UNIVERSIDADE FEDERAL DE PELOTAS
Programa de Pós-Graduação em Odontologia

Tese

Avaliação clínica dos efeitos de duas técnicas de isolamento do campo operatório no desempenho de restaurações Classe V e na condição periodontal

Silvia Terra Fontes

Pelotas, 2011

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

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NOTAS PRELIMINARES

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RESUMO

FONTES, Silvia Terra. **Avaliação clínica dos efeitos de duas técnicas de isolamento do campo operatório no desempenho de restaurações Classe V e na condição periodontal.** 2011. 84f. Tese (Doutorado) – Programa de Pós-Graduação em Odontologia. Universidade Federal de Pelotas, Pelotas.

Durante os procedimentos restauradores, diferentes métodos de isolamento do campo operatório podem ser utilizados a fim de promover controle de umidade e retração de tecidos gengivais. O objetivo do presente ensaio clinico foi avaliar os efeitos de duas técnicas de isolamento no desempenho clínico de restaurações Classe V, bem como na condição periodontal dos sítios restaurados. Pacientes apresentando, no mínimo, duas lesões cervicais não cariosas (LCNCs) foram selecionados para este estudo. As LCNCs foram randomizadas nos seguintes grupos: (1) isolamento com lençol de borracha e grampo retrator de gengiva e (2) isolamento com rolos de algodão e fio retrator de gengiva. Um sugador de saliva foi utilizado em ambas as técnicas. Todos os procedimentos restauradores foram executados com sistema adesivo autocondicionante e compósito restaurador nanoparticulado, seguindo as instruções dos fabricantes. O desempenho clinico das restaurações foi avaliado em termos de fratura e retenção da restauração, adaptação marginal, manchamento marginal, sensibilidade pós-operatória e preservação da vitalidade pulpar após 1 semana e 6 meses da inserção das restaurações. A condição periodontal dos sítios restaurados foi avaliada com base na presença de placa supragengival, sangramento gengival marginal, profundidade de sondagem e recessão gengival relativa. Trinta pacientes foram incluídos no estudo, resultando num total de 136 restaurações (68 restaurações por grupo). Após seis meses de acompanhamento, uma restauração do grupo isolado com lençol de borracha e três restaurações do grupo isolado com rolos de algodão perderam a retenção. Neste período, uma maior incidência de pequenos defeitos marginais foi observada no grupo que recebeu isolamento com rolos de algodão ($p= 0.01$). Ambos os grupos apresentaram um aumento significativo do acúmulo de placa supragengival após 6 meses da inserção das restaurações ($p< 0.05$). Porém, não foram detectadas diferenças estatisticamente significativas entre os dois grupos testados considerando os critérios utilizados para avaliação das restaurações e da condição periodontal ($p> 0.05$). Dentro das limitações deste estudo, foi possível concluir que ambas as técnicas de isolamento resultaram em restaurações clinicamente aceitáveis, sem produzir efeitos negativos nos tecidos periodontais.

Palavras-chave: Adesivos dentinários. Dentística operatória. Dique de borracha. Ensaio clínico. Periodonto.

ABSTRACT

FONTES, Silvia Terra. **Avaliação clínica dos efeitos de duas técnicas de isolamento do campo operatório no desempenho de restaurações Classe V e na condição periodontal.** 2011. 84f. Tese (Doutorado) – Programa de Pós-Graduação em Odontologia. Universidade Federal de Pelotas, Pelotas.

During restorative procedures, different isolation methods of the operative field can be used to promote moisture control and retraction of the gingival tissues. The aim of the present clinical trial was to evaluate the effects of two isolation techniques on the clinical performance of Class V restorations, as well on the periodontal conditions of restored sites. Patients presenting at least two noncarious cervical lesions (NCLs) were enrolled in this study. The NCLs were randomized into the following groups: (1) isolation performed with rubber dam and gingival retraction clamp and (2) isolation provided with cotton rolls and gingival retraction cord. Both techniques were used with a saliva suction device. All restorative procedures were performed using a self-etching adhesive system and a nanofilled composite resin according to the manufacturer's instructions. The clinical performance of restorations was recorded in terms of fracture and retention of restoration, marginal adaptation, marginal staining, postoperative hypersensitivity, and preservation of tooth vitality at 1 week and 6 months after placement. The periodontal condition of restored sites was evaluated based on the presence of supragingival plaque, gingival marginal bleeding, probing depth, and relative gingival recession. Thirty patients were enrolled in the study, yielding a total of 136 restorations (68 restorations per group). At the 6-month follow-up, one restoration from the rubber dam group and three restorations from the cotton roll group lost retention. In this period, the highest incidence of small marginal defects was observed in the group isolated with cotton rolls ($p= 0.01$). Both groups showed a statistically significant increase in supragingival plaque at six months after restoration placement ($p< 0.05$). However, no significant differences were detected among the two groups tested with respect to any of the criteria used to evaluate the restorations or the periodontal condition ($p> 0.05$). Within the limits of this study, it can be concluded that both isolation techniques resulted in equally clinically acceptable restorations without producing negative effects on periodontal tissues.

Keywords: Dentin-bonding agents. Operative dentistry. Rubber dam. Clinical trial. Periodontium.

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1.1 INTRODUÇÃO

Conforme a estratégia de união, os sistemas adesivos atualmente disponíveis podem ser classificados em convencionais e autocondicionantes. Enquanto os sistemas adesivos convencionais requerem tratamento do substrato com ácido fosfórico, lavagem, subsequente aplicação e infiltração de monômeros resinosos; os sistemas adesivos autocondicionantes dispensam a etapa preliminar de condicionamento e lavagem do substrato, em função da presença de monômeros ácidos na composição, os quais efetuam desmineralização e infiltração, simultaneamente (DE MUNCK et al., 2005; VAN MEERBEEK et al., 2003).

Sistemas adesivos simplificados contemplam a demanda por produtos com poucas etapas, rapidez e facilidade de aplicação, porém devem ser empregados mediante conhecimento de suas limitações (TAY; PASHLEY, 2003). Contudo, os sistemas adesivos convencionais de três passos são considerados padrão-ouro em termos de estabilidade de união; já que, de forma geral, os produtos simplificados não correspondem aos melhores resultados em termos de efetividade de adesão (PEUMANS et al., 2005a).

Na prática clínica, restaurações de lesões cervicais não cariosas (LCNCs) representam verdadeiros desafios para a adesão, pelo fato de combinarem determinadas condições desfavoráveis ao processo de união, dentre as quais, substratos altamente mineralizados e fibras colágenas desnaturadas (PERDIGÃO, 2010). Ademais, ensaios clínicos envolvendo restaurações Classe V são preferencialmente utilizados para avaliação da efetividade do sistema adesivo pelo fato de não apresentam quaisquer retenções macromecânicas, diferentemente das demais cavidades (VAN MEERBEEK et al.,1998).

Para avaliação do desempenho clínico de restaurações, recomenda-se ainda longo tempo de acompanhamento. Entretanto, é possível estabelecer critérios que constituirão falhas prematuras das restaurações em curtos períodos, incluindo desde

sensibilidade pós-operatória até a perda da restauração (HICKEL et al., 2007). De acordo com as orientações da *American Dental Association* (2001), o desempenho dos sistemas adesivos é considerado clinicamente aceitável, se houver retenção de, pelo menos, 95% das restaurações após 6 meses de acompanhamento. Para aumentar o índice de sucesso das restaurações alguns autores sugerem a criação de formas adicionais de retenção (KIM et al., 2009); outros propõem o condicionamento seletivo das margens de esmalte (PEUMANS et al., 2005b).

Apesar da existência de diversos estudos de acompanhamento de restaurações Classe V, a maioria tem-se restringido à avaliação do desempenho de produtos que diferem ora em marca comercial, ora em estratégia de união (PEUMANS et al., 2005a). Todavia, deve-se considerar que não apenas os materiais utilizados em si, mas a técnica empregada para isolamento do campo operatório é um fator que pode exercer influência significativa nos resultados e, portanto, devem ser investigados (DE MUNCK et al., 2005).

De forma geral, os métodos de controle de umidade mais conhecidos consistem no isolamento absoluto, conseguido essencialmente através do emprego de lençol de borracha, e no isolamento relativo, obtido com uso de rolos de algodão. Além disso, um sugador de saliva pode ser associado em ambos os métodos. Embora haja reconhecimento da superioridade do isolamento absoluto no controle de umidade, relutância e dificuldade em utilizá-lo são relatos frequentes (GILBERT et al., 2010). No entanto, um estudo clínico prospectivo demonstrou a ausência de diferenças significativas entre o desempenho clínico de restaurações em dentes posteriores realizadas através de diferentes técnicas de isolamento (RASKIN et al., 2000).

Métodos alternativos já foram sugeridos a fim de proporcionar controle de umidade e acesso ao limite cervical da cavidade sem, concomitantemente, gerar lesões iatrogênicas ao periodonto (BLUNCK, 2001; OWENS, 2006; PEREZ, 2010). Nota-se, inclusive, limitarem-se os estudos longitudinais envolvendo restaurações de LCNCs a mencionar, sucintamente, a etapa de isolamento do campo operatório, sem descrevê-la de forma detalhada.

1.2 JUSTIFICATIVA

Pelo fato de a umidade do campo operatório exercer influência no desempenho clínico de restaurações, percebe-se a necessidade de investigar clinicamente seu efeito através de dois métodos diferentes de isolamento. Este tema consiste num assunto de comum interesse a pesquisadores, estudantes e profissionais de Odontologia, principalmente daqueles que lidam diariamente com procedimentos adesivos.

Deve-se ainda considerar que o desenvolvimento e acompanhamento de um ensaio clínico randomizado, controlado, envolvendo a influência da técnica utilizada para isolamento do campo operatório no desempenho longitudinal de restaurações Classe V, poderá esclarecer lacunas existentes acerca do tema, além de servir como referência para o avanço da prática clínica baseada em evidências.

