	155 (85.6%)	24 (13.3%)	2 (1.1%)	181 (100%)

The survival analysis of the treatment associated with the filling material showed no difference in the rate of success (P=0.564) (Figure 2). Regarding the treatment, both groups presented a similar rate of success: SW=95.3% (4 failures) and PDR=94.7% (5 failures) (P=0.928). When the filling material was analyzed, resin composite restorations presented 96.8% of success and amalgam restorations presented 94.1% of success, showing no differences in the survival rate (P=0.446). The reason for failure was fracture of filling material.

Figure 2. Survival rates of the restorations according to treatment group and filling material at two year follow-up.



None of variables analyzed showed a significant causal association with the restorations survival (Table 7).

Table 7. Logistic regression analysis final model considering restorations success as the dependent variable. Age and family income were treated as continuous variables. All the other variables were categorical.

Variable	P	95% CI	
		Lower	Upper
Treatment	0.505	0.077	3.524
Filling material	0.128	0.645	32.409
Pulp sensitivity	0.998	0.000	
Age	0.054	0.463	1.007
Gender	0.262	0.050	2.261
Number of surfaces	0.998	0.000	
Size of the	0.175	0.039	1.806

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cavity			
Family income	0.158	0.995	1.001

4.4 Cost-effectiveness analysis (Article V)

The mean total cost of the PDR is R$ 68.16 and the mean total cost of the SW is R$ 211.53, providing an economy of R$ 143.37 (67.78) per treatment. The daily economy of the PDR is R$ 172.05, generating a monthly economy of R$ 3,784.99 and an annual economy of R$ 45,419.93. The economic value of the PDR in a public health center (528 patients/month) using the DFG method is R$ 440.309,76 (discount rate 12% annual). The overall economy in the annual cost of the public health center is 2.39%. These results showed that PDR is a much more efficient treatment than SW after one year of follow-up.

5. DISCUSSION

In the present study, two treatments for deep carious lesions were tested: stepwise excavation and partial caries removal in one session. After two years of follow up, the results showed that the PDR was more effective than SW in preserving the pulp vitality. Also, age, gender, family income, filling material and number of surfaces of the restoration presented no correlation with the treatment success.

The stepwise excavation was choose to be the control treatment due to: (a) the possibility of avoiding pulp exposure, and (b) the high rate of success found in several studies when one is dealing with deep caries lesions (2, 4-5). The alternative to the SW is the direct pulp capping, which has shown to be a much less safer choice to treat dentin lesions: success rate of 20% after 10 years of follow up (16). The presence of carious dentine during the direct pulp capping is an important factor to be considered when studies with this treatment are evaluated. Al-Hiyasat, Barrieshi-Nusair, Al-Omari (2006) (39) showed an overall success rate for direct pulp capping of 60% after three years, however, this rate decreases to 33.3% if the treatment was performed after carious exposure. The possibility to perform a complete removal of caries tissue and cause a pulp exposure was then consider not ethical. These facts lead the authors to consider, at the beginning of this study, the stepwise excavation as being the gold standard treatment for deep caries lesions.

It is important to stress that the present study is the first longitudinal randomized clinical trial in permanent teeth with deep caries lesions using a control group. The other studies found in the literature that performed partial

removal of deep caries lesions were conduct without a proper control group (8) or in deciduous teeth (40).

Bjorndal and Thylstrup (1998) (4) showed a 93.4% success of stepwise excavation in one year of follow up, a better result compared to this study – 74.1% of success after one year. The 93.7% of success after two years of partial removal of carious dentine showed in the present study is in agreement with the results of Oliveira et al (2006) (18), which observed a success rate of 97% after 18 months of follow up after partial dentine removal in deep carious lesions.

From the 27 cases of failure in the SW group, 12 occurred in patients who did not return at the appropriate time to performed the second step of the treatment, leading to temporary filling failure, followed by pulp injury. The dependence of patients' return to conclude the stepwise excavation, coupled with the lack of evidence of the need of cavity reopening for final excavation, suggest that the treatment in a single appointment may be preferable.

Of the 299 patients treated, 180 returned after one year and 122 after two years of the initial treatment. In order to assess the possible inclusion of a bias, patients who attended the 2-year follow-up were compared with those lost to recall. The two variables which were significantly different from one another were treatment and age. Regarding treatment, the stepwise excavation presented worse success rate, once this group presented the higher drop-out rate, not returning to complete the treatment. The maintenance of the temporary filling may lead to several negative results: fracture/loss of the temporary filling, fracture of the tooth structure, caries progression and, finally, irreversible

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damage to the pulp. Age not seems to compromise our results, once it has no association with pulp prognosis regarding pulp conservative therapies.

The age of the patients was a non determinant factor to the outcome evaluated, once the failures had occurred in subjects with 9 to 53 years old. In some studies, the age is consider an important factor when it comes to deep caries lesions, because of the pulp cells being more active in younger teeth (41). However, in the present study, 13 failure cases were found in patients with <20 years old and 5 cases were found in patients with >20 years. Bjorndal and Thylstrup (1998)(4) performed stepwise excavations procedures in patients from 11 to 65 years of age and, after 1 year of follow up, presented no relation between chronological age and treatment success. The lack of influence of age in the final results was also found in longitudinal direct pulp capping studies (39, 42).

After the regression analysis, there were no associations among the treatment success and the variables studied. Since after two years most studies, including this, show a high rate of success regarding restorative procedures, it seems natural that the number of surfaces evolved in the cavity or the filling material used did not present a positive relation to the success of the treatments. Alves et al (2010) (21) showed that after 18 months of follow up, there were no relation between the number of surfaces evolved and the success of the partial removal treatment. However, after ten years, all failure cases presented class II restorations, whereas from the 17 success cases, 12 presented class I restorations.

When the restoration survival was analyzed, the two-year follow-up showed that leaving dentine caries beneath the restoration and the filling

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material have no effect on the success of the restoration. The survival rate of the restorations (amalgam + resin composite) placed after complete caries removal (SW: 95.3% success) is in accordance with the literature (28, 32-33, 43-48). Similar results were observed in the restorations placed over carious tissue (PDR: 94.7% success). This result, although not from a long-term basis, may lead to the suggestion that leaving decayed tissue at the cavity bottom does not compromise the restoration clinical performance.

In studies of one and two year of follow-up, both amalgam and resin composite restorations placed in posterior teeth showed high rates of success, similar to those found in the present study (31, 47, 49-51). The annual failure rate of the resin composite restorations in this study was 1.97% (range from 1.92% to 2.01%) and no differences were observed regarding the type of caries tissue removal (SW or PDR). This results are in agreement with those found by a meta-analysis of the clinical performance of restorative materials in posterior teeth, which showed an annual failure rate of 2.2% (range from 0% to 9%) for resin composite restorations (28). In the present study, the amalgam annual failure rate was 1.97% (range from 1.93 to 2.00%), in accordance with the results of a retrospective study that evaluated restorations for up to 11 years (52). The meta-analysis cited above (28) found a slightly higher annual failure rate for amalgam restorations: 3.0% (standard deviation 1.9%).

There was no difference between amalgam and resin composite restorations in this two years study. However, Collins et al (1998) (32), in an eight years study, showed that the failure rate of the composite restorations was approximately two to three times that of the control high copper amalgam restorations. Bernardo et al (2007) (33), analyzing restorations placed in

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posterior teeth for up to seven years, showed a annual failure rates ranged from 0.16 to 2.83 percent for amalgam restorations and from 0.94 to 9.43 percent for composite restorations, resulting a better performance of amalgam over composite restorations. Van Nieuwenhuysen JP et al (2003) (37) showed a longer survival rate for amalgam restorations (12.8 years) compared to resin composite restorations (7.8 years). These studies showed that this difference was accentuated in large restorations. All these results showed that the long-term evaluation is important when amalgam and resin are compared, as well as the number of surfaces included in the restoration. In the present study, most restorations were placed in one surface and were followed for two years and these could be the possible reasons for the lack of differences observed between amalgam and resin fillings.

The most frequent reasons for failures reported in clinical studies of composite and amalgam fillings are fracture of the restoration and secondary caries (37, 53). Brunthaler et al (2003) (53) showed that the main cause of failure for resin restorations may vary according to the time used to follow-up: evaluations performed up to 5 years presented fracture as the main cause of failure, whereas in evaluation from 6 to 17 years pointed secondary caries as principal reason for failure. Other studies also observed fracture as the main reason for failure in less than three years of follow-up as the present study (54-55).

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6. CONCLUSIONS

I. Partial caries removal could be performed as definitive treatment and the procedure of re-opening the cavity to remove the residual infected dentine is not necessary. The maintenance of carious dentine does not interfere in the maintenance of pulp vitality. Two years results showed that partial carious dentine removal and restoration – placed at same visit to the dentist – presented a higher rate of success compared to stepwise excavation.

II. The presence of decayed tissue in deep caries lesions does not seem to interfere with the survival of the restorations. The filling material – amalgam or resin composite – presented the same failure rates.

III. Performing the partial removal of carious dentine in one session, which presents higher rate of success and a high economic value, generates benefits for the public finances (direct economy), for the public health services (increase in number of treatments performed) and for the patients (comfort and time).

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8. PAPERS

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State of art of dentine caries removal

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Abstract

This study reviews the literature regarding complete caries removal, direct pulp capping, sealing, stepwise excavation, indirect pulp capping and ultraconservative removal of carious dentine. In the cavity bottom of lesions reaching dentine outer half, the common sense still is the complete caries removal (CCR). Even though the results of one long-term study that shows restorations survival rates similar to those found when CCR is applied. In deep caries lesions, if all the decayed tissue is removed, there is a high risk of pulp exposure. The direct pulp capping does not present a good prognosis. An effective alternative to this treatment is the stepwise excavation technique. However, there is growing evidence that re-enter the cavity is not necessary.

Key words – deep carious lesions, stepwise excavation, indirect pulp capping, dentine caries, direct pulp capping.

The dental caries results from a series of factors affecting the biofilm located on the tooth surface, e.g. salivary components, diet and oral hygiene habits. Once a caries lesion is established on the enamel surface, if no measures are taken to control the caries disease, this initial mineral loss can continue and invade the dentine.

A unique feature of dentin is that it is a mineralized tissue which surrounds the pulp, an unmineralized tissue. The dental pulp not only functions to provide nutritional and sensory properties to dentin, but also has its own reparative capacity. This potential has important implications for dental therapy (1). The most common defense reaction by the pulp-dentin complex is the

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deposition of mineral within the dentinal tubules, a process called tubular sclerosis (2-4). Dentine's tubular sclerosis is visible even before the lesion reaches the enamel-dentine junction (EDJ) (5). Once the lesion comes to contact the EDJ, a brown discoloration of the dentine is seen, and this is the first sign of dentine demineralization. The other important defense reaction of the pulp-dentine complex is the formation of reactionary dentine, which may occur before the bacterial invasion of the dentine (2, 6). The important feature of this response is that there is no cell renewal, the odontoblasts survive the injury. This is in contrast to reparative dentinogenesis, where the intensity of the injury is of a magnitude that results in odontoblast death and cell renewal by a new generation of odontoblast-like cells (7). The process of reactionary dentinogenesis involves upregulation of odontoblast activity, often in quiescent cells at the stage of physiological secondary dentinogenesis, in response to the injury stimulus.

The presence of bacteria in the dentine tissue can be seen even in lesions confined clinically to the enamel (8). However, once a cavity is formed, a significant bacterial invasion can be observed. At this moment, a so called zone of destruction is formed, presenting the most superficial part of the dentine decomposed. Beneath this zone, tubular invasion of bacteria is frequently seen. With the progression of the lesion, odontoblastic process are destroyed (dead tracts in the dentine), without having produced tubular sclerosis. The empty tubules are invaded by bacteria and this area is called zone of bacterial penetration. In the sclerotic dentine, a zone called translucent is formed, resulting from acid demineralization (9-12).

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The formation of a cavity is a very important moment clinically, because now the biofilm is protected within a microcavity, ad unless the patient is able to clean this area, the caries process will continue (13). If the removal and/or disturbance of the biofilm in the cavity are not possible, a need for a restorative procedure maybe established in order to arrest the caries lesion.

