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Detecção e manejo de lesões de cárie ao redor de restaurações

Juliana Lays Stolfo Uehara

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Orientador: Prof. Dr. Maximiliano Sérgio Cenci

Coorientador: Profa. Dra. Cácia Signori
Prof. Dr. Fausto Medeiros Mendes

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Banca examinadora:
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Profa. Dra. Tamires Timm Maske (Suplente)
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“Aí sim, lá na chegada, onde o fim é evidente,
é que a gente percebe que foi tudo de
repente, e aprende na despedida que o
sentido da vida é sempre seguir em frente.”
(Bráulio Bressa)

Resumo

UEHARA, Juliana Lays Stolfo. **Detecção e manejo de lesões de cárie ao redor de restaurações.** Orientador: Maximiliano Sérgio Cenci. 2020. 187f. Tese (Doutorado em Clínica Odontológica com ênfase em Dentística e Cariologia) – Faculdade de Odontologia, Universidade Federal de Pelotas, Pelotas, 2020.

O objetivo deste trabalho foi avaliar o impacto do uso de dois critérios visuais na detecção de lesões de cárie ao redor de restaurações. Foram utilizados neste estudo dois critérios para inspeção visual: o critério da Federação Dental Internacional (FDI) e o critério desenvolvido pelo Sistema Internacional de Controle e Classificação de Cárie, denominado CARS (Caries Associated with Restorations and Sealants). A presente tese baseia-se em um ensaio clínico randomizado que resultou em 3 estudos. O ensaio clínico foi delineado randomizado, triplamente cego e com dois grupos paralelos: (i) pacientes que receberam a avaliação das restaurações e indicação de tratamento de acordo com o FDI – grupo FDI, e (ii) pacientes que receberam avaliação e indicação de tratamento de acordo com o CARS – grupo CARS. Um examinador calibrado realizou as avaliações de acordo com o critério randomizado. Após o estabelecimento do plano de tratamento, os pacientes foram avaliados de acordo com o segundo critério para posterior análises. Os pacientes foram tratados segundo o plano estabelecido de acordo com o critério randomizado, e foram acompanhados durante por até 38 meses. O estudo 1 avaliou a influência dos dois critérios de diagnóstico na avaliação de lesões de cárie ao redor de restaurações e decisão de tratamento em dentes posteriores. Concluiu-se que o critério de avaliação utilizado influenciou na decisão de substituição ou não das restaurações. Ainda, o uso dos critérios da FDI resultou em uma abordagem menos conservadora comparada a abordagem do CARS. O estudo 2 avaliou a acurácia dos critérios da FDI e CARS na detecção de lesões de cárie ao redor de restaurações. O CARS apresentou acurácia superior aos critérios da FDI para a detecção de lesões de cárie ao redor de restaurações. Os critérios da FDI apresentaram maior chance de indução de sobretratamentos. Já o estudo 3 avaliou o efeito do uso dos dois critérios sob investigação na decisão de tratamento e longevidade das restaurações. As restaurações incluídas no ensaio clínico foram avaliadas quanto a necessidade de novas intervenções no período de até 36 meses. Concluiu-se que a utilização de um critério com abordagem mais conservadora (CARS) para a detecção de lesões de cárie ao redor de restaurações tem um efeito similar à longo prazo comparado com um critério menos conservador (FDI). Finalmente, a presente tese conclui que a escolha do critério para diagnosticar lesões de cárie ao redor de restaurações tem impacto direto na decisão de tratamento. Os critérios da FDI resultam em uma abordagem menos conservadora, com maior indicação de tratamentos restauradores. Ainda, é possível assegurar a qualidade e longevidade das restaurações com uma abordagem minimamente invasiva durante a avaliação de lesões de cárie ao redor das restaurações.

Palavras-chave: Cárie dentária. Detecção de cárie. Decisão de tratamento. Cárie secundária.

Abstract

UEHARA, Juliana Lays Stolfo. **Detection and management of caries lesions around restorations.** Advisor: Maximiliano Sérgio Cenci. 2020. 187f. Thesis (PhD in Dental Clinic - emphasis in Dentistry and Cariology) – Graduate Program in Dentistry. Federal University of Pelotas, Pelotas, 2020.

The study aim was to evaluate the impact of two visual criteria in the detection of caries lesions around restorations. Two visual criteria were used in this study: the International Dental Federation (FDI) criterion and the criterion developed by the International Caries Control and Classification System, called CARS (Caries Associated with Restorations and Sealants). The present thesis is based on a clinical trial that resulted in 3 studies. It was a randomized triple-blind, controlled trial with two parallel-groups: patients who received the assessment of the restorations and treatment decision according to the FDI (International Dental Federation) criteria - FDI group; and patients who received the assessment of the restorations and treatment decision according to the CARS - CARS group. A calibrated examiner performed the evaluations according to the randomized criterion. After establishing the treatment plan, patients were evaluated according to the second criterion for further analysis. Patients were treated according to the established plan according to the randomized criterion, and they were followed for up 38 months. The study 1 evaluated the influence of the two diagnostic criteria on the evaluation of caries lesions around restorations and treatment decisions on posterior teeth. It was concluded that the evaluation criteria used influenced on the decision of replacement or not the restorations. In addition, the use of the FDI criteria resulted in a less conservative approach compared to the CARS criteria. The study 2 evaluated the accuracy of the FDI and CARS criteria in detecting caries lesions around restorations. The CARS criteria were more accurate than the FDI criteria for detecting caries lesions around restorations. The FDI criteria were more likely to induce overtreatment. Yet, the study 3 evaluated the effect of using the two criteria under investigation on the treatment decision and longevity of the restorations. The restorations included in the clinical trial were assessed for the need for further interventions in the period of up to 36 months. It was concluded that the use of a criterion with a more conservative approach (CARS) for the detection of caries lesions around restorations has a similar effect in long term compared to a less conservative criterion (FDI). Finally, the present thesis concludes that the choice of the criterion to diagnose caries lesions around restorations has a direct impact on the treatment decision. The FDI criteria results in a less conservative approach, with a higher indication of restorative treatments. In addition, it is possible to ensure the quality and longevity of the restorations with a minimally invasive approach during the evaluation of caries lesions around the restorations.

Key-words: Dental caries. Caries detection. Treatment decision. Secondary caries.

Sumário

1 Introdução

A redução mundial da incidência da cárie dentária, através da fluoretação da água e do uso de dentifrícios fluoretados, (RUGG-GUNN; BÁNÓCZY, 2013) contradiz os achados de que as lesões de cárie secundária figuram entre as maiores causas de reintervenções restauradores na prática odontológica. A literatura aponta que junto às fraturas, as lesões de cárie secundária são as principais causas de falhas de restaurações, principalmente em dentes posteriores (BÜCHER et al., 2014; DEMARCO et al., 2012; VAN DE SANDE et al., 2013). A cárie secundária, também chamada de cárie ao redor de restaurações, cárie recorrente, cárie recidivante, cárie adjacente a restaurações e cárie associada a restaurações ou selantes, é uma lesão de cárie primária, localizada na margem de uma restauração preexistente, chamada de lesão externa (BÜCHER et al., 2014; KIDD, 2001). Além de atingir interface restauração/dente, pode se desenvolver como uma lesão de parede (KIDD; JOYSTON-BECHAL; BEIGHTON, 1995), relacionada com a infiltração e percolação de fluidos em situações extremas, principalmente associada a defeitos maiores na margem de uma restauração (HALS; SIMONSEN, 1972; KUPER et al., 2013). Essas lesões presentam as mesmas características clínicas e histológicas, tanto em dentina como em esmalte, que as lesões de cárie primária (MJOR, 2005). Sendo assim, devem ser motivo de preocupação diante de sinais claros de atividade da lesão.

Observa-se uma grande diferença entre a incidência de lesões de cárie secundária diagnosticadas em estudos baseados na prática clínica (ELTAHLAH et al., 2018; OPDAM et al., 2014) e em ensaios clínicos controlados (HEINTZE; ROUSSON, 2012; MONCADA et al., 2015). A alta incidência de cárie secundária diagnosticada na pratica clínica pode, talvez, ser explicada pelo diagnóstico incorreto de alguns sinais normais de deterioração das restaurações. Microinfiltração, manchamento marginal, alterações de cor nas margens das restaurações, presença de fendas ou gaps, cárie

residual ou remanescente, materiais forradores, entre outros, (BROUWER et al., 2016a; HEWLETT et al., 1993; KIDD, 1990; KIDD; JOYSTON-BECHAL; BEIGHTON, 1995; MJOR, 2005) muitas vezes são confundidos durante a inspeção visual e radiográfica com lesões de cárie secundária.

Sabe-se que restaurações não se mantém da mesma forma em boca como quando realizadas. É natural ocorrer deterioração do material restaurador, seja ele qual for, mantendo a função e estabilidade da mesma, sem necessidade de intervenções quando não há defeitos maiores. A literatura mostra a longevidade de restaurações posteriores bem estabelecida (ALCARAZ et al., 2014; ALHAREKY; TAVARES, 2016; DA ROSA RODOLPHO et al., 2011; MORASCHINI et al., 2015; OPDAM et al., 2010), porém também mostra que mais da metade dos procedimentos realizados nos consultórios são substituições de restaurações preexistentes, ou seja, reintervencões restauradoras (DELIGEORGI; MJÖR; WILSON, 2001; WILSON et al., 2016).

O diagnóstico das lesões de cárie secundária não é baseado em critérios clínicos objetivos, tornando o processo de diagnóstico subjetivo e muitas vezes com caráter demasiado intervencionista (BROUWER et al., 2016b). A prática intervencionista advinda do diagnóstico 'talvez excessivo' de lesões de cárie secundária, vai contra a tendência de mínima intervenção que visa evitar o processo do ciclo restaurador repetitivo que acarreta na perda e enfraquecimento da estrutura dental sadia e consequentemente na saúde do paciente (SHEIHAM, 2002; WILSON et al., 2016). Há um aumento da evidência para ações como monitoramento e intervenções menos invasivas como acabamento, polimento ou reparo de restaurações no lugar de substituições de restaurações antigas atingidas por pequenos defeitos clinicamente irrelevantes (ELTAHLAH et al., 2018; WILSON et al., 2016). Tratamentos conservadores preservam a estrutura dental sadia e podem aumentar a longevidade do complexo dente-restauração trazendo benefícios ao paciente (OPDAM et al., 2012).

Atualmente, o diagnóstico dessas lesões é realizado em sua maioria, através da inspeção visual, tátil e radiográfica. Outros métodos também estão disponíveis, como métodos de quantificação induzida por luz ou por laser de diodo (BRAGA et al., 2010; HAMISHAKI et al., 2014; ZOELLNER et al., 2002). No entanto, não há um critério de avaliação padrão bem estabelecido para essa finalidade e, ainda, há uma ampla disparidade de decisões diagnósticas e de tratamento entre os cirurgiões-

dentistas (ALOMARI et al., 2009), a qual pode ser atribuída à diversidade de critérios para a detecção de lesões de cárie disponíveis.

Somente a partir do diagnóstico é que a tomada de decisão sobre a necessidade de intervenção ou não é realizada. Desta forma, o diagnóstico adequado pode influenciar diretamente na longevidade das restaurações. Alguns critérios para a classificação das restaurações podem ser utilizados para determinar quando e como deve ser realizada a intervenção. O FDI (International Dental Federation) (HICKEL et al., 2010), proposto pela Federação Dental Internacional, é um sistema baseado em três esferas, sendo elas critérios estéticos, funcionais e propriedades biológicas. Cada uma dessas categorias é subdividida em subcategorias totalizando 16 aspectos a serem avaliados. Cada uma dessas subcategorias recebe uma pontuação de 1 a 5 para a restauração. Por se tratar de um processo extenso de avaliação por englobar diversos aspectos a serem avaliados, os autores propõem que este índice seja adaptado conforme a necessidade do estudo em que será empregado. Desta forma, os critérios mais adequados para cada estudo devem ser selecionados e não necessariamente, todos as subcategorias necessitarão de avaliação.

O CARS (Caries Associated with Restorations or Sealants) (PITTS; EKSTRAND, 2013) advém do Sistema Internacional de Detecção e Avaliação de Cáries (ICDAS), criado pelo Sistema Internacional de Classificação e Gerenciamento de Cárie (ICCMS), agora recentemente atualizado para CariesCare 4D (MARTIGNON et al., 2019). O CARS utiliza o mesmo sistema de classificação utilizado pelo ICDAS, ou seja, a superfície dental é avaliada de 0 a 6, onde 0 constitui uma superfície hígida, e 6 caracteriza uma superfície cavitada, com dentina aparente, sendo que a cavitação atinge mais de 50% da superfície. Ainda, além da pontuação, é atribuída à superfície, uma classificação quanto à atividade da lesão.

Muitos estudos relacionavam a qualidade e longevidade das restaurações com o material utilizado e fatores relacionados a técnica restauradora, porém estudos recentes tem demonstrado que desfechos centrados no paciente, como experiência de cárie, estresse oclusal e status socioeconômico, exercem mais influência sobre as restaurações comparados aos materiais que as compõem (DEMARCO et al., 2012, 2017; VAN DE SANDE et al., 2016, 2013). Ainda, existe o fator operador, pouco estudado, mas quando feito, geralmente está relacionado apenas com o nível de treinamento dos profissionais. Porém, se levado em conta a subjetividade do processo de tomada de decisões, muitos outros fatores podem estar relacionados, como

aspectos culturais, nível de apelo estético dos pacientes, tipo de serviço, entre outros (DEMARCO et al., 2017). Diferenças notáveis no tipo de intervenção recomendada podem ser encontradas mesmo entre profissionais com nível de treinamento semelhante (LASKE et al., 2016, 2019). Não obstante, a troca de profissional que ocorre em muitos casos, quando os pacientes acabam buscando atendimento em profissionais diferentes, comprovadamente contribui para maiores chances de intervenções desnecessárias (BURKE; LUCAROTTI, 2009; GORDAN et al., 2014).

A utilização dos critérios para avaliação das restaurações como CARS e FDI tem crescido e isto pode ser observado pelo número de estudos encontrados relacionados a este tema (EKSTRAND et al., 2018; MARQUILLIER et al., 2018). A acurácia desses métodos, na detecção de lesões de cárie ao redor de restaurações, também tem sido alvo de estudos (BROUWER et al., 2016b; SIGNORI et al., 2018). Um critério ter boa acurácia implica em uma melhor estratégia para diagnosticar uma condição desejada, com diagnóstico mais preciso e evitando casos falsos-positivos (MACASKILL et al., 2010).

Porém, a avaliação desses critérios relacionados a sua relação com a tomada de decisão e mais ainda, com a necessidade de intervenção ainda não foi estudada. Desta forma, este estudo teve como objetivo, por meio de um ensaio clínico randomizado:

1) Avaliar a influência que o critério de diagnóstico utilizado para detecção de lesões de cárie ao redor de restaurações (CARS e FDI), exerce sobre a necessidade de intervenções em restaurações posteriores em dentes permanentes;
2) Avaliar a acurácia da avaliação realizada pelos critérios CARS e FDI; e,
3) Avaliar o comportamento das restaurações após avaliação e tratamento quanto ao surgimento de falhas em um período de até 38 meses.

2 Projeto de Pesquisa[1]

O presente projeto será apresentado em formato de artigo no qual o protocolo do ensaio clínico será descrito.

Study protocol for a diagnostic randomized clinical trial to evaluate the effect of the use of two clinical criteria in the assessment of caries lesions around restorations in adults – the Caries Cognition and Identification in Adults (CaCIA) trial

Cácia Signori[1], Bruna Lorena Pereira Moro[2], Juliana Lays Stolfo Uehara[3], Vitor Romero Digmayer[4], Elenara Ferreira de Oliveira[5], Mariana Minatel Braga[6], Maximiliano Sérgio Cenci[7], Fausto Medeiros Mendes[8*], CaCIA collaborative group[9], CARDEC collaborative group[10]

[1] Federal University of Pelotas, Graduate Program in Dentistry, Pelotas, Rio Grande do Sul, Brazil. caciasignori@gmail.com

[2] Department of Pediatric Dentistry, School of Dentistry, University of São Paulo, São Paulo, Brazil. bruna.moro@usp.br

[3] Federal University of Pelotas, Graduate Program in Dentistry, Pelotas, Rio Grande do Sul, Brazil. juliana_lsu@yahoo.com.br

[4] Federal University of Pelotas, Graduate Program in Dentistry, Pelotas, Rio Grande do Sul, Brazil. vitordigmayer@gmail.com

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[5] Federal University of Pelotas, Graduate Program in Dentistry, Pelotas, Rio Grande do Sul, Brazil. f.elenara@gmail.com

[6] Department of Pediatric Dentistry, School of Dentistry, University of São Paulo, São Paulo, Brazil. mmbraga@usp.br.

[7] Federal University of Pelotas, Graduate Program in Dentistry, Pelotas, Rio Grande do Sul, Brazil. cencims@gmail.com

[8] Department of Pediatric Dentistry, School of Dentistry, University of São Paulo, São Paulo, Brazil. fmmendes@usp.br.

[9] Corporate author

[10] Corporate author. cardec.fo@usp.br

*Corresponding author:
Maximiliano Sergio Cenci
Federal University of Pelotas, School of Dentistry
Address: R. Lobo da Costa, 447
96010150, Pelotas-RS, Brazil
Phone./Fax: +55 53 3284 3140
E-mail: maximiliano.cenci@ufpel.edu.br

Abstract

Background: The assessment of restored teeth in dentistry remains a challenge, mainly related to the detection of caries around restorations. There is a diversity of clinical criteria available to assess the caries lesions, which may result on differences on the diagnosis and treatment decision performed by the dentists. In addition, there is a lack of evidence regarding the best criteria to detect caries lesions around the restorations. Thus, the aim of the present protocol will be to evaluate the effect of the use of 2 visual criteria for the assessments of restored teeth on the outcomes related to the oral health in adults.

Methods: The design protocol of CaCIA (Caries Cognition and Identification in Adults) trial correspond to a triple-blind randomized, controlled clinical trial with parallel-groups. Two groups will be compared: patients who will receive the diagnosis and treatment decision according to FDI (World Dental federation) criteria - FDI group; and patients who will receive diagnosis and treatment decision according to the "Caries Associated with Restorations or Sealants" (CARS) criteria defined by the International Caries Classification and Management System (ICCMS group). The participants will be followed up after 6, 12, 18, 24 and 60 months. The restoration failure will be the primary outcome. The analysis will be conducted through Cox regression with shared frailty. The impact of oral health on quality of life and the cost-effectiveness of the methods used will be the secondary outcomes. Two-tailed analyzes will be used, considering a level of significance of 5%.

Discussion: This is the first clinical trial to assess the effect of the use of two visual methods for the detection of caries lesions around restorations on the outcomes related to oral health in adults. The findings of this study will define what is the best diagnostic strategy for the assessment of caries around restorations in permanent teeth.

Trial registrations: NCT03108586 (registered 11 April 2017).

Keywords: Caries detection, dental caries, restorations, secondary caries, caries around restorations, diagnosis, visual inspection, dental treatment, randomized clinical trial.

Background

Secondary caries was recognized as one of the conditions on dentistry of highest potential for improvement of future restorative treatment over the next 20 years [1]. Secondary caries is the designation given to a caries lesion adjacent to a restoration [2]. This condition is reported by the scientific literature as the main reason for restorations failures [2–5]. A recent review reported that the replacement of failed restorations due to secondary caries represents a high number of the restorations placed by the dentists (28.5-59% of cases). In contrast, the number of failed restorations due to secondary caries is notedly lower (2-3%) in controlled clinical trials [3,4], which raise doubts about the real prevalence of this condition and possibility of overtreatment. In addition, the dentists show heterogeneity on the treatment decision-making regarding secondary caries [6,7].

The correct diagnosis of caries around the restorations is often a challenge for dentists due to aspects as the presence of gaps between the restoration and tooth surface, marginal staining and due to the development on difficult areas of assessment, such as interproximal areas [8]. Some of these aspects can lead to an erroneous detection of caries lesion [9,10]. Different clinical criteria has been used in the visual detection of caries around restorations [11], which may imply different interpretations about what is a secondary caries lesion. Among these criteria two are highlighted due to the current use in research and clinic: the International Dental Federation (FDI) criteria [12] and CARS (Caries Associated with Restorations or Sealants) criteria, described in the International Caries Classification and Management System (ICCMS) [13].

Nevertheless, all studies on methods for caries detection around restorations are cross-sectional accuracy studies [11,14]. Moreover, the majority of studies fails to present clinical relevance and report of patient-centered outcomes [11]. No randomized clinical trial has been conducted so far to test the best method to detect caries around restorations. Thus, we will do a randomized clinical trial to investigate the best approach related to the diagnosis and decision of treatment of restorations in adults. The aim of the present protocol will be to evaluate the effect of the use of 2 visual criteria, FDI and CARS criteria, for the assessments of restored teeth on the outcomes related to oral health in adults.

Methods

Trial design

This is a triple-blind randomized, controlled, parallel-group clinical trial. Two groups will be compared: patients who will receive the diagnosis and treatment decision according to FDI criteria [12] - FDI group; and patients who will receive diagnosis and treatment decision according to the "Caries Associated with Restorations or Sealants" (CARS) criteria from ICCMS [13] - ICCMS group. The trial - **Ca**ries **C**ognition and **I**dentification in **A**dults (CaCIA) trial - has been registered with ClinicalTrial.gov (NCT03108586) and is currently in the active phase. The Standard Protocol Items for Clinical Trials (SPIRIT) was used to guide the present protocol as detailed in online supplementary appendix (appendix 1).

Participants, interventions, and outcomes

Setting

The study will be conducted at the clinic at the School of Dentistry of Federal University of Pelotas (UFPel). The patients (18 to 60 years old) will be randomly selected from a list of patients who sought dental treatment at the School of Dentistry.

Eligibility: inclusion and exclusion criteria

The inclusion criteria will consider the following:

a) patients who seek dental treatment at the School of Dentistry;

b) are aged 18 to 60 years;

c) patients who present at least one restoration of composite resin or amalgam on a posterior permanent tooth.

The exclusion criteria will consider the following:

a) patients who refuse to participate of the research;

b) patients who present systemic conditions or chronic diseases that require differentiated care and follow-up. These cases will be referred to the specific services available at the School of Dentistry.

c) restorations on teeth with conditions as fistula, abscess, pulp exposure, history of spontaneous dental pain or mobility will not be included.

Interventions

Firstly, all patients' dental surfaces will be examined according to the International Caries Detection and Assessment System (ICDAS) [13]. Patients meeting the inclusion criteria will be classified into subgroups. The individuals will be classified according to caries experience using the DMF-T (decayed, missing, filled teeth) in 2 groups: index less or equal to 4, or index greater than 4; and also, according to the caries activity (with or without caries activity), for later block stratification.

In this first appointment, a questionnaire will be applied to assess the impact of oral health on the quality of life of adults. The instrument used will be the validated Brazilian version of the OHIP-14 (Oral Health Impact Profile-14) questionnaire [15].

The participants will be allocated into two groups (Figure 1) according to the strategy used to diagnose and determine the treatment for caries lesions around restorations.

a) FDI group: diagnosis and treatment decision based on the International Dental Federation (FDI) criteria (Figure 2).

b) Experimental group: diagnosis and treatment decision according to CARS (Caries Associated with Restorations or Sealants) detection criteria, described in the ICCMS (Figures 3 and 4).

Figure 1. Study process.

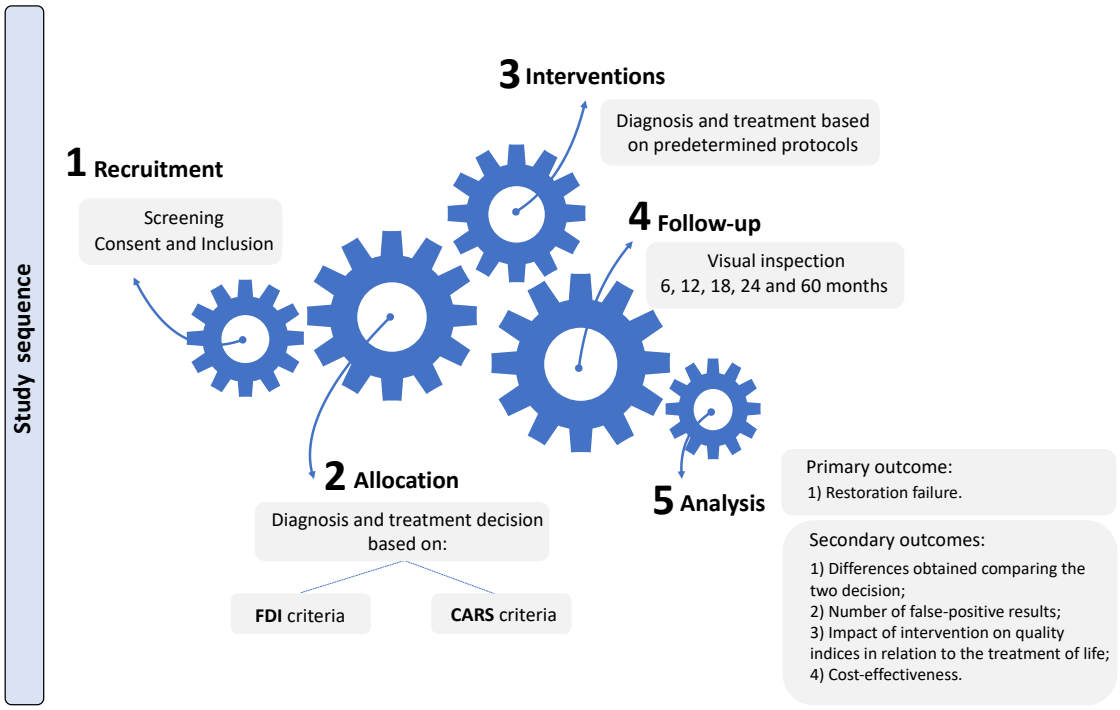
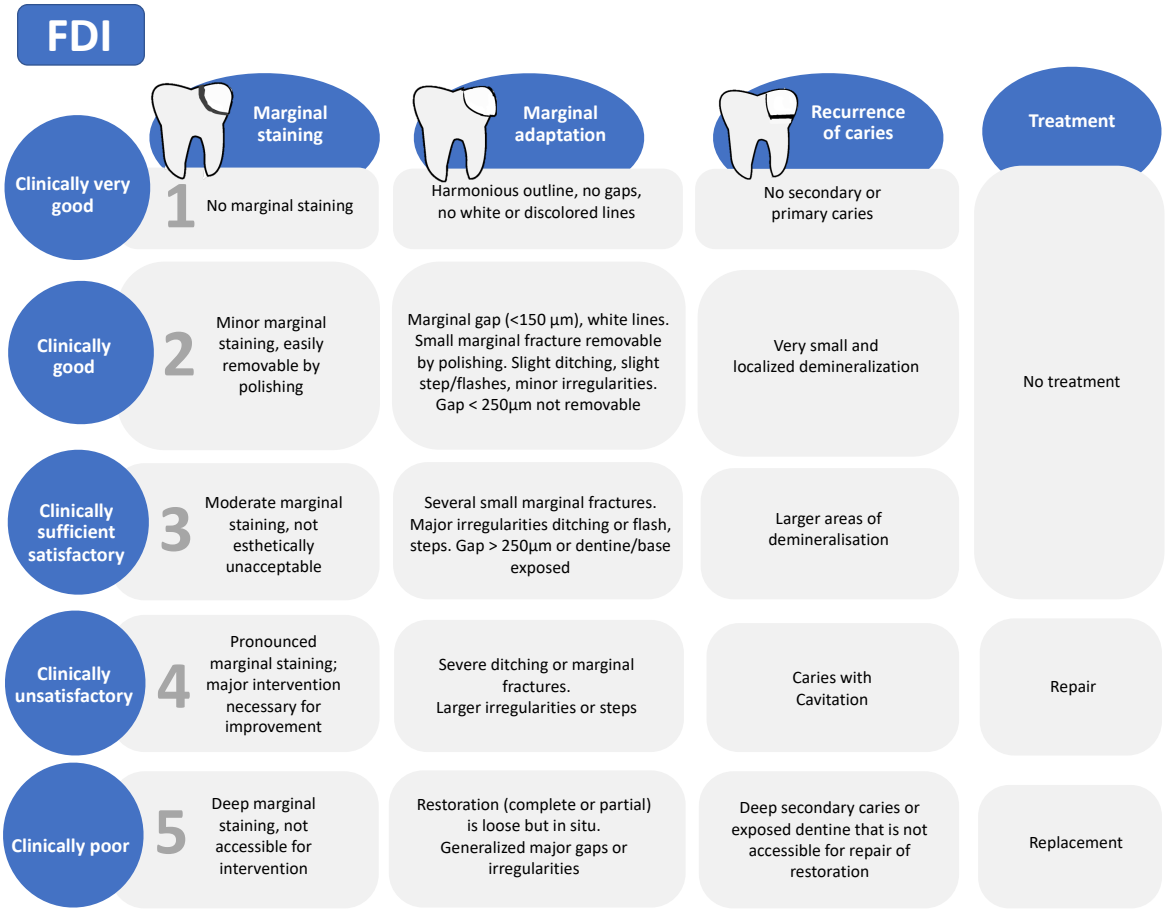


Figure 2. International Dental Federation (FDI) criterion linked to the treatment decision [12].