1.3 OBJETIVO

O objetivo do presente ensaio clínico randomizado será avaliar os efeitos de duas técnicas de isolamento do campo operatório no desempenho clínico de restaurações Classe V.

1.4 HIPÓTESE NULA

A hipótese nula a ser testada é que não haverá diferença no desempenho clínico de restaurações Classe V realizadas com duas técnicas diferentes de isolamento do campo operatório.

1.5 MATERIAIS E MÉTODOS

1.5.1 Considerações éticas

O presente estudo faz parte do projeto de pesquisa intitulado “Ensaio clínico randomizado comparando diferentes sistemas adesivos em restaurações de lesões cervicais não cariosas”, que foi submetido à apreciação do Comitê de Ética em Pesquisa da Faculdade de Odontologia da Universidade Federal de Pelotas (FOUFPEL), recebendo parecer favorável à sua execução (093/2009) (Anexo A). Ademais, o referido projeto foi encaminhado para avaliação do Conselho Coordenador do Ensino, Pesquisa e Extensão (COCEPE) desta universidade, sendo considerado aprovado (4.02.01.046).

1.5.2 Desenho experimental e cálculo amostral

Este ensaio clínico randomizado controlado será delineado e conduzido conforme as orientações do *Consolidated Standards of Reporting of Trials* (CONSORT) (ALTMAN et al., 2001).

O tamanho amostral terá como base um estudo clínico prévio (LOGUÉRCIO et al., 2006). Após início do presente estudo, o tamanho da amostra será recalculado, considerando poder de 80% e nível de significância de 5%.

1.5.3 Recrutamento e seleção dos pacientes

A estratégia de busca dos indivíduos interessados em participar deste ensaio clínico será realizada através da divulgação do projeto por meio da exposição de cartazes e distribuição de panfletos (Figura 1) na FOUFPEL. Além disso, os alunos líderes de turma, os professores chefes de disciplina e os dentistas da rede de saúde pública serão informados sobre o estudo, visando aumentar a receptividade e a taxa de adesão dos pacientes.

Figura 1. Cartaz de divulgação do projeto.

Todos os pacientes que forem encaminhados ou, diretamente, procurarem atendimento odontológico, apresentando diagnóstico de lesão cervical não cariosa, serão agendados para exame de avaliação. Um aluno realizará contato telefônico com tais pacientes e agendamento das consultas por ordem de disponibilidade dos mesmos.

Inicialmente, a presença de LCNCs será verificada através de inspeção com auxílio de uma espátula de madeira. Em caso afirmativo, será preenchido um prontuário do paciente, contendo dados de identificação, anamnese geral e odontológica. Ademais, odontograma e periograma serão realizados, utilizando espelho intrabucal, sonda exploradora, sonda periodontal milimetrada, pinça clínica, rolos de algodão e sugador de saliva. A partir do exame clínico, as LCNCs serão classificadas segundo avaliação de suas características (Tabela 1).

A sensibilidade dentinária será avaliada através da aplicação de jato de ar na superfície vestibular. O grau de sensibilidade será registrado a partir de uma escala visual analógica (Figura 2). A vitalidade pulpar será verificada através da aplicação de *spray* refrigerante.

Tabela 1. Características das lesões cervicais não cariosas.

Características clínicas	**Classificação**	
1. Forma	Angulada, em forma de cunha	
	Arredondada, em forma de pires	
2. Profundidade	≤ 1.0 mm	
	> 1.0 mm	
3. Altura	< 1.5 mm	
	1.5 a 2.5 mm	
	> 2.5 mm	
4. Margem cavo-superficial	≤ 50% em esmalte	
	> 50% em dentina	
5. Facetas de desgaste	≤ 50% da estrutura dental	
	> 50% da estrutura dental	
6. Esclerose dentinária	1 (ausente)	
	2 (leve)	
	3 (moderada)	
	4 (severa)	
7. Sensibilidade dentinária	1 (ausente)	
	2 (leve)	
	3 (moderada)	
	4 (considerável)	
	5 (severa)	
8. Distribuição na arcada	Maxila	Incisivo
	Mandíbula	Canino
		Pré-molar

Sensibilidade	Nenhuma	Leve	Moderada	Considerável	Severa
Escores	1	2	3	4	5

Figura 2. Escala visual analógica.

Os pacientes que se enquadrarem nos critérios de inclusão e exclusão (Tabela 2) receberão uma carta de informação sobre a natureza e proposição do estudo (Apêndice A). Após a leitura, será solicitado que os voluntários assinem um termo de consentimento livre e esclarecido (Apêndice B).

Tabela 2. Critérios de inclusão e exclusão.

Critérios	
Inclusão	✓ Presença de, no mínimo, duas lesões cervicais não cariosas na face vestibular de dentes vitais anteriores ou pré-molares;
Exclusão	✓ Fumantes; ✓ Pacientes com condição de saúde geral comprometida; ✓ Pacientes em tratamento ortodôntico; ✓ Pacientes com problemas oclusais; ✓ Presença de menos de 20 dentes em boca; ✓ Ausência de dente antagonista; ✓ Facetas de desgaste superior a 50% da estrutura incisal ou oclusal; ✓ Presença de caries ou restaurações na face vestibular; ✓ Índice de placa visível ou índice de sangramento gengival superior a 20%; ✓ Profundidade de sondagem e nível de inserção clínica igual ou superior a 4 mm em qualquer sítio bucal; ✓ Pacientes sem disposição para comparecer às consultas de reavaliação; ✓ Pacientes que se recusarem a participar do estudo.

Quatro semanas antes do início do estudo, os pacientes que necessitarem serão submetidos a sessões de raspagem e polimento supragengival. Além disso,

eles receberão instrução para controle mecânico de placa, incluindo orientação quanto à técnica de escovação e uso de fio dental. Durante o período de acompanhamento, também será oferecido suporte odontológico aos pacientes envolvidos no estudo.

1.5.4 Treinamento dos operadores

Seis candidatos a operadores (alunos da FOUFPEL) participarão de um processo de treinamento para assegurar a padronização dos procedimentos clínicos e minimizar as variações inerentes a diferentes operadores.

Primeira etapa: Será ministrada uma aula teórica, com duração de aproximadamente 2 horas, consistindo na apresentação dos materiais e técnicas disponíveis para controle de umidade no campo operatório, bem como restauração de lesões cervicais não cariosas. Também será realizada exposição detalhada da rotina a ser instituída durante os atendimentos clínicos. Um manual, contendo as instruções de uso dos materiais e o protocolo dos procedimentos, será disponibilizado aos alunos.

Segunda etapa: Os alunos passarão por atividades pré-clínicas, assistindo à demonstração dos procedimentos operatórios e, posteriormente, realizando restaurações Classe V em manequins. Num segundo momento, eles realizarão os mesmos procedimentos em voluntários que, embora apresentem LCNCs com necessidade restauradora, não serão incluídos neste estudo. Tais pacientes receberão tratamento sob condições idênticas aos pacientes envolvidos no estudo, porém não farão parte da amostra.

Ao final das etapas de treinamento, as funções da equipe de trabalho serão delegadas, utilizando o desempenho individual dos alunos como critério de seleção. Serão escolhidos dois operadores, que efetuarão os procedimentos operatórios, e dois auxiliares para apoio dos operadores e preenchimento dos prontuários. Os demais alunos ficarão encarregados da esterilização dos instrumentais, agendamento das consultas, registro fotográfico, orientação de higiene bucal, tratamento periodontal, dentre outros procedimentos odontológicos oferecidos aos pacientes. Todas as etapas acima mencionadas serão realizadas sob supervisão direta dos responsáveis pelo estudo.

1.5.5 Protocolo clínico

Inicialmente, a profilaxia do elemento a ser restaurado será feita com taça de borracha e pasta a base de pedra-pomes e água. Em seguida, a cor da restauração será selecionada com auxílio de uma escala de cores (Vitapan Classical, Vita Zahnfabrik, Bad Sackingen, Alemanha). As LCNCs serão randomizadas em dois grupos de acordo com o método de isolamento a ser efetuado. O processo de randomização foi realizado por um membro da equipe não envolvido diretamente nos procedimentos operatórios, nem na avaliação clínica das restaurações. Enfatiza-se, ainda, que cada operador realizará o mesmo número de intervenções.

O isolamento relativo do campo operatório será realizado através do uso de afastador labial, fio retrator #000 (Pro Retract, FGM, Joinville, SC, Brasil), roletes de algodão e sugador de saliva. O primeiro elemento a ser introduzido na cavidade bucal será o afastador labial, imprimindo afastamento de lábios e bochechas. Os rolos de algodão serão posicionados no sulco vestibular superior, no sulco vestibular inferior e na região sublingual, a fim de absorver o fluxo salivar proveniente, principalmente, das glândulas salivares maiores. O fio retrator será inserido no interior do sulco gengival com auxílio de espátula romba, sem gerar pressão excessiva no periodonto. O isolamento absoluto do campo operatório consistirá na utilização de lençol de borracha, arco de Young, grampo #212 (SS White-Duflex, Rio de Janeiro, RJ, Brasil) e sugador de saliva. Uma pinça porta-grampo será utilizada para distender e levar o grampo até a posição desejada, enquanto um perfurador será empregado para realização de orifícios no lençol de borracha. Godiva de baixa fusão e amarrias com fio dental serão utilizadas como dispositivos auxiliares para estabilização do grampo e do lençol de borracha, respectivamente. Com a mesma finalidade, outros modelos de grampos poderão ser posicionados na região mais distal da arcada.