The operative treatment of dentine lesions

Once the need for a restorative treatment is determined, the first important aspect that should observed is the method chosen to remove the decayed tissue. In a more classic way, prior to the restoration procedure, all the carious tissue (hardness criteria) should be removed. This procedure should result in an environment presenting a low level of bacterial contamination and a more organized dentine, favoring the next step of the restoration procedure – the cavity filling. However, the complete removal of carious dentine does not lead to a sterile tissue. Studies using hardness criteria (14) or a dye to guide the carious dentine excavation (15) showed that bacterial contamination can still be detected after the cavity preparation was performed. This discussion assumes that the bacteria within the dentin are important. Nevertheless, several studies have suggested that the bacterial in the biofilm are the ones who matters, and that sealing the bacteria within the cavity and restoration of the tooth, allowing regular biofilm removal, is a reliable measure to stop the caries process (16).

In order to allow a more comprehensible reading, the discussion on dentine caries removal will be divided according to the lesion depth: shallow – lesion confined to dentine outer half; and deep – lesion reaching dentine inner half.

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a. Dentine caries removal in shallow lesions

a.1 Complete removal of carious dentine (CCR)

The complete caries removal in lesions confined to dentine outer half seems to be the traditional procedure prior to a restoration. The dentine removal is traditionally based on hardness criteria, and all the soft and disorganized tissue is removed, using dental burs and/or manual instruments. Other methods to guide and performed the removal of carious tissue are proposed. Caries-detector dyes, as acid red solution, were proposed as a method to detect the dentine tissue that needs to be removed (infected dentine) (17). However, studies have established that these dyes are not suitable to guide the dentist during the caries removal, once they act in non-specific proteins instead of bacteria (15, 18-19). As they stain the organic matrix of less mineralized dentin, including normal circumpulpal dentin and sound dentin in the area of the amelo-dentinal junction, their use could lead to unnecessary removal of sound tissue (20). Chemomechanical methods to remove the decayed tissue were also proposed, aiming reduction in pain during caries removal (21-24). Clinical trials comparing the chemomechanical method and the conventional rotary instruments technique showed that the chemomechanical method significantly reduced the need for local anesthesia (25-26). Longitudinal studies (follow up periods 1-6 years) did not observe influence of the caries removal method on the survival of the restorations (25, 27). The survival of the restorations placed using CCR is high (failure rate 1-2% per year) and present a variation according to the filling material used (amalgam or resin composite) (28).

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a.2 Sealing carious dentine

A filling material placed over a frank cavitated lesion could form a physical barrier against nutrients from the oral cavity. Without these nutrients, the cariogenic organisms within the sealed lesion would not thrive, leading to an arrest of the carious process. Oon et al (2008) (29) performed a meta-analysis on the effect of dental sealants on bacteria levels in caries lesions. Six studies—three randomized controlled trials, two controlled trials and one before-and-after study—were included in the analysis. Although studies varied considerably, there were no findings of significant increases in bacteria under sealants. Sealing caries was associated with a100-fold reduction in mean total UFC (four studies, 138 samples). Sealants reduced the probability of viable bacteria by about 50.0 percent (four studies, 117 samples).

Mertz et al (1987) (30) performed the only long-term clinical study in which the complete removal of carious dentine prior to restoration was compared to the sealing of carious tissue beneath the filling material. The 10-year study evaluated bonded and sealed composite restorations placed directly over cavitated lesions extending into dentin outer half versus sealed conservative amalgam restorations and conventional unsealed amalgam restorations (31). The results indicate that both types of sealed restorations exhibited superior clinical performance and longevity compared with unsealed amalgam restorations. Also, the bonded and sealed composite restorations placed over the cavitated lesions arrested the clinical progress of these lesions for 10 years.

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b. Deep carious lesions

All the alternatives presented below are proposed to teeth presenting sings of pulp sensibility and no signs of irreversible damage to the pulp.

b.1 Complete removal of carious dentine

The complete removal of carious tissue in lesions reaching dentine inner half can lead to pulp exposure (32-33). If the pulp is exposed, the direct pulp capping technique can be considered in an attempt to preserve the vitality of the pulp and to stimulate it to produce a calcific barrier to wall off the exposure (34).

b1.1. ***The direct pulp capping (DPC)***

A direct pulp cap usually involves the placement of a calcium hydroxide preparation directly in contact with an exposed pulp (35-36). This technique depends on the health of the pulp and its healing capacity. A correct diagnosis of the pulp is essential to the therapy success. Rickets (2001) (34), in a review article about the management of the deep carious lesion, stated a list of criteria that should be fulfill in order to apply the DPC: no recurring or spontaneous pain; normal vitality tests; no tender to percussion; no radiographic evidence of periradicular pathology; radiographically obvious pulp chamber and root canal; clinical findings - pink pulp and bleed if touched but not excessively.

Besides the pulp diagnosis, the success of the DPC will also depend on a number of factors, including the age of the patient, the material used and the event leading to the exposure.

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In some studies, the age is consider an important factor when it comes to deep caries lesions, because of the pulp cells being more active in younger teeth (37). However, the lack of influence of age the therapy success rate was found in longitudinal direct pulp capping studies (38-39).

In spite of the positive experience with calcium hydroxide, the contemporary literature supports many newer materials for pulp capping, such as dentin adhesives, mineral trioxide aggregate, collagen, chondroitin sulfate, caboxylate cement, tricalcium phosphate, α-Tricalcium phosphate, tetracalcium phosphate, hydroxylapatite, bioactive ceramics, enamel matrix proteins, various growth factors, etc. Except for mineral trioxide aggregate all of these materials show less promising results than calcium hydroxide and are not recommended for pulp capping routinely at this time (36)**.** Mineral trioxide aggregate (MTA) compared with the traditional material of calcium hydroxide, has superior long-term sealing ability and stimulates a higher quality and greater amount of reparative dentin (40). The clinical data available on MTA pulp capping of cariously exposed permanent teeth are limited. Farsi et al (2006) (41) studied 30 asymptomatic permanent molars with pulp exposures treated by pulp capping using MTA. At 24 months, the clinical and radiographic success rate was 93%. Bogen et al (2008) (42), in an observational study, accompanied 37 patients (49 teeth) treated with MTA after pulp exposure between one and nine years (mean 3.94 years) and showed an overall success rate of 97.96%. Therefore, it appears that this material may be the material of choice for future pulp caps. However, it should be stressed that these two clinical studies do not present a high level of evidence towards the use of MTA in direct pulp capping, once they do not present randomization procedures as well as a control group

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(43). Besides, problems associated with the material's difficult handling properties, prolonged setting time and cost may preclude its widespread acceptance despite its superior therapeutic properties (34).

The presence of carious dentine during the direct pulp capping is an important factor to be considering when studies with this treatment are evaluated. Al-Hiyasat, Barrieshi-Nusair, Al-Omari (2006) (38) showed an overall success rate for direct pulp capping of 59.3% after three years. However, the success rate was 92.2% with mechanical exposure and 33.3% with carious exposure. The authors' conclusion was: "Direct pulp capping is recommended after mechanical exposure with immediate placement of permanent restoration, while root canal therapy would be the choice of treatment if the exposure was due to caries". A retrospective study evaluated the treatment outcome of pulp capping of caries exposure after 5 and 10 years. After 5 years, the failure rate was 44.5%, and after 10 years, 79.7% of the teeth presented necrosis and suffered a postoperative root canal treatment or an extraction (44).

In order to avoid pulp exposure and to preserve as much dental tissue as possible, a more conservative technique of carious tissue removal was proposed, called the stepwise excavation (32, 45-47).

b.1.2 The stepwise excavation

The stepwise excavation technique (SW) is considered a technique in which a complete caries removal is performed in two steps. It consists of partial removal of the decayed tissue at the bottom of the cavity, temporary sealing for 4 weeks to 12 months and then re-open the cavity, fully removal of carious tissue and restoration (32, 45). How much tissue remained over the pulp is not

well defined in the literature. Some authors excavated as close as possible to the pulp, leaving a thin layer of residual caries (32, 45). In other studies, a more conservative approach is applied (less invasive stepwise excavation) leaving a more thick layer of carious dentine (46, 48). The objective of the first excavation is to change the caries environment and not to remove as much carious dentin, eventually reaching the residual level close to the dentin-pulp interface (49). The aim of the SW procedure is to allow the occurrence of physiological reactions in the pulp-dentine complex represented by dentine sclerosis and tertiary dentine formation. During the 1-12 months of temporary sealing, it is expect that the carious dentine left become harder and dry, both characteristics of inactive lesions, presenting a low level of bacterial infection (32, 46, 48, 50-52), ensuring protection to pulp tissue on the re-entry, avoiding pulp exposure. The material used directly over the remained dentine (base material) do not appears to be an important issue regarding treatment success or dentine modifications (50, 53-55). Studies had demonstrated that this treatment can achieve a high level of success (32-33, 47, 56). Orhan, Ozcelik and Orhan (2008) (14) compared one-visit indirect pulp treatment (IPT), two-visit IPT (SW) and direct complete excavation (DCE) in deciduous and young permanent molars regarding microbial contamination. The results showed a significant reduction in bacterial counts after the sealing period (3 months) in all teeth submitted to SW. No significant differences were observed between the bacterial count found right after the temporary removal and the final excavation. In the DCE group, although the caries was completely removed until hard dentin was reached at the cavity floor; bacterial growth was still detected in 25.6% of the dentin samples. No statistical difference was found between the bacterial

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counts (total CFU, MS, lactobacilli) of two-visit IPT after the final excavation and DCE ($p>0.05$). The disadvantages of SW are mainly the risk of pulp exposure during re-entering the cavity (14, 33, 47), the failure of the temporary filling (51) and the cost (need of two sessions to complete the treatment). Also, some patients may never return to the second appointment, once their pain problem is solved.

b.2 Partial removal of carious dentine

b.2.1. Indirect pulp capping (IPC)

The differences between the SW and the IPC are that the IPC procedure involves almost complete removal of the affected dentin, leaving a thin layer of demineralized dentin. Re-entry is not attempted. In contrast, the stepwise excavation technique involves reentry at varying intervals (49). This type of treatment is well describe in the literature in deciduous teeth or young permanent molars (14, 54, 57-59).The longest follow up study (4 years) shows a success rate of IPC in primary teeth of 88%-93% (54). There are no reports from long-term studies using IPC in the permanent dentition in deep caries lesions.

b.2.2. Ultraconservative removal of carious dentine

Maltz et al (2002) (60) proposed a more conservative technique of dentine excavation performed in one session. In this treatment, the decayed dentine is fully removed from the cavity walls, except at the bottom of the lesion, in which only the necrotic and disorganized dentine is removed. In this single-arm clinical trial, patients with deep caries lesions in permanent posterior teeth

had been submitted to partial dentine removal and resin restoration in one session. A series of publications (60-63) have showed that the partial removal of caries dentine in deep lesions is a viable alternative to preserve dental vitality. After 10 years of follow-up, the overall success rate was 62%. Radiographically, there was an increase in radiopacity of the carious dentine left at the bottom of the cavity, indicating a possible mineral gain during time (61). The number of microorganisms also reduced after sealing the cavity, reaching the levels usually encountered in cavities where all the carious tissue was removed according to hardness criteria in both deciduous and permanent dentition (14, 64).

Conclusions

Prior to perform a restorative treatment, carious tissue needs to be completely removed from the cavity walls according to hardness criteria. In the cavity bottom of lesions reaching dentine outer half, the common sense still is the complete caries removal (CCR). Even though the results of one long-term study that shows restorations survival rates similar to those found when CCR is applied. In deep caries lesions, if all the decayed tissue is removed, there is a high risk of pulp exposure. The direct pulp capping does not present a good prognosis. An effective alternative to this treatment is the stepwise excavation technique. However, there is growing evidence that re-enter the cavity is not necessary. Nevertheless, there is no randomized clinical study in permanent teeth evaluating partial removal of carious dentine in one session.

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State of art of dentine caries removal

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Abstract

This study reviews the literature regarding complete caries removal, direct pulp capping, sealing, stepwise excavation, indirect pulp capping and ultraconservative removal of carious dentine. In the cavity bottom of lesions reaching dentine outer half, the common sense still is the complete caries removal (CCR). Even though the results of one long-term study that shows restorations survival rates similar to those found when CCR is applied. In deep caries lesions, if all the decayed tissue is removed, there is a high risk of pulp exposure. The direct pulp capping does not present a good prognosis. An effective alternative to this treatment is the stepwise excavation technique. However, there is growing evidence that re-enter the cavity is not necessary.