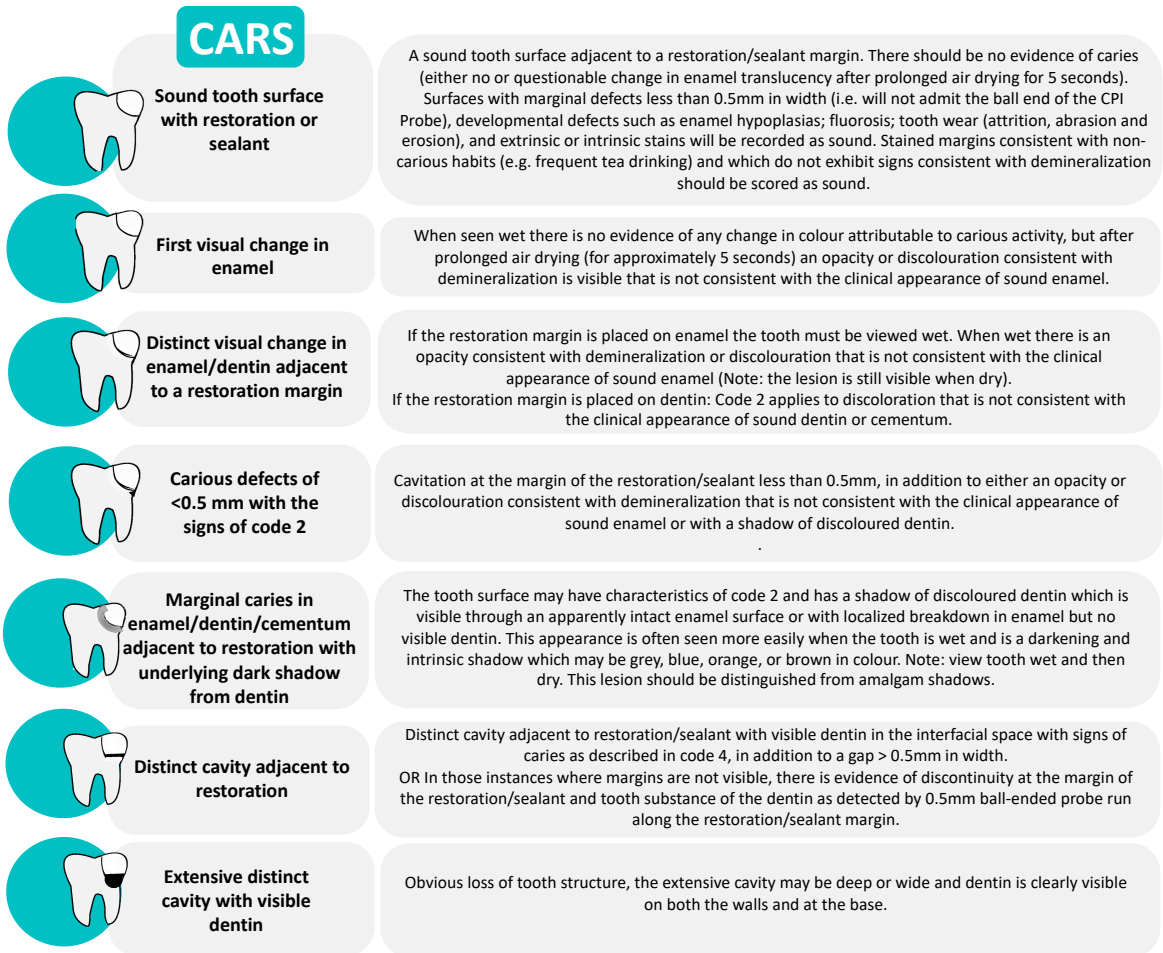


Clinical examination of the restorations will be performed by a calibrated examiner. The calibration was performed in two phases. In phase I a series of photos on restorations with marginal defects were projected in a television in a dark room for the examiner and one expert in restorative dentistry with training and experience in the diagnosis of restorations (gold standard). The discussion of the cases was performed. The phase II was performed at the clinic, both examiner and gold standard examined a series of patients, attributing the diagnosis and treatment according to FDI and CARS for each case. The answers were compared in the end, and disagreements were discussed.

In the clinical trial, after the clinical examination, the calibrated examiner will establish the treatment plan, according to the treatment indications of the criteria in which the patients were allocated. The same examiner will re-evaluate the restorations according to the other criteria. However, this procedure will only serve to future

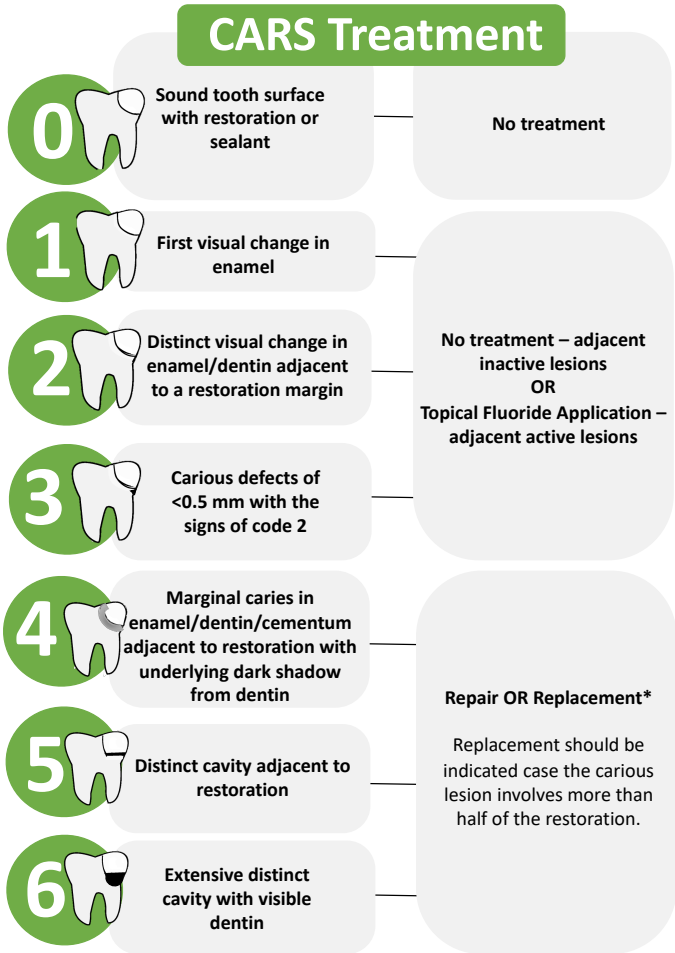
comparison among the methods. This new re-evaluation will not influence the classification and treatment proposed by the first criterion used.

Figure 3. Caries-Associated with Restorations and Sealants (CARS) Detection Criteria [13].



The tests will be conducted in a dental chair under lighting, after the teeth are cleaned with a low-rotation micromotor, rubber cup and Robinson brush using prophylactic paste. The exams will be performed with dental mirror and ball-point probe. For the assessment of the restorations of patients allocated in the FDI group, all surfaces will be dried prior to evaluation [12]. In the evaluation of the surfaces of the experimental group, the teeth will be evaluated wet and then dry for 5 seconds with the use of the triple syringe, according to the protocol established by the ICCMS [13].

Figure 4. Treatment decision linked to Caries Around Restorations System - CARS adapted.



Dental treatment protocols

The restorations, therefore, will be submitted to the proposed treatment according to the first evaluation performed. These treatments will be performed according to predefined protocols by operators blinded to the criterion used to reach the treatment decision.

In all situations, the carious tissue, if present, will be removed, as well as the dental restorations, when indicated.

Both repair and replacement of restorations will be performed following the adhesive protocol described by the manufacturer (Adper Scotchbond Multi-Purpose, 3M ESPE, USA) to the use on resin restorations. The conventional composite resin (Filtek Z350 XT, 3M ESPE, USA) will be inserted on the cavity using increments. Besides the proposed treatment for restorations, other necessary treatments for the patient will also be performed. Additional treatments (not involving

repairs/replacements) will be planned/ defined by the operator responsible for the initial clinical examination of the patient.

Follow-up visits

After completion of the treatment performed at the last restoration of each participant, they will return for evaluation of the outcomes after 6, 12, 18, 24 and 60 months.

The restorations will be evaluated through clinical inspection (mirror and ball point probe) by a previously calibrated examiner. The treatment needs will be established according to the demands of the patients. The examiner will be blind in relation to previous allocation groups and previously performed treatments. If the patient needs further treatment related or not to restorations, it will be performed.

The instrument OHIP-14 will be reapplied one week after the patients receive all the interventions needed, and at 24 months, and 60 months, to assess the impact on the quality of life in long-term.

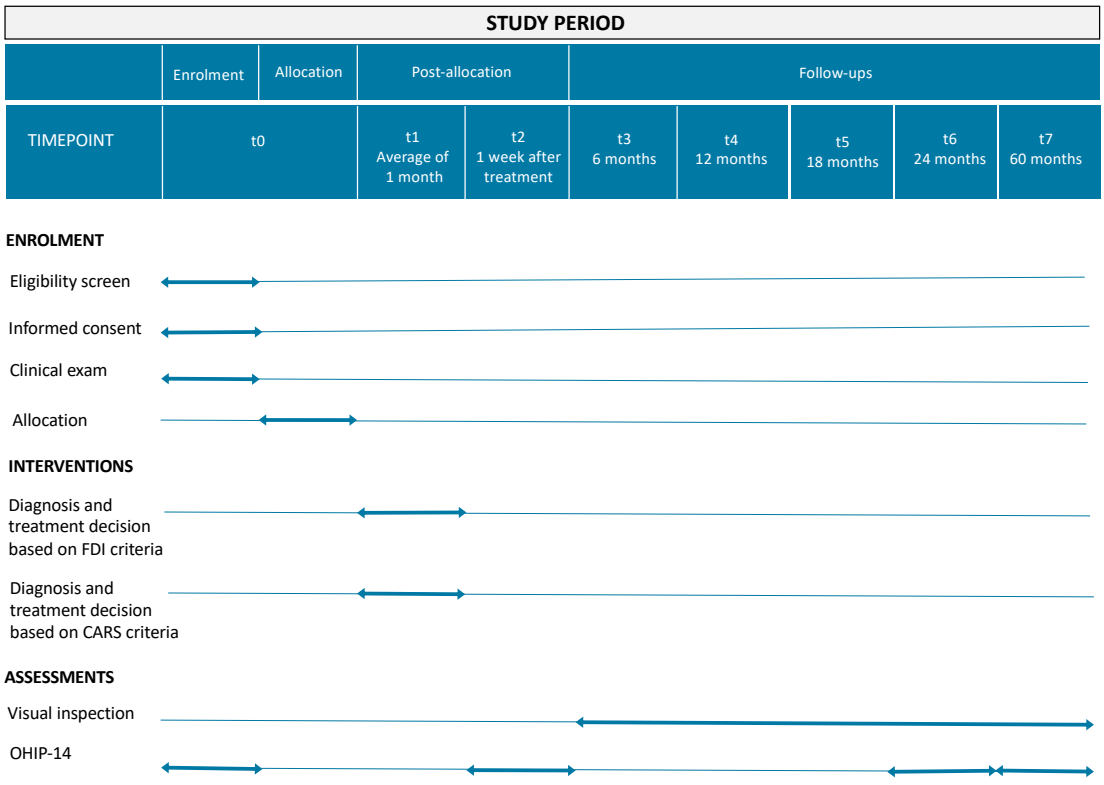
Outcomes

The primary outcome will be the restoration failure. The secondary outcomes will be the differences obtained comparing the two indices in relation to the treatment decision, number of false-positive results (cases initially indicated to repair or replacement, in which during the intervention no decayed tissue was found), impact of intervention on quality of life and cost-effectiveness.

Participant timeline

The study will be recruiting patients from October 2016 to December 2019. The enrollment in the study for each participant will lead approximately 61 months, estimating 1 month of treatment and 60 months of follow-up. The study phases are presented in Figure 5.

Figure 5. Standard protocol items: enrolment, interventions, and assessments.



Sample size

The sample calculation was performed based on the primary outcome of the randomized clinical trial (percentage of restorations requiring reintervention). The calculation considered a 2-year failure rate of approximately 10% for occlusal restorations [16] and 30% for occlusal-proximal restorations [17]. It was also taken into account that approximately 10% of the replaced restorations and 14% of the restorations undergoing repair fail again [18]. Thus, estimating that half of the sample is from occlusal restorations, an operative reintervention requirement rate of 24% was estimated in 2 years. The number of 522 restorations was reached, based on an absolute difference of 10% between the groups, using a two-tailed test. As a participant can contribute with more than one restoration, 20% was added to this value (n = 626). Thus, considering a predetermined average of inclusion of 5 teeth per patient, and adding 20% to possible sample losses, a minimum number of 152 patients was reached to be included in the trial.

Recruitment

The recruitment will occur in the School of Dentistry, as it receives a considerable number of patients looking for dental treatment.

Assignment of interventions

Allocation: sequence generation and concealment mechanism

The random list will be generated via website (www.sealedenvelope.com). The participants of the study will be examined, classified according to predetermined criteria determined by the randomization stratified by blocks, and then referred to the examiner who will perform the evaluation of the restorations. The strata will be: (1) dmf-t index less or equal to 4 without caries activity; (2) dmf-t index less or equal to 4 with caries activity; (3) dmf-t greater than 4 without caries activity; and (4) dmf-t greater than 4 with caries activity.

To ensure allocation confidentiality, we will use opaque, sealed and consecutively numbered envelopes. The allocated group will be revealed to the examiner before the start of the examination.

Implementation

The initial exam of the patient will be done by an examiner. Then, a pre-calibrated examiner will perform the examination of the restorations and indicate the treatments based on the criteria defined by the randomization. The responsible for the dental treatment will perform the treatments based on the treatment plan of the patient provided for them, without any access to the allocation group of the patient.

Blinding

The patients, care providers responsible for the dental treatment (undergraduate students and graduate students), and the assessor who will evaluate the outcomes will be blind to the allocation group of the participants.

Data collection, management, and analysis

The follow-up assessments will be performed by a pre-calibrated examiner, who does not have previous contact with the patient and with previous information about the allocation groups and treatments performed. The treatment needs will be established according to the demands of the patients.

The clinical data will be registered on sheets previously organized on Microsoft Excel Software. All data, except those that might reveal the participants' identities, will be share in a public repository after the acceptance of all manuscripts related to these studies.

The survival analysis will be used to analyze the primary outcome. Kaplan-Meyer graphs will be constructed, and the methods will be compared to each other with Cox regression with shared frailty. The calculation of sensitivity, specificity and accuracy will consider the results obtained with the indices and the classification of the presence or not of caries lesion by the proposed reference standard. 95% CI values will be calculated with adjustments as one individual may have more than one restoration included, using a suggestion previously published [19]. The sensitivity, specificity and accuracy between the methods will be compared using multilevel analysis (3 levels: assessment, tooth and child/adults). As also, for the comparisons between the treatment decisions obtained with the different criteria. The cost-effectiveness ratio will also be verified, considering as effect the prevention of the primary outcome, as well as other secondary endpoints of interest, and the cost spent to reach such a condition with each of the indices. For all tests, two-tailed analyzes will be used, considering a level of significance of 5%. Analyzes will be performed using the statistical package Stata 15.0 (Stata Corp, College Station, USA).

Monitoring

Data monitoring

An independent regulation of data collection, management and analysis will be assumed independently by MSC.

Harms

The procedures performed offer minimal risk to oral health of patients. The adverse effects are represented by the teeth with pain episodes, postoperative sensitivity, tooth fracture during the restorative procedure, teeth requiring endodontic treatment and exodontia. In dental treatment, the possibility of these effects happen are usually present.

Auditing

The data entered will be conducted by one of the authors of the study. The data will be weekly inspected. The inconsistencies will be verified, corrected and registered.

Ethics and dissemination

Research ethics approval

This study was submitted and approved by the Ethical Committee from the Federal University of Pelotas (No. CAAE: 53463316.1.0000.5318).

Consent and assent

An informed consent will be provided and assigned by the participants.

Confidentiality

Identification numbers will be used to assure participant confidentiality during data analysis. Participants files will be stored in a secure room.

Access to data

The full access to data from this clinical trial will be available via public repository after acceptance of the manuscripts.

Ancillary and post-trial care

The participants will receive dental treatment during and after the end of the study.

Dissemination policy

The findings will be reported in full through national and international journals, patient newsletters and via website.

Discussion

The assessment of restorations in dentistry remains a challenge, even after many years of research and discussion [5,11,20]. The main point of debate is the detection of caries around restorations. The dentists do not show to follow the same line of thinking about what is and what is not a caries lesion adjacent to the restoration. Also, there is a diversity of clinical criteria available to assess the caries lesions, which

may influence on the different opinions from the dentists and on the treatment decisions taken [6,7,11]. In addition, there is a lack of evidence regarding the best criterion to detect secondary caries lesions.

The studies available about the methods for caries detection around restorations are in general studies of accuracy with cross-sectional experimental design [11,14]. Still, there is a limited number of studies, with the majority of the studies being performed in vitro, showing high risk of bias [11]. The accuracy studies are important to investigate the validity of the diagnostic method, but the decision of the best methods to be used in clinical practice should not be made based solely on these studies [11,21,22]. Besides, the majority of studies fails to present clinical relevance and do not investigate patient-centered outcomes [11]. It is essential to explore which methods would assure more benefits to the patient's health [23]. And this is only possible through randomized clinical trials with proper follow-up periods.

Randomized clinical trials aiming to evaluate diagnostic tools are usual on the medical field. However, the same is not applied to dentistry, which shows a limited number of studies with this experimental design [24]. Until now, no study compared clinically the accuracy of FDI and CARS criteria to detect secondary caries on permanent teeth, and the impact of the use of the criteria on the restorative treatment decisions. It is also important to observe that in our study, the group based on the International Dental Federation (FDI) criteria included not only the recurrent caries criteria described by the FDI, but also considered the marginal staining and marginal adaptation criteria, in order to complement the assessment of the restorations. This decision was based on the fact that many dentists and studies associate these two defects (marginal staining and marginal adaptation) with the detection of caries lesions around the restorations [11].

The detection criteria are proposed and used to assess a particular condition and to aid on the selection of the most suitable treatment. Considering the restorative treatment, the proper treatment may range since the monitoring, repair or replacement of the restoration [25]. Still, the correct diagnosis of caries around the restorations can lead to a greater longevity of the restorative treatment, improving the oral health of the patients and reducing treatment costs [26]. A considerable burden on health care expenditure is attributed to the operative management of restorations due to the detection of secondary caries [5]. In addition, the clinical criteria used to the caries detection should be in line with the current philosophy of minimally invasive dentistry

[27]. The use of a method that tend to overtreatment, accelerating the restorative repetitive cycle is not desirable [28].

To the best of our knowledge, this will be the first study to assess the effect of two visual methods for the assessment of caries lesions around restorations on the outcomes related to oral health in adults. The hypothesis under evaluation is that there will not be difference between the interventions established considering the outcomes centered on the restoration, tooth or on the patient.

Trial status

The trial is recruiting participants. The recruitment has been in progress from October 2016 until now. The end of the recruitment is planned for December 2019. Figure 6 presents the CaCIA trial logotype.

Figure 6. CaCIA trial logotype.

List of abbreviations

CaCIA – Caries Cognition and Identification in Adults

CARDEC - CARies DEection in Children

CARS - Caries Associated with Restorations or Sealants

CI – Confidence Interval

DMF-T- decayed, missing, filled permanent teeth

FDI - World Dental federation

ICCMS - International Caries Classification and Management System

OHIP-14 - Oral Health Impact Profile-14

SPIRIT - Standard Protocol Items for Clinical Trials

UFPEL – Federal University of Pelotas

Declarations

Ethics approval and consent to participate

Ethical approval has been granted by the Ethics committee from Pelotas (No. 1.625.236/2016). The participants signed an inform consent term prior to the participation in the study.

Consent for publication

Not applicable.

Availability of data and material

The dataset will be available in a public repository after the acceptance of the manuscripts.

Competing interests

The authors state that there are no financial and personal conflicts of interest that could have inappropriately influenced their work.

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Authors' contributions

CS, BLPM, MSC, and FMM conceived the study idea. CS, BLPM, JLSU, VRD, EFO, MMB, MSC and FMM designed the study. CS, JLSU and VRD implemented the clinical trial. CS, JLSU and MSC are the trial coordinators. MSC and FMM are the principal investigators. CS is the examiners responsible for the treatment plans. CS, JLSU, and VRD are responsible for organizing and monitoring the treatments. All authors wrote and revised the manuscript.

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- CaCIA collaborative group (https://tinyurl.com/ybkjm4ba)

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- CARDEC collaborative group – trial 3 (https://bit.ly/2Waf4xd)

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* These persons are also included as individual co-authors.

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Additional files

Additional file 1: SPIRIT checklist.

SPIRIT Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	15
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	17
	2b	All items from the World Health Organization Trial Registration Data Set	_____
Protocol version	3	Date and version identifier	17
Funding	4	Sources and types of financial, material, and other support	31
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	15, 32
	5b	Name and contact information for the trial sponsor	31
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	31
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	31

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	18
	6b	Explanation for choice of comparators	18
Objectives	7	Specific objectives or hypotheses	18
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	19

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	19
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	19
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	20-23
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	24
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	24 (Figure 5)

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	25
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	26
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	26
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	26
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	26
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	26
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	26
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	26, 27
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	27
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	27
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	27
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	27
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	28
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	28
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	28

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	28
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	31
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	28
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	28
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	28
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

3 Relatório do Trabalho de Campo

O presente relatório de campo apresenta um breve resumo do desenvolvimento desta tese. A presente tese foi desenvolvida baseada em no projeto “Diagnóstico de cárie secundária: estabelecimento de parâmetros e efeito nas decisões de tratamento em odontologia” que derivou o protocolo apresentado acima. Este projeto foi qualificado pela Dra. Cacia Signori durante o seu doutorado, porém junto a outras metodologias já desenvolvidas e finalizadas por ela.

Minha qualificação baseou-se no projeto “Comportamento de diferentes estratégias restauradoras em dentes endodonticamente tratados frente a fatores de risco simulados” (Apêndice A). Após o processo de qualificação do referido projeto, o mesmo foi enviado para o Comitê de Ética em Pesquisa, tendo sido aprovado em 30 de novembro de 2017. Após a aprovação do Comitê (Anexo 1), o procedimento para desenvolvimento do Biorrepositório iniciou para a captação dos dentes necessários para a realização da pesquisa.

Em 2017, paralelamente ao desenvolvimento do projeto sobre restaurações do tipo endocrown, iniciei a participação no ensaio clínico CaCIA.

Em 2018, após algumas novas publicações a respeito do tema endocrown, optamos por alterar o tema da presente tese para trabalhar com a detecção de lesões de cárie ao redor de restaurações, devido a um maior envolvimento e afinidade com o tema, além de considerarmos naquele momento uma relevância clínica mais interessante para o tema e para o tipo de trabalho que poderia ser desenvolvido.

O ensaio clínico CaCIA (Caries Cognition and Identification in Adults) foi aprovado pelo Comitê de Ética em Pesquisa, da Faculdade de Odontologia da universidade Federal de Pelotas em 06 de julho de 2016, sob parecer 1.625.236 (Anexo 2). Este estudo consiste de um Ensaio Clínico Randomizado Controlado de dois grupos paralelos, com o objetivo de avaliar o efeito dos critérios da Federação

Dentária Internacional (FDI), comparado aos critérios de detecção CARS (“Caries Associated with Restorations or Sealants”) para avaliação de lesões de cárie ao redor de restaurações em dentes posteriores permanentes, nos desfechos relacionados à saúde oral de adultos.

Durante o ano de 2018 trabalhamos na inclusão de pacientes no ensaio clínico, finalização de tratamento destes e acompanhamento de 6, 12, 24 e 36 meses dos pacientes que já haviam recebido alta anteriormente, visto que o ensaio clínico teve início em 2016. Em 2019, trabalhamos basicamente na finalização das necessidades dos pacientes participantes e, principalmente, no acompanhamento das restaurações incluídas no estudo. Estas atividades de acompanhamento dos pacientes, em até 36 meses, foram desenvolvidas na Faculdade de Odontologia da Universidade Federal de Pelotas e através de visitas domiciliares, visto o expressivo número de pacientes que o contato foi perdido ou que não puderam se deslocar até a Universidade. A dificuldade de contato com os pacientes não nos possibilitou a finalização do acompanhamento de 100% dos pacientes até dezembro de 2019.

Baseado nos dados provenientes do ensaio clínico, foram desenvolvidos os estudos que compõem a presente tese. Com os dados da inclusão dos pacientes, desenvolvemos o artigo que compara os dois critérios avaliados pelo ensaio clínico quanto a decisão de substituir as restaurações. O segundo estudo desenvolvido refere-se à acurácia dos critérios de diagnóstico. E por fim, o terceiro estudo trata do acompanhamento das restaurações incluídas no CaCIA.

4 Artigo 1[1]

How the use of different clinical criteria on the assessment of posterior restorations impacts the treatment decision in permanent teeth?

Juliana Lays Stolfo Uehara[a], Cacia Signori[b], Vitor Henrique Digmayer Romero[a], Bruna Lorena Pereira Moro[c], Fausto Medeiros Mendes[c], Maximiliano Sérgio Cenci[a]

[a] Graduate Program in Dentistry, School of Dentistry, Federal University of Pelotas, Rua Gonçalves Chaves, 457, Pelotas, RS 96015-560, Brazil
[b] Department of Restorative Dentistry, School of Dentistry, Uniavan University Center, Av. Marginal Leste, 3600, Balneário Camboriú, SC 88339-125, Brazil
[c] Department of Pediatric Dentistry, School of Dentistry, University of São Paulo, Avenida Prof. Lineu Prestes, 2227, São Paulo, SP 05508-000, Brazil

Corresponding author:
Maximiliano Sergio Cenci
E-mail address: Maximiliano.Cenci@ufpel.edu.br
Phone number: (+55) (53) 3284 3140

[1] Artigo intitulado “How the use of different clinical criteria on the assessment of posterior restorations impacts on the treatment decision in permanent teeth?” formatado de acordo com as normas do periódico Clinical Oral Investigations

Abstract

Objective: This study aimed to evaluate the influence of the use of two different visual criteria for the assessment of caries around restorations on the treatment decision on restored permanent teeth. Materials and Methods: This is a cross-sectional study comparing two visual criteria for the assessments of restored teeth [FDI (International Dental Federation) criteria and CARS ("Caries Associated with Restorations or Sealants") criteria described by the International Caries Classification and Management System]. Adults were randomized according to the assessment strategy. One calibrated examiner assessed the restorations. After the diagnosis and establishment of the treatment decision according to the sorted criteria, the same restoration was examined again according to the criterion not sorted. Spearman's rank correlation analyses were conducted between CARS and FDI scores and to compare the treatment decision between both criteria. Univariate and multiple Poisson multilevel regression analysis were conducted considering the role of the explanatory variables (evaluation criteria, tooth, and patient) on the outcomes: replacement decision, any treatment indications and presence of caries. Results: A number of 717 restorations on posterior teeth from a total of 185 patients were included. The highest correlation was founded for the presence of caries lesions (Rho=0.829). FDI showing a more invasive outcome for replacement indication. DMF-T, caries activity, number of restored surfaces and the diagnostic method showed a positive interaction for restoration replacement or indication of any type of treatment. Conclusions: The method of visual assessment used to evaluate the restored tooth influences the decision to replace or not the restoration. The use of the FDI criteria results on a less conservative approach on permanent teeth, compared to the CARS criteria.

Clinical Relevance: The choice for more conservative criteria for the evaluation posterior restorations prevents the replacement of restorations and overtreatment.

Trial registrations: NCT03108586 (registered 11 April 2017).

Key-words: caries detection, dental caries, restorations, visual inspection, replacement, secondary caries.

Introduction

The repeated replacement of the restorations results on the loss of the sound tooth structure, and may cost, at some point, the tooth lost. This process is known as the “death spiral" [1] or the repetitive restorative cycle [2, 3]. The replacement of the restorations is a routine procedure on the dental office [4], corresponding to more than half of the interventions in restorative dentistry [5]. The main cause of replacement described in literature is the presence of caries lesions around the restorations [6–8]. The management of caries lesions around the restorations was considered as one of the highest potential for improvement on dentistry over the next 20 years [9].

The caries lesion around the restoration, also called as secondary caries, is characterized as a caries lesion which is developed adjacent to a restoration [10]. It can be established as an external lesion formed on a dental surface near to a restoration, similar to a primary caries lesion or as a wall lesion on the tooth-restoration interface. The detection of secondary caries usually is not an easy task. Some studies reported differences among dental professionals related to the detection and management of secondary caries [11, 12]. This may be attributed to some aspects, such as the presence of a gap in the tooth-restoration interface, the tooth tissue discoloration and marginal staining around the restoration, and even to the location of the lesion, sometimes in areas difficult to access [13]. Moreover, dentists usually mistake aspects of marginal degradation of restorations, such as marginal staining or marginal contour problems, with caries lesions [14–16].