Previamente à execução da restauração, não será realizado nenhum tipo de preparo cavitário, nem biselamento das margens da cavidade. Ambos os procedimentos restauradores serão realizados com sistema adesivo convencional (Adper Scotchbond Multi-Uso, 3M ESPE, St. Paul, MN, USA) e compósito restaurador nanoparticulado (Filtek Z350, 3M ESPE, St. Paul, MN, USA), seguindo rigorosamente as instruções de uso fornecidas pelo fabricante (Tabela 3). As restaurações serão confeccionadas pela técnica incremental, utilizando aproximadamente 2 ou 3 incrementos de compósito restaurador, conforme o tamanho das LCNCs. Os incrementos serão levados e adaptados à cavidade com

espátulas, pinceis e pontas siliconadas para resina composta. Um aparelho LED (Radii-Call, SDI, Bayswater, VI, Australia) será utilizado para fotoativação.

Finalmente, o acabamento das restaurações será realizado através da utilização de pontas diamantadas de granulação fina e brocas multilaminadas, a fim de remover excessos de material e/ou aperfeiçoar a forma de contorno das restaurações. O polimento das mesmas será realizado com emprego de pontas siliconadas, discos flexíveis de lixa (Sof-Lex Pop-On, 3M ESPE, St. Paul, MN, USA), discos de feltro e pastas específicas para polimento.

Tabela 3. Descrição dos materiais utilizados neste estudo.

Nome	**Fabricante**	**Categoria**	**Instruções de uso**
Adper Scotchbond Multi-Uso	3M ESPE	Sistema adesivo convencional	1. Aplique o ácido fosfórico em esmalte e dentina por 15 s. 2. Enxágue a superfície condicionada por 15 s. 3. Aplique ar por 5 s. 4. Aplique o *primer* às superfícies condicionadas de dentina. 5. Seque levemente por 5 s. 6. Aplique o adesivo às superfícies de esmalte e dentina.
Filtek Z350	3M ESPE	Resina composta fotopolimerizável	1. Aplique incrementos de, no máximo, 2 mm de espessura. 2. Fotopolimerize cada incremento por, no mínimo, 20 s.

1.5.6 Avaliação das restaurações e análise estatística

Dois examinadores (professores da FOUFPEL, possuindo título de mestrado e doutorado em Odontologia) passarão por um processo de treinamento e calibração até que apresentem índice de concordância de, no mínimo, 80%. Caso ocorra divergência quanto aos critérios de avaliação, os mesmos terão que entrar num consenso através da reavaliação direta das restaurações e/ou por meio das fotografias digitais. O registro fotográfico será feito antes da confecção da restauração, bem como em cada período de avaliação das restaurações.

Após a etapa de treinamento e calibração, os avaliadores cegos, ou seja, sem envolvimento algum com as condições clínicas as quais os pacientes foram submetidos, procederão, independentemente, às avaliações das restaurações. Neste momento, os avaliadores deverão utilizar espelho intrabucal, sonda exploradora, sonda periodontal milimetrada, pinça clínica, rolos de algodão e sugador de saliva. Dados referentes à sensibilidade dentária e vitalidade pulpar também serão coletados através da aplicação de jato de ar e *spray* refrigerante, respectivamente.

As avaliações serão realizadas em 1 semana (baseline) e 6 meses após a inserção das restaurações, considerando os critérios clínicos aprovados pela *FDI World Dental Federation* (HICKEL et al., 2007).

Os dados serão submetidos à análise estatística, considerando poder de 80% e nível de significância de 5%.

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2 Relatório do trabalho de campo

Após qualificação deste projeto de pesquisa sob portaria nº 13 de 1º de abril de 2010, as seguintes modificações foram realizadas:

- Em vez de um sistema adesivo convencional de três passos (Adper Scotchbond Multi-Uso, 3M ESPE, St. Paul, MN, USA), utilizou-se um adesivo autocondicionante de passo único (Adper Easy One, 3M ESPE, Seefeld, Germany). Esta alteração foi estimulada pela ausência de estudos clínicos avaliando o desempenho desse material. As instruções de uso fornecidas pelo fabricante foram seguidas durante sua aplicação.
- Em 2010, os critérios clínicos utilizados para avaliações de restaurações (HICKEL et al., 2007) sofreram modificações significativas. Por esse motivo, optou-se em utilizar a versão mais atualizada (HICKEL et al., 2010) para avaliação das restaurações deste estudo.
- Ademais, verificou-se a necessidade de utilizar parâmetros periodontais para avaliação dos efeitos do tipo de isolamento na condição periodontal.
- Inicialmente, o tamanho amostral foi baseado num ensaio clínico com tempo de acompanhamento de 6 meses (LOGUÉRCIO et al., 2006). Em posse dos resultados preliminares do presente estudo, o tamanho amostral foi recalculado observando-se a diferença entre os grupos com relação ao desfecho principal (perda da restauração), poder de 80% e nível de significância de 5%. Considerando as 136 restaurações realizadas em 30 pacientes, estima-se que diferenças estatisticamente significantes, a favor do grupo isolado com dique de borracha, serão observadas após 4 anos de acompanhamento.
- Embora resultados preliminares sejam utilizados para defesa desta tese, as avaliações clínicas permanecerão ocorrendo semestralmente ou enquanto houver pacientes dispostos a retornar às consultas de reavaliação.

3 Artigo 1

Title page

Title: Six-month evaluation of noncarious cervical restorations placed under two isolation methods: a randomized controlled clinical trial

Short title: Effects of two methods to isolate the operative field

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Abstract

Objective: This randomized controlled clinical trial evaluated the effects of two methods of isolating the operative field on the 6-month performances of cervical restorations. Methods: Thirty patients with at least two noncarious cervical lesions (NCLs) were enrolled in the study. A total of 136 NCLs were randomized into the following groups: (1) isolation performed with rubber dam and gingival retraction clamp, and (2) isolation provided with cotton rolls and gingival retraction cord. Both methods were used with a saliva suction device. An all-in-one self-etching adhesive (Adper Easy One, 3M ESPE) and a nanofilled composite resin (Filtek Z350, 3M ESPE) were used for both groups. The restorations were blindly assessed one week (baseline) and six months after placement, using the FDI criteria. Clinical performance was recorded in terms of material fracture and restoration retention, marginal adaptation, marginal staining, postoperative hypersensitivity and preservation of tooth vitality. Results: The recall rate at 6 months was 100%. Four restorations were lost over this period, resulting in an overall failure rate of 2.9%. Marginal defects increased in the cotton roll group ($p = 0.01$). However, no significant differences were detected among groups regarding any of the other evaluated criteria ($p > 0.05$). Significant decrease in sensitivity was observed between the pre and postoperative measurements ($p < 0.001$). Significance: Both isolation methods provided acceptable clinical performance of noncarious cervical restorations. After 6 months of clinical service, the overall restorations meet the ADA criteria for provisional acceptance, regardless of the type of isolation used for restorations' placement.

Keywords: adhesives; composite resins; controlled clinical trial; dental restoration; noncarious cervical lesions; rubber dam, self-etch.

1 Introduction

Self-etch adhesives (SEA) use non-rinse acidic monomers that demineralise and infiltrate the dental substrate simultaneously to the same depth [1]. Despite current trends towards adhesives with simplified application procedures, an inefficient clinical performance has been noted for the most tested one-step SEAs [2]. Fortunately, the latest generation of the single-bottle or all-in-one adhesives definitely seems to perform better. Nevertheless, the outcomes of bonded restorations not only depend on the adhesive category per se but also on operative aspects, such as the method used to isolate the operative field from the rest of the oral cavity [3]. It is generally accepted that adhesive restorations must be placed under well-controlled moisture conditions [4], which suggests that the rubber dam is the ideal method to accomplish this in routine restorative dentistry. Although a meta-analysis revealed no influence of the isolation type on the clinical performance of cervical restorations [5], few studies have addressed this important aspect. Furthermore, no randomized clinical trial (RCT) has been designed specifically to evaluate the role of isolation method on the longevity of restorations bonded with the newest generation of simplified SEAs.

Thus, the aim of this randomized controlled trial was to evaluate the effects of two isolation methods of the operative field on the clinical performance of noncarious cervical restorations. This study also provided information about the short-term clinical effectiveness of a new all-in-one self-etch adhesive to restore noncarious cervical lesions (NCL). The null hypothesis to be tested is that no significant differences among clinical performance of restorations placed under different isolation methods will be detected after a 6-month follow-up.

2 Materials and Methods

2.1 Study design and ethics considerations

This study was designed as a split-mouth, single-blind (clinical evaluators blinded), prospective and randomized controlled clinical trial. NCLs were randomly assigned by two different treatment groups, according to the method used to isolate the operative field. The sample size was based on information from a previous 6-month clinical trial, which placed a total of 116 restorations in 29 patients [6]. The protocol and the consent form for this study were approved by the local ethics committee on investigations involving human subjects (# 093/2009). Before beginning the experiment, the participants signed a written informed consent agreement to participate in the trial.

2.2 Patient and lesion selection

Recruitment of subjects was performed at the clinics of School of Dentistry (Federal University of Pelotas, Pelotas, RS, Brazil) through advertisements, considering patients who needed dental treatment of NCLs. Reasons for treatment were cervical tooth sensitivity, aesthetic complaints and/or prevention of tooth further damage.

The eligibility criteria for volunteers were being at least 18 years old and presenting more than one cervical lesion whose apical limit wasn't located below the gingival margin, with at least 1 mm of depth in a vital permanent incisor, canine, or premolar of the upper or the lower jaw. Typically, these defects were situated at the facial surface of the teeth, sometimes with a small part extending interproximally.

They were not admitted when any of the following criteria were presented: (1) smoking habits; (2) severe systemic diseases; (3) active orthodontic treatment; (4) malocclusion (Angle Class II or Class III); (5) less than 20 natural teeth in mouth; (6) absent

of antagonist tooth; (7) wear facets over more than 50% of the incisal/occlusion surface as a result of tooth attrition; (8) caries or restorations in the area to be treated; (9) full-mouth visible plaque index (VPI) or full-mouth gingival bleeding index (GBI) more than 20% [7]; (10) probing depth (PD) and clinical attachment level (CAL) values equal or greater than 4 mm with bleeding on probing (BOP); and (11) unwillingness to return for follow-ups or (12) refuse to participate.