Key words – deep carious lesions, stepwise excavation, indirect pulp capping, dentine caries, direct pulp capping.

The dental caries results from a series of factors affecting the biofilm located on the tooth surface, e.g. salivary components, diet and oral hygiene habits. Once a caries lesion is established on the enamel surface, if no measures are taken to control the caries disease, this initial mineral loss can continue and invade the dentine.

A unique feature of dentin is that it is a mineralized tissue which surrounds the pulp, an unmineralized tissue. The dental pulp not only functions to provide nutritional and sensory properties to dentin, but also has its own reparative capacity. This potential has important implications for dental therapy

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(1). The most common defense reaction by the pulp-dentin complex is the deposition of mineral within the dentinal tubules, a process called tubular sclerosis (2-4). Dentine's tubular sclerosis is visible even before the lesion reaches the enamel-dentine junction (EDJ) (5). Once the lesion comes to contact the EDJ, a brown discoloration of the dentine is seen, and this is the first sign of dentine demineralization. The other important defense reaction of the pulp-dentine complex is the formation of reactionary dentine, which may occur before the bacterial invasion of the dentine (2, 6). The important feature of this response is that there is no cell renewal, the odontoblasts survive the injury. This is in contrast to reparative dentinogenesis, where the intensity of the injury is of a magnitude that results in odontoblast death and cell renewal by a new generation of odontoblast-like cells (7). The process of reactionary dentinogenesis involves upregulation of odontoblast activity, often in quiescent cells at the stage of physiological secondary dentinogenesis, in response to the injury stimulus.

The presence of bacteria in the dentine tissue can be seen even in lesions confined clinically to the enamel (8). However, once a cavity is formed, a significant bacterial invasion can be observed. At this moment, a so called zone of destruction is formed, presenting the most superficial part of the dentine decomposed. Beneath this zone, tubular invasion of bacteria is frequently seen. With the progression of the lesion, odontoblastic process are destroyed (dead tracts in the dentine), without having produced tubular sclerosis. The empty tubules are invaded by bacteria and this area is called zone of bacterial penetration. In the sclerotic dentine, a zone called translucent is formed, resulting from acid demineralization (9-12).

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The formation of a cavity is a very important moment clinically, because now the biofilm is protected within a microcavity, ad unless the patient is able to clean this area, the caries process will continue (13). If the removal and/or disturbance of the biofilm in the cavity are not possible, a need for a restorative procedure maybe established in order to arrest the caries lesion.

The operative treatment of dentine lesions

Once the need for a restorative treatment is determined, the first important aspect that should observed is the method chosen to remove the decayed tissue. In a more classic way, prior to the restoration procedure, all the carious tissue (hardness criteria) should be removed. This procedure should result in an environment presenting a low level of bacterial contamination and a more organized dentine, favoring the next step of the restoration procedure – the cavity filling. However, the complete removal of carious dentine does not lead to a sterile tissue. Studies using hardness criteria (14) or a dye to guide the carious dentine excavation (15) showed that bacterial contamination can still be detected after the cavity preparation was performed. This discussion assumes that the bacteria within the dentin are important. Nevertheless, several studies have suggested that the bacterial in the biofilm are the ones who matters, and that sealing the bacteria within the cavity and restoration of the tooth, allowing regular biofilm removal, is a reliable measure to stop the caries process (16).

In order to allow a more comprehensible reading, the discussion on dentine caries removal will be divided according to the lesion depth: shallow – lesion confined to dentine outer half; and deep – lesion reaching dentine inner half.

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a. Dentine caries removal in shallow lesions

a.1 Complete removal of carious dentine (CCR)

The complete caries removal in lesions confined to dentine outer half seems to be the traditional procedure prior to a restoration. The dentine removal is traditionally based on hardness criteria, and all the soft and disorganized tissue is removed, using dental burs and/or manual instruments. Other methods to guide and performed the removal of carious tissue are proposed. Caries-detector dyes, as acid red solution, were proposed as a method to detect the dentine tissue that needs to be removed (infected dentine) (17). However, studies have established that these dyes are not suitable to guide the dentist during the caries removal, once they act in non-specific proteins instead of bacteria (15, 18-19). As they stain the organic matrix of less mineralized dentin, including normal circumpulpal dentin and sound dentin in the area of the amelo-dentinal junction, their use could lead to unnecessary removal of sound tissue (20). Chemomechanical methods to remove the decayed tissue were also proposed, aiming reduction in pain during caries removal (21-24). Clinical trials comparing the chemomechanical method and the conventional rotary instruments technique showed that the chemomechanical method significantly reduced the need for local anesthesia (25-26). Longitudinal studies (follow up periods 1-6 years) did not observe influence of the caries removal method on the survival of the restorations (25, 27). The survival of the restorations placed using CCR is high (failure rate 1-2% per year) and present a variation according to the filling material used (amalgam or resin composite) (28).

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a.2 Sealing carious dentine

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All the alternatives presented below are proposed to teeth presenting sings of pulp sensibility and no signs of irreversible damage to the pulp.

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The complete removal of carious tissue in lesions reaching dentine inner half can lead to pulp exposure (32-33). If the pulp is exposed, the direct pulp capping technique can be considered in an attempt to preserve the vitality of the pulp and to stimulate it to produce a calcific barrier to wall off the exposure (34).

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Besides the pulp diagnosis, the success of the DPC will also depend on a number of factors, including the age of the patient, the material used and the event leading to the exposure.

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In some studies, the age is consider an important factor when it comes to deep caries lesions, because of the pulp cells being more active in younger teeth (37). However, the lack of influence of age the therapy success rate was found in longitudinal direct pulp capping studies (38-39).

In spite of the positive experience with calcium hydroxide, the contemporary literature supports many newer materials for pulp capping, such as dentin adhesives, mineral trioxide aggregate, collagen, chondroitin sulfate, caboxylate cement, tricalcium phosphate, α-Tricalcium phosphate, tetracalcium phosphate, hydroxylapatite, bioactive ceramics, enamel matrix proteins, various growth factors, etc. Except for mineral trioxide aggregate all of these materials show less promising results than calcium hydroxide and are not recommended for pulp capping routinely at this time (36)**.** Mineral trioxide aggregate (MTA) compared with the traditional material of calcium hydroxide, has superior long-term sealing ability and stimulates a higher quality and greater amount of reparative dentin (40). The clinical data available on MTA pulp capping of cariously exposed permanent teeth are limited. Farsi et al (2006) (41) studied 30 asymptomatic permanent molars with pulp exposures treated by pulp capping using MTA. At 24 months, the clinical and radiographic success rate was 93%. Bogen et al (2008) (42), in an observational study, accompanied 37 patients (49 teeth) treated with MTA after pulp exposure between one and nine years (mean 3.94 years) and showed an overall success rate of 97.96%. Therefore, it appears that this material may be the material of choice for future pulp caps. However, it should be stressed that these two clinical studies do not present a high level of evidence towards the use of MTA in direct pulp capping, once they do not present randomization procedures as well as a control group

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(43). Besides, problems associated with the material's difficult handling properties, prolonged setting time and cost may preclude its widespread acceptance despite its superior therapeutic properties (34).

The presence of carious dentine during the direct pulp capping is an important factor to be considering when studies with this treatment are evaluated. Al-Hiyasat, Barrieshi-Nusair, Al-Omari (2006) (38) showed an overall success rate for direct pulp capping of 59.3% after three years. However, the success rate was 92.2% with mechanical exposure and 33.3% with carious exposure. The authors' conclusion was: "Direct pulp capping is recommended after mechanical exposure with immediate placement of permanent restoration, while root canal therapy would be the choice of treatment if the exposure was due to caries". A retrospective study evaluated the treatment outcome of pulp capping of caries exposure after 5 and 10 years. After 5 years, the failure rate was 44.5%, and after 10 years, 79.7% of the teeth presented necrosis and suffered a postoperative root canal treatment or an extraction (44).

In order to avoid pulp exposure and to preserve as much dental tissue as possible, a more conservative technique of carious tissue removal was proposed, called the stepwise excavation (32, 45-47).

b.1.2 The stepwise excavation

The stepwise excavation technique (SW) is considered a technique in which a complete caries removal is performed in two steps. It consists of partial removal of the decayed tissue at the bottom of the cavity, temporary sealing for 4 weeks to 12 months and then re-open the cavity, fully removal of carious tissue and restoration (32, 45). How much tissue remained over the pulp is not

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well defined in the literature. Some authors excavated as close as possible to the pulp, leaving a thin layer of residual caries (32, 45). In other studies, a more conservative approach is applied (less invasive stepwise excavation) leaving a more thick layer of carious dentine (46, 48). The objective of the first excavation is to change the caries environment and not to remove as much carious dentin, eventually reaching the residual level close to the dentin-pulp interface (49). The aim of the SW procedure is to allow the occurrence of physiological reactions in the pulp-dentine complex represented by dentine sclerosis and tertiary dentine formation. During the 1-12 months of temporary sealing, it is expect that the carious dentine left become harder and dry, both characteristics of inactive lesions, presenting a low level of bacterial infection (32, 46, 48, 50-52), ensuring protection to pulp tissue on the re-entry, avoiding pulp exposure. The material used directly over the remained dentine (base material) do not appears to be an important issue regarding treatment success or dentine modifications (50, 53-55). Studies had demonstrated that this treatment can achieve a high level of success (32-33, 47, 56). Orhan, Ozcelik and Orhan (2008) (14) compared one-visit indirect pulp treatment (IPT), two-visit IPT (SW) and direct complete excavation (DCE) in deciduous and young permanent molars regarding microbial contamination. The results showed a significant reduction in bacterial counts after the sealing period (3 months) in all teeth submitted to SW. No significant differences were observed between the bacterial count found right after the temporary removal and the final excavation. In the DCE group, although the caries was completely removed until hard dentin was reached at the cavity floor; bacterial growth was still detected in 25.6% of the dentin samples. No statistical difference was found between the bacterial

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counts (total CFU, MS, lactobacilli) of two-visit IPT after the final excavation and DCE ($p>0.05$). The disadvantages of SW are mainly the risk of pulp exposure during re-entering the cavity (14, 33, 47), the failure of the temporary filling (51) and the cost (need of two sessions to complete the treatment). Also, some patients may never return to the second appointment, once their pain problem is solved.

b.2 Partial removal of carious dentine

b.2.1. Indirect pulp capping (IPC)

The differences between the SW and the IPC are that the IPC procedure involves almost complete removal of the affected dentin, leaving a thin layer of demineralized dentin. Re-entry is not attempted. In contrast, the stepwise excavation technique involves reentry at varying intervals (49). This type of treatment is well describe in the literature in deciduous teeth or young permanent molars (14, 54, 57-59).The longest follow up study (4 years) shows a success rate of IPC in primary teeth of 88%-93% (54). There are no reports from long-term studies using IPC in the permanent dentition in deep caries lesions.

b.2.2. Ultraconservative removal of carious dentine

Maltz et al (2002) (60) proposed a more conservative technique of dentine excavation performed in one session. In this treatment, the decayed dentine is fully removed from the cavity walls, except at the bottom of the lesion, in which only the necrotic and disorganized dentine is removed. In this single-arm clinical trial, patients with deep caries lesions in permanent posterior teeth

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had been submitted to partial dentine removal and resin restoration in one session. A series of publications (60-63) have showed that the partial removal of caries dentine in deep lesions is a viable alternative to preserve dental vitality. After 10 years of follow-up, the overall success rate was 62%. Radiographically, there was an increase in radiopacity of the carious dentine left at the bottom of the cavity, indicating a possible mineral gain during time (61). The number of microorganisms also reduced after sealing the cavity, reaching the levels usually encountered in cavities where all the carious tissue was removed according to hardness criteria in both deciduous and permanent dentition (14, 64).

Conclusions

Prior to perform a restorative treatment, carious tissue needs to be completely removed from the cavity walls according to hardness criteria. In the cavity bottom of lesions reaching dentine outer half, the common sense still is the complete caries removal (CCR). Even though the results of one long-term study that shows restorations survival rates similar to those found when CCR is applied. In deep caries lesions, if all the decayed tissue is removed, there is a high risk of pulp exposure. The direct pulp capping does not present a good prognosis. An effective alternative to this treatment is the stepwise excavation technique. However, there is growing evidence that re-enter the cavity is not necessary. Nevertheless, there is no randomized clinical study in permanent teeth evaluating partial removal of carious dentine in one session.