The assessment of the restored tooth is an important step to allow a proper treatment decision of old restorations. Visual [17] and radiographic [18–20] inspection are excellent options to detect primary caries lesions. However, for caries around restoration, a limited number of studies screened the diagnosis process [11, 21]. In an attempt to make intervention decisions more accessible and equanimous, diagnostic criteria were created to standardize the assessment. Among them, two criteria, which were designed to be used in research and dental practice, are commonly reported on the literature: the International Dental Federation (FDI) criteria [22] and the Caries Associated with Restorations and Sealants (CARS) [23]. These two criteria have as the main difference in their

conception the fact that FDI looks more at the restoration's aspects, whereas CARS evaluates mostly the tooth condition and the presence of caries lesions. Therefore, using the FDI criteria would englobe taking actions also due to marginal problems in the restorations, considering that several clinicians consider these marginal defects as synonymous of caries lesions around restorations. However, the differences among these criteria related on the impact on the treatment decision on permanent teeth was not investigated so far. Besides, no standard criterion was universally established for the detection of caries around the restorations. Thus, the decision of when and how to intervene on these cases remain a point of discussion between dental practitioners, and even between researchers.

The process of decision-making performed by the treating clinicians is still subjective and still show a less conservative approach, even with the increased evidence for refurbishment and repair rather than replacement an old restoration with small defects, not clinically relevant [4, 24]. The monitoring or repairing of old restorations with small defects showed similar outcomes after 10 years compared to the restorations that were replaced [25]. Conservatives treatment preserve sound structure, and can improve the longevity of the tooth-restoration complex, providing benefits to the patient [25].

Thus, this study aimed to evaluate the influence of different clinical criteria (FDI and CARS) for secondary caries evaluation and other factors on replacement indication of restorations in a permanent tooth. The hypothesis tested is that there is no difference in the clinical outcome treatment determined by the two criteria or type of teeth and/or restoration included in the study.

Material and Methods

The STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) guideline [26] was used to write this manuscript.

Study design

This study is a cross-sectional study comparing two visual criteria for the assessments of restored teeth: FDI (International Dental Federation) criteria and CARS ("Caries Associated with Restorations or Sealants") criteria described by

the International Caries Classification and Management System. Adults were randomized according to the assessment strategy. One calibrated examiner assessed the restorations. After the diagnosis and establishment of the treatment decision by the examiner according to the sorted criteria, the same restoration was examined according to the criterion not sorted for comparison. Both criteria were assessed for all restorations. The outcome variables were the indication of the restorations replacement, the indication of any type of treatment and the presence of caries, for the restorations assessed by FDI and CARS criteria.

This study is nested in a clinical trial named Caries Cognition and Identification in Adults (CaCIA). The trial is registered on Clinicaltrials.gov under the number NCT03108586. The trial was approved by the local Ethics Committee in research (number: 1.625.236). Patients signed a term agreeing to participate with the study.

CaCIA is a randomized controlled clinical trial which investigate the impact of the use of two different visual criteria for the assessment of caries around restorations on the outcomes related to the oral health in adults, in short and long term. Two groups are being compared. One of them is formed for adults receiving the diagnosis and treatment according to the FDI criteria [22] (control group). And the second group corresponds to adults receiving the diagnosis and treatment according to the CARS criteria [23] (experimental group). The study recruited patients from October 2016 to December 2019. The patients are being evaluated at 6, 12, 18, 24, and 60 months. The primary outcome of the clinical trial will be the number of restorations that need further intervention after 12 to 36 months of follow-up.

This study was conducted at the School of Dentistry from the Federal University of Pelotas (Rio Grande do Sul, Brazil).

Inclusion criteria

The patient's inclusion on this study was based on the following inclusion criteria:

(1) patients seeking dental treatment at the School of Dentistry from the Federal University of Pelotas;

(2) aged 18 to 60 years;

(3) to present at least one restoration of composite resin or amalgam on a permanent posterior tooth.

Exclusion criteria

The exclusion criteria were:

(1) patients who refused to participate in the research;

(2) patients who presented systemic conditions or chronic diseases that require differentiated care and follow-up;

(3) restorations on teeth with compromised conditions, such as: fistula, abscess, pulp exposure, history of spontaneous dental pain, or mobility.

Interventions

Previously to the beginning of the study, one examiner (C.S) was calibrated to perform the assessments of the patients. The calibration process was conducted in two phases. In the first phase, a series of photographs with restorations presenting marginal defects was projected in a television in a dark room for the examiner, and one expert (M.S.C) in restorative dentistry discussed the cases with the examiner. The second phase was at the clinic. Both, examiner and the expert examined a series of patients, attributing the diagnosis and treatment according to FDI and CARS for each case. Disagreement between the examiner's answers were discussed and a consensus was established.

After calibration, one examiner (C.S) was responsible for realizing the first exam and the inclusion of the patient into the study. The second examiner (M.S.C) was responsible for performing the follow-up's evaluations to avoid possible bias.

The patients were examined in a dental chair and under lighting. Before the assessment, they received a standard dental cleaning with low-rotation micromotor, rubber cup, and brush with prophylactic paste. A dental mirror and a ball-point probe were used by the examiner to perform the assessment on the patient's teeth.

In the first appointment, one calibrated examiner (C.S) examined the patients according to the International Caries Detection and Assessment System (ICDAS) [23]. The DMF-T (decayed, missing, filled teeth) index and caries activity of the patient were also registered. Patients who met the inclusion criteria were

allocated into one of the two groups under investigation (FDI group or CARS group). The randomization was performed by block according to the caries experience classification using the DMF-T (index less or equal to 4, or index greater than 4) and according to the caries activity of the patient (with or without active caries lesions).

For FDI assessment, all surfaces were dried before the evaluation [22]. For the CARS assessment, surfaces were evaluated wet and after being dried by 5 seconds with the air of triple syringe [23].

First, the examiner performed the assessment based on the randomized criteria. The same examiner established the treatment plan according to the treatment indications of the criteria in which the patient was allocated. Immediately after, the restorations were evaluated again, but this time according to the other criteria (not sorted). And the treatment plan based on this last exam was also registered for further comparisons.

Criteria description

Briefly, the FDI system [22] is a criterion for the evaluation of direct and indirect restorations based on three properties: esthetic, functional, and biological. Each one of these aspects has subcategories, resulting in a total of 16 aspects that should be evaluated to determine the conditions of the restoration. Each of these 16 aspects can be scored from 1 to 5 [1 = clinically excellent/very good, 2 = clinically good, 3 = clinically sufficient/sactisfactory, 4= clinically unsatisfactory (but reparable), and, 5 = clinically poor (replacement necessary)] and the final score for the tooth is the highest value assigned among all subcategories. The FDI suggests that the researcher can choose the most critical subcategories to be evaluated for each study methodology. Based on this, three subcategories were chosen for the assessment of the restorations: marginal staining, marginal adaptation, and recurrence of caries. These three FDI subcategories chosen to be evaluated in this study aimed to simulate what can clinically be confused with caries around restorations and, consequently, be a reason for interventions in restorations in a daily routine. The choice of these three categories agrees with other studies that report them as the most used ones [27]. Considering the intrinsic pigmentation on tooth structure promoted by amalgam restorations, we decided to evaluate only marginal adaptation and

recurrence of caries for amalgam restorations. The assessment of marginal pigmentation for these restorations probably would end up always in a score of number 5, which would lead to the replacement of, if not all the amalgam restoration, probably the majority of the restorations. The description of the subcategories and respectful scores used in this study can be viewed in Table 1 and Table 1a.

Table 1: Description of FDI subcategories used to assess the restoration of this study.

FDI criteria	Description
Marginal staining	Marginal staining is primarily staining of the contents of a crevice between the cavity wall and the restoration, subsequently affecting the margins of the restoration.
Marginal adaptation	This is related to marginal gaps. To obtain better quality data for clinical prediction of, for instance, marginal staining or caries adjacent to restorations, restoration gap width should be classified. To classify the marginal gaps, two special probes are available with tip diameters of 150 and 250 μm. The depth of the gap should be at least the same size (0.25 mm). The use of a sharp explorer for gap or caries detection is not recommended. Debonding may lead to a loose filling, which requires replacement. However, also significant generalized marginal gaps and irregularities may justify the replacement of the entire restoration.
Recurrence of caries	Recurrence of previous or caries lesion at the restoration margins that cannot be alleviated by a minor intervention should be scored as unacceptable. A lesion that cannot be treated by remineralization and has to be treated operatively is given an unacceptable score. Initial secondary caries not requiring repair/replacement is recorded when there is visible demineralization without cavitation in tooth tissue adjacent to the restoration. This includes opacity and/or brown discoloration of arrested caries, which cannot be polished away. Care must be taken to distinguish defects from stained margins. Cavitation in the adjacent tooth tissue indicates established secondary caries and consequently, the need for operative intervention, such as repair or replacement. The recommendations of ICDAS should be used when diagnosing secondary caries.

The content of this table was based on the FDI criteria developed by International Dental Federation [22].

Table 1a: Description of scores of FDI subcategories used to assess the restoration of this study.

Subcategories	**1** **Clinically excellent**	**2** **Clinically good**	**3** **Clinically sufficient/ satisfactory**	**4** **Clinically unsatisfactory**	**5** **Clinically poor**
Marginal staining	No marginal staining	Minor staining, but easily removable by polishing	Moderate marginal staining, not esthetically unacceptable	Pronounced marginal staining; major intervention necessary for improvement	Deep marginal staining, not accessible for intervention
Marginal adaptation	Harmonious outline, no gaps, no white or discolored lines	Marginal gap (<150 μm), white lines. Small marginal fracture removable by polishing. Slight ditching, slight step/flashes, minor irregularities. Gap < 250μm not removable	Several small marginal fractures. Major irregularities ditching or flash, steps. Gap > 250μm or dentine/base exposed	Severe ditching or marginal fractures.Larger irregularities or steps	Restoration (complete or partial) is loose but in situ. Generalized major gaps or irregularities
Recurrence of caries	No secondary or primary caries	Very small and localized demineralization	Larger areas of demineralisation	Caries with cavitation	Deep secondary caries or exposed dentine that is not accessible for repair of restoration

The content of this table was based on the FDI criteria developed by International Dental Federation [22].

CARS criteria is derived from ICDAS proposed by International Caries Classification and Management System (ICCMS) [23] and now updated to CariesCare International 4D [28]. The assessment of the lesion characteristics for CARS was the same that proposed for CariesCare International 4D for primary caries. The definition of the lesions aspects and the treatment proposed for each score for CARS is presented in Table 2.

Table 2: Lesions characteristics and treatment indication, respectively, of each CARS code based on CariesCare International 4D.

Code	Lesion aspect	Description	Treatment indicated
0	Sound tooth surface with restoration or sealant	No evidence of change in enamel translucency due to caries after plaque removal and air-drying. Non-carious surfaces with developmental defects of enamel (including fluorosis), erosive tooth wear, and extrinsic/intrinsic stains are considered as sound for caries.	No treatment
1	First visual change in enamel	Changes in enamel seen as a carious opacity or visible discoloration (white/brown spot) not consistent with the clinical appearance of sound enamel with no evidence of surface breakdown, no underlying dentine shadowing or cavitation	No treatment – adjacent inactive lesions OR Topical Fluoride Application – adjacent active lesions
2	Distinct visual change in enamel/dentin adjacent to a restoration margin		
3	Carious defects of <0.5 mm with the signs of code 2	White/brown spot lesion with localized microcavity/discontinuity, without visible dentine exposure. Best seen after air-drying	
4	Marginal caries in enamel/dentin/cementum adjacent to restoration with underlying dark shadow from dentin	Obviously discolored dentine visible through apparently intact or micro-cavitated enamel surface, which originated on the surface being evaluated. Often seen easiest with the tooth surface wet	Repair OR Replacement* Replacement should be indicated case the carious lesion involves more than half of the restoration.
5	Distinct cavity adjacent to the restoration	Obvious visible dentine cavity in opaque/discolored enamel. A WHO/CPI/PSR probe can gently confirm the cavity extends into dentine	
6	Extensive distinct cavity with visible dentin		

The content of this table was based on the CARS criteria derived from ICDAS proposed by International Caries Classification and Management System (ICCMS) [23].

The treatment options for the included restorations considering both groups (FDI and CARS) were: (1) no treatment, (2) professional topical fluoride application, (3) refurbishment, (4) repair, and (5) replacement. After the treatment plan established, patients' needs were carried out in the clinic according to predefined protocols by blind operators to the criteria randomized.

Sample size

The sample used included all the patient from the randomized clinical trial CaCIA. Thus, in the present study 185 patients were included, and a total of 718 restorations were assessed. The sample size calculation details from the clinical trial may be consulted on the register published on the Clinicaltrials.gov under the number NCT03108586.

Explanatory Variables

The explanatory variables were divided into three different levels: the first level is related to the clinical evaluation considering the strategy used to assess the restorations (FDI and CARS) placed in permanent posterior teeth, and order of examination (the first criterion evaluated corresponds to the randomized criterion). The second level involves teeth aspects, such as: the type of teeth (molars and premolar), dental arch (upper or lower), number of restored surfaces (one surface, two surfaces, three or more surfaces), and restoration material (composite resin or amalgam). Patients related variables composes the third level. This level comprises sex, age (up to 30 years old or more than 30 years), DMF-T (decayed, missing and filled teeth), and caries activity.

Statistical analysis

Statistical analysis was conducted with statistical package Stata 13 (StataCorp LP, College Station, USA). Spearman's rank correlation analyses were conducted between CARS and FDI scores. Marginal staining, marginal adaptation, and recurrence of caries were analyzed separately. For these, Spearman's correlation coefficient (Rho) and respective 95% CIs were calculated. ‘Not evaluated’ corresponding to marginal staining for amalgam restorations.

The treatment for restorations assessed by both criteria was classified into: (1) no treatment (restorations without treatment needs or those with indication of topical

fluoride application), (2) repair, or (3) replacement. Spearman's correlation analysis was conducted. Chi-square test was used adjusted by the cluster in order to compare the treatment decision between FDI and CARS.

Besides that, univariate and multiple Poisson multilevel regression analysis between primary outcome and explanatory variables were calculated, as also the PR (prevalence ratio) values and 95% CIs. First, univariate analyses were carried out. Then, we conducted a multiple regression analysis. For this analysis, the variables named diagnostic method, and dental material was inserted, regardless of the level of significance. Order of examinations was also included in all multiple models, in order to adjust the analysis considering a possible occurrence of incorporation bias, since the first method could exert an influence on the second method. Other variables with p-value <0.05 were also maintained in the final model.

Similar Poisson multilevel regression analyses were also performed for the outcomes: any type of treatment and presence of caries lesions. The significance level was set as 5%.

Results

A total of 185 patients were included in this study, from which 120 (65%) were female, and 65 (35%) male. The mean age of the patients was 41.82. The DMF-T mean was 11.4. Regarding the caries activity at the baseline assessment, 130 patients (70.2%) were assigned without caries activity, while 55 patients (29.8%) showed caries activity at the first assessment. According to the randomization, 90 (48.6%) patients were assessed by the CARS criteria, while 95 (51.4%) were evaluated by the FDI criteria.

Table 3 shows the characteristics of the restorations included. Teeth sample was formed for 518 (72.1%) molars and 200 (27.9%) premolars. 345 (48%) teeth were located in the upper dental arch, while 373 (52%) teeth were at the lower dental arch. The majority of the restorations had only one surface involved (401 – 55.8%). And most of the restorations were in composite resin (57.1%).

Table 4 presents the correlation between the scores obtained from FDI and the scores obtained from the CARS evaluation. The stronger Spearman correlation coefficient (Rho) founded was related to the presence of caries lesions (Rho=0.829).

Marginal adaptation (Rho=0.457) and marginal staining (Rho=0.280) showed the lowest values.

Table 3. Descriptive analysis of included restorations characteristics.

Category	n	%
Type of tooth		
Molar	518	72.1
Premolar	200	27.9
Dental arch		
Upper	345	48.0
Lower	373	52.0
Number of restored surfaces		
1 surface	401	55.8
2 surfaces	214	29.8
3 or more surfaces	103	14.4
Restoration material		
Amalgam	308	42.9
Composite resin	410	57.1

A moderate correlation (Rho= 0.420) was founded between the treatment decisions proposed by the CARS and FDI criteria (Table 5). Considering the 718 restorations evaluated, CARS criteria decided to replace 16 restorations (2.2%) while FDI criteria indicated the replacement for 83 restorations (11.6%), indicating a more invasive approach by the FDI criteria. The CARS criterion indicated 2 (0.28%) more invasive treatments compared to the FDI. More than 90% of the restorations assessed by the CARS criterion did not needed operative treatment, while for the restorations evaluated by the FDI this number decrease for 66.4%.

The results of the adjusted Poisson multilevel regression analysis of the association among the explanatory variables and the restorations replacement is shown in Table 6. The analysis showed that the FDI criteria indicated five times more replacements when compared to the CARS criterion. A significant positive association between indication for restorations replacement and DMF-T and number of surfaces restored was observed. No significant association between restorations replacements and the restorative material was observed.

Table 4. Spearman correlation coefficient (Rho) for CARS and FDI subcategories (marginal staining, marginal adaptation, and recurrence of caries) evaluated for included restorations.

FDI criteria	CARS criteria							Total
	0	1	2	3	4	5	6	
FDI marginal staining								
1	57	1	12	1	6	7	0	84
2	52	2	22	11	6	8	3	104
3	33	0	43	26	8	15	0	125
4	20	2	29	7	10	5	0	73
5	6	0	6	6	8	2	1	29
Not evaluated	165	8	73	31	9	11	6	303
Rho = 0.280 (95% CI = 0.189 to 0.367)								
FDI marginal adaptation								
1	23	0	3	0	1	0	0	27
2	213	5	99	16	21	2	0	356
3	75	7	67	37	17	6	0	209
4	18	1	10	29	8	29	0	95
5	4	0	6	0	0	11	10	31
Rho = 0.457 (95% CI = 0.397 to 0.513)								
FDI recurrence of caries								
1	291	3	8	7	1	0	0	310
2	26	9	95	15	3	4	0	152
3	7	1	63	40	7	2	0	120
4	8	0	16	18	18	25	0	85
5	1	0	3	2	19	16	10	51
Rho = 0.829 (95% CI = 0.805 to 0.851)								
Total	**333**	**13**	**185**	**82**	**47**	**48**	**10**	**718**

Rho = Spearman correlation coefficient; 95% CI = 95% confidence interval

Table 5. The relationship among treatment decisions indicated for assessment restorations comparing CARS and FDI criteria.

FDI	CARS			Total
	No treatment	Repair	Replacement	
No treatment	476	0	1	477 (66.4%)
Repair	128	29	1	158 (22.0%)
Replacement	57	12	14	83 (11.6%)
Total	661 (92.1%)	41 (5.7%)	16 (2.2%)	718

Spearman correlation coefficient = 0.420 (95% Confidence interval = 0.358 to 0.478)
Chi-square adjusted by the cluster = 141.0; $p < 0.001$

Table 6. Comparison between explanatory variables and the indications of restorations replacement (outcome) assessment by FDI and CARS criteria.

Explanatory variables	Unadjusted PR (95%CI)	p	Adjusted PR (95%CI)	P
Variables related to the patient (3rd level)				
Sex (ref.: male)			*	
Female	1.41 (0.83 to 1.64)	0.206		
Age (ref.: up to 30 yrs-old)			*	
More than 30 yrs-old	1.01 (0.56 to 1.82)	0.978		
DMF-T (quant. variable)	1.04 (1.00 to 1.08)	0.034	1.04 (1.00 to 1.08)	0.031
Caries activity (ref.: no)				
Yes	1.35 (0.81 to 2.27)	0.251	1.62 (0.97 to 2.72)	0.067
Variables related to the restored tooth (2nd level)				
Type of teeth (ref.: Molars)			*	
Premolars	1.19 (0.75 to 1.88)	0.452		
Dental arch (ref.: upper)			*	
Lower	0.92 (0.61 to 1.41)	0.717		
Number of surfaces restored (ref.: 1 surface)				
2 surfaces	2.30 (1.42 to 3.72)	0.001	2.05 (1.25 to 3.37)	0.005
3 or more surfaces	2.60 (1.47 to 4.59)	0.001	2.19 (1.21 to 3.98)	0.010
Dental material (ref.: amalgam)				
Composite resin	1.66 (1.05 to 2.64)	0.031	1.42 (0.87 to 2.30)	0.157
Variables related to the clinical evaluation (1st level)				
Diagnostic method (ref.: CARS)				
FDI system	5.23 (3.07 to 8.93)	<0.001	5.22 (3.05 to 8.91)	<0.001
Order of examinations (ref.: 1st examination)				
2nd examination	1.02 (0.69 to 1.51)	0.904	0.95 (0.62 to 1.44)	0.809

* Variables not included in the final model
PR = prevalence ratio; 95%CI = 95% confidence intervals
DMF-T = decayed, missed and filled permanent teeth

When the outcome considered on the multilevel regression analysis was the indication of any type of treatment (Table 7), it was observed that caries active patients had 38% more indication for treatment. The FDI criteria proposed four times more interventions than the CARS criterion. Associations between the restorative material of the restorations were observed. More interventions were recommended to the composite resin restorations compared to the amalgam restorations. The restorations with two or more surfaces also showed a significant positive association.

Table 7. Comparison between explanatory variables and the indication of any type of treatment (outcome) assessment by FDI and CARS criteria.

Explanatory variables	Unadjusted PR (95%CI)	p	Adjusted PR (95%CI)	P
Variables related to the patient (3rd level)				
Sex (ref.: male)			*	
Female	1.10 (0.82 to 1.48)	0.512		
Age (ref.: up to 30 yrs-old)			*	
More than 30 yrs-old	0.95 (0.68 to 1.32)	0.751		
DMF-T (quant. variable)	1.01 (0.99 to 1.03)	0.233	*	
Caries activity (ref.: no)				
Yes	1.39 (1.05 to 1.85)	0.023	1.38 (1.07 to 1.76)	0.012
Variables related to the restored tooth (2nd level)				
Type of teeth (ref.: Molars)			*	
Premolars	1.17 (0.91 to 1.51)	0.228		
Dental arch (ref.: upper)			*	
Lower	0.90 (0.71 to 1.14)	0.373		
Number of surfaces restored (ref.: 1 surface)				
2 surfaces	1.98 (1.51 to 2.60)	<0.001	1.78 (1.35 to 2.33)	<0.001
3 or more surfaces	3.14 (2.34 to 4.21)	<0.001	2.58 (1.92 to 3.47)	<0.001
Dental material (ref.: amalgam)				
Composite resin	2.52 (1.91 to 3.33)	<0.001	1.96 (1.48 to 2.60)	<0.001
Variables related to the clinical evaluation (1st level)				
Diagnostic method (ref.: CARS)				
FDI system	4.24 (3.18 to 5.66)	<0.001	4.20 (3.15 to 5.61)	<0.001
Order of examinations (ref.: 1st examination)				
2nd examination	1.13 (0.90 to 1.42)	0.280	1.12 (0.89 to 1.40)	0.331

* Variables not included in the final model
PR = prevalence ratio; 95%CI = 95% confidence intervals
DMF-T = decayed, missed and filled permanent teeth

Finally, Table 8 shows the comparison between the explanatory variables and the presence of caries assessed by the FDI and CARS criteria. The FDI criteria identified 2.7 times more caries around restorations when compared to the CARS criterion. In addition, it was showed that restorations with three or more surfaces had more chance to have a carious lesion compared to a single surface restoration. No statistically significant associations were identified between the restorative material

and the presence of carious lesions, as well as concerning the order of evaluation by the two criteria.

Table 8. Comparison between explanatory variables and the presence of caries (outcome) assessment by FDI and CARS criteria.

Explanatory variables	Unadjusted PR (95%CI)	p	Adjusted PR (95%CI)	p
Variables related to the patient (3rd level)				
Sex (ref.: male)			*	
Female	0.98 (0.70 to 1.34)	0.843		
Age (ref.: up to 30 yrs-old)				
More than 30 yrs-old	0.74 (0.52 to 1.06)	0.098	0.83 (0.54 to 1.28)	0.403
DMF-T (quant. variable)	0.97 (0.95 to 1.00)	0.034	0.97 (0.95 to 1.00)	0.054
Caries activity (ref.: no)			*	
Yes	1.11 (0.79 to 1.57)	0.544		
Variables related to the restored tooth (2nd level)				
Type of teeth (ref.: Molars)			*	
Premolars	1.18 (0.85 to 1.63)	0.325		
Dental arch (ref.: upper)			*	
Lower	1.11 (0.82 to 1.51)	0.488		
Number of surfaces restored (ref.: 1 surface)				
2 surfaces	1.03 (0.72 to 1.47)	0.860	1.13 (0.78 to 1.62)	0.523
3 or more surfaces	1.65 (1.12 to 2.43)	0.011	1.89 (1.25 to 2.85)	0.002
Dental material (ref.: amalgam)				
Composite resin	1.02 (0.76 to 1.40)	0.857	0.81 (0.57 to 1.13)	0.215
Variables related to the clinical evaluation (1st level)				
Diagnostic method (ref.: CARS)				
FDI system	2.72 (1.93 to 3.83)	<0.001	2.71 (1.93 to 3.81)	0.001
Order of examinations (ref.: 1st examination)				
2nd examination	1.14 (0.85 to 1.55)	0.383	1.12 (0.83 to 1.51)	0.474

* Variables not included in the final model
PR = prevalence ratio; 95%CI = 95% confidence intervals
DMF-T = decayed, missed and filled permanent teeth

Discussion

This is the first study to assess the use of two visual criteria for the detection of caries lesions around restorations in permanent teeth. This study showed that the use of the FDI criteria tends to indicate more replacements of the restorations compared to the CARS criteria. Also, when considering the outcome as 'any treatment indication', the FDI criteria continued to indicate more interventions than CARS.

A recent review about the FDI system [26] showed that the use of this system for the assessment of the restorations was increased since 2010. Even though the evaluation of 16 criteria was initially proposed, the authors advise researchers to choose the most appropriate criteria to be used according to the outcomes. This scoping review [26] shows that an average of 8.5 criteria are used in the studies and that the three most used are marginal adaptation, marginal staining, and recurrence of caries, which agrees with the criteria chosen for this study.

The International Caries Detection and Assessment System (ICDAS) shows a list of well-described criteria for Caries Associated with Restorations and Sealants (CARS) [23]. Among the available criteria on the literature, the CARS criteria seem to be the most indicated to use nowadays. This criterion assesses the lesion severity and describe aspects such as marginal staining and amalgam shadows, not consistent with caries lesions, and also taken into account the presence or not of demineralization around the restoration with small defects [21].

A strong positive correlation related to the assessment of the presence of caries was observed between the criteria. This may be explained because the FDI criteria relies on similar criteria to those used by the International Caries Detection and Assessment System (ICDAS), assessing the presence of enamel opacities and dentine cavities, and therefore similar to the definitions adopted by CARS [22]. A moderate correlation was founded between CARS classification and the marginal adaptation of the restorations, assessed by the FDI criteria. The restorations with lack of marginal adaptation due to overhangs or gaps are more prone to the biofilm accumulation, and consequently, to the caries lesions development. However, the lack of adaptation does not necessarily imply the development of caries lesions around the restorations. It is also needed to consider the role of the patient, as caries lesions will occur in individuals with high caries risk and active caries [10]. The discrimination

between the presence of gaps and caries lesions at the tooth-restoration interface is still a matter of doubt among clinicians and researchers [28, 29].

On the other hand, a weak correlation was founded between the CARS criteria and the presence of marginal staining. The weak correlation can be explained since marginal staining is no longer understood as a factor related to the presence of secondary caries lesions [10, 30]. The presence of marginal staining and small defects are considered the main aspects that lead to misinterpretations [31]. Specially in tooth-colored restorations brown and black marginal staining may be misinterpreted as initial caries lesion, although the evidence showing the staining as a poor predictor of caries [10, 30]. Other factor that may have influenced the finding reported is that amalgam restorations were not assessed for this criterion. The decision of not perform the assessment of marginal staining on amalgam restorations was based on the fact that the majority of the amalgam restorations present an intrinsic pigmentation caused by the material on the dental structure [30]. So, we consider that probably an extremely high number of restorations would result in high scores for this aspect indicating the replacement of the majority of the restorations. This would lead to significative overtreatment. This is a limitation of this study.

In this study, we compared the CARS system with the FDI system to evaluate the presence of caries lesions around restorations and the indication of treatment according to each criterion. The multilevel regression analysis showed a moderate correlation between the FDI and CARS criteria regarding the treatment decision. Our results showed a less conservative approach by the FDI system. Studies available in the literature have shown the influence of factors such as caries experience, size of the restorations and occlusal stress on restoration longevity [7, 32–34], but no previous study so far has evaluated the influence of the diagnostic method used on the longevity of restorations in permanent teeth.