The screening of lesions was performed using a mouth mirror, an explorer, and a periodontal probe (University of North Carolina, Hu-Friedy, Chicago, IL, USA). The NCLs depths were measured by placing a probe into their deepest part, and their heights were calculated by the distance of the most coronal and apical points of the cavity margins. The degrees of dentin sclerosis were identified using a scale ranked from 1 to 4 [8]. Sensitivity was measured by blowing a stream of compressed air for 3 s at a distance of 2 to 3 cm, while shielding the adjacent teeth with fingers. Tooth vitality was tested by the application of an ice stick on the tooth and comparing the reaction with that of the adjacent teeth. No attempt was made to determine the aetiology of the cervical lesions.

Four weeks before the study began, the patients underwent a session of dental scaling and polishing by a single operator using periodontal manual curettes (Gracey and McCall, Trinity, São Paulo, SP, Brazil). They also received detailed oral hygiene instructions, including a non-traumatic brushing technique (coronally directed roll technique) with a soft toothbrush [9], and the use of the dental floss.

2.3 Random assignment

A preset random table was used to generate the random allocation sequence of the treatment groups among participants. While the first randomly selected treatment was used for the lowest quadrant number, the second treatment was used for the tooth with the second-lowest quadrant number (according to the FDI system). This method was repeated for every

other quadrant that required a cervical restoration. In instances of an uneven number of NCLs per patient, the unequal number of lesions of one group was adjusted by restoring one more lesion in the other group in the next patient presenting with an unequal number of cervical lesions. Opaque, sealed envelopes were employed to conceal the sequence until interventions were assigned.

2.4 Interventions

The operative procedures were performed by two trained, skilled operators familiar with adhesive restorative dentistry, under the supervision of an experienced clinician. They received thorough pre-clinical training in the field isolation and adhesive procedures. Each operator placed an equal number of restorations for each group.

Preoperatively, the teeth to be restored were cleaned with pumice and water in a rubber prophylaxis cup. Subsequently, the colour of the restoration was determined using a shade guide (Vitapan Classical, Vita, Zahnfabrik, Bad Sackingen, Germany). No additional mechanical retention or enamel bevel was prepared.

In order to secure moisture control of the operative field, two isolation methods were standardized by a detailed protocol, which is briefly summarized below.

(1) Rubber dam group: Moisture control was provided by a rubber dam and a gingival retraction clamp placed in the cervical area of the tooth.

(2) Cotton roll group: Moisture control was provided using a labial retractor, cotton rolls and gingival retraction cord placed into the gingival sulcus.

For both groups, a saliva suction device was held in position by an assistant during the restorative procedure. If necessary, local anaesthesia was given to prevent patient discomfort prior to treatment.

An all-in-one self-etch adhesive (Adper Easy One, 3M ESPE, Seefeld, Germany) was used according to the manufacturer's instructions (Table 1). The NCLs were restored with a direct restorative nanocomposite (Filtek Z350, 3M ESPE, Irvine, CA, USA) applied in at least two increments (not exceeding 2 mm in thickness), using a selected composite instrument (Hu-Friedy, Chicago, IL, USA). Each increment was cured for 20 s with a LED light-curing unit (Radii-Call, SDI, Bayswater, VI, Australia). All restorations were finished and polished with fine- and ultra-fine-grain diamond burs (KG Sorensen, Barueri, SP, Brazil) under water cooling, slow-speed flexible discs (Sof-Lex Pop-On, 3M ESPE, St Paul, MN, USA), polishing paste (Prisma Gloss, Dentsply Caulk, Milford, DE, USA), and rubber points (Enhance, Dentsply Caulk, Milford, DE, USA).

2.5 Clinical assessment

Criteria approved by the FDI World Dental Federation were used for clinical assessment of restorations [10]. The primary clinical outcome was material fracture and restoration retention. Secondary endpoints included the following criteria: (1) marginal adaptation, (2) marginal staining, and (3) postoperative hypersensitivity and preservation of tooth vitality. Each criterion was expressed with five scores, 3 for acceptable and 2 for unacceptable (1 for reparable and 1 for replacement). Restorations that needed repairs or replacements were considered clinical failures, receiving scores of 4 or 5, respectively (Table 2).

The evaluations were carried out by two independent examiners at 1 week (baseline) and 6 months after the insertion of the restoration. They were not the operators and were fully blinded to the assignment of interventions. A Web-based training and calibration tool called e-calib (www.ecalib.info) was used to train and calibrate the evaluators. After that, they evaluated cervical restorations in clinical settings. A pre-evaluation agreement of at least 80%

was obtained among them. When disagreement in evaluation occurred between the two examiners, consensus was reached by immediate re-examination and discussion at chair side. Photo documentation was made pre-operatively, at baseline and at recall.

2.6 Statistical analysis

Data were analyzed using the statistical software program SigmaStat (Version 3.5, Systat, Richmond, CA, USA). Descriptive statistics were used to describe the frequency distributions of the evaluated criteria. For each variable, the comparison between the groups (the rubber dam group and cotton roll group) was performed with the Mann-Whitney Rank Sum test. The Wilcoxon sign-ranked test was used to compare the changes across the periods (baseline and 6 months). The significance level of 0.05 was adopted for all statistical analyses.

3 Results

3.1 Baseline data

During the recruiting period of March to December 2010, 80 subjects were assessed for eligibility. Thirty patients (eight men and 22 women) were enrolled in the study, yielding a total of 136 restorations (68 restorations per group). The age of the included patients varied from 19 to 69 years (mean age of 48.5 ± 11.3 years). The average number of restorations per patient was four. NCLs included in the study were pre-operatively categorized in terms of tooth distribution, shape and height of the lesions, degree of sclerosis, and sensitivity (Table 3). No statistically significant differences were detected among groups for any of these characteristics ($p > 0.05$). Seventy-five teeth (55.1%) were restored in the upper jaw. Most restorations (72%) were placed on pre-molars. About 60% of all the lesions were pre-operatively sensitive to air. The flow diagram indicates the number of participants through each stage of the trial (Figure 1).

3.2 Evaluation results

Table 4 summarizes the evaluation criteria at baseline and at follow-up for both groups. The overall recall rate at 6 months was 100%. One restoration from the rubber dam group and three restorations from the cotton roll group were lost at 6 months, resulting in an overall failure rate of 2.9%. With regard to marginal adaptation, the cotton roll group showed a significant increase between the baseline and the 6-month findings ($p = 0.01$). This group also presented an increase in marginal staining; however, the difference was not statistically significant ($p = 0.055$). No significant differences were detected among groups for any of the other evaluated criteria ($p > 0.05$). Considering the sensitivity to air stimulus, a significant decrease was observed between the pre- and the postoperative measurements for all restored teeth ($p= 0.001$).

4 Discussion

The most common methods to isolate the operative field include rubber dam and cotton rolls, both frequently combined with saliva suction device. The literature emphasises that resin-composite restorations cannot be placed successfully in a cavity surface that is contaminated by blood or saliva [4], especially for restorations whose cervical margin is in direct contact with the periodontal tissues (e.g., noncarious class-V lesions). Beyond moisture control, the protection of the patient from possible aspiration and ingestion of dental foreign objects is an advantage only offered by the use of the rubber dam in dental practise [11]. Meanwhile, most clinicians are not sure which isolation method to choose and also show reluctance to use the rubber dam during the operative dentistry procedures [12]. According to a 10-year clinical study, similar performances were reported for posterior restorations placed under cotton rolls and rubber dam isolation [13]. Nevertheless, it is well recognised that only studies involving cervical restorations should be considered to investigate adhesion effectiveness, for a number of reasons previously discussed in the literature [14].

While the current trends favour simpler and faster clinical application steps, a systematic review of clinical trials reported that the most common SEAs do not seem to meet the expectations regarding bonding performance [2]. However, until now no peer-reviewed clinical study has attempted to evaluate the performance of Adper Easy One Self-Etch Adhesive, especially considering the influence of the isolation method on its clinical outcome. This self-etch adhesive can be considered as the true all in one, due to the combination of all the components into one single solution that does not require additional mixing. With regard to the pH and the interaction depth of such solution at dentin, it has been also referred as an ultra-mild self-etch approach ($pH > 2.5$) [1]. Although manufacturers introduced stronger SEAs ($pH \leq 1.0$) some years ago, serious problems (i.e., the hydrolytic instability of

methacrylates and intrinsic acid-based reaction of components) have apparently pushed them to an ultra-mild self-etch approach [15].

Despite the limitations of a 6-month follow-up period, the present findings clearly showed favourable results for the above-mentioned simplified adhesive regardless the method used to isolate the operative field. At 6 months, only four restorations were scored as clinically unacceptable (2.9% failure rate) due to the debonding of one restoration of the rubber dam group and three restorations of the cotton roll group. Taking the American Dental Association's guidelines as reference, resin-based enamel-dentin adhesives gain 'provisional acceptance' at 6 months if their retention loss in NCLs is less than 5% without mechanical retention features [16]. In addition to the loss of restoration, another criterion that could constitute an early failure at 6 months is severe postoperative hypersensitivity [17]. However, both groups performed equally well without reporting abnormal postoperative hypersensitivity after restoration. Yet, the frequency of tooth sensitivity to air stimulus was reduced from 60% to approximately 11% at 1 week and 5% at 6 months. In part, this favourable clinical benefit can be attributed to the less aggressive and more superficial interaction of an ultra-mild adhesive with dentin [1].