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Partial removal of carious dentine: a multicenter, randomized, controlled trial - 6 – 18 months results.

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Abstract

Objective: The aim of this multicenter, randomized, controlled, clinical trial is to evaluate the effectiveness of an alternative treatment for deep caries lesions in Health Services in Brazil. The treatment consists of partial removal of carious dentine followed by restoration in one session. Methods: Inclusion criteria: patients with ≥ nine years old, permanent molars with deep caries lesions and absence of periapical alterations, pulp sensibility; absence of spontaneous pain; negative percussion test. The subjects were assigned to: test-group - partial removal of carious dentine (PDR) and restoration, and control-group - stepwise excavation (SW). SW consists of partial removal of carious tissue, indirect pulp capping with calcium hydroxide cement; temporary filling; cavity re-opening after 60 days, removal of the remaining soft carious tissue and filling. The radiological exams were performed annually. Outcomes were defined as pulp sensitivity to cold test and absence of periapical alterations. The data were submitted to Kaplan-Meier, Log-rank test and logistic regression analysis, $p<0.05$. Results: There were performed 299 treatments, 146 SW and 153 PDR. There were no differences between the groups regarding baseline characteristics (age, gender and family income). After one year, 180 evaluations had been performed, showing 97.9% and 74.1% of success in PDR and SW groups ($p<0.000$). Reasons for failures were: PRC - 1 pulpitis, 1 osteitis; SW - 14 pulpitis, 6 necrosis, 1 tooth extraction and 1 tooth fracture. None of the baseline variables was significantly associated with the outcome. Conclusions: The maintenance of carious dentine does not interfere in the performance of the

restoration and in the pulp vitality. Partial caries removal could be performed as definitive treatment and the procedure of re-opening the cavity to remove the residual infected dentine is not necessary.

Key-words: dental caries; dentine; dental restoration; silver amalgam; resin composite; survival analysis.

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Partial removal of carious dentine: a multicenter, randomized, controlled trial – 6-18 months results.

Introduction

The management of deep caries lesions has been extensively discussed in the literature (1-10) These papers cover different subjects, including the appropriate instruments to remove the carious tissues, the amount of decayed tissue that needs to be remove (3) and yet the interaction between pulp and dentine(8, 11-12).

In order to preserve the dental structure as much as possible and also to avoid irreversible damages to the pulp, some conservative techniques have been proposed concerning the carious dentine removal (1-5). (1-5). The stepwise excavation technique (SW) is one of them and consists of partial removal of the decayed tissue at the bottom of the cavity, temporary sealing for 1-6 months and then re-open the cavity, fully removal of carious tissue and restoration (1-3). During the time of temporary sealing, it is expect that the carious dentine left become harder and dry, both characteristics of inactive lesions, presenting a low level of bacterial infection. The aim of this procedure is to tallow the occurrence of physiological reactions in the pulp-dentine complex represented by dentine sclerosis and tertiary dentine formation (13-14), ensuring protection to pulp tissue on the re-entry, avoiding pulp exposure. Many studies had demonstrated that this treatment can achieve a high level of success (1, 3, 7). The disadvantages of SW are mainly the risk of pulp exposure during re-entering the cavity (1, 3, 7) , the failure of the temporary filling and the

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cost (need of two sessions to complete the treatment). Also, some patients may never return to the second appointment, once their pain problem is solved.

Furthermore, if all the decayed tissue is removed in a deep carious lesion and the pulp is exposed, a very common treatment applied is the direct pulp capping. A retrospective study evaluated the treatment outcome of pulp capped teeth after 5 and 10 years and showed that 79.7% of the teeth presented necrosis and suffered a postoperative root canal treatment or an extraction after 10 years (15).

In order to solve these problems, it has been proposed that a definitive restoration should be placed at the same session in which the partial caries removal is performed (4, 16-20). This series of publications have showed that the partial removal of caries dentine in deep lesions is a viable alternative to preserve dental vitality. In a single-arm clinical trial, patients with deep caries lesions in permanent posterior teeth had been submitted to partial dentine removal and resin restoration in one session (4). After 10 years of follow-up, the overall success rate was 62%. Radiographically, there was an increase in radiopacity of the carious dentine left at the bottom of the cavity, indicating a possible mineral gain during time (20). The number of microorganisms also reduced after sealing the cavity, reaching the levels usually encountered in cavities where all the carious tissue was removed according to hardness criteria (4, 21-23). In deciduous teeth, after indirect pulp capping, the increase in dentine hardness observed clinically could be also confirmed in vitro through microhardness test (24-25).

Ricketts et al (2006) (10), on a systematic review of the literature regarding conservative management of carious lesion, found that the SW

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presented clinical success. However, there is no controlled clinical trial performed in permanent teeth analyzing sealing of carious tissue in deep carious lesions. Considering all that, there is still at least one question that needs to be answered: is there a real need to re-open the cavity after partial excavation? The aim of this multicenter randomized controlled clinical trial is to evaluate the effectiveness of an alternative treatment for deep caries lesions in Public Health Services in Brazil (Porto Alegre and Brasilia). The alternative treatment consists of partial removal of carious dentine followed by restoration in a single session.

Material and methods

Study design (Figure 1):

This is a multicenter randomized controlled clinical trial (Registration number at www.clinicaltrials.gov NCT00887952).

The clinical treatment was carried out by 22 dentists and supervised by the main researches (MM, LMP, HM and JJJ) during two years. The centers evolved were located at the cities of Brasília (Federal District - FD), at the Center-East of Brazil, and Porto Alegre (Rio Grande do Sul - RS), at the South region. The RS center was the main responsible by the research. In the FD center, both sample selection and treatments were performed by ten dentists of the Brasilia University Hospital. In the RS center, the sample selection and treatments were performed by five dentists of the Federal Health Service, four dentists of the Municipal Health Service and three dentists (two post-graduate students and a clinician) of the Federal University of Rio Grande do Sul. All

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dentists were updated and trained before the beginning of the clinical procedures by two main researchers (MM and LMP).

The material used to perform the treatments, as well as the clinical files, was supplied by the RS center to all the execution centers, ensuring that they were all standardized.

Sample

The sample size calculation was based on a difference in percentage of success of stepwise excavation and partial removal of caries after a 5-year follow-up period, of 60.9% (Clarissa no ORCA) versus 82% (Elelnara) respectively, at an $\alpha = 5\%$ with a power of 90%. This resulted in the need for 76 restorations per treatment group. Taking into account a dropout rate of 40% after 2 years (Busnello et al, 2001), the number of restorations required was at least 114 restorations per group.

The sample selection was performed by two ways: the exam of the usual subjects attending to the services and the active search by individuals that may fulfill the inclusion criteria. The active search was carried out by the researchers in community programs, local schools and through newspaper and radio advertisement.

Inclusion-criteria

2. At the time of the treatment, the patients should have at least nine years old.
3. Permanent molars presenting primary deep caries lesion were included,

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as long as the complete caries removal could lead to pulp exposure;

4. Caries lesion reaching dentine inner half detected by radiographic exam;
5. Positive response to the cold test (-20ºC refrigerated gas - Aerojet, Rio de Janeiro, RJ, Brazil);
6. Absence of spontaneous pain;
7. Negative sensitivity to percussion;
8. Absence of periapical lesion accessed by radiographic exam;

Exclusion criteria

3 Subjects with general diseases affecting their caries experience were not included in the project.

4 Cuspal loss.

Study groups

The subjects were randomly assigned to test or control groups:

Test - partial removal of carious dentine plus restoration in one session (PDR);

Control – stepwise excavation (SW).

Each of these groups was divided according to the filling material: amalgam or resin composite.

Randomization and blinding procedures

The choice between test and control was done by raffle: the treatment group was written on a paper, numerated and kept on a dark flask. A person other than the dentist executing the treatment selected a paper from the dark

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flask at the appropriate moment (see clinical procedures). The filling material was determined at weekly basis, alternating in each execution center between amalgam and resin.

Blinding of the participants was not possible due to the fact that the treatments needed a different number of appointments. Blinding of the operators was done for the caries removal procedure (see Clinical procedures).

Clinical procedures

All procedures were carrying out under local anesthesia and rubber dam. The treatments were performed as follow:

4 access to the lesion using rotator instruments (if necessary);

5 completely removal of carious tissue from the cavity walls (hardness criteria) using low-speed metal burs and/or hand excavator;

6 careful removal of the soft carious tissue from the cavity floor by hand excavator;

7 cleaning with distilled water and drying with sterile filter paper;

8 group randomization - the randomization was done at this time in order to avoid possible influence in the amount of carious dentine removed.

If the tooth was assigned to PDR group:

5 cavity partially filled by glass ionomer cement (Vitro Fil, DFL, Rio de Janeiro, RJ, Brazil);

6 restoration using amalgam (SDI, Bayswater WA, Australia) or resin composite (Tetric EvoCeram + Excite + Total Etch, Ivoclar/Vivadent, Liechtenstein) using the incremental technique and following the instructions of the manufacturer.

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If the tooth was assigned to SW:

1. indirect pulp capping with calcium hydroxide cement (Dycal, Caulk/Dentsply, Rio de Janeiro, RJ, Brazil);
2. temporary filling with a modified zinc oxide-eugenol cement (IRM, Caulk/Dentsply, Rio de Janeiro, RJ, Brazil);
3. cavity re-opening after 60 days, removal of the remaining soft carious tissue;
4. restoration following the same procedures described to PDR group.

The time (minutes) used to perform each treatment was recorded.

Clinical and radiographic evaluations

Outcomes were defined as pulp sensitivity to cold test and absence of periapical alterations, assuming those parameters as indicators of pulp vitality. The treatment evaluation was performed in annual basis.

The radiological registrations were performed at the very beginning of the study (periapical and bite-wing radiography), during screening, right after the treatment (bite-wing radiography) and annually (control visits, periapical radiography).

Clinical evaluation of the restorations was carried by trained dentists right after the treatment and then annually. The results from this evaluation will be published elsewhere.

As baseline characteristics, the following items were recorded: subjects' age, gender and family income. Regarding the treatment, the variables analyzed were surfaces evolved in the filling, time spent to complete the restoration and size of the cavity.

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All data were recorded at the clinical files and also via-web, using a digital system specially developed for the study (http://odonto.cityzoom.net).

Statistical data processing

Survival analyses were performed to estimate therapy success rate (Kaplan-Meier survival curves plus Log Rank test). The possible correlation between the variables recorded and the outcome was analyzed by logistic regression.

The significance level was set in 5% and the unit of analysis was the restoration.

All the analyses were made using Statistical Package for Social Science (SPSS) software, version 13.0.

Ethics

The study was approved by the Federal University of Rio Grande do Sul Ethics Committee, the Porto Alegre Municipal Ethics Committee, the Conceição Hospital Ethics Committee and the Brasilia University Hospital Ethics Committee. All participants signed an informed consent. All the dental needs presented by the subjects enrolled in this research were provided, except prosthetic rehabilitation and orthodontic treatment.

Results

There were performed 299 treatments, 146 SW and 153 tests. The participants were mainly adolescents studying in public schools. Regarding the socioeconomic status, most participants presented low family income. There

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were no differences between the groups regarding baseline characteristics - age, gender and family income (Table 1).

After one year of treatment performance, 180 restorations had been evaluated, showing 97.9% and 74.1% of success in test and control groups respectively. A significant difference was observed between the groups when the survival analysis was performed ($p<0.000$) (Figure 2). Reasons for failures were: PRC - 1 pulpitis, 1 osteitis; SW - 14 pulpitis, 6 necrosis, 1 tooth extraction, 1 tooth fracture. The reason for the tooth extraction is not clear, once it was performed by a dentist not enrolled in the research group.

During the performance of the SW four cases of pulp exposure were observed. Three cases were treated with direct pulp capping and one case received endodontic treatment right after the pulp exposure. After one year, two patients presented irreversible pulpitis and one patient maintained pulp sensitivity.

At the final model of logistic regression analysis, none of the variables included showed a significant causal influence on the success rate, besides the type of treatment (Table 2).

The time used to perform the treatments was different for all the groups. The PRC was the faster treatment performed, presenting 38.9% less time than the SW group (Table 3).

Discussion

In the present study, two treatments for deep carious lesions were tested: stepwise excavation and partial caries removal in one session. After one year of follow up, the results showed that the PRC was more effective than SW in

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preserving the pulp vitality. Also, age, gender, family income, filling material and number of surfaces of the restoration presented no correlation with the treatment success.