The literature shows that more conservative treatments should be chosen considering the benefits to the patients [1, 5, 35]. So, the choice of the criteria for restoration's assessment should follow this approach, avoiding unnecessary treatments. The higher number of interventions indicated by the FDI criteria may be explain in part because the caries activity is not assessed by these criteria. The CARS criteria take into account the caries activity characteristics, such as the presence of active enamel demineralization and cavities with soft tissues, and not only the lesion extension. The evaluation of the lesion activity is fundamental, since the treatment

should be mainly based on this characteristic. The lesion activity influences the treatment decision for operative or non-operative treatment [36, 37]. Arrested lesions that allows hygiene, even if cavitated, will not necessarily require operative treatments. On the other hand, cavities in which it is not possible to access biofilm should be restored.

It is important to note that the promotion of most interventions in the FDI group was due to the inclusion of marginal staining and marginal adaptation as “caries related problem”, while in the CARS criteria only the caries lesion presence was considered. We adopted this approach because clinicians still use marginal defects as “markers” for caries around the restorations and make treatment decisions based on these defects. Although evidence shows that marginal defects and pigmentations are not predictive factors for caries [16, 38, 39], they often end up being misinterpreted as caries lesions around restorations, leading to unnecessary interventions in clinical practice. Therefore, it is not the “clinical criteria” to be blamed for the overtreatment in the present study, but the dentist’s approach for caries detection around restorations. Nevertheless, although FDI appears to be less conservative, indicating a higher level of restorations replacement than CARS, and probably ending up in overtreatment, it is still not possible to state through a cross-sectional study which is the best criterion for the evaluation of restorations. This question will be only answered by the ongoing clinical trial reported in this study.

FDI diagnosis showed to be statistically different from the CARS diagnosis on the outcomes: replacement of the restorations, indication of any type of treatment, or caries presence. A consensus about the Replacement of Restorations wrote by the Academy of Operative Dentistry [4] reports that clinicians should change the old conduct of "if in doubt, take it out" to the new one: "as a last resort, take it out".

Restoration size (3 or more surfaces) proved to be a significant factor in the three outcomes evaluated (the indication of replacement, any treatment, and the presence of caries). Other studies [40, 41] already showed major failures in extensive restorations, in agreement with the findings of this study. The other variables such as caries activity, DMF-T index, and restoration material showed an impact on the outcomes evaluated, in agreement with published studies related to the longevity of the restorations [6, 7, 31, 32, 34, 42].

Regarding the restorative material, when the outcome any type of treatment’ was analyzed more interventions were recommended to the composite resin

restorations compared to the amalgam restorations. One hypothesis to explain this finding is probably the higher indication for repair of resin restorations compared to the amalgam ones. In addition, other points may be raised as follows. Some studies show the higher development for caries lesions around restorations on composite resin restorations compared to the amalgam restorations [8, 43–45]. On the other hand, there is also evidence that the material used has no influence on the caries lesion development [46]. This material-related interaction is not yet clear in the literature, but studies have focused on incorporating antimicrobial materials into composite resins in order to improve the properties of these materials. The technical sensitivity related to composite resins compared to amalgam may also be responsible for the higher occurrence of caries lesions around restorations, due to imperfections left during the execution of the procedure. It should be noted that, as mentioned in a widely defunded study [34], the material used on the restoration has a small role on the longevity of the restoration. The factors related to the patient, such as the caries risk, have a major role. The caries prevention depend basically of the oral hygiene and dietary habits, which is essential to decrease the incidence of caries around restorations and prolong the restorations longevity.

In addition, regarding the multilevel regression analysis, it was decided to include the order of the criteria examination as a variable related to the clinical evaluation. The aim of this inclusion was to improve the building of a reliable model. The examination order showed no statistically significant difference for the three outcomes evaluated, which may demonstrate that there was no bias in the restoration evaluation by the examiner according to the randomized criteria. Besides, this ratifies the study calibration process.

The use of standardized criteria may imply some limitations to this study. A limitation to be considered is that the FDI criterion is indicate to be used mainly on the clinical research [19], while the CARS criteria is mainly indicate for use by the clinicians [23, 27]. This may imply some bias to this study. Besides, although the analysis shows a more invasive approach by the FDI criterion indicating more replacements than CARS, it is still necessary to wait the results of the clinical trial on the long term to be affirm the accuracy of the methods. Further studies evaluating the influence of the diagnostic methods on treatment decisions should be performed.

Conclusions

In conclusion, the choice of the visual criteria used on the assessment of the restored teeth influences on the decision of intervene or not on the restoration. The use of the FDI criteria reflected a less conservative approach on permanent teeth, compared to the CARS criteria.

Conflicts of interest

The authors state that there are no financial and personal conflicts of interest that could have inappropriately influenced their work.

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5 Artigo 2[1]

Accuracy of two visual methods for the detection of caries around restorations: a delayed-type cross-sectional study

Short tittle: Accuracy of two visual methods for secondary caries detection

Juliana Lays Stolfo Uehara[a], Cácia Signori[b], Vitor Henrique Digmayer Romero[a], Fausto Medeiros Mendes[c], Maximiliano Sérgio Cenci[a]

[a] Graduate Program in Dentistry, School of Dentistry, Federal University of Pelotas, Rua Gonçalves Chaves, 457, Pelotas, RS 96015-560, Brazil

[b] Department of Restorative Dentistry, School of Dentistry, Uniavan University Center, Av. Marginal Leste, 3600, Balneário Camboriú, SC 88339-125, Brazil. caciasignori@gmail.com

[c] Department of Pediatric Dentistry, School of Dentistry, University of São Paulo, Avenida Prof. Lineu Prestes, 2227, São Paulo, SP 05508-000, Brazil. fmmendes@usp.br

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Corresponding author:
Maximiliano Sergio Cenci
E-mail adress: Maximiliano.Cenci@ufpel.edu.br
Phone number: (+55) (53) 3284 3140

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Accuracy of two visual methods for the detection of caries around restorations: a delayed-type cross-sectional study

Abstract

Objective: The aim of this study was to compare the performance of two visual criteria on the detection of caries around restorations in permanent teeth. Method: This is a delayed-type cross-sectional study designed to evaluate the accuracy of the visual inspection criteria on the detection of caries around restorations. The patients were randomized according to the visual criteria investigated in 2 groups: the FDI (International Dental Federation) criteria and the CARS ("Caries Associated with Restorations or Sealants") criteria, described by the International Caries Classification and Management System. The restored teeth were assessed according to the criteria sorted and the treatment was assigned. Two reference standards were used according to the treatment assigned to each restoration: i) for restorations indicated to operative interventions (repair/replacement) the restoration was (partially/totally) removed and the presence or absence of carious tissue was assessed; ii) for restorations indicated to non-operative intervention a follow-up of one year was established to evaluate the presence of lesions not detected at the baseline. The outcome variables were sensitivity, specificity and the accuracy of the criteria. For the analysis the FDI criteria was divided on the following variables as more than 1 aspect was examined: FDI presence of caries; FDI marginal adaptation, FDI marginal staining and FDI global criteria [extreme cases (FDI scores 4-5) of marginal staining and adaptation were considered as ‘presence of caries’]. A receiver operating characteristics (ROC) analyses considering the diagnostic criteria were conducted to calculate the area under ROC curves (AZ) with their respective 95% confidence intervals (95% CI). Sensitivity, specificity, and accuracy were calculated. Results: Only the FDI staining criterion showed a statistically significant difference when compared with the other methods for AZ. Higher sensitivity was founded for the FDI global criteria (90.3%) and higher specificity was founded for CARS (88.3%). The best accuracy was founded for CARS (85.6%). Conclusions: CARS criteria presented the best accuracy on the detection of caries around the restorations. The use of the FDI criteria should take into account the higher risk of overtreatment.

Clinical relevance: The use of diagnostic criteria with adequate sensitivity, specificity and accuracy helps on the correct treatment indication, avoiding overtreatment.

Introduction

Secondary caries is still considered the most common reason for restorations failure [1,2]. It is also known as ‘caries around restorations’ as it involves the development of a caries lesion adjacent to the margins of an existing restoration [3]. Although some studies have raised discussions about the differences between the characteristics of secondary caries lesions compared to the primary caries lesions, the literature has already showed that these lesions share similar mechanisms of development [4,5]. It can be developed as a ‘wall lesion’, which is located at the interface between the dental structure and the restoration, or as an ‘external lesion’ on the dental surface near to the restoration [6,7].The clinical detection of these lesions is a significative challenge in the dental routine [8]. Some clinical aspects can be confounded as secondary caries lesion in the diagnosis process and enhance the number of false-positive cases in dental care [5]. Aspects resulting from the natural restoration degradation, such as marginal staining, discoloration of the dental structure and small cracks of the restorative material may be erroneously interpreted as caries around restoration [8,9].

Visual inspection is still the method conventionally used for the detection of caries around restorations, but the validity of the visual criteria used was investigated by a limited number of studies [10]. Among the criteria available on the literature, two have been the most used ones. One of them is the FDI criteria proposed by the International Dental Federation [11] which have been widely used for the evaluation of restorations. And the other is a newer method created by The International Caries Detection and Assessment System (ICDAS) [12] which is focused on the detection of caries lesions around restorations and sealants (CARS).

The correct detection of caries around restorations impacts directly on the treatment decision, avoiding overtreatment [10]. A reliable detection criterion should present good sensitivity and specificity [13]. Sensitivity represents the ability to genuinely identify positive results, while specificity represents the ability to identify true negatives results [14]. Clinical studies are the best scenario for investigate the reliability of a diagnostic method [15]. Therefore, this study aims to compare the performance of CARS an FDI criteria in the detection of caries around restorations in permanent teeth. The hypothesis tested was that there would be no difference between the performance of the two methods tested.

Material and Methods

The Standards for Reporting Diagnostic accuracy studies (STARD) guideline was used to write this manuscript [16].

Study design

This is a delayed-type cross-sectional study designed to evaluate the accuracy of the visual inspection criteria on the detection of caries around restorations. The patients were randomized according to the visual criteria investigated: the FDI criteria and the CARS criteria. The restored teeth included were assessed according to the criteria sorted by a calibrated examiner. And the treatment was assigned. Two reference standards were used according to the treatment designated to each restoration: i) for restorations indicated to operative interventions (repair/replacement) the restoration was (partially/totally) removed and the presence or absence of carious tissue was assessed; ii) for restorations indicated to non-operative intervention a follow up of one year was established to evaluate the presence of lesions not detected at the baseline. The outcome variables were sensitivity, specificity and the accuracy of the criteria.

Sample characteristics

This study is nested in a randomized clinical trial called Caries Cognition and Identification in Adults (CaCIA). That study was registered in ClinicalTrial.gov under number NCT03108586. The study was approved by the local ethics committee (number: 1.625.236).

The CaCIA trial is a triple-blind (patients, operators and follow-up examiner), randomized, parallel-group study, which compares the diagnosis by two visual criteria: the FDI criteria (control group) proposed by the International Dental Federation [11]; and the Caries Associated with Restorations or Sealants (CARS) criteria (experimental group), described in the International Caries Classification and Management System (ICCMS) [12]. The main outcome is the need of new interventions on the restorations included.

Briefly, the CaCIA trial evaluated patients aged to 18 to 60 years, who sought dental care at the School of Dentistry of the Federal University of Pelotas, where the

study was conducted. The patients should have at least one restoration in permanent posterior teeth. Both amalgam and composite resin restorations were included. Patients who had any systemic condition requiring specialized treatment were not included. Also, restorations presenting spontaneous pain, fistula, abscess, pulp exposure or mobility, were excluded from the study.

Criteria Calibration

Two examiners were calibrated to participate from the study. One examiner was responsible for the inclusion of the patients according to the criteria randomization. And the other for the follow-up assessments after 1 year.

The calibration occurred in two phases. At first, photos with restorations showing marginal defects were presented to the examiners on a dark room in a high definition screen. The examiners discussed each case according to the FDI and CARS criteria. The second phase was performed at the clinic. The examiners assessed restorations at the clinic and assigned the scores for each restoration according to both criteria investigated. In the end all the cases were discussed and a consensus was established.

Randomization

Opaque, sealed and consecutively numbered envelopes were used for the randomization. A random list was generated in www.sealedenvelope.com website. The randomization was performed in blocks according to the DMF-T and caries activity, which were assessed on the first dental appointment. Four blocks were done: (1) dmf-t index less or equal to 4 without caries activity; (2) dmf-t index less or equal to 4 with caries activity; (3) dmf-t greater than 4 without caries activity; and (4) dmf-t greater than 4 with caries activity.

Examination

The patients were randomized and the restorations evaluated according to the sorted criteria. The treatment plan was established based on the assessment and according to the what is preconized by the criteria [11,12]. The treatment options according were no-treatment, repair, replacement, and topical fluoride application (only preconized by the CARS criteria). For the examination of the reference standard

method, other calibrated examiner performed the evaluations blinding about the test method in evaluation results.

Test methods

The criteria used in the study were the FDI and CARS criteria. FDI was established by the International Dental Federation [11] to assess direct and indirect restorations. It is composed for 16 items divided into three groups by properties (aesthetic, functional, and biological). Each of the items can be scored from 1 to 5, which indicates the treatment need of the restored tooth assessed [1 = clinically excellent/very good, 2 = clinically good, 3 = clinically sufficient/satisfactory, 4= clinically unsatisfactory (but reparable), and, 5 = clinically poor (replacement necessary)].

Considering the high number of criteria available, which may be unnecessary depending of the variable under study, and also implies a longer time to perform the assessments, it is suggested by the authors of the FDI criteria the choice for the most appropriate ones for the study outcome under investigation. Because of this, recurrent caries, marginal staining and marginal adaptation were evaluated for this study. We considered evaluating these factors because they are identified as factors evaluated clinically by dentists and which are often mistaken for caries around restorations. Details of the subcategories chosen to be evaluated in this study, and the respective treatment indications are available in Table 1.

The CARS criteria [12,17], attributes a number to the restored tooth related to the characteristics of the dental structure adjacent to the restoration. Also, it suggests the assessment of the lesion activity (active or inactive lesions) based on ICCMS recommendations [18]. Were considered active lesions those that the surface of enamel is whitish/yellowish, opaque with loss of luster, feels rough when the tip of the ball-ended probe is moved gently across the surface. Lesions in a plaque stagnation area or covered by thick plaque prior to cleaning. For dentin, active lesions were that dentin feels soft or leathery on gentle probing. Inactive lesions were those where the surface of enamel is whitish, brownish or black, shiny and feels hard and smooth when the tip of the ball ended probe is moved gently across the surface. The locations of these lesions are typically at some distance from the gingival margin. Dentin appearance for inactive lesions is shiny and hard on gentle probing [18].

The CARS scores can range from 0 to 6. Table 2 shows the characteristics, descriptions, and treatment indications suggested by the CARS criteria [12].

Table 1: Scores description of the FDI (International Dental Federation) subcategories used to assess the restorations.

Classification		Marginal staining	Marginal adaptation	Recurrence of caries	Treatment
1	Clinically very good	No marginal staining	Harmonious outline, no gaps, no white or discolored lines	No secondary or primary caries	
2	Clinically good	Minor marginal staining, easily removable by polishing	Marginal gap (<150 μm), white lines. Small marginal fracture removable by polishing. Slight ditching, slight step/flashes, minor irregularities. Gap < 250μm not removable	Very small and localized demineralization	No treatment
3	Clinically sufficient satisfactory	Moderate marginal staining, not esthetically unacceptable	Several small marginal fractures. Major irregularities ditching or flash, steps. Gap > 250μm or dentine/base exposed	Larger areas of demineralization	
4	Clinically unsatisfactory	Pronounced marginal staining; major intervention necessary for improvement	Severe ditching or marginal fractures. Larger irregularities or steps	Caries with cavitation	Repair
5	Clinically poor	Deep marginal staining, not accessible for intervention	Restoration (complete or partial) is loose but in situ. Generalized major gaps or irregularities	Deep secondary caries or exposed dentine that is not accessible for repair of restoration	Replacement

The content of this table was based on the FDI criteria developed by International Dental Federation [11].

Table 2: Lesions characteristics according to the CARS (Caries Associated with Restorations and Sealants) criteria and treatment indication.

Classification		Description	Treatment
0	Sound tooth surface with restoration or sealant	No evidence of change in enamel translucency due to caries after plaque removal and air-drying. Non-carious surfaces with developmental defects of enamel (including fluorosis), erosive tooth wear, and extrinsic/intrinsic stains are considered as sound for caries.	No treatment
1	First visual change in enamel	Changes in enamel seen as a carious opacity or visible discoloration (white/brown spot) not consistent with the clinical appearance of sound enamel with no evidence of surface breakdown, no underlying dentine shadowing or cavitation	No treatment – adjacent inactive lesions OR Topical Fluoride Application – adjacent active lesions
2	Distinct visual change in enamel/dentin adjacent to a restoration margin		
3	Carious defects of <0.5 mm with the signs of code 2	White/brown spot lesion with localized microcavity/discontinuity, without visible dentine exposure. Best seen after air-drying	
4	Marginal caries in enamel/dentin/cementum adjacent to restoration with underlying dark shadow from dentin	Obviously discolored dentine visible through apparently intact or micro-cavitated enamel surface, which originated on the surface being evaluated. Often seen easiest with the tooth surface wet	Repair OR Replacement* Replacement should be indicated case the carious lesion involves more than half of the restoration.
5	Distinct cavity adjacent to the restoration	Obvious visible dentine cavity in opaque/discolored enamel. A WHO/CPI/PSR probe can gently confirm the cavity extends into dentine	
6	Extensive distinct cavity with visible dentin		

The content of this table was based on the CARS criteria derived from ICDAS proposed by International Caries Classification and Management System (ICCMS) [12].

Reference standard

Two reference standards were used according to the treatment designated to each restoration (operative or non-operative treatment):

a) Operative treatment (repair/replacement): Restorations that were indicated to receive some type of operative treatment (repair or replacement) at the baseline assessment, were evaluated for the presence or absence of decayed tissue during the partial (repair) or total (replacement) restoration removal. The restorative material was carefully removed by the operators responsible for execute the procedures previously assigned. Only the defective restorative material was removed in the cases in which the indicated treatment was the repair of the restoration. In the cases in which the criteria indicated the replacement of the restoration, the whole restoration was removed. After the material removal, teeth were assessed to detect the presence or not of decayed tissue. The criteria for classifying existing decayed tissue activity followed the ICCMS recommendations [18].

b) Non-operative treatment: Restorations that were not indicated for operative treatment were followed-up for the period of one year. Follow-up during this period made it possible to evaluate the presence of lesions that were not detected in the baseline assessment because they were in an early stage. After one year the restorations were evaluated with the same criteria used on the baseline evaluation (FDI and CARS criteria), and the need for new interventions due to caries was assessed.

We don't use the histological analysis in this study as a reference standard test why this study was conducted nested in a randomized clinical trial.

Sample size

Sample size calculation was based on the main study. For the RCT 727 teeth were included on the study. More details about sample size calculation can be consulted on the register published on the Clinicaltrials.gov under the number NCT03108586. For this study a sample of 305 restorations were evaluated. This sample included the characteristics necessary to participate of this study.

Statistical analysis

The FDI criteria was divided on the following variables as more than 1 aspect was examined: FDI presence of caries; FDI marginal adaptation criterion, FDI marginal staining criterion and FDI global criteria. The FDI global criteria is a dichotomous variable based on the 3 aspects individually assessed by the FDI criteria (presence of caries, marginal adaptation, and marginal staining). The highest score received among the three aspects evaluated determined the final score of the FDI global variable (FDI scores 1-3 = sound; FDI scores 4-5 = decayed). Thus, the extreme cases (FDI scores 4-5) were considered as 'presence of caries' as well.

A descriptive analysis of the restorations included in this study was performed. After, receiver operating characteristics (ROC) analyses considering the diagnostic methods (CARS, FDI presence of caries, FDI marginal adaptation criterion, FDI marginal staining criterion and FDI global criteria) were conducted to calculate the area under ROC curves (AZ) with their respective 95% confidence intervals (95% CI). The AZ was not calculated for FDI Global criteria because is a dichotomous variable. The Az was compared among the methods using a Hanley and McNeil approach.

As regards other accuracy parameters, the cutoff points were predetermined according to the criteria. Using those cutoff points, we calculated sensitivity, specificity, and accuracy (percentage of corrected diagnosis considering both sound and decayed teeth) values (95% CI) through McNemar test.

Results

Table 3 presents a description of the study sample. A total of 305 restorations were included in this study. A number of 93 restorations were indicated for operative treatment (repair or replacement) at the baseline evaluation, and 211 for non-operative treatment. A prevalence of almost 90% of sound teeth was found. Only three teeth assessed after 1-year follow up presented decayed tissue.

Table 4 shows the best cutoff points, area under ROC curve (Az), sensitivity, specificity, and accuracy of the different methods. There was no difference among CARS, FDI presence of caries, and FDI adaptation on the Az. Only the FDI staining

criterion, due to the lower Az value (Az = 0.501), showed a statistically significant differences when compared with the other methods.

Table 3: Description of the sample of restorations included of the study

Diagnostic methods	Sound		Decayed		Total
	Operative treatment	Assessment after follow-up	Operative treatment	Assessment after follow-up	
Total	65	209	28	3	305
Caries prevalence	274 (89.8%)		31 (10.2%)		
CARS scores					
0	15	117	1	0	133
1	0	2	1	0	3
2	13	61	3	2	79
3	14	20	4	1	39
4	10	9	2	0	21
5	13	0	13	0	26
6	0	0	4	0	4
FDI presence of caries					
1	11	110	2	0	123
2	10	47	1	0	58
3	11	38	5	3	57
4	23	11	8	0	42
5	10	3	12	0	25
FDI adaptation					
1	0	14	0	0	14
2	15	118	3	1	137
3	13	67	3	1	84
4	35	10	13	1	59
5	2	0	9	0	11
FDI staining					
1	4	19	4	0	27
2	10	32	4	1	47
3	13	35	5	1	54
4	18	14	5	0	37
5	4	2	1	0	7
Total for FDI staining*	49	102	19	2	172

CARS = Caries Associated with Restorations or Sealants
FDI = International Dental Federation criteria
* The number of examined teeth is lower because this parameter was only used for teeth with composite restorations.

CARS, FDI presence of caries, and FDI marginal adaptation criterion presented similar sensitivities. The values were significantly higher for the FDI global criteria (90,3%) and significantly lower for FDI staining criterion (28,6%). Specificity showed similar values for the FDI presence of caries, FDI adaptation, and FDI staining criterion. The highest value was founded for CARS (88,3%), and the lowest value was founded com FDI global criteria (65,3%). The lowest accuracy value was founded for FDI global criteria (67,9%) while the CARS criteria showed the highest accuracy (85,6%).

Table 4: Area under ROC (AZ), best cutoff points, sensitivity, specificity and accuracy of the different diagnostic criteria assessing caries lesions around restorations.

	Area under ROC curve (AZ)	Cut-off point	Sensitivity	Specificity	Accuracy
CARS	0.854 a	> 3	0.613 b, c	0.883 a	0.856 a
	(0.810 to 0.892)		(0.422 to 0.782)	(0.839 to 0.919)	(0.813 to 0.892)
FDI presence	0.830 a	> 3	0.645 b, c	0.829 b	0.810 b, c
of caries	(0.783 to 0.871)		(0.454 to 0.808)	(0.779 to 0.871)	(0.763 to 0.851)
FDI adaptation	0.826 a	> 3	0.742 a, b	0.823 b	0.820 a, b
	(0.779 to 0.867)		(0.554 to 0.881)	(0.554 to 0.881)	(0.774 to 0.860)
FDI staining **	0.502 b	> 3	0.286 c	0.748 b	0.692 c
	(0.425 to 0.579)		(0.113 to 0.522)	(0.671 to 0.815)	(0.620 to 0.758)
FDI global	*		0.903 a	0.653 c	0.679 d
			(0.742 to 0.980)	(0.594 to 0.710)	(0.625 to 0.729)

CARS = Caries Associated with Restorations or Sealants
FDI = International Dental Federation criteria
ROC = Receiver Operating Characteristics
* Area under ROC curve was not calculated because FDI Global is a dichotomous variable
** n = 305 examined teeth, except for the method FDI staining (N = 172)
Different letters in the same column indicate statistically significant differences among the methods ($p < 0.05$, through McNemar test)

Discussion

To our knowledge this is the first clinical trial that compares the diagnostic sensitivity, specificity, and accuracy from the International Dental Federation (FDI) criteria and from the Caries Associated with Restorations and Sealants (CARS) criteria, developed by the International Caries Classification and Management System, on the assessment of caries around restorations in permanent teeth. The findings of

this study showed higher accuracy using the CARS criteria (85,6%) for the detection of caries around restorations compared to the FDI criteria (67,9%).

The caries lesions around restorations is one of the main reasons of restorations replacement [19]. Thus, a standardized detection method should be used in order to avoid unnecessary operative interventions. The accuracy of detection methods was previously investigated in in vitro studies or cross-sectional studies [20–26]. However, no clinical trial was developed so far to test the reliability of the methods and criteria used on the detection of caries around the restorations. Thus, the accuracy of the diagnostic methods is still a topic under investigations, since the validity of what is available in the literature needs to be clinically proved [8,10].

The visual-tactile examination is one of the methods most used nowadays on the evaluation of caries around restorations [25]. However, the visual-tactile exam has a subjective component, which may vary among the practitioners depending on the experience time and a less or more conservative approach, for exempli [9,27,28]. Significant variation among practitioners related to the detection of caries around restorations was already reported [29]. So, in an attempt to aid to standardize the diagnosis process, a criterion was created for the detection of caries lesions around restorations and sealants (CARS) based in the already existent International Caries Detection and Assessment System (ICDAS) [12]. Some in vitro studies have investigated the performance of the CARS criteria in comparison to other detection methods, such as the radiographic method [20,30], and the detection with optical devices [24,31,32], showing good results. However, the CARS criteria were not clinically compared to other visual criteria used to assess secondary caries in permanent teeth.

The FDI criteria from the International Dental Federation are also used to assess the quality of the restorations [11]. It is a widely used system, which have been used by several studies [33]. In this study, as already mentioned before, besides the recurrence of caries, we decided also to exam the aspects of marginal staining and marginal adaptation provided by the FDI system. This choice was made because deep marginal staining and/or the lack of adaptation lead many dentists to an erroneously diagnoses of secondary caries.

In our study, higher sensitivity was founded for the FDI global criteria. High sensitivity tests rarely ignore a real positive case [13]. However, the FDI global criteria also showed low specificity, which implies in a higher rate of false-positive diagnosis.

The FDI global criteria incorporated the three dimensions evaluated for the FDI group, considering the aspects ‘marginal staining’ and ‘marginal adaptation’ also as caries lesions on the analysis. This explain the low specificity. And reinforces the low prediction power of marginal defects on caries lesions. In addition, the FDI staining criterion showed lower sensitivity. The marginal staining was evaluated only for composite resin restorations, which is a limitation of this study. We have decided not to evaluate the marginal staining for amalgam restorations due to the pigmentation that the material naturally promotes in the dental structure. This could lead to an overestimation of the cases of caries around amalgam restorations due to this natural characteristic of amalgam restorations.

The CARS criteria and the FDI presence of caries criterion showed similar sensitivity. The description of what should be considered as a caries lesion by the FDI shows some similarities to the CARS criteria, being based on the classification of lesion severity [34]. However, the CARS criteria presented higher specificity compared to FDI presence of caries criterion.

The CARS criteria showed a higher value for specificity while the FDI global criteria presented the lower value for the same metric. The specificity is related to the identification of true negative cases, that is, positive results in tests with high specificity are useful to determine the disease. It means a high probability of the presence of the disease [13]. In this case, the teeth evaluated by the CARS criteria and identified with caries lesion around restoration will probably be true carriers of the disease. The CARS criteria showed a higher specificity value without significant loss of sensitivity, which results in a good accuracy to identify caries lesions around the restorations.

The CARS criteria showed the best accuracy. Accuracy is the proportion of true results, either true positive or true negative, in a population. The best accuracy results in a better diagnostic precision. The FDI global criteria showed the worst result, which probably is explained by the way the data was analyzed [11], as marginal staining and marginal adaptation were considered as caries lesions. The FDI presence of caries criterion, FDI adaptation criterion, and FDI staining criterion showed similar accuracy.

The use of the FDI criteria to detect caries lesions around restorations can promote a high level of false-positive diagnostics. The erroneous diagnostic can imply in overtreatment and can lead an unnecessary sound tooth structure loss, unnecessary operative reinterventions, and, consequently, unnecessary public or private costs. FDI system was developed to assess the quality of the restorations. However, it reflects

the routine practice with confounder factors that can be misinterpreted as caries lesions around restorations.