Taking into account that the sealing capacity of restorations has often been assessed by the integrity and colour changes along part or all of the margins [17], clinical signs of the degradation of bonded interfaces were observed in restorations placed under the cotton roll method. This group exhibited increased small marginal defects (especially at enamel margins) and a slightly marginal staining at follow-up compared to the baseline evaluation. However, findings were considered clinically acceptable, which suggests that the isolation method may have played an important role in the early deterioration of marginal integrity. Additionally, these minor shortcomings could be attributed to the superficial etching pattern of an ultra-mild self-etch adhesive. A similar phenomenon of increased marginal defects and superficial

discoloration was also observed in a long-term clinical trial evaluating a mild two-step self-etch adhesive [18]. That is why the literature so far indicates selective phosphoric-acid etching of the enamel cavity margins, followed by applying an ultra-mild SEA. The purpose of this combined approach is to provide a better self-etch interaction at enamel with favourable perspectives at dentin [1].

Furthermore, maybe the main challenge for dental adhesives is to provide an equally effective bond to hard tissues of a different nature. Noncarious class-V lesions exhibit margins located in enamel, as well as in dentin, high degrees of sclerosis, heterogeneous hyper-mineralized layer, and denatured collagen, seem to make difficult the bonding in such clinically relevant substrates [19–21]. Nevertheless, lesions were not excluded from the screening based on the proportion of margin involving enamel and dentin, nor on the degree of dentin sclerosis. On the other hand, the authors recognize that some specific habits of patients, such as poor oral hygiene, smoking, or bruxism, may influence the clinical outcomes [17]. For this reason, patients presenting severe wear facets were excluded from the present study. It was assumed that wear facets indicate a higher concentration of occlusal loads on the area, contributing to a higher debonding rate for restorations. Then again, this exclusion criterion prevents us from extrapolating our results to patients with parafunctional disorders.

With regard to the sample size, it was initially based on information from a previous 6-month clinical study [6], although the sample size was recalculated at the 6-months follow-up, taking into account the difference between groups with regard to our primary outcome (the restoration retention). Thus, it is expected that a significant difference in retention rates favouring the isolation method with a rubber dam will be detected over a period of 4 years, considering a power of 0.80 and a type I error of 0.05.

Based on the results of the present investigation, the null hypothesis was accepted, since no significant differences were detected among clinical performances of restorations

placed under different methods of isolation after a period of 6 months. However, the present findings must be interpreted with caution, considering the short-term follow-up.

5 Conclusion

Within the period of 6 months, noncarious cervical restorations placed with both isolation methods were equally successful. Isolation with cotton rolls had only some negative effects on secondary clinical criteria, such as a progressive incidence of small marginal defects. However, further long-term follow-up is needed to confirm the early effectiveness of this all-in-one SEA with regard to the method used to isolate the operative field.

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Tables and figures

Table 1. Composition and application mode of the adhesive system used.

Product	Manufacturer	Composition	Application procedure
Adper Easy One Self-Etch Adhesive lot: #384060, pH ≈ 2.7	3M ESPE AG, Seefeld, Germany	Bis-GMA, HEMA, methacrylated phosphoric esters, 1,6-hexanediol dimethacrylate, methacrylate functionalized polyalkenoic acid, water, ethanol, silica filler, initiators based on CQ and stabilizers.	1. Apply the adhesive with the disposable applicator for 20 s to all surfaces of cavity. 2. Rewet the disposable applicator as needed during application. 3. Then, air thin the liquid for approximately 5 s until the film no longer moves, indicating complete vaporization of the solvent. 4. Light cure the adhesive for 10 s.

Abbreviations: Bis-GMA, bisphenol A diglycidyl methacrylate; CQ, camphorquinone; HEMA, 2-hydroxyethyl methacrylate.

Table 2. FDI criteria and scores used for evaluation of restorations.

Score	1. Material fracture and retention	2. Marginal adaptation	3. Marginal staining	4. Postoperative hyper-sensitivity and tooth vitality
1. Clinical excellent / very good	1.1 No fractures/ cracks.	2.1 Harmonious outline, no gaps, no white or discolored lines.	3.1 No marginal staining.	4.1 No hypersensitivity, normal vitality.
2. Clinically good (polishing necessary)	1.2 Small hairline crack.	2.2.1 Marginal gap (< 150 µm), white lines. 2.2.2 Small marginal fracture. 2.2.3 Slight ditching, slight step/ flashes, minor irregularities.	3.2 Minor marginal staining, easily removable by polishing.	4.2 Minor hypersensitivity for a limited period of time, normal vitality.
3. Clinically sufficient / satisfactory	1.3 Two or more or larger hairline cracks and/ or material chip fracture not affecting the marginal integrity.	2.3.1 Gap < 250 µm not removable. 2.3.2 Several small marginal fractures. 2.3.3 Major irregularities, ditching or flash, steps.	3.3 Moderate marginal staining, not aesthetically unacceptable.	4.3.1 Moderate hypersensitivity. 4.3.2 Delayed/ mild sensitivity. No subjective complaints, no treatment needed.

4.	**Clinically unsatisfactory (repair necessary)**	1.4.1 Material chip fractures which damage marginal quality. 1.4.2 Bulk fractures with partial loss (less than half of the restoration).	2.4.1. Gap > 250 µm or dentin/ base exposed. 2.4.2 Severe ditching or marginal fractures. 2.4.3 Larger irregularities or steps (repair necessary).	3.4 Pronounced marginal staining. Major intervention necessary for improvement.	4.4.1 Intense hypersensitivity. 4.4.2 Delayed with minor subjective symptoms. 4.3.3 No clinical detectable sensitivity. Intervention necessary, but not replacement.
5.	**Clinically poor (replacement necessary)**	1.5 (Partial or complete) loss of restoration or multiple fractures.	2.5.1 Restoration (complete or partial) is loose but in situ. 2.5.2 Generalized major gaps or irregularities.	3.5 Deep marginal staining, not accessible for intervention.	4.5 Intense, acute pulpitis or nonvital tooth. Endodontic treatment is necessary and restoration has to be replaced.

Table 3. Data regarding the 136 NCLs included in the study.

Characteristics		**Rubber dam group**	**Cotton roll group**	**Total (%)**
Tooth distribution	Upper incisor	02	04	06 (4.4)
	Upper canine	11	11	22 (16.1)
	Upper premolar	25	22	47 (34.6)
	Lower incisor	02	03	05 (3.7)
	Lower canine	02	03	05 (3.7)
	Lower premolar	26	25	51 (37.5)
Shape of the lesion	Sharply defined, wedge-shaped	26	29	55 (40.4)
	Rounded, saucer-shaped	42	39	81 (59.6)
Height of the lesion	<1.5 mm	22	21	43 (31.6)
	1.5 - 2.5 mm	26	24	50 (36.8)
	> 2.5 mm	20	23	43 (31.6)
Degree of sclerosis	No sclerosis evident	46	42	88 (64.7)
	Slightly	17	20	37 (27.2)
	Moderately	02	04	06 (4.4)
	Severe	03	02	05 (3.7)
Pre-operative sensitivity	No	26	30	56 (41.2)
	Yes	42	38	80 (58.8)

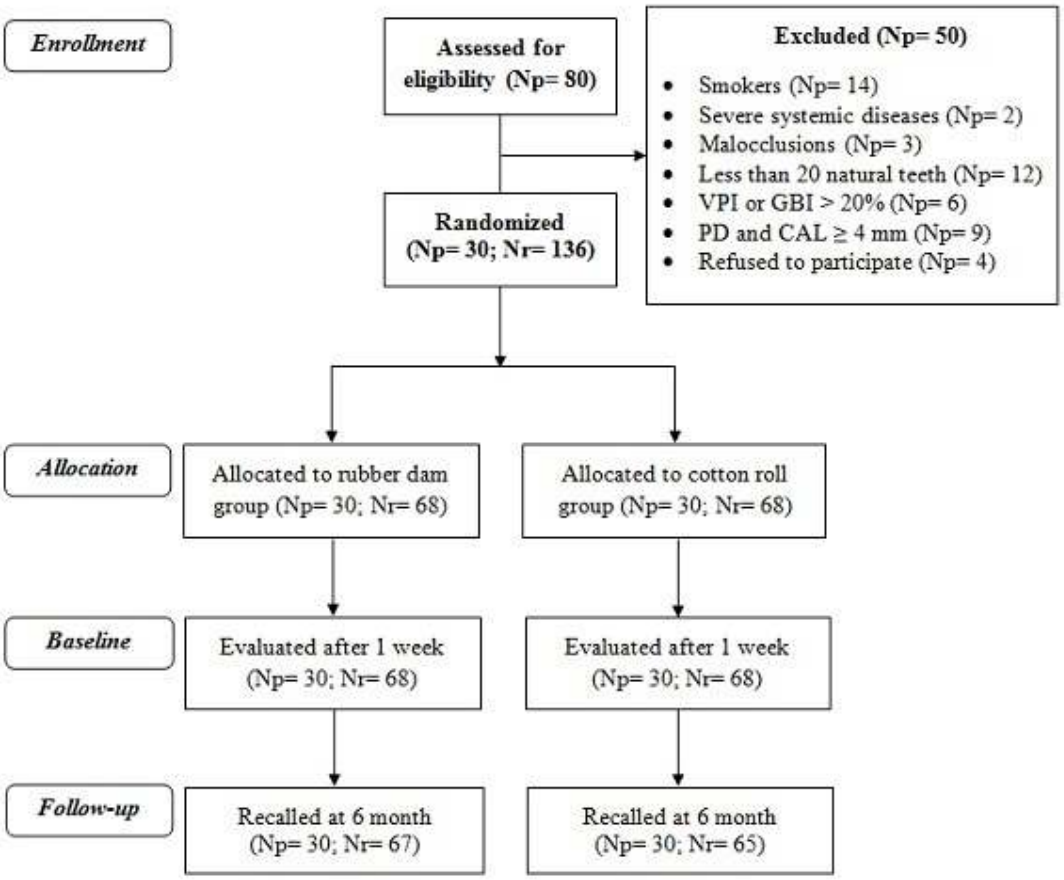
Abbreviations: NCLs, noncarious cervical lesions.

Table 4. Number (%) of evaluated restoration by criterion.