The stepwise excavation was choose to be the control treatment due to: (a) the possibility of avoiding pulp exposure, and (b) the high rate of success found in several studies when one is dealing with deep caries lesions (1, 3, 7). The alternative to the SW is the direct pulp capping, which has shown to be a much less safer choice to treat dentin lesions: success rate of 20% after 10 years of follow up (15). The presence of carious dentine during the direct pulp capping is an important factor to be considered when studies with this treatment are evaluated. Al-Hiyasat, Barrieshi-Nusair, Al-Omari (2006) (26) showed an overall success rate for direct pulp capping of 60% after three years, however, this rate decreases to 33.3% if the treatment was performed after carious exposure. The possibility to perform a complete removal of caries tissue and cause a pulp exposure was then consider not ethical. These facts lead the authors to consider, at the beginning of this study, the stepwise excavation as being the gold standard treatment for deep caries lesions.

It is important to stress that the present study is the first longitudinal randomized clinical trial in permanent teeth with deep caries lesions using a control group. The other studies found in the literature that performed partial removal of deep caries lesions were conduct without a proper control group (4) or in deciduous teeth (27).

After the regression analysis, there were no associations among the treatment success and the variables studied. Since after two years most studies, including this, show a high rate of success regarding restorative

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procedures, it seems natural that the number of surfaces evolved in the cavity or the filling material used did not present a positive relation to the success of the treatments. Alves et al (2010) (20) showed that after 18 months of follow up, there were no relation between the number of surfaces evolved and the success of the partial removal treatment. However, after ten years, all failure cases presented class II restorations, whereas from the 17 success cases, 12 presented class I restorations.

The age of the patients was also a non determinant factor to the outcome evaluated, once the failures had occurred in subjects with 9 to 53 years old. In some studies, the age is consider an important factor when it comes to deep caries lesions, because of the pulp cells being more active in younger teeth (28). However, in the present study, 13 failure cases were found in patients with <20 years old and 5 cases were found in patients with >20 years. Bjorndal and Thylstrup (1998) (3) performed stepwise excavations procedures in patients from 11 to 65 years of age and, after 1 year of follow up, presented no relation between chronological age and treatment success. The lack of influence of age in the final results was also found in longitudinal direct pulp capping studies (26, 29).

Bjorndal and Thylstrup (1998) (3) showed a 93.4% success of stepwise excavation in one year of follow up (including pulp exposures at the final excavation), a better result compared to this study – 74.1% of success after one year. From the 22 cases of failure in the SW group, 12 occurred in patients who did not return at the appropriate time to performed the second step of the treatment, leading to temporary filling failure, followed by pulp injury. The 97.9% of success after partial removal of carious dentine showed in the present study

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is in agreement with the results of Oliveira et al (2006) (17), which observed a success rate of 97% after 18 months of follow up after partial dentine removal in deep carious lesions.

Conclusion

Partial caries removal could be performed as definitive treatment and the procedure of re-opening the cavity to remove the residual infected dentine is not necessary. The maintenance of carious dentine does not interfere in the maintenance of pulp vitality. One year results showed that partial carious dentine removal and restoration – placed at same visit to the dentist – presented a higher rate of success compared to stepwise excavation.

Acknowledgment

Grants: CAPES, CNPq (403420/04-0) FAPERGS (04/1531-8). Financial support from industries: Ivoclar/Vivadent (Liechtenstein), DFL (Brazil), and SDI (Australia).

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Tables and figures

Figure 1. Study design.

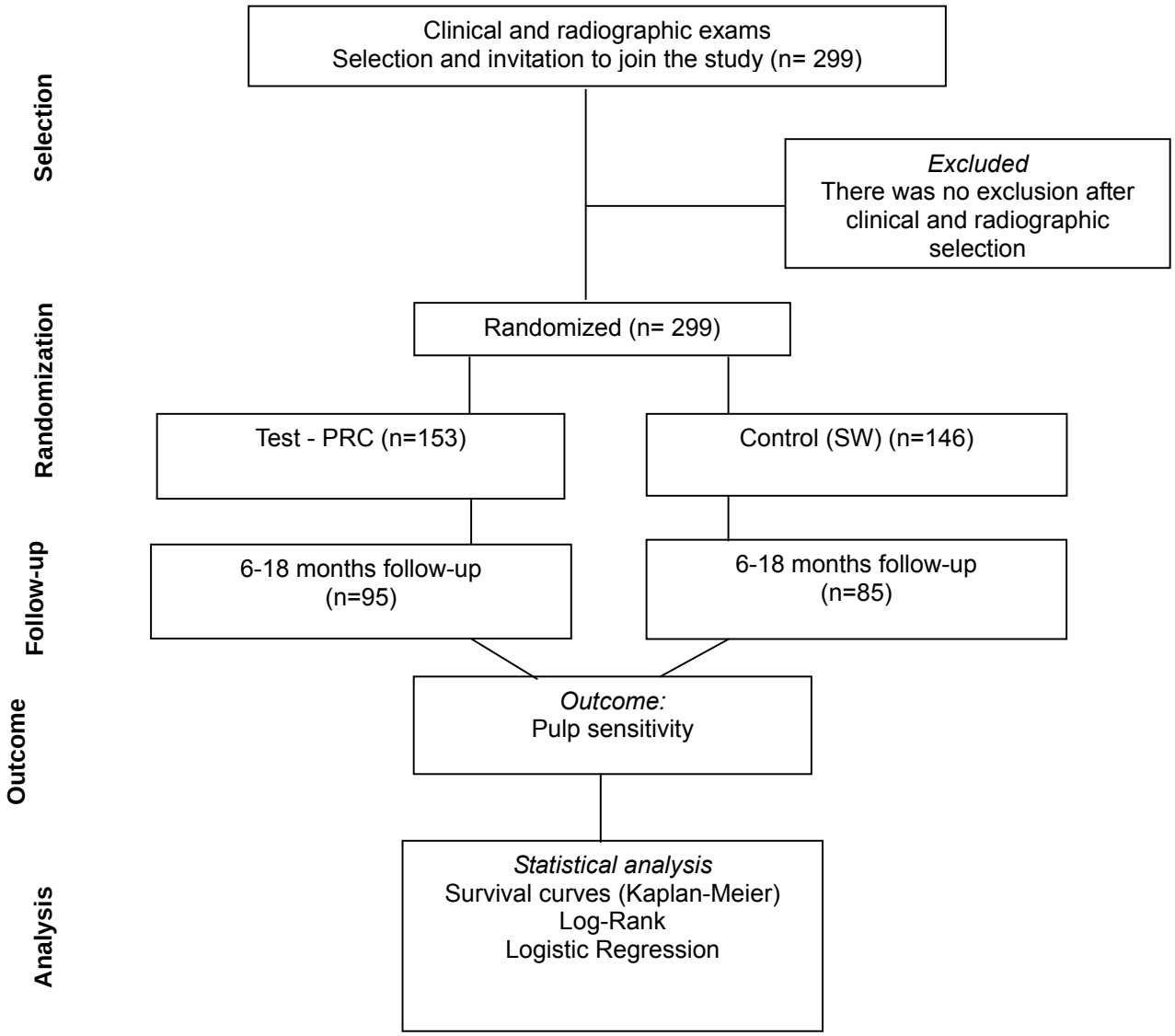

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Figure 2. Survival rates of the treatments regarding one year follow-up.

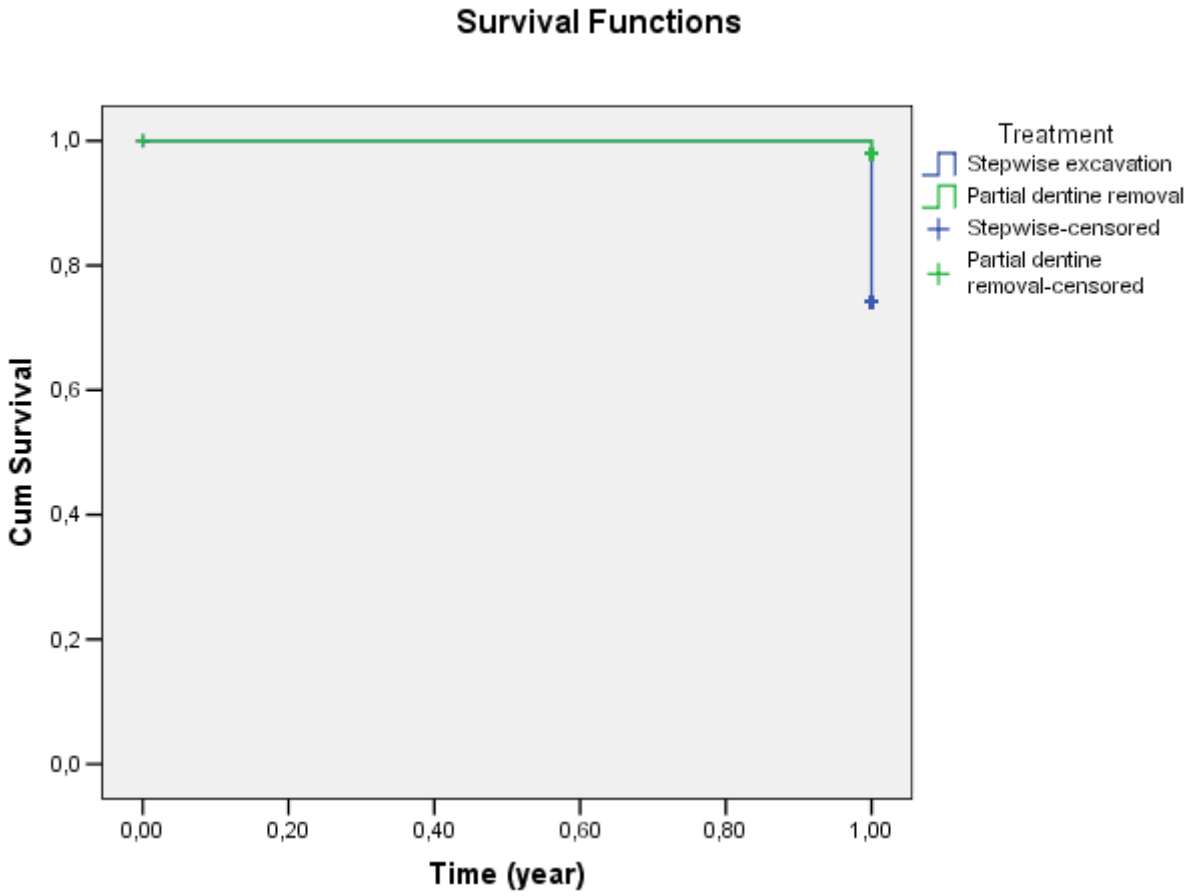

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Table 1. Subjects baseline characteristics according to treatments.

Group/ Variable	N	Age (years) mean±SD	Male	Female	Family income (R$) R$ 1 = US$ 1.75 Median (quartiles 75 and 25)
SW	146	16.6±7.5	56	90	600.00 (800.00-380.00)
PDR	153	16.3±7.2	54	99	600.00 (960.00-380.00)

There were no differences between the groups at baseline (p>0.05)

Table 2. Logistic regression analysis final model.

Variable	p	95% CI	
		Lower	Upper
Treatment	0.000	0.010	0.268
Filling material	0.423	0.503	5.142
Age	0.589	0.900	1.062
Gender	0.887	0.294	2.887
Number of surfaces	0.092	0.833	11.480
Size of the cavity	0.120	0.116	1.280
Family income	0.991	1.000	1.000

Table 3. Time used to perform the treatments according to groups and filling material.

Treatments	Time	
	Mean	SD
SW	78.3[a]	21.3
PDR	47.85[b]	15.4

Means followed by different letters are statically significant (p = 0,000)

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Partial caries removal in deep lesions: 19-30 months follow-up study.