The ICDAS accuracy for caries around restorations evaluation was previously assessed by published studies [24,30–32]. The ICDAS was compared to optical devices for detecting caries lesions [20,30,32], and showed to be a good method to detect caries around the restorations. In contrast, another study comparing the ICDAS with other optical device called 'Canary System' on the assessment of wall lesions around composite resins showed an inferior outcome for ICDAS [24]. Similar results were founded in another study from the same group, but this time assessing amalgam restorations [31]. However, both were in vitro studies with methodological limitations related to the lesion's simulation.

Only two studies have evaluated the accuracy of methods on the secondary caries detection under clinical conditions [22,35], but none compared the ICDAS, or more specifically the CARS criteria, with other visual criterion. The majority of the studies are in vitro studies. In vitro studies are easier to perform, and also has the advantage to allow the confirmation of the caries lesions by histological analysis. In the present study, we considered the removal of the restoration as a reference method when operative interventions were indicated, or in cases where the indication was non-treatment, the restorations were followed-up for 12 months in order to verify the progression of pre-existing and unidentified lesions. Thus, the reference method used is a limitation of this study. This study was conducted nested in a randomized clinical trial, which makes not possible to perform histological evaluations to confirm the presence of carious lesions.

A criterion with adequate accuracy, specificity, and sensibility promotes a precise diagnostic and, consequently, can improve the treatment decisions. The detection process of caries lesions around restorations still a challenge in dentistry research. A standardized criterion, mainly for caries lesions around restorations detection, can help on a correct treatment indication and avoid overtreatment. In this study, CARS presented the best value for accuracy and adequate results for sensibility and specificity compared with the FDI system. In these conditions, for the detection of caries lesions around restorations, the use of the FDI system can lead to false-positive diagnoses and consequent unnecessary interventions in cases where small marginal defects would not require operative interventions.

Conclusions

In conclusion, the CARS criteria presented the best accuracy on the detection of caries around the restorations. The use of the FDI criteria should take into account the higher risk of false positive results to avoid overtreatment.

Conflicts of interest

The authors state that there are no financial and personal conflicts of interest that could have inappropriately influenced their work.

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6 Artigo 3[1]

The effect of the use of two clinical criteria on the assessment of caries lesions around restorations in adults – the Caries Cognition and Identification in Adults (CaCIA) randomized controlled trial

Short title: Use of clinical criteria on the assessment of caries lesions around restorations in adults

Juliana Lays Stolfo Uehara[1], Cácia Signori[2], Vitor Henrique Digmayer Romero[1], Fausto Medeiros Mendes[3], Maximiliano Sérgio Cenci[1]

1 Graduate Program in Dentistry, School of Dentistry, Federal University of Pelotas, Rua Gonçalves Chaves, 457, Pelotas, RS 96015-560, Brazil

[2] Department of Restorative Dentistry, School of Dentistry, Uniavan University Center, Av. Marginal Leste, 3600, Balneário Camboriú, SC 88339-125, Brazil

3 Department of Pediatric Dentistry, School of Dentistry, University of São Paulo, Avenida Prof. Lineu Prestes, 2227, São Paulo, SP 05508-000, Brazil

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Corresponding author:
Maximiliano Sergio Cenci
E-mail address: Maximiliano.Cenci@ufpel.edu.br
Phone number: (+55) (53) 3284 3140

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Abstract

The aim of this study was to perform a clinical trial to evaluate the effect of using two visual criteria to assess caries around restorations on the treatment decision and longevity of restorations. This was a randomized triple-blind, controlled trial with two parallel-groups: patients who received the assessment of the restorations and treatment decision according to FDI (International Dental Federation) criteria - FDI group; and patients who received the assessment of the restorations and treatment decision according to the CARS (Caries Associated with Restorations or Sealants) criteria from the International Caries Classification and Management System - CARS group. The patients were followed-up for up to 38 months, with a mean of 20.4 months. The main outcome was the restoration failure. The univariate and multiple Cox regression analysis with shared frailty were conducted. A total of 185 patients were included on the study, totaling 727 teeth. A total of 55% of the restorations were assessed on the follow-up. The follow-up time ranged between 6 and 38 months. A total of 187 restorations randomized by the CARS criteria returned to the followed-up, of which 12 operative treatments were performed. A total of 218 restorations assessed by the FDI criteria returned to the followed-up, of which 67 interventions were performed. The multivariate Cox regression did not showed association between the restoration's failures and the main study variable (diagnostic strategy). The same was observed for the variables sex, age, caries experience, caries activity, type of teeth, dental arch and dental material. The restorations with three or more surfaces had almost eight times higher risk for failure compared to restorations with 1 restored surface. Material fracture and secondary caries were the main reasons of failures. In conclusion, the FDI criteria indicates more operative treatments compared to the CARS criteria. The use of a more conservative approach on the detection of caries around the restorations leading to less interventions at baseline and promoted the same need for reintervention on long term compared to a less conservative approach.

Introduction

The caries lesions around restorations, also called as secondary caries, are still poorly diagnosed on the dental practice, although considered as one of the main reasons for the restoration failure [1–3]. Secondary caries is defined as a primary caries lesion that develops around the restoration. Over the years, restorations may present some aspects such as marginal staining, tooth discoloration and small cracks. These aspects are the result from a natural process of the restorative material degradation, and could be considered as not clinically relevant [4]. Thus, the restoration remains clinically acceptable even presenting such small defects. However, these defects may be misdiagnosed as secondary caries lesions on the clinical practice [5–10], leading to the unnecessary restoration replacement. There is a significant difference between the number of secondary caries lesions reported on the daily practice routine (28.5-59%) [11] and on controlled clinical trials (2-3%) [12], and part of this difference could be due to misdiagnosis. The overtreatment of the restorations accelerates the restorative death spiral [13], which impacts directly on the patients' health. This raises a concern regarding the improvement of the detection of caries lesions around restorations.

The visual-tactile inspection and the radiographic assessment are the traditional methods used for the detection of caries lesions around restorations [14]. Nevertheless, different types of visual and radiographic criteria are used on the assessment of secondary caries, leading on different treatment indications. To aid in the standardization of the diagnostic process, some well-described clinical criteria were developed to assess visually the quality of the restorations and the presence of caries lesions. Among them the most used ones in the clinical research and clinical practice are the International Dental Federation (FDI) [15] criterion, and the Caries Associated with Restorations or Sealants (CARS) criteria, developed by the International Caries Classification and Management System (ICCMS - International Caries Classification and Management System) criterion [16,17].

Cross-sectional studies have been performed to evaluate the prevalence and characteristics of secondary caries lesions [18]. And also used to investigate the accuracy of the detection methods on the assessment of caries around restorations [6,14]. Although accuracy is an important parameter to choose the most appropriate strategy to be used to diagnose a specific condition, other aspects related to the

treatment decision and patient-centered outcomes should also be investigated to aid on the choice of the diagnostic strategies. It should follow the same logic used on medicine on the investigation of new diagnostic methods. However, most of the studies related to the detection of caries shows lack of clinical relevance and do not report patient-centered outcomes [14]. There are no records of prospective studies evaluating the use of different visual criteria on the assessment of caries around restorations and the impact under the treatment decision on restorations in permanent teeth.

Thus, the aim of this study was to perform a clinical trial to evaluate the effect of using 2 visual criteria (FDI and CARS criteria) to assess caries around restorations on the treatment decision and longevity of the restorations. The hypothesis tested was that after the follow-up period, the restoration failure rate would be the same for both criteria.

Material and methods

Study design

This clinical trial was designed to evaluate the impact of the visual criteria on the assessment of permanent restored teeth on the outcomes related to oral health in adults in long-term. This was a randomized triple-blind, controlled trial with two parallel-groups: patients who received the assessment of the restorations and treatment decision according to the FDI criteria [15] - FDI group; and patients who received the assessment of the restorations and treatment decision according to the CARS (Caries Associated with Restorations or Sealants) criteria from ICCMS [16] – CARS group. The patients were followed-up for up to 38 months. The main outcome was the restoration failure.

This trial is named Caries Cognition and Identification in Adults (CaCIA) trial, and it is registered at ClinicalTrials.gov (NCT03108586). It was approved by the Research and Ethical Committee (1.625.236) of the Federal University of Pelotas. Patients signed a term agreeing to participate in the study. The CONSORT recommendations were used to guide the report of this clinical study [19].

Participants

The patients who sought dental treatment at the School of Dentistry of the Federal University of Pelotas and filled the following eligibility criteria were included on the study.

1.Inclusion criteria:

a) Patients aged 18 to 60 years;

b) Patients who present at least one restoration of composite resin or amalgam on a posterior permanent tooth.

2. Exclusion criteria:

a) Patients who refuse to participate;

b) Patients with systemic conditions or chronic diseases that would require differentiated care and follow-up;

c) Restorations on teeth with the following conditions: fistula, abscess, pulp exposure, spontaneous dental pain or mobility.

Interventions

At the first dental visit, the patient was informed about the study and signed the informed consent form. The anamnesis of the systemic and oral conditions was performed. The patients were firstly examined according to the International Caries Detection and Assessment System (ICDAS) [16]. The caries activity was also assessed. If the patients met the eligibility criteria, they were randomized into two groups according to the diagnostic strategy:

a) Control group: diagnosis and treatment decision based on the International Dental Federation (FDI) criteria.

b) Experimental group: diagnosis and treatment decision according to the CARS detection criteria, described in the ICCMS.

Calibration process

The calibration process was performed in two phases. In the first phase, photos of restorations with marginal defects were projected on a television screen in a dark room, and the discussion about the cases was performed between the examiner and a gold standard evaluator, expert in restorative dentistry with training and experience in the assessment of restorations (M.S.C). The second phase was performed with

patients at the clinic. The examiner and the expert assessed a series of restorations and assigned the diagnosis and treatment according to the FDI and CARS criteria. If any disagreements were identified, the cases were discussed between then until they reach a consensus.

Criteria description

FDI criteria

The FDI system [20] is a criterion for the evaluation of direct and indirect restorations based on three properties: esthetic, functional, and biological. Each one of these aspects has subcategories, resulting in a total of 16 aspects that should be evaluated to determine the conditions of the restoration. Each of these 16 aspects can be scored from 1 to 5 [1 = clinically excellent/very good, 2 = clinically good, 3 = clinically sufficient/satisfactory, 4= clinically unsatisfactory (but reparable), and, 5 = clinically poor (replacement necessary)].

On this study three subcategories were chosen for the assessment of the restorations: marginal staining, marginal adaptation, and recurrence of caries (Table 1). Besides the recurrence of caries, in order to complement the assessment of the restorations the marginal staining and marginal adaptation were also assessed. This decision was based on the fact that many dentists associate these two defects with the presence and detection of caries lesions around the restorations.

In addition, considering the intrinsic pigmentation on tooth structure promoted by amalgam restorations, we decided to evaluate only marginal adaptation and recurrence of caries on amalgam restorations. We hypothesized that the assessment of marginal staining on these restorations probably would end up always in a score 5, which would lead to the replacement of the majority of them.

The treatment options for the restorations assessed were no treatment, refurbishment, repair, and replacement.

CARS criteria

The CARS criteria are derived from the ICDAS proposed by the International Caries Classification and Management System (ICCMS) [16], which was updated to the CariesCare International 4D [17]. The criteria are described in Table 2. The tooth is classified with a score ranging from 0 to 6, in which 0 refers to a sound surface and 6 to the presence of an extensive lesion.

Table 1. FDI (International Dental Federation) parameters and characteristics evaluated for all restorations for the study

		Marginal staining	Marginal adaptation	Recurrence of caries
1	Clinically excellent	No marginal staining	Harmonious outline, no gaps, no white or discolored lines	No secondary or primary caries
2	Clinically good	Minor staining, but easily removable by polishing	Marginal gap (<150 μm), white lines. Small marginal fracture removable by polishing. Slight ditching, slight step/flashes, minor irregularities. Gap < 250μm not removable	Very small and localized demineralization
3	Clinically sufficient/ satisfactory	Moderate marginal staining, not esthetically unacceptable	Several small marginal fractures. Major irregularities ditching or flash, steps. Gap > 250μm or dentine/base exposed	Larger areas of demineralization
4	Clinically unsatisfactory	Pronounced marginal staining; major intervention necessary for improvement	Severe ditching or marginal fractures. Larger irregularities or steps	Caries with cavitation
5	Clinically poor	Deep marginal staining, not accessible for intervention	Restoration (complete or partial) is loose but in situ. Generalized major gaps or irregularities	Deep secondary caries or exposed dentine that is not accessible for repair of restoration

Adapted from Hickel et al., 2007.

Table 2. CARS (Caries Associated with Restorations or Sealants) parameter evaluated for all restorations for the study

	Lesion aspect	Description
0	Sound tooth surface with restoration or sealant	A sound tooth surface adjacent to a restoration/sealant margin. There should be no evidence of caries (either no or questionable change in enamel translucency after prolonged air drying for 5 seconds). Surfaces with marginal defects less than 0.5mm in width (i.e. will not admit the ball end of the CPI Probe), developmental defects such as enamel hypoplasias; fluorosis; tooth wear (attrition, abrasion and erosion), and extrinsic or intrinsic stains will be recorded as sound. Stained margins consistent with non- carious habits (e.g. frequent tea drinking) and which do not exhibit signs consistent with demineralization should be scored as sound.
1	First visual change in enamel	When seen wet there is no evidence of any change in colour attributable to carious activity, but after prolonged air drying (for approximately 5 seconds) an opacity or discolouration consistent with demineralization is visible that is not consistent with the clinical appearance of sound enamel.
2	Distinct visual change in enamel/dentin adjacent to a restoration margin	If the restoration margin is placed on enamel the tooth must be viewed wet. When wet there is an opacity consistent with demineralization or discolouration that is not consistent with the clinical appearance of sound enamel (Note: the lesion is still visible when dry). If the restoration margin is placed on dentin: Code 2 applies to discoloration that is not consistent with the clinical appearance of sound dentin or cementum.
3	Carious defects of <0.5 mm with the signs of code 2	Cavitation at the margin of the restoration/sealant less than 0.5mm, in addition to either an opacity or discolouration consistent with demineralization that is not consistent with the clinical appearance of sound enamel or with a shadow of discoloured dentin.
4	Marginal caries in enamel/dentin/cementum adjacent to restoration with underlying dark shadow from dentin	The tooth surface may have characteristics of code 2 and has a shadow of discoloured dentin which is visible through an apparently intact enamel surface or with localized breakdown in enamel but no visible dentin. This appearance is often seen more easily when the tooth is wet and is a darkening and intrinsic shadow which may be grey, blue, orange, or brown in colour. Note: view tooth wet and then dry. This lesion should be distinguished from amalgam shadows.

5	Distinct cavity adjacent to restoration	Distinct cavity adjacent to restoration/sealant with visible dentin in the interfacial space with signs of caries as described in code 4, in addition to a gap > 0.5mm in width. OR In those instances where margins are not visible, there is evidence of discontinuity at the margin of the restoration/sealant and tooth substance of the dentin as detected by 0.5mm ball-ended probe run along the restoration/sealant margin.
6	Extensive distinct cavity with visible dentin	Obvious loss of tooth structure, the extensive cavity may be deep or wide and dentin is clearly visible on both the walls and the base

Adapted from Pitts, 2013.

In addition, in this study the caries activity was also assessed according to the ICCMS recommendations [21]. The lesions were considered active when the enamel surface was whitish/yellowish, opaque with loss of luster, felt rough when the tip of the ball-ended probe was moved gently across the surface, located generally in a plaque stagnation area. The dentin was soft or leathery on gentle probing. Inactive lesions were those that enamel surface was whitish, brownish or black, shiny and felt hard and smooth when the tip of the ball-ended probe was moved gently across the surface, located generally at some distance from the gingival margin. The dentin was considered inactive when the aspect was shiny and hard on gentle probing.

The treatment options for the restorations assessed by this criterion were no treatment, professional topical fluoride application in cases of active lesions restricted to the enamel around the restoration, repair (CARS scores 3, 4 and 5) and replacement (CARS score 6).

Patient inclusion and examination process

Before the exam, the teeth surfaces were cleaned using a low-rotation micromotor, rubber cup, Robinson brush and prophylactic paste. All exams were realized in a dental chair under lighting, using a dental mirror and ball-point probe. The FDI evaluation was performed after drying the teeth surfaces [15]. And for the CARS criteria evaluation, all teeth were first evaluated while wet, and then evaluated again after drying for 5 seconds [16].

A calibrated examiner (C.S) performed all the assessments of the restorations according to the randomized criteria, and the treatment plan was established by him. Immediately after this, the same examiner performed a new evaluation, but this time according to the other criteria, which was not sorted by the randomization process. This procedure was realized to perform future comparisons among the criteria. This second evaluation did not influence the treatment plan already established before according to the randomized criteria. The examiner always performed first the assessment by the randomized criteria, and after the assessment by the opposite group, to avoid any type of bias.

The bitewing radiography was realized after the assessments for the monitoring of all the restorations included in short and long term.

Dental treatment protocols

The treatment plan established by the examiner according to the randomized criteria was performed by blind operators. The team of trained operators was formed by undergraduate and graduate students. The operators received just the treatment plan, without any access to the criteria used. The operative procedures (repair or replacement) on the restorations were performed using the bond system Adper Scotchbond Multi-Purpose (3M ESPE, USA) and the Filtek Z350 XT composite (3M ESPE, USA), according to the instructions described by the manufacturers.

Follow-up visits

The follow-up visits were performed until 38 months from the date of discharge (when all the dental procedures were finished). The gold standard examiner (M.S.C) performed the assessments on the follow-up's visits. The need of new interventions was established and assigned as follows:

1. Monitoring: restorations with minor defects, without clinical disadvantages if untreated;
2. Refurbishment: restorations with defects that can be adjusted, i.e. excess removal or surface polishing;
3. Repair: restorations with presence of marginal fractures, clinically relevant gaps (>250μm), defects involving less than half of the restoration size; active caries lesion around restorations with localized and accessible dentin cavitation;
4. Replacement: restorations with large gaps and generalized irregularities, total or partial loss of restoration, defects involving more than half of the restorations size; active caries lesion around restoration and functional impairment.

If the patient complained about intervention in an included restored-tooth, each case was analyzed, and the adequate treatment was determined.

Bitewing radiographs were realized in each follow-up visit for monitoring the restorations.

The patients that did not attend any follow-up consultation, who did not finish the dental treatment, or who gave up participating in the study were considered as drop-outs.

Many attempts at contact were made before considering the patient as a loss. When the phone contact was lost, an attempt to contact the participant by social media was made. Without answer, a letter was sent and if no answer was received, a visit to the address informed by the patient was made to reestablish the contact. In some cases, the address was not found or the patient no longer resided at the address provided. After these, the patient was considered as drop-out of the study.

Outcomes

The outcome under analysis was the restoration failure on long term. The restorations were considered as failure if any necessity of operative reintervention (repair or replacement) was present on the follow up evaluation. The successful restorations were those that didn't require any additional operative intervention during the follow-up.

Sample size

The sample size calculation considered a 2-year failure rate of approximately 10% for occlusal restorations and 30% for occlusal-proximal restorations, based on previous studies [22,23]. It was also taken into account that approximately 10% of the replaced restorations and 14% of the restorations undergoing repair fail again [24]. Thus, estimating that half of the sample is from occlusal restorations, an operative reintervention requirement rate of 24% was estimated in 2 years. The number of 522 restorations was reached, based on an absolute difference of 10% between the groups, using a two-tailed test. As a participant can contribute with more than one restoration, 20% was added to this value (n = 626). Thus, considering a predetermined average of inclusion of 5 teeth per patient, and adding 20% to possible sample losses, a minimum number of 152 patients was reached to be included in the trial.

Randomization process

A random list was generated on the www.sealedenvelope.com website using stratification by blocks. Four blocks were considered based on the dmf-t index and caries activity: (1) dmf-t index less or equal to 4/ without caries activity; (2) dmf-t index less or equal to 4/ with caries activity; (3) dmf-t greater than 4/ without caries activity; and (4) dmf-t greater than 4/ with caries activity. Opaque, sealed and consecutively

numbered envelopes were used to keep the criteria on secrecy. The envelopes were only opened immediately before the examiner start the evaluation.

Blinding

The operators (undergraduate and graduate students), the examiner who performed the follow-up assessment and the patients were blinded to the participants allocation group.

Statistical analysis

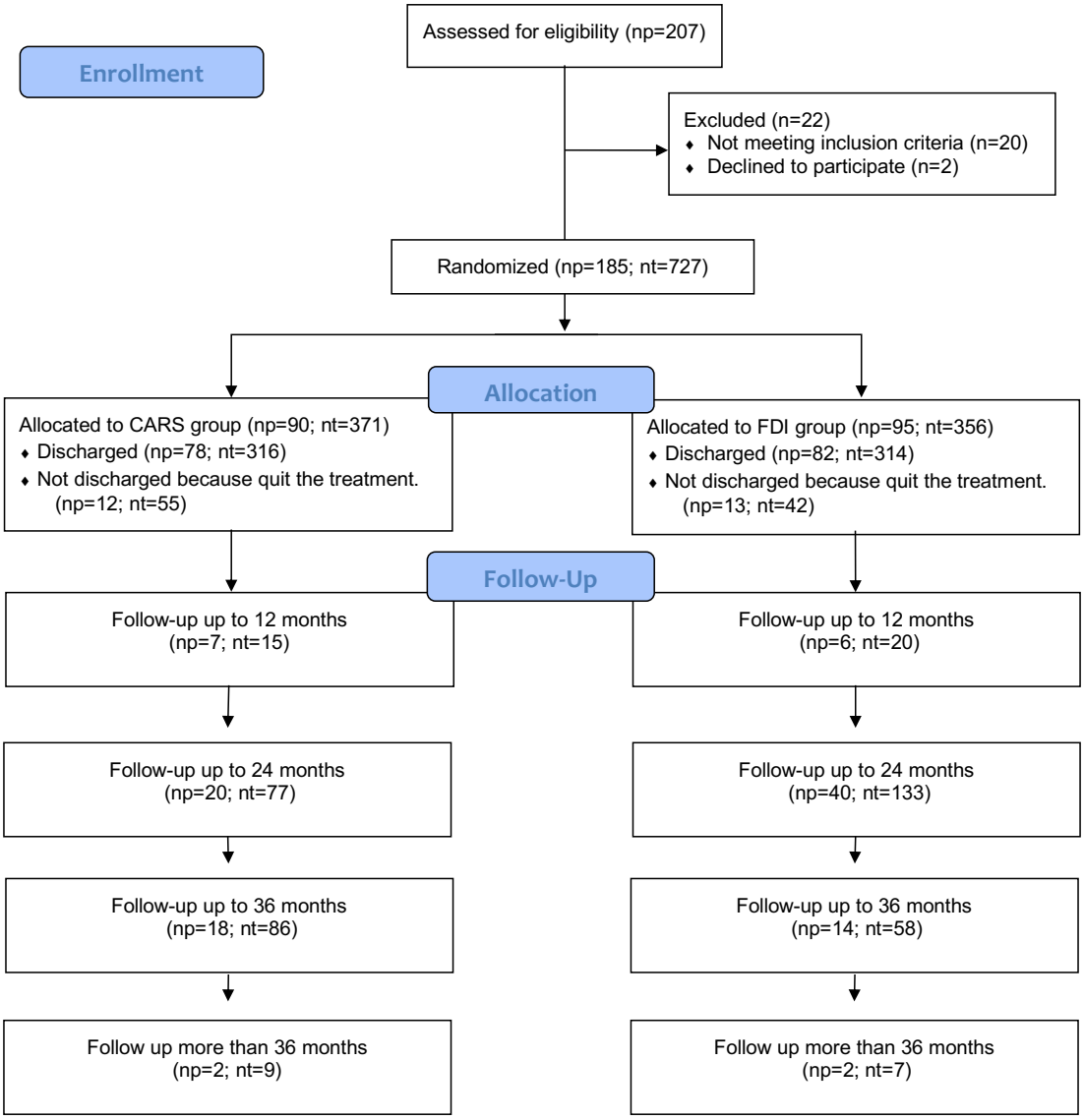
Statistical analysis was conducted with statistical package Stata 13 (StataCorp LP, College Station, USA). Descriptive statistics was performed. The patients who had at least one follow-up visit within a maximum period of 38 months were analysed. The univariate and multiple Cox regression analysis with shared frailty was conducted to compare the influence of the different variables on the occurrence of restorations failures. The Hazard Ratios (HRs) with respective 95% confidence intervals (CIs) were determined. A significance level of 5% was set for all the analyses.

Results

A total of 185 patients were included on the study between September 2016 and September 2018. The mean of 3.9 restored teeth were included by patient, totaling 727 teeth. Details of the recruitment, allocation and follow-ups in each stage of the trial are disclosed in the flow diagram (Fig. 1).

Table 3 shows the demographic characteristics of the patients according to the diagnostic strategy used for the caries detection around the restorations. The distribution of the patients for sex, age, caries experience, caries activity and DMF-T was similar for both groups at the baseline analysis ($p > 0.05$). When looking to the patients on the follow-up and the drop-outs, only the caries activity presented statistically significant difference ($p = 0.039$). A higher number of patients with caries activity dropped out.

Figure 1. Participants flow diagram in the different phases of the study.



Abbreviations: np - number of patients; nr – number of restorations

Table 3. Demographic characteristics of the patients (n=185) according to the diagnostic strategy used for the caries detection around the restorations and according to the follow-up assessment.

Characteristics of the patients	Baseline			Follow-up		
	CARS	FDI	p *	Follow-up	Drop-out	p *
Categorical variables	**n (%)**	**n (%)**		**n (%)**	**n (%)**	
Patients included (n)	90 (48.6)	95 (51.4)		94 (50.8)	91 (49.2)	
Groups						0.093
CARS				40 (21.6)	54 (29.2)	
FDI				50 (27.0)	41 (22.2)	
Sex			0.299			0.544
Female	55 (45.8)	65 (54.2)		59 (31.9)	61 (33.0)	
Male	35 (53.8)	30 (46.2)		35 (18.9)	30 (16.2)	
Age			0.957			0.528
Up to 30 yrs-old	24 (49.0)	25 (51.0)		23 (12.4)	26 (14.1)	
More than 30 yrs-old	66 (48.5)	70 (51.5)		71 (38.4)	65 (35.1)	
Caries experience			0.920			0.879
DMFT from 0 to 4	10 (47.6)	11 (52.4)		11 (5.9)	10 (5.4)	
DMFT > 4	80 (48.8)	84 (51.2)		83 (44.9)	81 (43.8)	
Caries activity			0.809			0.039
No	62 (48.1)	67 (51.9)		72 (38.9)	57 (30.8)	
Yes	28 (50.0)	28 (50.0)		22 (11.9)	34 (18.4)	
Quantitative variables	**Mean (SD)**		**p ****	**Mean (SD)**		**p ****
Age (years)	41.2 (15.5)	42.7 (16.1)	0.570	43.0 (15.9)	40.8 (15.7)	0.358
DMFT	11.5 (7.0)	11.5 (7.2)	0.959	11.9 (6.9)	11.0 (7.2)	0.334

* calculated by chi-square test.
** calculated by Mann-Whitney test
DMFT = number of decayed, missed or filled teeth. SD = Standard deviation
CARS = Caries Associated with Restorations or Sealants system
FDI = International Dental Federation Criteria

Table 4 presents the baseline clinical characteristics related to the restored teeth included on the study. No significant difference was founded at the baseline regarding the type of teeth, dental arch, number of restored surface and dental material. When comparing the follow-up restorations and the drop-out, a higher number of composite restorations was evaluated in the follow-up analysis (p = 0.024) compared to the amalgam restorations.

Table 4. Characteristics of the restored teeth (n=727) according to the diagnostic strategy used for the caries detection around the restorations and according to the follow-up assessment.