Criteria	Score	Baseline		6 months	
		Rubber dam group (n= 68)	Cotton roll group (n= 68)	Rubber dam group (n= 67)	Cotton roll group (n= 65)
Material fracture and retention	**1**	68 (100)	68 (100)	67 (98.5)	65 (95.6)
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0
	5	0	0	01 (1.5)	03 (4.4)
Marginal adaptation	**1**	57 (83.8)	62 (91.2)	52 (77.6)	48 (73.9)
	2	11 (16.2)	06 (8.8)	15 (22.4)	17 (26.1)
	3	0	0	0	0
	4	0	0	0	0
	5	0	0	0	0
Marginal staining	**1**	66 (97.1)	65 (95.6)	62 (92.5)	57 (87.7)
	2	02 (2.9)	03 (4.4)	04 (6.0)	06 (9.2)
	3	0	0	01 (1.5)	02 (3.1)
	4	0	0	0	0
	5	0	0	0	0
Postoperative hyper-sensitivity and tooth vitality	**1**	57 (83.8)	63 (92.6)	59 (88.0)	60 (92.3)
	2	11 (16.2)	04 (5.9)	04 (6.0)	03 (4.6)
	3	0	01 (1.5)	04 (6.0)	02 (3.1)
	4	0	0	0	0
	5	0	0	0	0

Scores: 1. Clinical excellent / very good; 2. Clinically good; 3. Clinically sufficient / satisfactory; 4. Clinically unsatisfactory; 5. Clinically poor. Regarding the variables ´marginal adaptation`, ´marginal staining` and ´postoperative hyper-sensitivity and tooth vitality` only retained restorations were considered.

Figure 1. Flowchart of the study participants.



Abbreviations: CAL, clinical attachment level; GBI, gingival bleeding index; Np, number of patients; Nr, number of restorations; PD, probing depth; VPI, visible plaque index.

4 Artigo 2

Title page

Effect of two gingival retraction techniques on periodontal health: a 6-month randomized controlled clinical trial

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Abstract

Background. During placement of cervical restorations, different isolation techniques of the operative field can be used to promote retraction of gingival tissues and moisture control of cavity margins. Objective. This 6-month randomized controlled clinical trial evaluated the effects of two gingival retraction techniques on the periodontal condition. Methods: Noncarious cervical lesions (NCLs) were assigned randomly to receive resin composite restorations under the following methods: (1) isolation performed with gingival retraction clamp and rubber dam, and (2) isolation provided with gingival retraction cord and cotton rolls. The periodontal condition of restored sites was record in terms of supragingival visible plaque (PL), gingival marginal bleeding (BL), probing depth (PD), and relative gingival recession (RGR) assessed as the distance from the apical gingival margin to the incisal border of the tooth. These periodontal parameters were blindly evaluated at baseline (immediately before the restorative procedures), 1-week and 6-months postoperatively. Intergroup and intragroup statistics were determined by the Mann-Whitney Rank Sum test and the Kruskal-Wallis one-way analysis of variance (ANOVA), respectively. The correlation analyses between the restorative criteria (marginal staining and marginal adaptation of restorations) and the periodontal parameters were performed with Spearman Ranks. The significance level of 0.05 was adopted for all statistical analyses. Results. Thirty patients were enrolled in this study, yielding a total of 136 NCLs (68 sites per group). No significant differences were found among the two groups tested with respect to any of the parameters evaluated ($P > 0.05$). However, both groups showed a significant increase in PL between the baseline and the 6-month findings ($P < 0.05$). Additionally, the marginal staining of restorations was positively correlated with RGR of restored sites ($P < 0.026$). Conclusion. Over a 6-month evaluation, both gingival retraction approaches provided similar periodontal results. Key Words. Controlled clinical trial; dental restoration; gingival retraction; periodontal health.

Introduction

Noncarious cervical lesions (NCLs) classically refer to the loss of tooth substance at the cement-enamel junction by a process unrelated to dental caries. Despite disagreement remains about the clinical management of NCLs, cervical restorations are one of the options considered in their treatment.[1] Because such lesions are more common on facial surfaces of incisors, canines and premolars, it generally provides good access for restorative procedures.[2] Meanwhile, dental fillings can not be placed successfully in cavities contaminated by blood, saliva or sulcus fluid.[3] This is especially true for Class V restorations that usually are rather close to the periodontal tissues.[4] Thus, the success of cervical restorations requires both an effective moisture control and an adequate gingival retraction technique.

For many years, the periodontal-restorative interaction has been truly investigated.[5,6] Periodontal literature recognizes that cervical defects can be successfully treated by different restorative materials, without produce clinically detectable damage to the adjacent gingival tissues.[7] However, data concerning outcomes of the operative field isolation methods in periodontium is lack. Therefore, the objective of this prospective randomized clinical trial (RCT) was to evaluate the effects of two gingival retraction techniques used during the operative field isolation on the periodontal conditions within the period of 6 months. Additionally, this study also aimed to evaluate the short-term clinical features occurring on the periodontium after placement of resin composite restorations. The null hypothesis to be tested is that both gingival retraction approaches will perform no significant influence on the periodontal clinic parameters in any of the periods of evaluation.

Subjects, materials and methods

Enrollment and sampling.

This study was designed as a split-mouth, single-blind (clinical evaluators blinded), prospective and randomized controlled clinical trial. The sample size was based on information from a previous 6-month clinical trial, which placed a total of 116 restorations in 29 patients.[8] The protocol and the consent form for this study were approved by the local ethics committee on investigations involving human subjects (# 093/2009). Patients were recruited from the clinics of School of Dentistry (Federal University of Pelotas, Pelotas, RS, Brazil) between March and December 2010. Before beginning the experiment, the participants signed a written informed consent agreement to participate in the trial.

As inclusion criteria, volunteers were being at least 18 years old and presenting more than one cervical lesion whose apical limit wasn't located below the gingival margin, with at least 1 mm of depth in a vital permanent incisor, canine, or premolar of the upper or the lower jaw. Typically, these defects were situated at the facial surface of the teeth, sometimes with a small part extending interproximally. They were not admitted when any of the following criteria were presented: (1) smoking habits; (2) severe systemic diseases; (3) active orthodontic treatment; (4) malocclusion (Angle Class II or Class III); (5) less than 20 natural teeth in mouth; (6) absent of antagonist tooth; (7) wear facets over more than 50% of the incisal/occlusion surface as a result of tooth attrition; (8) caries or restorations in the area to be treated; (9) full-mouth visible plaque index (VPI) or full-mouth gingival bleeding index (GBI) more than 20%;[9] (10) probing depth (PD) and clinical attachment level (CAL) values equal or greater than 4 mm with bleeding on probing (BOP); and (11) unwillingness to return for follow-ups or (12) refuse to participate.

Four weeks before the study began, the patients underwent a session of dental scaling and polishing by a single operator using periodontal manual curettes (Gracey and McCall,

Trinity, São Paulo, SP, Brazil). They also received detailed oral hygiene instructions, including a non-traumatic brushing technique (coronally directed roll technique) with a soft toothbrush,[10] and the use of the dental floss. After this initial therapy, patients were subjected to a full-mouth clinical examination performed in six sites per tooth (excluding third molars) using a mouth mirror, an explorer and a periodontal probe (University of North Carolina, Hu-Friedy, Chicago, IL, USA). Full-mouth VPI and full-mouth GBI were recorded as the % of tooth surfaces with the presence of visible plaque and gingival bleeding. PD was measured, in millimeters, as the distance from the gingival margin to the apical end of the gingival sulcus; while CAL was calculated, in millimeters, as the distance between the cemento-enamel junction and the end of the gingival sulcus. BOP was considered when bleeding occurred within 15 s after gentle probing.

Restorative procedures.

NCLs were assigned randomly to receive resin composite restorations under the following methods:

(1) Retraction clamp group: Isolation performed with gingival retraction clamp (SS White-Duflex, Rio de Janeiro, RJ, Brazil) placed in the cervical area of the tooth, and rubber dam for moisture control.

(2) Retraction cord group: Isolation provided with gingival retraction cord (Pro Retract, FGM, Joinville, SC, Brazil) placed into the gingival sulcus, and cotton rolls for moisture control.

For both groups, a saliva suction device was held in position by an assistant during the restorative procedure. If necessary, local anaesthesia was given to prevent patient discomfort prior to treatment. An all-in-one self-etch adhesive (Adper Easy One, 3M ESPE, Seefeld, Germany) and a direct restorative nanocomposite (Filtek Z350, 3M ESPE, Irvine, CA, USA)

were used for restorations. Each increment was cured for 20 s with a LED light-curing unit (Radii-Call, SDI, Bayswater, VI, Australia). All restorations were finished and polished with fine- and ultra-fine-grain diamond burs (KG Sorensen, Barueri, SP, Brazil) under water cooling, slow-speed flexible discs (Sof-Lex Pop-On, 3M ESPE, St Paul, MN, USA), polishing paste (Prisma Gloss, Dentsply Caulk, Milford, DE, USA), and rubber points (Enhance, Dentsply Caulk, Milford, DE, USA).

Periodontal assessments and statistical analyses.

All patients were subjected to an intra-oral clinical examination by a single trained calibrated examiner (κ= 0.72, data not shown), who was blinded to the restorative procedures. The following periodontal clinical parameters were recorded on the mid-buccal surface of sites included in the study: (1) presence or absence of supragingival visible plaque (PL); (2) presence or absence of gingival marginal bleeding (BL); (3) PD assessed as mentioned before; and (4) relative gingival recession (RGR) measured, in millimeters, as the distance from the apical gingival margin to the incisal border of the tooth. Assessments were carried out at baseline (immediately before the restorative procedures), 1-week and 6-months postoperatively. Criteria approved by the FDI World Dental Federation were used for clinical assessment of restorations.[11]

Data were analyzed using the statistical software program SigmaStat (Version 3.5, Systat, Richmond, CA, USA). For each clinical parameter, the comparison between the groups (retraction clamp group and retraction cord group) was performed with the Mann-Whitney Rank Sum test. The Kruskal-Wallis one-way analysis of variance (ANOVA) was used to compare the changes across the periods (baseline, 1-week and 6 months). The correlations were calculated by the coefficient of Spearman's correlation between restorative criteria (marginal staining and marginal adaptation) and periodontal parameters, considering

data from the two groups together. The significance level of 0.05 was adopted for all statistical analyses.