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Abstract

The aim of this multicenter randomized controlled clinical trial was is to evaluate the effectiveness of an alternative approach for deep caries lesions in Brazil (Porto Alegre and Brasilia) after 2-year follow-up. The treatment consisted of partial caries removal followed by restoration in a single session (PDR). Inclusion criteria: patients with ≥ nine years old presenting permanent molars with primary deep lesion reaching inner half of dentine, absence of periapical alterations (radiographic exam), pulp sensitivity (cold test), absence of spontaneous pain and negative percussion test. The subjects were randomly assigned to test group - PDR, or control group - stepwise excavation (SW). SW consisted of partial removal of carious dentine, indirect pulp capping with calcium hydroxide cement, temporary filling, cavity re-opening after 60 days, removal of the remaining soft carious dentine and filling. Each group was divided according to the filling material: amalgam or resin. The outcomes were defined as pulp sensibility to cold test and absence of periapical alterations, assuming those parameters as indicators of pulp vitality. Clinical and radiographic evaluations were performed in annual basis. There were performed 299 treatments, 153 PDR and 146 SW. There were no differences between the groups regarding baseline characteristics (gender, age and family income. After 2 years of follow-up, 181 restorations were evaluated and the therapy survival rates of PDR and SW were 93.7% and 73.3%, respectively (p=0.000). Reasons for failure in the PDR were pulpitis (n=3), osteitis (n=1), hyperemia (n=2). In SW, failures occurred due to pulpitis (n=15), necrosis (n=6),

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extraction (n=1) and restoration fracture (n=1). None variable (gender, age, treatment, restorative material and number of restored surfaces) was significantly associated with the outcome. After 2-year follow-up, it is possible to conclude that the PDR is a more successful treatment than SW.

Key-words: dental caries; dentine; dental restoration; silver amalgam; resin composite; survival analysis.

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Introduction

The conventional treatment of deep caries lesions involves complete removal of carious dentine followed by tooth restoration. In this technique, there is a potential risk of iatrogenic pulp exposure making the course of the treatment less predictable. Alternative approaches have been proposed to preserve pulp sensibility, such as indirect pulp capping (1) and stepwise excavation (2). This latter method consists in the removal of decayed tissue in two steps, in which a layer of soft and humid dentine is left over the cavity floor and the tooth is temporarily filled at the first appointment. After variable time intervals (60 days – 6 months), the residual carious dentine is removed before the placement of the definitive restoration. The aim of this procedure is to allow the occurrence of physiological reactions in the pulp-dentine complex represented by dentine sclerosis and tertiary dentine formation (1, 3), ensuring protection to pulp tissue on the re-entry. Some studies had presented favorable results for this treatment (4, 5). However, disadvantages related to the need of reopening for further excavation have been described: the risk of pulp exposure during re-entering the cavity, the failure of the temporary filling leading to caries progression, the default of the patient at the second appointment and additional costs and discomfort to the patient.

Recently, the real need to re-enter the cavity has been questioned in the literature (6, 7), taking into account the evidences of caries arrestment after its isolation from the oral environment. Several studies have shown clinical, microhardness, radiographic and microbiological modifications at the carious dentine after its sealing: (a) clinical signs of darkening and hardening (5, 8, 9, 10), which was confirmed by microhardness measurements (11, 12); (b)

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radiographic increase of the mineral content (9, 13, 14) and (c) substantial reduction of bacterial contamination due to the lack of nutrition (8, 9, 10, 15, 16, 17, 18). On a long-term basis, a 10-year follow-up study showed the control of caries process by sealants placed on caries lesions restricted to the outer half of dentine, recording a success rate of 86% (19). Based on all evidences described above, it has been suggested that the partial caries removal technique and the placement of the definitive restoration can be done at a single appointment, eliminating the possible complications of the stepwise excavation (6, 7).

A series of publication derived from a single-arm clinical trial showed favorable results of the partial caries removal in deep lesions (9, 13, 14, 20). After 10 years of monitoring, the success rate was 63% (20). Despite the importance of this study due to its long-term follow-up period and low drop-out rate, the lack of a control group impedes the assessment of the effectiveness of this treatment, turning essential the development of randomized controlled clinical trials in this field.

The aim of the present study was to assess longitudinally patients with deep caries lesions submitted to partial caries removal after a period of 2-year regarding tooth sensibility.

Materials and Methods

This multicenter randomized controlled clinical trial (registration number at www.clinicaltrials.gov NCT00887952) was conducted with patients submitted to a conservative approach to treat deep caries lesions in the permanent dentition. Clinical procedures were carried out in the Federal University of Rio

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Grande do Sul, Faculty of Sciences Health of the University of Brasília and Public Health Services. This study was approved by the Ethics Committees of Federal University of Rio Grande do Sul and University of Brasília. All patients were included in a preventive/therapeutic program. They or their legal guardians signed a free informed consent.

The initial sample consisted of 299 permanent posterior teeth with deep caries lesion from 232 patients (9 - 53 years of age). The inclusion criteria were: radiographic image of caries lesion in the inner half of dentine, positive response to the cold test with -20º refrigerated gas (Aerojet, Rio de Janeiro, RJ, Brazil), negative sensitivity to percussion test, no history of spontaneous pain, radiographic absence of a periapical lesion and absence of cuspal loss.

The patients were randomly assigned by raffle to: (1) test group - partial caries removal and restoration in one appointment (PDR) and (2) control group - stepwise excavation (SW). The raffle was performed by an assistant during the clinical procedure. Each of the groups was divided according to the filling material, determined at weekly basis, alternating between amalgam and resin composite.

Clinical procedures

The patients were submitted to the following procedures: anesthesia and rubber dam isolation of the area to be treated; access to the affected area using rotator instruments, if necessary; complete removal of carious dentine from the surrounding cavity walls according to hardness criteria (rotator instruments and/or hand excavator); removal of the necrotic disorganized dentine from the cavity floor (hand excavator); washing of the cavity with distilled water; drying

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with sterile filter paper; group randomization. The tooth of the PCR received: partial filling of the cavity with glass ionomer cement (Vitro Fil, DFL, Rio de Janeiro, RJ, Brazil); restoration using amalgam (SDI, Bayswater WA, Australia) or resin composite (Tetric EvoCeram + Excite + Total Etch, Ivoclar/Vivadent, Liechtenstein). The tooth of the SE 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); cavity reopening after 60 days, followed by removal of the remaining decayed dentine and filling according to the same procedures described to PCR.

Clinic and radiographic evaluation

The treatment was evaluated after one and two years using the clinical and radiographic criteria. Pulp sensitivity was assessed by cold test and patients were asked about the occurrence of pain or sensitivity during percussion, assuming those parameters as indicators of pulp sensibility. Periapical and bitewing radiographs were taken to analyze the integrity of the periapical region and the area of carious dentine left under the restoration.

Statistical data processing

Survival analyses was performed to estimate therapy success rate at different time points (1-year and 2-year follow-up). The time to failure was displayed through Kaplan-Meier survival curves. Log-rank test was used to compare the experimental groups.

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Logistic regression analysis was used to investigate possible associations between dichotomous outcome variable (success vs. failure) and independent variables: treatment, number of restored surfaces, age and gender.

Qui-square test or Mann-Whitney test was used to compare patients followed-up after two years and patients lost to recall.

A p-value less lower than 0.05 was considered statistically significant.

Statistical analyses were conducted using the Statistical Package for Social Science (SPSS) software, version 13.0, for Windows.

Results

There were performed 299 treatments, 153 PDR and 146 SW. There were no differences between the groups regarding baseline characteristics: age, gender and family income ($p>0.05$). The number of evaluated teeth after 1 and 2 years follow-ups is shown in Table 1.

A total of 29 therapeutic failures were observed, 6 in the PCR and 23 in the control group. Reasons for failure in the PDR were pulpitis (n=3), osteitis (n=1), hyperemia (n=2). In SW, failures occurred due to pulpitis (n=15), necrosis (n=6), extraction (n=1) and restoration fracture (n=1). There is no information regarding the reason for the extraction in the SE.

The number of teeth evaluated after one and two years were 180 and 122, been the cumulative drop-out rate was 40%. There were no differences between the evaluated patients and those lost to recall regarding family income, gender, restorative material and number of restored surface. However, differences were found regarding age and treatment (Table 1).

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After 2 years of follow-up, therapy survival rates of PDR and SW were 93.7% and 73.3%, respectively (p=0.000) (Figure 1). The significant difference observed between the groups at the first year was maintained at the two year evaluation. The number of failures in the SW group was 22 in the first year, increasing to 23 at the second year. In the PDR, 2 failures were observed in the first year, increasing to 6 at the second year.

At the logistic regression analysis, there was none significant association among the variables age, gender, family income, restorative material, number of restored surfaces, and a significant association with treatment and the outcome (Table 2).

Discussion

PDR in deep caries lesions presented a higher success rate than the SW after two years.

The SW is the therapy presenting a longer maintenance of pulp vitality and tooth structure compared to complete caries removal. The complete caries removal leads to a higher rate of pulp exposure, which has worse pulp prognosis (21) . The present study shows that the PDR in one session present a higher success rate than SW.

The SW group (n=146) recorded 27 cases (18.5%) of no return of the patient to conclude the treatment in the second appointment, highlighting the difficulty of using this approach in the clinical practice. The failure of the temporary restoration may lead to caries progression and endodontic complications after a certain period of time. The dependence of patients' return to conclude the stepwise excavation, coupled with the lack of evidence of the

need of cavity reopening for final excavation suggest that the treatment in a single appointment may be preferable. Longitudinal clinical studies require patient collaboration to attending follow-up appointments. Of the 299 patients treated, 180 returned after one year and 122 after two years of the initial treatment. In order to assess the possible inclusion of a bias, patients who attended the 2-year follow-up were compared with those lost to recall. The two variables which were significantly different from one another were age and treatment. Age not seem to compromise our results, once it has no association with pulp prognosis regarding pulp conservative therapies (5, 22, 23). Regarding treatment, the stepwise excavation presented worse success rate, once this group presented the higher drop-out rate, not returning to complete the treatment. The maintenance of the temporary filling may lead to several negative results: fracture/loss of the temporary filling, fracture of the tooth structure, caries progression and, finally, irreversible damage to the pulp.

In conclusion, based on our findings, it is possible to state that the partial caries removal is a more successful therapy than stepwise excavation after two years. This result corroborate previous studies suggesting that it is unnecessary to completely remove carious dentine prior to a restoration in order to maintain pulp sensibility.

Acknowledgments

We thank the support of National Coordination of Post-graduate Education (CAPES), Brazilian Ministry of Science and Technology through its agency National Council of Research (CNPq - Process number: 40.3420/04-0), Research Support Fund of Rio Grande do Sul (FAPERGS - Process number:

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Table 1. Subjects baseline characteristics according to the proportion of the evaluated patients and those lost to recall.

Variable	p
Gender	0.638
Age	0.029
Family income	0.146
Treatment	0.015
Restorative material	0.245
Number of restored surfaces	0.068

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Table 2. Logistic Regression Analysis final model

Variable	p	95% CI	
		Lower	Upper
Treatment	0.001	0.056	0.506
Filling material	0.355	0.573	4.731
Age	0.630	0.952	1.086
Gender	0.617	0.273	2.163
Number of surfaces	0.210	0.673	6.059
Size of the cavity	0.201	0.179	1.437
Family income	0.706	1.000	1.000