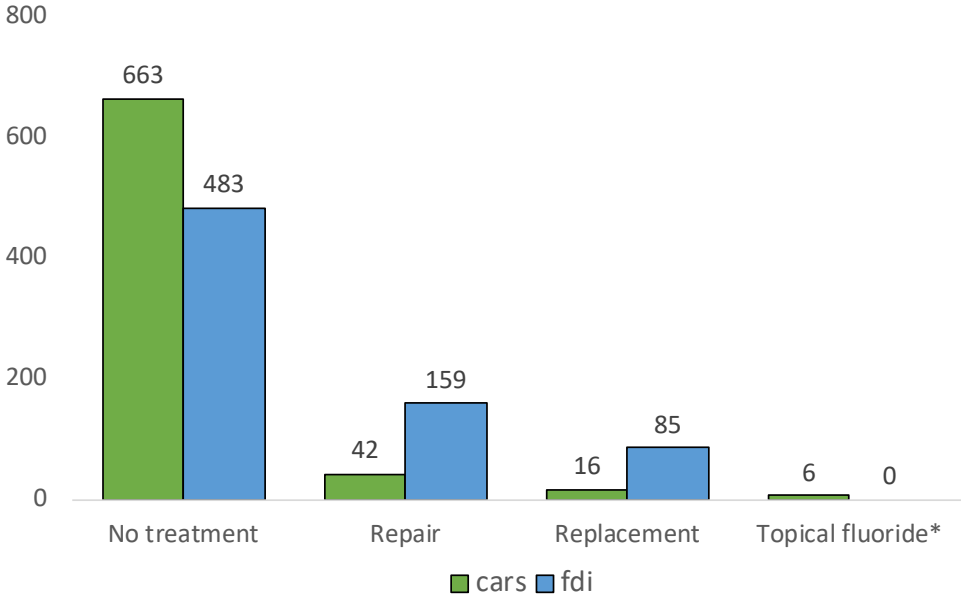
Characteristics of the restorations	Baseline			Follow-up		
	CARS	FDI		Follow-up	Drop-out	
Categorical variables	n (%)	n (%)	p *	n (%)	n (%)	p *
Teeth included (n)	371 (51.1)	356 (48.9)		405 (55.7)	322 (44.3)	
Groups						0.163
CARS				187 (25.7)	184 (25.3)	
FDI				218 (30.0)	138 (19.0)	
Type of teeth			0.430			0.855
Premolar	110 (53.9)	94 (46.1)		115 (15.8)	89 (12.2)	
Molar	261 (49.9)	262 (50.1)		290 (39.9)	233 (32.0)	
Dental arch			0.399			0.230
Upper	186 (52.8)	166 (47.2)		187 (25.7)	165 (22.7)	
Lower	185 (49.3)	190 (50.7)		218 (30.0)	157 (21.6)	
Number of restored surfaces			0.714			0.869
1 surface	206 (51.1)	197 (48.9)		229 (31.5)	174 (23.9)	
2 surfaces	114 (52.8)	102 (47.2)		118 (16.2)	98 (13.5)	
3 or more surfaces	51 (47.2)	57 (52.8)		58 (8.0)	50 (6.9)	
Dental material			0.151			0.024
Amalgam	172 (55.7)	137 (44.3)		194 (26.7)	115 (15.8)	
Composite	199 (47.6)	219 (52.4)		211 (29.0)	207 (28.5)	

* calculated by chi-square test adjusted by the cluster
CARS = Caries Associated with Restorations or Sealants system
FDI = International Dental Federation Criteria

Only 51% of the patients returned to the follow-ups. And a total of 55% of the restorations were assessed. The follow-up time ranged between 6 and 38 months, with a mean of 20.4 months. A total of 187 restorations randomized by the CARS criteria were followed-up, of which 12 operative treatments (8 repairs, 4 replacements) were performed according to the criterion indication. A total of 218 restorations assessed by the FDI criteria were followed-up, of which 67 interventions (35 repairs, 32 replacements) were performed.

Figure 2 brings an additional information related to the comparison between the treatment indication assigned by the criteria at the baseline assessment considering if the CARS criteria had been used to indicate the treatments of all the restorations included on the study, or whether the FDI criteria had been used. The FDI criteria would result in a high number of operative interventions compared to the CARS criteria.

Figure 2. Comparison between the treatment indication assigned by the criteria at the baseline assessment considering whether the CARS criteria had been used to indicate the treatment of all the restorations included on the study, or whether the FDI criteria had been used.



CARS = Caries Associated with Restorations or Sealants system
FDI = International Dental Federation Criteria
*Topical fluoride is considered as a treatment indication only by CARS criteria.
**Restorations without follow-up assessment.

The multivariate Cox regression did not showed association among the restoration's failures and the diagnostic strategy used. The same was observed for the variables sex, age, caries experience, caries activity, type of teeth, dental arch and dental material ($p > 0.05$). The multivariate Cox regression showed that restorations with three or more surfaces had almost eight times higher risk for failure compared to restorations with 1 restored surface ($p<0.001$) (Table 5).

The Kaplan-Meier survival curves with failures of the restored teeth assessed by the FDI and CARS criteria are illustrated in Figure 3. The reasons of failure are presented in Table 6. Material fracture (FDI = 3 cases; CARS = 4 cases) and secondary caries (FDI = 4 cases; CARS = 2 cases) were the main reasons of failure for both diagnostic methods. The marginal adaptation, tooth integrity, endodontic treatment, patients complain and intervention made by other professional without connection to the study were the other reasons of failure.

Table 5. Univariate and multiple Cox regression analysis with shared frailty related to the occurrence of failures of restorations assessed by the two different diagnostic strategies: Caries Associated with Restorations or Sealants System (CARS) and International Dental Federation criteria (FDI).

	Success n (%)	Failure n (%)	Unadjusted HR (95%CI)	p	Adjusted HR (95%CI)	p
Main study variable						
Diagnostic strategy						
CARS	175 (93.6)	12 (6.4)	1.00		1.00	
FDI	204 (93.6)	14 (6.4)	1.63 (0.51 to 5.24)	0.411	1.20 (0.48 to 3.04)	0.693
Other explanatory variables						
Sex					*	
Female	259 (93.2)	19 (6.8)	1.00			
Male	120 (94.5)	7 (5.5)	0.73 (0.20 to 2.60)	0.623		
Age					*	
Up to 30 yrs-old	54 (90.0)	6 (10.0)	1.00			
More than 30 yrs-old	325 (94.2)	20 (5.8)	0.49 (0.11 to 2.13)	0.339		
Caries experience						
DMFT from 0 to 4	15 (83.3)	3 (16.7)	1.00		1.00	
DMFT > 4	364 (94.1)	23 (5.9)	0.16 (0.03 to 0.92)	0.040	0.31 (0.07 to 1.25)	0.099
Caries activity					*	
No	313 (93.7)	21 (6.3)	1.00			
Yes	66 (93.0)	5 (7.0)	1.17 (0.25 to 5.46)	0.843		
Type of teeth					*	
Premolar	109 (94.8)	6 (5.2)	1.00			
Molar	270 (93.1)	20 (6.9)	1.61 (0.60 to 4.30)	0.345		
Dental arch					*	
Upper	175 (93.6)	12 (6.4)	1.00			
Lower	204 (93.6)	14 (6.4)	0.98 (0.43 to 2.26)	0.970		
Number of restored surfaces						
1 surface	220 (96.1)	9 (3.9)	1.00		1.00	
2 surfaces	113 (95.8)	5 (4.2)	1.39 (0.44 to 4.38)	0.570	1.34 (0.43 to 4.17)	0.610
3 or more surfaces	46 (79.3)	12 (20.7)	8.62 (3.22 to 23.06)	<0.001	7.73 (2.92 to 20.45)	<0.001
Dental material					*	
Amalgam	185 (95.4)	9 (4.6)	1.00			
Composite	194 (91.9)	17 (8.1)	2.12 (0.84 to 5.38)	0.111		

CARS = Caries Associated with Restorations or Sealants system
FDI = International Dental Federation Criteria
DMFT= number of decayed, missed or filled teeth
HR = Hazard ratio; 95%CI = 95% confidence intervals
* variables not included on the multilevel model

Figure 3. Survival graphic representing failures of the restored teeth assessed by the two different diagnostic strategies: Caries Around Detection System (CARS) and International Dental Federation criteria (FDI).

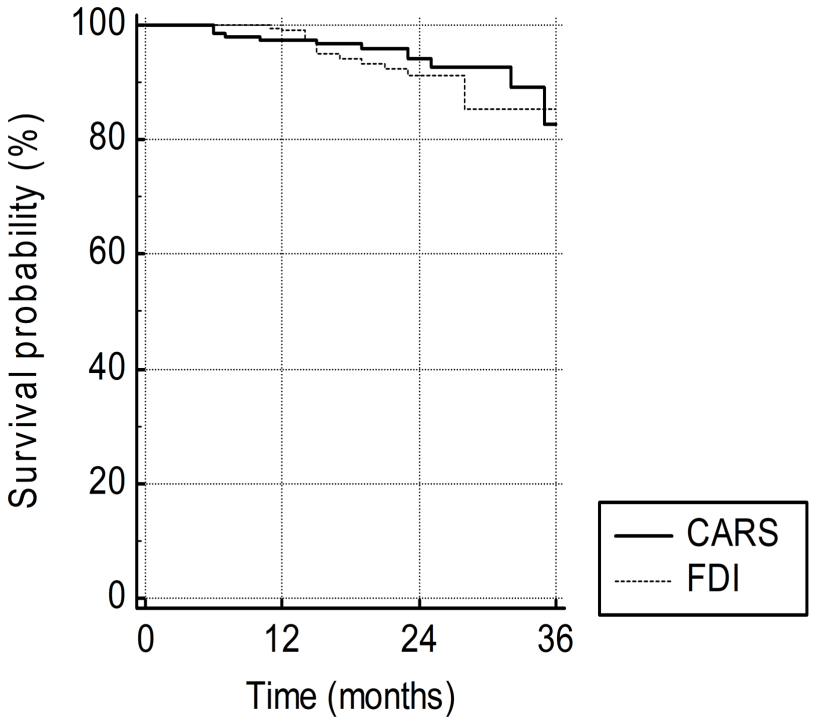


Table 6. Reason for failure of posterior restorations during the follow-up period.

Failures	Teeth (%)		
	FDI*	CARS*	Total
Success	204 (50.4)	175 (43.2)	379 (93.6)
Fracture and retention	3 (0.7)	4 (1.0)	7 (1.7)
Marginal adaptation	1 (0.2)	0 (0.0)	1 (0.2)
Secondary caries	4 (1.0)	2 (0.5)	6 (1.5)
Tooth integrity	0 (0.0)	2 (0.5)	2 (0.5)
Endodontic treatment	1 (0.2)	3 (0.7)	4 (1.0)
Patient complain	1 (0.2)	1 (0.2)	2 (0.5)
Intervention made by other professional without connection to the study	2 (0.5)	2 (0.5)	4 (1.0)

CARS = Caries Associated with Restorations or Sealants system
FDI = International Dental Federation Criteria

Discussion

This is the first clinical trial evaluating the influence of the use of two different clinical criteria used on the assessment of caries around restorations on long-term. To the best of our knowledge, no randomized clinical trial has investigated the use of the FDI criteria and the CARS criteria in the evaluation of caries lesions around restoration in permanent teeth. This study evaluated the influence of the detection method used to assess secondary caries on the longevity of posterior restorations on permanent teeth. No difference was found regarding restorations failures between the diagnostic strategies, showing similar results for restorations evaluated by the FDI and CARS criteria.

The randomized controlled clinical trials offer the best scientific evidence for changing and improve the clinical practice [25]. However, this type of study normally shows some drop-outs and missing data due to the longer follow-up periods [26]. The present study had a high rate of drop-out, which is an important limitation. The loss of contact with the patients was the main reason for the high number of drop-out on the follow-up. Some patients changed from phone contact and also from address without informing the responsible for the study. Several attempts were made in different ways to resume the patients' lost contact. In cases where no positive responses were found for the attempted contact, we consider these patients to be losses. Besides that, this study was conducted at the Federal University of Pelotas in Brazil, located in a city with high rates of urban mobility, and therefore many people ended up moving to another city, which influenced negatively the study sample [27].

A homogeneous sample of patients was observed in this clinical trial at the baseline evaluation. And this condition was overall maintained at the follow-up evaluation despite the drop-outs. The drop-out rates do not necessarily lead to biased effect sizes [26]. We observed during the follow-up period, an attrition bias related to the segment loss of patients with caries activity. This loss of patients can be related with an observed variables or/and the outcome (caries activity/presence of caries), in other words, this is a bias classified not at random [27], what implies in a specific segment lost, in this case, a lost in caries activity patients at the follow-up evaluation. Considering that it is a group of caries activity patients, they have a higher trend to do not adhere to the treatment properly and also to miss the follow-up appointments. This justifies the higher drop-out rates at this high-risk group. In addition, looking to the

restorative material, a higher loss of follow-up for amalgam restorations were observed. This type of missing data can be considered a random missing [27], when the probability of a patient missing a visit is independent of both observed and unobserved variables, it is missing due to a process unrelated to the data, and therefore, not interfering with the study findings.

In this study, two criteria were used to evaluate caries lesions around restorations. The FDI system [20] is an International Dental Federation criterion widely used to assess the quality of the restorations. The CARS system [16] is a relatively new criteria, which gained notoriety in the last years. It is used exclusively to the detection of caries around restorations. And the system differentiate marginal defects from caries lesions around restorations, helping to elucidate this factor of confusion between the dentists. The FDI criteria is characterized by indicating interventions considering several aspects related to the restoration's quality, while the CARS criterion is characterized by indicating interventions in cases of major carious lesions presence. Therefore, in this study, FDI criteria was chosen to bring a less conservative approach for the detection of secondary caries based on the fact that many dentists use restoration's marginal defects as indicators for secondary caries.

The study findings showed that the FDI criterion proposes a high number of restorative interventions in restorations when compared to the CARS criteria. The follow-up showed no differences between the criteria used on the failure of the restorations in long-term. Thus, it seems proper to use a criterion that indicates less interventions and presents the same success rate. The minimally invasive dentistry philosophy emphasizes that the 'treatment choice' should always be based on the more conservative approach, avoiding unnecessary replacements [28]. The choice for conservative treatments reflect in the preservation of tooth sound structures, and also in less treatment costs [13,29].

It is reported that restorations with a higher number of surfaces [30–32], and on patients with high caries risk [30,33] present high chance of failure. In our study, restorations with 3 or more surfaces showed almost 8 times more risk of failure than restorations with one surface. Other studies also showed the influence of the type of tooth and material on the restoration longevity [34–36]. The hazards ratios for caries risk [3,30,31,33,37], type of teeth [3,37,38] and dental material [34,35,39,40] from our study, follow the same tendency present in the literature. However, these statistically

significant differences were not seen in our results, although, a long time of follow-up may bring new evidences.

Fracture of the material and retention, and secondary caries were the most frequent causes of failure. Similar finding was reported by other studies, differing only on the rate of failure, which was lower in our study [31,35,37,41]. A few cases of failure have been identified so far, which may be due to the limited follow-up period, which was up to 36 months.

The detection of caries around the restorations is still a point of discussion among dentists [39]. The dentists do not show to follow the same pattern of diagnose about what is and what is not a caries lesion adjacent to the restoration. The different criteria available to assess the caries lesions may influence on the different opinions that dentists may have [38]. Retrospective studies conducted in the Netherlands [37,38], based on the operator's effect on the longevity of restorations, showed that the treatment decision is based on the clinical expertise. Lower restorations survival was observed in services with larger team practice, probably because in this type of service, patients are evaluated by several dentists, which results in different opinions about the treatment.

The present study aimed to elucidate the differences implied on the choice of the clinical criteria used to detected caries lesions around the restorations; since there is a lack of evidence regarding the best criterion to detect secondary caries lesions. In conclusion, the study hypothesis was accepted. Similar results were found for the two visual diagnostic criteria used for the detection of caries lesions around restorations related to the restoration failure. Thus, we encourage the adoption of more conservative approaches for the detection and treatment decision of caries lesions around restorations in order to avoid overtreatment, based on the similar success rates for both criteria.

Conclusions

The present study concluded the following:

1) The FDI criteria indicates a higher number of operative treatments compared to the CARS criteria.

2) The use of a more conservative approach on the detection of caries around the restorations showed to have the same effect in terms of need for reintervention on long term compared to a less conservative approach.
3) The CARS criteria preconized by the International Caries Classification and Management System seems to be more indicated to assess caries around the restorations.
4) It is possible to assure the quality and longevity of the restoration with a minimally invasive approach on the assessment of caries lesions around the restoration.

Conflicts of interest

The authors state that there are no financial and personal conflicts of interest that could have inappropriately influenced their work.

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7 Considerações finais

A presente tese se propôs a avaliar, em linhas gerais, a influencia da avaliação de dois critérios de diagnóstico visuais, na detecção de lesões de cárie ao redor de restaurações e tratamentos.

Através deste estudo, observou-se um caráter menos intervencionista para o CARS, quando comparado ao FDI. Assim, o critério escolhido para a avaliação de restaurações influencia na decisão de realizar ou não intervenções operatórias.

O critério CARS apresentou melhor acurácia quando comparado ao FDI. Recomenda-se atenção ao uso do critério da FDI devido a maiores chances de diagnóstico falso-positivo, para evitar tratamentos operatórios desnecessários ao paciente.

Por fim, após um período de acompanhamento das restaurações avaliadas pelos dois critérios de diagnóstico, o percentual de falha mostrou-se equivalente. Desta forma, o uso de um critério mais conservador (CARS) para a detecção de lesões de cárie ao redor de restaurações mostrou um efeito semelhante ao apresentado por um critério menos conservador (FDI), mostrando ser possível basear a avaliação e tratamento de restaurações em uma odontologia minimamente invasiva.

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Apêndices

Apêndice A – Projeto de pesquisa qualificado anteriormente

UNIVERSIDADE FEDERAL DE PELOTAS
Faculdade de Odontologia

Programa de Pós Graduação em Odontologia

Projeto de Tese

COMPORTAMENTO DE DIFERENTES ESTRATÉGIAS RESTAURADORAS EM DENTES ENDODONTICAMENTE TRATADOS FRENTE A FATORES DE RISCO SIMULADOS

Juliana Lays Stolfo Uehara

Pelotas, 2017

JULIANA LAYS STOLFO UEHARA

COMPORTAMENTO DE DIFERENTES ESTRATÉGIAS RESTAURADORAS EM DENTES ENDODONTICAMENTE TRATADOS FRENTE A FATORES DE RISCO SIMULADOS

Projeto de tese a ser apresentado ao Programa de Pós-Graduação em Odontologia, Área de concentração em Dentística da Faculdade de Odontologia da Universidade Federal de Pelotas

Orientador: Prof. Dr. Maximiliano Sérgio Cenci

Co-orientadores: Profª. Drª. Sandrina Henn Donassollo

Profª. Drª. Tatiana Pereira Cenci

Pelotas, 2017

Juliana Lays Stolfo Uehara your

COMPORTAMENTO DE DIFERENTES ESTRATÉGIAS RESTAURADORAS EM DENTES ENDODONTICAMENTE TRATADOS FRENTE A FATORES DE RISCO SIMULADOS

Projeto de Tese apresentado, como requisito parcial, para obtenção do grau de Doutor em Odontologia, Programa de Pós-Graduação em Odontologia, Faculdade de Odontologia de Pelotas, Universidade Federal de Pelotas.

Data da qualificação: 27/03/2017

Banca examinadora:

Prof. Dr. Maximiliano Sérgio Cenci (Orientador)
Doutor(a) em Dentística (Cariologia) pela Universidade Estadual de Campinas

Prof. Dr. Rafael Ratto de Moraes
Doutor(a) em Materiais Dentários pela Universidade Estadual de Campinas

Prof. Dr. Mateus Bertolini Fernandes dos Santos
Doutor(a) em Clínica Odontológica (Prótese Dentária) pela Universidade Estadual de Campinas

Prof. Dr. César Dalmolin Bergoli (Suplente)
Doutor(a) em Odontologia Restauradora (Prótese Dentária) pela Universidade Estadual Julio de Mesquita Filho

RESUMO

UEHARA, Juliana Lays Stolfo. **Comportamento de diferentes estratégias restauradoras em dentes endodonticamente tratados frente a fatores de risco simulados.** 2017. 43f. Projeto de Tese – Qualificação (Doutorado). Programa de Pós-Graduação em Odontologia, Universidade Federal de Pelotas, 2017.

A doença cárie ainda é a principal causadora da destruição da estrutura dental. Quando severamente comprometidos, os dentes precisam ser submetidos ao tratamento endodôntico para eliminação do foco de infecção e para permitir a correta reabilitação. A sobrevivência de restaurações em dentes tratados endodonticamente representa um desafio para a Odontologia, e ainda não há suficiente evidência para a escolha de materiais e técnicas restauradoras. O objetivo do presente estudo será avaliar o desempenho de diferentes estratégias restauradoras, aplicadas em dentes endodonticamente tratados com ampla destruição coronária, frente a fatores de risco simulados, através de um ensaio laboratorial *in vitro* que avaliará restaurações do tipo *endocrown* e coroas totais com uso de pino de fibra de vidro. Para isso, serão utilizados 140 primeiros molares humanos extraídos, divididos em sete grupos: *endocrown* de resina composta direta (0 mm de férula), *endocrown* de resina composta indireta (0 mm de férula), *endocrown* de cerâmica (0 mm de férula), *endocrown* de resina composta direta (2 mm de férula), *endocrown* de cerâmica (2 mm de férula), restauração de resina composta direta com cimentação de pino de fibra de vidro (0 mm de férula) e, coroa total cerâmica com cimentação de pino de fibra de vidro (0 mm de férula). Todas as restaurações terão as dimensões padronizadas, assim como a superfície oclusal que será modificada para que possa ser avaliado o comportamento da superfície do material restaurador utilizado. Cada grupo terá metade de seus espécimes submetidos ao estresse mecânico e desafio cariogênico e a outra metade será submetida ao estresse mecânico e desafio erosivo. Além disso, para avaliar a influência do preparo cavitário no comportamento das restaurações, serão comparados os resultados dos grupos de mesma técnica restauradora e material restaurador com diferentes espessuras de férula. Ainda, será avaliada a rugosidade e microdureza da superfície dos materiais, antes e após as respectivas simulações de fatores de risco. Será realizada a análise fractográfica dos espécimes fraturados. Os dados de todos os ensaios serão analisados a fim de verificar a normalidade da distribuição e submetidos a análise estatística apropriada.

Palavras-chave: *endocrown*; restauração de dentes endodonticamente tratados; *Rub&roll*

ABSTRACT

UEHARA, Juliana Lays Stolfo. **Behavior of differents strategies in endodontically treatment tooth front of simulated risk factors.** 2017. 43p. Thesis Project – Qualification (PhD). Graduate Program in Dentistry. Federal University of Pelotas, Pelotas, 2017.

Dental caries is still the main cause of tooth structure destruction. When severely compromised, the teeth need to undergo endodontic treatment to eliminate the focus of infection and to allow correct rehabilitation. The survival of restorations in endodontically treated teeth represents a challenge for dentistry, and there is still insufficient evidence for the choice of materials and restorative techniques. The aim of the present study will be to evaluate the performance of different restorative strategies applied to endodontically treated teeth with extensive coronary destruction, against simulated risk factors, through an in vitro laboratory assay with endocrown restorations and total crowns using fiberglass posts. For this purpose, 140 human first molars extracted will be used, divided into seven groups: direct composite resin endocrown (0 mm ferrule), indirect composite resin endocrown (0 mm ferrule), ceramic endocrown (0 mm ferrule), direct composite resin endocrown (0 mm ferrule), ceramic endocrown (2 mm ferrule), direct composite resin restoration with fiberglass post (0 mm ferrule) and total ceramic crown with fiberglass post (0 mm of ferrule). All restorations will have the standardized dimensions, as well as the occlusal surface that will be modified so that the surface behavior of the restorative material used can be evaluated. Each group will have half of their specimens submitted to mechanical stress and cariogenic challenge and the other half will be submitted to mechanical stress and erosive challenge. In addition, to evaluate the influence of the cavity preparation on the behavior of the restorations, the results of the groups of the same restorative technique and restorative material with different thickness of ferrule will be compared. Also, the roughness and microhardness of the surface of the materials will be evaluated, before and after the respective simulations of risk factors. A fractographic analysis of the fractured specimens will be performed. The data from all the tests will be analyzed in order to verify the normality of the distribution and submitted to appropriate statistical analysis.

Key-words: *endocrown*; restorations in endodontically treated teeth; *Rub&roll*

SUMÁRIO

1 Introdução

A doença cárie é ainda a principal causa da severa destruição dos dentes (FRON CHABOUIS; SMAIL FAUGERON; ATTAL, 2013). Neste contexto, muitas vezes, a perda de estrutura dentária pode levar a uma possibilidade maior de fratura. Considerando que esta pode levar a perda do dente, é importante que seja indicado um tratamento adequado que auxilie na prevenção de danos e manutenção da saúde do dente, como por exemplo tratamentos ortodônticos, restauradores e endodônticos, bem indicados e executados (ELLIS; MCCORD; BURKE, 1999).

Restaurações aceitáveis são aquelas que proporcionam adequado reestabelecimento da anatomia, função, contatos proximais e estabilidade oclusal (TRUSHKOWSKY, 2014). A longevidade dessas restaurações está diretamente relacionada à preservação da estrutura dental sadia e corretos procedimentos adesivos (DIETSCHI et al., 2008). Os procedimentos restauradores utilizando resina composta direta conseguem prover estética e função, através de técnicas minimamente invasivas. Essas restaurações possuem custos inferiores quando comparados a tratamentos indiretos, sejam estes utilizando resinas ou cerâmicas odontológicas, além de possuírem mais rápida execução. Além disto, o uso das resinas compostas de forma direta sobre a estrutura dental já está claramente relatado na literatura como altamente viável, uma vez que apresentam altas taxas de longevidade e sucesso clínico (DA ROSA RODOLPHO et al., 2011; DEMARCO et al., 2012; OPDAM et al., 2010, 2014, VAN DE SANDE et al., 2016, 2015; VAN DIJKEN, 2010).

As resinas compostas são indicadas para o uso em dentes posteriores, devido a preservação de estrutura dentária, e a eficiência clínica deste tratamento, demonstrado por diversos estudos (ANGELETAKI et al., 2016; CASAGRANDE et al., 2016; DEMARCO et al., 2012), substituindo atualmente o uso do amálgama ou até mesmo das coroas metálicas (MITTAL et al., 2016). Ainda, cabe salientar que uma

das grandes vantagens da utilização das resinas compostas é a possibilidade de reparo como uma forma de prolongar a longevidade da restauração (LYNCH et al., 2014).

O tratamento restaurador direto com resina composta em dentes endodonticamente tratados mostrou maior resistência às forças oclusais quando comparado com outros materiais, como amálgama e cimento de ionômero de vidro (MINCIK et al., 2016). A técnica empregada para a confecção da restauração também apresenta-se como um fator a ser considerado, uma vez que o recobrimento de cúspides em restaurações com ampla perda de tecido promove melhores resultados no que diz respeito à resistência do tratamento (MANNOCCI et al., 2009; SANGWAN et al., 2016).

Por sua vez, as restaurações cerâmicas são consideradas mais resistentes quando comparadas às realizadas com resinas compostas, por concentrarem as tensões internamente na restauração e consequentemente transmitirem menos forças à estrutura remanescente quando comparado à resina composta (COSTA et al., 2014). Porém, este tipo de material restaurador exerce maior estresse ao elemento antagonista através da dissipação das forças e, quando ocorre a utilização de peças cerâmicas, há a formação de uma interface de união que pode sofrer degradação gerando micro infiltração e decimentação da peça e portanto, causando o insucesso do tratamento (TRUSHKOWSKY; BURGESS, 2002). As cerâmicas oferecem as melhores propriedades estéticas, mas devido às suas propriedades mecânicas, sua utilização deve ser limitadas à zona estética, especialmente para pacientes com bruxismo (OPDAM; FRANKENBERGER; MAGNE, 2016).

Apesar de alguns trabalhos mostrarem evidências de que restaurações cerâmicas possuem comportamento superior àquelas confeccionadas com resina composta, não se pode afirmar a superioridade do tratamento com cerâmicas, uma vez que não há na literatura, estudos de longos períodos de acompanhamento clínico que comparem restaurações diretas em resina composta e indiretas do tipo metalocerâmicas (FRON CHABOUIS; SMAIL FAUGERON; ATTAL, 2013; SKUPIEN et al., 2016).

Tradicionalmente, as restaurações indiretas seriam indicadas em casos de destruição coronária extensa, pois estava estabelecida a crença de que essas apresentariam maior resistência e longevidade quando comparadas às restaurações diretas. Porém, a odontologia contemporânea admite que, graças aos princípios

adesivos e conservadores, essa diferença entre procedimentos diretos e indiretos em termos de longevidade não é significativa. Segundo Opdam, Frankenberger e Magne, (2016), em casos onde há a necessidade de múltiplas e extensas restaurações, onde o enceramento prévio fornece melhor reestabelecimento da oclusão, onde a forma e estética necessitam de excelência e em casos onde a confecção de uma restauração direta é de muito difícil execução, as restaurações indiretas são indicadas. Por outro lado, em pacientes jovens, em casos de mínima intervenção, quando é necessário optar por um tratamento de baixo custo, tratamentos diretos são os mais indicados. Segundo os autores, deve-se então levar em conta que as restaurações do tipo coroa total tem indicação limitada, devendo ser indicadas em caso de substituição de coroa pré-existente, para restaurações de implantes ou para serem utilizadas como suporte de pônticos. Em outros casos, opções menos invasivas devem ser preferidas. Ainda, é necessário observar que independente da técnica restauradora escolhida, os procedimentos devem primar pela mínima invasão, com selamento da dentina e elevação da margem subgengival quando necessário.

Quando o dente é amplamente atingido pela doença cárie ou por outros fatores que levem a uma grande destruição coronária, diversas vezes torna-se necessária a realização do tratamento endodôntico, visando a manutenção do elemento na cavidade bucal por mais tempo (BITTER; KIELBASSA, 2007). Dentes tratados endodonticamente necessitam geralmente de extensas restaurações. A sobrevivência do tratamento restaurador é fator determinante, uma vez que o insucesso do tratamento endodôntico ou restaurador que levem a fraturas verticais radiculares por exemplo, pode resultar na perda do dente. Os reparos de destas extensas restaurações são em sua maioria, de difícil execução e, como podem estar relacionados à perda dentária, precisam ser acompanhado por longos períodos (SKUPIEN et al., 2013).