Results

Thirty patients (8 men and 22 women) were enrolled in the present study. The age of the included patients varied from 19 to 69 years (mean age of 48.5 ± 11.3 years). In total 136 NCLs were selected to be restored, yielding 68 sites randomly assigned in each group. Seventy-five NCLs were located in the upper jaw (6 incisors, 22 canines and 47 premolars); while 61 NCLs were located in the lower jaw (5 incisors, 5 canines and 51 premolars). Table 1 summarizes the full-mouth VPI, GBI, PD and CAL means of subjects participating of this study.

Table 2 shows the frequency of supragingival visible plaque (PL) and gingival marginal bleeding (BL) on the mid-buccal surface of sites included in the study over the time. For these parameters, no statistically significant differences were detected among the groups at any time point ($P > 0.05$). However, a significant increase in PL was observed at 6-months for the retraction clamp group ($P = 0.044$) and the retraction cord group ($P = 0.017$).

Table 3 reports the means (± SD) for probing depth (PD) and relative gingival recession (RGR) on the mid-buccal surface of sites included in the study over the time. No significant differences were found among the groups neither at any time point, nor within the groups over the time ($P > 0.05$).

The correlations between restorative criteria and periodontal parameters are presented in Table 4. At 6-months, the marginal staining of overall restorations was positively correlated with RGR of restored sites ($P < 0.026$).

Discussion

Considering there has been an increasing demand for aesthetic restorations in recent years, the isolation method of the operative field has become of paramount importance in restorative procedures, especially those involves adhesive approaches.[3] Several clinical trials have focused their attention on the effectiveness of adhesive restorations;[12] whereas research regarding the periodontal response to operative dentistry procedures is still scarce. Bennani and colleagues[13] described a variety of gingival retraction techniques used for making impressions in fixed prosthodontics. However, little has been published about their use during the operative field isolation.[4]

Despite the present investigation showed no significant differences among the two gingival retraction methods; the null hypothesis was rejected since both groups allowed an increase in plaque accumulation at 6 months. Therefore, non signs of gingival inflammation were demonstrated by the absence of gingival bleeding in the buccal aspect of restored sites. A reasonable explanation for these findings might be related to the high standard of oral hygiene obtaining by the enrolled participants. Potentially limiting, the present study did not include a measure of the full-month VPI and GBI at follow-ups, which was less than 20% when assessed before the beginning of the study. The authors assume the most important mechanism that dental restorations may affect the periodontal health is the enhancement of plaque accumulation. In addition, investigators reported resin composite restorations seems to play a negative role in the quantity and quality of subgingival plaque as compared with others restorative materials.[7]

In terms of management of NCLs, clinical studies in periodontics have shown that lesions associated with gingival recession can be successfully treated by restoration combined with coronally positioned flap,[14,15] with or without connective tissue graft.[16] In the present

study, the authors recognize that the selection of a restorative technique as a single therapy to treat such conditions may not content the esthetic demands of the patients, which often concern for the clinical crown length of the restored teeth. In this context, aesthetic is the main reason to require the combined use of both surgical and restorative procedures.[17] Yet, because the NCLs are frequently seen affecting part of the root and crow of the tooth, the cemento-enamel junction (CEJ) might disappear with the progression of the lesion. In order to avoid confusion regarding the identification of the CEJ location, the incisal border of the tooth was used as reference point to assess the gingival margin position, namely RGR.

The major challenge of cervical restorations seems to be the apical cavity margin that is almost always very close to the periodontal tissues, requiring the use of gingival retraction methods.[4] Although literature report various iatrogenic factors can lead to a periodontal breakdown, which may be manifested clinically as gingivitis, increased probing depth or migration of the marginal tissue to an apical position;[6] the present investigation found no significant changes in PD and RGR between baseline and postoperative periods for both groups. It is important to emphasize that a 6-month RCT is a sufficient period to evaluate the effects of gingival retraction techniques on the periodontal conditions, since the gingival mechanical retractors (e.g. clamps or cords) are removed after the end of the operative procedure.

Finally, no correlation was revealed between restorative criteria and the majority of periodontal parameters recorded over the period of evaluation. This is probably due to the fact that lesions whose apical margins were located below the gingival margin were not included in this investigation, considering literature so far indicates supragingival restorative margins as the most favorable position to periodontal health.[6] However, a significant correlation was found between the marginal staining of restorations and the relative gingival recession of restored sites at 6 months. Despite that, all these marginal shortcomings were judged as

clinically acceptable without needing repair or replacement of restorations. Furthermore, it must be mentioned that the marginal staining of restorations may not be exclusively linked to the operative technique, but may also be influenced by the degradation of the dentin/enamel bonding agent system.[11] For this reason, the present results should be interpreted with caution and long-term follow-up is strongly recommended to confirm such correlation.

Conclusion

Within the limits of this clinical trial, it can be concluded that cervical restorations placed by gingival retraction clamp or gingival retraction cord during the operative field isolation provided similar periodontal conditions in a 6-month period without negatively affect the periodontal health.

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Tables

Table 1. Mean values and standard deviation for full-mouth periodontal parameters.

Periodontal parameters	Means (±SD)
VPI (%)	12.2 (± 4.8)
GBI (%)	12.6 (± 5.6)
PD (mm)	1.8 (± 0.2)
CAL (mm)	2.1 (± 0.4)

Abbreviations: CAL, clinical attachment level; GBI, gingival bleeding index; PD, probing deep; VPI, visible plaque index.

Table 2. Frequency of PL and BL on the mid-buccal surface of sites included in the study over the time.

	PL			**BL**		
	Retraction clamp group	**Retraction cord group**		**Retraction clamp group**	**Retraction cord group**	
Baseline	0	2	NS	3	5	NS
1-week	3	3	NS	7	5	NS
6-months	6	10	NS	2	6	NS
P-value	0.044*	0.017*		NS	NS	

Abbreviations: BL, gingival marginal bleeding; NS, none statistically significant differences; PL, supragingival visible plaque.

Intergroup and intragroup statistical analysis determined by Mann-Whitney and Kruskal-Wallis tests, respectively. Statistically significant differences, $\alpha = 5\%$ (*).

Table 3. Mean values and standard deviation for PD and RGR on the mid-buccal surface of sites included in the study over the time.

	PD (mm)			RGR (mm)		
	Retraction clamp group	**Retraction cord group**		**Retraction clamp group**	**Retraction cord group**	
Baseline	1.2 (± 0.4)	1.2 (± 0.4)	NS	10.6 (± 1.7)	10.9 (± 1.7)	NS
1-week	1.2 (± 0.4)	1.1 (± 0.3)	NS	10.6 (± 1.7)	10.9 (± 1.7)	NS
6-months	1.1 (± 0.4)	1.1 (± 0.4)	NS	10.7 (± 1.6)	11.0 (± 1.9)	NS
	NS	NS		NS	NS	

Abbreviations: NS, none statistically significant differences; PD, probing depth; RGR, relative gingival recession.

Intergroup and intragroup statistical analysis determined by Mann-Whitney and Kruskal-Wallis tests, respectively.

Table 4. Correlations between restorative criteria and periodontal parameters at 1-week and 6-months after the treatment.

	Marginal staining				**Marginal adaptation**			
	PL	**BL**	**PD**	**RGR**	**PL**	**BL**	**PD**	**RGR**
1-week	-0.042	0.077	0.049	0.088	-0.081	0.039	0.007	0.054
6-months	-0.040	-0.084	-0.099	0.194*	0.020	-0.070	0.059	0.116

Abbreviations: BL, gingival marginal bleeding; PD, probing depth; PL, supragingival visible plaque; RGR, relative gingival recession.

Correlation analysis performed with Spearman Ranks. Statistically significant differences, α= 5% (*).

CONCLUSÕES

Com base na metodologia empregada neste estudo, pode-se concluir que as restaurações Classe V realizadas com ambas as técnicas de isolamento do campo operatório apresentaram-se clinicamente aceitáveis após seis meses de acompanhamento. Observou-se, entretanto, uma incidência significativa de pequenos defeitos marginais no grupo que recebeu isolamento com rolos de algodão. Adicionalmente, verificou-se um aumento do acúmulo de placa supragengival em ambos os grupos, sem produzir efeitos clinicamente significativos na condição periodontal.