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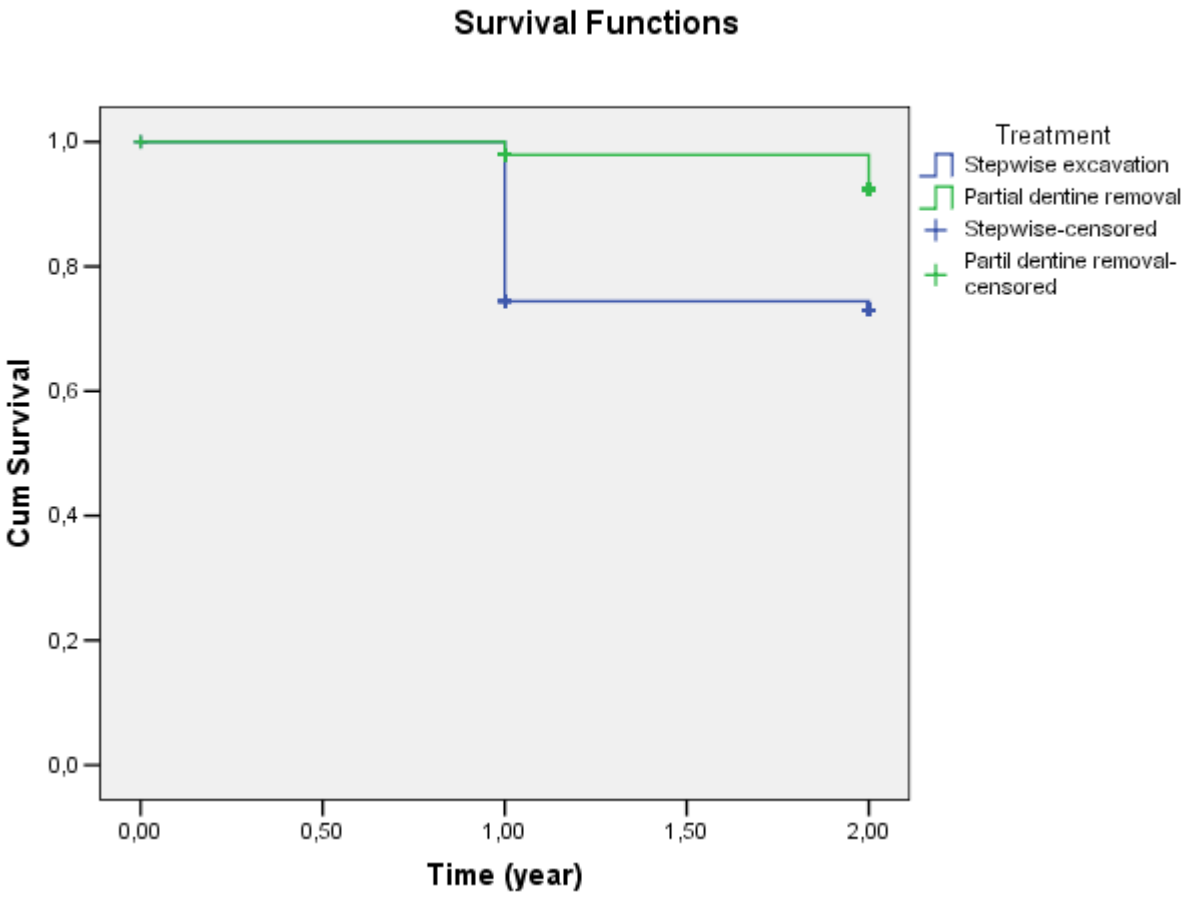
Figure 1. Survival analysis of treatments according to time (in year).



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Amalgam and resin composite restorations placed over decayed tissue in deep carious lesions – 19 - 30 months follow-up.

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Abstract

The aim of this study was to compare the clinical performance of amalgam and resin composite restorations placed in deep caries lesions with or without decayed tissue beneath them. This study used data collected in a multicenter randomized controlled clinical trial. The inclusion criteria were: patients aged > 9 years old, permanent molars presenting primary deep caries lesion (reaching dentine inner half detected by radiographic exam); positive response to the cold test (refrigerated gas); absence of spontaneous pain; negative sensitivity to percussion and absence of periapical lesion (radiographic exam). Patients presenting cuspal loss were excluded from the study. The subjects were to: Test - partial removal of carious dentine plus restoration in one session (PDR); or Control – stepwise excavation (SW). Each of these groups was divided according to the filling material: amalgam or resin composite. There were performed 299 treatments, 146 SW and 153 PDR, 122 amalgam restorations and 168 resin composite restorations. The treatment groups presented no differences regarding age (mainly adolescents), socioeconomic status (mainly low family income) and gender. After two year of follow-up, 181 restorations had been evaluated, 86 from the SW group and 95 from the PDR group; 65.8% were from the resin composite group and 34.2% were amalgam restorations. The majority of the restorations were placed in one tooth surface.The survival analysis of the treatment associated with the filling material showed no difference in the rate of success (p=0.564). Regarding the treatment, both groups presented a similar rate of success: SW=95.3% (4 failures) and

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PDR=94.7% (5 failures) (p=0.928). Resin composite restorations presented 96.8% of success and amalgam restorations presented 94.1% of success (p=0.446). The reason for failure was fracture of filling material. None of variables analyzed showed a significant causal association with the restorations survival. The presence of decayed tissue in deep caries lesions does not seem to interfere with the survival of the restorations. Also, the filling material – amalgam or resin composite – presented the same failure rates, despite the type of carious tissue removal technique used.

Key-words: dental caries; dentine; dental restoration; silver amalgam; resin composite; survival analysis.

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Introduction

Among the several stages of caries lesion development, when the demineralization process reaches dentine inner half, there is a need of restorative treatment. Prior to the filling material insertion, the removal of carious dentine is performed either partially or completely. If all the carious tissue is removed using harness criteria, there is a high risk of pulp exposure (1-2). In order to avoid it and to preserve as much dental structure as possible, the stepwise excavation became an alternative to be used, being a complete caries removal technique performed in two steps (2-3). Another possibility is the partial removal of carious dentine followed by restoration in one session (4-5).

Several studies were developed regarding the biological and clinical events evolved in the partial removal of carious dentine targeting pulp vitality and dentine reactions (3-13). However, just a few were conducted aiming the clinical characteristics of the fillings placed over decayed tissue.

In the permanent dentition, a 10 year follow-up study showed that amalgam restorations placed over decayed tissue presented rates of success similar to those obtained when complete caries removal is applied (14). However, the caries lesions assigned for this study were confined to dentine outer half. Maltz et al (2002) (4), performed a single-arm clinical trial, in which patients with deep caries lesions in posterior teeth had been submitted to partial dentine removal and resin composite restoration in one session. After 10 years of follow-up, the restorations survival rate was 80% (unpublished results). This result is similar to the one found in studies were complete caries removal is performed (15-23).

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The amount of carious tissue to be removed is only one aspect of the direct restoration procedure in deep carious lesions. The type of filling material to be used is also discussed, most of the studies varying between amalgam and resin composite (21). A greater need for aesthetics, the possibility to preserve more dental tissue and being metal free are some of the facts that had lead to choose and to improve resin composites for use in posterior teeth (24-26). Despite the improvement in the clinical performance and longevity of resin composite restorations placed in molars or premolars, the dental amalgam still presents higher rates of survival in a long-term basis (16, 23). The studies already published comparing amalgam versus resin composite in posterior teeth were performed using complete caries removal.

There is a lack of information regarding survival of restorations placed over decayed tissue in permanent dentition using a proper control group. The aim of this study was to compare the clinical performance of amalgam and resin composite restorations placed in deep caries lesions with or without decayed tissue beneath them. The risk factors that could be associated to restoration failure were also evaluated.

Materials and Methods

Study design

This study used data collected in a multicenter randomized controlled clinical trial (Registration number at www.clinicaltrials.gov NCT00887952).

Briefly, the study was carried out by 22 dentists during two years, evolving centers located at two Brazilian cities: Brasília (Federal District - FD)

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and Porto Alegre (Rio Grande do Sul – RS). The clinical procedures were performed at public health centers. Main researchers of each region (JJJ, MM, HDM, LMP) supervised the operators during treatments. The study was approved by the Ethics Committee of each center. All participants signed an informed consent. The patients had all their dental needs provided by the researchers, except prosthetic rehabilitation and orthodontic treatment.

Sample

Subjects attending to the public services, community programs and local schools, aged from 9 to 60 years and presenting good general health were enrolled to the study. The inclusion criteria were: permanent molars presenting primary deep caries lesion (reaching dentine inner half detected by radiographic exam); positive response to the cold test (refrigerated gas); absence of spontaneous pain; negative sensitivity to percussion and absence of periapical lesion (radiographic exam). Patients presenting cuspal loss were excluded from the study.

Study groups and randomization procedures

The subjects were randomly assigned to test or control groups: Test - partial removal of carious dentine plus restoration in one session (PDR); or Control – stepwise excavation (SW). Each of these groups was divided according to the filling material: amalgam or resin composite.

The randomization procedure was performed by raffle. The treatment group was printed on a paper, numerated and kept on a dark flask. A different person from the operator selected a paper from the dark flask at the appropriate

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moment (see clinical procedures). The filling material was determined at weekly basis, alternating in each execution center between amalgam and resin.

There were performed 299 treatments, 146 SW and 153 PDR, 122 amalgam restorations and 168 resin composite restorations. The treatment groups presented no differences regarding age (mainly adolescents), socioeconomic status (mainly low family income) and gender.

Clinical and evaluation procedures

The patients were submitted to the following procedures: anesthesia and rubber dam isolation of the area to be treated; access to the affected area using rotator instruments, if necessary; complete removal of carious dentine from the surrounding cavity walls according to hardness criteria (low-speed metal burs and/or hand excavator); removal of the necrotic disorganized dentine from the cavity floor (hand excavator); washing of the cavity with distilled water; drying with sterile filter paper; group randomization. The tooth of the PDR received: partial filling of the cavity with glass ionomer cement (Vitro Fil, DFL, Rio de Janeiro, RJ, Brazil); restoration using amalgam (SDI, Bayswater WA, Australia) or resin composite (Tetric EvoCeram + Excite + Total Etch, Ivoclar/Vivadent, Liechtenstein). In the resin composite restorations, the incremental technique was used. The tooth of the 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); cavity reopening after 60 days, followed by removal of the remaining decayed dentine and filling according to the same procedures described to PDR.

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Clinical evaluation of the restorations was carried by trained dentists right after the treatment and then annually. The restorations were recorded as (1) in function, (2) censored, if the patient dropped out of the study or (3) failed, if they were repaired or replaced or the tooth was indicated for extraction (27).

Subjects' age, gender, surfaces evolved in the filling and cavity size were recorded as baseline characteristics.

Statistical data processing

Survival analyses were performed to estimate therapy success rate (Kaplan-Meier survival curves and Log Rank Test). The possible correlation between the variables recorded (subjects' age, gender, surfaces evolved in the filling, pulp sensitivity and treatment group) and the outcome (restoration success) was analyzed by logistic regression.

The significance level was set in 5% and the unit of analysis was the restoration.

All the analyses were made using Statistical Package for Social Science (SPSS) software, version 13.0.

Results

After two year of follow-up, 181 restorations had been evaluated, 86 from the SW group and 95 from the PDR group. Regarding the filling material, 65.8% were from the resin composite group and 34.2% were amalgam restorations. The majority of the restorations were placed in one tooth surface (Table 1).

The survival analysis of the treatment associated with the filling material showed no difference in the rate of success (p=0.564) (Figure 1). Regarding the

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treatment, both groups presented a similar rate of success: SW=95.3% (4 failures) and PDR=94.7% (5 failures) (p=0.928). When the filling material was analyzed, resin composite restorations presented 96.8% of success and amalgam restorations presented 94.1% of success, showing no differences in the survival rate (p=0.446). The reason for failure was fracture of filling material.

None of variables analyzed showed a significant causal association with the restorations survival (Table 2).

Discussion

This study compared the performance of amalgam and resin composite restorations, placed in permanent molars with deep carious lesions after complete or partial removal of carious tissue. The two year follow-up showed that leaving dentine caries beneath the restoration and the filling material have no effect on the success of the restoration. Also, none of the variables studied (treatment, filling material, pulp sensitivity, age, gender, number of surfaces, size of the cavity and family income) configured a risk factor for the restorations survival rates.

The two-year follow-up showed that leaving dentine caries beneath the restoration and the filling material have no effect on the success of the restoration. The survival rate of the restorations (amalgam + resin composite) placed after complete caries removal (SW: 95.3% success) is in accordance with the literature (15-23). Similar results were observed in the restorations placed over carious tissue (PDR: 94.7% success). This result, although not from

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a long-term basis, may lead to the suggestion that leaving decayed tissue at the cavity bottom does not compromise the restoration clinical performance.

In studies of one and two year of follow-up, both amalgam and resin composite restorations placed in posterior teeth showed high rates of success, similar to those found in the present study (20, 26, 28-30). The annual failure rate of the resin composite restorations in this study was 1.97% (range from 1.92% to 2.01%) and no differences were observed regarding the type of caries tissue removal (SW or PDR). This results are in agreement with those found by a meta-analysis of the clinical performance of restorative materials in posterior teeth, which showed an annual failure rate of 2.2% (range from 0% to 9%) for resin composite restorations (21). In the present study, the amalgam annual failure rate was 1.97% (range from 1.93 to 2.00%), in accordance with the results of a retrospective study that evaluated restorations for up to 11 years (31). The meta-analysis cited above (21) found a slightly higher annual failure rate for amalgam restorations: 3.0% (standard deviation 1.9%).