Tamanho e localização da restauração, possibilidade de isolamento ou correta realização de técnicas adesivas, risco de cárie, idade do paciente, apelo estético, hábitos parafuncionais e preservação da estrutura dentária parecem ser fatores determinantes na escolha do procedimento restaurador (TRUSHKOWSKY; BURGESS, 2002).

O procedimento clássico restaurador em casos de dentes tratados endodonticamente com grande perda de estrutura coronária, envolve o uso de retentores intrarradiculares, seguido da confecção de núcleos e restauração através

de coroas totais (DIETSCHI et al., 2008, DIETSCHI et al., 2008). Para a cimentação de um pino ou retentor intrarradicular, seja este metálico fundido ou pré-fabricado de fibra de vidro, é necessário remover parte da estrutura dental sadia da porção radicular. No caso do uso de pinos de fibra de vidro, quando comparados aos pinos metálicos fundidos, esta remoção de tecido é menor, porém, quando comparados à não utilização de pinos intrarradiculares, é considerado um tratamento mais invasivo. A remoção de tecido sadio em prol da utilização de pinos, pode causar o enfraquecimento da estrutura dental remanescente e aumentar o risco de perfurações radiculares (CHANG et al., 2009; LAZARI et al., 2013; SOARES et al., 2007).

Neste sentido, restaurações do tipo *endocrown* mostram superioridade quando comparadas às confeccionadas aliadas à cimentação de pinos de fibra de vidro. Estas restaurações chamadas de *endocrown*, podem ser confeccionadas em diferentes materiais, e baseiam-se no princípio de que uma única peça, um monobloco, que une a coroa e o núcleo, sem a necessidade de uso de um retentor intrarradicular (BIACCHI; BASTING, 2012; CHANG et al., 2009). São uma opção positiva de tratamento para elementos severamente comprometidos pela perda de estrutura de tecidos duros, resultando em tratamentos mais estéticos e conservadores e com menor custo e tempo clínico quando comparados à coroas metálicas ou metalocerâmicas (SEDREZ-PORTO et al., 2016). São indicadas em casos nos quais o espaço interoclusal é limitado e, portanto, não é possível ter espessura adequada de cerâmica para recobrir a infraestrutura (BIACCHI; MELLO; BASTING, 2013). Ainda, sua utilização é possível, quando o elemento dental apresenta raízes frágeis, condutos radiculares dilacerados, curtos ou obliterados (BIACCHI; MELLO; BASTING, 2013; CHANG et al., 2009).

O uso de *endocrowns* está baseado na macro-retenção proporcionada pela ancoragem do material no interior da câmara pulpar aliada à micro-retenção promovida pelas propriedades adesivas do material de cimentação (BIACCHI; BASTING, 2012; CHANG et al., 2009). A possibilidade de confecção de uma restauração em um único bloco, permite que esta possua maior espessura oclusal do material, aumentando assim a resistência à fratura quando comparada a coroas tradicionais (SEDREZ-PORTO et al., 2016). Apesar das indicações serem favoráveis para a utilização de restaurações do tipo *endocrown*, ainda é escassa a evidência clínica disponível na literatura acerca deste tema.

2 Objetivos

2.1 Objetivo geral

Avaliar o desempenho de diferentes estratégias restauradoras para dentes endodonticamente tratados com ampla destruição coronária frente a fatores de risco simulados.

2.2 Objetivos específicos

- avaliar o comportamento de restaurações extensas em dentes endodonticamente tratados frente à combinação do desafio cariogênico e estresse mastigatório em um ambiente simulado;
- avaliar o comportamento de restaurações extensas em dentes endodonticamente tratados frente a combinação de estresse mecânico e desafio erosivo em um ambiente simulado;
- avaliar se alterações de preparo cavitário interferem no desempenho da restauração frente a desafios simulados; e,
- verificar a resposta do material frente ao desafio erosivo, cariogênico e stress mastigatório, quanto a dureza e rugosidade e propagação de trincas.

3 Hipótese

A hipótese do estudo é de que ambos tipos de restauração comportar-se-ão de forma semelhante em relação aos desafios induzidos e quanto às variáveis de desfecho estudadas.

4 Materiais e métodos

4.1 Comportamento de restaurações extensas frente a desafios simulados

4.1.1 Descrição geral dos procedimentos e técnicas restauradoras

Serão utilizadas neste estudo duas técnicas restauradoras distintas, restaurações tipo *endocrown* e restaurações com a utilização de pinos de fibra de vidro e dois materiais, resina composta e cerâmica. As restaurações do tipo *endocrown* serão divididas em cinco subgrupos: (G1) restauração *endocrown* em resina composta convencional direta (0mm de férula); (G2) restauração *endocrown* em resina composta convencional indireta (0mm de férula); (G3) restauração *endocrown* de cerâmica (0mm de férula), (G4) restauração *endocrown* de resina composta convencional direta (2mm de férula) e, (G7) restauração *endocrown* de cerâmica (2mm de férula). As restaurações com a utilização de pino de fibra de vidro serão divididas em dois subgrupos: (G5) restauração direta de RC com pino de fibra de vidro (0mm de férula) e, (G6) coroa total em cerâmica reforçada por dissilicato de lítio (0mm de férula) (Quadro 1). Os espécimes de cada grupo serão aleatoriamente divididos, sendo que metade será submetida ao desafio cariogênico e a outra metade ao desafio erosivo, não ocorrendo, desta forma, dois desafios em um mesmo elemento.

Quadro 1. Esquematização dos grupos experimentais do estudo.

Grupo	Material		Tipo			Técnica		Férula	
	RC	Cerâmica	*Endocrown*	Coroa total	Pino fibra de vidro	Direta	Indireta	2mm	0mm
G1	X		X			X			X
G2	X		X				X		X
G3		X	X				X		X
G4	X		X			X		X	
G5		X	X				X	X	
G6	X				X	X			X
G7		X		X	X		X		X

Ambas as técnicas serão realizadas em primeiros molares inferiores extraídos, com a finalidade de simular uma restauração em boca. Na técnica direta será utilizado o sistema adesivo convencional (Adper SingleBond Universal, 3M ESPE, EUA) e a restauração será confeccionada com resina composta nanoparticulada (Resina Z350, 3M ESPE, EUA), através da técnica incremental, respeitando a indicação do tamanho dos incrementos do fabricante do material. Os mesmos materiais serão utilizados para a confecção das restaurações indiretas em resina composta.

As restaurações cerâmicas serão confeccionadas pela técnica de injeção e posteriormente cimentadas com cimento autoadesivo (RelyX U200, 3M ESPE, EUA). Para a cimentação dos pinos, em ambos os grupos, será utilizado o mesmo cimento autoadesivo.

Todas as restaurações terão a superfície oclusal com anatomia, altura e diâmetro padronizados, para evitar que as variações anatômicas induzam diferentes distribuições de força durante o experimento. Além disso, a cúspide mésio-lingual terá sua anatomia modificada com a finalidade de produzir uma superfície plana (Figura 1) que possibilite a avaliação da dureza e rugosidade do material. Para isso, o dente que possuir maior volume de coroa e raiz será restaurado e terá sua anatomia copiada para servir então de molde para as demais restaurações. Este molde será confeccionado em silicone de adição (Express XT, 3M ESPE, EUA) para enviar ao laboratório que confeccionará as peças em cerâmica e para as restaurações

confeccionadas em resina composta, será utilizada a técnica do carimbo, com silicone de adição transparente (Scan Translux, Yller, Brasil).

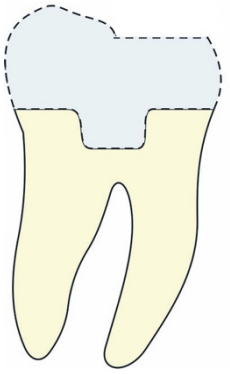

Figura 1 - Esquema da padronização das restaurações com a cúspide mésio-lingual planificada para avaliar dureza e rugosidade.

Após a confecção das restaurações, todos os espécimes ficarão armazenados em água destilada até o momento de realização dos respectivos ensaios.

4.1.2 Seleção/obtenção dos dentes

Para o estudo serão utilizados 140 primeiros molares inferiores (n=20) (BIACCHI; MELLO; BASTING, 2013). Para a realização desta pesquisa, será criado um Biorrepositório para coleta e armazenamento dos elementos dentais que serão utilizados. Os pacientes doadores serão esclarecidos da finalidade da doação e assinarão um termo de consentimento livre e esclarecido (TCLE) (Apêndice A). O Biorrepositório ficará localizado na Universidade Federal de Pelotas, sob responsabilidade do orientador desta pesquisa, Prof. Dr. Maximiliano Sérgio Cenci, sendo que a Instituição possui todas as condições e estrutura física necessária para coleta, armazenamento e descarte do material biológico. Caixas de coleta, com potes individuais contendo água destilada e termos de consentimento livre e esclarecido (TCLE) serão disponibilizados para as clínicas. Quando um paciente possuir indicação de extração de um dente de interesse para a pesquisa, o mesmo será informado sobre a possibilidade de ceder seu dente para o Biorrepositório destinado a esta pesquisa.

Caso haja interesse do paciente, o TCLE será lido, esclarecido e assinado. Após o procedimento cirúrgico, o dente será acondicionado em um dos potes com água destilada que será identificado com o número do TCLE correspondente e encaminhado ao pesquisador. Os dentes coletados serão limpos de remanescentes de tecidos moles e/ou cálculo dentário, utilizando curetas manuais e aparelho de ultrassom. Em seguida, serão catalogados, numerados individualmente e seguirão para a esterilização em autoclave ou esterilização química (Formalina 10%) caso o elemento possua restaurações de amálgama (DOMINICI et al., 2001; KUMAR et al., 2005). Após este processo, serão armazenados em novos potes individuais contendo água destilada, em geladeira.

Para serem utilizados nesta pesquisa, os elementos, mesmo que atingidos por lesões de cárie ou restaurações, deverão possuir pelo menos a porção radicular e o terço cervical íntegros. Após, serão analisados com a finalidade de verificar a presença de trincas ou fraturas na porção cervical ou radicular, que impossibilitem sua utilização. Ainda, serão escolhidos aqueles dentes que possuírem dimensões semelhantes, tanto no sentido mésio/distal quanto vestíbulo/lingual.

4.1.3 Preparo dos dentes

Após a desinfecção, estes elementos serão distribuídos aleatoriamente dentre os grupos experimentais. As coroas serão recortadas com o auxílio do recortador de gesso (Essence Dental VH, Brasil), até que reste o volume de férula determinado para cada grupo experimental. Em todos os espécimes será realizado o tratamento endodôntico. Após a endodontia, para os grupos que receberão restauração do tipo *endocrown* serão desobturados 4mm do canal distal. Para aqueles que receberão a cimentação de pino de fibra de vidro será desobturado o canal distal até que restem 4 mm de material obturado no ápice radicular. Ainda, os elementos que serão restaurados pela técnica da coroa total receberão o preparo tradicional, removendo a porção de esmalte cervical, para a confecção do término da restauração. Os dentes serão armazenados em água destilada até sua utilização.

4.1.4 Tratamento endodôntico

Os canais radiculares serão preparados com limas rotatórias do sistema Protaper Next Maillefer (Dentsply Sirona, EUA) nos tamanhos X1, X2 e X3. A odontometria será realizada com uma lima #10 e o auxílio de um localizador foraminal (Root ZX II, J Morita, Japão), sendo que a instrumentação será realizada 1 mm aquém da distância foraminal. A irrigação dos canais será feita com NaOCl 2,5% (Asfer, Brasil) e EDTA 17% (Asfer, Brasil).

As raízes serão obturadas com guta-percha (Dentsply Sirona, EUA) e cimento (Endofil, Dentsply Sirona, EUA) e seladas com cera utilidade (Cera Utilidade Rosa, Asfer, Brasil) utilizando a técnica de condensação termoplastificada com MacSpadden (Dentsply Sirona, EUA).

4.1.5 Restauração dos dentes

4.1.5.1 Restaurações do tipo *endocrown*

Os grupos restaurados com a técnica *endocrown* serão submetidos ao preparo da estrutura remanescente, realizado com pontas diamantadas em alta rotação (3131, KG Sorensen, Brasil), sob irrigação constante. O preparo final deve possuir ângulos internos arredondados, paredes axiais ligeiramente expulsivas e, o assoalho da câmera pulpar deve ser reto (Figura 2).

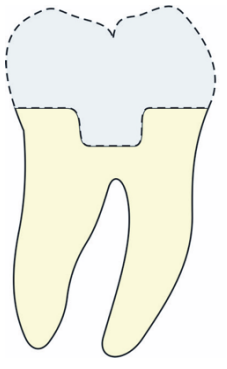

Figura 2 - Representação esquemática do aspecto de um elemento restaurado com a técnica *endocrown.*

No grupo das restaurações *endocrown* diretas de resina composta com 2 mm de férula, após o preparo do elemento que possuirá 2 mm de estrutura remanescente, será realizada a restauração de resina composta convencional, utilizando ácido fosfórico 37% (Condac, FGM, Brasil), sistema adesivo de dois passos (Adper SingleBond Universal, 3M ESPE, EUA) e a resina composta nanoparticulada (Resina Z350, 3M ESPE, EUA), através da técnica incremental, seguindo as orientações quanto ao tempo de polimerização e tamanho do incremento, de acordo com o fabricante. Os incrementos possuirão espessura máxima de 2 mm e o tempo de polimerização compreende 20 s para resina de esmalte e 40 s para resina de dentina. O volume e altura da restauração serão determinados através do molde já pré-estabelecido para a padronização de todas as restaurações. A porção oclusal será confeccionada através da técnica do carimbo, onde um incremento de resina será colocado sobre o dente e então, a matriz de silicone transparente será colocada sobre a resina para definir a anatomia. O conjunto será polimerizado, a matriz será removida e a resina será novamente polimerizada. A confecção da superfície oclusal se dará da mesma forma para todos os grupos experimentais. Após a finalização, os excessos da região cervical serão removidos com auxílio de discos de lixa (Sof-Lex Pop On, 3M ESPE, EUA), e a restauração receberá os procedimentos de acabamento e polimento. Este procedimento será realizado com pontas de silicone abrasivas (Ponta Optimize, TDV, Brasil) seguido de aplicação de pasta de polimento (Diamond Gloss, TDV, Brasil) e disco de feltro (Disco Feltro Polimax, TDV, Brasil).

Para o grupo das restaurações *endocrown* indiretas de resina composta com 2mm de férula o preparo será moldado com silicone de adição (Express XT, 3M ESPE, EUA) em duas consistências, pela técnica de dupla impressão utilizando moldeiras parciais. A restauração será confeccionada com resina composta nanoparticulada (Resina Z350 3M ESPE, EUA), através da técnica incremental, seguindo as orientações quanto ao tempo de polimerização e tamanho do incremento, já citadas, sobre o modelo de gesso (Gesso Pedra Especial Zero Stone Tipo IV, Dentona, Alemanha) previamente isolado com isolante para resina (Cel-Lac, SS White, EUA) para evitar a adesão da restauração ao modelo. A padronização da restauração seguirá os mesmos passos já citados anteriormente. A cimentação da peça ao

elemento dental, será realizada com o cimento autoadesivo (RelyX U200, 3M ESPE, EUA) sendo que a peça será condicionada com ácido fosfórico 37% (Condac 37%, FGM, Brasil) por 30 s e após a lavagem, receberá aplicação do sistema adesivo (Adper SingleBond Universal, 3M ESPE, EUA). No elemento dentário somente será realizada lavagem com água previamente à cimentação. O cimento será dispensado em uma placa de vidro e as pastas serão misturadas até que se obtenha uma única fase, ou seja, uma mistura homogênea. O cimento então será inserido no interior da peça e assentado sobre o elemento dental. Os excessos de cimento serão removidos, e o conjunto será mantido sob pressão digital por 6 min para a presa química do material e então será fotoativado por 20 s em cada face. O acabamento será realizado da mesma forma descrita para o grupo de *endocrown* de resina direta.

O grupo de *endocrown* de cerâmica com 2mm de férula, será preparado da mesma forma que o grupo das *endocrowns* de resina indireta. Após a moldagem com silicona, o molde será encaminhado para o laboratório que confeccionará a restauração pela técnica de injeção, com cerâmica reforçada por dissilicato de lítio (IPS e.max, Ivoclar Vivadent, Liechtenstein) seguindo o mesmo padrão de anatomia e volume das demais restaurações. A cimentação será realizada com o cimento autoadesivo (RelyX U200, 3M ESPE, EUA) sendo que a peça será condicionada com ácido fluorídrico 5% (Condac Porcelana 5%, FGM, Brasil) por 20 s seguido de lavagem e aplicação de sistema adesivo (Adper SingleBond Universal, 3M ESPE, EUA), antes da cimentação. No substrato dental será utilizada pasta de pedra pomes e água para a remoção de debris, seguida de lavagem e remoção da umidade excessiva, mantendo a superfície brilhante. O cimento será dispensado em uma placa de vidro e as pastas serão misturadas até que se obtenha uma única fase, ou seja, uma mistura homogênea. O cimento então será inserido no interior da peça e assentado sobre o elemento dental com pressão digital. Os excessos serão removidos com instrumentos adequados e será aguardado o período de 6 min com a restauração sob pressão digital para que então o conjunto seja fotoativado por 20 s em cada face. Será realizado o acabamento e polimento com pontas de borracha específicas para o uso em cerâmica reforçada por dissilicato de lítio (EVE DIAPOL Cerâmicas, OdontoMega, Brasil)

O grupo de *endocrown* de resina composta direta com 1mm de férula, será confeccionado da mesma forma já apresentada para o grupo de *endocrown* de resina direta com 2 mm de férula, com a diferença de que, para o preparo do elemento dental

no recortador de gesso, será deixado apenas 1mm de estrutura dental remanescente a partir da junção amelo-cementária.

O grupo *endocrown* de cerâmica com 1mm de férula seguirá o mesmo procedimento do grupo de *endocrown* cerâmica com 2 mm de férula, porém, o preparo será limitado a 1 mm de estrutura dental remanescente a partir da junção amelo-cementária.

Todos os dentes restaurados serão armazenados sob refrigeração em água destilada até o momento da sua utilização.

4.1.5.2 Restaurações utilizando reforço com pino de fibra de vidro

Nos grupos que receberão a cimentação de pinos de fibra de vidro, o canal com maior diâmetro será desobturado até que restem aproximadamente 4mm de guta percha no ápice do canal radicular.

O conduto radicular será limpo utilizando hipoclorito de sódio 2,5% seguido de lavagem abundante com água. O excesso de umidade será removido com pontas de papel absorvente. O pino será limpo com álcool e secado com leve jato de ar por 5 s. Uma camada de silano será aplicada (Prosil, FGM, Brasil) seguida de leve jato de ar. Para a inserção do cimento no conduto radicular, será utilizada a ponta misturadora com a ponta aplicadora intracanal. A primeira porção de cimento será descartada para então o cimento ser inserido no interior do canal radicular da porção apical para a cervical. O pino será inserido, os excessos removidos, a polimerização química será aguardada por 6 min seguida da fotoativação por 20 s. Após a presa total do cimento, o remanescente dental será condicionado com ácido fosfórico (Condac 37%, FGM, Brasil) por 30 s em esmalte. Após a lavagem e secagem, será aplicado o sistema adesivo (Adper SingleBond Universal, 3M ESPE, EUA) e polimerizado por 20 s para que o núcleo em resina composta possa ser confeccionado (Resina Z350, 3M ESPE, EUA). Cada incremento, com no máximo 2 mm de espessura será polimerizado por 40 s. Após a finalização da construção do núcleo, o mesmo será adaptado com pontas diamantadas (KGSorensen, Brasil), obedecendo as características do preparo para núcleo, que deve apresentar paredes lisas, ângulos internos arredondados e leve expulsividade.

A restauração do grupo de restauração em resina composta direta com 2 mm de férula e pino de fibra de vidro, será confeccionada com resina composta nanoparticulada (Z350, 3M ESPE, EUA), através da técnica incremental, com incrementos de no máximo 2mm, polimerizados por 20 s quando utilizada resina de esmalte e 40 s para resina de dentina. A superfície oclusal será confeccionada da mesma forma que nas restaurações do tipo *endocrown*, com o auxílio da matriz de silicone.

O grupo de coroa em cerâmica com 2mm de férula, após a cimentação do pino e confecção do núcleo (descrito no item 4.1.1), será moldado com silicone de adição (Express XT, 3M ESPE, EUA) em duas consistências, pela técnica de dupla impressão. O molde será enviado ao laboratório que confeccionará uma restauração do tipo coroa com cerâmica reforçada com dissilicato de lítio. A cimentação será realizada com o cimento autoadesivo (RelyX U200, 3M ESPE, EUA) sendo que a peça será condicionada com ácido fluorídrico 5% por 20 s seguido de lavagem e aplicação de sistema adesivo (Adper SingleBond Universal, 3M ESPE, EUA), antes da cimentação. O dente será limpo e o cimento será dispensado em uma placa de vidro onde as pastas serão misturadas até que se obtenha uma única fase, ou seja, uma mistura homogênea. O cimento então será inserido no interior da peça e assentado sobre o elemento dental com pressão digital. Os excessos serão removidos com instrumentos adequados e será aguardado o período de 6 min com a restauração sob pressão digital para que então o conjunto seja fotoativado por 20 s em cada face. Será realizado o acabamento e polimento com pontas de borracha específicas para o uso em cerâmica reforçada por dissilicato de lítio (EVE DIAPOL Cerâmicas, OdontoMega, Brasil)

Todos os dentes restaurados serão armazenados sob refrigeração em água deionizada até o momento da sua utilização.

4.1.6 Simulação de estresse mastigatório através do equipamento *Rub&Roll*

Com a finalidade de avaliar a resistência à fadiga mecânica e ao desgaste das restaurações, através de um simulador da cavidade oral humana, os espécimes serão estressados no equipamento *Rub & Roll* (RUBEN et al., 2014). Este equipamento tem

a capacidade de, através da aplicação controlada de força, velocidade e tempo, simular os movimentos da cavidade oral e provocar danos semelhantes aos que ocorrem em um ambiente real, sendo possível aliar ensaios como o desafio cariogênico e o desafio erosivo, através da utilização de determinados líquidos durante a realização dos testes.

Este equipamento é composto por dois cilindros, onde o cilindro interno abriga o espaço para alocação dos espécimes. Entre estes cilindros, há um espaço onde podem ser instaladas hastes que irão promover as forças sobre os espécimes. Quando iniciado o funcionamento, os cilindros trabalham girando em direções opostas, fazendo com que as hastes rolem sobre os espécimes, gerando uma força sobre os mesmos. A velocidade de rotação pode ser ajustada para simular a velocidade da mastigação. Ainda, é possível utilizar diferentes líquidos no equipamento, permitindo então controlar carga mecânica e química.

O equipamento *Rub&Roll* será utilizado nas seguintes configurações: velocidade de 20rpm a 0.2Hz, com força de 30N, por 15 dias, simulando um ano de função clínica (RUBEN et al., 2014).

Todos os espécimes de todos os grupos amostrais do estudo, após serem restaurados, serão estressados com o simulador *Rub&Roll*, para então, serem posteriormente submetidos ao ensaio de compressão e avaliação em microscópio eletrônico de varredura, descritos nos itens 4.1.6.4 e 4.1.6.5 respectivamente. Cada grupo amostral é composto por 20 elementos, sendo que, metade destes (n=10) sofrerá estresse mastigatório e desafio cariogênico, e a outra metade (n=10), será submetida ao estresse mastigatório e desafio erosivo.

4.1.6.1 Simulação de estresse mastigatório e desafio cariogênico (Artigo 1)

Com a finalidade de avaliar o comportamento dos elementos restaurados frente ao estresse mastigatório sob um ambiente que simule o processo de desmineralização/remineralização, os espécimes serão submetidos ao desafio cariogênico para estabelecer a comparação do comportamento dos diversos grupos experimentais quando submetidos às variáveis citadas.

4.1.6.1.1 Grupos experimentais

Serão utilizados cinco grupos experimentais conforme o Quadro 2. Os grupos experimentais representados pela letra “a” possuem as mesmas características dos respectivos grupos, porém correspondem a 50% dos espécimes totais, ou seja, serão testados 10 elementos de um total de 20 de cada grupo na simulação do estresse mastigatório e desafio cariogênico.

Quadro 2. Esquematização dos grupos experimentais submetidos ao estresse mastigatório sob desafio cariogênico.

Grupo	Material		Tipo			Técnica		Férula	
	RC	Cerâmica	*Endocrown*	Coroa total	Pino fibra de vidro	Direta	Indireta	2mm	0mm
G1a	X		X			X			X
G2a	X		X				X		X
G3a		X	X				X		X
G6a	X				X	X			X
G7a		X		X	X		X		X

Serão submetidos a este teste, os dentes restaurados com *endocrown* de resina composta direta, *endocrown* de resina composta indireta, *endocrown* de cerâmica, restauração de resina composta direta com uso de pino de fibra de vidro e coroa total cerâmica com pino de fibra de vidro, sendo que todos os grupos possuirão 0mm de férula e são compostos por 10 unidades amostrais.

4.1.6.1.2 Procedimento experimental

Dez espécimes de cada grupo do quadro acima serão submetidos ao desafio

cariogênico através da ciclagem de pH, com a finalidade de simular o processo de desmineralização e remineralização da estrutura dental, simultaneamente ao estresse mastigatório, no simulador de cavidade oral *Rub&Roll.* Esta técnica permite a avaliação da perda ou ganho mineral do conjunto esmalte/dentina simulando o processo natural da cárie dental. Para isto, será utilizada uma solução tampão com pH 5.0, 50% (solução desmineralizante) saturada em relação à composição do esmalte (0,05 mol/L solução tampão com pH 5,0 + 1,28 mmol/L Ca + 0,74 mmol/L P_i + 0.03 mg F/mL). Os espécimes ficarão imersos nesta solução por 6h com o equipamento *Rub&Roll* em funcionamento, em seguida serão lavados com água deionizada e recolocados no equipamento em funcionamento por 2h com a solução remineralizante com pH 7.0 (1,5 mmol/L Ca + 0,9 mmol/L P + 150 mmol/L KCl + 0,05 mg F/mL em solução tampão pH 7,0, 0,1 mol/L). Serão utilizados 6,25 ml/mm2 de solução desmineralizante e 3,12 ml/mm^2 da solução remineralizante, de acordo com a área dos espécimes. Após este período, os espécimes continuarão imersos nesta solução por 16h, totalizando um ciclo de 24h. Este ciclo será repetido por 15 dias (Adaptado de QUEIROZ et al., 2008).

4.1.6.2 Simulação de estresse mastigatório e desafio erosivo (Artigo 2)

Através desta metodologia objetiva-se avaliar o comportamento de restaurações em dentes endodonticamente tratados, frente ao estresse mastigatório e o fenômeno da erosão. Para isso, os espécimes dos grupos experimentais serão submetidos à ciclagem mecânica sob a ação de um líquido erosivo, simulando fenômenos que ocorrem na cavidade oral.

4.1.6.2.1 Grupos experimentais

Serão utilizados cinco grupos experimentais conforme o Quadro 3. Os grupos experimentais representados pela letra “b” possuem as mesmas características dos respectivos grupos, porém correspondem a 50% dos espécimes totais, ou seja, serão

testados 10 elementos de um total de 20 de cada grupo na simulação do estresse mastigatório e desafio erosivo.

Quadro 3. Esquematização dos grupos experimentais submetidos ao estresse mastigatório sob desafio erosivo.

Grupo	Material		Tipo			Técnica		Férula	
	RC	Cerâmica	*Endocrown*	Coroa total	Pino fibra de vidro	Direta	Indireta	2mm	0mm
G1b	X		X			X			X
G2b	X		X				X		X
G3b		X	X				X		X
G6b	X				X	X			X
G7b		X		X	X		X		X

Serão submetidos a este teste, os dentes restaurados com *endocrown* de resina composta direta, *endocrown* de resina composta indireta, *endocrown* de cerâmica, restauração de resina composta direta com uso de pino de fibra de vidro e coroa total cerâmica com pino de fibra de vidro, sendo que todos os grupos possuirão 0 mm de férula e são compostos por 10 unidades amostrais.

4.1.6.2.2 Procedimento experimental

Os espécimes serão submetidos ao desafio erosivo através da utilização de um meio ácido, para simular os danos sofridos pela estrutura dental frente à exposição de ácidos originários de alimentos, bebidas ou ácidos gástricos, simultaneamente à simulação de estresse mastigatório. Para isto, será utilizado ácido cítrico (3%) como agente erosivo, obtido através da adição de 3 g de ácido cítrico (Dinâmica, Brasil) em 1 l de água deionizada com pH de aproximadamente 2,6. Os espécimes ficarão em contato com a solução ácida no equipamento por 2 min ao dia, seis vezes ao dia, com intervalo de 30 min (os espécimes continuarão o estresse mecânico no equipamento com água deionizada), por 5 dias. No restante dos dias, para totalizar o tempo de execução do ensaio de estresse mastigatório (mais 10 dias), o equipamento funcionará somente com água deionizada (ÁVILA et al., 2017; RUBEN et al., 2014).