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ORÇAMENTO

Descrição	**Quantidade**	**Custo (unidade)**	**Custo (total)**
Afastador de lábios	3 um	R$ 18,00	R$ 54,00
Afastadores de lábios para fotografia	3 conj	R$ 20,00	R$ 60,00
Agulha longa	2 cx	R$ 24,50	R$ 49,00
Anestésico local	2 cx	R$ 20,00	R$ 40,00
Anestésico tópico	3 um	R$ 6,00	R$ 18,00
Arco de Young metálico	3 um	R$ 14,00	R$ 42,00
Arquivo para guardar fichas	2 um	R$ 20,00	R$ 40,00
Babadores descartáveis	3 cx	R$ 16,00	R$ 48,00
Barreira gengival fotopolimerizável	5 un	R$ 27,00	R$ 135,00
Cabo de bisturi	3 un	R$ 8,00	R$ 24,00
Caneta para retroprojetor com ponta fina	3 un	R$ 3,00	R$ 9,00
Caneta esferográfica	5 un	R$ 2,00	R$ 10,00
Capa protetora para seringa tríplice	1 pacote	R$ 12,00	R$ 12,00
Carpule	3 un	R$ 25,00	R$ 75,00
Casulo para resina composta	3 un	R$ 40,00	R$ 120,00
Cianoacrilato	5 un	R$ 4,00	R$ 20,00
Discos de feutro	4 cx	R$ 35,00	R$ 140,00
Discos de polimento	2 kit	R$ 215,00	R$ 430,00
Escala de cor	1 un	R$ 320,00	R$ 320,00
Escova de Robinson	40 un	R$ 1,50	R$ 60,00
Espátula para resina composta	3 un	R$ 80,00	R$ 240,00
Espelho metálico para fotografia	2 un	R$ 80,00	R$ 160,00
Espelho intrabucal (com cabo)	6 un	R$ 10,00	R$ 60,00

Folhas de papel A4 para impressão	3 pacotes	R$ 12,00	R$ 36,00
Filme PVC para proteção do equipo	5 rolos	R$ 5,00	R$ 25,00
Filtro de papel recortado	2 cx	R$ 5,00	R$ 10,00
Fio dental encerado	3 un	R$ 4,00	R$ 12,00
Fio retractor gengival #000	2 un	R$ 50,00	R$ 100,00
Fita para autoclave	3 un	R$ 4,00	R$ 12,00
Fita “veda-rosca”	1 un	R$ 3,00	R$ 3,00
Fototpolimerizador	2 un	R$ 1.500,00	R$ 3.000,00
Gaveteiro para estoque de materiais	1 un	R$ 100,00	R$ 100,00
Gaze	2 pacotes	R$ 45,00	R$ 90,00
Gesso especial tipo IV	4 un	R$ 25,00	R$ 100,00
Glutaraldeído	1 frasco	R$ 25,00	R$ 25,00
Grampos para isolamento	20 un	R$ 25,00	R$ 500,00
Godiva em bastão	3 cx	R$ 20,00	R$ 60,00
Gorros descartáveis	1 cx	R$ 15,00	R$ 30,00
Guardanapo de papel	6 pacotes	R$ 3,00	R$ 18,00
Isqueiro	3 un	R$ 4,00	R$ 12,00
Lâmina de bisturi #12	2 cx	R$ 30,00	R$ 60,00
Lamparina à álcool	1 un	R$ 20,00	R$ 20,00
Lençol de borracha	4 cx	R$ 20,00	R$ 80,00
Lubrificante para alta e baixa rotação	1 un	R$ 28,00	R$ 28,00
Lubrificante para lábios	1 un	R$ 10,00	R$ 10,00
Luvas de procedimento descartáveis	4 cx	R$ 20,00	R$ 60,00
Mandril para discos de polimento	3 un	R$ 20,00	R$ 60,00
Máscaras descartáveis	3 cx	R$ 10,00	R$ 30,00
Matriz de polyester	1 cx	R$ 50,00	R$ 50,00
Óculos de proteção	3 un	R$ 8,00	R$ 24,00
Papel articular	1 cx	R$ 60,00	R$ 60,00
Pasta para polimento	10 un	R$ 26,00	R$ 260,00
Pedra-pomes	1 un	R$ 9,00	R$ 9,00
Perfurador de borracha	3 un	R$ 46,00	R$ 138,00
Pilhas para máquina fotográfica	2 un	R$ 30,00	R$ 60,00
Pinça clínica	6 un	R$ 20,00	R$ 120,00

Pinça porta-agulha	3 un	R$ 25,00	R$ 75,00
Pinça Miller	3 un	R$ 20,00	R$ 60,00
Pinça porta-grampo	3 um	R$ 50,00	R$ 150,00
Pinceis descartáveis para adesivo	4 cx	R$ 10,00	R$ 40,00
Pinceis para resina composta	10 um	R$ 15,00	R$ 150,00
Pontas diamantadas (3 tipos)	30 um	R$ 4,50	R$ 135,00
Pontas multilaminadas	10 um	R$ 4,50	R$ 45,00
Pontas siliconadas	3 kits	R$ 150,00	R$ 450,00
Prancheta para anotações	2 um	R$ 4,00	R$ 8,00
Prendedor para babador descartável	4 um	R$ 5,00	R$ 20,00
Resina composta (8 cores)	20 um	R$ 90,00	R$ 1.800,00
Rolos de algodão	12 pacotes	R$ 2,00	R$ 24,00
Sacolé	2 pacotes	R$ 4,00	R$ 8,00
Sacos para esterilização	2 rolos	R$ 40,00	R$ 80,00
Sistema adesivo	2 um	R$ 200,00	R$ 400,00
Sobre-luvas	2 pacotes	R$ 20,00	R$ 40,00
Sonda exploradora	6 um	R$ 4,00	R$ 24,00
Sonda periodontal milimetrada	2 um	R$ 68,00	R$ 136,00
Spray para teste de vitalidade pulpar	4 um	R$ 35,00	R$ 140,00
Sugador de saliva descartável	3 pacotes	R$ 5,00	R$ 15,00
Tesoura cirúrgica	3 um	R$ 12,00	R$ 36,00
Tira de lixa	1 cx	R$ 50,00	R$ 50,00
		Total	**R$ 11.484,00**

CRONOGRAMA

Mês/Ano	Revisão de literatura.	Envio do projeto para CEP e COCEPE.	Treinamento de operadores.	Treinamento e calibração de avaliadores.	Aquisição dos materiais.	Recrutamento e seleção de pacientes.	Qualificação do projeto de pesquisa.	Tratamento restaurador.	Avaliação clínica das restaurações.	Análise estatística dos dados.	Redação de artigos científicos.	Submissão de pedido de defesa.	Entrega de documentos à banca.	Defesa de tese.
2009	X	X	X	X	X									
Jan/2010	X		X	X	X									
Fev/2010	X		X	X	X									
Mar/2010	X					X								
Abr/2010	X					X	X							
Mai/2010	X					X								
Jun/2010	X					X		X	X					
Jul/2010	X					X		X	X					
Ago/2010	X					X		X	X					
Set/2010	X					X		X	X					
Out/2010	X					X		X	X					
Nov/2010	X					X		X	X					
Dez/2010	X					X		X	X					
Jan/2011	X								X					

Fev/2011	X								X					
Mar/2011	X								X					
Abr/2011	X								X					
Mai/2011	X								X					
Jun/2011	X								X	X	X			
Jul/2011	X									X	X			
Ago/2011	X									X	X			
Set/2011	X										X			
Out/2011	X										X	X		
Nov/2011													X	
Dez/2011														X

Apêndices

APÊNDICE A – Carta de informação ao paciente.

Universidade Federal de Pelotas

Faculdade de Odontologia

Programa de Pós-Graduação em Odontologia

CARTA DE INFORMAÇÃO AO PACIENTE

O objetivo deste estudo será verificar a influência da técnica de isolamento utilizada para controle de umidade do campo operatório através da avaliação do desempenho clínico longitudinal de restaurações em lesões cervicais não-cariosas.

As técnicas de isolamento constituem métodos empregados rotineiramente para controle de umidade na prática clínica. Os materiais utilizados estão disponíveis no mercado odontológico e foram previamente avaliados quanto as suas propriedades físicas e biológicas, sem demonstrar nenhum risco à integridade do ser humano.

Sendo assim, dou pleno consentimento para a Faculdade de Odontologia da Universidade Federal de Pelotas (FOUFPEL), por intermédio de aluno(s) de graduação, aluno(s) de pós-graduação e professor(es) devidamente autorizados e envolvidos neste estudo, realizar diagnóstico, planejamento, tratamento, fotografias, moldagens, além de consultas de avaliação, de acordo com os conhecimentos enquadrados no campo desta especialidade.

Concordo, ainda, que a documentação referente aos exames efetuados e quaisquer outras informações concernentes ao estudo constituem propriedade exclusiva da FOUFPEL, à qual concedo pleno direito de uso para fins de ensino e divulgação, respeitando os respectivos códigos de ética. Também me disponho a participar das reavaliações clínicas para controle do tratamento.

Pelotas, _____ de _____ de 2010.

_____ Documento nº: _____

Assinatura do paciente

APÊNDICE B – Termo de consentimento livre e esclarecido.

Universidade Federal de Pelotas

Faculdade de Odontologia

Programa de Pós-Graduação em Odontologia

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Título do projeto: **Influência do isolamento do campo operatório em restaurações Classe V: Ensaio clínico randomizado.**

Pesquisador responsável pelo estudo: Silvia Terra Fontes

Nome do paciente: _____ Ficha nº: _____

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

Fica claro que o paciente ou seu representante legal pode, a qualquer momento, retirar seu consentimento livre e esclarecido, sem ser prejudicado no tratamento, deixando de participar do estudo alvo da pesquisa e estando ciente que todo trabalho realizado torna-se informação confidencial guardada por força do sigilo profissional (Art. 9º do Código de Ética Odontológica).

Por estarem entendidos e conformados, assinam o presente termo.

Pelotas, _____ de _____ de 2010.

_____ _____

Assinatura do paciente Assinatura do pesquisador

Anexos

ANEXO A – Parecer do Comitê de Ética em Pesquisa.

MINISTÉRIO DA EDUCAÇÃO
UNIVERSIDADE FEDERAL DE PELOTAS
FACULDADE DE ODONTOLOGIA
COMITÊ DE ÉTICA EM PESQUISA

PELOTAS, 15 de maio de 2009.

PARECER Nº 093/2009

O projeto de pesquisa intitulado **ENSAIO CLÍNICO RANDOMIZADO COMPARANDO DIFERENTES SISTEMAS ADESIVOS EM RESTAURAÇÕES DE LESÕES CERVICAIS NÃO-CARIOSAS** está constituído de forma adequada, cumprindo, na suas plenitudes preceitos éticos estabelecidos por este Comitê e pela legislação vigente, recebendo, portanto, **PARECER FAVORÁVEL** à sua execução.

Prof º. Marcos Antonio Torriani
Coordenador do CEP/FO/UFPel

Prof. Marcos A. Torriani
Coordenador
Comitê de Ética e Pesquisa