There was no difference between amalgam and resin composite restorations in this two years study. However, Collins et al (1998) (16), in an eight years study, showed that the failure rate of the composite restorations was approximately two to three times that of the control high copper amalgam restorations. Bernardo et al (2007) (23), analyzing restorations placed in posterior teeth for up to seven years, showed a annual failure rates ranged from 0.16 to 2.83 percent for amalgam restorations and from 0.94 to 9.43 percent for composite restorations, resulting a better performance of amalgam over composite restorations. Van Nieuwenhuysen JP et al (2003) (27) showed a longer survival rate for amalgam restorations (12.8 years) compared to resin

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composite restorations (7.8 years). These studies showed that this difference was accentuated in large restorations. All these results showed that the long-term evaluation is important when amalgam and resin are compared, as well as the number of surfaces included in the restoration. In the present study, most restorations were placed in one surface and were followed for two years and these could be the possible reasons for the lack of differences observed between amalgam and resin fillings.

The most frequent reasons for failures reported in clinical studies of composite and amalgam fillings are fracture of the restoration and secondary caries (27, 32). Brunthaler et al (2003) (32) showed that the main cause of failure for resin restorations may vary according to the time used to follow-up: evaluations performed up to 5 years presented fracture as the main cause of failure, whereas in evaluation from 6 to 17 years pointed secondary caries as principal reason for failure. Other studies also observed fracture as the main reason for failure in less than three years of follow-up as the present study (33-34).

Conclusions

This study showed that, after a two year follow-up period, the amount of decayed tissue removed in deep caries lesions does not seem to interfere with the survival of the restorations. Also, the filling material – amalgam or resin composite – presented the same failure rates, despite the type of carious tissue removal technique used.

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Tables and Figures

Table 1. Distribution of treatments and filling materials according to the number of surfaces included in the restoration (% within the treatment group and of total).

Treatment	Number of surfaces			Total
	1	2	3	
SW	76 (88.4%)	10 (11.6%)	0 (0.0%)	86 (47.5%)
PDR	79 (83.2%)	14 (14.7%)	2 (2.1%)	95 (52.5%)
Filling Material	**1**	**2**	**3**	**Total**

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Amalgam	52 (83.9%)	9 (14.5%)	1 (1.6%)	62 (34.2%)
Resin composite	103 (86.6%)	15 (12.6%)	1 (0.8%)	119 (65.8%)
Total	155 (85.6%)	24 (13.3%)	2 (1.1%)	181 (100%)

Table 2. Logistic Regression Analysis final model

Variable	p	95% CI	
		Lower	Upper
Treatment	0.505	0.077	3.524
Filling material	0.128	0.645	32.409
Pulp sensitivity	0.998	0.000	
Age	0.054	0.463	1.007
Gender	0.262	0.050	2.261
Number of surfaces	0.998	0.000	
Size of the cavity	0.175	0.039	1.806
Family income	0.158	0.995	1.001

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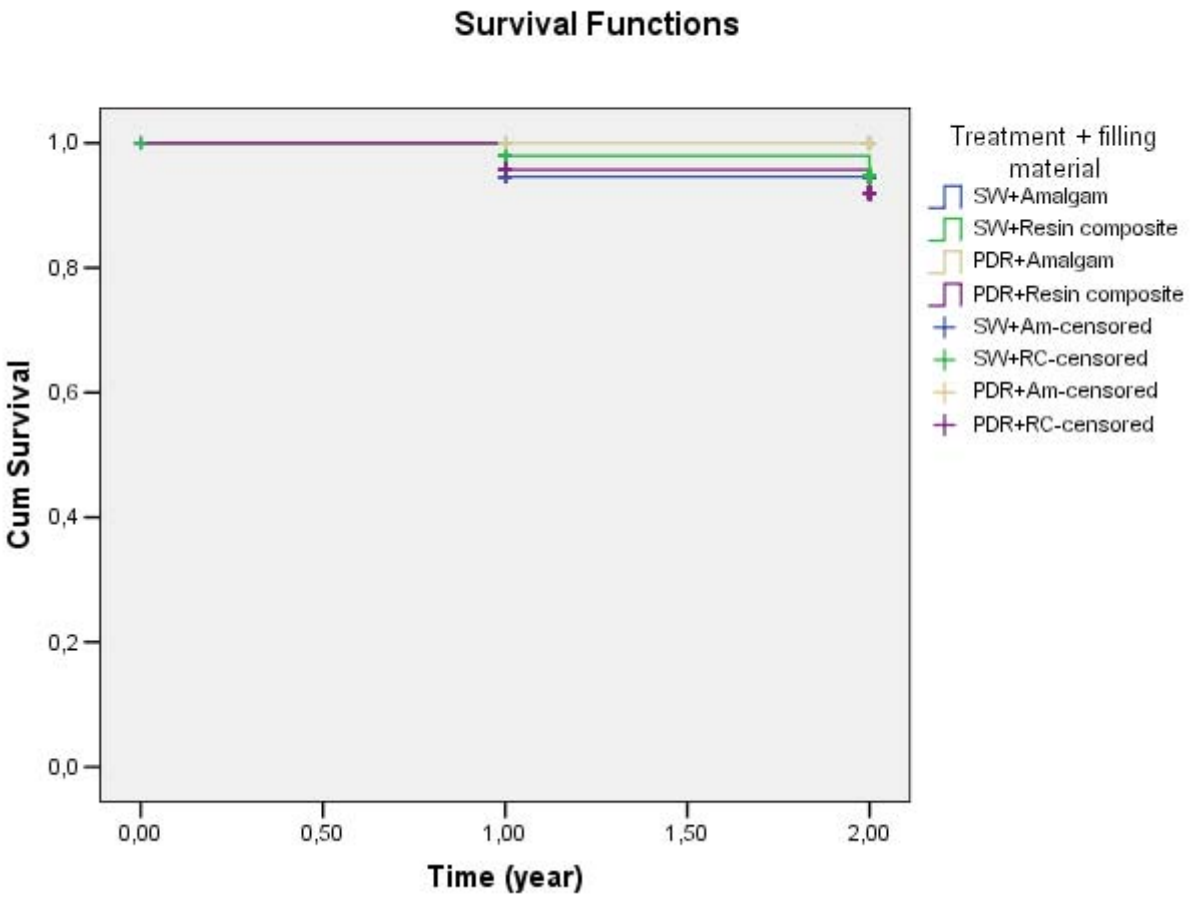
Figure 1. Survival rates of the restorations according to treatment group and filling material at two year follow-up.

- Short Communication -



Cost-effectiveness of partial removal of carious dentine in deep caries lesion in Brazil

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Abstract

In a previous study, two treatments for deep caries lesions in permanent molars were analyzed concerning therapy success rates after one year. The stepwise excavation technique (SW) was compared to partial removal of carious dentine in one session (PDR) in public health services in Brazil. In the present short communication, the previous study is complemented by a cost-effectiveness analysis. To determine the cost-effectiveness of the treatments, the discount cash flow method was adopted. After one year of treatment performance, 180 restorations had been evaluated, showing 97.9% and 74.1% of success in test and control groups respectively (p<0.000). The PDR provides and economy of 67.78 per treatment compared to SW. The overall economy in the annual cost of the public health center is 2.39%. In conclusion, performing the partial removal of carious dentine in one session, which presents higher rate of success and a high economic value, generates benefits for the public finances (direct economy), for the public health services (increase in number of treatments performed) and for the patients (comfort and time).

Methods:

In a multicenter randomized controlled clinical trial (Registration number at www.clinicaltrials.gov NCT00887952), the clinical treatments were carried out

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by 22 dentists and supervised by the main researches (MM, LMP, HM and JJJ) during one year. The centers evolved were located at the cities of Brasília (Federal District - FD), at the Center-East of Brazil, and Porto Alegre (Rio Grande do Sul - RS), at the South region. The subjects were randomly assigned to test or control groups: Test - partial removal of carious dentine plus restoration in one session (PDR), and Control – stepwise excavation (SW). Each of these groups was divided according to the filling material: amalgam or resin composite. Outcomes were defined as pulp sensitivity to cold test and absence of periapical alterations, assuming those parameters as indicators of pulp vitality. After one year of treatment performance, 180 restorations had been evaluated, showing 97.9% and 74.1% of success in test and control groups respectively. A significant difference was observed between the groups when the survival analysis was performed ($p<0.000$).

To determine the cost-effectiveness of the treatments, the discount cash flow method (DCF) was adopted. This is a method of valuing a project, company, or asset using the concepts of the time value of money. All future cash flows are estimated and discounted to give their present values – the sum of all future cash flows, both incoming and outgoing, is the net present value (NPV), which is taken as the value or price of the cash flows in question. Using DCF analysis to compute the NPV takes as input cash flows and a discount rate and gives as output a price. By far the most widely used method of discounting is exponential discounting, which values future cash flows as "how much money would have to be invested currently, at a given rate of return, to yield the cash flow in future". The value of an asset is the value of the future benefits it brings. The value of an investment is that cash flows that it will generate for the

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investor: interest payments, dividends, repayments, returns of capital, etc. (Financial Library). In the present study, a 12% annual discount rate was used.

The costs of the treatments were defined according to the charges published by the Federal Council of Odontology. The costs were expressed in the local currency (R$ 1 = US$ 1.76). The total cost of each treatment was calculated using the following parameters:

Filling material: silver amalgam. This is the most used filling material in the public health services which took part of the study.

X-ray exam: one periapical radiography (R$ 11.23) for the PDR group and two for the SW group (before and after temporary sealing).

Number of faces involved in the restoration: a mean cost of the treatments was calculated using the prevalence of the number of faces registered in the clinical study (1 surface 85.6%; 2 surfaces 13.3%; 3 surfaces 1.1%) to composed the final cost. Thus, the mean cost of an amalgam restoration was set as follow: one surface restoration costs R$ 47.91 multiplied by 0.86 + two surfaces R$ 59.32 multiplied by 0.13 + three surfaces R$ 68.48 multiplied by 0.01.

The cost of the failures for each group was added to the cost calculation according to the rates from the one year follow-up (2% of the cost for the PDR group and 26% for the SW group). The failure of the therapy was considered the lack of pulp vitality, so the cost of an endodontic treatment for molar teeth was used (R$ 366.52).

In the SW group, the cost of the temporary filling (R$ 36.85) was added to the final cost of the treatment reached for the PDR group.

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To calculate the economic value of the alternative treatment (PDR), a public health service unit composed by three dentists in four hour work shifts was used. The number of treatments performed per day was supposed to be eight per dentist, being a total of 528/month. The prevalence of deep caries lesions in permanent molars that fulfill the inclusion criteria of the study was set in 5%, using data from the study sample selection (528 patients/month, 22 days in a month, 1.2/day). The economy of the PDR was determined in daily, monthly and annual basis.

Results and Discussion

The mean total cost of the PDR is R$ 68.16 and the mean total cost of the SW is R$ 211.53, providing an economy of R$ 143.37 (67.78) per treatment. The daily economy of the PDR is R$ 172.05, generating an monthly economy of R$ 3,784.99 and an annual economy of R$ 45,419.93. The economic value of the PDR in a public health center (528 patients/month) using the DFG method is R$ 440.309,76 (discount rate 12% annual). The overall economy in the annual cost of the public health center is 2.39%. These results showed that PDR is a much more efficient treatment than SW after one year of follow-up.

In this cost-effectiveness analysis, the cost of the failure was considered the endodontic treatment followed by a direct restoration involving one surface. However, the economy generated using PDR could be even greater if one consider that other types of restorations are needed after an endodontic treatment, depending on the number of surfaces involved in the previous filling. For posterior teeth, full cuspal coverage, posts or crowns typically are indicated, as they provide resistance to fracture (Sorenson and Martinoff, 1984; Gelfand et

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al, 1984; Aquilino and Caplan, 2002; Manocci et al, 2002; Lynch et al, 2004). All those options are more expensive than a single surface amalgam restoration and should significantly increase the costs of the failures, improving the economy toward PDR treatment.

Besides, one should consider that using the PDR, an increase in the disposable time of the dentists is create, once the treatment is completed in one session instead of two (SW). As a result, the overall number of treatments performed in the public health center is increased, extending the services to a wider part of the population. The improvement in patient comfort and time should also be considered.

In conclusion, performing the partial removal of carious dentine in one session, which presents higher rate of success and a high economic value, generates benefits for the public finances (direct economy), for the public health services (increase in number of treatments performed) and for the patients (comfort and time).

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