4.1.6.3 Influência do preparo cavitário frente a fatores de riscos simulados (Artigo 3)

Com a finalidade de avaliar como diferentes preparos cavitários podem influenciar no desempenho de amplas restaurações em dentes endodonticamente tratados, serão comparadas restaurações que possuam 2 mm de férula e 0 mm de férula, e que sejam confeccionadas com a mesma técnica e mesmo material. Para isso, os espécimes serão submetidos à ciclagem mecânica combinada com dois diferentes desafios, cariogênico e erosivo.

4.1.6.3.1 Grupos experimentais

Para este experimento, serão utilizados dois novos grupos, que sofrerão maior remoção de estrutura dental, sem restar férula (0 mm), mas com as mesmas técnicas restauradoras já descritas, sendo *endocrown* de resina composta direta com 0 mm de férula e *endocrown* de cerâmica com 0 mm de férula. Os resultados já obtidos para os grupos de *endocrown* de resina composta direta com 2 mm de férula e *endocrown* de cerâmica com 2 mm de férula, submetidos ao estresse mastigatório e desafio cariogênico e estresse mastigatório e desafio erosivo, serão utilizados neste experimento.

Quadro 4. Esquematização dos grupos experimentais com diferentes preparos cavitários submetidos ao estresse mastigatório, desafio cariogênico e desafio erosivo.

Grupo	Material		Tipo			Técnica		Férula	
	RC	Cerâmica	*Endocrown*	Coroa total	Pino fibra de vidro	Direta	Indireta	2mm	0mm
G1	X		X			X			X
G3		X	X				X		X
G4	X		X			X		X	

G5		X	X				X	X	

Serão portanto, avaliados neste experimento, a técnica de restauração *endocrown*, confeccionada em dois materiais e em dois diferentes preparos cavitário. Sendo assim, ficam constituídos os grupos por *endocrown* de resina composta direta com 0 mm de férula, *endocrown* de cerâmica com 0 mm de férula, *endocrown* de resina composta direta com 2 mm de férula e, *endocrown* de cerâmica com 2 mm de férula.

4.1.6.3.2 Procedimentos experimentais

Cada grupo terá metade de seus espécimes submetidos ao desafio cariogênico (n=10) e a outra metade submetida ao desafio erosivo (n=10) seguindo os mesmos padrões e variáveis citados nos itens 4.1.6.1.2 e 4.1.6.2.2 respectivamente.

4.1.6.4 Ensaio de compressão

Após a realização da simulação dos desafios erosivos e cariogênicos aliados à simulação do estresse mastigatório, todos os espécimes serão testados em uma máquina de ensaio universal (DL 2000 EMIC, Instron Brasil Equipamentos Científicos Ltda, Brasil) sob ação de um pistão metálico, com carga de 100kN, velocidade cruzada de 0,5 mm/min até a falha (MONTAGNER; PEREIRA-CENCI; CENCI, 2015).

4.1.6.5 Avaliação da propagação de trincas e fraturas

Após a falha, todos os espécimes serão avaliados visualmente, com o auxílio de um estereomicroscópio, para determinar quais são adequados para análise fractográfica. Os espécimes fraturados selecionados serão cobertos por carbono para

então serem analisados sob microscopia eletrônica de varredura (SSX-550, Shimadzu, Japão) para verificar as características das trincas e fraturas e identificar a origem da falha no material restaurador, remanescente dentário e interface da restauração. A direção da propagação das fissuras e da origem da falha serão avaliadas em todos os espécimes. Os tipos de falha serão determinados e comparados. Será realizada uma distinção entre fraturas catastróficas (não reparáveis, abaixo da junção cemento-esmalte) e fraturas não-catastróficas (reparáveis, acima da junção cemento-esmalte) (ROCCA et al., 2015, 2016; SPAZZIN et al., 2017).

4.1.7 Avaliação do comportamento da superfície do material restaurador (Artigo 4)

Com a finalidade de avaliar o comportamento dos materiais restauradores frente aos fatores de riscos simulados, será realizada a avaliação da microdureza, rugosidade do material e propagação de trincas.

4.1.7.1 Avaliação de rugosidade da superfície do material restaurador

Para avaliar a rugosidade da superfície, um perfilômetro será calibrado e a rugosidade inicial será avaliada (baseline) e após a aplicação dos testes em três diferentes locais da cúspide plana (Figura 3). A média das três avaliações para cada espécime será calculada (LINS et al., 2016).

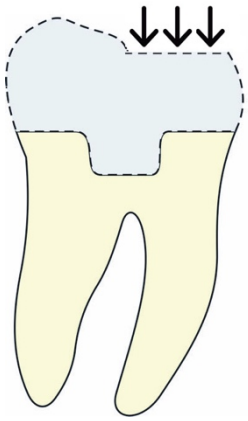

Figura 3 - Representação esquemática do local das avaliações realizadas pelo perfilômetro para avaliação da rugosidade superficial.

4.1.7.2 Avaliação da microdureza da superfície do material restaurador

Quanto à microdureza, todos os espécimes serão submetidos ao teste de microdureza superficial *Knoop* (Micro Hardness Tester, FM 700, Future-Tech Corp., Japão) antes da realização dos ensaios, onde três endentações serão feitas sobre a cúspide planificada. O resultado da média das três aferições será o valor da microdureza inicial de cada espécime (baseline). Após a finalização dos tratamentos, a mesma metodologia será realizada e, nova média será calculada (ATIMA, 2016; CHINELATTI et al., 2015; MASKE et al., 2016).

4.1.8 Análise estatística

Os dados serão tabulados e submetidos à análise estatística no programa Sigma Stat 3.5. Os testes serão escolhidos de acordo com a normalidade dos dados e $p<0,05$ será considerado como estatisticamente significante.

5 Cronograma

No quadro abaixo estão relacionadas as atividades e respectivos períodos de ocorrência relacionados à execução do trabalho no período de janeiro de 2016 a dezembro de 2019.

Quadro 5. Cronograma do estudo do período de janeiro de 2016 a dezembro de 2019.

Atividades		Pesquisa bibliográfica	Qualificação	Metodologia	Descrição dos resultados	Análise estatística	Redação dos artigos	Envio para publicação	Redação da tese	Defesa da tese
2016	J									
	F									
	M									
	A									
	M									
	J									
	J									
	A									
	S									
	O									
	N									
	D									
2017	J									
	F									
	M									
	A									
	M									
	J									
	J									
	A									
	S									
	O									
	N									
	D									
2018	J									
	F									

	M									
	A									
	M									
	J									
	J									
	A									
	S									
	O									
	N									
	D									
2019	J									
	F									
	M									
	A									
	M									
	J									
	J									
	A									
	S									
	O									
	N									
	D									

6 Orçamento

No quadro abaixo estão descritos os principais materiais que serão utilizados para o desenvolvimento do estudo, com quantidades e valores previstos.

Quadro 6. Relação dos materiais que serão utilizados com respectivas quantidades estimadas e preços.

Item	Descrição do produto	Quantidade	Preço unitário	Custo total
1	Ácido fluorídrico 5% (FGM)	4	21,59	86,36
2	Ácido fosfórico 37% (FGM)	3	12,86	38,58
3	Adesivo Adper Single Bond 2 (3M ESPE)	3	116,00	348,00
4	Cimento U200 (3M ESPE)	3	399,00	1197,00
5	Disco de Lixa Sof-Lex Pop On (3M ESPE)	3	315,00	945,00
6	Gesso Tipo IV (Dentsply)	2	26,30	52,60
7	Microaplicador (KG Sorensen)	3	14,50	43,50
8	Pasta de polimento (FGM)	3	27,84	83,52
9	Pinos de fibra de vidro (FGM)	12	52,28	627,36
10	Pontas diamantadas (KG Sorensen)	30	10,50	315,00
11	Resina Filtek Z350 XT (3M ESPE)	14	131,75	1844,50
12	Restaurações cerâmicas	60	300,00	18000,00
13	Silano (FGM)	3	47,80	143,40
14	Silicone de adição Express XT (3M ESPE)	1	643,50	643,50
15	Silicone transparente (Yller)	1	120,00	120,00
			Total	24369,52

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Apêndices

Apêndice A – Termo de consentimento ético para doação de órgão dental para biorrepositório

UNIVERSIDADE FEDERAL DE PELOTAS FACULDADE DE ODONTOLOGIA
Pós-Graduação em Odontologia
Área de Concentração em Dentística

Termo de consentimento livre e esclarecido

Autorização para Doação de Órgão Dental para Biorrepositório

O Sr.(a) está sendo convidado(a) como voluntário(a) a participar da pesquisa **"Comportamento de diferentes estratégias restauradoras em dentes endodonticamente tratados frente a fatores de risco simulados".** Para tanto, pedimos sua autorização para a coleta, o depósito, o armazenamento, a utilização e o descarte do material biológico humano **"dente"**. A utilização do material biológico está vinculada somente a este projeto de pesquisa. Nesta pesquisa, pretendemos avaliar o comportamento de grandes restaurações em dentes tratados endodonticamente, frente a fatores de risco simulados. Para esta pesquisa, os elementos dentais serão submetidos ao tratamento endodôntico e restaurador para então passarem por testes para avaliar o comportamento das restaurações. Os riscos para o doador compreendem o constrangimento e medo de realizar a doação do elemento dental. A pesquisa contribuirá para verificar, sob as condições simuladas, o tipo de restauração que se comporta da melhor maneira.

Para participar deste estudo o Sr.(a) não terá nenhum custo e nem receberá qualquer vantagem financeira. O Sr.(a) terá o esclarecimento sobre o estudo em qualquer aspecto que desejar e estará livre para participar ou recusar-se a participar e a qualquer tempo e sem quaisquer prejuízos, pode retirar o consentimento de guarda e utilização do material biológico armazenado no biorrepositório, valendo a desistência a partir da data de formalização desta. A sua participação é voluntaria, e a recusa em participar não acarretará qualquer penalidade ou modificação na forma em que o Sr.(a) é atendido(a) pelo pesquisador, que tratará a sua identidade com padrões profissionais de sigilo. Os resultados obtidos pela pesquisa, a partir de seu material

biológico, estarão a sua disposição quando finalizada. Seu nome ou o material que indique sua participação não serão liberados sem a sua permissão.

O(A) Sr.(a) não será identificado(a) em nenhuma publicação que resultar.

Este termo de consentimento encontra-se impresso em duas vias originais, sendo que uma será arquivada pelo pesquisador responsável, na Universidade Federal de Pelotas, e a outra será fornecida ao Sr.(a). os dados, materiais e instrumentos utilizados na pesquisa ficarão arquivados com o pesquisador responsável por um período máximo de 10 (dez) anos e após esse tempo serão destruídos. Os pesquisadores tratarão a sua identidade com padrões de sigilo, atendendo a legislação brasileira (Resoluções Nº 466/12; 441/11 e a Portaria 2.201 do Conselho Nacional de Saúde e suas complementares), utilizando informações somente para os fins acadêmicos e científicos.

Eu,_____,

portador do documento de identidade _____

fui informado(a) dos objetivos da pesquisa **"Comportamento de diferentes estratégias restauradoras em dentes endodonticamente tratados frente a fatores de risco simulados"**, de maneira clara e detalhada e esclareci minhas dúvidas. Sei que a qualquer momento poderei solicitar novas informações e modificar minha decisão de participar se assim o desejar.

Declaro que concordo em participar desta pesquisa. Recebi uma via original deste termo de consentimento livre e esclarecido e me foi dada a oportunidade de ler e esclarecer as minhas dúvidas.

Pelotas, _____ de _____ de 20___.

_____ _____

Nome do participante Assinatura do participante

Data: ___/___/____

_____

Assinatura do pesquisador

Data: ___/___/___

Apêndice B – Termo de Consentimento Livre e Esclarecido para participação no Ensaio Clínico Randomizado CaCIA.

UNIVERIDADE FEDERAL DE PELOTAS
FACULDADE DE ODONTOLOGIA
PÓS-GRADUAÇÃO EM DENTÍSTICA

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Título da pesquisa:

"Diagnóstico de cárie secundária: estabelecimento de parâmetros e efeito nas decisões de tratamento em odontologia"

Você está sendo convidado a participar da pesquisa: "Diagnóstico de cárie secundária: estabelecimento de parâmetros e efeito nas decisões de tratamento em odontologia". O objetivo deste estudo será avaliar com diferentes critérios usados na odontologia o estado de restaurações de resina composta (material da mesma cor do dente) e de amálgama (liga metálica), instituindo dessa forma o diagnóstico, tratamento e acompanhamento das mesmas.

Os atendimentos serão realizados por alunos de graduação e pós-graduação envolvidos nesse estudo, os quais realizarão o diagnóstico, planejamento, tratamento, fotografias, além de consultas de avaliação odontológica. O tratamento dependerá do exame clínico de cada restauração, e poderá compreender somente o acompanhamento da restauração, reparo ou substituição.

Sua contribuição é importante, pois ajudará os cirurgiões-dentistas no esclarecimento da real relação da cárie com a falha de restaurações, e na investigação da melhor forma de tratar restaurações com falhas. É importante que o(a) Senhor(a) saiba que sua saúde bucal será acompanhada ao longo do tempo, nos períodos de 12 meses e 24 meses.

Com base no exame clínico, todo e qualquer tratamento necessário, que se enquadre nos procedimentos ofertados pela Faculdade de Odontologia, será oferecido e realizado pelos pesquisadores, mesmo que o(a) Senhor(a) venha a desistir de participar do estudo. Gostaríamos de esclarecer que os procedimentos

restauradores executados oferecem risco mínimo a sua saúde bucal, tais como sensibilidade pós-operatória, ou em casos pontuais pode ocorrer exposição da polpa ou fratura do dente durante o procedimento restaurador.

A participação nessa pesquisa é totalmente voluntária, podendo o(a) Senhor(a): recusar-se a participar, ou mesmo desistir a qualquer momento sem que isto acarrete qualquer prejuízo à sua pessoa.

Garantimos que suas informações serão tratadas com o mais absoluto sigilo e confidencialidade, de modo a preservar a sua identidade. Informamos que Senhor(a) não pagará nem será remunerado por sua participação. Garantimos, no entanto, que todas as despesas decorrentes da pesquisa serão ressarcidas, quando devidas e decorrentes especificamente da participação na pesquisa.

Em caso de dúvidas você pode entrar em contato com os pesquisadores responsáveis (**Pesquisadores Responsáveis:** Maximiliano Sérgio Cenci (Orientador) /E-mail.: cencims@gmail.com e Cácia Signori, Cel.: 8134-2804/E-mail: caciasignori@gmail.com).

*Este termo deverá será preenchido em duas vias de igual teor, sendo uma delas, devidamente preenchida, assinada e entregue ao(a) senhor(a).

Por esse termo, eu _____, RG nº _____, aceito participar do projeto descrito nesse termo e autorizo a realização dos procedimentos descritos acima e a utilização de dados e imagens referentes à minha pessoa pelos pesquisadores envolvidos no estudo. Pelotas, ____/____/_____.

_____ Assinatura

_____ Assinatura (Pesquisador responsável)

Apêndice C – STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) checklist utilizado para conduzir o artigo 1 (How the use of different clinical criteria on the assessment of posterior restorations impacts on the treatment decision in permanent teeth?)

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
Outcome data	15*	Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included

		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

Apêndice D – STARD (Standards for Reporting Diagnostic accuracy studies) checklist utilizado para conduzir o artigo 2 (Accuracy of two visual methods for the detection of caries around restorations: a delayed-type cross-sectional study).

Section & Topic	No	Item	Reported on page #
TITLE OR ABSTRACT			
	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	71
ABSTRACT			
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	73
INTRODUCTION			
	3	Scientific and clinical background, including the intended use and clinical role of the index test	75
	4	Study objectives and hypotheses	75
METHODS			
Study design	**5**	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	75
Participants	**6**	Eligibility criteria	75
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	75
	8	Where and when potentially eligible participants were identified (setting, location and dates)	75,76
	9	Whether participants formed a consecutive, random or convenience series	75
Test methods	**10a**	Index test, in sufficient detail to allow replication	78-80
	10b	Reference standard, in sufficient detail to allow replication	81
	11	Rationale for choosing the reference standard (if alternatives exist)	-
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	82
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	-
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	76-77
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	-
Analysis	**14**	Methods for estimating or comparing measures of diagnostic accuracy	82
	15	How indeterminate index test or reference standard results were handled	82
	16	How missing data on the index test and reference standard were handled	-
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	82
	18	Intended sample size and how it was determined	81
RESULTS			
Participants	**19**	Flow of participants, using a diagram	-
	20	Baseline demographic and clinical characteristics of participants	82,83
	21a	Distribution of severity of disease in those with the target condition	83
	21b	Distribution of alternative diagnoses in those without the target condition	-

	22	Time interval and any clinical interventions between index test and reference standard	-
Test results	**23**	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	-
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	82-84
	25	Any adverse events from performing the index test or the reference standard	-
DISCUSSION			
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	86,87
	27	Implications for practice, including the intended use and clinical role of the index test	85,87
OTHER INFORMATION			
	28	Registration number and name of registry	76
	29	Where the full study protocol can be accessed	-
	30	Sources of funding and other support; role of funders	89

Apêndice E – CONSORT (Consolidated Standards of Reporting Trials) checklist utilizado para conduzir o artigo 3 (The effect of the use of two clinical criteria on the assessment of caries lesions around restorations in adults – the Caries Cognition and Identification in Adults (CaCIA) randomized controlled trial)

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	94
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	96
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	97,98
	2b	Specific objectives or hypotheses	98
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	98
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	99
	4b	Settings and locations where the data were collected	99
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	99
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	106
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	106
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			

Sequence generation	8a	Method used to generate the random allocation sequence	106
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	106,107
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	106
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	104
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	107
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	107
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	-
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	107, Table 3, Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	107
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	107, 109, 110, Table 3, Table 4
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	107, 109, 110, Table 3, Table 4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	111, Table 5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	111, Table 5

Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	113, 114
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	115, 116
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	113-115
Other information			
Registration	23	Registration number and name of trial registry	98
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	117

Anexos

Anexo A - Parecer Consubstanciado do Comitê de Ética em Pesquisa do projeto Comportamento de diferentes estratégias restauradoras em dentes endodonticamente tratados frente a fatores de risco simulados

UFPEL - FACULDADE DE ODONTOLOGIA DA UNIVERSIDADE FEDERAL DE

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: COMPORTAMENTO DE DIFERENTES ESTRATÉGIAS RESTAURADORAS EM DENTES ENDODONTICAMENTE TRATADOS FRENTE A FATORES DE RISCO

Pesquisador: JULIANA LAYS STOLFO UEHARA

Área Temática:

Versão: 2

CAAE: 70405517.9.0000.5318

Instituição Proponente: Faculdade de Odontologia da Universidade Federal de Pelotas/ FO-UFPel

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.407.635

Apresentação do Projeto:

Reconhece-se que a sobrevivência de restaurações em dentes tratados endodonticamente representa um desafio para a Odontologia, e, segundo os autores, ainda não há suficiente evidência para a escolha de materiais e técnicas restauradoras.

Objetivo da Pesquisa:

O objetivo do estudo será avaliar o desempenho de diferentes estratégias restauradoras, aplicadas em dentes endodonticamente tratados com ampla destruição coronária, frente a fatores de risco simulados, através de um ensaio laboratorial in vitro que avaliará restaurações do tipo endocrown e coroas totais com uso de pino de fibra de vidro.

Avaliação dos Riscos e Benefícios:

Não há riscos relacionados à pesquisa. Apenas o constrangimento e medo de realizar a doação do elemento dental. O benefício será aumentar o conhecimento sobre a escolha das restaurações.

Comentários e Considerações sobre a Pesquisa:

O método está bem detalhado, inclusive quanto a obtenção dos dentes. Os primeiros molares (140) utilizados serão extraídos e destinados ao biorrepositório, ou seja, serão armazenados apenas durante a pesquisa e após, serão descartados.

Considerações sobre os Termos de apresentação obrigatória:

O TCLE está claro e em duas vias, foi incluído o contato do pesquisador no TCLE.

Endereço: Rua Gonçalves Chaves, 457
Bairro: Centro **CEP:** 96.015-560
UF: RS **Município:** PELOTAS
Telefone: (53)3222-4439 **Fax:** (53)3222-4439 **E-mail:** cep.fop@gmail.com

UFPEL - FACULDADE DE ODONTOLOGIA DA UNIVERSIDADE FEDERAL DE

Continuação do Parecer: 2.407.635

Recomendações:

Aprovação

Conclusões ou Pendências e Lista de Inadequações:

O pesquisador incluiu na revisão as fontes de financiamento e o TCLE foi corrigido.

Todas as alterações solicitadas foram realizadas.

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_934093.pdf	25/09/2017 17:39:00		Aceito
Projeto Detalhado / Brochura Investigador	DOUTORADO_JULIANAUEHARA_RESPOSTACEP.docx	25/09/2017 17:38:25	JULIANA LAYS STOLFO UEHARA	Aceito
Orçamento	ORCAMENTO_RESPOSTACEP.docx	25/09/2017 17:37:51	JULIANA LAYS STOLFO UEHARA	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_RESPOSTACEP.docx	25/09/2017 17:37:05	JULIANA LAYS STOLFO UEHARA	Aceito
Cronograma	Cronograma.docx	20/06/2017 15:40:26	JULIANA LAYS STOLFO UEHARA	Aceito
Folha de Rosto	folha_rosto.pdf	20/06/2017 15:30:22	JULIANA LAYS STOLFO UEHARA	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

PELOTAS, 30 de Novembro de 2017

Assinado por:
Fernanda G Pappen
(Coordenador)

Endereço: Rua Gonçalves Chaves, 457
Bairro: Centro **CEP:** 96.015-560
UF: RS **Município:** PELOTAS
Telefone: (53)3222-4439 **Fax:** (53)3222-4439 **E-mail:** cep.fop@gmail.com

Anexo B – Parecer Consubstanciado do Comitê de Ética em Pesquisa do projeto Diagnóstico de cárie secundária: estabelecimento de parâmetro e efeito nas decisões de tratamento em Odontologia

FACULDADE DE ODONTOLOGIA DA UNIVERSIDADE FEDERAL DE

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Diagnóstico de Cárie Secundária: estabelecimento de parâmetros e efeito nas decisões de tratamento em Odontologia

Pesquisador: Maximiliano Sérgio Cenci

Área Temática:

Versão: 2

CAAE: 53463316.1.0000.5318

Instituição Proponente: Faculdade de Odontologia da Universidade Federal de Pelotas/ FO-UFPel

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.625.236

Apresentação do Projeto:

O projeto trata-se de 5 diferentes metodologias para responder a questionamentos sobre o assunto carie secundária. Após adequação às solicitações deste comitê ele está bem claro e justificado, devido a sua importância cientifica, uma vez que a substituição de restaurações supostamente com falhas é um procedimento rotineiro na prática odontológica, sendo as lesões de cárie secundária o principal tipo de problema reportado.

Objetivo da Pesquisa:

O objetivo geral dessa tese será investigar os parâmetros diagnósticos e de decisão de tratamento no manejo de lesões de cárie secundária, e seu potencial impacto na saúde bucal dos pacientes. Cinco estudos serão realizados: no estudo 1, uma revisão sistemática investigará os métodos de detecção visual e/ou radiográfica utilizados em estudos sobre o diagnóstico de lesões de cárie secundária em dentes permanentes, com relação à relevância clínica (associação entre método diagnóstico e decisão de tratamento) e validade de conteúdo (avaliação dos critérios utilizados por cada sistema no diagnóstico da lesão de cárie secundária). Uma análise descritiva será realizada. O estudo 2 consistirá na elaboração e aplicação de um questionário acerca da conduta do cirurgião-dentista frente ao diagnóstico e tratamento de lesões de cárie secundária no consultório. Será um estudo transversal com seleção aleatória de uma amostra de cirurgiões-dentistas residentes no

Endereço: Rua Gonçalves Chaves, 457
Bairro: Centro **CEP:** 96.015-560
UF: RS **Município:** PELOTAS
Telefone: (53)3222-4439 **Fax:** (53)3222-4439 **E-mail:** cep.fop@gmail.com

estado do Rio Grande do Sul. Os questionários serão disponibilizados via e-mail. Os fatores em estudo serão: o perfil do profissional, e sua conduta frente ao diagnóstico e tratamento da cárie secundária. Paralelamente a isso, o estudo 3 se baseará na construção de um biorrepositório de dentes com lesões de cárie ao redor de restaurações com casos em fases diferenciadas. O estudo será in vitro. Três condições de cárie (lesão de mancha branca em estágio inicial, avançado e lesão em dentina) serão induzidas em quatro tipos de dentes/restaurações (incisivos – restaurações classe IV, pré-molares – classe II, molares – classes II e V). O experimento ocorrerá em quintuplicata. A variável de desfecho avaliada será o aspecto visual. O estudo 4 investigará os benefícios do emprego de uma oficina de diagnóstico no processo de ensino-aprendizagem de alunos de graduação do curso de odontologia. A oficina de diagnóstico será realizada a partir do biorrepositório de dentes com lesões de cárie secundária. Será um estudo clínico randomizado (distribuição dos alunos) de grupos paralelos (aula teórica e aula teórica somada à oficina de diagnóstico). Parte dos acadêmicos passará por aula teórica e participará da oficina, enquanto a outra parte apenas por aula teórica. Após, todos participarão de avaliação teórica e prática, para estabelecer o diagnóstico e tratamento de diferentes casos sugestivos de lesões de cárie secundária. As variáveis de desfecho serão a melhora da performance no diagnóstico, custo-efetividade da realização da atividade e retenção de conhecimento. Por fim, o último estudo avaliará o efeito do uso de diferentes critérios de avaliação de cárie ao redor de restaurações, nos desfechos relacionados à saúde bucal de adultos. Os critérios da Federação Dentária Internacional (FDI) serão comparados aos critérios de detecção CARS (“Caries Associated with Restorations or Sealants”), do ICCMS (International Caries Classification and Management
4
System). Será um ensaio clínico randomizado controlado de dois grupos paralelos (grupo controle - diagnóstico e indicação de tratamento conforme os critérios da FDI; grupo experimental - diagnóstico e decisão de tratamento segundo os critérios de detecção CARS). Serão realizadas avaliações aos 12 e 24 meses. O desfecho primário consistirá no número de superfícies restauradas com necessidade de reintervenção. Os desfechos secundários serão: impacto da intervenção na qualidade de vida e relação de custo-efetividade. Os dados dos estudos 2, 4 e 5 serão submetidos à análise estatística, considerando poder de 80% e nível de significância de 5%.

Avaliação dos Riscos e Benefícios:

Riscos mínimos em todas as metodologias apresentadas.

Benefícios: maior longevidade e sucesso clínico de restaurações de Resina composta.

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Continuação do Parecer: 1.625.236

Comentários e Considerações sobre a Pesquisa:

Mérito inquestionável e contribui com o esclarecimento de lacunas na literatura.

Considerações sobre os Termos de apresentação obrigatória:

Todos foram adequados e devidamente apresentados.

Recomendações:

Nenhuma.

Conclusões ou Pendências e Lista de Inadequações:

Nenhuma pendência, todas as recomendações solicitadas no parecer número 1.517.623 foram acatadas.

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_664594.pdf	05/05/2016 16:27:33		Aceito
Outros	CARTA_RESPOSTA.pdf	05/05/2016 16:26:47	CÁCIA SIGNORI	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_estudo4.pdf	05/05/2016 16:25:31	CÁCIA SIGNORI	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_ESTUDO3.pdf	05/05/2016 16:25:16	CÁCIA SIGNORI	Aceito
Outros	Cartaconvite_nova.pdf	05/05/2016 16:24:48	CÁCIA SIGNORI	Aceito
Cronograma	CRONOGRAMA_novo.pdf	05/05/2016 16:24:14	CÁCIA SIGNORI	Aceito
Projeto Detalhado / Brochura Investigador	projetodetese_corrigido.pdf	05/05/2016 16:23:53	CÁCIA SIGNORI	Aceito
Folha de Rosto	Folhaderosto.pdf	18/02/2016 11:00:14	CÁCIA SIGNORI	Aceito
Orçamento	ORCAMENTO.pdf	17/02/2016 22:13:08	CÁCIA SIGNORI	Aceito
TCLE / Termos de Assentimento / Justificativa de	TCLE_ESTUDO5.pdf	17/02/2016 22:07:19	CÁCIA SIGNORI	Aceito

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Ausência	TCLE_ESTUDO5.pdf	17/02/2016 22:07:19	CÁCIA SIGNORI	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

PELOTAS, 06 de Julho de 2016

Assinado por:
ANDREIA MORALES CASCAES
(Coordenador)

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